operator may keep the record elsewhere if the record is immediately accessible from the mine site by electronic transmission.

(2) Upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators must promptly provide access to any such training record. Whenever an operator ceases to do business, that operator must transfer the training records, or a copy, to any successor operator who must maintain them for the required period.

§ 72.520 Diesel equipment inventory.

(a) The operator of each mine that utilizes diesel equipment underground, shall prepare and submit in writing to the District Manager, an inventory of diesel equipment used in the mine. The inventory shall include the number and type of diesel-powered units used underground, including make and model of unit, type of equipment, make and model of engine, serial number of engine, brake horsepower rating of engine, emissions of engine in grams per hour or grams per brake horsepower-hour, approval number of engine, make and model of aftertreatment device, serial number of aftertreatment device if available, and efficiency of aftertreatment device.

(b) The mine operator shall make changes to the diesel equipment inventory as equipment or emission control systems are added, deleted or modified and submit revisions, to the District Manager, within 7 calendar days.

(c) If requested, the mine operator shall provide a copy of the diesel equipment inventory to the representative of the miners within 3 days of the request.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 57

RIN 1219–AB11

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: This rule establishes new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines.

This rule is designed to reduce the risks to underground metal and nonmetal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter (dpm). DPM is a very small particle in diesel exhaust. Underground miners are exposed to far higher concentrations of this fine particulate than any other group of workers. The best available evidence indicates that such high exposures put these miners at excess risk of a variety of adverse health effects, including lung cancer.

The final rule for underground metal and nonmetal mines would establish a concentration limit for dpm, and require mine operators to use engineering and work practice controls to reduce dpm to that limit. Underground metal and nonmetal mine operators would also be required to implement certain ''best practice'' work controls similar to those already required of underground coal mine operators under MSHA's 1996 diesel equipment rule. These operators would also be required to train miners about the hazards of dpm exposure.

By separate notice, MSHA has published a rule to reduce dpm exposures in underground coal mines.

DATES: The provisions of the final rule are effective March 20, 2001. However, §57.5060 (a) will not apply until July 19, 2002 and §57.5060 (b) will not apply until January 19, 2006.

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Director, Office of Standards, Regulations, and Variances, MSHA, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Mr. Meyer can be reached at dmeyer@msha.gov (Internet E-mail), 703–235–1910 (voice), or 703–235–5551 (fax). You may obtain copies of the final rule in alternative formats by calling this number. The alternative formats available are either a large print version of the final rule or the final rule in an electronic file on computer disk. The final rule also is available on the Internet at http://www.msha.gov/REGSINFO.HTM.

SUPPLEMENTARY INFORMATION:

I. Overview of the Final Rule

This Part: (1) Summarizes the key provisions of the final rule; and (2) summarizes MSHA's responses to some of the fundamental questions raised during the rulemaking proceeding—the need for the rule, the ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments, and the feasibility of the requirements for this sector of the mining industry.

(1) Summary of Key Provisions of the Final Rule

The final rule applies only to underground areas of underground metal and nonmetal mines.

The final rule requires operators: (A) To observe a concentration limit where miners normally work or travel by the application of engineering controls, with certain limited exceptions, compliance with which will be determined by MSHA sampling; (B) to observe a set of best practices to minimize dpm generation; (C) to limit engines newly introduced underground to those meeting basic emissions standards; (D) to provide annual training to miners on dpm hazards and controls; and (E) to conduct sampling as often as necessary to effectively evaluate dpm concentrations at the mine. A list of effective dates for the provisions of the rule follows this summary.

(A) Observe a limit on the concentration of dpm in all areas of an underground metal or nonmetal mine where miners work or travel, with certain specific exceptions. The rule would limit dpm concentrations to which miners are exposed to about 200 micrograms per cubic meter of air—expressed as 200_{DPM} µg/m^3. However, the rule expresses the limit so as to reflect the measurement method MSHA will be using for compliance purposes to determine dpm concentrations. That method is specified in the rule itself. As discussed in detail in response to Question 2, the method analyzes a dust sample to determine the amount of total carbon present. Total carbon comprises 80–85% of the dpm emitted by diesel engines. Accordingly, using the lower boundary of 80%, a concentration limit of 200_{DPM} µg/m^3 can be achieved by restricting total carbon to 160_{TC} µg/m^3. This is the way the standard is expressed:

> After January 19, 2006 any mine operator covered by this part shall limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 160 micrograms per cubic meter of air (160_{TC} µg/m^3).

All underground metal and nonmetal mines would be given a full five years to meet this limit, which is referred to in this preamble as the ''final'' concentration limit. However, starting July 19, 2002, underground metal and nonmetal mines have to observe an ''interim'' dpm concentration limit—expressed as a restriction on the concentration of total carbon of 400 micrograms per cubic meter (400_{TC} µg/m^3). The interim limit would bring the concentration of whole dpm in underground metal and nonmetal mines to which miners are exposed down to about 500 micrograms per cubic meter. No limit at all on the concentration of dpm is applicable for the first eighteen months following promulgation. Instead, this period would be used to provide compliance assistance to the metal and nonmetal mining community to ensure it understands how to measure and control diesel particulate matter concentrations in individual operations.

In general, a mine operator has to use engineering or work practice controls to keep dpm concentrations below the applicable limit. The use of administrative controls (*e.g.,* the rotation of miners) is explicitly barred. The use of personal protective equipment (*e.g.,* respirators) is also explicitly barred except in two situations noted below. An operator can filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, or use a variety of other readily available controls; the selection of controls is left to the operator's discretion.

Special extension. The rule provides that if an operator of a metal or nonmetal mine can demonstrate that there is no combination of controls that can, due to technological constraints, be implemented by January 19, 2006, MSHA may approve an application for an additional extension of time to comply with the dpm concentration limit. Such a special extension is available only once, and is limited to 2 years. To obtain a special extension, an operator must provide information in the application adequate for MSHA to ensure that the operator will: (a) Maintain concentrations at the lowest limit which is technologically achievable; and (b) take appropriate actions to minimize miner exposure (*e.g.,* provide suitable respiratory protection during the extension period).

It is MSHA's intent that primary responsibility for analysis of the operator's application for a special extension will rest with MSHA's district managers. District managers are the most familiar with the conditions of mines in their districts, and have the best opportunity to consult with miners as well. At the same time, MSHA recognizes that district managers may need assistance with respect to the latest technologies and solutions being used in similar mines elsewhere in the country. Accordingly, the Agency intends to establish within its Technical Support directorate in Arlington, Va., a special panel to consult on these issues, to provide assistance to district managers, and to give final approval of any application for a special extension.

Special rule for employees engaged in inspection, maintenance or repair activities. The final rule provides that with the advance approval of the Secretary, employees engaged in such activities may work in concentrations of dpm exceeding the applicable concentration limit. However, the Secretary may only approve such work under three circumstances: when the activities are to be conducted are in areas where miners work or travel infrequently or for brief periods of time; when the miners work exclusively inside enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; or when the miners work in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are used for access into the mine or egress from the mine. Moreover, to approve such an exception, the Secretary must determine that it is not feasible to reduce the concentration of dpm in these areas, and that adequate safeguards (including personal protective equipment) will be employed to minimize the dpm exposure of the miners involved.

An operator plan providing such details must be submitted; it is MSHA's intent to review these in the same manner as applications for a special extension. Such plans can only be approved for one year, but may be resubmitted each year.

Compliance determinations with concentration limit. Measurements to determine noncompliance with the dpm concentration limit will be made directly by MSHA, rather than having the Agency rely upon operator samples. Under the rule, a single Agency sample, using the sampling and analytical method prescribed by the rule, is explicitly deemed adequate to establish a violation.

The rule requires that if an underground metal or nonmetal mine exceeds the applicable limit on the concentration of dpm, a diesel particulate matter control plan must be established and remain in effect for 3 years. The purpose of such plans is to ensure that the mine has instituted practices that will demonstrably control dpm levels thereafter. Reflecting current practices in this sector, the plan does not have to be preapproved by MSHA. The plan must include information about the diesel-powered equipment in the mine and applicable controls. The rule requires operator sampling to verify that the plan is effective in bringing dpm levels down below the applicable limit, using the same sampling and analytical methods as MSHA, with the records kept at the mine site with the plan to facilitate review. Failure of an operator to comply with the requirements of the dpm control plan or to conduct adequate verification sampling is a violation of the rule; MSHA is not be required to sample to establish such a violation.

(B) *Observe best practices.* The rule requires that operators observe the following best practices to minimize the dpm generated by diesel-powered equipment in underground areas:

- Only low-sulfur (0.05% or less) diesel fuel may be used. The rule does not at this time require the use of ultra-low sulfur fuel by the mining community. MSHA is aware that the Environmental Protection Agency issued final regulations addressing emissions standards (December 2000) for new model year 2007 heavy-duty diesel engines and the low-sulfur fuel rule. The regulations require ultra-low sulfur fuel be phased in during 2006–2010.
- Only EPA-approved fuel additives may be used.
- Approved diesel engines have to be maintained in approved condition; the emission related components of non-approved engines have to be maintained in accordance with manufacturer specifications; and any installed emission devices have to be maintained in effective operating condition.
- Equipment operators are authorized and required to tag equipment with potential emissions-related problems, and tagged equipment has to be promptly referred for a maintenance check by persons qualified by virtue of training or experience to perform the maintenance.

(C) *Limit newly introduced engines to those meeting basic emission standards.* The rule requires that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine after January 19, 2001 must either be an engine approved by MSHA under Part 7 or Part 36, or an engine meeting certain EPA requirements on particulate matter specified in the rule. Since not all engines are MSHA approved, this ensures a wide variety of choice in meeting the engine requirements of this rule.

(D) *Provide annual training to miners on dpm hazards and controls.* Mines using diesel-powered equipment must annually train miners exposed to dpm in the hazards associated with that exposure, and in the controls being used by the operator to limit dpm concentrations. An operator may propose including this training in the Part 48 training plan.

(E) *Conduct sampling as often as necessary to effectively evaluate dpm concentrations at the mine.* The purpose of this requirement is to assure that operators are familiar with current dpm concentrations so as to be able to protect miners. Since mine conditions vary, MSHA is not requiring a specific schedule for operator sampling, nor a specific sampling method. The Agency will evaluate compliance with this sampling obligation by reviewing evidence of operator compliance with the concentration limit, as well as information retained by operators about their sampling. Consistent with the statute, the rule requires that miners and their representatives have the right to observe any operator monitoring—including any sampling required to verify the effectiveness of a dpm control plan.

Summary of Effective Dates. As of March 20, 2001, operators must comply with the requirement that new engines added to a mine's inventory be either MSHA approved or meet the listed EPA standards.

As of March 20, 2001, underground metal and nonmetal mine operators must comply with the requirement to provide basic hazard training to miners who are exposed underground to dpm and the best practice requirements listed above under (B).

As of July 19, 2002, underground metal and nonmetal mine operators must also comply with the interim dpm concentration limit of 400 micrograms of total carbon per cubic meter of air.

Finally, as of January 19, 2006, all underground metal and nonmetal mines have to comply with a final dpm concentration limit.

MSHA intends to provide considerable technical assistance and guidance to the mining community before the various requirements go into effect, and be sure MSHA personnel are fully trained in the requirements of the rule. A number of actions have already been taken toward this end. The Agency held workshops on this topic in 1995 which provided the mining community an opportunity to share advice on how to control dpm concentrations. The Agency has published a ''toolbox'' of methods available to mining operators to achieve reductions in dpm concentration, often referred to during the rulemaking proceedings. MSHA also developed a computer spreadsheet template which allows an operator to model the application of alternative engineering controls to reduce dpm, which it has published in the literature and disseminated to the mining community. The Agency is committed to issuing a compliance guide for mine operators providing additional advice on implementing the rule.

A note on surface mines. Surface areas of underground mines, and surface mines, are not covered by this rule. In certain situations the concentrations of dpm at surface mines may be a cause for concern: *e.g.,* production areas where miners work in the open air in close proximity to loader-haulers and trucks powered by older, out-of-tune diesel engines, shops, or other confined spaces where diesel engines are running. The Agency believes, however, that these problems are currently limited and readily controlled through education and technical assistance. The Agency would like to emphasize, however, that surface miners are entitled to the same level of protection as other miners; and the Agency's risk assessment indicates that even short-term exposures to concentrations of dpm like those observed may result in serious health problems. Accordingly, in addition to providing education and technical assistance to surface mines, the Agency will also continue to evaluate the hazards of diesel particulate exposure at surface mines and will take any necessary action, including regulatory action if warranted, to help the mining community minimize any hazards.

(2) Summary of MSHA's Responses to Several Fundamental Questions About This Rule

During the rulemaking proceeding, the mining community raised some fundamental questions about: (A) The need for the rule; (B) the ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments; and (C) the feasibility of the requirements for this sector of the mining industry. MSHA gave serious considerations to these questions, has made some adjustments in the final rule and its economic assessment as a result thereof, and has provided detailed responses in this preamble. These responses are briefly summarized here.

(A) *The need for the rule.* MSHA has to act in accordance with the requirements of the Mine Safety and Health Act. Section 101(a)(6)(A) of the Act specifies that any health standard must:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary of Labor (Secretary), in promulgating mandatory standards pertaining to toxic materials or harmful physical agents, base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration. (More information about what constitutes ''feasibility'' is discussed below in item C).

In proposing this rule, MSHA sought comment on its risk assessment, which it published in full as part of the preamble to the proposed rule. In that risk assessment, the agency carefully laid out the evidence available to it, including shortcomings inherent in that evidence. Although not required to do so by law, MSHA had this risk assessment independently peer reviewed, and incorporated the reviewers recommendations. The reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Based on the information in that risk assessment, the agency made some tentative conclusions. First, its tentative conclusion that miners are exposed to far higher concentrations of dpm than anybody else. The agency noted that median concentrations of dpm had been observed in individual dieselized metal and nonmetal underground mines up to 180 times as high as average environmental exposures in the most heavily polluted urban areas and up to 8 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups. Moreover, MSHA noted its tentative conclusion that exposure to high concentrations of dpm can result in a variety of serious health effects. These health effects include: (i) Sensory irritations and respiratory symptoms serious enough to distract or disable miners; (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. After a review of all the evidence, MSHA tentatively concluded that:

(1) The best available evidence is that the health effects associated with exposure to dpm can materially impair miner health or functional capacity.

(2) At levels of exposure currently observed in underground mining, many miners are presently at significant risk of incurring these material impairments over a working lifetime.

(3) The reduction in dpm exposures that is expected to result from implementation of the rule proposed by the agency for underground metal and nonmetal mines would substantially reduce the significant risks currently faced by underground metal and nonmetal miners exposed to dpm.

During the hearings and in written comments, some representatives of the mining industry raised a number of objections to parts of MSHA's proposed risk assessment, thus questioning the scientific basis for this rulemaking. It has been asserted that MSHA's observations of dpm concentrations in underground metal and nonmetal mines do not accurately represent exposures in the industry. It has been asserted that if dpm concentrations are not this high in general, or only on an intermittent basis, then the agency is incorrect in determining that the conditions in these mines put miners at significant risk of material impairment of their health. Moreover it has been asserted that there is insufficient evidence to establish a causal connection between dpm exposure and significant adverse health effects, that the agency has no hard evidence that reducing exposures to a particular level will in fact reduce the risks, and that it has no rational basis for selecting the concentration limit it did. In addition, it has been asserted that the risks of dpm exposure at any level are not well enough established to provide the basis for regulation at this time, and that action should be postponed pending the completion of various studies now underway that might shed more light on these risks.

MSHA has carefully evaluated all of these comments, and the evidence submitted in support of these positions. The agency's risk assessment has been modified as a result.

Exposures of underground metal and nonmetal miners. MSHA has clarified the charts of exposure measurements in Part III of this preamble to ensure that they fully reflect all studies in the record.

MSHA has not and does not claim that the actual exposure measurements in the record are a random or fully representative sample of the industry. What they do show is that exposures far higher than those which have been observed in other industries can and do occur in an underground mining environment.

Moreover, MSHA also placed into the record of the proposed rule several studies it had recently conducted in which dpm concentrations for several underground metal and nonmetal mines were estimated based upon the actual equipment and dpm controls currently available in those mines. Those simulations were performed using a software tool known as the Estimator (described in detail in an appendix to Part V of the preamble of the proposed rule, and since published in the literature (Haney and Saseen, April 2000). These studies of specific mines demonstrated that the type of equipment found in such mines, even after the application of current ventilation and controls, can be expected to produce localized high concentrations of dpm. The agency acknowledged that these simulations were conducted in mines that were not typical for the industry (they were chosen because the agency thought dpm concentrations might be particularly difficult to control in these mines, which turned out not to be the case); nevertheless, they indicate what is likely to be the case in at least some sections of many underground metal and nonmetal mines. To the extent that an individual mine has no covered mining areas with concentrations higher than those observed in other industries, it will not be impacted by the concentration limit established through this rulemaking. That is because the rule does not eliminate exposures, or even to reduce them to a safe level, but only to reduce them to the levels observed in other industries.

The nature of risks associated with dpm exposure. Although there were some commenters who suggested that symptoms reported by miners working around diesel equipment might be due to the gases present rather than dpm, there was nothing in the comments that changed MSHA's conclusions about the health problems associated with dpm exposure.

There are a number of studies quantifying significant adverse health effects—as measured by lost work days, hospitalization and increased mortality rates—suffered by the general public when exposed to concentrations of fine particulate matter like dpm far lower than concentrations to which some miners are exposed. The evidence from these fine particulate studies was the basis for recent rulemaking by the Environmental Protection Agency [1] to further restrict the exposure of the general public to fine particulates, and the evidence was given very widespread and close scrutiny before that action was made final. Of particular interest to the mining community is that these fine particulate studies indicate that smokers and those who have pre-existing pulmonary problems are particularly at risk. Many individual miners in fact have such pulmonary problems and are especially susceptible to the adverse health effects of inhaling fine particles.

Although no epidemiological study is flawless, numerous epidemiological studies have shown that long term exposure to diesel exhaust in a variety of occupational circumstances is associated with an increased risk of lung cancer. With only rare exceptions, involving relatively few workers and/or observation periods too short to reliably detect excess cancer risk, the human studies have consistently shown a greater risk of lung cancer among workers exposed to dpm than among comparable unexposed workers. When results from the human studies are combined, the risk is estimated to be 30–40 percent greater among exposed workers, if all other factors (such as smoking habits) are held constant. The consistency of the human study results, supported by experimental data establishing the plausibility of a causal connection, provides strong evidence that chronic dpm exposure at high levels significantly increases the risk of lung cancer in humans.

Moreover, all of the occupational studies indicating an increased frequency of lung cancer among workers exposed to dpm involved exposure levels estimated, on average, to be far below levels observed in underground mines. Except for miners, the workers

[1] The basis for the $PM_{2.5}$ NAAQS was a large body of scientific data indicating that particles in this size range are responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable public attention, and hearings by Congress, in which the scientific evidence was further discussed. Moreover, challenges to the EPA's determination that this size category warranted rulemaking were rejected by a three-judge panel of the DC Circuit Court. (ATA v. EPA, 175 F.3d 1027, D.C. Circuit 1999).

included in these studies were exposed to average dpm levels below the limit established by this rule.

As noted in Part III, MSHA views extrapolations from animal experiments as subordinate to results obtained from human studies. However, it is noteworthy that dpm exposure levels recorded in some underground mines have been of the same order of magnitude that produced tumors in rats.

Based on the scientific data available in 1988, the National Institute for Occupational Safety and Health (NIOSH) identified dpm as a probable or potential human carcinogen and recommended that it be controlled. Other organizations have made similar recommendations. Most recently, the National Toxicology Program listed dpm as ''reasonably anticipated to be a human carcinogen'' in the Ninth Edition (Year 2000) of the National Report on Carcinogens.

The relationship between exposures and risks. Commenters noted MSHA's caution about trying to define a quantitative relationship between dpm exposure and particular health outcomes. They roundly attacked the agency's benefit analysis and a NIOSH paper reviewing quantification efforts as implying that such a relationship could be established in a valid way.

As MSHA acknowledged in the preamble to the proposed rule, the scientific community has not yet widely accepted any exposure-response relationship between the amount of dpm exposure and the likelihood of adverse health outcomes (63FR 58167). There are, however, two lung cancer studies in the record that show increasing risk of lung cancer with increasing levels of dpm exposure. Quantitative results from these studies, both conducted specifically on underground miners, can be used to estimate the reduction in lung cancer risk expected when dpm exposure is reduced in accordance with this rule. Depending on the study and method of statistical analysis used, these estimates range from 68 to 620 lung cancer deaths prevented, over an initial 65-year period, per 1000 affected miners with lifetime (45-year) exposure to dpm.

NIOSH and the National Cancer Institute (NCI) are collaborating on a cancer mortality study designed to provide additional information in this regard. The study is projected to take about seven years.

Notwithstanding this situation, MSHA believes the Agency is required under its statute to take action now to protect miners' health. As noted by the Supreme Court in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straightjacket.'' *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 100 S.Ct. 2844 (1980). The Court noted that when regulating on the edge of scientific knowledge, absolute scientific certainty may not be possible, and:

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. (Id. at 656).

This advice has special significance for the mining community, because a singular historical factor behind the enactment of the current Mine Act was the slowness of the mining community in coming to grips with the harmful effects of other respirable dust (coal dust).

It is worth noting that while the cohort selected for the NIOSH/NCI study consists of underground miners (specifically, underground metal and nonmetal miners), this choice is in no way linked to MSHA's regulatory framework or to miners in particular. This cohort was selected for the study because it provides the best population for scientists to study. For example, one part of the study would compare the health experiences of miners who have worked underground in mines with long histories of diesel use with the health experiences of similar miners who work in surface areas where exposure is significantly lower. Since the general health of these two groups is very similar, this will help researchers to quantify the impacts of diesel exposure. No other population is likely to be as easy to study for this purpose. But as with any such epidemiological study, the insights gained are not limited to the specific population used in the study. Rather, the study will provide information about the relationship between exposure and health effects that will be useful in assessing the risks to any group of workers in a dieselized industry.

Because of the lack of a generally accepted dose-response relationship, some commenters questioned the agency's rationale in picking a particular concentration limit: 160_{TC} µg/m^3 or around 200_{DPM} µg/m^3. Capping dpm concentrations at this level will eliminate the worst mining exposures, and bring miner exposures down to a level commensurate with those reported for other groups of workers who use diesel-powered equipment. The proposed rule would not bring concentrations down as far as the proposed ACGIH TLV^R of 150_{DPM} µg/m^3. Nor does MSHA's risk assessment suggest that the proposed rule would completely eliminate the significant risks to miners of dpm exposure.

In setting the concentration limit at this particular value, the Agency is acting in accord with its statutory obligation to attain the highest degree of safety and health protection for miners that is feasible. The Agency's risk assessment supports reduction of dpm to the lowest level possible. But feasibility considerations dictated proposing a concentration limit that does not completely eliminate the significant risks that dpm exposure poses to miners.

The Agency specifically explored the implications of requiring mines in this sector to comply with a lower concentration limit than that being adopted. The results, discussed in Part V of this preamble, indicate that although the matter is not free from question, it still may not be feasible at this time for the underground metal and nonmetal mining industry as a whole to comply with a significantly lower limit than that being adopted. The Agency notes that since this rulemaking was initiated, the efficiency of hot gas filters has improved significantly, the dpm emissions from new engines continue to decline under EPA requirements, and the availability of ultra-low sulfur fuel should make controls even more efficient than at present.

The agency also explored the idea of bridging the gap between risk and feasibility by establishing an ''action level''. In the case of MSHA's noise rule, for example, MSHA adopted a ''permissible exposure level'' of a time-weighted 8-hour average (TWA_8) of 90 dBA (decibels, A-weighted), and an ''action level'' of half that amount—a TWA_8 of 85 dBA. In that case, MSHA determined that miners are at significant risk of material harm at a TWA_8 of 85 dBA, but technological and feasibility considerations preclude the industry as a whole, at this time, below a TWA_8 of 90 dBA. Accordingly, to limit miner exposure to noise at or above a TWA_8 of 85 dBA, MSHA requires that mine operators must take certain actions that are feasible (*e.g.,* provide hearing protectors).

MSHA considered the establishment of a similar ''action level'' for dpm—probably at half the proposed concentration limit, or 80_{TC} µg/m^3. Under such an approach, mine operators whose dpm concentrations are above the ''action level'' would be required to implement a series of ''best practices''—*e.g.,* limits on fuel types, idling, and engine maintenance. Only one commenter supported the creation of an Action Level for dpm. However, this commenter suggested that such an Action Level be adopted in lieu of a rule incorporating a concentration limit requiring mandatory compliance. The agency determined it is feasible for the entire underground mining community to implement these best practices to minimize the risks of dpm exposure without the need for a trigger at an Action Level.

Some of the comments suggesting that the agency had no rational basis for setting the exposure limit at 160_{TC} µg/m^3 seem to suggest that the statute itself does not provide the Agency with adequate guidance in this regard. The Agency recognizes that the Supreme Court has scheduled argument on a case that raises the question of how specific a regulatory statute must be with respect to how an agency must make standards determinations in order to be deemed a constitutional delegation of authority from the Congress. A decision is not expected until 2001. However, unless and until determined otherwise, MSHA presumes the Mine Act does pass constitutional muster in this regard, consistent with the existing case law concerning the very similar Occupational Safety and Health Act.

(B) The ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments. As MSHA noted in the preamble to the proposed rule, there are a number of methods which can measure dpm concentrations with reasonable accuracy when it is at high concentrations and when the purpose is exposure assessment. Measurements for the purpose of compliance determinations must be more accurate, especially if they are to measure compliance with a dpm concentration of 200_{DPM} µg/m^3 or lower. Accordingly, MSHA noted that it needed to address a number of questions as to whether such any existing method could produce accurate, reliable and reproducible results in the full variety of underground mines, and whether the infrastructure (samplers and laboratories) existed to support such determinations. (See 63 FR 58127 *et seq.*).

MSHA concluded that there was no method suitable for such compliance measurements in underground coal mines, due to the inability of the available methods to distinguish between dpm and coal dust. Accordingly, the agency developed a rule for the coal mining sector that does not depend upon ambient dpm measurements.

By contrast, the agency tentatively concluded that by using a sampler developed by the Bureau of Mines, and an analytical method developed by the National Institute for Occupational Safety and Health (NIOSH) to detect the total amount of carbon in a sample, MSHA could accurately measure dpm levels at the required concentrations in underground metal and nonmetal mines. While not requiring operators to use this method for their own sampling, MSHA did commit itself through provisions of the proposed rule to use this approach (or a method subsequently determined by NIOSH to provide equal or improved accuracy) for its own sampling. Moreover the agency proposed that MSHA sampling be the sole basis upon which determinations would be made of compliance by metal and nonmetal mine operators with applicable compliance limits, and that a single sample would be adequate for such purposes. Specifically, proposed § 57.5061 provided as follows:

§ 57.5061 Compliance Determinations

(a) A single sample collected and analyzed by the Secretary in accordance with the procedure set forth in paragraph (b) of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect and analyze samples of diesel particulate matter by using the method described in NIOSH Analytical Method 5040 and determining the amount of total carbon, or by using any method subsequently determined by NIOSH to provide equal or improved accuracy in mines subject to this part.

This part of MSHA's proposed rule received considerable comment. Some commenters challenged the accuracy, precision and sensitivity of NIOSH Analytical Method 5040. Some challenged whether the amount of total carbon determined by the method is a reliable way to determine the amount of dpm. Others questioned whether the sampler developed by the Bureau of Mines would provide an accurate sample to be analyzed, and whether such samplers and analytical procedures would be commercially available. Commenters also questioned the use of a single sample as the basis for a compliance determination, and the use of area sampling in compliance determinations. These comments are addressed elsewhere in this preamble (section 3 of Part II, and in connection with section 5061 in Part IV).

Here, MSHA summarizes its views on the most common assertion made by commenters: that the sampling and analytical methods the agency proposed to use are not able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke.

Interferences: what MSHA said in preamble to proposed rule. In the preamble to the proposed rule, MSHA recognized that there might be some interferences from other common organic carbon sources in underground metal and nonmetal mines: specifically, oil mists and cigarette smoke. The agency noted it had no data on oil mists, but had not encountered the problem in its own sampling. With respect to cigarette smoke, the agency noted that: ''Cigarette smoke is under the control of operators, during sampling times in particular, and hence should not be a consideration.'' (63FR 58129)

The agency also discussed the potential advantages and disadvantages of using a special device on the sampler—a submicron impactor—to eliminate certain other possible interferences (See Figure I–1). The submicron impactor stops particles larger than a micron from being collected by the sampler, while allowing the smaller dpm to be collected. Thus, an advantage of using the impactor would be to ensure that the sampler was not inadvertently collecting materials other than dpm. However MSHA pointed out that while samples in underground metal and nonmetal mines could be taken with a submicrometer impactor, this could lead to underestimating the total amount of dpm present (63FR 58129). This is because the fraction of dpm particles greater than 1 micron in size in the environment of noncoal mines can be as great as 20% (Vuk, Jones, and Johnson, 1976).

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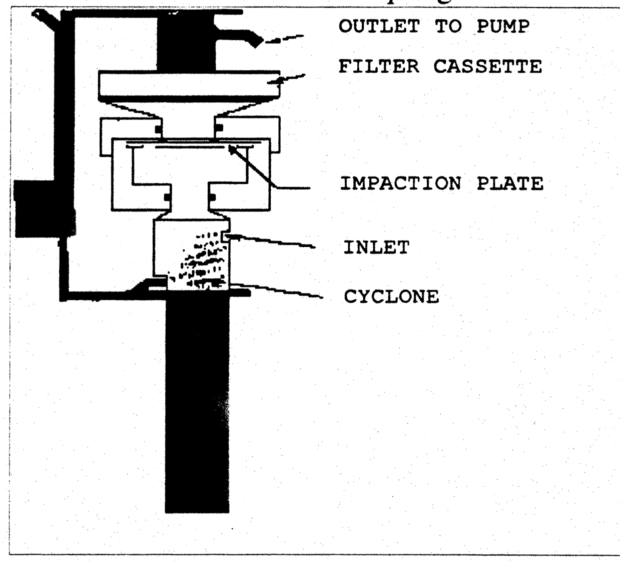
Figure II- 3
Personal Sampler For Submicrometer Particulate Sampling



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Interferences: comments and MSHA efforts to verify. Many commenters asserted that no matter how it is performed in underground metal and nonmetal mines, the sampling and analysis proposed by MSHA to determine the amount of diesel particulate present would suffer from one or more of the aforementioned interferences. A number asserted that their own measurements using this approach provided clear evidence of such interferences. Although MSHA repeatedly asked for actual data and information about the procedures used to verify these assertions, very little was provided. Nevertheless, rather than conclude that these assertions were baseless, MSHA decided to attempt to verify these assertions itself. Accordingly, appropriate field and laboratory measurements were conducted toward this end, the results written up in appropriate fashion, and added to the record of this rulemaking. The agency has taken those results into account in ascertaining what weight to give to the assertions made by commenters and how to deal with those assertions supported by its measurements.

As described in detail in section 3 of Part II, MSHA's verifications demonstrate that the submicron impactor can eliminate any interferences from carbonates, carbonaceous minerals, and graphitic ores. Accordingly, although use of the impactor will result in an undercount of dpm, the final rule provides that MSHA will always use the submicron impactor in compliance sampling.

MSHA's verifications also demonstrated that oil mists as well as cigarette smoke, can in fact, under certain circumstances, create interferences even with the use of the impactor. MSHA presumes the same would happen with organic vapors. The verifications demonstrated that the problems occur in the immediate vicinity of the interferent (*e.g.,* close to a drill or smoker). However, the verifications also demonstrated that the interference dissipates when the sampling device is located a certain distance away from the interferent.

Accordingly, as detailed in the discussion of section 5061 in Part IV of this preamble, MSHA's sampling strategy for dpm will take these problems into account. For example, if a miner works in an enclosed cab all day and smokes, MSHA will not place a sampler in that cab or on that miner. If a miner works part of a day drilling, MSHA will not place a sampler on that miner. But MSHA can, for example, take an area sample in an area of a mine where drilling is being performed without concern about interferences from oil mists if it locates the sampler far enough away from the drill. MSHA's compliance manual will provide specific instructions to inspectors on how to avoid interferences.

The organic interferences (diesel mist, smoking) could be avoided by only analyzing a sample for elemental carbon, pursuant to the NIOSH method. As it indicated in the preamble to the proposed rule, however, MSHA does not at this time know the ratio between the amount of elemental carbon and the amount of dpm. Accordingly, rather than deal with the uncertainties in all samples which this approach would present, MSHA is going to use a method (i.e., sampling and analyzing for both organic carbon and elemental carbon) that, if properly applied, provides accurate results.

(C) The feasibility of the requirements for this sector of the mining industry. The Mine Act generally requires MSHA to set the standard that is most protective of miner health while still being technologically and economically feasible. In addition, consistent with the Regulatory Flexibility Act, the agency pays particular attention to the impact of any standard on small mining operations.

(1) Technological feasibility of the rule. It has been clear since the beginning of this rulemaking that if technological feasibility was an issue, it would be in the context of requiring all underground metal and nonmetal mines to meet a particular limit. While the Mine Act does not require that each mine be able to meet a standard for it to be considered technologically feasible—only that the standard be feasible for the industry as a whole—the extent to which various mines might have a problem complying is the evidence upon which this conclusion must be based.

Accordingly, MSHA evaluated the technological feasibility of the concentration limit in the underground metal and nonmetal sector by evaluating whether it was possible, using a combination of existing control approaches, to reach the concentration limit even in situations in which the Agency's engineers determined that compliance might be the most difficult. In this regard, the Agency examined how emissions generated by the actual equipment in four different underground mining operations could be controlled. The mines were very diverse—an underground limestone mine, an underground (and underwater) salt mine, and an underground gold mine. Yet in each case, the analysis revealed that there are available combinations of controls that can bring dpm concentrations down to well below the final limit—even when the controls that needed to be purchased were not as extensive as those which the Agency is assuming will be needed in determining the costs of the final rule. (The results of these analyses are discussed in Part V of the preamble, together with the methodology used in modeling the results—just as they were discussed in the preamble accompanying the proposed rule.) As a result of these studies, the Agency has concluded that there are engineering and work practice controls available to bring dpm concentrations in all underground metal and nonmetal mines down to the required levels.

The best actions for an individual operator to take to come into compliance with the interim and final concentration limits will depend upon an analysis of the unique conditions at the mine. The final rule provides 18 months after it is promulgated for MSHA to provide technical assistance to individual mine operators. It also gives all mine operators in this sector an additional three and a half years to bring dpm concentrations down to the proposed final concentration limit—using an interim concentration limit during this time which the Agency is confident every mine in this sector can timely meet. And the rule provides an opportunity for a special extension for an additional two years for mines that have unique technological problems meeting the final concentration limit.

As noted during 1995 workshops co-sponsored by MSHA on methods for controlling diesel particulate, many underground metal and nonmetal mine operators have already successfully determined how to reduce diesel particulate concentrations in their mines. MSHA has disseminated the ideas discussed at these workshops to the entire mining community in a publication, ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox''. The control methods are divided into eight categories: use of low emission engines; use of low sulfur fuel; use of aftertreatment devices; use of ventilation; use of enclosed cabs; diesel engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Moreover, MSHA designed a model in the form of a computer spreadsheet that can be used to simulate the effects of various controls on dpm concentrations. (This model is discussed in Part V of the preamble.) This makes it possible for individual underground mine operators to evaluate the impact on diesel particulate levels of various combinations of control methods, prior to making any investments, so each can select the most feasible approach for his or her mine.

(2) Economic Feasability of the Rule. The underground metal and nonmetal industry uses a lot of diesel-powered equipment, and it is widely distributed. Accordingly, MSHA recognizes that the costs of bringing mines into compliance with this rule will be widely felt in this sector (although, unlike underground coal mines, this sector did not have to comply with MSHA's 1996 diesel equipment rule).

In summary, the costs per year to the underground metal and nonmetal industry are about $25.1 million. The cost for an average underground metal and nonmetal mine is expected to be about $128,000 annually.

The Agency's initial cost estimates of $19.2 million a year were challenged during the rulemaking proceeding. As a result, the Agency reconsidered the costs.

In its initial estimate of the costs for the industry to comply with the concentration limit, MSHA assumed that a variety of engineering controls, such as low emission engines, ceramic filters, oxidation catalytic converters, and cabs would be needed on diesel powered equipment. Most of the engineering controls would be needed on diesel equipment used for production, while a small amount of diesel equipment that is used for support purposes would need engineering controls. In addition to these controls, MSHA assumed that some underground metal and nonmetal mines would need to make ventilation changes in order to meet the proposed concentration limits.

Specifically, in the PREA, MSHA assumed that: (1) the interim standard would be met by replacing engines, installing oxidation catalytic converters, and improving ventilation; and (2) the final standard would be met by adding cabs and filters. Comments on the PREA and data collected by the Agency since publication of the proposed rule indicate that engine replacement is more expensive than originally thought and filters are more effective relative to engine replacement. The revised compliance strategy, upon which MSHA bases its revised estimates of compliance costs, reverses the two most widely used measures. MSHA now anticipates that: (1) the interim standard will be met with filters, cabs, and ventilation; and (2) the final standard will be met with more filters, ventilation, and such turnover in equipment and engines as will have occurred in the baseline. This new approach uses the same toolbox and optimization strategy that was used in the PREA. Since relative costs are different, however, the tools used and cost estimated are different.

(3) Impact on small mines. As required by the Regulatory Flexibility Act, MSHA has performed a review of the effects of the proposed rule on ''small entities''.

The Small Business Administration generally considers a small mining entity to be one with less than 500 employees. MSHA has traditionally defined a small mine to be one with less than 20 miners, and has focused special attention on the problems experienced by such mines in implementing safety and health rules. Accordingly, MSHA has separately analyzed the impact of the rule on three categories of mines: large mines (more than 500 employees), middle size mines (20–500 employees), and small mines (those with less than 20 miners).

As required by law, MSHA has also developed a preliminary and final regulatory flexibility analysis. The Agency published its preliminary Regulatory Flexibility Analysis with its proposed rule and specifically requested comments thereon; the agency's final Regulatory Flexibility Analysis is included in the Agency's REA. In addition to a succinct statement of the objectives of the rule and other information required by the Regulatory Flexibility Act, the analysis reviews alternatives considered by the Agency with an eye toward the nature of small business entities.

In promulgating standards, MSHA is required to protect the health and safety of all the Nation's miners and may not include provisions that provide less protection for miners in small mines than for those in larger mines. But MSHA does consider the impact of its standards on even the smallest mines when it evaluates the feasibility of various alternatives. For example, a major reason why MSHA concluded it needed to stagger the effective dates of some of the requirements in the rule is to ensure that it would be feasible for the smallest mines to have adequate time to come into compliance.

MSHA recognizes that smaller mines may need particular assistance from the agency in coming into compliance with this standard. Before the dpm concentration goes into effect in 18 months, the Agency plans to provide extensive compliance assistance to the mining community. The metal and nonmetal community will also have an additional three and a half years to comply with the final concentration limit, which in many cases means these mines may have a full five years of technical assistance before any engineering controls are required. MSHA intends to focus its efforts on smaller operators in particular—training them in measuring dpm concentrations, and providing technical assistance on available controls. The Agency will also issue a compliance guide, and continue its current efforts to disseminate educational materials and software.

(4) Benefits of the final rule Benefits of the rule include reductions in lung cancer. In the long run, as the mining population turns over, MSHA estimates that a minimum of 8.5 lung cancer deaths will be avoided per year.[2]

Benefits of the rule will also include reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes and in sensory irritation and respiratory symptoms. MSHA does not believe that the available data can support reliable or precise quantitative estimates of these benefits. Nevertheless, the expected reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes appear to be significant, and the expected reductions in sensory irritation and respiratory symptoms appear to be rather large.

II. General Information

This part provides the context for this preamble. The nine topics covered are:

(1) The role of diesel-powered equipment in underground metal and nonmetal mining in the United States;

(2) The composition of diesel exhaust and diesel particulate matter (dpm);

(3) The sampling and analytical techniques for measuring ambient dpm in underground metal and nonmetal mines;

(4) Limiting the public's exposure to diesel and other final particulates—ambient air quality standards;

(5) The effects of existing standards—MSHA standards on diesel exhaust gases (CO, CO_2, NO, NO_2, and SO_2), and EPA diesel engine emission standards—on the concentration of dpm in underground metal and nonmetal mines;

(6) Methods for controlling dpm concentrations in underground metal and nonmetal mines;

(7) MSHA's approach to diesel safety and health in underground coal mines and its effect on dpm;

(8) Information on how certain states are restricting occupational exposure to dpm; and

(9) A history of this rulemaking.

Material on these subjects which was available to MSHA at the time of the proposed rulemaking was included in Part II of the preamble that accompanied the proposed rule. (63 FR 58123 et seq). Portions of that material relevant to underground metal and nonmetal mines is reiterated here (although somewhat reorganized), and the material is amended and supplemented where appropriate as a result of comments and additional information added to the record since the proposal was published.

(1) The Role of Diesel-Powered Equipment in Underground Metal and Nonmetal Mining in the United States

Diesel engines, first developed about a century ago, now power a full range of mining equipment in underground metal and nonmetal mines, and are used extensively in this sector. This sector's reliance upon diesel engines to power equipment in underground metal and nonmetal mines appears likely to continue for some time.

Historical Overview of Diesel Power Use in Mining. As discussed in the notice of proposed rulemaking, the diesel engine was developed in 1892 by the German engineer Rudolph Diesel. It was originally intended to burn coal dust with high thermodynamic efficiency. Later, the diesel engine was modified to burn middle distillate petroleum (diesel fuel). In diesel engines, liquid fuel droplets are injected into a prechamber or directly into the cylinder of the engine. Due to compression of air in the cylinder the temperature rises high enough in the cylinder to ignite the fuel.

The first diesel engines were not suited for many tasks because they were too large and heavy (weighing 450 lbs. per horsepower). It was not until the 1920's that the diesel engine became an efficient lightweight power unit. Since diesel engines were built ruggedly and had few operational failures, they were used in the military, railway, farm, construction, trucking, and busing industries. The U.S. mining industry was slow, however, to begin using these engines. Thus, when in 1935 the former U.S. Bureau of Mines published a comprehensive overview on metal mine ventilation (McElroy, 1935), it did not even mention ventilation requirements for diesel-powered equipment. By contrast, the European mining community began using these engines in significant numbers, and various reports on the subject were published during the 1930's. According to a 1936 summary of these reports (Rice, 1936), the diesel engine had been introduced into German mines by 1927. By 1936, diesel engines were used extensively in coal mines in Germany, France, Belgium and Great Britain. Diesel engines were also used in potash, iron and other mines in Europe. Their primary use was in locomotives for hauling material.

It was not until 1939 that the first diesel engine was used in the United States mining industry, when a diesel haulage truck was used in a limestone mine in Pennsylvania, and not until 1946 was a diesel engine used in a coal mine. Today, however, diesel engines are used to power a wide variety of equipment in all sectors of U.S. mining. Production equipment includes vehicles such as haultrucks and shuttle cars, front-end loaders, hydraulic shovels, load-haul-dump units, face drills, and explosives trucks. Diesel engines are also used in support equipment including generators and air compressors, ambulances, fire trucks, crane trucks, ditch diggers, forklifts, graders, locomotives, lube units, personnel carriers, hydraulic power units, longwall component carriers, scalers, bull dozers, pumps (fixed, mobile and portable), roof drills, elevating work platforms, tractors, utility trucks, water spray units and welders.

Current Patterns of Diesel Power Use in Underground Metal and Nonmetal Mining. Table II–1 provides information on the current utilization of diesel equipment in underground metal and nonmetal mines.

[2] This lower bound figure could significantly underestimate the magnitude of the health benefits. For example the estimate based on the mean value of all the studies examined is 49 lung cancer deaths avoided per year.

TABLE II–1.—DIESEL EQUIPMENT IN UNDERGROUND METAL AND NONMETAL MINES

Mine size	Number of underground mines [A]	Number of mines with diesels [B]	Number of Engines [B]
Small [C]	134	77	584
Large	130	119	3,414
All	264	196	3,998

(A) Number of underground mines is based on those reporting operations for FY1999 (preliminary data).
(B) Number of mines using diesels are based on January 1998 count, by MSHA inspectors, of underground metal and nonmetal mines that used diesel powered equipment, and the number of engines (the latter rounded to the nearest 25) was determined in the same count with reference to equipment normally in use.
(C) A ''small'' mine is one with less than 20 miners.

As noted in Table II–1, a majority of underground metal and nonmetal mines use diesel-powered equipment.

Diesel engines in metal and nonmetal underground mines, and in surface coal mines, range up to 750 HP or greater, although equipment size, and thus the size of the engine, can be limited by production requirements, the dimensions of mine openings, and other factors. By contrast, in underground coal mines, the average engine size is less than 150 HP. The reason for this disparity is the nature of the equipment powered by diesel engines. In underground metal and nonmetal mines, and surface mines, diesel engines are widely used in all types of equipment—both the equipment used under the heavy stresses of production and the equipment used for support. In underground metal and nonmetal mines, of the approximate 4,000 pieces of diesel equipment normally in use, about 1,800 units are used for loading and hauling. By contrast, the great majority of the diesel usage in underground coal mines is in support equipment.

This fact is significant for dpm control in underground metal and nonmetal mines. As the horsepower size of the engine increases, the mass of dpm emissions produced per hour increases. (A smaller engine may produce the same or higher levels of particulate emissions per volume of exhaust as a large engine, but the mass of particulate matter increases with the engine size). Accordingly, as engine size increases, control of emissions may require additional efforts.

Another factor relevant to control of dpm emissions in this sector is that fewer than 15 underground metal and nonmetal mines are required to use Part 36 permissible equipment because of the possibility of the presence of explosive mixtures of methane and air. The surface temperature of diesel powered equipment in underground metal and nonmetal mines classified as gassy must be controlled to less than 400°F. Such mines must use equipment approved as permissible under Part 36 if the equipment is utilized in areas where permissible equipment is required. These gassy metal and nonmetal mines have been using the same permissible engines and power packages as those approved for underground coal mines. (MSHA has not certified a diesel engine exclusively for a Part 36 permissible machine for the metal and nonmetal sector since 1985 and has certified only one permissible power package; however, that engine model has been retired and is no longer available as a new purchase to the industry). As a result, engine size (and thus dpm production of each engine) is more limited in these mines, and, as explained in section 6 of this part, the exhaust from these engines is cool enough to add a paper type of filtration device directly to the equipment.

By contrast, since in nongassy underground metal and nonmetal mines mine operators can use conventional construction equipment in their production sections without the need for modifications to the machines, they tend to do so. Two examples are haulage vehicles and front-end loaders. As a result, these mines can and do use engines with larger horsepower and hot exhaust. As explained in section 6 of this part, the exhaust from such engines must be cooled by a wet or dry device before a paper filter can be used, or high temperature filters (*e.g.,* ceramics) must be used.

At this time, diesel power faces little competition from other power sources in underground metal and nonmetal mines. As can be seen from the chart, there are some small metal and nonmetal mines (less than 20 employees) which do not use diesel-powered equipment; most of these used compressed air for drilling and battery-powered rail equipment for haulage.

It is unclear at this time, how quickly new ways to generate energy to run mobile vehicles will be available for use in a wide range of underground metal and nonmetal mining activities. New hybrid electric automobiles are being introduced this year by two manufacturers (Honda and Toyota); such vehicles combine traditional internal combustion power sources (in this case gasoline) with electric storage and generating devices that can take over during part of the operating period. By reducing the time the vehicle is directly powered by combustion, such vehicles reduce emissions. Further developments in electric storage devices (batteries), and chemical systems that generate electricity (fuel cells) are being encouraged by government-private sector partnerships. For further information on recent developments, see the Department of Energy alternative fuels web site at http://www.afdc.doe.gov/altfuels.html, and ''The Future of Fuel Cells'' in the July 1999 issue of *Scientific American.* Until such new technologies mature, are available for use in large equipment, and are reviewed for safe use underground, however, MSHA assumes that the underground metal and nonmetal mining community's significant reliance upon the use of diesel-power will continue.

(2) The Composition of Diesel Exhaust and Diesel Particulate Matter (DPM)

The emissions from diesel engines are actually a complex mixture of compounds, containing gaseous and particulate fractions. The specific composition of the diesel exhaust in a mine will vary with the type of engines being used and how they are used. Factors such as type of fuel, load cycle, engine maintenance, tuning, and exhaust treatment will affect the composition of both the gaseous and particulate fractions of the exhaust. This complexity is compounded by the multitude of environmental settings in which diesel-powered equipment is operated. Nevertheless, there are a few basic facts about diesel emissions that are of general applicability.

The gaseous constituents of diesel exhaust include oxides of carbon, nitrogen and sulfur, alkanes and alkenes (*e.g.,* butadiene), aldehydes (*e.g.,* formaldehyde), monocyclic aromatics (*e.g.,* benzene, toluene), and polycyclic aromatic hydrocarbons (*e.g.,* phenanthrene, fluoranthene). The oxides of nitrogen (NO_X) are worth particular mention because in the atmosphere they can precipitate into particulate matter. Thus, controlling the emissions of NO_X is one way that engine manufacturers can control particulate production indirectly. (See section 5 of this part).

The particulate components of the diesel exhaust gas include the so-called diesel soot and solid aerosols such as ash particulates, metallic abrasion particles, sulfates and silicates. The vast majority of these particulates are in the invisible sub-micron range of 100nm.

The main particulate fraction of diesel exhaust is made up of very small individual particles. These particles have a solid core mainly consisting of elemental carbon. They also have a very surface-rich morphology. This surface absorbs many other toxic substances, that are transported with the particulates, and can penetrate deep into the lungs. There can be up to 1,800 different organic compounds adsorbed onto the elemental carbon core. A portion of this hydrocarbon material is the result of incomplete combustion of fuel; however, the majority is derived from the engine lube oil. In addition, the diesel particles contain a fraction of non-organic adsorbed materials. Figure II–1 illustrates the composition of dpm.

Diesel particles released to the atmosphere can be in the form of individual particles or chain aggregates (Vuk, Jones, and Johnson, 1976). In underground coal mines, more than 90% of these particles and chain aggregates are submicrometer in size (i.e., less than 1 micrometer (1 micron) in diameter). Dust generated by mining and crushing of material—*e.g.,* silica dust, coal dust, rock dust—is generally not submicrometer in size. Figure II–2 shows a typical size distribution of the particles found in the environment of a mine that uses equipment powered by diesel engines (Cantrell and Rubow, 1992). The vertical axis represents relative concentration, and the horizontal axis the particle diameter. As can be seen, the distribution is bimodal, with dpm generally being well less than 1 µm in size and dust generated by the mining process being well greater than 1 µm.

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Figure II-1
DPM components

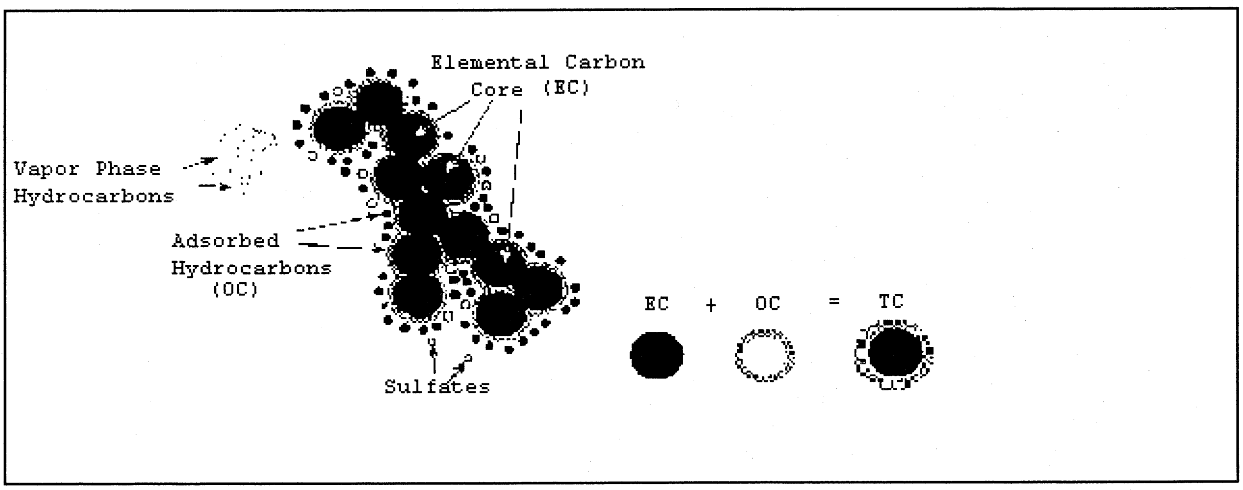


Figure II-2 -Typical distribution of dpm relative to distribution of other mining particulates.

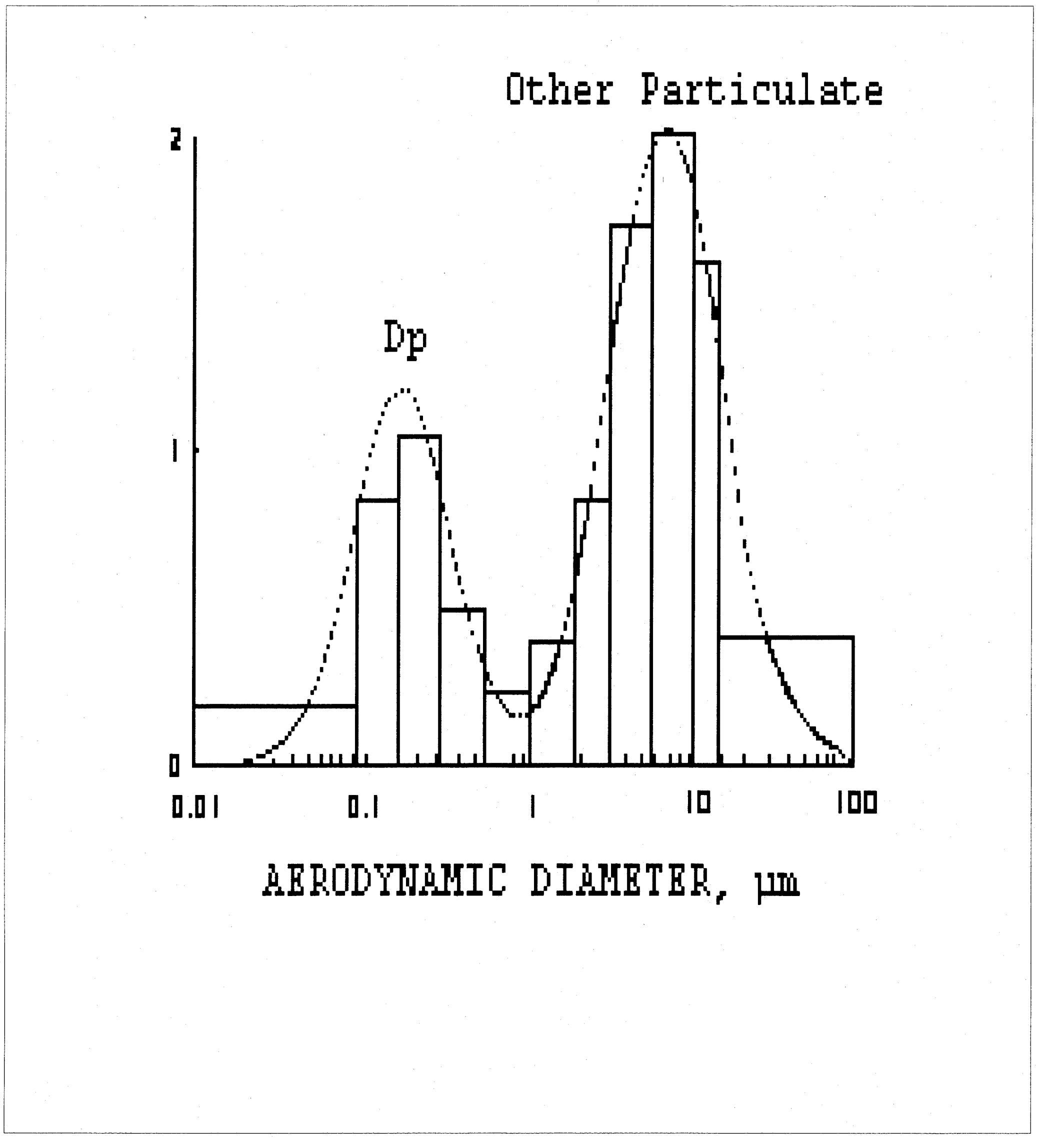
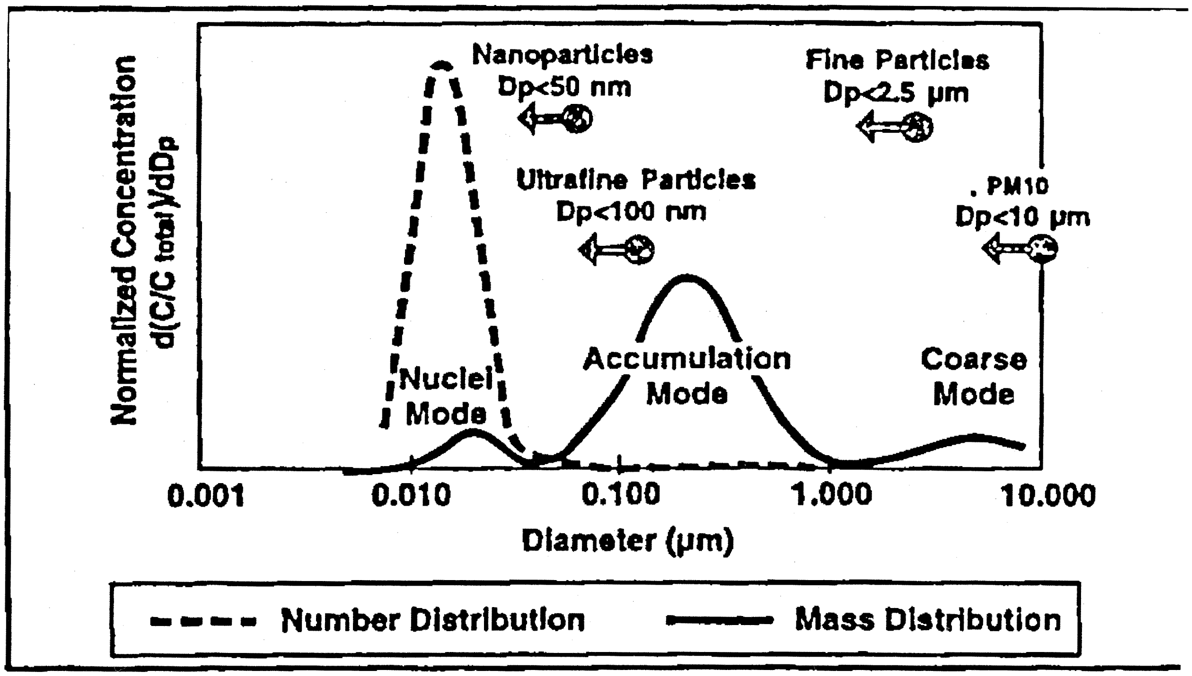


Figure II-3



Diesel particulate size distribution.

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As shown on Figure II–3 (Majewski, W. Addy, Diesel Progress June, 1998) diesel particulates have a bimodal size distribution which includes small nuclei mode particles and larger accumulation mode particles. As further shown, most of diesel particle mass is contained in the accumulation mode but most of the particle number can be found in the nuclei mode.

The particles in the nuclei mode, also known as nanoparticles, are being investigated as to their health hazard relevance. The interest in these particles has been sparked by the finding that newer ''low polluting engines emit higher numbers of small particles than the old technology engines. Although the exact composition of diesel nanoparticles is not known, it was found that they may be composed of condensates (hydrocarbons, water, sulfuric acid). The amount of these condensates and the number of nanoparticles depends very significantly on the particulate sampling conditions, such as dilution ratios, which were applied during the measurement.

Both the maximum particle concentration and the position of the nuclei and accumulation mode peaks, however, depend on which representation is chosen. In mass distributions, the majority of the particulates (*i.e.,* the particulate mass) is found in the accumulation mode. The nuclei mode, depending on the engine technology and particle sampling technique, may be as low as a few percent, sometimes even less than 1%. A different picture is presented when the number distribution representation is used. Generally, the number of particles in the nuclei mode contributes to more than 50% of the total particle count. However, sometimes the nuclei mode particles represent as much as 99% of the total particulate number. The topic of nanoparticles is discussed further in section 5 of this Part.

(3) The Sampling and Analytical Techniques for Measuring Ambient dpm in Underground Metal and Nonmetal Mines

As MSHA noted in the preamble to the proposed rule, there are a number of methods which can measure dpm concentrations with reasonable accuracy when it is at high concentrations and when the purpose is exposure assessment. Measurements for the purpose of compliance determinations must be more accurate, especially if they are to measure compliance with a dpm concentration as low as 200 µg/m^3 or lower. Accordingly, MSHA noted that it needed to address a number of questions as to whether any existing method could produce accurate, reliable and reproducible results in the full variety of underground mines, and whether the samplers and laboratories existed to support such determinations. (See 63 FR 58127 *et.seq*).

MSHA concluded that there was no method suitable for such compliance measurements in underground coal mines, due to the inability of the available methods to distinguish between dpm and coal dust. Accordingly, the agency developed a rule for the coal mining sector that does not depend upon ambient dpm measurements.

By contrast, the agency concluded that by using a sampler developed by the former Bureau of Mines, and an analytical method developed by the National Institute for Occupational Safety and Health (NIOSH), MSHA could accurately measure dpm levels at the required concentrations in underground metal and nonmetal mines. While not requiring operators to use this method for their own sampling, MSHA did commit itself to use this approach (or a method subsequently determined by NIOSH to provide equal or improved accuracy) for its own sampling. Moreover the agency proposed that MSHA sampling be the sole basis for determining compliance by metal and nonmetal mine operators with applicable compliance limits, and that a single sample would be adequate for such purposes. Specifically, proposed § 57.5061 would have provided:

Section 57.5061 Compliance determinations.

(a) A single sample collected and analyzed by the Secretary in accordance with the procedure set forth in paragraph (b) of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect and analyze samples of diesel particulate matter by using the method described in NIOSH Analytical Method 5040 and determining the amount of total carbon, or by using any method subsequently determined by NIOSH to provide equal or improved accuracy in mines subject to this part.

This part of MSHA's proposed rule received considerable comment. Some commenters challenged the accuracy, precision and sensitivity of NIOSH Analytical Method 5040. Some challenged whether the amount of total carbon determined by the method is a reliable way to determine the amount of dpm. Others questioned whether the sampler developed by the former Bureau of Mines would provide an accurate sample to be analyzed. Many commenters asserted that the analytical method would not be able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke. (It should be noted that commenters also questioned the use of a single sample as the basis for a compliance determination, and the use of area sampling in compliance determinations; these comments are reviewed and responded to in Part IV of this preamble in connection with the discussion of § 57.5061.)

The agency has carefully reviewed the information and data submitted by commenters. Where necessary to verify the validity of comments, MSHA collected additional information which it has placed in the record, and which in turn were the subject of an additional round of comments.

Background. As discussed in section 2 of this part, diesel particulate consists of a core of elemental carbon (EC), adsorbed organic carbon (OC) compounds, sulfates, vapor phase hydrocarbons and traces of other compounds. The method developed by NIOSH provides for the collection of a sample on a quartz fiber filter. As originally conceived, the filter is mounted in an open face filter holder that allows for the sample to be uniformly deposited on the filter surface. After sampling, a section of the filter is analyzed using a thermal-optical technique (Birch and Cary, 1996). This technique allows the EC and OC species to be separately identified and quantified. Adding the EC and OC species together provides a measure of the total carbon concentration in the environment.

Studies have shown that the sum of the carbon (C) components (EC + OC) associated with dpm accounts for 80–85% of the total dpm concentration when low sulfur fuel is used (Birch and Cary, 1996). Therefore, in the preamble to the proposed rule, MSHA asserted that since the TC:DPM relationship is consistent, it provides a method for determining the amount of dpm. MSHA noted that the method can detect as little as 1 $\mu g/m^3$ of TC. Moreover, NIOSH has investigated the method and found it to meet NIOSH's accuracy criterion (NIOSH, 1995)—i.e., that measurements come within 25 percent of the true TC concentration at least 95 percent of the time.

In the preamble to the proposed rule, MSHA recognized that there might be some interferences from other common organic carbon sources in underground metal and nonmetal mines: specifically, oil mists and cigarette smoke. The agency noted it had no data on oil mists, but had not encountered the problem in its own sampling. With respect to cigarette smoke, the agency noted that: ''Cigarette smoke is under the control of operators, during sampling times in particular, and hence should not be a consideration.'' (63 FR 58129).

The agency also discussed the potential advantages and disadvantages of using a special device on the sampler to eliminate certain other possible interferences. NIOSH had recommended the use of a submicron impactor when taking samples in coal mines to filter out particles more than one micron in size. See Figure III–3. The idea is to ensure that a sample taken in a coal mine does not include significant amounts of coal dust, since the analytical method would capture the organic carbon in the coal dust just like the carbon in dpm. Coal dust is generally larger than one micron, while dpm is generally smaller than one micron. However, MSHA pointed out that while samples in underground metal and nonmetal mines could be taken with a submicrometer impactor, this could lead to underestimating the total amount of dpm present. This is because the fraction of dpm particles greater than 1 micron in size in the environment of noncoal mines can be as great as 20%.

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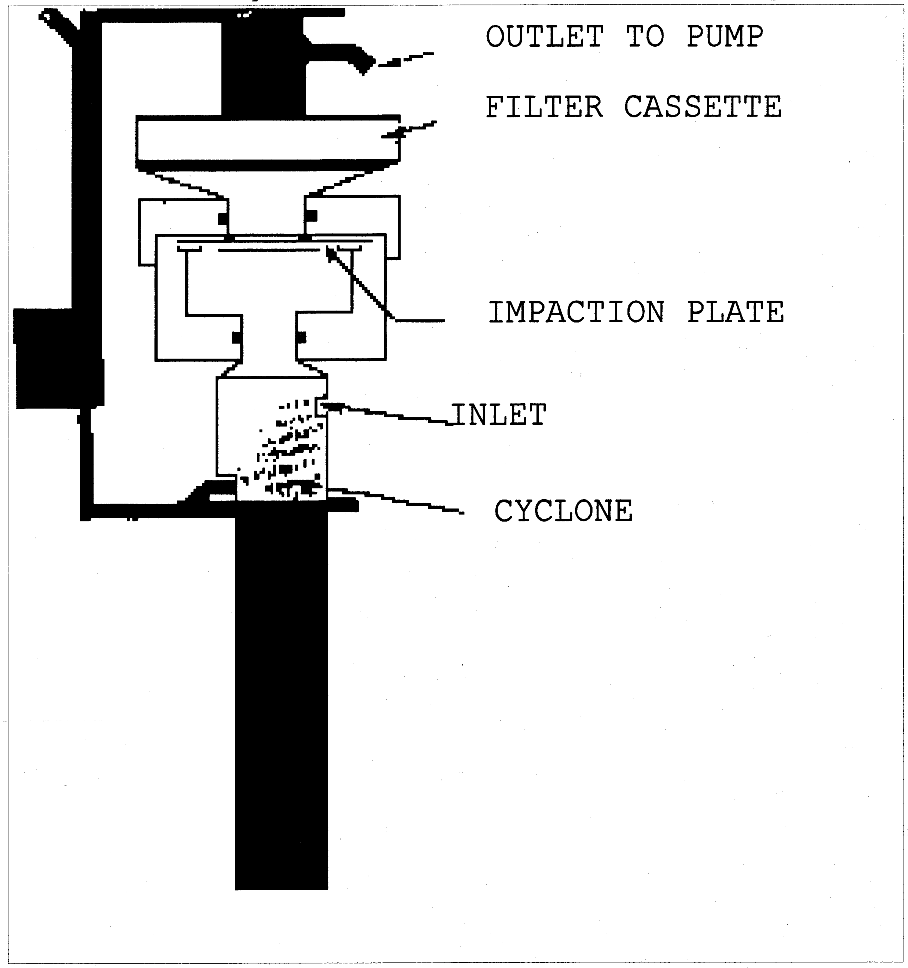
Figure II- 3
Personal Sampler For Submicrometer Particulate Sampling



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MSHA also noted that while NIOSH Method 5040 requires no specialized equipment for collecting a dpm sample, the sample would most probably require analysis by a commercial laboratory. The agency noted it did not foresee the availability of qualified testing facilities as a problem. The agency likewise discussed the availability of the sampling device, and noted steps that were underway to develop a disposable sampler. (63 FR 58130)

Sample Collection Methods. Some commenters raised questions about how dpm samples should be taken: using open face sampling, respirable sampling and submicron sampling. All three are discussed in NIOSH Analytical Method 5040. Because diesel particulate matter is primarily submicron in size any of the three sampling methods could be used.

The choice of sample collection method considers the cost and potential interferences that the method can contribute. Regardless of the sampling method, the sampling media (filter) must be one that does not interfere with the analysis. For this reason a pre-fired quartz fiber filter has been chosen. The quartz fiber filter is capable of withstanding the temperatures from the analytical procedure. The filter is pre-fired to remove residual carbon, attached to the filter during manufacturing.

Total Dust Sampling. Total dust sampling is the least expensive method to collect an airborne dust sample. It is commonly used to collect a sample that is representative of all the dust in the environment; i.e., the particles are not preclassified during the collection process. Total dust sampling can be performed using a filter cassette that allows the whole face of the filter to be exposed during collection of the sample (open face) or using a filter cassette with a small inlet opening (referred to as a closed face filter cassette). The latter method is used by MSHA for compliance sampling for total dust in the metal and nonmetal sector. Because the sample collected is representative of all the particulate matter in the environment, there is the potential for interference from mineral contaminants when sampling for diesel particulate matter. While in many cases the analytical results can be corrected for these interferences, in some instances the interferences may be so large that they can not be quantified with the analytical procedure, thus preventing the analytical result to be corrected for the interference.

Additionally, MSHA has noted that in some cases when using the total dust sampler with the small inlet hole, distribution of the collected sample on the filter is not uniform. The distribution of sample is concentrated in the center of the filter. This can result in the effect of an interference being magnified. As a result, MSHA considers that total dust sampling is not an appropriate sampling method for the mining industry to use when sampling diesel particulate matter.

Respirable Dust Sample Collection. Respirable dust sampling is commonly used when a size selective criteria for dust is required. The mining industry is familiar with size selective sampling for the collection of coal mine dust samples in coal mines and for collecting respirable silica samples in metal and nonmetal mines. For respirable dust sampling MSHA uses a 10 millimeter, Dorr Oliver nylon cyclone as a particle classifier to separate the respirable fraction of the aerosol from the total aerosol sampled. The use of this particle classifier would be suitable when sampling diesel particulate, provided significant amounts of interfering minerals are not present. This is because 90 percent of the diesel particulate is typically less than 1 micrometer in size. Particles less than 1 micrometer in size pass through the cyclone and are deposited on the filter. While in many cases, these interferences could be removed during the analytical procedures, the analytical procedures alone can not be assured to remove the interferences when large amounts of mineral dust are present.

Additionally, MSHA has observed that in some sampling equipment the cyclone outlet hole has been reduced when interfacing it with the filter capsule. MSHA has further observed that where this has occurred, the distribution of sample on the collection filter may not be uniform. In this circumstance the sample is also concentrated in the center of the filter which can result in the effect of a mineral interference being magnified. As a result, MSHA considers that respirable dust sampling is not a universally applicable sampling method for the mining industry to use for sampling diesel particulate matter.

Submicron Dust Sample Collection. Since only a small fraction of a mineral dust aerosol is less than 1 micrometer in size, a submicrometer impactor (Cantrell and Rubow, 1992) was developed to permit the sampling of diesel particulate without sampling potential mineral interferences. The submicrometer impactor was initially developed to remove the interference from coal mine dust when sampling diesel particulate in coal mines. It was designed to remove the carbon coal particles, that are greater than 0.8 micrometer in size, when sampling for diesel particulate matter at a pump flowrate of 2.0 liters per minute. As a result the submicrometer impactor cleans potentially interfering mineral dust from the sample.

As noted in the preamble to the proposed rule, use of this method to measure dpm does result in the exclusion of that portion of dpm that is not submicron in size, and this can be significant. On the other hand, this method avoids problems associated with the other methods described above. Moreover, as discussed in more detail below under the topic of ''interferences'', the submicron impactor can eliminate certain substances that in metal and nonmetal mines would otherwise make it difficult for the analytical method to be used for compliance purposes.

Accuracy of Analytical Method, NIOSH Method 5040. Commenters challenged the accuracy, precision and sensitivity of the analytical method (NIOSH Method 5040) used for the diesel particulate analysis. MSHA has carefully reviewed these concerns, and has concluded that provided a submicron impactor is used with the sampling device in underground metal and nonmetal mines, NIOSH Method 5040 does provide the accuracy, precision and sensitivity necessary to use in compliance sampling for dpm in such mines.

As noted above, NIOSH Method 5040 is an analytical method that is used to determine elemental and organic carbon content from an airborne sample. It is more versatile than other carbon analytical methods in that it differentiates the carbon into its organic and elemental carbon components. The method accomplishes this through a thermal optical process. An airborne sample is collected on a quartz fiber filter. A portion of the filter, (approximately 2 square centimeters in area) is placed into an oven. The temperature of the oven is increased in increments. At certain oven temperature and atmospheric conditions (helium, helium-oxygen), carbon on the filter is oxidized into carbon dioxide. The carbon dioxide gas is then passed over a catalyst and reduced to methane. The methane concentration is measured and carbon content is determined. Separation of different types of organic carbon is accomplished through temperature and atmospheric control. The instrument is programmed to increase temperature in steps over time. This step by step increase in temperature allows for differentiation between various types of organic carbon.

A laser is used to differentiate the organic carbon from the elemental carbon. The laser penetrates the filter and when the laser transmittance reaches its initial value this determines when elemental carbon begins to evolve. The computer software supplied with the instrumentation indicates this separation by a vertical line. The separation point can be adjusted by the analyst. As a result, there may be small differences in the determination of organic and elemental carbon between analysts, but the total carbon (sum of elemental and organic carbon) does not change. The software also allows the analyst to identify and quantify the different types of organic carbon using identifiable individual peaks. This permits the mathematical subtraction of a particular carbon peak. This feature is particularly useful in removing contributions from carbonates or other carbonaceous minerals. In other total carbon methods, samples have to be acidified to remove carbonate interference. A thermogram is produced with each analysis that shows the temperature ramps, oven atmospheric conditions and the amount of carbon evolved during each step.

A range of five separate sucrose standards between 10–100 μg/cm^2 carbon are initially analyzed to check the linearity of the internal calibration determined using a constant methane concentration. This constant methane concentration is injected at the end of each analysis. To monitor this methane constant, sucrose standards are analyzed several times during a run to determine that this constant does not deviate by more than 5–10%.

The method has the sensitivity to analyze environmental samples containing 1 to 10 μg/m^3 of elemental carbon. The method will be used in mining applications to determination total carbon contamination where the diesel particulate concentration will be limited to 400 $\mu g/m^3{}_{TC}$ and 160 $\mu g/m^3{}_{TC}$. NIOSH has reported that the lower limit of detection for the method is 0.1 μg/cm^2 elemental carbon for an oven pre-fired filter portion and 0.5 μg/cm^2 organic carbon for an oven pre-fired filter portion. For a full shift sample, this detection limit represents approximately 1 and 5 μg/m^3 of elemental and organic carbon, respectively. Additionally, NIOSH has conducted a round robin program to assess interlaboratory variability of the method. This study indicated a relative standard deviation for total carbon, of less than 15 percent.

A typical diesel particulate thermogram is shown in Figure II–4. The thermogram generally contains five or six carbon peaks, one for each temperature ramp on the analyzer. The first four peaks (occurring during a helium atmosphere ranging from a temperature of 210C to 870C) are associated with organic carbon determination and the fifth and/or sixth peak (occurring during a helium/oxygen atmosphere ranging in temperature from 610C to 890C) is the elemental carbon determination.

The fourth peak (temperature ~750C) is also where carbonate and other carbonaceous minerals are evolved in the analysis. For a diesel particulate sample without interferences present, this fourth peak is usually minimal as it is attributed to heavy distillant organics not normally associated with diesel operations in underground mining applications. If this peak is due to carbonate, the carbonate interference can be verified by analyzing a second portion of the sample after acidification as described in the NIOSH 5040 method. If the fourth peak is caused by some other carbonaceous mineral, the acidification process may not completely remove the interference and may, on occasion cause a positive bias to elemental carbon.

As explained below in the discussion of interferences, these analytical interferences from carbonaceous materials can be corrected by using the submicron impactor preceded by a cyclone (respirable classifier) to collect diesel particulate matter samples, since nearly all the particles of these minerals are greater than 1 micrometer in size. Accordingly, MSHA has determined it should utilize a submicron impactor in taking any samples in underground metal and nonmetal mines, and has included this requirement in the rule. Specifically, 57.5061(b) now provides:

(b) The Secretary will collect samples of diesel particulate matter by using a respirable dust sampler equipped with a submicrometer impactor and analyze the samples for the amount of total carbon using the method described in NIOSH Analytical Method 5040, except that the Secretary may also use any methods of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of diesel particulate matter in mines subject to this part.

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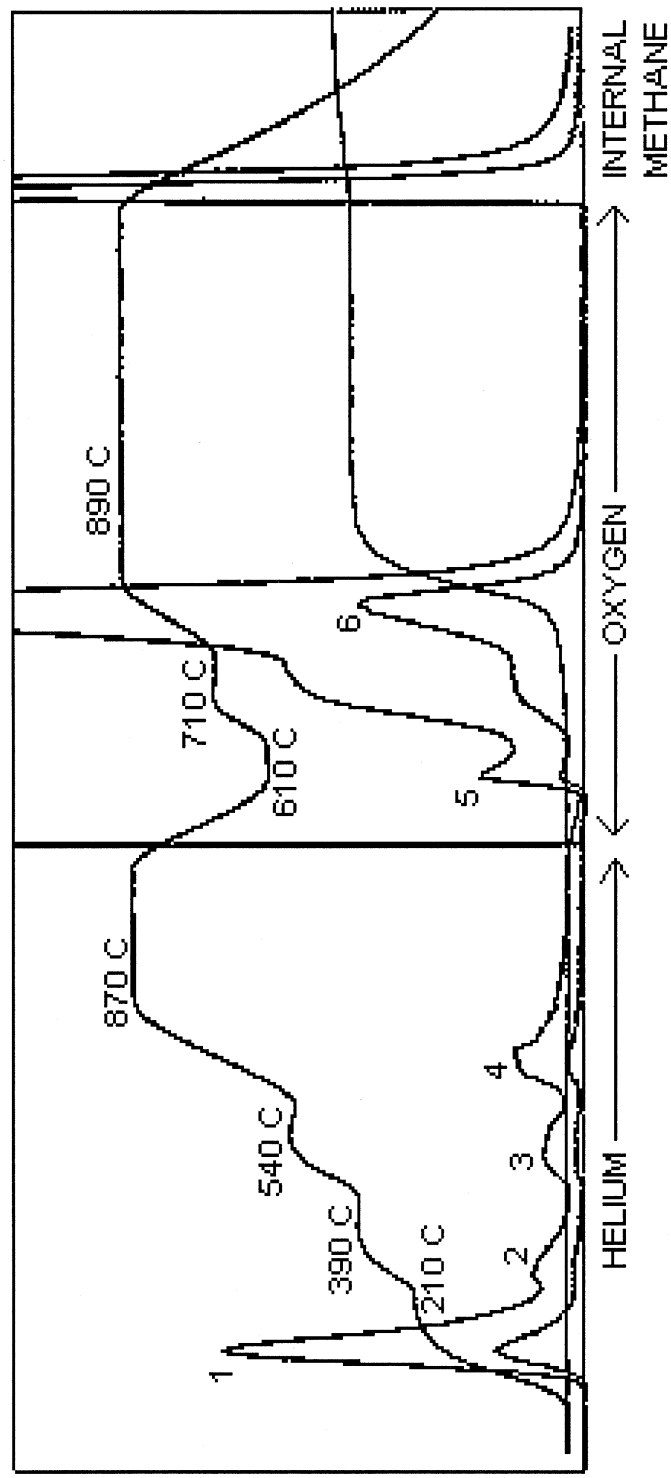

Figure II-4 Thermogram from analysis of a respirable dust sample.

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In keeping with established metal and nonmetal sampling protocol, the samplers will be operated at a flow rate of 1.7 LPM. At a flow rate of 1.7 LPM, the cut point for the impactor is 0.9 micrometers.

Any organic carbon detected at the fourth peak will be subtracted from the organic carbon portion of the sample analysis using the software supplied with the analytical program. The only samples that MSHA anticipates that will be acidified are those collected in trona mines. These samples contain a bicarbonate which evolves in several of the organic peaks but can be removed by acidification. Use of the submicron impactor will also insure a uniform distribution of diesel particulate and mineral dust on the filter.

Some Commenters indicated that a uniform deposit of mineral dust was sometimes not obtained with certain respirable dust sampler configurations. For some commodities such as salt and potash, where carbonate may not be an interference, it is probably not necessary to sample with the submicron impactor. However, in order to be consistent, MSHA will sample all commodities using a respirable dust sampler equipped with a submicrom impactor, and has so noted in the rule.

Proper use of sample blanks. Each set of samples collected to measure the diesel particulate concentration of a mine environment, must be accompanied by a field blank (a filter cassette that is treated and handled in the same manner as filters used to collect the samples) when submitted for analysis. The amount of total carbon determined from the analysis of the blank sample must be applied to (subtracted from) the carbon analysis of each individual sample. The field blank correction is applied to account for non-sampled carbon that attaches to the filter media. The blank correction is applied to the organic fraction as, typically, no elemental carbon is found on the blank filters.

Failure to adjust for the blanks can lead to incorrect results, as was the case with samples collected by some commenters. While field blanks were submitted and analyzed with their samples, the field blank analytical results were not used to correct the individual samples for nonsampled carbon content. Typically the carbon content on the reviewed field blanks ranged from 2 to 3 μg/square centimeter of filter area. For a one-hour sample, not using a blank correction of this magnitude, could result in an overestimate of 250 μg/m³ of dpm (3×8.55×1000/(1.7 * 60)=250). For an eight-hour sample, not using a blank correction, could result in an overestimate of 30 μg/m³ of dpm (3×8.55×1000/(1.7* 480)=30).

Variability of Sample Blanks

In response to the July 1, 2000, reopening of the record, one commenter submitted summary data from a study that examined diesel exposures in seven underground facilities where trona, salt, limestone, and potash were mined. The purpose of this study was to determine the precision and accuracy of the NIOSH 5040 method in these environments. According to the commenter, the study data ''provide strong evidence that the NIOSH 5040 Method * * * is not feasible as a measure of DPM exposure.'' The commenter's conclusion was based on five ''difficulties'' that, according to the commenter, were documented when sampling for DPM using organic carbon or total carbon as a surrogate. These difficulties were:

(1) High and variable blank values from filters;

(2) High variability from duplicate punches from the same sampling filter;

(3) Consistently positive interference when open-faced monitors were sampled side-by-side with cyclones;

(4) Poor correlation of organic carbon to total carbon levels; and

(5) Interference from limestone that could not be adequately corrected with acid-washing.

As discussed elsewhere in this preamble, difficulties #3 and #5 will be resolved by the use of a submicrometer impactor sampler. Difficulty #4, the lack of a strong correlation between organic carbon and total carbon, has long been recognized by MSHA. That is one of the reasons MSHA chose total carbon (TC=EC+OC) as the best surrogate to use for assessing DPM levels in underground metal and nonmetal mines. MSHA has never proposed using organic carbon as a surrogate measure of DPM.

The summary data that the commenter submitted do not appear to demonstrate the first two items of ''difficulties'' with respect to TC measurements. Because MSHA has not experienced the difficulties of (1) high and variable blank values and (2) high variability between duplicate punches from the same sampling filter, MSHA also performed its own analysis of the data submitted by the commenter. MSHA's examination of the data included:

- Estimating the mean, within-mine standard deviation, and relative standard deviation (RSD) for blank TC values, based on the ''Summary of Blank Sample Results'' submitted; and
- Estimating the variability (expressed as RSD) associated with the TC analysis of duplicate punches from the same filter, based on individual sample data submitted earlier by the same commenter for five of the mines.

Based on the summary data, the overall average mean TC content per blank filter, weighted by the number of blank samples in each mine, was 16.9 μg TC. This represents the average value that would be subtracted from the TC measurement from an exposed sample before making a noncompliance determination. At a TC concentration of 160 μg/m³ (the final limit established by this rule), the TC accumulated on a filter after an 8-hour sampling period would be approximately 130 μg. Therefore, these data show that the mean TC value for a blank is less than 13 percent of TC accumulated at the concentration limit, and an even lower percentage of total TC accumulated at concentrations exceeding the limit. MSHA considers this to be acceptable for samples used to make noncompliance determinations. Based on the same summary data presented for TC measurements on blank samples, the weighted average of within-mine standard deviations is 6.4 μg. Compared to TC values greater than or equal to 130 μg, this corresponds to an RSD no greater than 6.4/130 = 4.9 percent. MSHA also regards this degree of variability in blank TC values to be acceptable for purposes of noncompliance determination.

To estimate the measurement variability associated with analytical errors in the TC measurements, MSHA examined the individual TC results from duplicate punches on the same filter. These data were submitted earlier by the same commenter for five mines. As shown, by the commenter's summary table, data obtained from the first mine were invalid, leaving data from four mines (2–5) for MSHA's data analysis. Data were provided on a total of 73 filters obtained from these four mines, yielding 73 pairs of duplicate TC measurements, using the initial and first repeated measurement provided for both elemental and organic carbon. MSHA calculated the mean percent difference within these 73 pairs of TC measurements (relative to the average for each pair) to be 8.2 percent (95-percent confidence interval = 5.6 to 10.9 percent). Based on the same data, MSHA calculated an estimated RSD = 10.0 percent for the analytical error in a single determination of TC.[1] Contrary

[1] This estimate was obtained by first calculating the standard deviation of the differences between the natural logarithms of the TC measurements within each pair. Since each of these differences

to the commenter's conclusion, this result supports MSHA's position that TC measurements do not normally exhibit excessive analytical errors.

This estimate of the RSD = 10.0 percent for TC measurements is also consistent with the replicated area sample results submitted by the commenter for the seven mines. In this part of the study, designed to evaluate measurement precision, 69 sets of simultaneous samples were collected at the seven mines. Each set, or ''basket,'' of samples normally consisted of five simultaneous samples taken at essentially the same location. Since the standard deviation of the TC measurements within each basket was based on a maximum of five samples, the standard deviation calculated within baskets is statistically unstable and does not provide a statistically reliable basis for estimating the RSD within individual baskets. However, as shown in the summary table submitted by the commenter, the mean RSD across all 69 baskets was 10.6 percent. This RSD, which includes the effects of normal analytical variability, variability in the volume of air pumped, and variability in the physical characteristics of individual sampler units, is not unusually high, in the context of standard industrial hygiene practice.

MSHA also examined data submitted by another commenter to estimate the total variability associated with TC sample analysis by different laboratories. Based on 25 pairs of simultaneous TC samples (using a cyclone) analyzed by different laboratories, this analysis showed a total RSD of approximately 20.6 percent. If the most extreme of three statistical outliers in these data is excluded, the result based on 24 pairs is an estimated RSD of 11.7 percent. Like the first commenter's estimate of RSD = 10.6 percent, based on simultaneous samples analyzed at the same laboratory, these RSD's include not only normal analytical variability in a TC determination, but also variability in the volume of air pumped and variability in the physical characteristics of individual sampler units. The higher estimates, however, also cover uncertainty in a TC measurement attributable to differences between laboratories.

contains two TC determinations, and two corresponding analytical errors, this standard deviation was divided by the square root of 2. Using standard propagation of error formulas, the result provides a reasonably good estimate of the RSD over the range of TC values reported. MSHA used the same technique to estimate the RSD for the 25 pairs of TC samples analyzed at different laboratories, as described below.

Based on these analyses, MSHA has concluded that the data submitted to the record by commenters support the Agency's position that NIOSH Method 5040 is a feasible method for measuring DPM concentrations in underground M/NM mines.

Availability of analysis and samplers. One of the concerns expressed by commenters was the limited number of commercial laboratories available to analyze diesel particulate samples, and the availability of required samplers. While MSHA will be doing all compliance sampling itself, and running the analyses in its AIHA accredited laboratory in Pittsburgh, pursuant to § 57.5071 of the rule, operators in underground metal and nonmetal mines will be required to do environmental monitoring; and although they will not be required to use the same methods as MSHA to determine dpm concentrations, MSHA presumes that many will wish to do so. Moreover, there are certain situations (*e.g.,* verification that a dpm control plan is working) where the rule requires operators to use this method (§ 57.5062(c)).

Currently there are four commercial labs that have the capability to analyze for dpm using the NIOSH 5040 Method. These labs are: Sunset Laboratory, Forest Grove, Oregon and Chapel Hill, North Carolina; Data Chem, Salt Lake City, Utah; and Clayton Group Services, Detroit, MI. All of these labs, as well as including the NIOSH Laboratories in Cincinnati and Pittsburgh and the MSHA laboratory in Pittsburgh participate in a round robin analytical test to verify the accuracy and precision of the analytical method being used by each. As MSHA indicated in the preamble to its proposed rule, it believes that once there is a commercial demand for these tests, additional laboratories will offer such services.

The cost of the analysis from the commercial labs is approximately $30 to $50 for a single punch analysis and a report. This is about the same amount as a respirable silica analysis. The labs charge another $75 to acidify and analyze a second punch from the same filter and to prepare an analytical report. The labs report both organic and elemental carbon. By using the submicron impactor, operators can significantly reduce the number of situations where acidification is required, and thus reduce the cost of sample analysis.

The availability of samplers has been the subject of many comments—not so much because of concern about availability once the rule is in effect, but because of assertions that they are not available now. In particular, it has been alleged by some commenters that they have been unable to conduct their own ''independent evaluation'' of the NIOSH method because the agency has kept from them the samplers needed to properly conduct such testing. Some commenters even accused the agency of deliberately withholding the needed samplers.

As indicated in MSHA's toolbox and the preamble to the proposed rule, the former Bureau of Mines (BOM) submitted information on the development of a prototype dichotomous impactor sampling device that separates and collects the submicron respirable particulate from the respirable dust sampled. Information on this sampling device has been available to the industry since 1992. A picture of the sampler is shown above as Figure II–3. The impactor plate is made out of brass and the nozzles are drilled. The former BOM made available to all interested parties detailed design drawings that permitted construction of the dichotomous impactor sampler by any local machine shop. NIOSH and MSHA had hundreds of these sampling devices made for use in their programs to measure dpm concentrations. Anyone could have had impactor samplers built by a local machine shop at a cost ranging from $50 to $100.

In 1998, MSHA provided NIOSH with research funds for the development of a disposable sampling device that would have the same sampling characteristics as the BOM sampler, and including an impactor with the same sampling characteristics as the metal one. NIOSH awarded SKC the contract for the development of the disposable sampler. MSHA estimates the cost of the disposable sampler will be less than $50. The sampler is designed to interface with the standard 10 millimeter Dorr Oliver cyclone particle classifier and to fit in a standard MSHA respirable dust breast plate assembly. The quartz fiber filter used for the collection of diesel particulate in accordance with NIOSH Method 5040 has been encapsulated in an aluminum foil to make handling during the analytical procedure easier. To reduce manufacturing expense (and therefore, sampler cost), the nozzle plate in the SKC sampler is made of plastic instead of brass. In order to ensure that the nozzles in the impaction plate would hold their tolerances during manufacturing, the plastic nozzle plate for the SKC sampler is fitted with synthetic sapphire nozzles. This nozzle plate and nozzle assembly have the same performance as the BOM-designed sampler.

As of the time MSHA conducted its verification sampling for interferences, SKC had developed several prototypes of the disposable unit. However, testing of the devices by NIOSH indicated that a minor design modification was needed to better secure the impaction plate and nozzle plate to the sampler housing for a production unit. In its verification sampling, MSHA used both BOM designed and SKC prototype samplers. Prior to its verification tests, MSHA replaced the brass nozzle plates in the BOM design impactors with plastic nozzle-plates fitted with sapphire nozzles, as used in the SKC prototype sampler. However, because there was no change in nozzle geometry, this change in the BOM impactors did not affect their performance. During MSHA's verifications testing, no problems were experienced with dislodgement of the impaction plates or nozzle plates. The impactors used by MSHA in its verification sampling were not defective in any way, as suggested by several Commenters.

Under the Mine Act, MSHA has no obligation to make devices available to the mining community to conduct its own test sampling or to verify MSHA's results, nor does the mining industry have any explicit authority under the Mine Act to ''independently evaluate'' MSHA's results. The responsibility for determining the accuracy of the device and method for sampling rests with the agency, not the mining community. Accordingly, although some commenters requested that MSHA remove its interference studies from the record, the agency declines to do so. These studies are discussed in more detail below; additional questions raised about the sampling devices used in the studies, and the procedures for that sampling, are discussed in that context.

Some commenters initially asserted that their inability to conduct their own testing would prevent them from making comments of MSHA's verification studies. Based on the detailed comments subsequently provided, this initial concern appears to have been overstated.

It appears from some of the comments on MSHA's studies that members of the mining community may have understood MSHA to say that use of an impactor sampler would remove all interferences. MSHA can find no such statement. As noted in more detail below, use of the impactor will remove most of the interferences (albeit at the cost of eliminating some dpm as well).

Choice of Total Carbon as Measurement of Diesel Particulate Matter. MSHA asserted that the amount of total carbon (determined by the sampling and analytical methods discussed above) would provided the agency with an accurate representation of the amount of dpm present in an underground metal and nonmetal mine atmosphere at the concentration levels which will have to be maintained under the new standard. Some commenters questioned MSHA's statements concerning the consistency of the ratio between total carbon and diesel particulate, and the amount of that ratio. Other commenters suggested that elemental carbon may be a better indicator of diesel particulate because it is not subject to the interference that could effect a total carbon measurement.

Under the approach incorporated into the final rule, the concentration of organic and elemental carbon (in μg per square centimeter) are separately determined from the sample analysis and added together to determine the amount of total carbon. The interference from carbonate or mineral dust quantified by the fourth organic carbon peak is subtracted from the organic carbon results. The field blank correction is then subtracted from the organic analysis (the blank does not typically contain elemental carbon). Concentrations (time weighted average) of carbon are calculated from the following formula:

$$\frac{C\left(\mu g/cm^2\right) * A\left(cm^2\right) * 1{,}000\ L/m^3}{1.7\ LPM * \text{time (min)}}$$

Where:

C=The Organic Carbon (OC) or Elemental Carbon (EC) concentration, in μg/m^3, measured in the thermal/optical carbon analyzer (corrected for carbonate and field blank).

A=The surface area of the filter media used. The surface areas of the filters are as follows: quartz fiber filter without aluminum cover is 8.55 cm^2; quartz fiber filter with aluminum cover is 8.04 cm^2.

The 80 percent factor MSHA used to establish the total carbon level equivalents of the 500 μg/m^3 and 200 μg/m^3 dpm concentration limits being set by the rule was based on information obtained from laboratory measurements conducted on diesel engines (Birch and Cary, 1996). Since the publishing of the proposed rule, this value has been confirmed by measurements collected in underground mines in Canada (Watts, 1999)

MSHA agrees that the total carbon measurement is more subject to interferences than the elemental carbon measurement. However, because the ratio of elemental carbon to total carbon in underground mines is dependent on the duty cycle at which the diesel engine is operated (found to vary between 0.2 and 0.7), MSHA believes that total carbon is the best indicator of diesel particulate for underground mines. Additionally, MSHA has observed that some controls, such as filtration systems on cabs can alter the ratio of elemental to total carbon. The ratio can be different inside and outside a cab on a piece of diesel equipment. MSHA notes that NIOSH has asserted that the ratio of elemental carbon to dpm is consistent enough to provide the basis for a standard based on elemental carbon (''* * * the literature and the MSHA laboratory tests support the assertion that DPM, on average, is approximately 60 to 80% elemental carbon, firmly establishing EC as a valid surrogate for DPM''). However, while an average value for elemental carbon percent may be a useful measure for research purposes, data submitted by commenters show that elemental carbon can range from 8 percent to 81 percent of total carbon.

MSHA does not believe elemental carbon is a valid surrogate for dpm in the context of a compliance determination that, like all other metal and nonmetal health standards, can be based on a single sample. By contrast, as noted above, studies have shown that there is a consistent ratio between total carbon and dpm (from 80 to 85%). Moreover, although the ratio of the elemental carbon to organic carbon components obtained using the NIOSH Method 5040 may vary, total carbon determinations obtained with this method are very consistent, and agree with other carbon methods (Birch, 1999). Accordingly, while total carbon sampling does necessitate sampling protocols to avoid interferences, of the sort discussed below, MSHA has concluded that it would not be suitable at this time to use elemental carbon as a surrogate for dpm.

Potential Sample Interferences/ Contributions. As noted in the introduction to this section, many commenters asserted that the analytical method would not be able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke. The agency carefully reviewed the information submitted by commenters, both during the hearings and in writing, and found that it was in general insufficient to establish that such interferences would be a problem. Limitations in the data submitted by the commenters included, for example, failure to utilize blanks, failure to blank correct sample results, open face and respirable samples that were collected in the presence of high levels of carbonate interference, the amount of carbonate interference was not quantified, dpm was not uniformly deposited on filters and sample punches were taken where the deposit was heaviest, failure to adjust sample results due to short sampling times, failure to consider the impact of interferences such as carbonate, oil mist, and cigarette smoke on dpm exposure.

Rather than dismiss these assertions, however, the agency decided to conduct some investigations to verify the validity of the comments. As a result of these tests, the agency has determined that certain interferences can exist, within certain parameters; and was also able to demonstrate how these interferences can be minimized or avoided. The material which follows reviews the information MSHA has on this topic, including representative comments MSHA received on these verification studies. Part IV of this preamble reviews in some detail the adjustments MSHA has made to the proposed rule, and the practices MSHA will follow in compliance sampling, to avoid these interferences.

General discussion of interference studies. As noted above, MSHA conducted the verifications to determine if the alleged interferences were in fact measurable in underground mining environments. At the same time, the studies gave MSHA an opportunity to identify sampling techniques that would minimize or eliminate the interferences, evaluate analytical techniques to minimize or eliminate the interferences from the samples, and develop a sampling and analytical strategy to assure reliable dpm measurements in underground mines.

A total of six studies were conducted. One field study was conducted at Homestake Mine, a gold mine in Lead, South Dakota, three field studies were conducted at gold mines near Carlin, Nevada. These included Newmont, South Area Carlin Mine and Barrick Goldstrike. One study was conducted in the NIOSH Research Laboratory's experimental mine in Pittsburgh, Pennsylvania and one study conducted in a laboratory dust chamber at the NIOSH Pittsburgh Research Laboratory. For example the studies conducted at Carlin and Homestake were to evaluate interference from oil mist and the studies conducted at Homestake, Newmont and Barrick were to assess interference from carbonaceous dust. These locations were carefully selected in light of the assertions about interferences which had been made by commenters.

Despite the care that went into designing where to conduct the verification samples, there were a number of comments asserting the samples were not representative. For example, it was asserted that MSHA did not sample a representative particle size distribution and sampled the wrong material (i.e., ores with the highest carbon content). On the contrary the samples that MSHA collected were representative of the respirable and submicron fractions of the dust in the environment as well as the total dust in the environment. Therefore, MSHA believes that the particle size distribution of the samples collected were representative. Also, MSHA obtained a bulk sample of the various ores tested. While the samples collected at the crushers were low carbon content (0–10.3%), the carbon content (30.3%) of the ore collected at the underground mining area sampled at Carlin was similar to the high carbon content (31.4%) ores obtained at Barrick. The sampling therefore included a cross section of the ores in question.

Some commenters objected to the fact that no personal samples were collected in these studies. Packages of samplers were placed in areas that were close to the breathing zone of the workers. Upwind and downwind samples were used to determine the extent of the interference. The regulation recognizes the validity of area samples. As a result these samples provided valid information on interferences that are likely to be encountered during sampling by MSHA inspectors.

More generally, commenters asserted that MSHA lacked enough studies for statistical analysis. MSHA notes again that the studies were conducted to verify specific industry assertions, and were properly designed to try and verify those assertions. However, the same studies which confirmed that such interferences could be measured in certain conditions were also able to determine that these interferences could not be measured, or were not significant in scope, if some of the conditions were changed. Part IV of this preamble discusses what actions the agency plans to take as a result of its current information on this matter.

Some commenters asserted that MSHA made certain incorrect technical assumptions in its verification sampling: about the sampling method used to conclude that overall dust levels would meet MSHA's standards; about the concentration of EC in submicrometer dust; and about the variability of carbonaceous ores. With respect to the first point, the final sampling strategy adopted by MSHA for dpm allows for either personal or area sampling using a submicrometer sampler preceded by a respirable cyclone. Because of the sampling and analytic procedures, the only potential mineral interferent would be the graphitic contribution (elemental carbon). The carbonate and carbonaceous contribution would be eliminated or reduced by the use of the impactor sampler and using the software integration procedure described in Method 5040.

With respect to the second point, the concentration of EC in the submicrometer dust, for personal and most area samples, the allowable silica exposure would limit the amount of submicrometer mineral dust sampled. This has been demonstrated for samples collected in coal mines where the coal dust contains high levels of elemental carbon, but the interference for EC from submicrometer samples has been less that 4 $\mu g/m^3$.

With respect to the last point which addresses the geology of the ore, MSHA acknowledges that there would be variation in the carbon content of the ore. However, it would be unlikely that the carbon content would exceed that of coal mine dust where the elemental carbon interference has been found to be negligible.

The sampling was performed with the BOM designed or SKC prototype samplers as described in the prior section. All samplers used the more precise sapphire nozzles. Samples were collected using standard procedures developed by MSHA for assessing particulate concentrations in mine environments. Samples were analyzed for total carbon using NIOSH Method 5040. The analyses was performed by MSHA at the Pittsburgh Safety and Health Technology Center's Dust Division laboratory. For some samples a second analysis was performed using an acidification procedure.

Commenters alleged a number of technical problems with how the sampling was performed. Some asserted that defective devices were used for the sampling, or that MSHA did not properly calibrate its equipment. MSHA did not experience any problems with the samplers, and did calibrate its equipment according to standard procedures. Some pointed out that MSHA conducted the verifications with samplers different from those required by the rule. MSHA presumes this comment reflects the fact that the proposed rule did not require an impactor to be used; this is, however, the case with the final rule.

Some commenters noted that MSHA voided some sample results and that, lacking further explanation, it might be assumed the agency simply eliminated those samples which gave results that did not agree with the conclusions it sought. The only samples that were voided were chamber samples. Some voided samples were higher than, and some void samples were lower than, the sample used. These were duplicate samples collected for short time periods. Samples were voided because they were inconsistent with other samples in the set of six samples collected. These inconsistencies as-well-as variability between other duplicate samples were attributed to short sample times. Voided sample results are shown for Homestake (1 of 12 impactors). No impactor samples were voided at Barrick nor at the Newmont crusher. In the Jackleg drill tests conducted at Carlin Mine, there were 2 of 6 impactor samples voided.

Others asserted that MSHA failed to validate the design of the box which held the sampling equipment. In fact, all of the issues mentioned relative to the sampling box (i.e., pressure build up, leakage of chamber, impaction of particles, pump calibration) had been carefully examined by MSHA prior to the tests and found not to be a problem. Also, this sample chamber has been used extensively in other field tests where duplicate samples or a variety of samplers have been used and has worked extremely well.

One commenter stated that these studies confirm that measurement interference cannot be eliminated by blank correction and longer sample times, and that the proposed single sample enforcement policy would not be representative of typical mine conditions. MSHA disagrees with this conclusion from the verification tests. The MSHA tests demonstrated that blank correction does eliminate a source of interference. The residual organic carbon indicated in several of the samples collected at crushers were attributed to short sample time and normal variation in the range of blank values. The verification tests did not address sample time. However, when converting the mass collected to a concentration, the mass is divided by the sample time. Dividing by a longer time will always reduce an interference caused by a positive bias.

Other commenters alleged that there were problems with the MSHA personnel performing the studies. Some asserted these personnel failed to listen to suggestions made by representatives of mine companies who accompanied MSHA in their facilities during in-mine testing, suggestions which they assert would have corrected asserted problems in the testing procedure. Others simply assert that the MSHA personnel were biased, manipulated the data, and tried to conform the study results to those they wanted to find. It was also asserted that any potential for bias should have been removed through independent peer review of the results, or performance or confirmation of the studies by independent personnel or laboratories.

The tests were designed and conducted by personnel from MSHA's Pittsburgh Safety and Heath Technology's Dust Division. This laboratory at this facility is AIHA accreditated, and its personnel are among the foremost experts in particulate sampling analysis in the mining industry. They are widely published and are accustomed to performing work that must survive legal and scientific scrutiny. Moreover, the personnel designing and performing these studies have more experience than anybody else with dust sampling in general, and with this particular measurement application. While the agency welcomes scrutiny of its work, and repetition by others, it also recognizes that such efforts take time. In this case, the agency elected to conduct tests to address specific concerns, given its obligation to respond to the risks to miners reviewed in Part III of this preamble. It did so using a sound study design and expert personnel, and has made the detailed results of its studies a matter of public record.

In this regard, a number of commenters made reference to a study currently being conducted by NIOSH of possible interferences with the 5040 method. Some of these commenters provided MSHA with a copy of what is apparently the final protocol for the study, asserted that it would provide better information than the verification studies conducted by MSHA, and urged the agency to wait for completion of this study.

MSHA welcomes the NIOSH study, and will carefully consider its results—and the results of any other studies of this matter—in refining the compliance practices outlined in part IV of this preamble. But given the agency's obligation to respond to the risks to miners reviewed in Part III of this preamble, and the recommendations of NIOSH to take action in light of that risk, it would be inappropriate to await the results of another study.

Carbonates and Carbonaceous Minerals. As noted in the discussion of the analytical method (NIOSH Method 5040), carbonates have been known to cause an interference when determining the total carbon content of a diesel particulate sample. Carbonates are generally in two forms—carbonates such as limestone and dolomite and bicarbonate which is associated with trona (soda ash). As further noted, the amount of carbonate and bicarbonate collected on a sample can be significantly reduced or eliminated through the use of a submicrometer impactor. If the total carbon analysis of a sample indicates that a carbonate interference exists after the use of a submicrometer impactor, any remaining interfering effect may be removed or diminished using the acidification process described in NIOSH Method 5040.

Carbonate interference can also be removed during the analytical process by mathematically subtracting the organic carbon quantified by the fourth peak in the thermogram. Because bicarbonate is evolved over several temperature ranges, subtraction of only one peak does not remove all of the interference from bicarbonate. As a result, the sample needs to be acidified to remove all of the bicarbonate interference.

Commenters correctly pointed out that other carbonaceous minerals are not removed by the acidification process and in fact in some cases, the acidification process may cause a positive bias to the elemental carbon measurement. However, MSHA has verified that through the use of the submicrometer impactor, which reduces the mineral dust collected, combined with the subtraction of organic carbon quantified by the fourth organic carbon peak, this source of interference can be eliminated (PS&HTC–DD–505, PS&HTC–DD–509, PS&HTC–DD–510 and PS&HTC–DD–00–523).

MSHA has verified the use of a submicron impactor to remove carbonate interference through field and laboratory measurements. In the field measurements, simultaneous respirable and submicron dust samples were collected near crushing operations where there was no diesel equipment operating. In the laboratory measurements, a aerosol containing carbonate dust was introduced into a dust chamber and simultaneous submicron, respirable and total dust samples were collected. For both the field and laboratory measurements, the samples were analyzed for carbon using NIOSH Method 5040. Results of analysis of these samples showed that for respirable dust samples, acidification of the sample removed the carbonate.

Carbonate was evolved in the fourth peak of the organic portion of the analysis. The carbon evolved by the analysis was approximately 10 percent of the carbonate collected on the gravimetric sample, roughly equating to 12 percent carbon contained in calcium carbonate tested (limestone). Sampling with the submicron impactor removed the carbonate and carbonaceous component from the sample. A commenter noted that in the dust chamber tests, organic carbon was reported, even though the carbonate was removed by sampling, acidification or software integration. This organic carbon was attributed to oil vapors leaking from the compressor that delivered the dust to the chamber. This oil leak was reported to MSHA after the tests were completed.

Sample results further indicated that the total carbon mass determined for the respirable diesel particulate samples was approximately 95 percent of the diesel particulate mass determined gravimetrically and the total carbon mass determined from the impactor diesel particulate samples was approximately 82 percent of the respirable value. Use of the impactor reduced the amounts of carbonate collected on the sample by 90 percent.

The difference between the respirable total carbon determinations and the gravimetric diesel particulate can be attributed to sulfates or other noncarbonaceous minerals in the diesel particulate. The difference between the submicron total carbon and the respirable total carbon determinations is attributed to the removal of diesel particulate particles that are greater than 0.9 micrometers in size. The difference between the carbonate measured by NIOSH Analytical Method 5040 and the gravimetric carbonate is attributed to impurities in the material. The expected ratio of evolved carbon from the carbonate to carbonate (C/CaCo3) would be 0.12 (12/(40 + 12 + 48)).

Graphitic Minerals. Commenters reported that several ores, primarily associated with gold mines, contain graphitic carbon, and that this carbon shows up as elemental carbon in an airborne dust sample. MSHA has collected samples of this ore and has found that in fact this is true (PS&HTC-DD–505, PS&HTC-DD–509, PS&HTC-DD–510). MSHA has verified the use of a submicron impactor to remove graphitic carbon interference through field measurements.

In the field measurements, simultaneous respirable and submicron dust samples were collected near crushing operations where there was no diesel equipment operating. For both the field and laboratory measurements, the samples were analyzed for carbon using NIOSH Method 5040. Results of analysis of these samples showed that for respirable dust samples, several µg/m^3 of elemental carbon could be present in the sample.

However, MSHA has found this interference is very small, and can be reduced still further through the use of the submicron impactor on the sampler. The highest elemental carbon content of the ores was less than 5 percent. These ores also contain at least 20 percent respirable silica, as determined from samples collected near crushers where diesel particulate was not present. Based on a 20 percent respirable silica content in the dust in the environment, the allowable respirable dust exposure would be limited to 0.45 mg/m^3. Based on a 5 percent elemental carbon content in the sample, this sample could contain 23 µg/m^3 of elemental carbon. Typically 10 percent of mineral dust is less than one micron. By using the submicron impactor, the interference from graphitic carbon in the ore would be less than 3 µg/m^3. Samples collected by MSHA, near crushing operations, using submicron impactors, did not contain elemental carbon.

Accordingly, MSHA plans to sample for diesel particulate matter using submicron impactors to reduce the potential interference from carbonates, carbonaceous minerals and graphitic ores. As noted previously, this requirement is being specifically added to the regulation.

Oil Mist and Organic Vapors. Commenters indicated that diesel particulate sample interference can occur from sampling around drilling operations and from organic solvents.

To verify the existence and extent of any such interference, MSHA collected samples at stoper drilling, jack leg drilling and face drilling operations. The stoper drill and jack leg drill were pneumatic. The face drill was electrohydraulic. Interference from drill oil mist was observed for both the stoper drill and jack leg drill operations (PS&HTC–DD–505, PS&HTC–DD–511). Respirable and submicron samples were collected in the stope, the intake air to the stope and the exhaust air from the stope. Interference from drill oil mist was not found in submicron samples collected on the electrohydraulic face drill (PS&HTC–DD–505). The oil mist interference for the stoper drill was confined to the drill location due to the use of a high viscosity lube grease. The amount of interference in the stope on a submicron sample for the stoper drill was 4.5 µg/m^3 per hour of drilling. The interference from the oil mist on the jack leg operation extended throughout the mining stope area, but it did not extent into the main ventilation heading. The amount of interference in the stope on a submicron sample for the jack leg drill was 9 to 11 µg/m^3 per hour of drilling. MSHA believes that similar interferences could occur when miners are working near organic solvents.

Accordingly, this is an interference that can be addressed by not sampling too close to the source of the interference. As discussed in more detail in Part IV of this preamble, when MSHA collects compliance samples on drilling operations that produce an oil mist, or where organic solvents are used, personal samples will not be collected. Instead, an area sample will be collected, upwind of the driller or organic solvent source.

A commenter suggested that the lack of organic carbon reduction from outside to inside the cab at Homestake Mine indicated additional sources of organic carbon that have not been identified. MSHA believes that the reduction in elemental but not organic carbon from outside to inside the cab at Homestake Mine was attributed to size distribution. The organic carbon is small enough to pass through a filter. The organic carbon in the cab could not have been generated from a source inside the cab or attributed to residual cigarette smoke as the air exchange rate for the cab was one air change per minute. The cab operator did not smoke.

Cigarette Smoke. Cigarette smoke is a form of organic carbon. Commentors indicated that cigarette smoke can interfere with a diesel particulate measurement when total carbon is used as the indicator of dpm. Industry Commenters collected samples in a surface ''smoke room'' where the airflow and number of cigarettes were not monitored.

To verify the existence and the extent of any such interference, MSHA took samples in an underground mine where controlled smoking took place. Two series of cigarette tests were conducted. A test site was chosen in the NIOSH, PRL, Experimental Mine. The site consisted of approximately 75 feet of straight entry. The entry was approximately 18.5 feet wide and 6.2 feet high (115 square feet area). In the first test, the airflow rate through the test area was 6,000 cfm and 4 cigarettes were smoked over a 120 minute period. In the second test, the airflow was 3,000 cfm and 28 cigarettes were smoked over a 210 minute period. A control filter was used to adjust for organic carbon present on the filter media. MSHA collected samples on the smokers, twenty-five feet upwind of the smokers, twenty-five feet downwind of the smokers and fifty feet downwind of the smokers. Results of the underground test did verify that smoking could be an interference on a dpm measurement.

Analysis of the thermogram from the smoking test showed that cigarette smoke showed up only in the organic portion of the analysis. In this test with the cigarette smoke, a fifth organic peak was observed. This peak contributed approximately 0.5 $\mu g/m^2$ to the analysis. This would be equivalent to an 8 hour full shift concentration of 5 $\mu g/m^3$. The thermogram otherwise is not distinguishable from the organic portion of a thermogram for a diesel particulate sample. Analysis of the thermogram indicated that 30 percent of the organic carbon appeared in the first organic peak, 15 percent appeared in the second organic peak, 10 percent appeared in the third organic peak, 25 percent of the cigarette smoke appeared in the fourth organic peak, and 20 percent of the cigarette smoke appeared in the fifth organic peak. While the amount of carbon identified by the fourth organic peak can be quantified and mathematically subtracted from the amount of total carbon measured, the remaining three peaks, representing 83 percent of the total carbon associated with smoking, would be an interferrant to the diesel particulate matter measurement.

However, the effect of cigarette smoke was even more localized to the smoker than the oil mist was to the stoper or jack leg drill operator. Twenty five feet upwind of the smoker, no carbon attributed to cigarette smoke was detected. For the smoker, each cigarette smoked would add 5 to 10 $\mu g/m^3$ to the exposure, depending on the airflow. Smoking 10 cigarettes would add 50 to 100 $\mu g/m^3$ to a worker's exposure. At both twenty five feet and fifty feet downwind of the smoker, after mixing with the ventilating air, the contribution of carbon attributed to smoking was reduced to 0.3 $\mu g/m^3$ for each cigarette smoked. Sampling twenty-five to fifty feet down wind of a worker smoking 10 cigarettes per day would add no more than 3 $\mu g/m^3$ to the worker's exposure (PS&HTC–DD–518). The air velocities in this test (30 to 60 feet per minute) were relatively low compared to typical mine air velocities. The interference would be even less at the higher air velocities normally found in mines.

Accordingly, as discussed in more detail in Part IV of this preamble, when MSHA collects compliance samples, miners will be requested not to smoke. If a miner does want to smoke while being sampled, and is not prohibited from doing so by the mine operator, the inspector will collect an area sample a minimum of twenty-five feet upwind or downwind of the smoker. Smokers working inside cabs will not be sampled.

Summary of Conclusions from Verification Studies. In summary, MSHA was able to draw the following conclusions from these studies:

- As specified in NIOSH Method 5040, it is essential to use a blank to correct organic carbon measurements.
- Contamination (interference) from carbonate and carbonaceous minerals is evolved in the fourth organic peak of the thermogram.
- Interference from graphitic minerals may appear in the elemental carbon portion of the analysis.
- Interference from cigarette smoke and oil mist from pneumatic drills appears in several peaks of the organic analysis.
- Use of the submicron impactor removes the mineral interference from carbonate, carbonaceous minerals and graphitic minerals.
- Acidification is required to remove the interference from bicarbonate which maybe evolved in several of the organic peaks.
- Subtraction of the fourth organic peak by software integration can be used to correct for interference from carbonaceous minerals.
- Interference from cigarette smoke and oil mist from pneumatic drills is localized. It can be avoided by sampling upwind or downwind of the interfering source.
- Total carbon from cigarettes smoke and oil mist are small compared to emissions from a diesel engine.
- Sampling can be conducted down wind of the interfering source after the contaminated air current has been diluted with another air current.

The magnitude of interferences measured during the verifications were small compared to the levels of total carbon measured in underground mines (as reported in Part III of this preamble). The discussion of section 5061 in Part IV of this preamble provides further information on how MSHA will take this information about interferences into account in compliance sampling; in addition, MSHA will provide specific guidance to inspectors as to how to avoid interferences when taking compliance samples.

(4) Limiting the Public's Exposure to Diesel and Other Fine Particulates—Ambient Air Quality Standards.

Pursuant to the Clean Air Act, the Federal Environmental Protection Agency (EPA) is responsible for setting air pollution standards to protect the public from toxic air contaminants. These include standards to limit exposure to particulate matter. The pressures to comply with these limits have an impact upon the mining industry, which limits various types of particulate matter into the environment during mining operations, and a special impact on the coal mining industry whose product is used extensively in particulate emission generating power facilities. But those standards hold interest for the mining community in other ways as well, for underlying some of them is a large body of evidence on the harmful effects of airborne particulate matter on human health. Increasingly, that evidence has pointed toward the risks of the smallest particulates—including the particles generated by diesel engines.

This section provides an overview of EPA's rulemaking efforts to limit the ambient air concentration of particulate matter, including its recent particular focus on diesel and other fine particulates. Additional and up-to-date information about the most current rulemaking in this regard is available on EPA's Web site, http://www.epa.gov/ttn/oarpg/naaqsfin/.

EPA is also engaged in other work of interest to the mining community. Together with some state environmental agencies, EPA has actually established limits on the amount of particulate matter that can be emitted by diesel engines. This topic is discussed in the next section of this Part (section 5). Environmental regulations also establish the maximum sulfur content permitted in diesel fuel, and such sulfur content can be an important factor in dpm generation. This topic is discussed in section 6 of this Part. In addition, EPA and some state environmental agencies have also been exploring whether diesel particulate matter is a carcinogen or a toxic material at the concentrations in which it appears in the ambient atmosphere. Discussion of these studies can be found in Part III of this preamble.

Background. Air quality standards involve a two-step process: standard setting by EPA, and implementation by each State.

Under the law, EPA is specifically responsible for reviewing the scientific literature concerning air pollutants, and establishing and revising National Ambient Air Quality Standards (NAAQS) to minimize the risks to health and the environment associated with such pollutants. This review is to be conducted every five years. Feasibility of compliance by pollution sources is not supposed to be a factor in establishing NAAQS. Rather, EPA is required to set the level that provides ''an adequate margin of safety'' in protecting the health of the public.

Implementation of each national standard is the responsibility of the states. Each must develop a state implementation plan that ensures air quality in the state consistent with the ambient air quality standard. Thus, each state has a great deal of flexibility in targeting particular modes of emission (*e.g.,* mobile or stationary, specific industry or all, public sources of emissions vs. private-sector sources), and in what requirements to impose on polluters. However, EPA must approve the state plans pursuant to criteria it establishes, and then take pollution measurements to determine whether all counties within the state are meeting each ambient air quality standard. An area not meeting an NAAQS is known as a ''nonattainment area''.

TSP. Particulate matter originates from all types of stationary, mobile and natural sources, and can also be created from the transformation of a variety of gaseous emissions from such sources. In the context of a global atmosphere, all these particles are mixed together, and both people and the environment are exposed to a ''particulate soup'' the chemical and physical properties of which vary greatly with time, region, meteorology, and source category.

The first ambient air quality standards dealing with particulate matter did not distinguish among these particles. Rather, the EPA established a single NAAQS for ''total suspended particulates'', known as ''TSP.'' Under this approach, the states could come into compliance with the ambient air requirement by controlling any type or size of TSP. As long as the total TSP was under the NAAQS—which was established based on the science available in the 1970s—the state met the requirement.

PM_{10}. When the EPA completed a new review of the scientific evidence in the mid-eighties, its conclusions led it to revise the particulate NAAQS to focus more narrowly on those particulates less than 10 microns in diameter, or PM_{10}. The standard issued in 1987 contained two components: an annual average limit of 50 µg/m^3, and a 24-hour limit of 150 µg/m^3. This new standard required the states to reevaluate their situations and, if they had areas that exceeded the new PM_{10} limit, to refocus their compliance plans on reducing those particulates smaller than 10 microns in size. Sources of PM_{10} include power plants, iron and steel production, chemical and wood products manufacturing, wind-blown and roadway fugitive dust, secondary aerosols and many natural sources.

Some state implementation plans required surface mines to take actions to help the state meet the PM_{10} standard. In particular, some surface mines in Western states were required to control the coarser particles—*e.g.,* by spraying water on roadways to limit dust. The mining industry has objected to such controls, arguing that the coarser particles do not adversely impact health, and has sought to have them excluded from the EPA ambient air standards.

$PM_{2.5}$. The next scientific review was completed in 1996, following suit by the American Lung Association and others. A proposed rule was published in November of 1996, and, after public hearings and review by the Office Management and Budget, a final rule was promulgated on July 18, 1997. (62 FR 38651).

The new rule further modifies the standard for particulate matter. Under the new rule, the existing national ambient air quality standard for PM_{10} remains basically the same—an annual average limit of 50 µg/m^3 (with some adjustment as to how this is measured for compliance purposes), and a 24-hour ceiling of 150 µg/m^3. In addition, however, a new NAAQS has now been established for ''fine particulate matter'' that is less than 2.5 microns in size. The $PM_{2.5}$ annual limit is set at 15 µg/m^3, with a 24-hour ceiling of 65 µg/m^3.

The basis for the $PM_{2.5}$ NAAQS is a large body of scientific data suggesting that particles in this size range are the ones responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable press attention, and hearings by Congress, in which this scientific evidence was further discussed. Moreover, challenges to EPA's determination that this size category warranted rulemaking were rejected by a three judge panel of the DC Circuit Court. (American Trucking Association vs. EPA, 275 F.3d 1027).

Second, the majority of the panel agreed with challenges to the EPA's determination to keep the existing requirements on PM10 as a surrogate for the coarser particulates in this category (those particulates between 2.5 and 10 microns in diameter); instead, the panel ordered EPA to develop a new standard for this size category. (Op.Cit., *23.)

Implications for the Mining Community. As noted earlier in this part, diesel particulate matter is mostly less than 1.0 micron in size. It is, therefore, a fine particulate; indeed, in some regions of the country, diesel particulate generated by highway and off-road vehicles constitutes a significant portion of the ambient fine particulate (June 16, 1997, PM–2.5 Composition and Sources, Office of Air Quality Planning and Standards, EPA). Moreover, as noted in Part III of this preamble, some of the scientific studies of health risk from fine particulates used to support the EPA rulemaking were conducted in areas where the major fine particulate was from diesel emissions. Accordingly, MSHA has concluded that it must consider the body of evidence of human health risk from environmental exposure to fine particulates in assessing the risk of harm to miners of occupational exposure to diesel particulate. Comments on the appropriateness of the conclusion by MSHA, and whether MSHA should be working on a fine particulate standard rater than just one focused on diesel particulate are reviewed in Part III.

(5) The Effects of Existing Standards—MSHA Standards on Diesel Exhaust Gases (CO, CO_2, NO, NO_2, and SO_2), and EPA Diesel Engine Emission Standards—on the Concentration of dpm in Underground Metal and Nonmetal Mines

With the exception of diesel engines used in certain classifications of gassy mines, MSHA does not require that the emissions from diesel engines used in underground metal and nonmetal mines, as measured at the tailpipe, meet certain minimum standards of cleanliness. (Some states may require engines used in underground metal and nonmetal mines to be MSHA Approved.) This is in contrast to underground coal mines, where only engines which meet certain standards with respect to gaseous emissions are ''approved'' for use in underground coal mines. Indeed, as discussed in section 7 of this part, the whole underground coal mine fleet must now consist of approved engines, and the engines must be maintained in approved condition. While such restrictions do not directly control dpm emissions of underground coal equipment, they do have some indirect impact on them.

MSHA does have some requirements for underground metal and nonmetal mines that limit the exposure of miners to certain gases emitted by diesel engines. Accordingly, those requirements are discussed here.

Engine emissions of dpm in underground metal and nonmetal mines are gradually being impacted by Federal environmental regulations, supplemented in some cases by State restrictions. Over time, these regulations have required, and are continuing to require, that new diesel engines meet tighter and tighter standards on dpm emissions. As these cleaner engines replace or supplement older engines in underground metal and nonmetal mines, they can significantly reduce the amount of dpm emitted by the underground fleet. Much of this section reviews developments in this area. Although this subject was discussed in the preamble of the proposed dpm rule (63 FR 58130 *et seq.*), the review here updates the relevant information.

MSHA Limitations on Diesel Gases. MSHA limits on the exposure of miners to certain gases in underground mines are listed in Table II–2, for both coal mines and metal/nonmetal mines, together with information about the recommendations in this regard of other organizations. As indicated in the table, MSHA requires mine operators to comply with gas specific threshold limit values (TLV®s) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1972 (for coal mines) and in 1973 (for metal and nonmetal mines).

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TABLE II-2 GASEOUS EXPOSURE LIMITS (PPM)

Pollutant	Range of Limits Recommended		MSHA Limits	
			$Coal_A$	M/NM_B
HCHO (formaldehyde)	0.016_C	0.3_D	2	2
CO	25_D	50	50	50
CO_2	$5,000_C$	5,000	5,000	5,000
NO	$25_{C,D,E}$	25	25	25
NO_2	1_F	3_D	5	5
SO_2	$2_{C,D}$	5_E	2	5

Table Notes:
A) ACGIH, 1972
B) ACGIH, 1973
C) NIOSH recommended exposure limit (REL), based on a 10-hour, time-weighted average
D) ACGIH, 1996
E) OSHA permissible exposure limit (PEL)
F) NIOSH recommends only a 1-ppm, 15-minutes, short-term exposure limit (STEL)

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To change an exposure limit at this point in time requires a regulatory action; the rule does not provide for their automatic updating. In 1989, MSHA proposed changing some of these gas limits in the context of a proposed rule on air quality standards. (54 FR 35760). Following opportunity for comment and hearings, a portion of that proposed rule, concerning control of drill dust and abrasive blasting, has been promulgated, but the other components are still under review.

One commenter expressed concern that MSHA would attempt to regulate dpm together with diesel exhaust gases based on their additive or combined effects. As discussed in greater detail in Part IV of this preamble, MSHA does not, at this time, have sufficient information upon which to enforcement limits for dpm and diesel exhaust gases on the basis of their additive or combined effects, if any.

Authority for Environmental Engine Emission Standards. The Clean Air Act authorizes the Federal Environmental Protection Agency (EPA) to establish nationwide standards for mobile vehicles, including those powered by diesel engines (often referred to in environmental regulations as ''compression ignition'' or ''CI'' engines). These standards are designed to reduce the amount of certain harmful atmospheric pollutants emanating from mobile sources: the mass of particulate matter, nitrogen oxides (which as previously noted, can result in the generation of particulates in the atmosphere), hydrocarbons and carbon monoxide.

California has its own engine emission standards. New engines destined for use in California must meet standards under the law of that State. The standards are issued and administered by the California Air Resources Board (CARB). In many cases, the California standards are the same as the national standards; as noted herein, the EPA and CARB have worked on certain agreements with the industry toward that end. In other situations, the California standards may be more stringent.

Regulatory responsibility for implementation of the Clean Air Act is vested in the Office of Transportation and Air Quality (formerly the Office of Mobile Sources), part of the Office of Air and Radiation of the EPA. Some of the discussion which follows was derived from materials which can be accessed from the agency's home page on the World Wide Web at (http://www.epa.gov/omswww/omshome.htm). Information about the California standards may be found at the CARB home page at (http://www.arb.ca.gov/homepage.htm).

Diesel engines are generally divided into three broad categories for purposes of engine emissions standards, in accordance with the primary use for which the type of engine is designed: (1) light duty vehicles and light duty trucks (i.e., those engines designed primarily to power passenger transport or transportation of property); (2) heavy duty highway engines (i.e., those designed primarily to power over-the-road truck hauling); and (3) nonroad vehicles (i.e., those engines designed primarily to power small equipment, construction equipment, locomotives and other non-highway uses).

The exact emission standards which a new diesel engine must meet varies with engine category and the date of manufacture. Through a series of regulatory actions, EPA has developed a detailed implementation schedule for each of the three engine categories noted. The schedule generally forces technology while taking into account certain technological realities.

Detailed information about each of the three engine categories is provided below; a summary table of particulate matter emission limits is included at the end of the discussion.

EPA Emission Standards for Light-Duty Vehicles and Light Duty Trucks.[2] Current light-duty vehicles generally comply with the Tier 1 and National LEV emission standards. Particulate matter emission limits are found in 40 CFR Part 86. In 1999, EPA issued new Tier 2 standards that will be applicable to light-duty cars and trucks beginning in 2004. With respect to pm, the new rules phase in tighter emissions limits to parts of production runs for various subcategories of these engines over several years; by 2008, all light duty trucks must limit pm emissions to a maximum of 0.02 g/mi. (40 CFR 86.1811–04(c)). Engine manufacturers may, of course, produce complying engines before the various dates required.

EPA Emissions Standards for Heavy-Duty Highway Engines. In 1988, a standard limiting particulate matter emitted from the heavy duty highway diesel engines went into effect, limiting dpm emissions to 0.6 g/bhp-hr. The Clean Air Act Amendments of 1990 and associated regulations provided for phasing in even tighter controls on NO_X and particulate matter through 1998. Thus, engines had to meet ever tighter standards for NO^X in model years 1990, 1991 and 1998; and tighter standards for PM in 1991 (0.25 g/bhp-hr) and 1994 (0.10 g/bhp-hr). The latter remains the standard for PM from these engines for current production runs (40 CFR 86.094–11(a)(1)(iv)(B)). Since any heavy duty highway engine manufactured since 1994 must meet this standard, there is a supply of engines available today which meet this standard. These engines are used in mining in the commercial type pickup trucks.

New standards for this category of engines are gradually being put into place. On October 21, 1997, EPA issued a new rule for certain gaseous emissions from heavy duty highway engines that will take effect for engine model years starting in 2004 (62 FR 54693). The rule establishes a combined requirement for NO_X and Non-methane Hydrocarbon (NMHC). The combined standard is set at 2.5 g/bhp-hr, which includes a cap of 0.5 g/bhp-hr for NMHC. EPA promulgated a rulemaking on December 22, 2000 (65 FR 80776) to adopt the next phase of new standards for these engines. EPA is taking an integrated approach to: (a) Reduce the content of sulfur in diesel fuel; and thereafter, (b) require heavy-duty highway engines to meet tighter emission standards, including standards for PM. The purpose of the diesel fuel component of the rulemaking is to make it technologically feasible for engine manufacturers and emissions control device makers to produce engines in which dpm emissions are limited to desired levels in this and other engine categories. The EPA's rule will reduce pm emissions from new heavy-duty engines to 0.01 g/bhp-hr, a reduction from the current 0.1 g/bhp-hr. MSHA assumes it will be some time before there is a significant supply of engines that can meet this standard, and the fuel supply to make that possible.

EPA Emissions Standards for Nonroad Engines. Nonroad engines are those designed primarily to power small portable equipment such as compressors and generators, large construction equipment such as haul trucks, loaders and graders, locomotives and other miscellaneous equipment with non-highway uses. Engines of this type are the ones used most frequently in the underground coal mines to power equipment.

Nonroad diesel engines were not subjected to emission controls as early as other diesel engines. The 1990 Clean Air Act Amendments specifically directed EPA to study the contribution of nonroad engines to air pollution, and

[2] The discussion focuses on the particulate matter requirements for light duty trucks, although the current pm requirement for light duty vehicles is the same. The EPA regulations for these categories apply to the unit, rather than just to the engine itself; for heavy-duty highway engines and nonroad engines, the regulations attach to the engines.

regulate them if warranted (Section 213 of the Clean Air Act). In 1991, EPA released a study that documented higher than expected emission levels across a broad spectrum of nonroad engines and equipment (EPA Fact Sheet, EPA420–F–96–009, 1996). In response, EPA initiated several regulatory programs. One of these set Tier 1 emission standards for larger land-based nonroad engines (other than for rail use). Limits were established for engine emissions of hydrocarbons, carbon monoxide, NO_X, and dpm. The limits were phased in with model years from 1996 to 2000. With respect to particulate matter, the rules required that starting in model year 1996, nonroad engines from 175 to 750 hp meet a limit on pm emissions of 0.4 g/bhp-hr, and that starting in model year 2000, nonroad engines over 750 hp meet the same limit.

Particulate matter standards for locomotive engines were set subsequently (63 FR 18978, April, 1998). The standards are different for line-haul duty-cycle engine and switch duty-cycle engines. For model years from 2000–2004, the standards limit pm emissions to 0.45 g/bhp-hr and 0.54 g/bhp-hr respectively for those engines; after model year 2005, the limits drop to 0.20 g/bhp-hr and 0.24 g/bhp-hr respectively.

In October 1998, EPA established additional standards for nonroad engines (63 FR 56968). Among these are gaseous and particulate matter limits for the first time (Tier 1 limits) for nonroad engines under 50 hp. Tier 2 emissions standards for engines between 50 and 175 hp include pm standards for the first time. Moreover, they establish Tier 2 particulate matter limits for all other land-based nonroad engines (other than locomotives which already had Tier 2 standards). Some of the non-particulate emissions limits set by the 1998 rule are subject to a technology review in 2001 to ensure that the levels required to be met are feasible; EPA has indicated that in the context of that review, it intends to consider further limits for particulate matter, including transient emission measurement procedures. Because of the phase-in of these Tier 2 pm standards, and the fact that some manufacturers will produce engines meeting the standard before the requirements go into effect, there are or soon will be some Tier 2 pm engines in some sizes available, but it is likely to be a few years before a full size range of Tier 2 pm nonroad engines is available.

Table II–3, EPA NonRoad Engine PM Requirements, provides a full list of the EPA required particulate matter limitations on nonroad diesel engines. For example, a nonroad engine of 175 hp produced in 2001 must meet a standard of 0.4 g/hp-hr; a similar engine produced in 2003 or thereafter must meet a standard of 0.15 g/hp-hr.

TABLE II–3.—EPA NONROAD ENGINE PM REQUIREMENTS

kW range	Tier	Year first applicable	PM limit (g/kW-hr)
kW<8	1	2000	1.00
	2	2005	0.80
8≤kW<19	1	2000	0.80
19≤kW<37	1	1999	0.80
	2	2004	0.60
37≤kW<75	1	1998	....
	2	2004	0.40
75≤kW<130	1	1997	....
	2	2003	0.30
130≤kW<225	1	1996	0.54
	2	2003	0.20
225≤kW<450	1	1996	0.54
	2	2001	0.20
450≤kW<560	1	1996	0.54
	2	2002	0.20
kW>560	1	2000	0.54
	2	2006	0.20

The Impact of EPA Engine Emission Standards on the Underground Metal and Nonmetal Mining Fleet. In the mining industry, engines and equipment are often purchased in used condition. Thus, many of the diesel engines in an underground mine's fleet may only meet older environmental emission standards, or no environmental standards at all.

By requiring that underground coal mine engines be approved, MSHA regulations have led to a less polluting fleet in that sector than would otherwise be the case. Many highly polluting engines have been barred or phased out as a result. As noted in Part IV of this preamble, such a requirement for the underground metal and nonmetal sector is being added by this rulemaking; however, it will be some time before its effects are felt. Moreover, although the environmental tailpipe requirements will bring about gradual reduction in the overall contribution of diesel pollution to the atmosphere, the beneficial effects on mining atmospheres may require a long timeframe absent actions that accelerate the turnover of mining fleets to engines that emit less dpm.

The Question of Nanoparticles. Comments received from several commenters on the proposed rule for diesel particulate matter exposure of underground coal miners raised questions relative to ''nanoparticles'; i.e., particles found in the exhaust of diesel engines that are characterized by diameters less than 50 nanometers (nm). As the topic may be of interest to this sector as well, MSHA's discussion on the topic is being repeated in this preamble for informational purposes.

One commenter was concerned about recent indications that nanoparticles may pose more of a health risk than the larger particles that are emitted from a diesel engine. This commenter submitted information demonstrating that nanoparticles emitted from the engine could be effectively removed from the exhaust using aftertreatment devices such as ceramic traps. Another commenter was concerned that MSHA's proposed rule for underground coal mines is based on removing 95% of the particulate by mass. His concern was focused on the fact that this reduction in mass was attributed to those particles greater than 0.1µm but less than 1µm and did not address the recent scientific hypothesis that it may be the very small nanopaticles that are responsible for adverse health effects. Based on the recent specific information on the potential health effects resulting from exposure to nanoparticles, this commenter did not believe that the risk to cancer would be reduced if exposure levels to nanoparticles increased. He indicated that studies suggest that the increase in nanoparticles will exceed 6 times their current levels.

Current environmental emission standards established by EPA and CARB, and the particulate index calculated by MSHA, focus on the total mass of diesel particulate matter emitted by an engine—for example, the number of grams per some unit of measure (i.e., grams/brake-horsepower). Thus, the technology being developed by the engine industry to meet the standards accordingly focuses on reducing the mass of dpm being emitted from the engine.

There is some evidence, however, that some aspects of this new technology, particularly fuel injection, is resulting in an increase in the number of nanoparticles being emitted from the engine.

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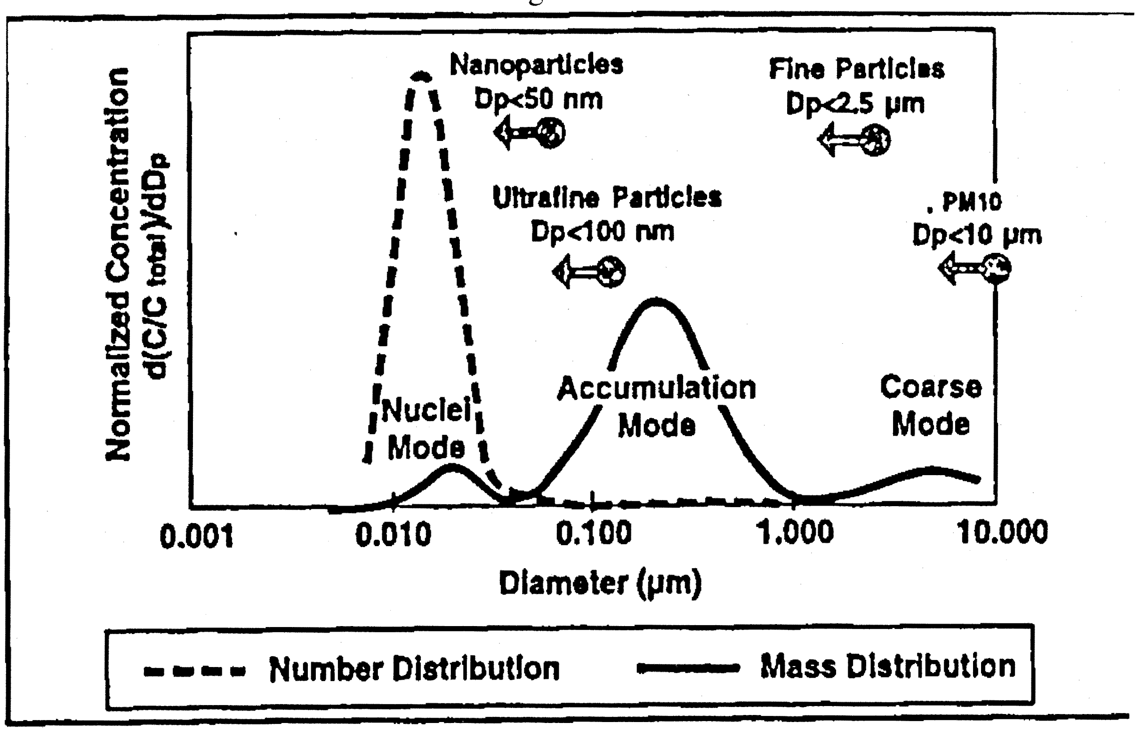
Figure II-3, repeated here from section 2 of this Part, illustrates this situation (Majewski, W. Addy, Diesel Progress, June, 1998).

Figure II-3



Diesel particulate size distribution.

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The formation of particulates starts with particle nucleation followed by subsequent agglomeration of the nuclei particles into an accumulation mode. Thus, as illustrated in Figure II–3, the majority of the mass of dpm is found in the accumulation mode, where the particles are generally between 0.1 and 1 micron in diameter. However, when considering the number of particles emitted from the engine, more than half and sometimes almost all of the particles (by number) are in the nuclei mode.

Various studies have demonstrated that the size of the particles emitted from the new low emission diesel engines, has shifted toward the generation of nuclei mode particles. One study compared a comparable 1991 engine to its 1988 counterpart. The total PM mass in the newer engine was reduced by about 80%; but the new engine generated thousands of times more particles than the older engine (3000 times as much at 75 percent load and about 14,000 times as much at 25 percent load). One hypothesis offered for this phenomenon is that the cleaner engines produce less soot particles on which particulates can condense and accumulate, and hence they remain in nuclei mode. The accumulation particles act as a ''sponge'' for the condensation and/or adsorption of volatile materials. In the absence of that sponge, gas species which are to become liquid or solid will nucleate to form large numbers of small particles (diesel.net technology guide). Mayer, while pointing out that nanoparticle production was a problem with older engines as well, concurs that the technology being used to clean up pollution in newer engines is not having any positive impact on nanoparticle production. While there is scientific evidence that the newer engines, designed to reduce the mass of pollutants emitted from the diesel engine, emit more particles in the nuclei mode, quantifying the magnitude of these particles has been difficult because as dpm is released into the atmosphere the diesel particulate undergoes very complex changes. In addition, current testing procedures can produce spurious increases in the number of nanoparticles that would not necessarily occur under more realistic atmospheric conditions.

Experimental work conducted at WVU (Bukarski) indicate that nanoparticles are not generated during the combustion process, but rather during various physical and chemical processes which the exhaust undergoes in after treatment systems.

While current medical research findings indicate that small particulates, particularly those below 2µm in size, may be more harmful to humans than the larger ones, much more medical research and diesel emission studies are needed to fully characterize diesel nanoparticles emissions and their impact on human health. If nanoparticles are found to have an adverse health impact by virtue of size and number, it could require significant adjustments in environmental engine emission regulation and technology. It could also have implications for the type of controls utilized, with some asserting that aftertreatment filters are the only effective way to limit the emission of nanoparticles and others asserting that aftertreatment filters may under certain circumstances limit the number of nanoparticles.

Research on nanoparticles and their health effects is currently a topic of investigation. (Bagley et al., 1996, EPA Grant). Based on the comments received and a review of the literature currently available on the nanoparticle issue, MSHA believes that, at this time, promulgation of the final rules for underground coal and metal and nonmetal mines is necessary to protect miners. The nanoparticle issues discussed above will not be resolved for some time because of the extensive research required to address the questions raised.

(6) Methods for controlling dpm concentrations in underground metal and nonmetal mines

As discussed in the last section, the introduction of new engines underground will certainly play a significant role in reducing the concentration of dpm in underground metal/nonmetal mines. There are, however, many other approaches to reducing dpm concentrations and occupational exposures to dpm in underground metal/nonmetal mines. Among these are: aftertreatment devices to eliminate particulates emitted by an engine; altering fuel composition to minimize engine particulate emission; maintenance practices and diagnostic systems to ensure that fuel, engine and aftertreatment technologies work as intended to minimize emissions; enhancing ventilation to reduce particulate concentrations in a work area; enclosing workers in cabs or other filtered areas to protect them from exposure; and work and fleet practices that reduce miner exposures to emissions.

As noted in section 9 of this Part, information about these approaches was solicited from the mining community in a series of workshops in 1995, and highlights were published by MSHA as an appendix to the proposed rule on dpm ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox.'' During the hearings and in written comments on this rulemaking, mention was made of all these control methods.

This section provides updated information on two methods for controlling dpm emissions: aftertreatment devices and diesel fuel content. There was considerable comment on aftertreatment devices because MSHA's proposed rule would require high-efficiency particulate filters be installed on a certain percentage of the fleet in order to meet both the interim and final dpm concentration; and the current and potential efficiency of such devices remains an important issue in determining the technological and economic feasibility of the final rule. Moreover, some commenters strongly favored the use of oxidation catalytic converters, a type of aftertreatment device used to reduce gaseous emission but which can also impact dpm levels. Accordingly, information about such devices is reviewed here. With respect to diesel fuel composition, a recent rulemaking initiative by EPA, and actions taken by other countries in this regard, are discussed here because of the implications of such developments for the mining community.

Emissions aftertreatment devices. One of the most discussed approaches to controlling dpm emissions involves the use of devices placed on the end of the tailpipe to physically trap diesel particulate emissions and thus limit their discharge into the mine atmosphere. These aftertreatment devices are often referred to as ''particle traps'' or ''soot traps'', but the term filter is often used. The two primary categories of particulate traps are those composed of ceramic materials (and thus capable of handling uncooled exhaust), and those composed of paper materials (which require the exhaust to first be cooled). Typically, the latter are designed for conventional permissible equipment mainly used in coal mining which have water scrubbers installed which cool the exhaust. However, another alternative that is now utilized in coal is the ''dry system technology'' which cools the diesel exhaust with a heat exchanger and then uses a paper filter. The dry system was first developed for oil shale mining applications where permissibility was required. However, when development of the oil shale industry faltered, manufacturers looked to coal mining for application of the dry system technology. However, dry systems could be used as an alternative to the wet scrubbers for the relatively small number of permissible machines used in the metal/nonmetal industry. In addition, ''oxidation catalytic converters,'' devices used to limit the emission of diesel gases, and ''water scrubbers'', devices used to cool the exhaust gases, are discussed here as well, because they also can have a significant effect on limiting particle emission.

Water Scrubbers. Water scrubbers are devices added to the exhaust system of certain diesel equipment. Water scrubbers are essentially metal boxes containing water through which the diesel exhaust gas is passed. The exhaust gas is cooled, generally to below 170 degrees F. A small fraction of the unburned hydrocarbons are condensed and remain in the water along with a portion of the dpm. Tests conducted by the former Bureau of Mines and others indicate that no more than 20 to 30 percent of the dpm is removed. This information was presented in the Toolbox publication. The water scrubber does not remove any of the carbon monoxide, the oxides of nitrogen, or any other gaseous emission that remains a gas at room temperature so their effectiveness as aftertreatment devices is questionable.

The water scrubber does serve as an effective spark and flame arrester and as a means to cool the exhaust gas when permissibility is required. Consequently, it is used in the majority of the permissible diesel equipment in mining as part of the safety components needed to gain MSHA approval.

The water scrubber has several operating characteristics which keep it from being a candidate for use as an aftertreatment device on nonpermissible equipment. The space required on the vehicle to store sufficient water for an 8 hour shift is not available on some equipment. Furthermore, the exhaust contains a great deal of water vapor which condenses under some mining conditions creating a fog which can adversely effect visibility. Also, operation of the equipment on slopes can cause the water level in the scrubber to change resulting in water being blown out the exhaust pipe. Control devices are sometimes placed within the scrubber to maintain the appropriate water level. Because these devices are in contact with the water through which the exhaust gas has passed, they need frequent maintenance to insure that they are operating properly and have not been corroded by the acidic water created by the exhaust gas. The water scrubber must be flushed frequently to remove the acidic water and the dpm and other exhaust residue which forms a sludge that adversely effects the operation of the unit. These problems, coupled with the relatively low dpm removal efficiency, have prevented widespread use of water scrubbers as a dpm control device on nonpermissible equipment.

Oxidation Catalytic Converters. Oxidation catalytic converters (OCCs) were among the first devices added to diesel engines in mines to reduce the concentration of harmful gaseous emissions discharged into the mine environment. OCCs began to be used in underground mines in the 1960's to control carbon monoxide, hydrocarbons and odor. That use has been widespread. It has been estimated that more than 10,000 OCCs have been put into the mining industry over the years.

Several of the harmful emissions in diesel exhaust are produced as a result of incomplete combustion of the diesel fuel in the combustion chamber of the engine. These include carbon monoxide and unburned hydrocarbons including harmful aldehydes. Catalytic converters, when operating properly, remove significant percentages of the carbon monoxide and unburned hydrocarbons. Higher operating temperatures, achieved by hotter exhaust gas, improve the conversion efficiency.

Oxidation catalytic converters operate by, in effect, continuing the combustion process outside the combustion chamber. This is accomplished by utilizing the oxygen in the exhaust gas to oxidize the contaminants. A very small amount of material with catalytic properties, usually platinum or some combination of the noble metals, is deposited on the surfaces of the catalytic converter over which the exhaust gas passes. This catalyst allows the chemical oxidation reaction to occur at a lower temperature than would normally be required.

For the catalytic converter to work effectively, the exhaust gas temperature must be above 370 degrees Fahrenheit for carbon monoxide and 500 degrees Fahrenheit for hydrocarbons. Most converters are installed as close to the exhaust manifold as possible to minimize the heat loss from the exhaust gas through the walls of the exhaust pipe. Insulating the segment of the exhaust pipe between the exhaust manifold and the catalytic converter extends the portion of the vehicle duty cycle in which the converter works effectively.

The earliest catalytic converters for mining use consisted of alumina pellets coated with the catalytic material and enclosed in a container. The exhaust gas flowed through the pellet bed and the exhaust gas came into contact with the catalyst. Designs have evolved, and the most common design is a metallic substrate, formed to resemble a honeycomb, housed in a metal shell. The catalyst is deposited on the surfaces of the honeycomb. The exhaust gas flows through the honeycomb and comes into contact with the catalyst.

Soon after catalytic converters were introduced, it became apparent that there was a problem brought about by the sulfur found in diesel fuels in use at that time. Most diesel fuels in the United States contained anywhere from 0.25 to 0.50 percent sulfur or more on a mass basis. In the combustion chamber, this sulfur was converted to SO_2, SO_3, or SO_4 in various concentrations, depending on the engine operating conditions. In general, most of the sulfur was converted to gaseous SO_2. When exhaust containing the gaseous sulfur dioxide passed through the catalytic converter, a large proportion of the SO_2 was converted to solid sulphates which are in fact, diesel particulate. Sulfates can ''poison'' the catalyst, severely reducing its life.

Recently, as described elsewhere in this preamble, the EPA required that diesel fuel used for over the road trucks contain no more than 500 ppm sulfur. This action made low sulfur fuel available throughout the United States. MSHA, in its recently promulgated regulations for the use of diesel powered equipment in underground coal mines requires that this low sulfur fuel be used. MSHA is now extending this requirement for low sulfur fuel (<500ppm) to underground metal/nonmetal mines in this final rule. When the low sulfur fuel is burned in an engine and passed through a converter with a moderately active catalyst, only small amounts of SO_2 and additional sulfate based particulate are created. However, when a very active catalyst is used, to lower the operating temperature of the converter or to enhance the CO removal efficiency, even the low sulfur fuel has sufficient sulfur present to create an SO_2 and sulfate based particulate problem. Consequently, as discussed later in this section, the EPA has notified the public of its intentions to promulgate regulations that would limit the sulfur content of future diesel fuel to 15 ppm for on-highway use in 2006.

The particulate reduction capabilities of some OCCs are significant in gravimetric terms. In 1995, the EPA implemented standards requiring older buses in urban areas to reduce the dpm emissions from rebuilt bus engines. (40

CFR 85.1403). Aftertreatment manufacturers developed catalytic converter systems capable of reducing dpm by 25%. Such systems are available for larger diesel engines common in the underground metal and nonmetal sector. However, as has been pointed out by Mayer, the portion of particulate mass that seems to be impacted by OCCs is the soluble component, and this is a smaller percentage of particulate mass in utility vehicle engines than in automotive engines. Moreover, some measurements indicate that more than 40% of NO is converted to more toxic NO_2, and that particulate mass actually increases using an OCC at full load due to the formation of sulfates. In summation, Mayer concluded that the OCCs do not reduce the combustion particulates, produce sulfate particulates, have unfavorable gaseous phase reactions increasing toxicity, and that the positive effects are irrelevant for construction site diesel engines. Indeed, he indicates the negative effects outweigh the benefits. (Mayer, 1998. The Phase 1 interim data report of the Diesel Emission Control-Sulfur Effects (DECSE) Program (a joint government-industry program to explore lower sulfur content that is discussed in more detail later in this section) similarly indicates that using OCCs under certain operating conditions can increase dpm emissions due to an increase in the sulfate fraction (DECSE Program Summary, Dec. 1999). Another commenter also notes that oxidation catalytic activity can increase sulfates and submicron particles under certain operating conditions.

Other commenters during the rulemaking strongly supported the use of OCCs as an interim measure to reduce particulate and other diesel emission to address transitory employee effects that were mentioned in the proposed preamble. MSHA views the use of OCCs as one tool that mine operators can use to reduce the dpm emissions from certain vehicles alone or in combination of other aftertreatment controls to meet the interim and final dpm standards. The overall reduction in dpm emissions achieved with the exclusive use of an OCC is low compared to the reductions required to meet the standards. MSHA is aware of the negative effects produced by OCCs. However, with the use of low sulfur fuel and a catalyst that is formulated for low sulfate production, this problem can be resolved. Mine operators must work with aftertreatment manufacturers to come up with the best plan for their fleet for dpm control.

Hot gas filters. Throughout this preamble, MSHA is referring to the particulate traps (filters) that can be used in the undiluted hot exhaust stream from the diesel engine as hot gas filters. Hot gas filters refer to the current commercially available particulate filters, such as ceramic cell, woven fiber filters, sintered metal filters, etc.

Following publication of EPA rules in 1985 limiting diesel particulate emissions from heavy duty diesel engines, aftertreatment devices capable of significant reductions in particulate levels began to be developed for commercial applications.

The wall flow type ceramic honeycomb diesel particulate filter system was initially the most promising approach. These consisted of a ceramic substrate encased in a shock and vibration absorbing material and covered with a protective metal shell. The ceramic substrate is arranged in the shape of a honeycomb with the openings parallel to the centerline. The ends of the openings of the honeycomb cells are plugged alternately. When the exhaust gas flows through the particulate trap, it is forced by the plugged end to flow through the ceramic wall to the adjacent passage and then out into the mine atmosphere. The ceramic material is engineered with pores in the ceramic material sufficiently large to allow the gas to pass through without adding excessive back pressure on the engine, but small enough to trap the particulate on the wall of the ceramic material. Consequently, these units are called wall flow traps.

Work with ceramic filters in the last few years has led to the development of the ceramic fiber wound filter cartridge (SAE, SP–1073, 1995). The ceramic fiber has been reported by the manufacturer to have dpm reduction efficiencies up to 80 percent. This system has been used on vehicles to comply with German requirements that all diesel engines used in confined areas be filtered. Other manufacturers have made the wall flow type ceramic honeycomb dpm filter system commercially available to meet the German standard.

The development of these devices has proceeded in response to international and national efforts to regulate dpm emissions. However, due to the extensive work performed by the engine manufacturers on new technological designs of the diesel engine's combustion system, and the use of low sulfur fuel, particulate traps turned out to be unnecessary to comply with the EPA standards of the time for vehicle engines.

These devices proved to be very effective at removing particulate achieving particulate removal efficiencies of greater than 90 percent.

It was quickly recognized that this technology, while not immediately required for most vehicles, might be particularly useful in mining applications. The former Bureau of Mines investigated the use of catalyzed diesel particulate filters in underground mines in the United States (BOM, RI–9478, 1993). The investigation demonstrated that filters could work, but that there were problems associated with their use on individual unit installations, and the Bureau made recommendations for installation of ceramic filters on mining vehicles.

Canadian mines also began to experiment with ceramic traps in the 1980's with similar results (BOM, IC 9324, 1992). Work in Canada today continues under the auspices of the Diesel Emission Evaluation Program (DEEP), established by the Canadian Centre for Mineral and Energy Technology in 1996 (DEEP Plenary Proceedings, November 1996). The goals of DEEP are to: (1) Evaluate aerosol sampling and analytical methods for dpm; and (2) evaluate the in-mine performance and costs of various diesel exhaust control strategies.

Perhaps because experience is still limited, the general perception within the mining industry of the state of this technology in recent years is that it remains limited in certain respects; as expressed by one commenter at one of the MSHA workshops in 1995, ''while ceramic filters give good results early in their life cycle, they have a relatively short life, are very expensive and unreliable.''

One commenter reported unsuccessful experiments with ceramic filters in 1991 due to their inability to regenerate at low temperatures, lack of reliability, high cost of purchase and installation, and short life.

In response to the proposed rule, MSHA received a variety of information and claims about the current efficiency of such technologies. Commenters stated that in terms of technical feasibility to meet the standards, the appropriate aftertreament controls are not readily available on the market for the types and sizes of equipment used in underground mines. Another commenter stated that MSHA has not identified a technology capable of meeting the proposed standards at their mine and they were not aware of any technology currently available or on the horizon that would be capable of attaining the standards. Yet another commenter stated that both ceramic and paper filters are not technically feasible at their mine because of the high operating temperatures needed to regenerate filters or the difficulties presented by periodic removal of the filters for regeneration. Periodic removal of fragile ceramic filters subjects them to chipping and cracking and requires a large inventory of surplus filters. Commenter also stated that paper filters require exhaust gas cooling so that the paper filter does not burn. Commenter stated that they have been working with a manufacturer on installing one of these on a piece of equipment, but it is experimental and this installation was the first time a paper filter would be used on equipment of this size and type.

In response to the paper filter comment, dry system technology as described above was first tested on a large haul truck used in oil shale mining and then later applied to coal mining equipment. Paper filter systems have also been successfully installed on coal mining equipment that is identical to LHD machines used in metal/nonmetal mines. Therefore this technology has been applied to engine of the type and size used in metal/nonmetal mines. Commenters have stated that filters are not feasible at this time from the above comments. However, MSHA believes that the technology needed to reduce dpm emissions to both the interim and final standards is feasible. Much work has occurred in the development of aftertreatment controls, especially OCCs and hot gas filters. Aftertreatment control manufacturers have been improving both OCCs and ceramic type filters to provide better performance and reliability. New materials are currently available commercially and new filter systems are being developed especially in light of the recent requirements in Europe and the new proposals from the EPA. Consequently, MSHA does not agree with the commenter concerning chipping of the traps when removed. As stated, manufacturers have designed systems to either be removed easily or even regenerated on the vehicle by simply plugging the unit in without removing the filter.

Two groups in particular have been doing some research comparing the efficiency of recent ceramic models: West Virginia University, as part of that State's efforts to develop rules on the use of diesel-powered equipment underground; and VERT (Verminderung der Emissionen von Realmaschinen in Tunnelbau), a consortium of several European agencies conducting such research in connection with major planned tunneling projects in Austria, Switzerland and Germany to protect occupational health and subsequent legislation in each of the three countries restricting diesel emissions in tunneling.

The State of West Virginia legislature enacted the West Virginia Diesel Act, thereby creating the West Virginia Diesel Commission and setting forth an administrative vehicle to allow and regulate the use of diesel equipment in underground coal mines in West Virginia. West Virginia University was appropriated funds to test diesel exhaust controls, as well as an array of diesel particulate filters. The University was asked to provide technical support and data necessary for the Commission to make decisions on standards for emission controls. Even though the studies were intended for the Commission's work for underground coal, the control technologies tested are relevant to metal/nonmetal mines.

The University reported data on four different engines and an assortment of configurations of available control devices, both hot gas filters and the DST® system, a system which first cools the exhaust and then runs it through a paper filter. The range of collection efficiencies reported for the ceramic filters and oxidation catalysts combined fell between 65% and 78%. The highest collection efficiency obtained using the ISO 8 mode test cycle (test cycle described in rule) was 81% on the DST® system (intended for coal use). The University did report problems with this system that would account for the lower than expected efficiency for a paper filter type system.

VERT's studies of particulate traps are detailed in two articles published in 1999 which have been widely disseminated to the diesel community here through www.DieselNet.com. The March article focuses on the efficiency of the traps; the April article compares the efficiency of other approaches (OCCs, fuel reformulation, engine modifications to reduce ultra-fine particulates) with that of the traps. Here we focus only on the information about particulate traps.

The authors of the March article report that 29 particulate trap systems were tested using various ceramic, metal and fiber filter media and several regeneration systems. The authors of the March article summarize their conclusions as follows:

> The results of the 4-year investigations of construction site engines on test rigs and in the field are clear: particulate trap technology is the only acceptable choice among all available measures. Traps proved to be an extremely efficient method to curtail the finest particles. Several systems demonstrated a filtration rate of more than 99% for ultra-fine particulates. Specific development may further improve the filtration rate.
>
> A two-year field test, with subsequent trap inspection, confirmed the results pertaining to filtration characteristics of ultra-fine particles. No curtailment of the ultra-fine particles is obtained with any of the following: reformulated fuel, new lubricants, oxidation catalytic converters, and optimization of the engine combustion.
>
> Particulate traps represent the best available technology (BAT). Traps must therefore be employed to curtail the particulate emissions that the law demands are minimized. This technology was implemented in occupational health programs in Germany, Switzerland and Austria.

On the bench tests, it appears that the traps reduce the overall particulate matter by between 70 and 80%, with better results for solid ultrafine particulates; under hot gas conditions, it appears the non-solid components of particulate matter cannot be dependably retained by these traps. Consistent with this finding, it was found that polycyclic aromatic hydrocarbons (PAHs) decreased proportionately to the gravimetric decrease of carbon mass. The tests also explored the impact of additives on trap efficiency, and the impact of back pressure.

The field tests confirmed that the traps were easy to mount and retained their reliability over time, although regeneration was required when low exhaust temperatures failed to do this automatically. Electronic monitoring of back pressure was recommended. In general, the tests confirmed that a whole series of trap systems have a high filtration rate and stable long time properties and are capable of performing under difficult construction site conditions. Again, the field tests indicated a very high reduction (97–99%) of particulates by count, but a lower rate of reduction in terms of mass.

Subsequently, VERT has evaluated additional commercially available filter systems. The filtration efficiency, expressed on a gravimetric basis is shown in the column headed "PMAG—without additive". The filtration efficiencies determined by VERT for these 6 filter systems range from 80.7% to 94.5%. The average efficiency of these filters is 87%. MSHA will be updating the list of VERT's evaluated systems as they become available.

VERT has also published information on the extent of dpm filter usage in Europe as evidence that the filter technology has attained wide spread acceptance. This information is included in the record of the coal dpm rulemaking where it has particular significance; it is noted here for informational purposes. The information isn't critical in this case because operators have a choice of controls. MSHA didn't explicitly add the latest VERT data to the Metal/

Nonmetal record during the latest reopening of the record. MSHA believes this information is relevant to metal/nonmetal mining because the tunneling equipment on which these filters are installed is similar to metal/nonmetal equipment. VERT stated that over 4,500 filter systems have been deployed in England, Scandinavia, and Germany. Deutz Corporation has deployed 400 systems (Deutz's design) with full flow burners for regeneration of filters installed on engines between 50–600kw. The company Oberland-Mangold has approximately 1,000 systems in the field which have accumulated an average of 8,400 operating hours in forklift trucks, 10,600 operating hours in construction site engines, and 19,200 operating hours in stationary equipment. The company Unikat has introduced in Switzerland over 250 traps since 1989 and 3,000 worldwide with some operating more than 20,000 hours. German industry annually installs approximately 1,500 traps in forklifts.

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Table II-4

Efficiency of Diesel Particulate Traps VERT-Certification Test

Average 4 operation points, ISO 8187

Trap	Date	PMAG		PZAG		ECAG	
		without Additive	with Additive	without Additive	with Additive	without Additive	with Additive
3M	VERT-Certification Test Part 1 (new)	80.7	-	98.6	99.6	-	-
Oberland		90.5	-	98.4	99.4	-	-
JMC		94.5	-	99.3	-	-	-
IBIDEN		87.2	-	99.9	-	-	-
Corning		84.9	-	99.5	99.8	-	-
HJS/CRT		83.8	-	99.4	-	98.2	-
SHW(LIB1)	After VERT Field Test Part 3 (after 2000 hrs)	3.2	22.2	96.3	97.1	-	93.1
SHW(CAT1)		77.5	87.6	97.8	98.8	97.2	96.5
BUCK(LIB2)		76.5	81.0	95.4	97.8	94.0	95.5
BUCK(CAT3)		64.2	76.2	91.0	96.8	(87.0) [2]	95.3
ECS(LIB3)		12.4	43.0	99.9	99.9	99.3	99.0
DEUTZ(LIB4) [1]		(70.5)	(76.1)	(86.6)	(91.6)	(84.2)	
UNIKAT(CAT4)		54.7	76.2	99.0	99.6	98.1	98.4
AVERAGE		66.4		98.3		97.2	

[1] Small melting damage
[2] Uncertain data
[3] Coulometry is optional for VERT certification test

PMAG:Efficiency according to Total Particulate Mass PM
PZAG:Efficiency according to Integrated Particulate Count (20 - 300 nm) PZ
ECAG:Efficiency according to Elementary Carbon EC (2 state Coulometry)

$$PMAG = \frac{PM_{before\ trap} - PM_{after\ trapF}}{PM_{before\ trapF}} = \frac{PM_{Ref} - PM_{after\ trap}}{PM_{Ref}} \ (X\ 100\%)$$

$$PZAG = \frac{PZ_{before\ trap} - PZ_{after\ trap}}{PZ_{before\ trap}} = \frac{PZ_{Ref} - PZ_{after\ trap}}{PZ_{Ref}} \ (X\ 100\%)$$

$$Penetration = 1 - Efficiency = = \frac{PZ_{after\ PF}}{PZ_{Ref}} \ (X\ 100\%)$$

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Some commenters asserted that the VERT work was for relatively small engines and not for large engines, *i.e.,* 600–700 hp, and hence could not be relied upon to demonstrate the availability of filters of such high efficiencies for the larger equipment used in some underground mines. MSHA believes this comment is misplaced. The efficiency of a filter is attributable to the design of the filter and not the size of the engine. VERT is documenting filter efficiencies of commercially available filters. It is customary in the industry, however, for the filter manufacturer to size the filter to fit the size of the engine. The mine operator must work with the filter manufacturer to verify that the filter needed will work for the intended machine. MSHA believes that this is no different for other types of options installed on machines for underground mining use.

More information about the results of the VERT tests on specific filters, and how MSHA intends to use this information to aid the mining industry to comply with the requirements of the standards are discussed in Part IV of this preamble.

The accumulated dpm must be removed from all particulate traps periodically. This is usually done by burning off the accumulated particulate in a controlled manner, called regeneration. If the diesel equipment on which the trap is installed has a duty cycle which creates an exhaust gas temperature greater than about 650 degrees Fahrenheit for more than 25 percent of the operating time, the unit will be self cleaning. That is, the hot exhaust gas will burn off the particulate as it accumulates. Unfortunately, only hard working equipment, such as load-haul-dump and haulage equipment usually satisfies the exhaust gas temperature and duration requirements.

Techniques are available to lower the temperature required to initiate the regeneration. One technique under development is to use a fuel additive. A comparatively small amount of a chemical is added to the diesel fuel and burns along with the fuel in the combustion chamber. The additive is reported to lower the required regeneration temperature significantly. The additive combustion products are retained as a residue in the particulate trap. The trap must be removed from the equipment periodically to flush the residue. Another technique used to lower the regeneration temperature is to apply a catalyst to the surfaces of the trap material. The action of the catalyst has a similar effect as the fuel additive. The catalyst also lowers the concentration of some gaseous emissions in the same manner as the oxidation catalytic converter described earlier.

A very active catalyst applied to the particulate trap surfaces and a very active catalyst in a catalytic converter installed upstream of the trap can create a situation in which the trap performs less efficiently than expected. Burning low sulfur diesel fuel, containing less than 500 ppm sulfur, will result in the creation of significant quantities of sulfates in the exhaust gas. These sulfates will still be in the gaseous state when they reach the ceramic trap and will pass through the trap. These sulfates will condense later forming diesel particulate. Special care must be taken in the selection of the catalyst formulation to ensure that sulfate formation is avoided. This problem is not present on systems which are designed with a catalytic converter upstream of a water scrubber. The gaseous phase sulfates will condense when contacting the water in the scrubber and will not be discharged into the mine atmosphere. Thus far, no permissible diesel packages have been approved which incorporate a catalytic converter upstream of the water scrubber.

One research project conducted by the former Bureau of Mines which attempted this arrangement was unsuccessful. The means selected to maintain a surface temperature less than the 300 degrees Fahrenheit required for permissibility purposes caused the exhaust gas to be cooled to the point that the catalytic converter did not reach the necessary operating temperature. It would appear that a means to isolate the catalytic converter from the exhaust gas water jacket is necessary for the arrangement to function as intended.

If the machine on which the particulate trap is installed does not work hard enough to regenerate the trap with the hot exhaust gas and the option to use a fuel additive or catalyzed trap is not appropriate, the trap can still be regenerated while installed on the machine. Systems are available whereby air is heated by an externally applied heat source and caused to flow through the particle trap with the engine stopped. The heat can be supplied by an electrical resistance element installed in front of the trap. The heat can also be supplied by a burner installed into the exhaust pipe in front of the trap fueled by an auxiliary fuel line. The fuel is ignited creating large quantities of hot gas. With both systems, an air line is also connected to the exhaust pipe to create a flow of hot gases through the particulate trap. Both systems utilize operator panels to control the regeneration process.

Some equipment owners may choose to remove the particle trap from the machine to perform the regeneration. Particle traps are available with quick release devices that allow maintenance personnel to readily remove the unit from the machine. The trap is then placed on a specially designed device that creates a controlled flow of heated air that is passed through the filter burning off the accumulated particulate.

The selection of the most appropriate means to regenerate the trap is dependent on the equipment type, the equipment duty cycle, and the equipment utilization practices at the mine.

A program under the Canadian DEEP project is field testing dpm filter systems in a New Brunswick Mine. The project is testing four filter systems on trucks and scoops. The initial feedback from Canada is very favorable concerning the performance of filters. Operators are very positive and are requesting the vehicles equipped with the filters because of the noticeable improvement in air quality and an absence of smoke even under transient load conditions. One system being tested utilizes an electrical heating element installed in the filter system to provide the heated air for regeneration of the filter. This heating element requires that the filter be connected to an external electrical source at the end of the shift. Initial results have been successful.

Paper filters. In 1990, the former Bureau of Mines conducted a project to develop a means to reduce the amount of dpm emitted from permissible diesel powered equipment using technologies that were available commercially and that could be applied to existing equipment. The project was conducted with the cooperation of an equipment manufacturer, a mine operator, and MSHA. In light of the fact that all permissible diesel powered equipment in coal and metal/nonmetal, at that time, utilized water scrubbers to meet the MSHA approval requirements, the physical characteristics of the exhaust from that type of equipment were the basis for the selection of candidate technologies. The technology selected for development was the pleated media filter or paper filter as it came to be called. The filter selected was an intake air cleaner normally used for over the road trucks. That filter was acceptable for use with permissible diesel equipment because the temperature of the exhaust gas from the water scrubber was less than 170 degrees F which was well below the ignition point of the filter material.

Recognizing that under some operating modes water would be discharged along with the exhaust, a water trap was installed in the exhaust stream before it passed through the filter. After MSHA conducted a thorough permissibility evaluation of the modified system, this filter was installed on a permissible diesel coal haulage vehicle and a series of in mine trials conducted. It was determined, by in mine ambient gravimetric sampling, that the particulate filter reduced dpm emissions by 95 percent compared to that same machine without the filter. The testing determined that the filters would last between one and two shifts, depending on how hard the equipment worked. (BOM, IC 9324).

Following the successful completion of the former Bureau of Mines mine trial, several equipment manufacturers applied for and received MSHA approval to offer the paper filter kits as options on a number of permissible diesel machines. These filter kits were installed on other machines at the mine where the original tests were conducted, and later, on machines at other mines. MSHA is not aware of any paper filters installed on permissible equipment in m/nm to date.

Despite the initial reports on the high efficiency of paper filters, during the coal public hearings and in the coal comments on this rulemaking a number of commenters at the coal public hearings questioned whether in practice paper filters could achieve efficiencies on the order of 95% when used on existing permissible equipment. In order to determine whether it could verify those concerns, MSHA contracted with the Southwest Research Institute to verify the ability of such a filter to reduce the dpm generated by a typical engine used in permissible equipment. The results of this verification effort confirmed that paper filters has a dpm removal efficiency greater than 95%. The information about MSHA's verification effort with respect to paper filters is discussed in detail in connection with the companion rule for the coal sector, where it has particular significance.

Dry systems technology. As mentioned earlier, the most recently developed means of achieving permissibility with diesel powered equipment in the United States is the dry exhaust conditioning system or dry system. This system combines several of the concepts described above as well as new, innovative approaches. The system also solves some of the problems encountered with older technologies.

The dry system in its most basic form consists of a heat exchanger to cool the exhaust gas, a mechanical flame arrestor to prevent the discharge of any flame from within the engine into the mine atmosphere, and a spark arrestor to prevent sparks for being discharged. The surfaces of all of these components and the piping connecting them are maintained below the 300 degrees F required by MSHA approval requirements. A filter, of the type normally used as an intake air filter element, is installed in the exhaust system as the spark arrestor. In terms of this dpm regulation, the most significant feature of the system is the use of this air filter element as a particulate filter. The filter media has an allowable operating temperature rating greater than the 300 degree F exhaust gas temperature allowed by MSHA approval regulations. These filters are reported to last up to sixteen hours, depending on how hard the machine operates.

The dry system can operate on any grade without the problems encountered by water scrubbers. Furthermore, there is no problem with fog created by operation of the water scrubber. Dry systems have been installed and are operating successfully in coal mines on diesel haulage equipment, longwall component carriers, longwall component extraction equipment, and in nonpermissible form, on locomotives.

Although the systems were originally designed for permissible equipment applications, they can also be used directly on nonpermissible equipment (whose emissions are not already cooled), or to replace water scrubbers used to cool most permissible equipment with a system that includes additional aftertreatment.

Reformulated fuels. It has long been known that sulfur content can have a significant effect on dpm emissions. In its diesel equipment rule for underground coal mines, MSHA requires that any fuel used in underground coal mines have less than 0.05% (500 ppm) sulfur. EPA regulations requiring that such low-sulfur fuel (less than 500 ppm) be used in highway engines, in order to limit air pollution, have in practice ensured that this type of diesel fuel is available to mine operators, and they currently use this type of fuel for all engines.

EPA has proposed a rule which would require further reductions in the sulfur content of highway diesel fuel. Such an action was taken for gasoline fuel on December 21, 1999.

On May 13, 1999 (64 FR 26142) EPA published an Advance Notice of Proposed Rulemaking (ANPRM) relative to changes for diesel fuel. In explaining why it was initiating this action, EPA noted that diesel engines ''contribute greatly'' to a number of serious air pollution problems, and that diesel emissions account for a large portion of the country's particulate matter and nitrogen oxides a key precursor to ozone. EPA noted that while these emissions come mostly from heavy-duty truck and nonroad engines, they expected the contribution to dpm emissions of light-duty equipment to grow due to manufacturers' plans to greatly increase the sale of light duty trucks. These vehicles are now subject to Tier 2 emission standards whether powered by gasoline or diesel fuel, and such standards may be difficult to meet without advanced catalyst technologies that in turn would seem to require sulfur reductions in the fuel.

Moreover, planned Tier 3 standards for nonroad vehicles would require similar action (64 FR 26143). The EPA noted that the European Union has adopted new specifications for diesel fuel that would limit it to 50 ppm by 2005, (an interim limit of 350 ppm by this year), that the entire diesel fuel supply in the United Kingdom should soon be at 50 ppm, and that Japan and other nations were working toward the same goal (64 FR 26148). In the ANPRM, the EPA specifically noted that while continuously regenerating ceramic filters have shown considerable promise for limiting dpm emissions even at fairly low exhaust temperatures, the systems are fairly intolerant of fuel sulfur. Accordingly, the agency hopes to gather information on whether or not low sulfur fuel is needed for effective PM control (64 FR 26150). EPA's proposed rule was published in June 2000, (65 FR 35430) and proposed a sulfur limit of 15 ppm for on-highway use in 2006–2009.

A joint government-industry partnership is also investigating the relationship between varying levels of sulfur content and emissions reduction performance on various control technologies, including particulate filters and oxidation catalytic convertors. This program is supported by the Department of Energy's Office of Heavy Vehicles Technologies, two national laboratories, the Engine Manufacturers Association, and the Manufacturers of Emission Controls Association. It is known as the Diesel Emission Control-Sulfur Effects (DECSE) Program; more information is available from its web site, http://www.ott.doe.gov/decse.

MSHA expects that once such cleaner fuel is required for transportation use, it will in practice become the fuel used in mining as well—directly reducing engine particulate emissions, increasing the efficiency of aftertreatment devices, and eventually through the introduction of new generation of cleaner equipment. Mayer states that reducing sulfur content, decreasing aromatic components and increasing the Cetane index of diesel fuel can generally result in a 5% to 15% reduction in total particulate emissions.

Meyer reports the test by VERT of a special synthetic fuel containing neither sulfur nor bound nitrogen nor aromatics, with a very high Cetane index. The fuel performed very well, but produced only abut 10% fewer particulates than low sulfur diesel fuel, nor did it have the slightest improvement in diminishing nonparticulate emissions.

NIOSH provided information on the work that has been done with Biodiesel fuel. Biodiesel fuel is a registered fuel and fuel additive with the EPA and meets clean diesel standards established by the California Air Resources Board. NIOSH stated that the undisputed consensus among the research conducted is that the use of biodiesel will significantly reduce dpm and other harmful emissions in underground mines. MSHA agrees that biodiesel fuel is an option that mine operators can use from the toolbox to meet the dpm standards.

Cabs. A cab is an enclosure around the operator installed on a piece of mobile equipment. It can provide the same type of protection as a booth at a crusher station. While cabs are not available for all mining equipment, they are available for much of the larger equipment that also has application in the construction industry.

Even though cabs are not the type of control device that is bolted onto the exhaust of the diesel engine to reduce emissions, cabs can protect miners from environmental exposures to dpm. Both cabs and control booths are discussed in the context of reducing miners exposures to dpm.

To be effective, a cab should be tightly sealed with windows and doors must be closed. Rubber seals around doors and windows should be in good conditions. Door and window latches should operate properly. In addition to being well sealed, the cab should have an air filtration and space pressurizing system. Air intake should be located away from engine exhaust. The airflow should provide one air change per minute for the cab and should pressurize the cab to 0.20 inches of water. While these are not absolute requirements, they do provide a guideline of how a cab should be designed. If a cab does not have an air filtration and pressurizing system, the diesel particulate concentration inside the cab will be similar to the diesel particulate concentration outside the cab.

MSHA has evaluated the efficiency of cab filters for diesel particulate reduction (Commercial Stone Study, PS&HTC–DD–98–346, Commercial Stone Study, PS&HTC–DD–99–402 and Homestake Mine Study, PS&HTC–DD–00–505.) Several different types of filter media have been tested in underground mines. Depending on the filter media, cabs can reduce diesel particulate exposures by 45 to 90 percent.

(7) MSHA's Diesel Safety Rule for Underground Coal Mines and its Effect on dpm

MSHA's proposed rule to limit the concentration of dpm in underground metal and nonmetal mines included a number of elements which have already proven successful in helping to reduce dpm concentrations in the coal sector. Accordingly, this section provides some background on the substance of the rules that have been in effect in underground coal mines (for more information on the history of rulemaking in the coal sector, please refer to section 9 of this Part). It should be noted, however, that not all of the requirements discussed here are going to be required for underground metal and nonmetal mines; see Part IV of this preamble for details on what is included in the final rule.

Diesel Equipment Rule in Underground Coal Mines. On October 25, 1996, MSHA promulgated standards for the ''Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines,'' sometimes referred to as the ''diesel equipment rule'' (61 FR 55412; the history of this rulemaking is briefly discussed in section 9 of this Part). The diesel equipment rule focuses on the safe use of diesels in underground coal mines. Integrated requirements are established for the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines.

MSHA Approval Requirements for Engines Used in Underground Coal Mines. MSHA requires that all diesel engines used in underground coal mines be ''approved'' by MSHA for such use, and be maintained by operators in approved condition. Among other things, approval of an engine by MSHA ensures that engines exceeding certain pollutant standards are not used in underground coal mines. MSHA sets the standards for such approval, establishes the testing criteria for the approval process, and administers the tests. The costs to obtain approval of an engine are usually borne by the engine manufacturer or equipment manufacturer. MSHA's 1996 diesel equipment rule made some significant changes to the consequences of approval. The new rule required the whole underground coal fleet to convert to approved engines no later than November 1999.

The new rule also required that during the approval process the agency determine the particulate index (PI) for the engine. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates the air quantity necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air.

The PI does not appear on the engine's approval plate. (61 FR 55421). Furthermore, the particulate index of an engine is not, under the diesel equipment rule, used to determine whether or not the engine can be used in an underground coal mine.

At the time the equipment rule was issued, MSHA explicitly deferred the question of whether to require engines used in mining environments to meet a particular PI. (61 FR 55420–21, 55437). While there was some discussion of using it in this fashion during the diesel equipment rulemaking, the approach taken in the final rule was to adopt, instead, the multi-level approach recommended by the Diesel Advisory Committee. This multi-level approach included the requirement to use clean fuel, low emission engines, equipment design, maintenance, and ventilation, all of which appear in the final rule. The requirement for determining the particulate index was included in the diesel equipment rule in order to provide information to the mining community in purchasing equipment—so that mine operators can compare the particulate levels generated by different engines. Mine operators and equipment manufacturers can use the information along with consideration of the type of machine the engines would power and the area of the mine in which it would be used to make decisions concerning the engine's contribution of diesel particulate to the mine's total respirable dust. Equipment manufactures can use the particulate index to design and install exhaust after-treatments. (61 FR 55421). So that the PI for any engine is known to the mining community, MSHA reports the index in the approval letter, posted the PI and ventilating air requirement for all approved engines on its website, and publishes the index with its lists of approved engines.

Gas Monitoring. As discussed in section 5, there are limitations on the exposure of miners to various gases emitted from diesel engines in both underground coal mines and underground metal and nonmetal mines.

The 1996 diesel equipment rule for underground coal mines supplemented these protections in that sector by providing for the monitoring and control of gaseous diesel exhaust emissions. (30 CFR part 70; 61 FR 55413). The rule requires that underground coal mine operators take samples of carbon monoxide and nitrogen dioxide as part of existing onshift workplace examinations. Samples exceeding an action level of 50 percent of the threshold limits set forth in 30 CFR 75.322 trigger corrective action by the mine operator.

Engine Maintenance. The diesel equipment rule also requires that diesel-powered equipment be maintained in safe and approved condition. As explained in the preamble, maintenance requirements were included because of MSHA's recognition that inadequate equipment maintenance can, among other things, result in increased levels of harmful gaseous and particulate components from diesel exhaust.

Among other things, the rule requires the weekly examination of diesel-powered equipment in underground coal mines. To determine if more extensive maintenance is required, the rule further requires that a weekly check of the gaseous CO emission levels on permissible and heavy duty outby machines be made. The CO check requires that the engine be operated at a repeatable loaded condition and the CO measured. The carbon monoxide concentration in the exhaust provides a good indication of engine condition. If the CO measurement increases to a higher concentration than what was normally measured during the past weekly checks, then a maintenance person would know that a problem has developed that requires further investigation. In addition, underground coal mine operators are required to establish programs to ensure that those performing maintenance on diesel equipment are qualified.

Fuel. The diesel equipment rule also requires that underground coal mine operators use diesel fuel with a sulfur content of 0.05% (500 ppm) or less. Some types of exhaust aftertreatment technology designed to lower hazardous diesel emissions work more effectively when the sulfur content of the fuel is low. More effective aftertreatment devices will result in reduced hydrocarbons, carbon monoxide, and particulate levels. Low sulfur fuel also greatly reduces the sulfate production from the catalytic converters currently in use in underground coal mines, thereby decreasing exhaust particulate. To further reduce miners' exposure to diesel exhaust, the final rule prohibits operators from unnecessarily idling diesel-powered equipment.

Ventilation. The diesel equipment rule requires that as part of the approval process, ventilating air quantities necessary to maintain the gaseous emissions of diesel engines within existing required ambient limits be set. The ventilating air quantities are required to appear on the engine's approval plate. The rule also requires that mine operators maintain the approval plate quantity minimum airflow in areas of underground coal mines where diesel-powered equipment is operated. The engine's approval plate air quantity is also used to determine the minimum air quantity in areas where multiple units of diesel powered equipment are being operated. The minimum ventilating air quantity where multiple units of diesel powered equipment are operated on working sections and in areas where mechanized mining equipment is being installed or removed, must be the sum of 100 percent of the approval plate quantities of all of the equipment. As set forth in the preamble of the diesel equipment rule, MSHA believes that effective mine ventilation is a key component in the control of miners' exposure to gasses and particulate emissions generated by diesel equipment.

Impact of the diesel equipment rule on dpm levels in underground coal mines. The diesel equipment rule has many features which, by reducing the emission and concentration of harmful diesel emissions in underground coal mines, will indirectly reduce particulate emissions.

In developing the diesel equipment rule, however, MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines. It was understood that the agency would be taking a separate look at the health risks of dpm exposure. For example, the agency explicitly deferred discussion of whether to make operators use only equipment that complied with a specific Particulate Index.

(8) Information on How Certain States are Restricting Occupational Exposure to DPM.

As noted earlier in this part, the Federal government has long been involved in efforts to restrict diesel particulate emissions into the environment—both through ambient air quality standards, and through restrictions on diesel engine emissions. While MSHA's actions to limit the concentration of dpm in underground mines are the first effort by the Federal government to deal with the special risks faced by workers exposed to diesel exhaust on the job, several states have already taken actions in this regard with respect to underground coal mines.

This section reviews some of these actions, as they were the subject of considerable discussion and comment during this rulemaking.

Pennsylvania. As indicated in section 1, Pennsylvania essentially had a ban on the use of diesel-powered equipment in underground coal mines for many years. As noted by one commenter, diesel engines were permitted provided the request was approved by the Secretary of the Department of Environmental Protection.

In 1995, one company in the State submitted a plan for approval and started negotiations with its local union representatives. This led to statewide discussions and the adoption of a new law in the State that permits the use of diesel-powered equipment in deep coal mines under certain circumstances specified in the law (Act 182). As further noted by this commenter, the drafters of the law completed their work before the issuance of MSHA's new regulation on the safe use of diesel-powered equipment in underground coal mines. The Pennsylvania law, unlike MSHA's diesel equipment rule, specifically addresses diesel particulate. The State did not set a limit on the exposure of miners to dpm, nor did it establish a limit on the concentration of dpm in deep coal mines. Rather, it approached the issue by imposing controls that will limit dpm emissions at the source.

First, all diesel engines used in underground deep coal mines in Pennsylvania must be MSHA-approved engines with an ''exhaust emissions control and conditioning system'' that meets certain tests. (Article II-A, Section 203-A, Exhaust Emission Controls). Among these are dpm emissions from each engine no greater than ''an average concentration of 0.12 mg/m^3 diluted by fifty percent of the MSHA approval plate ventilation for that diesel engine.'' In addition, any exhaust emissions control and conditioning system must include a ''Diesel Particulate Matter (DPM) filter capable of an average of ninety-five percent or greater reduction of dpm emissions.'' It also requires the use of an oxidation catalytic converter. Thus, the Pennsylvania statute requires the use of low-emitting engines, and then the use of aftertreatment devices that significantly reduce the particulates emitted from these engines.

The Pennsylvania law also has a number of other requirements for the safe use of diesel-powered equipment in the particularly hazardous environments of underground coal mines. Many of these parallel the requirements in MSHA's diesel equipment rule. Like MSHA's requirements, they too can result in reducing miner exposure to diesel particulate—*e.g.,* regular maintenance of diesel engines by qualified personnel and equipment operator examinations. The requirements in the Pennsylvania law take into account the need to maintain the aftertreatment devices required to control diesel particulate.

While both mine operators and labor supported this approach, it remains controversial. During the hearings on this rulemaking, one commenter indicated that at the time the standards were established, it would have taken a 95% filter to reduce dpm from certain equipment to the 0.12 mg/m^3 emissions standard because 0.25 sulfur fuel was being utilized. This test reported by the commenter was completed prior to MSHA promulgating the diesel equipment rule that required the use of .05% sulfur fuel. Another commenter pointed out that as operators in the state began considering the use of newer, less polluting engines, achieving an efficiency of 95% reduction of the emissions from any such engines would become even more difficult. There was some disagreement among the commenters as to whether existing technology would permit operators to meet the 0.12 mg/m^3 emission standard in many situations. One commenter described efforts to get a small outby unit approved under Pennsylvania law. Accordingly, the industry has indicated that it would seek changes to the Pennsylvania diesel law. Commenters representing miners indicated that they were involved in these discussions.

West Virginia. Until 1997, West Virginia law banned the use of diesel-powered equipment in underground coal mines. In that year, the State created the joint labor-management West Virginia Diesel Equipment Commission (Commission) and charged it with developing regulations to permit and govern diesel engine use in underground coal mines. As explained by several commenters, the Commission, in collaboration with West Virginia University (WVU), developed a protocol for testing diesel engine exhaust controls, and the legislature appropriated more than $150,000 for WVU to test diesel exhaust controls and an array of diesel particulate filters.

There were a number of comments received by MSHA on the test protocols and results. These are discussed in part IV this preamble. One commenter noted that various manufacturers of products have been very interested in how their products compare to those of other manufacturers tested by the WVU. Another asserted that mine operators had been slowing the scheduling of tests by WVA.

Pursuant to the West Virginia law establishing the Commission, the Commission was given only a limited time to determine the applicable rules for the use of diesel engines underground, or the matter was required to be referred to an arbitrator for resolution. One commenter during the hearings noted that the Commission had not been able to reach resolution and that indeed arbitration was the next step. Other commenters described the proposal of the industry members of the Commission—0.5mg/m^3 for all equipment, as configured, before approval is granted. In this regard, the industry members of the West Virginia Commission said:

''We urge you to accelerate the finalization of * * * these proposed rules. We believe that will aid our cause, as well as the other states that currently don't use diesel.'' (*Id*)

Virginia. According to one commenter, diesel engine use in underground mining was legalized in Virginia in the mid-1980s. It was originally used on some heavy production equipment, but the haze it created was so thick it led to a drop in production. Thereafter, most diesel equipment has been used outby (805 pieces). The current state regulations consist of requiring that MSHA approved engines be used, and that the ''most up-to-date, approved, available diesel engine exhaust aftertreatment package'' be utilized. There are no distinctions between types of equipment. The commenter noted that more hearings were planned soon. Under a directive from the governor of Virginia, the state is reviewing its regulations and making recommendations for revisions to sections of its law on diesels.

Ohio. The record of this rulemaking contains little specific information on the restrictions on the underground use of diesel-powered equipment in Ohio. MSHA understands, however, that in practice it is not used. According to a communication with the Division of Mines and Reclamation of the Ohio Division of Natural Resources, this outcome stems from a law enacted on October 29, 1995, now codified as section 1567.35 of Ohio Revised Code Title 15, which imposes strict safety restrictions on the use of various fuels underground.

(9) History of this Rulemaking.

As discussed throughout this part, the Federal government has worked closely with the mining community to ascertain whether and how diesel-powered equipment might be used safely and healthfully in this industry. As the evidence began to grow that exposure to diesel exhaust might be harmful to miners, particularly in underground mines, formal agency actions were initiated to investigate this possibility and to determine what, if any, actions might be appropriate. These actions, including a number of non-regulatory initiatives taken by MSHA, are summarized here in chronological sequence.

Activities Prior to Proposed Rulemaking on DPM. In 1984, the National Institute for Occupational Safety and Health (NIOSH) established a standing Mine Health Research Advisory Committee to advise it on matters involving or related to mine health research. In turn, that standing body established the Mine Health Research Advisory Committee Diesel Subgroup to determine if:

* * * there is a scientific basis for developing a recommendation on the use of diesel equipment in underground mining operations and defining the limits of current knowledge, and recommending areas of research for NIOSH, if any, taking into account other investigators' ongoing and planned research. (49 FR 37174).

In 1985, MSHA established an Interagency Task Group with NIOSH and the former Bureau of Mines (BOM) to assess the health and safety implications of the use of diesel-powered equipment in underground coal mines.

In April 1986, in part as a result of the recommendation of the Task Group, MSHA began drafting proposed regulations on the approval and use of diesel-powered equipment in underground coal mines. Also in 1986, the Mine Health Research Advisory Committee Diesel Subgroup (which, as noted above, was created by a standing NIOSH committee) summarized the evidence available at that time as follows:

It is our opinion that although there are some data suggesting a small excess risk of adverse health effects associated with exposure to diesel exhaust, these data are not compelling enough to exclude diesels from underground mines. In cases where diesel equipment is used in mines, controls should be employed to minimize exposure to diesel exhaust.

On October 6, 1987, pursuant to Section 102(c) of the Mine Act, 30 U.S.C. 812(c), which authorizes MSHA to appoint advisory committees as he deems appropriate, the agency appointed an advisory committee ''to provide advice on the complex issues concerning the use of diesel-powered equipment in underground coal mines.'' (52 FR 37381). MSHA appointed nine members to this committee, officially known as The Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines (hereafter the MSHA Diesel Advisory Committee). As required by section 101(a)(1) of the Mine Act, MSHA provided the MSHA Diesel Advisory Committee with draft regulations on the approval and use of diesel-powered equipment in underground coal mines. The draft regulations did not include standards setting specific limitations on diesel particulate, nor had MSHA at that time determined that such standards would be promulgated.

In July 1988, the MSHA Diesel Advisory Committee completed its work with the issuance of a report entitled ''Report of the Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines.'' It also recommended that MSHA promulgate standards governing the approval and use of diesel-powered equipment in underground coal mines. The MSHA Diesel Advisory Committee recommended that MSHA promulgate standards limiting underground coal miners' exposure to diesel exhaust.

With respect to diesel particulate, the MSHA Diesel Advisory Committee recommended that MSHA ''set in motion a mechanism whereby a diesel particulate standard can be set.'' (MSHA, 1988). In this regard, the MSHA Diesel Advisory Committee determined that because of inadequacies in the data on the health effects of diesel particulate matter and inadequacies in the technology for monitoring the amount of diesel particulate matter at that time, it could not recommend that MSHA promulgate a standard specifically limiting the level of diesel particulate matter in underground coal mines (*Id.* 64–65). Instead, the MSHA Diesel Advisory Committee recommended that MSHA ask NIOSH and the former Bureau of Mines to prioritize research in the development of sampling methods and devices for diesel particulate.

The MSHA Diesel Advisory Committee also recommended that MSHA request a study on the chronic and acute effects of diesel emissions (*Id*). In addition, the MSHA Diesel Advisory Committee recommended that the control of diesel particulate ''be accomplished through a combination of measures including fuel requirements, equipment design, and in-mine controls such as the ventilation system and equipment maintenance in conjunction with undiluted exhaust measurements.'' The MSHA Diesel Advisory Committee further recommended that particulate emissions ''be evaluated in the equipment approval process and a particulate emission index reported.'' (*Id.* at 9).

In addition, the MSHA Diesel Advisory Committee recommended that ''the total respirable particulate, including diesel particulate, should not exceed the existing two milligrams per cubic meter respirable dust standard.'' (*Id.* at 9.) It should be noted that section 202(b)(2) of the Mine Act requires that coal mine operators maintain the average concentration of respirable dust at their mines at or below two milligrams per cubic meter which effectively prohibits diesel particulate matter in excess of two milligrams per cubic meter (30 U.S.C. 842(b)(2)).

As noted, the MSHA Diesel Advisory Committee issued its report in 1988. During that year, NIOSH issued a Current Intelligence Bulletin recommending that whole diesel exhaust be regarded as a potential carcinogen and controlled to the lowest feasible exposure level (NIOSH, 1988). In its bulletin, NIOSH concluded that although the excess risk of cancer in diesel exhaust exposed workers has not been quantitatively estimated, it is logical to assume that reductions in exposure to diesel exhaust in the workplace would reduce the excess risk. NIOSH stated that ''[g]iven what we currently know, there is an urgent need for efforts to be made to reduce occupational exposures to DEP [dpm] in mines.''

Consistent with the MSHA Diesel Advisory Committee's research recommendations, MSHA, in September 1988, formally requested NIOSH to perform a risk assessment for exposure to diesel particulate. (57 FR 500). MSHA also requested assistance from NIOSH and the former BOM in developing sampling and analytical methodologies for assessing exposure to diesel particulate in mining operations. (*Id.*). In part, as a result of the MSHA Diesel Advisory Committee's recommendation, MSHA also participated in studies on diesel particulate sampling methodologies and determination of underground occupational exposure to diesel particulate.

On October 4, 1989, MSHA published a Notice of Proposed Rulemaking on approval requirements, exposure monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (54 FR 40950). The proposed rule followed the MSHA Diesel Advisory Committee's recommendation that MSHA promulgate regulations requiring the approval of diesel engines.

On January 6, 1992, MSHA published an Advance Notice of Proposed Rulemaking (ANPRM) (57 FR 500). In the ANPRM, MSHA, among other things, sought comment on specific reports on diesel particulate prepared by NIOSH and the former BOM. MSHA also sought comment on reports on diesel particulate which were prepared by or in conjunction with MSHA. The ANPRM also sought comments on the health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a diesel particulate rule. The notice also identified five specific areas where the agency was particularly interested in comments, and about which it asked a number of detailed questions: (1) Exposure limits, including the basis thereof; (2) the validity of the NIOSH risk assessment model and the validity of various types of studies; (3) information about non-cancer risks, non-lung routes of entry, and the confounding effects of tobacco smoking; (4) the availability, accuracy and proper use of sampling and monitoring methods for diesel particulate; and (5) the technological and economic feasibility of various types of controls, including ventilation, diesel fuel, engine design, aftertreatment devices, and maintenance by mechanics with specialized training. The notice also solicited specific information from the mining community on ''the need for a medical surveillance or screening program and on the use of respiratory equipment.'' (57 FR 500). The comment period on the ANPRM closed on July 10, 1992.

While MSHA was completing a ''comprehensive analysis of the comments and any other information received'' in response to the ANPRM (57 FR 501), it took also several actions to encourage the mining community to begin to deal with the problems identified.

In 1995, MSHA sponsored three workshops ''to bring together in a forum format the U.S. organizations who have a stake in limiting the exposure of miners to diesel particulate (including) mine operators, labor unions, trade organizations, engine manufacturers, fuel producers, exhaust aftertreatment manufacturers, and academia.'' (McAteer, 1995). The sessions provided an overview of the literature and of diesel particulate exposures in the mining industry, state-of-the-art technologies available for reducing diesel particulate levels, presentations on engineering technologies toward that end, and identification of possible strategies whereby miners' exposure to diesel particulate matter can be limited both practically and effectively.

The first workshop was held in Beckley, West Virginia on September 12 and 13, and the other two were held on October 6, and October 12 and 13, 1995, in Mt Vernon, Illinois and Salt Lake City, Utah, respectively. A transcript was made. During a speech early the next year, the Deputy Assistant Secretary for MSHA characterized what took place at these workshops:

> The biggest debate at the workshops was whether or not diesel exhaust causes lung cancer and whether MSHA should move to regulate exposures. Despite this debate, what emerged at the workshops was a general recognition and agreement that a health problem seems to exist with the current high levels of diesel exhaust exposure in the mines. One could observe that while all the debate about the studies and the level of risk was going on, something else interesting was happening at the workshops: one by one miners, mining companies, and manufacturers began describing efforts already underway to reduce exposures. Many are actively trying to solve what they clearly recognize is a problem. Some mine operators had switched to low sulfur fuel that reduces particulate levels. Some had increased mine ventilation. One company had tried a soy-based fuel and found it lowered particulate levels. Several were instituting better maintenance techniques for equipment. Another had hired extra diesel mechanics. Several companies had purchased electronically controlled, cleaner, engines. Another was testing a prototype of a new filter system. Yet another was using disposable diesel exhaust filters. These were not all flawless attempts, nor were they all inexpensive. But one presenter after another described examples of serious efforts currently underway to reduce diesel emissions. (Hricko, 1996).

In March of 1997, MSHA issued, in draft form, a publication entitled ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox''. The draft publication was disseminated by MSHA to all underground mines known to use diesel equipment and posted on MSHA's Web site.

As explained in the publication, the Toolbox was designed to disseminate to the mining community information gained through the workshops about methods being used to reduce miner exposures to dpm. MSHA's Toolbox provided specific information about nine types of controls that can reduce dpm exposures: low emission engines; fuels; aftertreatment devices; ventilation; enclosed cabs; engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Some of these approaches reduce emissions from diesel engines; others focus on reducing miner exposure to whatever emissions are present. Quotations from workshop participants were used to illustrate when and how such controls might be helpful.

As it clearly stated in its introductory section entitled ''How to Use This Publication,'' the Toolbox was not designed as a guide to existing or pending regulations. As MSHA noted in that regard:

''While the (regulatory) requirements that will ultimately be implemented, and the schedule of implementation, are of course uncertain at this time, MSHA encourages the mining community not to wait to protect miners' health. MSHA is confident that whatever the final requirements may be, the mining community will find this Toolbox information of significant value.''

On October 25, 1996, MSHA published a final rule addressing approval, exhaust monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines (61 FR 55412). The final rule addresses, and in large part is consistent with, the specific recommendations made by the MSHA Diesel Advisory Committee for limiting underground coal miners' exposure to diesel exhaust. As noted in section 7 of this part, the diesel safety rule was implemented in steps concluding in late 1999. Aspects of this diesel safety rule had a significant impact on this rulemaking.

In the Fall of 1997, following comment, MSHA's Toolbox was finalized and disseminated to the mining community. At the same time, MSHA made available to the mining community a software modeling tool developed by the Agency to facilitate dpm control. This model enables an operator to evaluate the effect which various alternative combinations of controls would have on the dpm concentration in a particular mine—before making the investment. MSHA refers to this model as ''the Estimator.'' The Estimator is in the form of a template that can be used on standard computer spreadsheet programs. As information about a new combination of controls is entered, the results are promptly displayed.

On April 9, 1998, MSHA published a proposed rule to ''reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter'' (63 FR 17492). In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule, a dozen ''plain language'' questions and answers.

The proposed rule to limit the concentration of dpm in underground coal mines (63 FR 17578) focused on the exclusive use of aftertreatment filters on permissible and heavy duty nonpermissible equipment to limit the concentration of dpm in underground coal mines. In its Questions and Answers, however, and throughout the preamble, MSHA presented considerable information on a number of other approaches that might have merit in limiting the concentration of dpm in underground coal mines, and drew special attention to the fact that the text of the rule being proposed represented only one of the approaches on which the agency was interested in receiving comment. Training of miners in the hazards of dpm was also proposed.

The Proposed Rule to Limit DPM Concentrations in Underground Metal and Nonmetal Mines and Related Actions. On October 29, 1998 (63 FR 58104), MSHA published a proposed rule establishing new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines.

In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule, 30 ''plain language'' questions and answers.

The notice of proposed rulemaking reviewed and discussed the comments received in response to the ANPRM, including information on such control approaches as fuel type, fuel additives, and maintenance practices (63 FR 58134). For the convenience of the mining community, a copy of MSHA's Toolbox was also reprinted as an Appendix at the end of the notice of proposed rulemaking (63 FR 58223). A complete description of the Estimator, and several examples, were also presented in the preamble of the proposed rule.

MSHA proposed to adopt (63 FR 58104) a different rule to address dpm exposure in underground metal and nonmetal mines.

MSHA proposed a limit on the concentration of dpm to which underground metal and nonmetal miners would be exposed.

The proposed rule would have limited dpm concentrations in underground metal and nonmetal mines to about 200 micrograms per cubic meter of air. Operators would have been able to select whatever combination of engineering and work practice controls they wanted to keep the dpm concentration in the mine below this limit.

The concentration limit would have been implemented in two stages: an interim limit that would go into effect following 18 months of education and technical assistance by MSHA, and a final limit after 5 years. MSHA sampling would be used to determine compliance.

The proposal would also have required that all underground metal and nonmetal mines using diesel-powered equipment observe a set of ''best practices'' to reduce engine emissions—*e.g.,* to use low-sulfur fuel.

Additionally, the Agency also considered alternatives that would have led to a significantly lower-cost proposal, *e.g.,* establishing a less stringent concentration limit in underground metal and nonmetal mines, or increasing the time for mine operators to come into compliance. However, MSHA concluded at that time that such approaches would not be as protective, and that the approach proposed was both economically and technologically feasible.

MSHA also explored whether to permit the use of administrative controls (*e.g.,* rotation of personnel) and personal protective equipment (*e.g.,* respirators) to reduce the diesel particulate exposure of miners. It is generally accepted industrial hygiene practice, however, to eliminate or minimize hazards at the source before resorting to personal protective equipment. Moreover, such a practice is generally not considered acceptable in the case of carcinogens since it merely places more workers at risk. Accordingly, the proposal explicitly prohibited the use of such approaches, except in those limited cases where MSHA approves, due to technological constraints, a 2-year extension for an underground metal and nonmetal mine on the time to comply with the final concentration limit.

MSHA sought comments from the mining community on the proposed regulatory text as well as throughout the entire preamble.

In addition, the Agency specifically requested comments on the following issues:

(a) *Assessment of Risk/Benefits of the Rule.* The Agency welcomed comments on the significance of the material already in the record, and any information that could supplement the record. For example, information on the health risks associated with exposure to dpm—especially observations by trained observers or studies of acute or chronic effects of exposure to known levels of dpm or fine particles in general, information about pre-existing health conditions in individual miners or miners as a group that might affect their reactions to exposures to dpm or other fine particles; information about how dpm affects human health; information on the costs to miners, their families and their employers of the various health problems linked to dpm exposure, and the assumptions and approach to use in quantifying the benefits to be derived from this rule.

(b) *Proposed rule.* MSHA sought comments on specific alternative approaches discussed in Part V. The options discussed included: adjusting the concentration limit for dpm; adjusting the phase-in time for the concentration limit; and requiring that specific technology be used in lieu of establishing a concentration limit.

The Agency also requested comments on the composition of the diesel fleet, what controls cannot be utilized due to special conditions, and any studies of alternative controls using the computer spreadsheet described in the Appendix to Part V of the proposed rule preamble. The Agency also requested information about the availability and costs of various control technologies being developed (*e.g.,* high-efficiency ceramic filters), experience with the use of available controls, and information that would help the Agency evaluate alternative approaches for underground metal and nonmetal mines. In addition, the Agency requested comments from the underground coal sector on the implementation to date of diesel work practices (like the rule limiting idling, and the training of those who provide maintenance) to help evaluate related proposals for the underground metal and nonmetal sector. The Agency also asked for information about any unusual situations that might warrant the application of special provisions.

(c) *Compliance Guidance.* The Agency solicited comments on any topics on which initial guidance ought to be provided as well as any alternative practices which MSHA should accept for compliance before various provisions of the rule go into effect; and

(d) *Minimizing Adverse Impact of the Proposed Rule.* The Agency set forth assumptions about impacts (*e.g.,* costs, paperwork, and impact on smaller mines in particular) in some detail in the preamble and in the PREA. We sought comments on the methodology, and information on current operator equipment replacement planning cycles, tax, State requirements, or other information that might be relevant to purchasing new engines or control technology. The Agency also welcomed comments on the financial situation of the underground metal and nonmetal sector, including information that may be relevant to only certain commodities.

From this point on, the actions taken on the rulemakings in underground coal mines and underground metal and nonmetal mines began to overlap in chronology. There is considerable overlap between the coal and metal/nonmetal communities, and so their participation in these separate rulemakings was often intertwined.

In November 1998, MSHA held hearings on the proposed rule for underground coal mines in Salt Lake City, Utah and Beckley, West Virginia. In December 1998, hearings were held in Mt. Vernon, Illinois, and Birmingham, Alabama.

Hearings concerning the proposed rule for underground coal mines were well attended, including representatives from both the coal and metal and nonmetal sectors. Testimony was presented by individual miners, representatives of miners, mine operators, mining industry associations, representatives of engine and equipment manufacturers, and one individual manufacturer. Members of the mining community participating had an extensive opportunity to hear and respond to alternative views; some participated in several hearings. They also had an opportunity to exchange in direct dialogues with the members of MSHA's dpm rulemaking committee—responding to questions and asking questions of their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about the need for diesel powered equipment in this sector, the risks associated with its use, the need for regulation in this sector, alternative approaches including those on which MSHA sought comment, and the technological and economic feasibility of various alternatives.

On February 12, 1999, (64 FR 7144) MSHA published a notice in the **Federal Register** announcing: (1) The availability of three additional studies applicable to the proposals; (2) the extension of the post-hearing comment period and close of record on the proposed rule for underground coal mines for 60 additional days, until April 30, 1999; (3) the extension of the comment period on the proposed rule for metal and nonmetal mines for an additional 60 days, until April 30, 1999; and (4) an announcement that the Agency would hold public hearings on the metal and nonmetal proposal.

On March 24, 1999, (64 FR 14200) MSHA published a notice in the **Federal Register** announcing the dates, time, and location of four public hearings for the metal and nonmetal proposed rule.

The notice also announced that the close of the post-hearing comment period would be on July 26, 1999.

On April 27, 1999, (64 FR 22592) in response to requests from the public, MSHA extended the post-hearing comment period and close of record on the proposed rule for underground coal for 90 additional days, until July 26, 1999.

In May 1999, hearings on the metal and nonmetal proposed rule were held in Salt Lake City, Ut; Albuquerque, NM; St. Louis, MO and Knoxville, TN.

Hearings were well attended and testimony was presented by both labor (miners) and industry (mining associations, coal companies) and government (NIOSH). Testimony was presented by individual mining companies, mining industry associations, mining industry consultants and the National Institute of Occupational Safety and Health. The hearings were held for MSHA to obtain specific comments on the proposed rule for diesel particulate matter exposure of metal and nonmetal miners; additional information on existing and projected exposures to diesel particulate matter and to other fine particulates in various mining operations; information on the health risk associated with exposure to diesel particulate matter; information on the cost to miners, their families and their employers of the various health problems linked to diesel particulate matter; and information on additional benefits to be expected from reducing diesel particulate matter exposure.

Members of the mining community participating, had an extensive opportunity to hear and respond to alternative views; some participated in several of the hearings. They also had an opportunity to exchange in direct dialogues with members of MSHA's dpm rulemaking committee—responding to questions and asking questions of their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about potential interferences with the method used to measure dpm, the studies that MSHA used to document the risk associated with exposure to dpm, the cost estimates derived by MSHA for industry implementation, and the technology and economic feasibility of various alternatives (specifically, industry use of a tool box approach without accountability for an exposure limit).

One commenter, at the Knoxville hearing, specifically requested that the credentials and experience (related to the medical field, epidemiology, metal and nonmetal mining, mining engineering, and diesel engineering) of the hearing panelists be made a part of the public record. The commenter was informed by one of the panelists at the hearing that if this information was wanted it should be requested under the Freedom Of Information Act (FOIA). Such a request was submitted to MSHA by the commenter and appropriately responded to by the Agency.

On July 8, 1999, (64 FR 36826) MSHA published a notice in the **Federal Register** correcting technical errors in the preamble discussion on the Diesel Emission Control Estimator formula in the Appendix to Part V of the proposed rulemaking notice, and correcting Figure V–5 of the preamble. Comments on these changes were solicited. (The Estimator model was subsequently published in the literature (Haney, R.A. and Saseen, G.P., ''Estimation of diesel particulate concentrations in underground mines'', Mining Engineering, Volume 52, Number 5, April 2000)).

The rulemaking records of both rules closed on July 26, 1999, nine months after the date the proposed rule on metal and nonmetal mines was published for public notice. The post-hearing comments, like the hearings, reflected extensive participation in this effort by the full range of interests in the mining community and covered a full range of ideas and alternatives.

On June 30, 2000, the rulemaking record was reopened for 30 days in order to obtain public comment on certain additional documents which the agency determined should be placed in the rulemaking record. Those documents were the verification studies concerning NIOSH Method 5040 mentioned in section 3 of this Part. In addition, the notice provided an opportunity for comment on additional documents being placed in the rulemaking record for the related rulemaking for underground coal mines (paper filter verification investigation and recent hot gas filter test results from VERT), and an opportunity to comment on some additional documents on risk being placed in both records. In this regard, the notice reassured the mining community that any comments filed on risk in either rulemaking proceeding would be placed in both records, since the two rulemakings utilize the same risk assessment.

Part III. Risk Assessment

Introduction

MSHA has reviewed the scientific literature to evaluate the potential health effects of occupational dpm exposures at levels encountered in the mining industry. This part of the preamble presents MSHA's review of the currently available information and MSHA's assessment of health risks associated with those exposures. All material submitted during the public comment periods was considered before MSHA drew its final conclusions.

The risk assessment begins, in Section III.1, with a discussion of dpm exposure levels observed by MSHA in the mining industry. This is followed by a review, in Section III.2, of information available to MSHA on health effects that have been studied in association with dpm exposure. Finally, in Section III.3 entitled ''Characterization of Risk,'' the Agency considers three questions that must be addressed for rulemaking under the Mine Act and relates the available information about risks of dpm exposure at current levels to the regulatory requirements.

A risk assessment must be technical enough to present the evidence and describe the main controversies surrounding it. At the same time, an overly technical presentation could cause stakeholders to lose sight of the main points. MSHA is guided by the first principle the National Research Council established for risk characterization, that the approach be:

> [a] decision driven activity, directed toward informing choices and solving problems * * * Oversimplifying the science or skewing the results through selectivity can lead to the inappropriate use of scientific information in risk management decisions, but providing full information, if it does not address key concerns of the intended audience, can undermine that audience's trust in the risk analysis.

Although the final rule covers only one sector, this portion of the preamble was intended to enable MSHA and other interested parties to assess risks throughout the coal and M/NM mining industries. Accordingly, the risk assessment includes information pertaining to all sectors of the mining industry. All public comments on the exposures of miners and the health effects of dpm exposure—whether submitted specifically for the coal rulemaking or for the metal/nonmetal rulemaking—were incorporated into the record for each rulemaking and have been considered for this assessment.

MSHA had an earlier version of this risk assessment independently peer reviewed. The risk assessment as proposed incorporated revisions made in accordance with the reviewers' recommendations, and the final version presented here contains clarifications and other responses to public comments. With regard to the risk assessment as published in the proposed preamble, the reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Some commenters generally agreed with this opinion. Dr. James Weeks, representing the UMWA, found the proposed risk assessment to be ''balanced, thorough, and systematic.'' Dr. Paul Schulte, representing NIOSH, stated that ''MSHA has prepared a thorough review of the health effects associated with exposure to high concentrations of dpm, and NIOSH concurs with the published [proposed] characterization of risks associated with these exposures.'' Dr. Michael Silverstein, representing the Washington State Dept. of Labor and Industries, found MSHA's ''regulatory logic * * * thoroughly persuasive.'' He commented that ''the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health * * * the evidence * * * is particularly strong and certainly provides a sufficient basis for regulatory action.''

Many commenters, however, vigorously criticized various aspects of the proposed assessment and some of the scientific studies on which it was based. MSHA's final assessment, published here, was modified to respond to all of these criticisms. Also, in response to commenters' suggestions, this assessment incorporates some research studies and literature reviews not covered or inadequately discussed in the previous version.

Some commenters expressed the opinion that the proposed risk assessment should have been peer-reviewed by a group representing government, labor, industry, and independent scientists. Since the rulemaking process included a pre-hearing comment period, eight public hearings (four for coal and four for M/NM), and two post-hearing comment periods, these constituencies had ample opportunity to review and comment upon MSHA's proposed risk assessment. The length of the comment period for the Coal Dpm proposal was 15 months. The length of the comment period for the Metal/Nonmetal Dpm proposal was nine months.

1. Exposures of U.S. Miners

Information about U.S. miner exposures comes from published studies and from additional mine investigations conducted by MSHA since 1993.[1] Previously published studies of exposures to dpm among U.S. miners are: Watts (1989, 1992), Cantrell (1992, 1993), Haney (1992), and Tomb and Haney (1995). MSHA has also conducted investigations subsequent to the period covered in Tomb and Haney (1995), and the previously unpublished data through mid-1998 are included here. Both the published and unpublished studies were placed in the record with the proposal, giving MSHA's stakeholders the opportunity to analyze and comment on all of the exposure data considered.

MSHA's field studies involved measuring dpm concentrations at a total of 50 mines: 27 underground metal and nonmetal (M/NM) mines, 12 underground coal mines, and 11 surface mining operations (both coal and M/NM). At all surface mines and all underground coal mines, dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. With few exceptions, dpm measurements at underground M/NM mines were made using the Respirable Combustible Dust (RCD) method (with no impactor). At two of the underground M/NM mines, measurements were made using the total carbon (TC) method, and at one, RCD measurements were made in one year and TC measurements in another. Measurements at the two remaining underground M/NM mines were made using the size-selective method, as in

[1] MSHA has only limited information about miner exposures in other countries. Based on 223 personal and area samples, average exposures at 21 Canadian noncoal mines were reported to range from 170 to 1300 µg/m^3 (respirable combustible dust), with maximum measurements ranging from 1020 to 3100 µg/m^3 (Gangel and Dainty, 1993). Among 622 full shift measurements collected since 1989 in German underground noncoal mines, 91 (15%) exceeded 400 µg/m^3 (total carbon) (Dahmann et al., 1996). As explained elsewhere in this preamble, 400 µg/m^3 (total carbon) corresponds to approximately 500 µg/m^3 dpm.

coal and surface mines.[2] Weighing errors inherent in the gravimetric analysis required for both size-selective and RCD methods become statistically insignificant at the relatively high dpm concentrations observed.

According to MSHA's experience, the dpm samples reflect exposures typical of mines known to use diesel equipment for face haulage in the U.S. However, they do not constitute a random sample of mines, and care was taken in the proposed risk assessment not to characterize results as necessarily representing conditions in all mines. Several commenters objected to MSHA's use of these exposure measurements in making comparisons to exposures reported in other industries and, for M/NM, in estimating the proposed rule's impact. These objections are addressed in Sections III.1.d and III.3.b.ii(3)(c) below. Comments related to the measurement methods used in underground coal and M/NM mines are addressed, respectively, in Sections III.1.b and III.1.c.

Each underground study typically included personal dpm exposure measurements for approximately five production workers. Also, area samples were collected in return airways of underground mines to determine diesel particulate emission rates.[3] Operational information such as the amount and type of equipment, airflow rates, fuel, and maintenance was also recorded. Mines were selected to obtain a wide range of diesel equipment usage and mining methods. Mines with greater than 175 horsepower and less than 175 horsepower production equipment were sampled. Single and multiple level mines were sampled. Mine level heights ranged from eight to one-hundred feet. In general, MSHA's studies focused on face production areas of mines, where the highest concentrations of dpm could be expected; but, since some miners do not spend their time in face areas, samples were collected in other areas as well, to get a more complete picture of miner exposure. Because of potential interferences from tobacco smoke in underground M/NM mines, samples were not collected on or near smokers.

Table III–1 summarizes key results from MSHA's studies. The higher concentrations in underground mines were typically found in the haulageways and face areas where numerous pieces of equipment were operating, or where airflow was low relative to the amount of equipment operating. In production areas and haulageways of underground mines where diesel powered equipment was used, the mean dpm concentration observed was 644 $\mu g/m^3$ for coal and 808 $\mu g/m^3$ for M/NM. In travelways of underground mines where diesel powered equipment was used, the mean dpm concentration (based on 112 area samples not included in Table III–1) was 517 $\mu g/m^3$ for M/NM and 103 $\mu g/m^3$ for coal. In surface mines, the higher concentrations were generally associated with truck drivers and front-end loader operators. The mean dpm concentration observed was less than 200 $\mu g/m^3$ at all eleven of the surface mines in which measurements were made. More information about the dpm concentrations observed in each sector is presented in the material that follows.

TABLE III–1.—FULL-SHIFT DIESEL PARTICULATE MATTER CONCENTRATIONS OBSERVED IN PRODUCTION AREAS AND HAULAGEWAYS OF 50 DIESELIZED U.S. MINES

Mine type	Number of mines	Number of samples	Mean exposure ($\mu g/m^3$)	Standard error of mean ($\mu g/m^3$)	Exposure range ($\mu g/m^3$)
Surface	11	45	88	11	9–380
Underground coal	12	226	644	41	0–3,650
Underground metal and nonmetal	27	355	808	39	10–5,570

Note: Intake and return area samples are excluded.

a. Underground Coal Mines

Approximately 145 out of the 910 existing underground coal mines currently utilize diesel powered equipment. Of these 145 mines, 32 mines currently use diesel equipment for face coal haulage. The remaining mines use diesel equipment for transportation, materials handling and other support operations. MSHA focused its efforts in measuring dpm concentrations in coal mines on mines that use diesel powered equipment for face coal haulage. Twelve mines using diesel-powered face haulage were sampled. Mines with diesel powered face haulage were selected because the face is an area with a high concentration of vehicles operating at a heavy duty cycle at the furthest end of the mine's ventilation system.

Diesel particulate levels in underground mines depend on: (1) The amount, size, and workload of diesel equipment; (2) the rate of ventilation; and, (3) the effectiveness of whatever diesel particulate control technology may be in place. In the dieselized mines studied by MSHA, the sections used either two or three diesel coal haulage vehicles. In eastern mines, the haulage vehicles were equipped with a nominal 100 horsepower engine. In western mines, the haulage vehicles were equipped with a nominal 150 horsepower engine. Ventilation rates ranged from the approval plate requirement, based on the 100–75–50 percent rule (Holtz, 1960), to ten times the approval plate requirement. In most cases, the section airflow was approximately twice the approval plate requirement. Other control technology included aftertreatment filters and fuel. Two types of aftertreatment filters were used. These filters included a disposable diesel emission filter (DDEF) and a Wire Mesh Filter (WMF). The DDEF is a commercially available product; the WMF was developed by and only used at one mine. Both low sulfur and high sulfur fuels were used.

Figure III–1 displays the range of exposure measurements obtained by MSHA in the field studies it conducted in underground coal mines. A study normally consisted of collecting samples on the continuous miner operator and coal haulage vehicle

[2] The various methods of measuring dpm are explained in section 3 of Part II of the preamble to the proposed rule. This explanation, along with additional information on these methods, is also provided in section 3 of Part II of the preamble to the final M/NM rule.

[3] Since area samples in return airways do not necessarily represent locations where miners normally work or travel, they were excluded from the present analysis. A number of area samples were included, however, as described in Sections III.1.b and III.1.c. The included area samples were all taken in production areas and haulageways.

operators for two to three shifts, along with area samples in the haulageways. A total of 142 personal samples and 84 area samples were collected, excluding any area samples taken in intake or return airways.

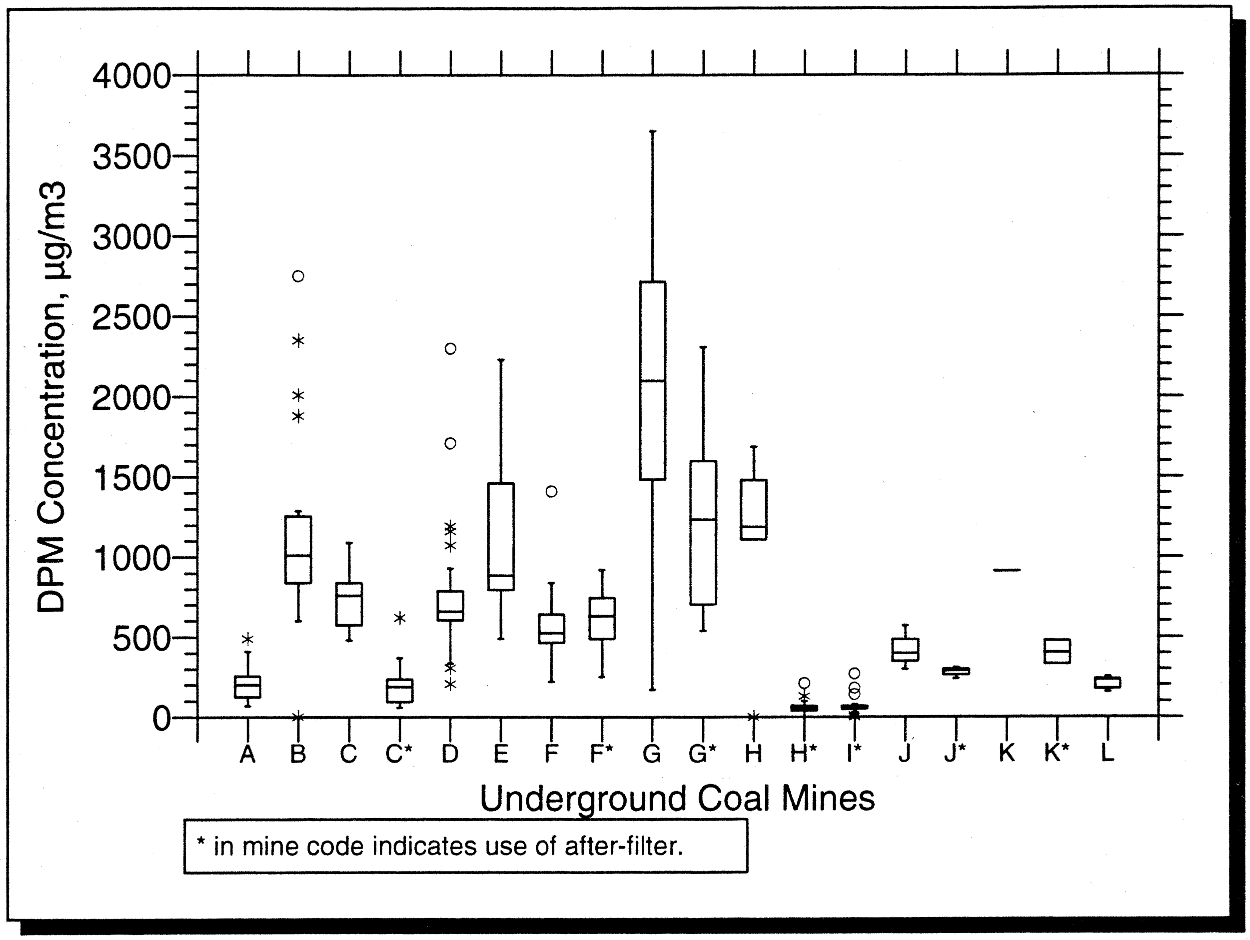

Figure 1 Box plots (Tukey, 1977) for dpm concentrations observed at 12 underground coal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor.

As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[4] A total of 19 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. Although the three highest of these were from area samples, nine of the 19 measurements exceeding 1500 µg/m³ were from personal samples.

In six mines, measurements were taken both with and without use of disposable after-treatment filters, so that a total of eighteen studies, carried out in twelve mines, are displayed. Without use of after-treatment filters, average observed dpm concentrations exceeded 500 µg/m³ in eight of the twelve mines and exceeded 1000 µg/m³ in four.[5] At five of the twelve mines, all dpm measurements were 300 µg/m³ or greater in the absence of after-treatment filters.

The highest dpm concentrations observed at coal mines were collected at Mine "G." Eight of these samples were collected during employment of WMFs, and eight were collected while filters were not being employed. Without filters, the mean dpm concentration observed at Mine "G" was 2052 µg/m³ (median = 2100 µg/m³). With employment of WMFs, the mean

[4] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 142 personal samples, the mean dpm concentration measurement was 608 µg/m³, with a standard error of 42.5 µg/m³. For the 84 area samples, the mean was 705 µg/m³, with a standard error of 82.1 µg/m³. The significance level (p-value) of a t-test comparing these means is 0.29 using a separate-variance test or 0.25 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at any confidence level greater than 75%.

Here, and in other sections of this risk assessment, MSHA has employed standard statistical methods described in textbooks on elementary statistical inference.

[5] In coal mine E, the average as expressed by the mean exceeded 1000 µg/m³, but the median did not.

dropped to 1241 µg/m³ (median = 1235 µg/m³).

Filters were employed during three of the four studies showing median dpm concentration at or below 200 µg/m³. After adjusting for outby sources of dpm, exposures were found to be reduced by up to 95 percent in mines using the DDEF and by approximately 50 percent in the mine using the WMF.

The higher dpm concentrations observed at the mine using the WMF (Mine ''G*'') are attributable partly to the lower section airflow. The only study without filters showing a median concentration at or below 200 µg/m³ was conducted in a mine (Mine ''A'') which had section airflow approximately ten times the nameplate requirement. The section airflow at the mine using the WMF was approximately the nameplate requirement.

Some commenters [*e.g.,* WV Coal Assoc and Energy West] objected to MSHA's presentation of underground coal mine exposures based on measurements made using the size-selective method (gravimetric determination of the amount of submicrometer dust collected with an impactor). These commenters argued that the data were ''* * * collected with emissions monitoring devices discredited by MSHA itself in the preamble * * *'' and that these measurements do not reliably ''* * * distinguish it [dpm] from other particles in coal mine dust, at the critical upper end range of submicron particles.''

MSHA did not ''discredit'' use of the size-selective method for all purposes. As discussed elsewhere in this preamble, the size-selective method of measuring dpm was designed by the former BOM specifically for use in coal mines, and the size distribution of coal mine dust was taken into account in its development. Despite the recognized interference from a small fraction of coal mine dust particles, MSHA considers gravimetric size-selective measurements to be reasonably accurate in measuring dpm concentrations greater than 200 µg/m³, based on a full-shift sample, when coal mine dust concentrations are not excessive (i.e., not greater than 2.0 mg/m³). Interference from submicrometer coal mine dust is counter-balanced, to some extent, by the fraction of larger size, uncaptured dpm. Coal mine dust concentrations were not excessive when MSHA collected its size-selective samples. Therefore, even if as much as 10 percent of the coal mine dust were submicrometer, this fraction would not have contributed significantly to the high concentrations observed at the sampled mines.

At lower concentrations, or shorter sampling times, random variability in the gravimetric determination of weight gain becomes significant, compared to the weight of dust accumulated on the filter. For this reason, MSHA has rejected the use of the gravimetric size-selective method for enforcement purposes.[6] This does not mean, however, that MSHA has ''discredited'' this method for other purposes, including detection of very high dpm concentrations at coal mines (*i.e.*, greater than 500 µg/m³) and estimation of average dpm concentrations, based on multiple samples, when coal mine dust concentrations are not excessive. On the contrary, MSHA regards the gravimetric size-selective method as a useful tool for detecting and monitoring very high dpm concentrations and for estimating average exposures.

b. Underground Metal and Nonmetal Mines

Currently there are approximately 265 underground M/NM mines in the United States. Nearly all of these mines utilize diesel powered equipment, and 27 of those doing so were sampled by MSHA for dpm.[7] The M/NM studies typically included measurements of dpm exposure for dieselized production equipment operators (such as truck drivers, roof bolters, haulage vehicles) on two to three shifts. A number of area samples were also collected. None of the M/NM mines studied were using diesel particulate afterfilters.

Figure III–2 displays the range of dpm concentrations measured by MSHA in the 27 underground M/NM mines studied. A total of 275 personal samples and 80 area samples were collected, excluding intake and return area samples. Personal exposures observed ranged from less than 100 µg/m³ to more than 3500 µg/m³. Exposure measurements based on area samples ranged from less than 100 µg/m³ to more than 3000 µg/m³. With the exception of Mine ''V'', personal exposures were for face workers. Mine ''V'' did not use dieselized face equipment.

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[6] MSHA has concluded that random weighing variability would make it impractical to use the size-selective method to enforce compliance with any dpm concentration limit less than about 300 µg/m³. MSHA believes that, at such levels, single-sample noncompliance determinations based on the size-selective method could not be made at a sufficiently high confidence level.

[7] The proposal discussed data from 25 underground M/NM mines. Studies at two additional mines, carried out too late to be included in the proposal, were placed into the public record along with the earlier studies. During the proceedings, MSHA provided copies of all of these studies to stakeholders requesting them.

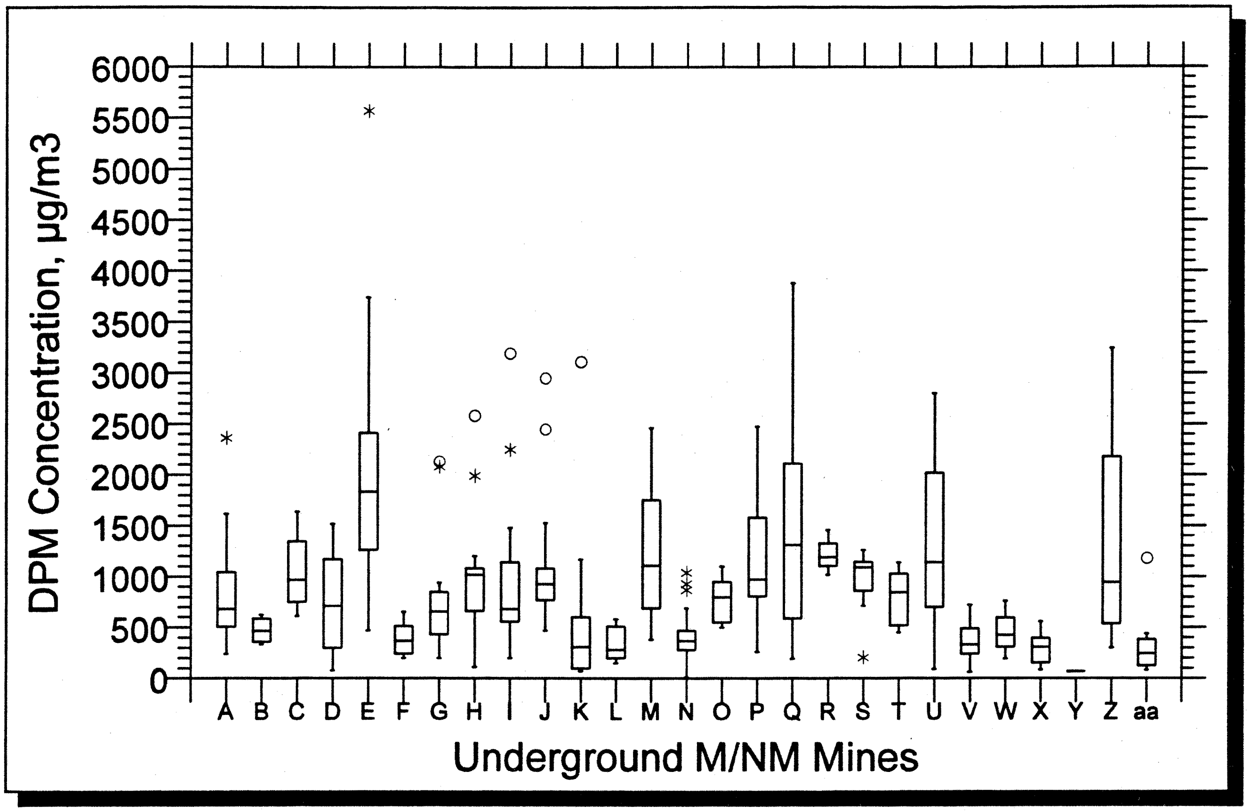

Figure 2 Box plots (Tukey, 1977) for dpm concentrations observed at 27 underground metal and nonmetal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at same mine. Measurements at Mine "T" and on one visit to mine "D" were made using the size-selective method, based on gravimetric determinationof the amount of submicrometer dust collected with an impactor. Measurements on another visit to mine "D" and at Mines "Z" and "aa" were made using TC method. All other measurements were made using RCD method. Because of potential interferences from cigarette smoke, samples were not collected on or near smokers.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[8] A total of 45 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. The three highest of these, all exceeding 3500 µg/m³, were from personal samples. Of the 45 measurements exceeding 1500 µg/m³, 30 were from personal samples and 15 were from area samples.

Average observed dpm concentrations exceeded 500 µg/m³ in 18 of the 27 underground M/NM mines and exceeded 1000 µg/m³ in 12.[9] At eight of the 27 mines, all dpm measurements exceeded 300 µg/m³. The highest dpm concentrations observed at M/NM mines were collected at Mine ''E''. Based on 16 samples, the mean dpm concentration observed at Mine ''E'' was 2008 µg/m³ (median = 1835 µg/m³). Twenty-five percent of the dpm measurements at this mine exceeded 2400 µg/m³. All four of these were based on personal samples.

As with underground coal mines, dpm levels in underground M/NM mines are related to the amount and size of equipment, to the ventilation rate, and to the effectiveness of the diesel particulate control technology employed. In the dieselized M/NM mines studied by MSHA, front-end-loaders were used either to load ore onto trucks or to haul and load ore onto belts. Additional pieces of diesel powered support equipment, such as bolters and mantrips, were also used at the mines. The typical piece of production equipment was rated at 150 to 350 horsepower. Ventilation rates in the M/NM mines studied mostly ranged from 100 to 200 cfm per horsepower of equipment. In only a few of the mines inventoried did ventilation exceed 200 cfm/hp. For single-level mines, working areas were ventilated in series (*i.e.,* the exhaust air from one area became the intake for the next working area). For multi-level mines, each level typically had a separate fresh air supply. One or two working areas could be on a level. Control technology used to reduce diesel particulate emissions in mines inventoried included oxidation catalytic converters and engine maintenance programs. Both low sulfur and high sulfur fuel were used; some mines used aviation grade low sulfur fuel.

Some commenters argued that, because of the limited number of underground M/NM mines sampled by MSHA, ''* * * results of MSHA's admittedly non-random sample cannot be extrapolated to other mines.'' [MARG] More specifically, IMC Global claimed that since only 25 [now 27] of about 260 underground M/NM mines were sampled,[10] then ''if the * * * measurements are correct, this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector and then only for certain unlisted commodities.''[11] IMC Global went on to suggest that MSHA should ''perform sufficient additional exposure monitoring * * * to show that the diesel particulate exposures are representative of the entire industry before promulgating regulations that will be applicable to the entire industry.''

As mentioned earlier, MSHA acknowledges that the mines for which dpm measurements are available do not comprise a statistically random sample of all underground M/NM mines. MSHA also acknowledges that the results obtained for these mines cannot be extrapolated in a statistically rigorous way to the entire population of underground M/NM mines. According to MSHA's experience, however, the selected mines (and sampling locations within those mines) represent typical diesel equipment use condition at underground M/NM. MSHA believes that results at these mines, as depicted in Figure III–2, in fact fairly reflect the broad range of diesel equipment used by the industry, regardless of type of M/NM mine. Based on its extensive experience with underground mines, MSHA believes that this body of data better represents those diverse diesel equipment use conditions, with respect to dpm exposures, than any other body of data currently available.

MSHA strongly disagrees with IMC Global's contention that, ''* * * this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector.'' IMC Global apparently drew this conclusion from the fact that MSHA sampled approximately ten percent of all underground M/NM mines. This line of argument, however, depends on an unwarranted and highly unrealistic assumption: namely, that all of the underground M/NM mines not included in the sampled group of 25 experience essentially no ''potential [dpm] exposure problems.'' MSHA certainly did not go out and, by chance or design, pick for sampling just exactly those mines experiencing the highest dpm concentrations. IMC Global's argument fails to recognize that the sampled mines could be fairly representative without being randomly chosen.

MSHA also disagrees with the premise that 27 [or 25 as in the proposal] is an inherently insufficient number of mines to sample for the purpose of identifying an industry-wide dpm exposure problem that would justify regulation. The between-mine standard deviation of the 27 mean concentrations observed within mines was 450 µg/m³. Therefore, the standard error of the estimated grand mean, based on the variability observed between mines, was $450/\sqrt{27} = 87$ µg/m³.[12] MSHA considers this degree of uncertainty to be acceptable, given that the overall mean concentration observed exceeded 800 µg/m³.

Several commenters questioned MSHA's use of the RCD and size-selective methods for measuring dpm exposures at underground M/NM mines. IMC Global indicated that MSHA's RCD measurements might systematically inflate the dpm concentrations presented in this section, because ''* * * estimates for the non-diesel particulate component of RCD actually vary between 10% to 50%, *averaging 33%.*''

MSHA considers the size-selective, gravimetric method capable of providing reasonably accurate

[8] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 275 personal samples, the mean dpm concentration measurement was 770 µg/m³, with a standard error of 42.8 µg/m³. For the 80 area samples, the mean was 939 µg/m³, with a standard error of 86.6 µg/m³. The significance level (p-value) of a t-test comparing these means is 0.08 using a separate-variance test or 0.07 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at a 95% confidence level.

[9] At M/NM mines C, I, J, P, and Z the average as expressed by the mean exceeded 1000 µg/m³ but the median did not. At M/NM mines H and S, the median exceeded 1000 µg/m³ but the mean did not. At M/NM mine K, the mean exceeded 500 µg/m³, but the median did not.

[10] Three underground M/NM mine surveys, carried out too late to be included in the discussion, were placed into the public record and provided to interested stakeholders. These surveys contained data from two additional underground M/NM mines (''Z'' and ''aa'') and additional data for a mine (''d'') that had previously been surveyed. The risk assessment has now been updated to include these data, representing a total of 27 underground M/NM mines.

[11] A breakdown by commodity is given at the end of this subsection.

[12] This quantity, 87 µg/m³, differs from the standard error of the mean of individual measurements for underground M/NM mines, presented in Table III–1. The tabled value is based on 355 measurements whose standard deviation is 727µg/m³. Therefore, the standard error of the mean of all individual measurements is $727/\sqrt{355} = 39$ µg/m³, as shown in the table. Similarly, the mean of all individual measurements (listed in Table III–1 as 808 µg/m³) differs from the grand mean of individual mean concentrations observed within mines, which is 838 µg/m³.

measurements when the dpm concentration is greater than 200 $\mu g/m^3$, interferences are adequately limited, and the measurement is based on a full-shift sample. Relatively few M/NM measurements were made using this method, and none at the mines showing the highest dpm concentrations. No evidence was presented that the size distribution of coal mine dust (for which the impactor was specifically developed) differs from that of other mineral dusts in a way that significantly alters the impactor's performance. Similarly, MSHA considers the RCD method, when properly applied, to be capable of providing reasonably accurate dpm measurements at concentrations greater than 200 $\mu g/m^3$. As with the size selective method, however, random weighing errors can significantly reduce the precision of even full-shift RCD measurements at lower dpm concentrations. For this reason, in order to maintain a sufficiently high confidence level for its noncompliance determinations, MSHA will not use the RCD method for enforcement purposes. This does not mean, however, that MSHA has ''discredited'' the RCD measurements for all other purposes, including detection of very high dpm concentrations (i.e., greater than 300 $\mu g/m^3$) and estimation of average concentrations based on multiple samples. On the contrary, MSHA considers the RCD method to be a useful tool for detecting and monitoring very high dpm concentrations in appropriate environments and for estimating average exposures when those exposures are excessive.

MSHA did not employ an impactor in its RCD measurements, and it is true that some of these measurements may have been subject to interference from lubrication oil mists. However, MSHA believes that the high estimates sometimes made of the non-dpm component of RCD (cited by IMC Global) do not apply to the RCD measurements depicted in Figure III–2. MSHA has three reasons for believing these RCD measurements consisted almost entirely of dpm:

(1) MSHA took special care to sample only environments where interferences would not be significant. No samples were taken near pneumatic drills or smoking miners.

(2) There was no interference from carbonates. The RCD analysis was performed at 500° C, and carbonates are not released below 1000° C. (Gangel and Dainty, 1993)

(3) Although high sulphur fuel was used in some mines, thereby adding sulfates to the RCD measurement, these sulfates are considered part of the dpm, as explained in section 2 of Part II of this preamble. Sulfates should not be regarded as an interference in RCD measurements of dpm.

Commenters presented no evidence that there were substantial interferences in MSHA's RCD measurements, and, as stated above, MSHA was careful to avoid them. Therefore, MSHA considers it reasonable, in the context of this risk assessment, to assume that all of the RCD was in fact dpm. Moreover, in the majority of underground M/NM mines sampled, even if the RCD measurements were reduced by ⅓, the mine's average would still be excessive: it would still exceed the maximum exposure level reported for non-mining occupations presented in section III.1.d.

The breakdown, as suggested by IMC Global, of sampled underground M/NM mines by commodity is as follows:

Commodity	Number of mines
Copper	2
Gold	1
Lead/Zinc	6
Limestone	6
Potash	2
Salt	6
Trona (soda ash)	2
Other Nonmetal	2
Total	27

c. Surface Mines

Currently, there are approximately 12,620 surface mining operations in the United States. The total consists of approximately 1,550 coal mines and 11,070 M/NM mines. Virtually all of these mines utilize diesel powered equipment.

MSHA conducted dpm studies at eleven surface mining operations: eight coal mines and three M/NM mines. MSHA deliberately directed its surface sampling efforts toward occupations likely to experience high dpm concentrations. To help select such occupations, MSHA first made a visual examination (based on blackness of the filter) of surface mine respirable dust samples collected during a November 1994 study of surface coal mines. This preliminary screening of samples indicated that relatively high surface mine dpm concentrations are typically associated with front-end-loader operators and haulage-truck operators; accordingly, sampling focused on these operations. A total of 45 samples was collected.

Figure III–3 displays the range of dpm concentrations measured at the eleven surface mines. The average dpm concentration observed was less than 200 $\mu g/m^3$ at all mines sampled. The maximum dpm concentration observed was less than or equal to 200 $\mu g/m^3$ in 8 of the 11 mines (73%). The surface mine studies suggest that even when sampling is performed at the areas of surface mines believed most likely to have high exposures, dpm concentrations are generally likely to be less than 200 $\mu g/m^3$.

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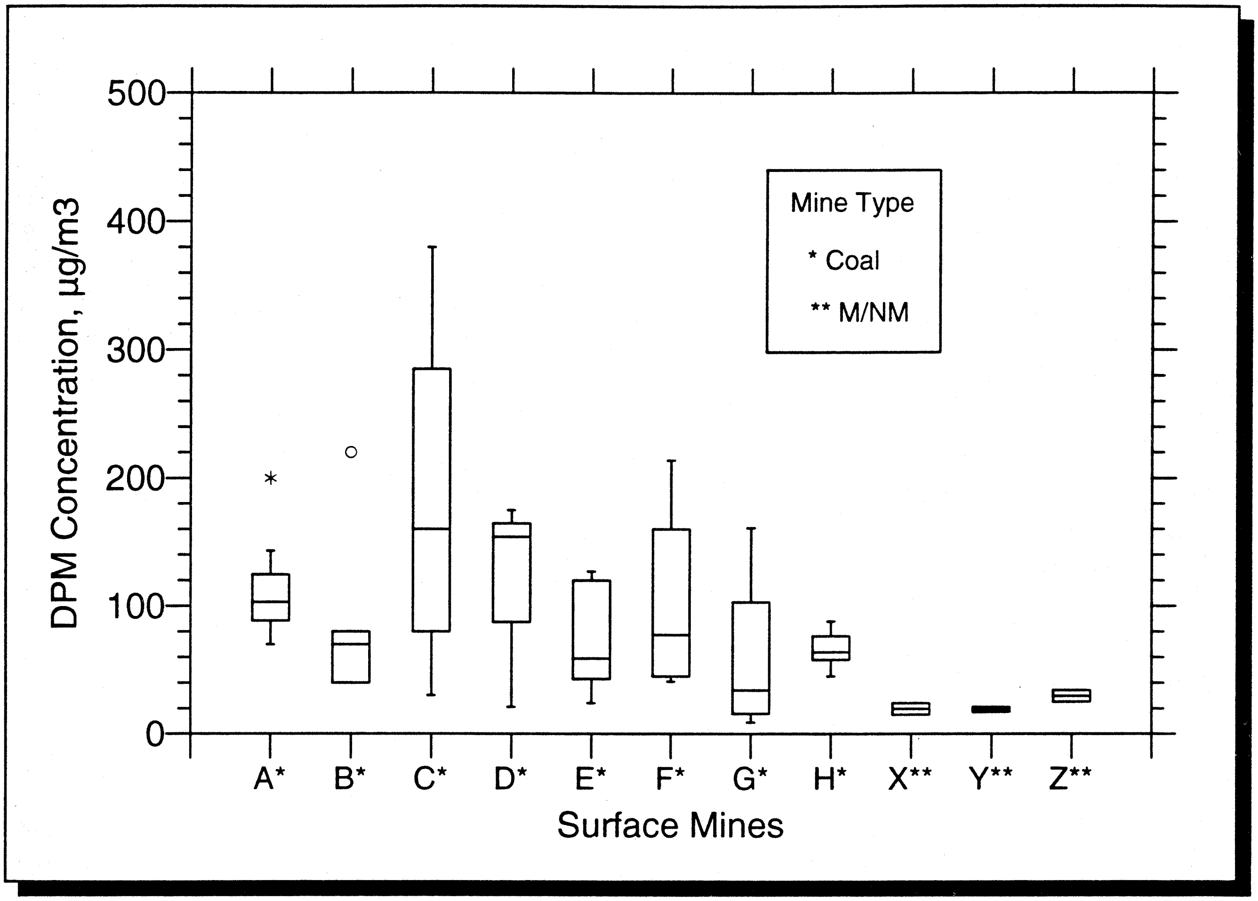

Figure 3 Box plots (Tukey, 1977) for dpm concentrations observed at 11 surface mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. Because of potential interferences from cigarette smoke, samples were not collected on smokeres who worked inside enclosures.

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d. Miner Exposures Compared to Exposures of Other Groups

Occupational exposure to diesel particulate primarily originates from industrial operations employing equipment powered with diesel engines. Diesel engines are used to power ships, locomotives, heavy duty trucks, heavy machinery, as well as a small number of light-duty passenger cars and trucks. NIOSH has estimated that approximately 1.35 million workers are occupationally exposed to the combustion products of diesel fuel in approximately 80,000 workplaces in the United States. (NIOSH 1988) Workers who are likely to be exposed to diesel emissions include: mine workers; bridge and tunnel workers; railroad workers; loading dock workers; truck drivers; fork-lift drivers; farm workers; and, auto, truck, and bus maintenance garage workers (NIOSH, 1988). Besides miners, groups for which occupational exposures have been reported and health effects have been studied include loading dock workers, truck drivers, and railroad workers.

As estimated by the reported geometric mean,[13] the median site-specific occupational exposures for loading dock workers operating or otherwise exposed to unfiltered diesel fork lift trucks ranged from 23 to 55 μg/m³, as measured by submicrometer elemental carbon (EC) (NIOSH, 1990). Reported geometric mean concentrations of submicrometer EC ranged from 2.0 to 7.0 μg/m³ for truck drivers and from 4.8 to 28 μg/m³ for truck mechanics, depending on weather conditions (Zaebst et al., 1991).

Because these exposure averages, unlike those for railroad workers and miners, were reported in terms of EC, it is necessary, for purposes of comparison, to convert them to estimates of total dpm. Watts (1995) states that ''elemental carbon generally accounts for about 40% to 60% of diesel particulate mass.'' Therefore, in earlier versions of this risk assessment, a 2.0 conversion factor was assumed for dock workers, truck drivers, and truck mechanics, based on the midpoint of the 40–60% range proposed by Watts.

Some commenters objected to MSHA's use of this conversion factor. IMC Global, for example, asserted that Watts' ''* * * 40 to 60% relationship between elemental carbon and diesel particulate mass * * * applies only to underground coal mines where diesel haulage equipment is used.'' IMC Global, and other commenters, also objected to MSHA's use of a single conversion factor for ''* * * different types of diesel engines under different duty cycles with different fuels and different types of emission control devices (if any) subjected to varying degrees of maintenance.''

MSHA's quotation from Watts (1995) was taken from the ''Summary'' section of his paper. That paper covers a variety of occupational environments, and the summary makes no mention of coal mines. The sentence immediately preceding the quoted passage refers to the ''occupational environment'' in general, and there is no indication that Watts meant to restrict the 40- to 60-percent range to any specific environment. It seems clear that the 40- to 60-percent range refers to average values across a spectrum of occupational environments.

IMC Global mistakenly attributed to MSHA ''the blanket statement'' that the same ratio of elemental carbon to dpm applies ''for all diesel engines in different industries for all patterns of use.'' MSHA made no such statement. On the contrary, MSHA agrees with Watts (and IMC Global) that ''the percentage of elemental carbon in total diesel particulate matter fluctuates'' depending on ''engine type, duty cycle, fuel, lube oil consumption, state of engine maintenance, and the presence or absence of an emission control device.'' (Watts, op cit.) Indeed, MSHA acknowledges that, because of these factors, the percentage on a particular day in a particular environment may frequently fall outside the stated range. But MSHA is not applying a single conversion factor to individual elemental carbon measurements and claiming knowledge of the total dpm corresponding to each separate measurement. Instead, MSHA is applying an average conversion factor to an average of measurements in order to derive an estimate of an average dpm exposure. Averages are always less widely dispersed than individual values.

[13] Median concentrations were not reported. The geometric mean provides a smoothed estimate of the median.

Still, MSHA agrees with IMC Global that better estimates of dpm exposure levels are attainable by applying conversion factors more specifically related to the separate categories within the trucking industry: dock workers, truck drivers, and truck mechanics. Based on a total of 63 field measurements, the mean ratios (in percent) of EC to total carbon (TC) reported for these three categories were 47.3, 36.6, and 34.2, respectively (Zaebst et al., 1991).[14] As explained elsewhere in this preamble, TC amounts to approximately 80 percent, by weight, of total dpm. Therefore, each of these ratios must be multiplied by 0.8 in order to estimate the corresponding percentage of EC in dpm.

It follows that the median mass concentration of dpm can be estimated as 2.64 (i.e., 1/(0.473×0.8)) times the geometric mean EC reported for dock workers, 3.42 times the geometric mean EC for truck drivers, and 3.65 times the geometric mean EC for truck mechanics. Applying the 2.64 conversion factor to the range of geometric mean EC concentrations reported for dock workers (i.e, 23 to 55 μg/m^3) results in an estimated range of 61 to 145 μg/m^3 in median dpm concentrations at various docks. Similarly, the estimated range of median dpm concentrations is calculated to be 6.8 to 24 μg/m^3 for truck drivers and 18 to 102 μg/m^3 for truck mechanics. It should be noted that MSHA is using conversion factors only for those occupational groups whose geometric mean exposures have been reported in terms of EC measurements.

Average exposures of railroad workers to dpm were estimated by Woskie et al. (1988) and Schenker et al. (1990). As measured by total respirable particulate matter other than cigarette smoke, Woskie et al. reported geometric mean concentrations for various occupational categories of exposed railroad workers ranging from 49 to 191 μg/m^3.

For comparison with the exposures reported for these other industries, median dpm exposures measured within sampled mines were calculated directly from the data described in subsections a, b, and c above. The median within each mine is shown as the horizontal ''belt'' plotted for the mine in Figures III–1, III–2, and III–3.

Figure III–4 compares the range of median dpm concentrations observed for mine workers within different mines to a range of dpm exposure levels estimated for urban ambient air and to the ranges of median dpm concentrations estimated for loading dock workers operating or otherwise exposed to diesel fork lift trucks, truck drivers, truck mechanics, and railroad workers. The range for ambient air, 1 to 10 μg/m^3, was obtained from Cass and Gray (1995). For dock workers, truck drivers, truck mechanics, and railroad workers, the estimated ranges of median dpm exposures are, respectively: 61 to 145 μg/m^3, 6.8 to 24 μg/m^3, 18 to 102 μg/m^3 and 49 to 191 μg/m^3. The range of median dpm concentrations observed at different underground coal mines is 55 to 2100 μg/m^3, with filters employed at mines showing the lower concentrations.[15] For underground M/NM mines, the corresponding range is 68 to 1835 μg/m^3, and for surface mines it is 19 to 160 μg/m^3. Since each range plotted is a range of median values or (for ambient air) mean values, the plots do not encompass all of the individual measurements reported.

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[14] MSHA calculated the ratio for truck drivers by taking a weighted average of the ratios reported for ''local drivers'' and ''road drivers.''

[15] One commenter misinterpreted the tops of the ranges plotted in Figure III–4. This commenter apparently mistook the top of the range depicted for underground coal mines as the mean or median dpm exposure concentration measured across all underground coal mines. The top of this range (at 2100 μg/m^3, actually represents the highest median concentration at any of the coal mines sampled. It corresponds to the ''belt'' plotted for Mine ''G'' (with no after-filters) in Figure III–1. The bottom of the same bar, at 55 μg/m^3, corresponds to the ''belt'' plotted for Mine H* (with after-filters) in Figure III–1.

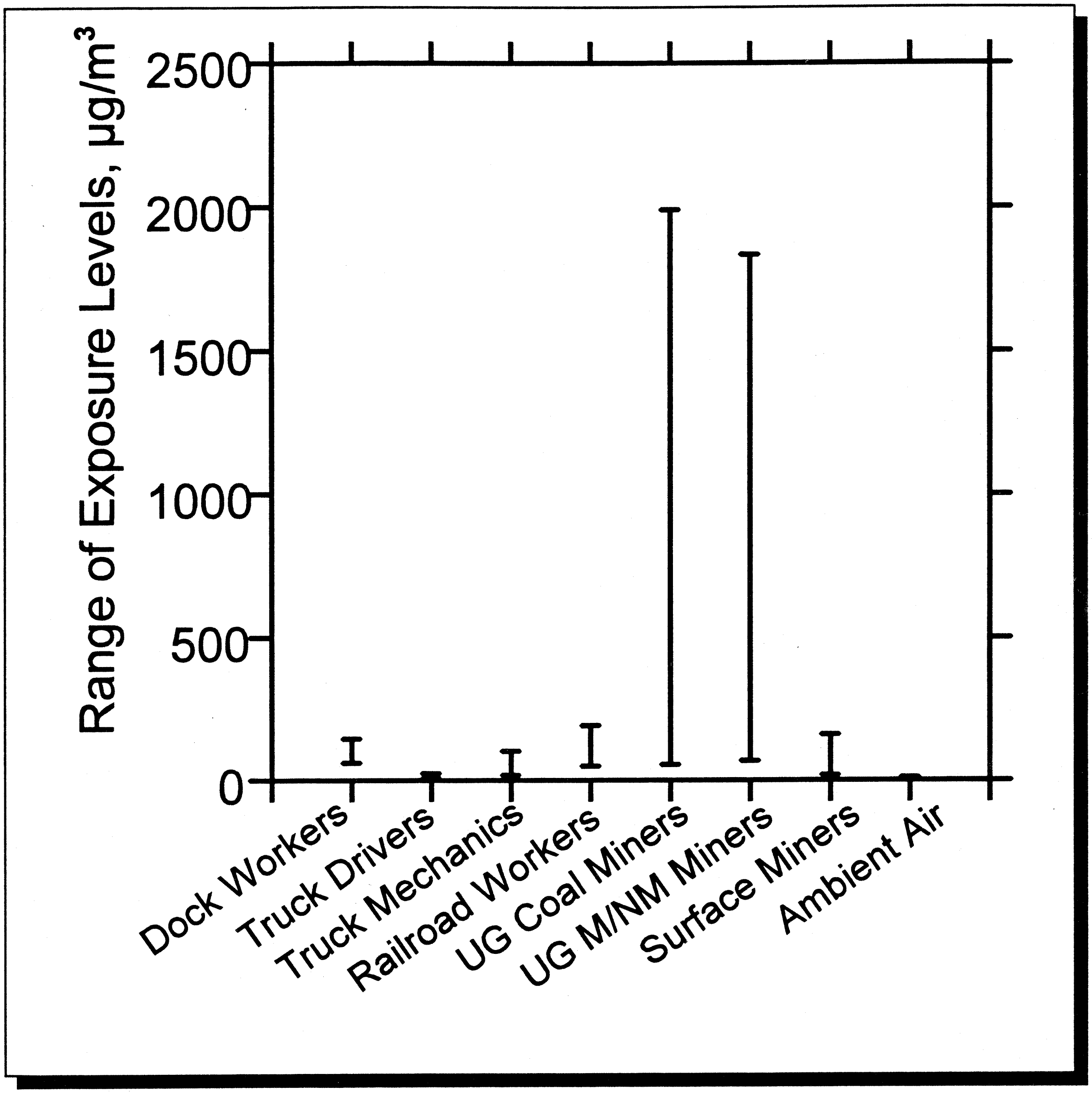

Figure III-4. — Range of median dpm exposure levels observed within various mines for underground and surface miners compared to range of median Dpm exposure levels estimated for other occupations. Range of dpm exposure levels for ambient air is for urban environments only and is based on the monthly mean for different months and locations in Southern California. Range for ambient air is roughly 1 to 10 μg/m³.

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As shown in Figure III–4, some miners are exposed to far higher concentrations of dpm than are any other populations for which exposure data have been reported. Indeed, median dpm concentrations observed in some underground mines are up to 200 times as high as mean environmental exposures in the most heavily polluted urban areas,[16] and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups.

Several commenters objected to Figure III–4 and, more generally, to MSHA's comparison of dpm exposure levels for miners against the levels reported for other occupations. The objections to MSHA's method of estimating ranges of median dpm exposure for job categories within the trucking industry have already been discussed and addressed above. Other objections to the comparison were based on claims of insufficient accuracy in the RCD and gravimetric size selective measurements MSHA used to measure dpm levels for miners. MSHA considers its use of these methods appropriate for purposes of this comparison and has responded to criticisms of the dpm measurements for miners in Subsections 1.a and 1.b of this risk assessment.[17]

Some commenters objected to MSHA's basing a characterization of dpm exposures to miners on data spanning a ten-year period. These commenters contended that, in at least some M/NM mines, dpm levels had improved substantially during that period. No data were submitted, however, to support the premise that dpm exposures throughout the mining industry have declined to the levels reported for other occupations. As stated in the proposal and emphasized above, MSHA's dpm measurements were not technically designed as a random or statistically representative sample of the industry. They do show, however, that very high exposures have recently occurred in some mines. For example, as shown in Figure III–2, more than 25 percent of MSHA's dpm measurements exceeded 2000 μg/m³ at underground M/NM mines ''U'' and ''Z''—and these measurements were made in 1996–7. In M/NM mines where exposures are actually commensurate with other industries already, little or nothing would need to be changed to meet the exposure limits.

IMC Global further objected to Figure III–4 on the grounds that ''* * * the assumptions that MSHA used to develop that figure are grossly inaccurate and do not do make sense in the context of a dose-response relationship between lung cancer and dpm exposure.'' IMC Global suggested that the comparison in Figure III–4 be deleted for this reason. MSHA believes that the comparison is informative and that empirical evidence should be used, when it is available, even though the evidence was not generated under ideal, theoretical dose-response model conditions. The issue of whether Figure III–4 is consistent with an exposure-response relationship for dpm is addressed in Subsection 3.a.iii(4) of this risk assessment.

2. Health Effects Associated With DPM Exposures

This section reviews the various health effects (of which MSHA is aware) that may be associated with dpm exposures. The review is divided into three main sections: acute effects, such as diminished pulmonary function and eye irritation; chronic effects, such as lung cancer; and mechanisms of toxicity. Prior to that review, however, the relevance of certain types of information will be considered. This discussion will address the relevance of health effects observed in animals, health effects that are reversible, and health effects associated with fine particulate matter in the ambient air.

Several commenters described medical surveillance studies that NIOSH and/or the former Bureau of Mines had carried out in the late 1970s and early 1980s on underground miners employed in western, dieselized coal mines. These commenters urged MSHA to make these studies available and to consider the results in this rulemaking. Some of these commenters also suggested that these data would provide a useful baseline for pulmonary function and lung diseases among miners exposed to dpm, and recommended that follow-up examinations now be conducted to evaluate the possible effects of chronic dpm exposure.

In response to such comments presented at some of the public hearings, another commenter wrote:

> First of all, MSHA is not a research agency, it is a regulatory agency, so that it would be inappropriate for MSHA to initiate research. MSHA did request that NIOSH conduct a risk assessment on the health effects of diesel exhaust and encouraged NIOSH and is currently collaborating with NIOSH (and NCI) on research of other underground miners exposed to diesel exhaust. And third, research on the possible carcinogenicity of diesel particulate matter was not undertaken on coal miners in the West or anywhere else because of the confounding exposure to crystalline silica, also considered a carcinogen, because too few coal miners have been exposed, and for too short a time to conduct a valid study. It was not arbitrariness or indifference on MSHA's part that it did not initiate research on coal miners; it was not within their mandate and it is inappropriate in any event. [UMWA]

Three reports summarizing and presenting results from these medical surveillance studies related to dpm exposures in coal mines were, in fact, utilized and cited in the proposed risk assessment (Ames et al., 1982; Reger et al., 1982; Ames et al., 1984). Ames et al. (1982) evaluated acute respiratory effects, and their results are considered in Subsection 2.b.ii of this risk assessment. Reger et al. (1982) and Ames et al. (1984) evaluated chronic effects, and their results are considered in Subsection 2.c.i(1).

A fourth report (Glenn et al., 1983) summarized results from the overall research program of which the coal mine studies were a part. This health and environmental research program included not only coal miners, but also workers at potash, trona, salt, and metal mines. All subjects were given chest radiographs and spirometric tests and were questioned about respiratory symptoms, smoking and occupational history. In conjunction with these medical evaluations, industrial hygiene surveys were conducted to characterize the mine environments where diesel equipment was used. Diesel exhaust exposure levels were characterized by area and personal samples of NO_2 (and, in some cases, additional gasses), aldehydes, and both respirable and total dust. For the evaluations of acute effects, exposure measures were based on the shift concentrations to which the examined workers were exposed. For the evaluations of chronic effects, exposures were usually estimated by summing the products of time spent in various locations by each miner by concentrations estimated for the various locations. Results of studies on acute effects in salt mines were reported by Gamble et al. (1978) and are considered

[16] It should be noted, however, that 24-hour environmental exposures for a full lifetime are not directly comparable with workday exposures over an occupational lifetime. If it is assumed that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day, then the amount of air inhaled over the course of a 70-year lifetime is approximately 4.7 times the amount inhaled over a 45-year occupational lifetime with 240 working days per year.

[17] One commenter pointed out that the measurements for miners included both area and personal samples but provided no evidence that this would invalidate the comparison. As pointed out in Subsections 1.a and 1.b, area samples did not dominate the upper end of MSHA's dpm measurements. Furthermore, Figure III–4 presents a comparison of medians rather than means or individual measurements, so inclusion of the area samples has very little impact on the results.

in Subsection 2.b.ii of this risk assessment. Attfield (1979), Attfield et al. (1982), and Gamble et al. (1983) evaluated effects in M/NM mines, and their results are considered in Subsection 2.c.i(1). The general summary provided by Glenn et al. (1983) was among the reports that one commenter (MARG) listed as having received inadequate attention in the proposed risk assessment. In that context, the general results summarized in this report are discussed, under the heading of ''Counter-Evidence,'' in Subsection 2.c.i(2)(a) of this risk assessment.

a. Relevancy Considerations

i. Animal Studies. Since the lungs of different species may react differently to particle inhalation, it is necessary to treat the results of animal studies with some caution. Evidence from animal studies can nevertheless be valuable—both in helping to identify potential human health hazards and in providing a means for studying toxicological mechanisms. Respondents to MSHA's ANPRM who addressed the question of relevancy urged consideration of all animal studies related to the health effects of diesel exhaust.

Unlike humans, laboratory animals are bred to be homogeneous and can be randomly selected for either non-exposure or exposure to varying levels of a potentially toxic agent. This permits setting up experimental and control groups of animals that exhibit relatively little biological variation prior to exposure. The consequences of exposure can then be determined by comparing responses in the experimental and control groups. After a prescribed duration of deliberate exposure, laboratory animals can also be sacrificed, dissected, and examined. This can contribute to an understanding of mechanisms by which inhaled particles may exert their effects on health. For this reason, discussion of the animal evidence is placed in the section entitled ''Mechanisms of Toxicity'' below.

Animal evidence also can help isolate the cause of adverse health effects observed among humans exposed to a variety of potentially hazardous substances. If, for example, the epidemiologic data are unable to distinguish between several possible causes of increased risk of disease in a certain population, then controlled animal studies may provide evidence useful in suggesting the most likely explanation—and provide that information years in advance of definitive evidence from human observations.

Furthermore, results from animal studies may also serve as a check on the credibility of observations from epidemiologic studies of human populations. If a particular health effect is observed in animals under controlled laboratory conditions, this tends to corroborate observations of similar effects in humans.

One commenter objected to MSHA's reference to using animal studies as a ''check'' on epidemiologic studies. This commenter emphasized that animal studies provide far more than just corroborative information and that researchers use epidemiologic and animal studies ''* * * to help understand different aspects of the carcinogenic process.'' [18] MSHA does not dispute the utility of animal studies in helping to provide an understanding of toxicological processes and did not intend to belittle their importance for this purpose. In fact, MSHA places the bulk of its discussion of these studies in a section entitled ''Mechanisms of Toxicity.'' However, MSHA considers the use of animal studies for corroborating epidemiologic associations to be also important—especially with respect to ruling out potential confounding effects and helping to establish causal linkages. Animal studies make possible a degree of experimental design and statistical rigor that is not attainable in human studies.

Other commenters disputed the relevance of at least some animal data to human risk assessment. For example, The West Virginia Coal Association indicated the following comments by Dr. Peter Valberg:

> * * * scientists and scientific advisory groups have treated the rat bioassay for inhaled particles as unrepresentative of human lung-cancer risks. For example, the Presidential/Congressional Commission on Risk Assessment and Risk Management (''CCRARM'') noted that the response of rat lungs to inhaled particulate in general is not likely to be predictive of human cancer risks. More specific to dpm, the Clean Air Scientific Advisory Committee (''CASAC''), a peer-review group for the U.S. EPA, has commented on two drafts (1995 and 1998) of the EPA's Health Assessment Document on Diesel Exhaust. On both occasions, CASAC emphasized that the data from rats are not relevant for human risk assessment. Likewise, the Health Effects Institute also has concluded that rat data should not be used for assessing human lung cancer risk.

Similarly, the NMA commented that the 1998 CASAC review ''makes it crystal clear that the rat studies cited by MSHA should not be relied upon as legitimate indicators of the carcinogenicity of Dpm in humans.'' The Nevada Mining Association, endorsing Dr. Valberg's comments, added:

> * * * to the extent that MSHA wishes to rest its case on rat studies, Dr. Valberg, among others, has impressively demonstrated that these studies are worthless for human comparison because of rats' unique and species-specific susceptibility to inhaled insoluble particles.

However, neither Dr. Valberg nor the Nevada Mining Association provided evidence that rats' susceptibility to inhaled insoluble particles was ''unique'' and that humans, for example, were not also susceptible to lung overload at sufficiently high concentrations of fine particles. Even if (as has apparently been demonstrated) some species (such as hamsters) do not exhibit susceptibility similar to rats, this by no means implies that rats are the only species exhibiting such susceptibility.

These commenters appear at times to be saying that, because studies of lung cancer in rats are (in the commenters' view) irrelevant to humans, MSHA should completely ignore all animal studies related to dpm. To the extent that this was the position advocated, the commenters' line of reasoning neglects several important points:

1. The animal studies under consideration are not restricted to studies of lung cancer responses in rats. They include studies of bioavailability and metabolism as well as studies of immunological and genotoxic responses in a variety of animal species.

2. The context for the determinations cited by Dr. Valberg was risk assessment at ambient levels, rather than the much higher dpm levels to which miners are exposed. The 1995 HEI report to which Dr. Valberg alludes acknowledged a potential mechanism of lung overload in humans at dpm concentrations exceeding 500 $\mu g/m^3$ (HEI, 1995). Since miners may concurrently be exposed to concentrations of mineral dusts significantly exceeding 500 $\mu g/m^3$, evidence related to the consequences of lung overload has special significance for mining environments.

3. The scientific authorities cited by Dr. Valberg and other commenters objected to using existing animal studies for quantitative human risk assessment. MSHA has not proposed doing that. There is an important distinction between extrapolating results from the rat studies to human populations and using them to confirm epidemiologic findings and to identify and explore potential mechanisms of toxicity.

[18] This risk assessment is not limited to cancer effects, but the commenter's point can be generalized.

MSHA by no means ''wishes to rest its case on rat studies,'' and it has no intention of doing so. MSHA does believe, however, that judicious consideration of evidence from animal studies is appropriate. The extent to which MSHA utilizes such evidence to help draw specific conclusions will be clarified below in connection with those conclusions.

ii. *Reversible Health Effects.* Some reported health effects associated with dpm are apparently reversible—*i.e.,* if the worker is moved away from the source for a few days, the symptoms dissipate. A good example is eye irritation.

In response to the ANPRM, questions were raised as to whether so-called ''reversible'' effects can constitute a ''material'' impairment. For example, a predecessor constituent of the National Mining Association (NMA) argued that ''it is totally inappropriate for the agency to set permissible exposure limits based on temporary, reversible sensory irritation'' because such effects cannot be a ''material'' impairment of health or functional capacity within the definition of the Mine Act (American Mining Congress, 87–0–21, Executive Summary, p. 1, and Appendix A).

MSHA does not agree with this categorical view. Although the legislative history of the Mine Act is silent concerning the meaning of the term ''material impairment of health or functional capacity,'' and the issue has not been litigated within the context of the Mine Act, the statutory language about risk in the Mine Act is similar to that under the OSH Act. A similar argument was dispositively resolved in favor of the Occupational Safety and Health Administration (OSHA) by the 11th Circuit Court of Appeals in *AFL–CIO* v. *OSHA,* 965 F.2d 962, 974 (1992).

In that case, OSHA proposed new limits on 428 diverse substances. It grouped these into 18 categories based upon the primary health effects of those substances: *e.g.,* neuropathic effects, sensory irritation, and cancer. (54 FR 2402). Challenges to this rule included the assertion that a ''sensory irritation'' was not a ''material impairment of health or functional capacity'' which could be regulated under the OSH Act. Industry petitioners argued that since irritant effects are transient in nature, they did not constitute a ''material impairment.'' The Court of Appeals decisively rejected this argument.

The court noted OSHA's position that effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and be seriously disabling in some cases. Moreover, there was evidence that workers exposed to these sensory irritants could be distracted as a result of their symptoms, thereby endangering other workers and increasing the risk of accidents. (*Id.* at 974). This evidence included information from NIOSH about the general consequences of sensory irritants on job performance, as well as testimony by commenters on the proposed rule supporting the view that such health effects should be regarded as material health impairments. While acknowledging that ''irritation'' covers a spectrum of effects, some of which can be minor, OSHA had concluded that the health effects associated with exposure to these substances warranted action—to ensure timely medical treatment, reduce the risks from increased absorption, and avoid a decreased resistance to infection (*Id* at 975). Finding OSHA's evaluation adequate, the Court of Appeals rejected petitioners' argument and stated the following:

> We interpret this explanation as indicating that OSHA finds that although minor irritation may not be a material impairment, there is a level at which such irritation becomes so severe that employee health and job performance are seriously threatened, even though those effects may be transitory. We find this explanation adequate. OSHA is not required to state with scientific certainty or precision the exact point at which each type of sensory or physical irritation becomes a material impairment. Moreover, section 6(b)(5) of the Act charges OSHA with addressing all forms of ''material impairment of health or functional capacity,'' and not exclusively ''death or serious physical harm'' or ''grave danger'' from exposure to toxic substances. See 29 U.S.C. 654(a)(1), 655(c). [*Id.* at 974].

In its comments on the proposed rule, the NMA claimed that MSHA had overstated the court's holding. In making this claim, the NMA attributed to MSHA an interpretation of the holding that MSHA did not put forth. In fact, MSHA agrees with the NMA's interpretation as stated in the following paragraph and takes special note of the NMA's acknowledgment that transitory or reversible effects can sometimes be so severe as to seriously threaten miners' health and safety:

> NMA reads the Court's decision to mean (as it stated) that ''minor irritation may not be a material impairment'' * * * but that irritation can reach ''a level at which [it] becomes so severe that employee health and job performance are seriously threatened even though those effects may be transitory.'' * * * AMC in 1992 and NMA today are fully in accord with the view of the 11th Circuit that when health effects, transitory or otherwise, become so ''severe'' as to ''seriously threaten'' a miner's health or job performance, the materiality threshold has been met.

The NMA, then, apparently agrees with MSHA that sensory irritations and respiratory symptoms can be so severe that they cross the material impairment threshold, regardless of whether they are ''reversible.'' Therefore, as MSHA has maintained, such health effects are highly relevant to this risk assessment—especially since impairments of a miner's job performance in an underground mining environment could seriously threaten the safety of both the miner and his or her co-workers. Sensory irritations may also impede miners' ability to escape during emergencies.

The NMA, however, went on to emphasize that ''* * * federal appeals courts have held that 'mild discomfort' or even 'moderate irritation' do not constitute 'significant' or 'material' health effects'':

> In International Union v. Pendergrass, 878 F. 2d 389 (1989), the D.C. Circuit upheld OSHA's formaldehyde standard against a challenge that it did not adequately protect against significant noncarcinogenic health effects, even though OSHA had found that, at the permissible level of exposure, ''20% of workers suffer 'mild discomfort', while 30% more experience 'slight discomfort','' *Id.* at 398. Likewise, in Texas Independent Ginners Ass'n. v. Marshall, 630 F, 2d 398 (1980), the Fifth Circuit Court of Appeals held that minor reversible symptoms do not constitute material impairment unless OSHA shows that those effects might develop into chronic disease. *Id.* at 408–09.

MSHA is fully aware of the distinction that courts have made between mild discomfort or irritation and transitory health effects that can seriously threaten a miner's health and safety. MSHA's position, after reviewing the scientific literature, public testimony, and comments, is that all of the health effects considered in this risk assessment fall into the latter category.

iii. Health Effects Associated with $PM_{2.5}$ in Ambient Air. There have been many studies in recent years designed to determine whether the mix of particulate matter in ambient air is harmful to health. The evidence linking particulates in air pollution to health problems has long been compelling enough to warrant direction from the Congress to limit the concentration of such particulates (see part II, section 5 of this preamble). In recent years, the evidence of harmful effects due to airborne particulates has increased, suggesting that ''fine'' particulates (*i.e.,* particles less than 2.5 µm in diameter) are more strongly associated than ''coarse'' respirable particulates (*i.e.,* particles greater than 2.5 µm but less than 10 µm in diameter) with the adverse health effects observed (EPA, 1996).

MSHA recognizes that there are two difficulties involved in utilizing the evidence from such studies in assessing risks to miners from occupational dpm exposures. First, although dpm is a fine particulate, ambient air also contains fine particulates other than dpm. Therefore, health effects associated with exposures to fine particulate matter in air pollution studies are not associated specifically with exposures to dpm or any other one kind of fine particulate matter. Second, observations of adverse health effects in segments of the general population do not necessarily apply to the population of miners. Since, due to age and selection factors, the health of miners differs from that of the public as a whole, it is possible that fine particles might not affect miners, as a group, to the same degree as the general population.

Some commenters reiterated these two points, recognized by MSHA in the proposal, without addressing MSHA's stated reasons for including health effects associated with fine particulates in this risk assessment. There are compelling reasons why MSHA considered this body of evidence in this rulemaking.

Since dpm is a type of respirable particle, information about health effects associated with exposures to respirable particles, and especially to fine particulate matter, is certainly relevant, even if difficult to apply directly to dpm exposures. Adverse health effects in the general population have been observed at ambient atmospheric particulate concentrations well below the dpm concentrations studied in occupational settings. The potency of dpm differs from the total fine particulate found in ambient air. This makes it difficult to establish a specific exposure-response relationship for dpm that is based on fine particle results. However, this does not mean that these results should be ignored in a dpm risk assessment. The available evidence of adverse health effects associated with fine particulates is still highly relevant for dpm hazard identification. Furthermore, as shown in Subsection 3.c.ii of this risk assessment, the fine particle research findings can be used to construct a rough exposure-response relationship for dpm, showing significantly increased risks of material impairment among exposed miners. MSHA's estimates are based on the best available epidemiologic evidence and show risks high enough to warrant regulatory action.

Moreover, extensive scientific literature shows that occupational dust exposures contribute to the development of Chronic Obstructive Pulmonary Diseases (COPD), thereby compromising the pulmonary reserve of some miners. Miners experience COPD at a significantly higher rate than the general population (Becklake 1989, 1992; Oxman 1993; NIOSH 1995). In addition, many miners also smoke tobacco. This places affected miners in subpopulations specifically identified as susceptible to the adverse health effects of respirable particle pollution (EPA, 1996). Some commenters (*e.g.,* MARG) repeated MSHA's observation that the population of miners differs from the general population but failed to address MSHA's concern for miners' increased susceptibility due to COPD incidence and/or smoking habits. The Mine Act requires that standards ''* * * most adequately assure on the basis of the best available evidence that *no miner* suffer material impairment of health or functional capacity * * *'' (Section 101(a)(6), emphasis added). This most certainly authorizes MSHA to protect miners who have COPD and/or smoke tobacco.

MARG also submitted the opinion that if ''* * * regulation of fine particulate matter is necessary, it [MSHA] should propose a rule dealing specifically with the issue of concern, rather than a rule that limits total airborne carbon or arbitrarily singles out diesel exhaust * * *.'' MSHA's concern is not with ''total airborne carbon'' but with dpm, which consists mostly of submicrometer airborne carbon. At issue here, however, are the adverse health effects associated with dpm exposure. Dpm is a type of fine particulate, and there is no evidence to suggest that the dpm fraction contributes less than other fine particulates to adverse health effects linked to exposures in ambient air.

For this reason, and because miners may be especially susceptible to fine particle effects, MSHA has concluded, after considering the public comments, that the body of evidence from air pollution studies is highly relevant to this risk assessment. The Agency is, therefore, taking that evidence fully into account.

b. Acute Health Effects

Information pertaining to the acute health effects of dpm includes anecdotal reports of symptoms experienced by exposed miners, studies based on exposures to diesel emissions, and studies based on exposures to particulate matter in the ambient air. These will be discussed in turn. Subsection 2.a.iii of this risk assessment addressed the relevance to dpm of studies based on exposures to particulate matter in the ambient air.

Only the evidence from human studies will be addressed in this section. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Section 3.a and 3.b contain MSHA's interpretation of the evidence relating dpm exposures to acute health hazards.

i. Symptoms Reported by Exposed Miners. Miners working in mines with diesel equipment have long reported adverse effects after exposure to diesel exhaust. For example, at the dpm workshops conducted in 1995, a miner reported headaches and nausea experienced by several operators after short periods of exposure (dpm Workshop; Mt. Vernon, IL, 1995). Another miner reported that smoke from poorly maintained equipment, or from improper fuel use, irritates the eyes, nose, and throat. ''We've had people sick time and time again * * * at times we've had to use oxygen for people to get them to come back around to where they can feel normal again.'' (dpm Workshop; Beckley, WV, 1995). Other miners (dpm Workshops; Beckley, WV, 1995; Salt Lake City, UT, 1995), reported similar symptoms in the various mines where they worked.

At the 1998 public hearings on MSHA's proposed dpm rule for coal mines, one miner, with work experience in a coal mine utilizing diesel haulage equipment at the face, testified that

> * * * unlike many, I have not experienced the headaches, the watering of the eyes, the cold-like symptoms and walking around in this cloud of smoke. Maybe it's because of the maintenance programs. Maybe it's because of complying with ventilation. * * * after 25 years, I have not shown any effects. [SLC, 1998].

Other miners working at dieselized coal mines testified at those hearings that they had personally experienced eye irritation and/or respiratory ailments immediately after exposure to diesel exhaust, and they attributed these ailments to their exposure. For example, one miner attributed a case of pneumonia to a specific episode of unusually high exposure. (Birm., 1998) The safety and training manager of the mining company involved noted that ''there had been a problem recognized in review with that exhaust system on that particular piece of equipment'' and that the pneumonia may have developed due to ''idiosyncracy of his lungs that respond to any type of a respiratory irritant.'' The manager suggested that this incident should not be generalized to other situations but provided no evidence that the miner's lungs were unusually susceptible to irritation.[19]

Another miner, who had worked at the same underground mine before and after diesel haulage equipment was introduced, indicated that he and his co-workers began experiencing acute symptoms after the diesel equipment was introduced. This miner suggested that these effects were linked to exposure, and referring to a co-worker stated:

> * * * had respiratory problems, after * * * diesel equipment was brought into that mine—he can take off for two weeks vacation, come back—after that two weeks, he felt pretty good, his respiratory problems would straighten up, but at the very instant that he gets back in the face of diesel-powered equipment, it starts up again, his respiratory problems will flare up again, coughing, sore throat, numerous problems in his chest. (Birm., 1998).

Several other underground miners asserted there was a correlation between diesel exposure levels and the frequency and/or intensity of respiratory symptoms, eye irritations, and chest ailments. One miner, for example, stated:

> I've experienced [these symptoms] myself. * * * other miners experience the same kind of distresses * * * Some of the stresses you actually can feel—you don't need a gauge to measure this—your burning eyes, nose, throat, your chest irritation. The more you're exposed to, the higher this goes. This includes headaches and nausea and some lasting congestion, depending on how long you've been exposed per shift or per week.
>
> The men I represent have experienced more cold-like symptoms, especially over the past, I would say, eight to ten years, when diesel has really peaked and we no longer really use much of anything else. [SLC, 1998].

Kahn et al. (1988) conducted a study of the prevalence and seriousness of such complaints, based on United Mine Workers of America records and subsequent interviews with the miners involved. The review involved reports at five underground coal mines in Utah and Colorado between 1974 and 1985. Of the 13 miners reporting symptoms: 12 reported mucous membrane irritation, headache and light-headiness; eight reported nausea; four reported heartburn; three reported vomiting and weakness, numbness, and tingling in extremities; two reported chest tightness; and two reported wheezing (although one of these complained of recurrent wheezing without exposure). All of these incidents were severe enough to result in lost work time due to the symptoms (which subsided within 24 to 48 hours).

In comments submitted for this rulemaking, the NMA pointed out, as has MSHA, that the evidence presented in this subsection is anecdotal. The NMA, further, suggested that the cited article by Kahn et al. typified this kind of evidence in that it was ''totally devoid of any correlation to actual exposure levels.'' A lack of concurrent exposure measurements is, unfortunately, not restricted to anecdotal evidence; and MSHA must base its evaluation on the available evidence. MSHA recognizes the scientific limitations of anecdotal evidence and has, therefore, compiled and considered it separately from more formal evidence. MSHA nevertheless considers such evidence potentially valuable for identifying acute health hazards, with the understanding that confirmation requires more rigorous investigation.[20]

With respect to the same article (Kahn et al., 1988), and notwithstanding the NMA's claim that the article was totally devoid of any correlation to exposure levels, the NMA also stated that MSHA:

> * * * neglects to include in the preamble the article's description of the conditions under which the ''overexposures'' occurred, *e.g.,* ''poor engine maintenance, poor maintenance of emission controls, prolonged idling of machinery, engines pulling heavy loads, use of equipment during times when ventilation was disrupted (such as during a move of longwall machinery), use of several pieces of equipment exhausting into the fresh-air intake, and use of poor quality fuel.

The NMA asserted that these conditions, cited in the article, ''have been addressed by MSHA's final standards for diesel equipment in underground coal mines issued October 25, 1996.''[21] Furthermore, despite its reservations about anecdotal evidence:

> NMA is mindful of the testimony of several miners in the coal proceeding who complained of transient irritation owing to exposure to diesel exhaust * * * the October 1996 regulations together with the phased-in introduction of catalytic converters on all outby equipment and the introduction of such devices on permissible equipment when such technology becomes available will address the complaints raised by the miners.

The NMA provided no evidence, however, that elimination of the conditions described by Kahn et al., or implementation of the 1996 diesel regulations for coal mines, would reduce dpm levels sufficiently to prevent the sensory irritations and respiratory symptoms described. Nor did the NMA provide evidence that these are the only conditions under which complaints of sensory irritations and respiratory symptoms occur, or explain why eliminating them would reduce the need to prevent excessive exposure under other conditions.

In the proposal for the present rule, MSHA requested additional information about such effects from medical personnel who have treated miners. IMC Global submitted letters from four healthcare practitioners in Carlsbad, NM, including three physicians. None of these practitioners attributed any cases of respiratory problems or other acute symptoms to dpm exposure. Three of the four practitioners noted that they had observed respiratory symptoms among exposed miners but attributed these symptoms to chronic lung conditions, smoking, or other factors. One physician stated that ''[IMC Global], which has used diesel equipment in its mining operations for over 20 years, has never experienced a single case of injury or illness caused by exposures to diesel particulates.''

ii. Studies Based on Exposures to Diesel Emissions. Several experimental and statistical studies have been conducted to investigate acute effects of exposure to diesel emissions. These more formal studies provide data that are more scientifically rigorous than the anecdotal evidence presented in the preceding subsection. Unless otherwise indicated, diesel exhaust exposures were determined qualitatively.

In a clinical study (Battigelli, 1965), volunteers were exposed to three concentrations of diluted diesel exhaust and then evaluated to determine the effects of exposure on pulmonary resistance and the degree of eye irritation. The investigators stated that ''levels utilized for these controlled exposures are comparable to realistic values such as those found in railroad shops.'' No statistically significant change in pulmonary function was detected, but exposure for ten minutes to diesel exhaust diluted to the middle level produced ''intolerable'' irritation in some subjects while the average irritation score was midway between ''some'' irritation and a ''conspicuous but tolerable'' irritation level. Diluting

[19] MSHA realizes the incidents related in this subsection are anecdotal and draws no statistical conclusions from them. Since they pertain to specific experiences, however, they can be useful in identifying a potential hazard.

[20] MSHA sees potential value in anecdotal evidence when it relates to immediate experiences. MSHA regards anecdotal evidence to be less appropriate for identifying chronic health effects, since chronic effects cannot readily be linked to specific experiences. Accordingly, this risk assessment places little weight on anecdotal evidence for the chronic health hazards considered.

[21] The 1996 regulations to which the NMA was referring do not apply to M/NM mines.

the concentration by 50% substantially reduced the irritation. At the highest exposure level, more than 50 percent of the volunteers discontinued the experiment before 10 minutes because of ''intolerable'' eye irritation.

A study of underground iron ore miners exposed to diesel emissions found no difference in spirometry measurements taken before and after a work shift (Jörgensen and Svensson 1970). Similarly, another study of coal miners exposed to diesel emissions detected no statistically significant relationship between exposure and changes in pulmonary function (Ames et al. 1982). However, the authors noted that the lack of a statistically significant result might be due to the low concentrations of diesel emissions involved.

Gamble et al. (1978) observed decreases in pulmonary function over a single shift in salt miners exposed to diesel emissions. Pulmonary function appeared to deteriorate in relation to the concentration of diesel exhaust, as indicated by NO_2; but this effect was confounded by the presence of NO_2 due to the use of explosives.

Gamble et al. (1987a) assessed response to diesel exposure among 232 bus garage workers by means of a questionnaire and before- and after-shift spirometry. No significant relationship was detected between diesel exposure and change in pulmonary function. However, after adjusting for age and smoking status, a significantly elevated prevalence of reported symptoms was found in the high-exposure group. The strongest associations with exposure were found for eye irritation, labored breathing, chest tightness, and wheeze. The questionnaire was also used to compare various acute symptoms reported by the garage workers and a similar population of workers at a lead acid battery plant who were not exposed to diesel fumes. The prevalence of work-related eye irritations, headaches, difficult or labored breathing, nausea, and wheeze was significantly higher in the diesel bus garage workers, but the prevalence of work-related sneezing was significantly lower.

Ulfvarson et al. (1987) studied effects over a single shift on 47 stevedores exposed to dpm at particle concentrations ranging from 130 $\mu g/m^3$ to 1000 $\mu g/m^3$. Diesel particulate concentrations were determined by collecting particles on glass fiber filters of unspecified efficiency. A statistically significant loss of pulmonary function was observed, with recovery after 3 days of no occupational exposure.

To investigate whether removal of the particles from diesel exhaust might reduce the ''acute irritative effect on the lungs'' observed in their earlier study, Ulfvarson and Alexandersson (1990) compared pulmonary effects in a group of 24 stevedores exposed to unfiltered diesel exhaust to a group of 18 stevedores exposed to filtered exhaust, and to a control group of 17 occupationally unexposed workers. The filters used were specially constructed from 144 layers of glass fiber with ''99.97% degrees of retention of dioctylphthalate mist with particle size 0.3 µm.'' Workers in all three groups were nonsmokers and had normal spirometry values, adjusted for sex, age, and height, prior to the experimental workshift.

In addition to confirming the earlier observation of significantly reduced pulmonary function after a single shift of occupational exposure, the study found that the stevedores in the group exposed only to filtered exhaust had 50–60% less of a decline in forced vital capacity (FVC) than did those stevedores who worked with unfiltered equipment. Similar results were observed for a subgroup of six stevedores who were exposed to filtered exhaust on one shift and unfiltered exhaust on another. No loss of pulmonary function was observed for the unexposed control group. The authors suggested that these results ''support the idea that the irritative effect of diesel exhausts [sic] to the lungs is the result of an interaction between particles and gaseous components and not of the gaseous components alone.'' They concluded that ''* * * it should be a useful practice to filter off particles from diesel exhausts in work places even if potentially irritant gases remain in the emissions'' and that ''removal of the particulate fraction by filtering is an important factor in reducing the adverse effect of diesel exhaust on pulmonary function.''

Rudell et al. (1996) carried out a series of double-blind experiments on 12 healthy, non-smoking subjects to investigate whether a particle trap on the tailpipe of an idling diesel engine would reduce acute effects of diesel exhaust, compared with exposure to unfiltered exhaust. Symptoms associated with exposure included headache, dizziness, nausea, tiredness, tightness of chest, coughing, and difficulty in breathing. The most prominent symptoms were found to be irritation of the eyes and nose, and a sensation of unpleasant smell. Among the various pulmonary function tests performed, exposure was found to result in significant changes only as measured by increased airway resistance and specific airway resistance. The ceramic wall flow particle trap reduced the number of particles by 46 percent, but resulted in no significant attenuation of symptoms or lung function effects. The authors concluded that diluted diesel exhaust caused increased irritant symptoms of the eyes and nose, unpleasant smell, and bronchoconstriction, but that the 46-percent reduction in median particle number concentration observed was not sufficient to protect against these effects in the populations studied.

Wade and Newman (1993) documented three cases in which railroad workers developed persistent asthma following exposure to diesel emissions while riding immediately behind the lead engines of trains having no caboose. None of these workers were smokers or had any prior history of asthma or other respiratory disease. Asthma diagnosis was based on symptoms, pulmonary function tests, and measurement of airway hyperreactivity to methacholine or exercise.

Although MSHA is not aware of any other published report directly relating diesel emissions exposures to the development of asthma, there have been a number of recent studies indicating that dpm exposure can induce bronchial inflammation and respiratory immunological allergic responses in humans. Studies published through 1997 are reviewed in Peterson and Saxon (1996) and Diaz-Sanchez (1997).

Diaz-Sanchez et al.(1994) challenged healthy human volunteers by spraying 300 µg dpm into their nostrils.[22] Immunoglobulin E (IgE) binds to mast cells where it binds antigen leading to secretion of biologically active amines (*e.g.,* histamine) causing dilation and increased permeability of blood vessels. These amines are largely responsible for clinical manifestations of such allergic reactions as hay fever, asthma, and hives. Enhanced IgE levels were found in nasal washes in as little as 24 hours, with peak production observed 4 days after the dpm was administered.[23] No effect was observed on the levels of other immunoglobulin proteins. The selective enhancement of local IgE production was demonstrated by a dramatic increase in IgE-secreting cells. The authors suggested that dpm may augment human allergic disease

[22] Assuming that a working miner inhales approximately 1.25 m^3 of air per hour, this dose corresponds to a 1-hour exposure at a dpm concentration of 240 $\mu g/m^3$.

[23] IgE is one of five types of immunoglobulin, which are proteins produced in response to allergens. Cytokine (mentioned later) is a substance involved in regulating IgE production.

responses by enhancing the production of IgE antibodies. Building on these results, Diaz-Sanchez et al.(1996) measured cytokine production in nasal lavage cells from healthy human volunteers challenged with 150 μg dpm sprayed into each nostril. Based on the responses observed, including a broad increase in cytokine production, along with the results of the 1994 paper, the authors concluded that dpm exposure contributes to enhanced local IgE production and thus plays a role in allergic airway disease.

Salvi et al. (1999) exposed healthy human volunteers to diluted diesel exhaust at a dpm concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Although there were no changes in pulmonary function, there were significant increases in various markers of allergic response in airway lavage fluid. Bronchial biopsies obtained six hours after exposure also showed significant increases in markers of immunologic response in the bronchial tissue. Significant increases in other markers of immunologic response were also observed in peripheral blood following exposure. A marked cellular inflammatory response in the airways was reported. The authors concluded that ''at high ambient concentrations, acute short-term DE [diesel exhaust] exposure produces a well-defined and marked systemic and pulmonary inflammatory response in healthy human volunteers, which is underestimated by standard lung function measurements.''

iii. Studies Based on Exposures to Particulate Matter in Ambient Air. Due to an incident in Belgium's industrial Meuse Valley, it was known as early as the 1930s that large increases in particulate air pollution, created by winter weather inversions, could be associated with large simultaneous increases in mortality and morbidity. More than 60 persons died from this incident, and several hundred suffered respiratory problems. The mortality rate during the episode was more than ten times higher than normal, and it was estimated that over 3,000 sudden deaths would occur if a similar incident occurred in London. Although no measurements of pollutants in the ambient air during the episode are available, high PM levels were obviously present (EPA, 1996).

A significant elevation in particulate matter (along with SO_2 and its oxidation products) was measured during a 1948 incident in Donora, PA. Of the Donora population, 42.7 percent experienced some acute adverse health effect, mainly due to irritation of the respiratory tract. Twelve percent of the population reported difficulty in breathing, with a steep rise in frequency as age progressed to 55 years (Schrenk, 1949).

Approximately as projected by Firket (1931), an estimated 4,000 deaths occurred in response to a 1952 episode of extreme air pollution in London. The nature of these deaths is unknown, but there is clear evidence that bronchial irritation, dyspnea, bronchospasm, and, in some cases, cyanosis occurred with unusual prevalence (Martin, 1964).

These three episodes ''left little doubt about causality in regard to the induction of serious health effects by very high concentrations of particle-laden air pollutant mixtures'' and stimulated additional research to characterize exposure-response relationships (EPA, 1996). Based on several analyses of the 1952 London data, along with several additional acute exposure mortality analyses of London data covering later time periods, the U.S. Environmental Protection Agency (EPA) concluded that increased risk of mortality is associated with exposure to combined particulate and SO_2 levels in the range of 500–1000 $\mu g/m^3$. The EPA also concluded that relatively small, but statistically significant increases in mortality risk exist at particulate (but not SO_2) levels below 500 $\mu g/m^3$, with no indications of a specific threshold level yet indicated at lower concentrations (EPA, 1986).

Subsequently, between 1986 and 1996, increasingly sophisticated techniques of particulate measurement and statistical analysis have enabled investigators to address these questions more quantitatively. The studies on acute effects carried out since 1986 are reviewed in the 1996 EPA Air Quality Criteria for Particulate Matter, which forms the basis for the discussion below (EPA, 1996).

At least 21 studies have been conducted that evaluate associations between acute mortality and morbidity effects and various measures of fine particulate levels in the ambient air. These studies are identified in Tables III–2 and III–3. Table III–2 lists 11 studies that measured primarily fine particulate matter using filter-based optical techniques and, therefore, provide mainly qualitative support for associating observed effects with fine particles. Table III–3 lists quantitative results from 10 studies that reported gravimetric measurements of either the fine particulate fraction or of components, such as sulfates, that serve as indicators or surrogates of fine particulate exposures.

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Table III-2. —Studies of acute health effects using filter based optical indicators of fine particles in the ambient air.

City	Study Years	Indicator*	Reference†
Acute Mortality			
London	1963-1972 (winters) 1965-1972 (winters)	BS	Thurston et al., 1989 Ito et al., 1993
Athens	1975-1987 July, 1987 1984-1988	BS	Katsouyanni et al., 1990 Katsouyanni et al., 1993 Touloumi et al., 1994
Los Angeles	1970-1979 1970-1979	KM	Shumway et al., 1988 Kinney and Ozkaynak, 1991
Santa Clara	1980-1986 (winters)	COH	Fairley, 1990
Increased Hospitalization			
Barcelona	1985-1989	BS	Sunyer et al., 1993
Acute Change in Pulmonary Function			
Wageningen, Netherlands		BS	Hoek and Brunkreef, 1993
Netherlands		BS	Roemer et al., 1993

† All references are from EPA, 1996

*BS (black smoke), KM (carbonaceous material), and COH (coefficient of haze) are optical measurements that are most directly related to elemental carbon concentrations, but only indirectly to mass. Site specific calibrations and/or comparisons of such optical measurements with gravimetric mass measurements in the same time and city are needed to make inferences about particle mass. However, all three of these indicators preferentially measure carbon particles found in the fine fraction of total airborne particulate matter. (EPA, 1996).

Table III-3. —Studies of acute health effects using gravimetric indicators of fine particles in the ambient air.

Study	Indicator	RR per 25 $\mu g/m^3$ $PM_{2.5}$ Increase (95% Confidence Interval)	Mean $PM_{2.5}$ Levels (Min/Max)†
Acute Mortality			
Six Cities[A] (overall)	$PM_{2.5}$	1.038 (1.026, 1.055)	
Portage, WI	$PM_{2.5}$	1.030 (0.993, 1.071)	11.2 (±7.8)
Topeka, KS	$PM_{2.5}$	1.020 (0.951, 1.092)	12.2 (±7.4)
Boston, MA	$PM_{2.5}$	1.056 (1.038, 1.071)	15.7 (±9.2)
St. Louis, MO	$PM_{2.5}$	1.028 (1.010, 1.043)	18.7 (±10.5)
Kingston/Knoxville, TN	$PM_{2.5}$	1.035 (1.005, 1.066)	20.8 (±9.6)
Steubenville, OH	$PM_{2.5}$	1.025 (0.998, 1.053)	29.6 (±21.9)
Increased Hospitalization			
Ontario, CAN[B]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 3.1 - 8.2
Ontario, CAN[C]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 2.0 - 7.7
	O_3	1.03 (1.02, 1.05)	
NYC/Buffalo, NY[D]	$SO_4^=$	1.05 (1.01, 1.10)	NR
Toronto, CAN[D]	H^+(Nmol/m^3)	1.16 (1.03, 1.30)*	28.8 (NR, 391)
	$SO_4^=$	1.12 (1.00, 1.24)	7.6 (NR, 48.7)
	$PM_{2.5}$	1.15 (1.02, 1.78)	18.6 (NR, 66.0)
Increased Respiratory Symptoms			
Southern California[F]	$SO_4^=$	1.48 (1.14, 1.91)	R = 2 - 37
Six Cities[G] (Cough)	$PM_{2.5}$	1.19 (1.01, 1.42)**	18.0 (7.2, 37)***
	$PM_{2.5}$ Sulfur	1.23 (0.95, 1.59)**	2.5 (3.1, 61)***
	H^+	1.06 (0.87, 1.29)**	18.1 (0.8, 5.9)***
Six Cities[G] (Lower Resp. Symp.)	$PM_{2.5}$	1.44 (1.15 - 1.82)**	18.0 (7.2, 37)***
	$PM_{2.5}$ Sulfur	1.82 (1.28 - 2.59)**	2.5 (0.8, 5.9)***
	H^+	1.05 (0.25 - 1.30)**	18.1 (3.1, 61)***
Denver, CO[P] (Cough, adult asthmatics)	$PM_{2.5}$	0.0012 (0.0043)****	0.41 - 73
	$SO_4^=$	0.0042 (0.00035)****	0.12 - 12
	H^+	0.0076 (0.0038)****	2.0 - 41
Decreased Lung Function			
Uniontown, PA[E]	$PM_{2.5}$	PEFR 23.1 (-0.3,36.9) (per 25 $\mu g/m^3$)	25/88 (NR/88)
Seattle, WA[Q] (Asthmatics)	$b_{ext.}$ calibrated by $PM_{2.5}$	FEV1 42 ml (12,73) FVC 45 ml (20,70)	5/45

References from EPA, 1996, Staff Report

[A] Schwartz et al. (1996a)

[B] Burnett et al. (1994)

[C] Burnett et al. (1995) O_3

[D] Thurston et al. (1992, 1994)

[E] Neas et al. (1995)

[F] Ostro et al. (1993)

[G] Schwartz et al. (1994)

[P] Ostro et al. (1991)

[Q] Koenig et al. (1993)

† Min/Max 24-hr PM indicator level shown in parentheses unless otherwise noted as (±S.D.), 10 and 90 percentile (10,90).

* Change per 100 nmoles/m^3.

** Change per 20 $\mu g/m^3$ for $PM_{2.5}$; per 5 $\mu g/m^3$ for $PM_{2.5}$ sulfur; per 25 nmoles/m^3 for H^+.

*** 50th percentile value (10,90 percentile).

**** Coefficient and SE in parenthesis.

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A total of 38 studies examining relationships between short-term particulate levels and increased mortality, including nine with fine particulate measurements, were published between 1988 and 1996 (EPA, 1996). Most of these found statistically significant positive associations. Daily or several-day elevations of particulate concentrations, at average levels as low as 18–58 μ/m^3, were associated with increased mortality, with stronger relationships observed in those with preexisting respiratory and cardiovascular disease. Overall, these studies suggest that an increase of 50 $\mu g/m^3$ in the 24-hour average of PM_{10} is associated with a 2.5 to 5-percent increase in the risk of mortality in the general population, excluding accidents, suicides, and homicides. Based on Schwartz et al. (1996), the relative risk (RR) of mortality in the general population increases by about 2.6 to 5.5 percent per 25 $\mu g/m^3$ of fine particulate ($PM_{2.5}$) (EPA, 1996). More specifically, Schwartz et al. (1996) reported significantly elevated risks of mortality due to pneumonia, chronic obstructive pulmonary disease (COPD), and ischemic heart disease (IHD). For these three causes of death, the estimated increases in risk per incremental increase of 10 $\mu g/m^3$ in the concentration of $PM_{2.5}$ were 4.0 percent, 3.3 percent, and 2.1 percent, respectively. Each of these three results was statistically significant at a 95-percent confidence level.

A total of 22 studies were published on associations between short-term particulate levels and hospital admissions, outpatient visits, and emergency room visits for respiratory disease, Chronic Obstructive Pulmonary Disease (COPD), pneumonia, and heart disease (EPA, 1996). Fifteen of these studies were focused on the elderly. Of the seven that dealt with all ages (or in one case, persons less than 65 years old), all showed positive results. All of the five studies relating fine particulate measurements to increased hospitalization, listed in Tables III–2 and III–3, dealt with general age populations and showed statistically significant associations. The estimated increase in risk ranges from 3 to 16 percent per 25 $\mu g/m^3$ of fine particulate. Overall, these studies are indicative of acute morbidity effects being related to fine particulate matter and support the mortality findings.

Most of the 14 published quantitative studies on ambient particulate exposures and acute respiratory diseases were restricted to children (EPA, 1996, Table 12–12). Although they generally showed positive associations, and may be of considerable biological relevance, evidence of toxicity in children is not necessarily applicable to adults. The few studies on adults have not produced statistically significant evidence of a relationship.

Thirteen studies since 1982 have investigated associations between ambient particulate levels and loss of pulmonary function (EPA, 1996, Table 12–13). In general, these studies suggest a short term effect, especially in symptomatic groups such as asthmatics, but most were carried out on children only. In a study of adults with mild COPD, Pope and Kanner (1993) found a 29±10 ml decrease in 1-second Forced Expiratory Volume (FEV_1) per 50 $\mu g/m^3$ increase in PM_{10}, which is similar in magnitude to the change generally observed in the studies on children. In another study of adults, with PM_{10} ranging from 4 to 137 $\mu g/m^3$, Dusseldorp et al. (1995) found 45 and 77 ml/sec decreases, respectively, for evening and morning Peak Expiratory Flow Rate (PEFR) per 50 $\mu g/m^3$ increase in PM_{10} (EPA, 1996). In the only study carried out on adults that specifically measured fine particulate ($PM_{2.5}$), Perry et al. (1983) did not detect any association of exposure with loss of pulmonary function. This study, however, was conducted on only 24 adults (all asthmatics) exposed at relatively low concentrations of $PM_{2.5}$ and,therefore, had very little power to detect any such association.

c. Chronic Health Effects

During the 1995 dpm workshops, miners reported observable adverse health effects among those who have worked a long time in dieselized mines. For example, a miner (dpm Workshop; Salt Lake City, UT, 1995), stated that miners who work with diesel ''have spit up black stuff every night, big black—what they call black (expletive) * * * [they] have the congestion every night * * * the 60-year-old man working there 40 years.'' Similarly, in comments submitted in response to MSHA's proposed dpm regulations, several miners reported cancers and chronic respiratory ailments they attributed to dpm exposure.

Scientific investigation of the chronic health effects of dpm exposure includes studies based specifically on exposures to diesel emissions and studies based more generally on exposures to fine particulate matter in the ambient air. Only the evidence from human studies will be addressed in this section of the risk assessment. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Subsection 3.a(iii) contains MSHA's interpretation of the evidence relating dpm exposures to one chronic health hazard: lung cancer.

i. Studies Based on Exposures to Diesel Emissions. The discussion will (1) summarize the epidemiologic literature on chronic effects other than cancer, and then (2) concentrate on the epidemiology of cancer in workers exposed to dpm.

(1) Chronic Effects other than Cancer

A number of epidemiologic studies have investigated relationships between diesel exposure and the risk of developing persistent respiratory symptoms (i.e., chronic cough, chronic phlegm, and breathlessness) or measurable loss in lung function. Three studies involved coal miners (Reger et al., 1982; Ames et al., 1984; Jacobsen et al., 1988); four studies involved metal and nonmetal miners (Jörgenson & Svensson, 1970; Attfield, 1979; Attfield et al., 1982; Gamble et al., 1983). Three studies involved other groups of workers—railroad workers (Battigelli et al., 1964), bus garage workers (Gamble et al., 1987), and stevedores (Purdham et al., 1987).

Reger et al. (1982) examined the prevalence of respiratory symptoms and the level of pulmonary function among more than 1,600 underground and surface U.S. coal miners, comparing results for workers (matched for smoking status, age, height, and years worked underground) at diesel and non-diesel mines. Those working at underground dieselized mines showed some increased respiratory symptoms and reduced lung function, but a similar pattern was found in surface miners who presumably would have experienced less diesel exposure. Miners in the dieselized mines, however, had worked underground for less than 5 years on average.

In a study of 1,118 U.S. coal miners, Ames et al. (1984) did not detect any pattern of chronic respiratory effects associated with exposure to diesel emissions. The analysis, however, took no account of baseline differences in lung function or symptom prevalence, and the authors noted a low level of exposure to diesel-exhaust contaminants in the exposed population.

In a cohort of 19,901 British coal miners investigated over a 5-year period, Jacobsen et al. (1988) found increased work absence due to self-reported chest illness in underground workers exposed to diesel exhaust, as compared to surface workers, but found no correlation with their estimated level of exposure.

Jörgenson & Svensson (1970) found higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among Swedish underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine. No significant difference was found in spirometry results.

Using questionnaires collected from 4,924 miners at 21 U.S. metal and nonmetal mines, Attfield (1979) evaluated the effects of exposure to silica dust and diesel exhaust and obtained inconclusive results with respect to diesel exposure. For both smokers and non-smokers, miners occupationally exposed to diesel for five or more years showed an elevated prevalence of persistent cough, persistent phlegm, and shortness of breath, as compared to miners exposed for less than five years, but the differences were not statistically significant. Four quantitative indicators of diesel use failed to show consistent trends with symptoms and lung function.

Attfield et al. (1982) reported on a medical surveillance study of 630 white male miners at 6 U.S. potash mines. No relationships were found between measures of diesel use or exposure and various health indices, based on self-reported respiratory symptoms, chest radiographs, and spirometry.

In a study of U.S. salt miners, Gamble and Jones (1983) observed some elevation in cough, phlegm, and dyspnea associated with mines ranked according to level of diesel exhaust exposure. No association between respiratory symptoms and estimated cumulative diesel exposure was found after adjusting for differences among mines. However, since the mines varied widely with respect to diesel exposure levels, this adjustment may have masked a relationship.

Battigelli et al. (1964) compared pulmonary function and complaints of respiratory symptoms in 210 U.S. railroad repair shop employees, exposed to diesel for an average of 10 years, to a control group of 154 unexposed railroad workers. Respiratory symptoms were less prevalent in the exposed group, and there was no difference in pulmonary function; but no adjustment was made for differences in smoking habits.

In a study of workers at four diesel bus garages in two U.S. cities, Gamble et al. (1987b) investigated relationships between job tenure (as a surrogate for cumulative exposure) and respiratory symptoms, chest radiographs, and pulmonary function. The study population was also compared to an unexposed control group of workers with similar socioeconomic background. After indirect adjustment for age, race, and smoking, the exposed workers showed an increased prevalence of cough, phlegm, and wheezing, but no association was found with job tenure. Age- and height-adjusted pulmonary function was found to decline with duration of exposure, but was elevated on average, as compared to the control group. The number of positive radiographs was too small to support any conclusions. The authors concluded that the exposed workers may have experienced some chronic respiratory effects.

Purdham et al. (1987) compared baseline pulmonary function and respiratory symptoms in 17 exposed Canadian stevedores to a control group of 11 port office workers. After adjustment for smoking, there was no statistically significant difference in self-reported respiratory symptoms between the two groups. However, after adjustment for smoking, age, and height, exposed workers showed lower baseline pulmonary function, consistent with an obstructive ventilatory defect, as compared to both the control group and the general metropolitan population.

In a review of these studies, Cohen and Higgins (1995) concluded that they did not provide strong or consistent evidence for chronic, nonmalignant respiratory effects associated with occupational exposure to diesel exhaust. These reviewers stated, however, that ‘‘several studies are suggestive of such effects * * * particularly when viewed in the context of possible biases in study design and analysis.’’ Glenn et al (1983) noted that the studies of chronic respiratory effects carried out by NIOSH researchers in coal, salt, potash, and trona mines all ‘‘revealed an excess of cough and phlegm in the diesel exposed group.’’ IPCS (1996) noted that ‘‘[a]lthough excess respiratory symptoms and reduced pulmonary function have been reported in some studies, it is not clear whether these are long-term effects of exposure.’’ Similarly, Morgan et al. (1997) concluded that while there is ‘‘some evidence that the chronic inhalation of diesel fumes leads to the development of cough and sputum, that is chronic bronchitis, it is usually impossible to show a cause and effect relationship * * *.’’ MSHA agrees that these dpm studies considers them to be suggestive of adverse chronic, non-cancerous respiratory effects.

(2) Cancer

Because diesel exhaust has long been known to contain carcinogenic compounds (*e.g.,* benzene in the gaseous fraction and benzopyrene and nitropyrene in the dpm fraction), a great deal of research has been conducted to determine if occupational exposure to diesel exhaust actually results in an increased risk of cancer. Evidence that exposure to dpm increases the risk of developing cancer comes from three kinds of studies: human studies, genotoxicity studies, and animal studies. In this risk assessment, MSHA has placed the most weight on evidence from the human epidemiologic studies and views the genotoxicity and animal studies as lending support to the epidemiologic evidence.

In the epidemiologic studies, it is generally impossible to disassociate exposure to dpm from exposure to the gasses and vapors that form the remainder of whole diesel exhaust. However, the animal evidence shows no significant increase in the risk of lung cancer from exposure to the gaseous fraction alone (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). Therefore, dpm, rather than the gaseous fraction of diesel exhaust, is usually assumed to be the agent associated with any excess prevalence of lung cancer observed in the epidemiologic studies. Subsection 2.d of this risk assessment contains a summary of evidence supporting this assumption.

(a) Lung Cancer

MSHA evaluated 47 epidemiologic studies examining the prevalence of lung cancer within groups of workers occupationally exposed to dpm. This includes four studies not included in MSHA’s risk assessment as originally proposed.[24] The earliest of these studies was published in 1957 and the latest in 1999. The most recent published reviews of these studies are by Mauderly (1992), Cohen and Higgins (1995), Muscat and Wynder (1995), IPCS (1996), Stöber and Abel (1996), Cox (1997), Morgan et al. (1997), Cal-EPA (1998), ACGIH (1998), and U.S. EPA (1999). In response to both the ANPRM and the 1998 proposals, several commenters also provided MSHA with their own reviews of many of these studies. In arriving at its conclusions, MSHA considered all of these reviews,

[24] One of these studies (Christie et al., 1995) was cited in the discussion on mechanisms of toxicity but not considered in connection with studies involving dpm exposures. Several commenters advocated that it be considered. The other three were published in 1997 or later. Johnston et al. (1997) was introduced to these proceedings in 64FR7144. Säverin et al. (1999) is the published English version of a German study submitted as part of the public comments by NIOSH on May 27, 1999. The remaining study is Brüske-Hohlfeld et al. (1999).

including those of the commenters, as well as the 47 source studies available to MSHA.

In addition, MSHA relied on two comprehensive statistical ''meta-analyses'' [25] of the epidemiologic literature: Lipsett and Campleman (1999)[26] and Bhatia et al. (1998).[27] These meta-analyses, which weight, combine, and analyze data from the various epidemiologic studies, were themselves the subject of considerable public comment and are discussed primarily in Subsection 3.a.iii of this risk assessment. The present section tabulates results of the studies and addresses their individual strengths and weaknesses. Interpretation and evaluation of the collective evidence, including discussion of potential publication bias or any other systematic biases, is deferred to Subsection 3.a.iii.

Tables III–4 (27 cohort studies) and III–5 (20 case-control studies) identify all 47 known epidemiologic studies that MSHA considers relevant to an assessment of lung cancer risk associated with dpm exposure.[28] These tables include, for each of the 47 studies listed, a brief description of the study and its findings, the method of exposure assessment, and comments on potential biases or other limitations. Presence or absence of an adjustment for smoking habits is highlighted, and adjustments for other potentially confounding factors are indicated when applicable. Although MSHA constructed these tables based primarily on its own reading of the 48 source publications, the tables also incorporate strengths and weaknesses noted in the literature reviews and/or in the public comments submitted.

Some degree of association between occupational dpm exposure and an excess prevalence of lung cancer was reported in 41 of the 47 studies reviewed by MSHA: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Despite some commenters' use of conflicting terminology, which will be addressed below, MSHA refers to these 41 studies as ''positive.'' The 22 positive cohort studies in Table III–4 are identified as those reporting a relative risk (RR) or standardized mortality ratio (SMR) exceeding 1.0. The 19 positive case-control studies in Table III–5 are identified as those reporting an RR or odds ratio (OR) exceeding 1.0. A study does not need to be statistically significant (at the 0.05 level) or meet all criteria described, in order to be considered a ''positive'' study. The six remaining studies were entirely negative: they reported a deficit in the prevalence of lung cancer among exposed workers, relative to whatever population was used in the study as a basis for comparison. These six negative studies are identified as those reporting no relative risk (RR), standard mortality ratio (SMR), or odds ratio (OR) greater than 1.0.[29]

MSHA recognizes that these 47 studies are not of equal importance for determining whether dpm exposure leads to an increased risk of lung cancer. Some of the studies provide much better evidence than others. Furthermore, since no epidemiologic study can be perfectly controlled, the studies exhibit various strengths and weaknesses, as described by both this risk assessment and a number of commenters. Several commenters, and some of the reviewers cited above, focused on the weaknesses and argued that none of the existing studies is conclusive. MSHA, in accordance with other reviewers and commenters, maintains: (1) that the weaknesses identified in both negative and positive studies mainly cause underestimation of risks associated with high occupational dpm exposure; (2) that it is legitimate to base conclusions on the combined weight of all available evidence and that, therefore, it is not necessary for any individual study to be conclusive; and (3) that even though the 41 positive studies vary a great deal in strength, nearly all of them contribute something to the weight of positive evidence.

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig.[b]	Comments
Ahlberg et al. (1981).	Male truck drivers	35,883	1961–73	Occupation only		RR = 1.33 for drivers of ''ordinary'' trucks.	(*)	Risk relative to males employed in trades thought to have no exposure to ''petroleum products or other chemicals.'' Comparison controlled for age and province of residence (Sweden). Based on comparison of smoking habits between truck drivers and general Stockholm population, authors concluded that excess rate of lung cancer could not be entirely attributed to smoking.

[25] MSHA restricts the term ''meta-analysis'' to formal, statistical analyses of the pooled data taken from several studies. Some commenters (and Cox in the article itself) referred to the review by Cox (op.cit.) as a meta-analysis. Although this article seeks to identify characteristics of the individual studies that might account for the general pattern of results, it performs no statistical analysis on the pooled epidemiologic data. For this reason, MSHA does not regard the Cox article as a meta-analysis in the same sense as the two studies so identified. MSHA does, however, recognize that the Cox article evaluates and rejects the collective evidence for causality, based on the common characteristics identified. In that context, Cox's arguments and conclusions are addressed in Subsection 3.a.iii. Cox also presents a statistical analysis of data from one of the studies, and that portion of the article is considered here, along with his observations about other individual studies.

[26] MSHA's risk assessment as originally proposed cited an unpublished version, attributed to Lipsett and Alexexeff (1998), of essentially the same meta-analysis. Both the 1999 and 1998 versions are now in the public record.

[27] Silverman (1998) reviewed the meta-analysis by Bhatia et al. (op cit.) and discussed, in general terms, the body of available epidemiologic evidence on which it is based. Some commenters stated that MSHA had not sufficiently considered Silverman's views on the limitations of this evidence. MSHA has thoroughly considered these views and addresses them in Subsection 3.a.(iii).

[28] For simplicity, the epidemiologic studies considered here are placed into two broad categories. A *cohort study* compares the health of persons having different exposures, diets, etc. A *case-control study* starts with two defined groups known to differ in health and compares their exposure characteristics.

[29] The six entirely negative studies are: Kaplan (1959); DeCoufle et al. (1977); Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995).

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig.[b]	Comments
Ahlman et al. (1991).	Underground sulfide ore miners.	597	1968–86	Job histories from personnel records. Measurements of alpha energy concentration from radon daughters at each mine worked.		RR = 1.45 overall. RR = 2.9 for 45–64 age group (calculated by MSHA).		Age-adjusted relative risk compared to males living in same area of Finland. No excess observed among 338 surface workers at same mines, with similar smoking and alcohol consumption, based on questionnaire. Based on calculation of expected lung cancers due to radon, excess risk attributed by author partly to radon exposure and partly to diesel exhaust & silica exposure.
Balarajan & McDowall (1988).	Professional drivers.	3,392	1950–84	Occupation only		SMR = 0.86 for taxi drivers.. SMR = 1.42 for bus drivers.. SMR = 1.59 for truck drivers.	(*)	Possibly higher rates of smoking among bus and truck drivers than among taxi drivers.
Bender et al. (1989).	Highway maintenance workers.	4,849	1945–84	Occupation only		SMR = 0.69		No adjustment for healthy worker effect.
Boffetta et al. (1988).	Railroad workers Truck drivers Heavy Eq. Op's Miners	2,973 16,208 855 2,034	1982–84	Occupation and diesel exposure by questionnaire.		RR = 1.24 for truck drivers. RR = 1.59 for railroad workers RR = 2.60 for heavy Eq. Op's RR = 2.67 for miners	(*) (*)	Risk relative to reporting that they never worked in these four occupations and were never occupationally exposed to diesel exhaust. Adjusted for age and smoking only.
Do	All workers	476,648	1982–84	Occupation and diesel exposure by questionnaire.		RR = 1.05 for 1–15 years. RR = 1.21 for 16+ years.		Based on self-reported exposure, relative to unexposed workers. Adjusted for occupational exposures to asbestos, coal and stone dusts, coal tar & pitch, and gasoline exhaust (in addition to age and smoking). Possible biases due to volunteered participation and elevated lung cancer rate among 98,026 subjects with unknown dpm exposure.
Christie et al. (1994, 1995).	Coal miners	23,630	1973–92	Occupation only		SMR = 0.76		No adjustment for healthy worker effect. Cohort includes workers who entered workforce up through 1992. SMR reported to be greater than for occupationally unexposed petroleum workers.
Dubrow & Wegman (1984).	Truck & tractor drivers.	Not reported	1971–73	Occupation only		sMOR = 1.73 based on 176 deaths.	(*)	Excess cancers observed over the entire respiratory system and upper alimentary tract.
Edling et al. (1987)	Bus workers	694	1951–83	Occupation only		SMR = 0.7 for overall cohort.		Small size of cohort lacks statistical power to detect excess risk of lung cancer. No adjustment for healthy worker effect.
Garshick et al. (1988, 1991).	Railroad workers	55,395 (1991 report).	1959–80	Job in 1959 & years of diesel exposure since 1959.		RR = 1.31 for 1–4 years. RR = 1.28 for 5–9 years. RR = 1.19 for 10–14 years. RR = 1.40 for 15 or more years.	(*) (*) (*) .	Adjusted for attained age (1991 report). Cumulative diesel exposure-years lagged by 5 years. Subjects with likely asbestos exposure excluded from cohort. Statistically significant results corroborated if 12,872 shopworkers and hostlers possibly exposed to asbestos are also excluded. Missing 12% of death certificates. Cigarette smoking judged to be uncorrelated with diesel exposure within cohort. Higher RR for each exposure group if shopworkers and hostlers are excluded.
Guberan et al (1992).	Professional drivers.	1,726	1961–86	Occupation only		SMR = 1.50	(*)	Approximately 1/3 to 1/4 of cohort reported to be long-haul truck drivers. SMR based on regional lung cancer mortality rate.
Gustafsson et al. (1986).	Dock workers	6,071	1961–80	Occupation only		SMR = 1.32 (mortality). SMR = 1.68 (morbidity)	(*) (*)	No adjustment for healthy worker effect.

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig.[b]	Comments
Gustavsson et al. (1990).	Bus garage workers.	708	1952–86	Semi-quantitative, based on job history & exposure intensity estimated for each job.		SMR = 1.22 for overall cohort. SMR = 1.27 for highest-exposed subgroup.		Lack of statistical significance may be attributed to small size of cohort.
Hansen (1993)	Truck drivers	14,225	1970–80	Occupation only		SMR = 1.60 for overall cohort. Some indication of increasing SMR with age (i.e., greater cumulative exposure).	(*)	Compared to unexposed control group of 38,301 laborers considered to "resemble the group of truck drivers in terms of work-related demands on physical strength and fitness, educational background, social class, and life style." Correction for estimated differences in smoking habits between cohort and control group reduces SMR from 1.60 to 1.52. Results judged "unlikely *** [to] have been seriously confounded by smoking habit differences."
Howe et al. (1983)	Railroad workers	43,826	1965–77	Jobs classified by diesel exposure.		RR = 1.20 for "possibly exposed.".	(*)	Risk is relative to unexposed subgroup of cohort. Similar results obtained for coal dust exposure.
						RR = 1.35 for "probably exposed.".	(*)	Possible confounding with asbestos and coal dust.
Johnston et al. (1997).	Underground coal miners.	18,166	1950–85	Quantitative, based on detailed job history & surrogate dpm measurements.		Mine-adjusted model: RR = 1.156 per g-hr/m³.		Risk is relative to unexposed workers in coal miners based on cohort. Adjusted for age, smoking habit & intensity, mine site, and cohort entry date. Mine site highly correlated with dpm exposure.
						Mine-unadjusted model: RR = 1.227 per g-hr/m³.		Both models lag exposure by 15 years.
Kaplan (1959)	Railroad workers	Approx. 32000	1953–58	Jobs classified by diesel exposure.		SMR=0.88 for operationally exposed.		No adjustment for healthy worker effect. Clerks (in rarely exposed group) found more likely to have had urban residence than occupationally exposed workers.
						SMR = 0.72 for somewha exposed SMR = 0.80 for rarely exposed.		No attempt to distinguish between diesel and coal-fired locomotives. Results may be attributable to short duration of exposure and/or inadequate follow-up time.
Leupker & Smith (1978).	Truck drivers	183,791	May–July, 1976	Occupation only		SMR = 1.21		Lack of statistical significance may be due to inadequate follow-up period. Retirees excluded from cohort, so lung cancers occurring after retirement were not included.
Lindsay et al. (1933).	Truck drivers	Not reported	1965–79	Occupation only		SMR = 1.15	(*)	
Menck & Henderson (1976).	Truck drivers	34,800 estimated	1968–73	Occupation only		SMR = 1.65	(*)	Number of subjects in cohort estimated from census data.
Raffle (1957)	Transport engineers.	2,666 estimated from manyears at risk.	1950–55	Occupation only		SMR = 1.42		SMR calculated by combining data presented for four quadrants of London. Excluded from most retirees and lung cancers occurring after retirement.
Rafnsson & Gunnarsdottir (1991).	Truck drivers	868	1951–88	Occupation only		SMR = 2.14	(*)	No trend of increasing risk with increased duration of employment or increased follow-up time. Based on survey of smoking habits in cohort compared to general male population, and fact that there were fewer than expected deaths from respiratory disease, authors concluded that differences in smoking habits were unlikely to be enough to explain excess rate of lung cancer. However, not all trucks were diesel prior to 1951, and there is possible confounding by asbestos exposure.

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig.[b]	Comments
Rushton et al. (1983).	Bus maintenamce workers.	8,480	5.9 yrs (mean)	Occupation only		SMR = 1.01 for overall cohort. SMR = 1.33 for "general hand" subgroup.	(*)	Short follow-up period. SMR based on comparison to national rates, with no adjustment for regional or socioeconomic differences, which could account for excess lung cancers observed among general hands. No adjustment for healthy worker effect.
Säverin et al. (1999).	Underground potash miners.	5,536	1970–94	Quantitative, based on TC measurements & detailed job history.		RR = 2.17 for highest compared to least exposed categories. RR = 1.03 to 1.225 per mg-yr/m^3, depending on statistical model & inclusion criteria.		Based on routine measurements, miners determined to have had no occupational exposure to radon progeny. Authors judged asbestos exposure minor, with negligible effects. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Schenker et al. (1984).	Railroad workers	2,519	1967–79	Job histories, with exposure classified as unexposed, high, low, or undefined.		RR = 1.50 for low exposure subgroup. RR = 2.77 for high exposure subgroup.		Risk relative to unexposed subgroup. Jobs considered to have similar socioeconomic status. Differences in smoking calculated to be insufficient to explain findings. Possible confounding by asbestos exposure.
Waller (1981)	Bus workers	16,828 Est. from manyears at risk.	1950–74	Occupation only		SMR = 0.79 for overall cohort.		Lung cancers occurring after retirement or resignation from London Transport Authority were not counted. No adjustment for healthy worker effect.
Waxweiler et al. (1973).	Potash miners	3,886	1941–67	Miners classified as underground or surface.		SMR = 1.1 for both underground and surface miners.		No adjustment for healthy worker effect. SMR based on national lung cancer mortality, which is about 1/3 higher than lung cancer mortality rate in New Mexico, where miners resided. Authors judged this to be balanced by smoking among miners. A substantial percentage of the underground subgroup may have had little or no occupational exposure to diesel exhaust.
Wong et al. (1973)	Heavy equipment operators.	34,156	1964–78	Job histories, latency, & years of union membership.		SMR = 0.99 for overall cohort. SMR = 1.07 for ≥20 yr member SMR = 1.12 for ≥20 yr. latency. SMR = 1.30 for 4,075 "normal" retirees.	(*)	Increasing trend in SMR with latency and (up to 15 yr) with duration of union membership. No adjustment for healthy worker effect.
						SMR = 3.43 for "high exposure" dozer operators with 15–19 yr union membership & ≥20 yr latency.	(*)	

[a] RR = Relative Risk; SMR = Standardized Mortality Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.
[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
Benhamou et al. (1988).	Histologically confirmed lung cancers.	Non-tobacco released diseases.	1,625	3,091	Occupational history by questionnaire.	√	sex, age at diagnosis, hospital, interviewer.	RR=2.14 for miners.	(*)	Mine type not reported.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
								RR=1.42 for professional drivers.	(*)	No evidence of an increase in risk with duration of exposure.
Boffetta et al. (1990).	Hospitalized males with histologically confirmed lung cancer.	Hospitalized males with no tobacco related disease.	2,584	5,099	Occupation classified by probability of diesel exposure.	√	Sex, age within 2 yr, hospital, year of interview.	OR=0.95 for 13 jobs with probable exposure. OR=1.49 for more than 30 yr in "probable" jobs.		Adjusted for race, asbestos exposure, education, & number of cigarettes per day.
Do			477	846	Occupational history & duration of diesel exposure by interview.	√	......do	OR=1.21 for any self-reported diesel exposure. OR=2.39 for more than 30 yr of self-reported diesel exposure..		
Brüske-Hohlfeld et al. (1999).	Cytologically and/or histologically confirmed lung cancers.	Randomly selected from compulsory registries of residents.	3,498	3,541	Occupational history by interview; total duration of diesel exposure compiled from individual job episodes.	√	Sex, age, region of residence.	OR=1.43 for any occupational diesel exposure during lifetime. OR=1.56 for West German professional drivers post-1955. OR=2.88 for > 20 yr in "traffic-related" jobs other than driving. OR=6.81 for > 30 yr as full-time driver of farm tractors. OR=4.30 for > 20 yr as heavy equipment operator.	(*) (*) (*) (*) (*)	Adjusted for cumulative smoking & asbestos exposure. All interviews conducted directly with cases and controls. Lack of elevated risk for East German professional drivers attributed to relatively low traffic density & low proportion of vehicles with diesel engines in East Germany. Non-driving "traffic-related jobs" include switchmen & operators of diesel locomotives & forklifts.
Buiatti et al. (1985).	Histologically confirmed lung cancers.	Patients at same hospital.	376	892	Occupational history from interview.	√	Sex, age, admission date.	OR=1.8 for taxi drivers.		Adjusted for current and past smoking patterns and for asbestos exposure.
Coggon et al. (1984).	Lung cancer deaths of males under 40.	Deaths from other causes in males under 40.	598	1,180	Occupation from death certificate, classified as high, low, or no diesel exposure.		Sex, death year, region, and birth year (approx.).	RR=1.3 for all jobs with diesel exposure. RR=1.1 for jobs classified as high exposure.	(*)	Only most recent full-time occupation recorded on death certificate.
Damber & Larsson (1985).	Male patients with lung cancer.	One living and one deceased without lung cancer.	604	1,071	Job, with tenure, from mailed questionnaire.	√	Sex, death year, age, municipality.	RR=1.9 for nonsmoking truck drivers aged <70 yr. RR=4.5 for nonsmoking truck drivers aged ≥70 yr.	(*)	Ex-smokers who did not smoke for at least last 10 years included with non-smokers.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
DeCoufle et al. (1997).	Male patients with lung cancer.	Non-neoplastic disease patients.	6,434	([c])	Occupation only, from questionnaire.	√	Unmatched	RR=0.92 for bus, taxi, and truck drivers. RR=0.94 for locomotive engineers.		Selected occupation compared to clerical workers. Positive associations found before smoking adjustment.
Emmelin et al. (1993).	Deaths from primary lung cancer among dock workers.	Dock workers without lung cancer.	50	154	Semi-quantitative from work history & records of diesel fuel usage.	√	Date of birth, port, and survival to within 2 years of case's diagnosis of lung cancer.	RR = 1.6 for "medium" duration of exposure.. RR = 2.9 for "high" duration of exposure.		Increasing relative risk also observed using exposure estimates based on machine usage & diesel fuel consumption. Confounding from asbestos may be significant.
Garshick et al. (1987).	Deaths with primary lung cancer among railroad workers.	Deaths from other than cancer, suicide, accidents, or unknown causes.	1,256	2,385	Job history and tenure combined with current exposure levels measured for each job.	√	Date of birth and death.	RR = 1.41 for 20+ diesel-years in workers aged ≤ 64 yr.. RR = 0.91 for 20+ diesel-years in workers aged ≥ 65 yr.	(*)	Adjusted for asbestos exposure. Older workers had relatively short diesel exposure, or none.
Gustavsson et al. (1990).	Deaths from lung cancer among bus garage workers.	Non-cases within cohort mortality study.	20	120	Semi-quantitative based on job, tenure, & exposure class for each job.		Born within two years of case.	RR = 1.34, 1.81, and 2.43 for increasing cumulative diesel exposure categories, relative to lowest exposure category.	(*)	Authors judged smoking habits to be similar for different exposure categories. RR did not increase with increasing asbestos exposure.
Hall & Wynder (1984).	Hospitalized males with lung cancer.	Hospitalized males with no tobacco-related diseases.	502	502	Usual occupation by interview.	√	Age, race, hospital, and hospital room status.	RR = 1.4 for jobs with diesel exposure.. RR = 1.9 for heavy equipment operators & repairmen.		Confounding with other occupational exposures possible.
Hayes et al. (1989).	Lung cancer deaths pooled from 3 studies.	Various—lung disease excluded.	2,291	2,570	Occupational history by interview.	√	Sex, age, and either race or area of residence.	OR = 1.5 for ≥ 10 yr truck driving. OR = 2.1 for ≥ 10 yr operating heavy equipment. OR = 1.7 for ≥ 10 yr bus driving.	(*)	OR adjusted for birth-year cohort and state of residence (FL, NJ, or LA), in addition to average cigarette use. Smaller OR for < 10 yr in these jobs.
Lerchen et al. (1987).	New Mexico residents with lung cancer.	Medicare recipients.	506	771	Occupational history, industry, & self-reported exposure, by interview.	√	Sex, age, ethnicity.	OR = 0.6 for ≥ 1 yr occupational exposure to diesel exhaust.. OR = 2.1 for underground non-uranium mining.		Small number of cases and controls in diesel-exposed jobs. Possibly insufficient exposure duration. Not matched on date of birth or death.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching: Smk.	Matching: Additional	Findings [a]	Stat. sig.[b]	Comments
Milne et al. (1983).	Lung cancer deaths.	Deaths from any other cancer.	925	6,565	Occupation from death certificate.		None	OR = 3.5 for bus drivers. OR = 1.6 for truck drivers.	(*)	Inadequate latency allowance.
Morabia et al. (1992).	Male lung cancer patients.	Patients without lung cancer or other tobacco-related condition.	1,793	3,228	Job, with coal and asbestos exposure durations, by interview.	√	Race, age, hospital, and smoking history.	OR=2.3 for miners.. OR=1.1 for bus drivers.. OR=1.0 for truck or tractor drivers.		Mine type not specified. Potential confounding by other occupational exposures for miners.
Pfluger and Minder (1994).	Professional drivers.	Workers in occupational categories with no known excess lung cancer risk.	284	1,301	Occupation only, from death certificate.		None	OR=1.48 for professional drivers.	(*)	Stratified by age. Indirectly adjusted for smoking, based on smoking-rate for occupation.
Siemiatycki et al. (1988).	Squamous cell lung cancer patients by type of lung cancer.	Other cancer patients.	359	1,523	Semi-quantitative, from occupational history by interview, & exposure class for each job.	√	None	OR=1.2 for diesel exposure;. OR=2.8 for mining.		Stratified by age, socio-economic status, ethnicity, and blue- vs. white-collar job history. Examination of files indicated that most miners "were exposed to diesel exhaust for short periods of time." Mining included quarrying, so result is likely to be confounded by silica exposure.
Steenland et al. (1990, 1992, 1998).	Deaths from lung CA among Teamsters.	Deaths other than lung or bladder cancer or motor vehicle accidents.	996	1,085	Occupational history and tenure from next-of-kin, supplemented by IH data.	√	Time of death within 2 years.	OR=1.27 for diesel truck drivers with 1–24 yr tenure.. OR=1.26 for diesel truck drivers with 25–34 yr tenure.. OR=1.89 for diesel truck drivers with ≥35 yr tenure.. OR=1.50 for truck mechanics with ≥18 yr tenure after 1959.	(*)	Years of tenure not necessarily all at main job (i.e., diesel truck driver). OR adjusted for asbestos exposure.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings [a]	Stat. sig.[b]	Comments
						Smk.	Additional			
Swanson et al. (1993) See also Burns & Swanson (1991).	Histologically confirmed Detroit metro area lung cancers.	Colon or rectal cancer cases.	[d]3,792 [e]5,935	[d]1,966 [e]3,956	Occupational history from interview.	√	None	OR = 1.4 for heavy truck drivers with 1–9 yr tenure.		OR for truck drivers & RR workers is for white males, relative to corresponding group with < 1 yr tenure, adjusted for age at diagnosis. Pattern of increasing risk with duration of employment also reported for black male railroad workers, based on fewer cases. (1993 report).
								OR = 1.6 for heavy truck drivers with 10–19 yr tenure		
								OR = 2.5 for heavy truck drivers with ≥20 yr tenure	(*)	
								OR = 1.2 for railroad workers with 1–9 yr tenure.		
								OR = 2.5 for railroad workers with ≧10 yr tenure	(*)	
								OR = 2.98 for mining industry workers.	(*)	OR for mining machinery operators and mining is for all males, adjusted for race and age at diagnosis. Type of mining not reported. Potential confounding by.
								OR = 5.03 for mining machinery operators	(*)	
Williams et al. (1977).	Male lung cancer patients.	Other male cancer patients.	432	2,817	Main lifetime occupation from interview.	√	Sex	OR = 1.52 for male truck drivers.		Controlled for age, race, alcohol use, and socioeconomic status. Unexplained discrepancies in reported number of controls.

[a] RR = Relative Risk; OR = Odds Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.
[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.
[c] Not reported. [d] Males. [e] Total.

(i) Evaluation Criteria. Several commenters contended that MSHA paid more attention to positive studies than to negative ones and indicated that MSHA had not sufficiently explained its reasons for discounting studies they regarded as providing negative evidence. MSHA used five principal criteria to evaluate the strengths and weaknesses of the individual studies:

(1) power of the study to detect an exposure effect;
(2) composition of comparison groups;
(3) exposure assessment;
(4) statistical significance; and
(5) potential confounders.

These criteria are consistent with those proposed by the HEI Diesel Epidemiology Expert Panel (HEI, 1999). To help explain MSHA's reasons for valuing some studies over others, these five criteria will now be discussed in turn.

Power of The Study

There are several factors that contribute to a study's power, or ability to detect an increased risk of lung cancer in an exposed population. First is the study's size—i.e., the number of subjects in a cohort or the number of lung cancer cases in a case-control study. If few subjects or cases are included, then any statistical relationships are likely to go undetected. Second is the duration and intensity of exposure among members of the exposed group. The greater the exposure, the more likely it is that the study will detect an effect if it exists. Conversely, a study in which few members of the exposed group experienced cumulative exposures significantly greater than the background level is unlikely to detect an exposure effect. Third is the length of time the study allows for lung cancer to exhibit a statistical impact after exposure begins. This involves a latency period, which is the time required for lung cancer to develop in affected individuals, or (mainly pertaining to cohort studies) a follow-up period, which is the time allotted, including latency, for lung cancers in affected individuals to show up in the study. It is generally acknowledged that lung cancer studies should, at the very minimum, allow for a latency period of at least 10 years from the time exposure begins and that it is preferable to allow for latency periods of at least 20 years. The shorter the latency allowance, the less power the study has to detect any increased risk of lung cancer that may be associated with exposure.

As stated above, six of the 47 studies did not show positive results: One of these studies (Edling et al.) was based on a small cohort of 694 bus workers, thus having little statistical power. Three other of these studies (DeCoufle, Kaplan, and Christie) included exposed workers for whom there was an inadequate latency allowance (i.e., less than 10 years). The entire period of follow-up in the Kaplan study was 1953–1958. The Christie study was designed in such a way as to provide for neither a minimum period of exposure nor a minimum period of latency: the report covers lung cancers diagnosed only through 1992, but the ''exposed'' cohort includes workers who may have entered the work force (and thus begun their exposure) as late as Dec. 31, 1992. Such workers would not be expected to develop lung cancer during the study period. The remaining two negative studies (Bender, 1989 and Waller, 1981) appear to have been included a reasonably adequate number of exposed workers and to have allowed for an adequate latency period.

Some of the 41 positive studies also had little power, either because they included relatively few exposed workers (*e.g.,* Lerchen et al., 1987, Ahlman et al., 1991; Gustavsson et al., 1990) or an inadequate latency allowance or follow-up period (*e.g.,* Leupker and Smith (1978); Milne, 1983; Rushton et al., 1983). In those based on few exposed workers, there is a strong possibility that the positive association arose merely by chance.[30] The other studies, however, found increased prevalence of lung cancer despite the relatively short periods of latency and follow-up time involved. It should be noted that, for reasons other than lack of power, MSHA places very little weight on the Milne and Rushton studies. As mentioned in Table III–4, the Rushton study compared the cohort to the national population, with no adjustment for regional or socioeconomic differences. This may account for the excess rate of lung cancers reported for the exposed ''general hand'' job category. The Milne study did not control for potentially important ''confounding'' variables, as explained below in MSHA's discussion of that criterion.

Composition of Comparison Groups

This criterion addresses the question of how equitable is the comparison between the exposed and unexposed populations in a cohort study, or between the subjects with lung cancer (i.e., the ''cases'') and the subjects without lung cancer (i.e., the ''controls'') in a case-control study. MSHA includes bias due to confounding variables under this criterion if the groups differ systematically with respect to such factors as age or exposure to non-diesel carcinogens. For example, unless adequate adjustments are made, comparisons of underground miners to the general population may be systematically biased by the miners' greater exposure to radon gas. Confounding not built into a study's design or otherwise documented is considered potential rather than systematic and is considered under a separate criterion below. Other factors included under the present criterion are systematic (i.e., ''differential'') misclassification of those placed into the ''exposed'' and ''unexposed'' groups, selection bias, and bias due to the ''healthy worker effect.''

In several of the studies, a group identified with diesel exposure may have systematically included workers who, in fact, received little or no occupational diesel exposure. For example, a substantial percentage of the ''underground miner'' subgroup in Waxweiler et al. (1973) worked in underground mines with no diesel equipment. This would have diluted any effect of dpm exposure on the group of underground miners as a whole.[31] Similarly, the groups classified as miners in Benhamou et al. (1988), Boffetta et al. (1988), and Swanson et al. (1993) included substantial percentages of miners who were probably not occupationally exposed to diesel emissions. Potential effects of exposure misclassification are discussed further under the criterion of ''Exposure Assessment'' below.

Selection bias refers to systematic differences in characteristics of the comparison groups due to the criteria and/or methods used to select those included in the study. For example, three of the cohort studies (Raffle, 1957; Leupker and Smith, 1976; Waller, 1981) systematically excluded retirees from the cohort of exposed workers—but not from the population used for comparison. Therefore, cases of lung cancer that developed after retirement were counted against the comparison population but not against the cohort. This artificially reduced the SMR calculated for the exposed cohort in these three studies.

Another type of selection bias may occur when members of the control group in a case-control study are non-randomly selected. This happens when cases and controls are selected from the same larger population of patients or death certificates, and the controls are simply selected (prior to case matching) from the group remaining after those with lung cancer are removed. Such selection can lead to a control group that is biased with respect to occupation and smoking habits. Specifically, ''* * * a severely distorted estimate of the association between exposure to diesel exhaust and lung cancer, and a severely distorted picture of the direction and degree of confounding by cigarette smoking, can come from case-control studies in which the controls are a collection of 'other deaths' '' when the cause of most 'other deaths' is itself correlated with smoking or occupational choice (HEI, 1999). This selection bias can distort results in either direction.

MSHA judged that seven of the 20 available case-control studies were susceptible to this type of selection bias because controls were drawn from a population of ''other deaths'' or ''other patients.''[32] These control groups were likely to have over-represented cases of cardiovascular disease, which is known to be highly correlated with smoking and is possibly also correlated with

[30] As noted in Table III–4, the underground sulfide ore miners studied by Ahlman et al. (1991) were exposed to radon in addition to diesel emissions. The total number of lung cancers observed, however, was greater than what was attributable to the radon exposure, based on a calculation by the authors. Therefore, the authors attributed a portion of the excess risk to diesel exposure.

[31] Furthermore, as pointed out in comments submitted by Dr. Peter Valberg through the NMA, the subgroup of underground miners working at mines with diesel engines was small, and the exposure duration in one of the mines with diesel engines was only ten years. Therefore, the power of the study was inadequate to detect an excess risk of lung cancer for that subgroup by itself.

[32] These were: Buiatti et al. (1985), Coggan et al. (1984), DeCoufle et al. (1977), Garshick et al. (1987), Hayes et al. (1989), Lerchen et al. (1987), and Steenland et al. (1990).

occupation. The only case-control study not reporting a positive result (DeCoufle et al., 1977) fell into this group of seven. The remaining 13 case-control studies all reported positive results.

It is ''well established that persons in the work force tend to be 'healthier' than persons not employed, and therefore healthier than the general population. Worker mortality tends to be below average for all major causes of death.'' (HEI, 1999) Because workers tend to be healthier than non-workers, the prevalence of disease found among workers exposed to a toxic substance may be lower than the rate prevailing in the general population, but higher than the rate occurring in an unexposed population of similar workers. This phenomenon is called the ''healthy worker effect.''

All five cohort studies reporting entirely negative results drew comparisons against the general population and made no adjustments to take the healthy worker effect into account. (Kaplan, 1959; Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995). The sixth negative study (DeCoufle, 1977) was a case-control study in which vehicle drivers and locomotive engineers were compared to clerical workers. As mentioned earlier, this study did not meet the criterion for a minimum 10-year latency period. All other studies in which exposed workers were compared against similar but unexposed workers reported some degree of elevated lung cancer risk for exposed workers.

Many of the 41 positive studies also drew comparisons against the general population with no compensating adjustment for the healthy worker effect. But the healthy worker effect can influence results even when the age-adjusted mortality or morbidity rate observed among exposed workers is greater than that found in the general population. In such studies, comparison with the general population tends to reduce the excess risk attributable to the substance being investigated. For example, Gustafsson et al. (1986), Rushton et al. (1983), and Wong et al. (1985) each reported an unadjusted SMR exceeding 1.0 for lung cancer in exposed workers and an SMR significantly less than 1.0 for all causes of death combined. Since the SMR for all causes is less than 1.0, there is evidence of a healthy worker effect. Therefore, the SMR reported for lung cancer was probably lower than if the comparison had been made against a more similar population of unexposed workers. Bhatia et al. (1998) constructed a simple estimate of the healthy worker effect evident in these studies, based on the SMR for all causes of death except lung cancer. This estimate was then used to adjust the SMR reported for lung cancer. For the three positive studies mentioned, the adjustment raised the SMR from 1.29 to 1.48, from 1.01 to 1.23, and from 1.07 to 1.34, respectively.[33]

Exposure Assessment

Many commenters suggested that a lack of concurrent exposure measurements in available studies limits their utility for quantitative risk assessment (QRA). MSHA is fully aware of these limitations but also recognizes that less desirable surrogates of exposure must frequently be employed out of practical necessity. As stated by HEI's expert panel on diesel epidemiology:

> Quantitative measures of exposures are important in any epidemiologic study used for QRA. The greater the detail regarding specific exposure, including how much, for how long, and at what concentration, the more useful the study is for this purpose. Frequently, however, individual measurements are not available, and surrogate measures or markers are used. For example, the most general surrogate measures of exposure in occupational epidemiologic studies are job classification and work location. (HEI, 1999)

It is important to distinguish, moreover, between studies used to identify a hazard (i.e., to establish that dpm exposure is associated with an excess risk of lung cancer) and studies used for QRA (i.e., to quantify the amount of excess risk corresponding to a given level of exposure). Although detailed exposure measurements are desirable in any epidemiologic study, they are more important for QRA than for identifying and characterizing a hazard. Conversely, epidemiologic studies can be highly useful for purposes of hazard identification and characterization even if a lack of personal exposure measurements renders them less than ideal for QRA.

Still, MSHA agrees that the quality of exposure assessment affects the value of a study for even hazard identification. Accordingly, MSHA has divided the 47 studies into four categories, depending on the degree to which exposures were quantified for the specific workers included. This ranking refers only to exposure assessment and does not necessarily correspond to the overall weight MSHA places on any of the studies.

The highest rank, with respect to this criterion, is reserved for studies having quantitative, concurrent exposure measurements for specific workers or for specific jobs coupled with detailed work histories. Only two studies (Johnston et al., 1997 and Säverin et al., 1999) fall into this category.[34] Both of these recent cohort studies took smoking habits into account. These studies both reported an excess risk of lung cancer associated with dpm exposure.

The second rank is defined by semi-quantitative exposure assessments, based on job history and an estimated exposure level for each job. The exposure estimates in these studies are crude, compared to those in the first rank, and they are subject to many more kinds of error. This severely restricts the utility of these studies for QRA (i.e., for quantifying the change in risk associated with various specified exposure levels). For purposes of hazard identification and characterization, however, crude exposure estimates are better than no exposure estimates at all. MSHA places two cohort studies and five case-control studies into this category.[35] All seven of these studies reported an excess risk of lung cancer risk associated with diesel exposure. Thus, results were positive in all nine studies with quantitative or semi-quantitative exposure assessments.

The next rank belongs to those studies with only enough information on individual workers to construct estimates of exposure duration. Although these studies present no data relating excess risk to specific exposure levels, they do provide excess risk estimates for those working a specified minimum number of years in a job associated with diesel exposure. One cohort study and five case-control studies fall into this category, and all six of them reported an excess risk of lung cancer.[36] With one exception

[33] A similar adjustment was applied to the SMR for lung cancer reported in one of the negative studies (Edling et al., 1987). This raised the SMR from 0.67 to 0.80. Because of insufficient data, Bhatia et al. did not carry out the adjustment for the three other studies they considered with potentially important healthy worker effects. (Bhatia et al., 1998)

[34] The study of German potash miners by Säverin et al. was introduced by NIOSH at the Knoxville public hearing prior to publication. The study, as cited, was later published in English. Although the dpm measurements (total carbon) were all made in one year, the authors provide a justification for assuming that the mining technology and type of machinery used did not change substantially during the period miners were exposed (ibid., p.420).

[35] The cohort studies are Garshick et al. (1988) and Gustavsson et al. (1990). The case-control studies are Emmelin et al. (1993), Garshick et al. (1997), Gustavsson et al. (1990), Siemiatycki et al. (1988), and Steenland et al. (1990, 1992).

[36] The cohort study is Wong et al. (1985). The case-control studies are Brüske-Hohlfeld et al. (1999), Benhamou et al. (1988), Boffetta et al. (1990), Hayes et al. (1989), and Swanson et al. (1993).

(Benhamou et al. 1988), these studies also presented evidence of increased age-adjusted risk for workers with longer exposures and/or latency periods.

The bottom rank, with respect to exposure assessment, consists of studies in which no exposure information was collected for individual workers. These studies used only job title to distinguish between exposed and unexposed workers. The remaining 32 studies, including five of the six with entirely negative results, fall into this category.

Studies basing exposure assessments on only a current job title (or even a history of job titles) are susceptible to significant misclassification of exposed and unexposed workers. Unless the study is poorly designed, this misclassification is ''nondifferential''—i.e., those who are misclassified are no more and no less likely to develop lung cancer (or to have been exposed to carcinogens such as tobacco smoke) than those who are correctly classified. If workers are sometimes misclassified nondifferentially, then this will tend to mask or dilute any excess risk attributable to exposure. Furthermore, differential misclassification in these studies usually consists of systematically including workers with little or no diesel exposure in a job category identified as ''exposed.'' This too would generally mask or dilute any excess risk attributable to exposure. Therefore, MSHA assumes that in most of these studies, more rigorous and detailed exposure assessments would have resulted in somewhat higher estimates of excess risk.

IMC Global, MARG, and some other commenters expressed special concern about potential exposure misclassification and suggested that such misclassification might be partly responsible for results showing excess risk. IMC Global, for example, quoted a textbook observation that, contrary to popular misconceptions, nondifferential exposure misclassification can sometimes bias results away from the null. MSHA recognizes that this can happen under certain special conditions. However, there is an important distinction between ''can sometimes'' and ''can frequently.'' There is an even more important distinction between ''can sometimes'' and ''in this case does.'' As noted by the HEI Expert Panel on Diesel Epidemiology (HEI, 1999, p. 48), ''* * * nondifferential misclassification most often leads to an overall underestimation of effect.'' Similarly, Silverman (1998) noted, specifically with respect to the diesel studies, that ''* * * this [exposure misclassification] bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates [of excess risk] toward the null value.''

Statistical Significance

A ''statistically significant'' finding is a finding unlikely to have arisen by chance in the particular group, or statistical sample, of persons being studied. An association arising by chance would have no predictive value for exposed workers outside the sample. However, a specific epidemiologic study may fail to achieve statistical significance for two very different reasons: (1) there may be no real difference in risk between the two groups being compared, or (2) the study may lack the power needed to detect whatever difference actually exists. As described earlier, a lack of sufficient power comes largely from limitations such as a small number of subjects in the sample, low exposure and/or duration of exposure, or too short a period of latency or follow-up time. Therefore, a lack of statistical significance in an individual study does not demonstrate that the results of that study were due merely to chance—only that the study (viewed in isolation) is statistically inconclusive.

As explained earlier, MSHA classifies a reported RR, SMR, or OR (*i.e.,* the point estimate of relative risk) as ''positive'' if it exceeds 1.0 and ''negative'' if it is less than or equal to 1.0. By common convention, a positive result is considered statistically significant if its 95-percent confidence interval does not overlap 1.0. If all other relevant factors are equal, then a statistically significant positive result provides stronger evidence of an underlying relationship than one that is not statistically significant. On the other hand, a study must meet two requirements in order to provide statistically significant evidence of no positive relationship: (1) the upper limit of its 95-percent confidence interval must not exceed 1.0 by an appreciable amount [37] and (2) it must have allowed for sufficient exposure, latency, and follow-up time to have detected an existing relationship.

As shown in Tables III–4 and III–5, statistically significant positive results were reported in 25 of the 47 studies: 11 of the 19 positive case-control studies and 14 of the 22 positive cohort studies. In 16 of the 41 studies showing a positive association, the association observed was not statistically significant. Results in five of the six negative studies were not statistically significant. One of the six negative studies (Christie *et al.,* 1995, in full version), reported a statistically significant deficit in lung cancer for miners. This study, however, provided for no minimum period of exposure or latency and, therefore, lacked the power necessary to provide statistically significant evidence.[38]

Whether or not a study provides statistically significant evidence is dependent upon many variables, such as study size, adequate follow-up time (to account for enough exposure and latency), and adequate case ascertainment. In the ideal world, a sufficiently powerful study that failed to demonstrate a statistically significant positive relationship would, by its very failure, provide statistically significant evidence that an underlying relationship between an exposure and a specific disease was unlikely. It is important to note that MSHA regards a real 10-percent increase in the risk of lung cancer (*i.e.,* a relative risk of 1.1) as constituting a clearly significant health hazard. Therefore, ''sufficiently powerful'' in this context means that the study would have to be of such scale and quality as to detect a 10-percent increase in risk if it existed. The outcome of such a study could plausibly be called ''negative'' even if the estimated RR slightly exceeded 1.0—so long as the lower confidence limit did not exceed 1.0 and the upper confidence limit did not exceed 1.05. Rarely does an epidemiological study fall into this ''ideal'' study category. MSHA reviewed the dpm epidemiologic studies to determine which of them could plausibly be considered to be negative.

For example, one study (Waxweiller *et al.,* 1973) reported positive but statistically non-significant results corresponding to an RR of about 1.1. Among the studies MSHA counts as positive, this is the one that is numerically closest to being ''negative''. This study, however, relied on a relatively small cohort containing an indeterminate but probably substantial percentage of occupationally unexposed workers. Furthermore, there was no minimum latency allowance for the exposed workers. Therefore, even if MSHA were to use 1.1 rather than 1.05 as a threshold for significant relative risk, the study had insufficient statistical power to merit ''negative'' status.

One commenter (Dr. James Weeks, representing the UMWA) argued that ''MSHA's reliance on * * * statistical

[37] As a matter of practicality, MSHA places the threshold at 1.05.

[38] More detailed discussion of this study appears later in this subsection.

significance is somewhat misplaced. Results that are not significant statistically * * * can nevertheless indicate that the exposure in question caused the outcome.'' MSHA agrees that an otherwise sound study may yield positive (or negative) results that provide valuable evidence for (or against) an underlying relationship but fail, because of an insufficient number of exposed study subjects, to achieve statistical significance. In the absence of other evidence to the contrary, a single positive but not statistically significant result could even show that a causal relationship is more likely than not. By definition, however, such a result would not be conclusive at a high level of confidence. A finding of even very high excess risk in a single, well-designed study would be far from conclusive if based on a very small number of observed lung cancer cases or if it were in conflict with evidence from toxicity studies.

MSHA agrees that evidence should not be ignored simply because it is not conclusive at a conventional but arbitrary 95-percent confidence level. Lower confidence levels may represent weaker but still important evidence. Nevertheless, to rule out chance effects, the statistical significance of individual studies merits serious consideration when only a few studies are available. That is not the case, however, for the epidemiology literature relating lung cancer to diesel exposure. Since many studies contribute to the overall weight of evidence, the statistical significance of individual studies is far less important than the statistical significance of all findings combined. Statistical significance of the combined findings is addressed in Subsection 3.a.iii of this risk assessment.

Potential Confounders

There are many variables, both known and unknown, that can potentially distort the results of an epidemiologic study. In studies involving lung cancer, the most important example is tobacco smoking. Smoking is highly correlated with the development of lung cancer. If the exposed workers in a study tend to smoke more (or less) than the population to which they are being compared, then smoking becomes what is called a ''confounding variable'' or ''confounder'' for the study. In general, any variable affecting the risk of lung cancer potentially confounds observed relationships between lung cancer and diesel exposure. Conspicuous examples are age, smoking habits, and exposure to airborne carcinogens such as asbestos or radon progeny. Diet and other lifestyle factors may also be potential confounders, but these are probably less important for lung cancer than for other forms of cancer, such as bladder cancer.

There are two ways to avoid distortion of study results by a potential confounder: (1) design the study so that the populations being compared are essentially equivalent with respect to the potentially confounding variable; or (2) allow the confounding to take place, but adjust the results to compensate for its effects. Obviously, the second approach can be applied only to known confounders. Since no adjustment can be made for unknown confounders, it is important to minimize their effects by designing the comparison groups to be as similar as possible.

The first approach requires a high degree of control over the two groups being compared (exposed and unexposed in a cohort study; with and without lung cancer in a case-control study). For example, the effects of age in a case-control study can be controlled by matching each case of lung cancer with one or more controls having the same year of birth and age in year of diagnosis or death. Matching on age is never perfect, because it is generally not feasible to match within a day or even a month. Similarly, the effects of smoking in a case-control study can be imperfectly controlled by matching on smoking habits to the maximum extent possible.[39] In a cohort study, there is no confounding unless the exposed cohort and the comparison group differ with respect to a potential confounder. For example, if both groups consist entirely of never-smokers, then smoking is not a confounder in the study. If both groups contain the same percentage of smokers, then smoking is still an important confounder to the extent that smoking intensity and history differ between the two groups. In an attempt to minimize such differences (along with potentially important differences in diet and lifestyle) some studies restrict comparisons to workers of similar socioeconomic status and area of residence. Studies may also explicitly investigate smoking habits and histories and forego any adjustment of results if these factors are found to be homogeneously distributed across comparison groups. In that case, smoking would not actually appear to function as a confounder, and a smoking adjustment might not be required or even desirable. Nevertheless, a certain amount of smoking data is still necessary in order to check or verify homogeneity. The study's credibility may also be an important consideration. Therefore, MSHA agrees with the HEI's expert panel that even when smoking appears not to be a confounder,

> * * * a study is open to criticism if no smoking data are collected and the association between exposure and outcome is weak. * * * When the magnitude of the association of interest is weak, uncontrolled confounding, particularly from a strong confounder such as cigarette smoking, can have a major impact on the study's results and on the credibility of their use. [HEI, 1999]

However, this does not mean that a study cannot, by means of an efficient study design and/or statistical verification of homogeneity, demonstrate adequate control for smoking without applying a smoking adjustment.

The second approach to dealing with a confounder requires knowledge or estimation both of the differences in group composition with respect to the confounder and of the effect that the confounder has on lung cancer. Ideally, this would entail specific, quantitative knowledge of how the variable affects lung cancer risk for each member of both groups being compared. For example, a standardized mortality ratio (SMR) can be used to adjust for age differences when a cohort of exposed workers with known birth dates is compared to an unexposed reference population with known, age-dependent lung cancer rates.[40] In practice, it is not usually possible to obtain detailed information, and the effects of smoking and other known confounders cannot be precisely quantified.

Stöober and Abel (1996) argue, along with Morgan *et al.* (1997) and some commenters, that even in those epidemiologic studies that are adjusted for smoking and show a statistically significant association, the magnitude of relative or excess risk observed is too small to demonstrate any causal link between dpm exposure and cancer. Their reasoning is that in these studies, errors in the collection or interpretation of smoking data can create a bias in the results larger than any potential contribution attributable to diesel particulate. They propose that studies

[39] If cases and controls cannot be closely matched on smoking or other potentially important confounder, then a hybrid approach is often taken. Cases and controls are matched as closely as possible, differences are quantified, and the study results are adjusted to account for the differences.

[40] Since these rates may vary by race, geographic region, or other factors, the validity of this adjustment depends heavily on choice of an appropriate reference population. For example, Waxweiler *et al.* (1973) based SMRs for a New Mexico cohort on national lung cancer mortality rates. Since the national age-adjusted rate of lung cancer is about 1/3 higher than the New Mexico rate, the reported SMRs were roughly 3/4 of what they would have been if based on rates specific to New Mexico.

failing to account for smoking habits should be disqualified from consideration, and that evidence of an association from the remaining, smoking-adjusted studies should be discounted because of potential confounding due to erroneous, incomplete, or otherwise inadequate characterization of smoking histories.

It should be noted, first of all, that five of the six negative studies neither matched nor adjusted for smoking.[41] But more importantly, MSHA concurs with IARC (1989), Cohen and Higgins (1995), IPCS (1996), CAL–EPA (1998), ACGIH (1998), Bhatia *et al.* (1998), and Lipsett and Campleman (1999) in not accepting the view that studies should automatically be disqualified from consideration because of potential confounders. MSHA recognizes that unknown exposures to tobacco smoke or other human carcinogens can distort the results of some lung cancer studies. MSHA also recognizes, however, that it is not possible to design a human epidemiologic study that perfectly controls for all potential confounders. It is also important to note that a confounding variable does not necessarily inflate an observed association. For example, if the exposed members of a cohort smoke less than the reference group to which they are compared, then this will tend to reduce the apparent effects of exposure on lung cancer development. In the absence of evidence to the contrary, it is reasonable to assume that a confounder is equally likely to inflate or to deflate the results.

As shown in Tables III–4 and III–5, 18 of the published epidemiologic studies involving lung cancer did, in fact, control or adjust for exposure to tobacco smoke, and five of these 18 also controlled or adjusted for exposure to asbestos and other carcinogenic substances (Garshick *et al.*, 1987; Boffetta *et al.*, 1988; Steenland *et al.*, 1990; Morabia *et al.*, 1992; Brüske-Hohlfeld *et al.*, 1999). These results are less likely to be confounded than results from most of the studies with no adjustment. All but one of these 18 studies reported some degree of excess risk associated with occupational exposure to diesel particulate, with statistically significant results reported in eight.

In addition, several of the studies with no smoking adjustment took the first approach described above for preventing or substantially mitigating potential confounding by smoking habits: they drew comparisons against internal control groups or other control groups likely to have similar smoking habits as the exposed groups (*e.g.,* Garshick *et al.*, 1988; Gustavsson *et al.*, 1990; Hansen, 1993; and Säverin *et al.*, 1999). Therefore, MSHA places more weight on these studies than on studies drawing comparisons against dissimilar groups with no smoking controls or adjustments. This emphasis is in accordance with the conclusion by Bhatia *et al.* (1998) that smoking homogeneity typically exists within cohorts and is associated with a uniform lifestyle and social class. Although it was not yet available at the time Bhatia *et al.* performed their analysis, an analysis of smoking patterns by Säverin *et al.* (op cit.) within the cohort they studied also supports this conclusion.

IMC Global and MARG objected to MSHA's position on potential confounders and submitted comments in general agreement with the views of Morgan *et al.* (op cit.) and Stöbel and Abel (op cit.). Specifically, they suggested that studies reporting relative risks solely between 1.0 and 2.0 should be discounted because of potential confounders. Of the 41 positive studies considered by MSHA, 22 fall into this category (16 cohort and 6 case-control). In support of their suggestion, IMC Global quoted Speizer (1986), Muscat and Wynder (1995), Lee (1989), WHO (1980), and NCI (1994). These authorities all urged great caution when interpreting the results of such studies, because of potential confounders. MSHA agrees that none of these studies, considered individually, is conclusive and that each result must be considered with due caution. None of the quoted authorities, however, proposed that such studies should automatically be counted as ''negative'' or that they could not add incrementally to an aggregate body of positive evidence.

IMC Global also submitted the following reference to two Federal Court decisions pertaining to estimated relative risks less than 2.0:

> The Ninth Circuit concluded in Daubert v. Merrell Dow Pharmaceuticals'' that ''for an epidemiologic study to show causation * * * the relative risk * * * arising from the epidemiologic data will, at a minimum, have to exceed 2.'' Similarly, a District Court stated in Hall v. Baxter Healthcare Corp. 49: The threshold for concluding that an agent was more likely the cause of the disease than not is relative risk greater than 2.0. Recall that a relative risk of 1.0 means that the agent has no affect on the incidence of disease. When the relative risk reaches 2.0. the agent is responsible for an equal number of cases of disease as all other background causes. Thus a relative risk of 2.0 implies a 50% likelihood that an exposed individual's disease was caused by the agent. [IMC Global]

In contrast with the two cases cited, the purpose of this risk assessment is not to establish civil liabilities for personal injury. MSHA's concern is with reducing the risk of lung cancer, not with establishing the specific cause of lung cancer for an individual miner. The excess risk of an outcome, given an excessive exposure, is not the same thing as the likelihood that an excessive exposure caused the outcome in a given case. To understand the difference, it may be helpful to consider two analogies: (1) The likelihood that a given death was caused by a lightning strike is relatively low, yet exposure to lightning is rather hazardous; (2) a specific smoker may not be able to prove that his or her lung cancer was ''more likely than not'' caused by radon exposure, yet radon exposure significantly increases the risk—especially for smokers. Lung cancer has a variety of alternative causes, but this fact does not reduce the risk associated with any one of them.

Furthermore, there is ample precedent for utilizing epidemiologic studies reporting relative risks less than 2.0 in making clinical and public policy decisions. For example, the following table contains the RR for death from cardiovascular disease associated with cigarette smoking reported in several prospective epidemiologic studies:

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[41] The exception is DeCoufle *et al.* (1977), a case-control study that apparently did not match or otherwise adjust for age.

Study on cigarette smoking	Estimate of RR of death from cardiovascular disease
British doctors	1.6
Males in 25 states	
ages 45-64	2.08
ages 65-79	1.36
U.S. Veterans	1.74
Japanese study	1.96
Canadian veterans	1.6
Males in nine states	1.70
Swedish males	1.7
Swedish females	1.3
California occupations	2.0

Source: U.S. Department of Health and Human Services (1989)

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By IMC Global's rule of thumb, all but one or two of these studies would be discounted as evidence of increased risk attributable to smoking. These studies, however, have not been widely discounted by scientific authorities. To the contrary, they have been instrumental in establishing that cigarette smoking is a principal cause of heart disease.

A second example is provided by the increased risk of lung cancer found to be caused by residential exposure to radon progeny. As in the case of dpm, tobacco smoking has been an important potential confounder in epidemiological studies used to investigate whether exposures to radon concentrations at residential levels can cause lung cancer. Yet, in the eight largest residential epidemiological studies used to help establish the reality of this now widely accepted risk, the reported relative risks were all less than 2.0. Based on a meta-analysis of these eight studies, the combined relative risk of lung cancer attributable to residential radon exposure was 1.14. This elevation in the risk of lung cancer, though smaller than that reported in most studies of dpm effects, was found to be statistically significant at a 95-percent confidence level (National Research Council, 1999, Table G–25).

(ii) Studies Involving Miners. In the proposed risk assessment, MSHA identified seven epidemiologic studies reporting an excess risk of lung cancer among miners thought to have been exposed occupationally to diesel exhaust. As stated in the proposal, two of these studies specifically investigated miners, and the other five treated miners as a subgroup within a larger population of workers.[42] MSHA placed two additional studies specific to exposed coal miners (Christie *et al.,* 1995; Johnston *et al.,* 1997) into the public record with its Feb. 12, 1999 **Federal Register** notice. Another study,[43] investigating lung cancer in exposed potash miners, was introduced by NIOSH at the Knoxville public hearing on May 27, 1999 and later published as Säverin *et al.,* 1999. Finally, one study reporting an excess risk of lung cancer for presumably exposed miners was listed in Table III–5 as originally published, and considered by MSHA in its overall assessment, but inadvertently left out of the discussion on studies involving miners in the previous version of this risk assessment.[44] There are, therefore, available to MSHA a total of 11 epidemiologic studies addressing the risk of lung cancer for miners, and five of these studies are specific to miners.

Five cohort studies (Waxweiler *et al.,* 1973; Ahlman *et al.,* 1991; Christie *et al.,* 1996; Johnston *et al.,* 1997; Säverin *et al.,* 1999) were performed specifically on groups of miners, and one (Boffetta *et al.,* 1988) addressed miners as a subgroup of a larger population. Except for the study by Christie *et al.,* the cohort studies all showed elevated lung cancer rates for miners in general or for the most highly exposed miners within a cohort. In addition, all five case-control studies reported elevated rates of lung cancer for miners (Benhamou *et al.,* 1988; Lerchen *et al.,* 1987; Siemiatycki *et al.,* 1988; Morabia *et al.,* 1992; Burns and Swanson, 1991).

Despite the risk assessment's emphasis on human studies, some members of the mining community apparently believed that the risk assessment relied primarily on animal studies and that this was because studies on miners were unavailable. Canyon Fuels, for example, expressed concerns about relying on animal studies instead of studies on western diesel-exposed miners:

> Since there are over a thousand miners here in the West that have fifteen or more years of exposure to diesel exhaust, why has there been no study of the health status of those miners? Why must we rely on animal studies that are questionable and inconclusive?

Actually, western miners were involved in several studies of health effects other than cancer, as described earlier in this risk assessment. With respect to lung cancer, there are many reasons why workers from a particular group of mines might not be selected for study. Lung cancer often takes considerably more than 15 years to develop, and a valid study must allow not only for adequate duration of exposure but also for an adequate period of latency following exposure. Furthermore, many mines contain radioactive gases and/or respirable silica dust, making it difficult to isolate the effects of a potential carcinogen.

Similarly, at the public hearing in Albuquerque on May 13, 1999, a representative of Getchell Gold stated that he thought comparing miners to rats was irrational and that ''there has not been a study on these miners as to what the effects are.'' To correct the impression that MSHA was basing its risk assessment primarily on laboratory animal studies, an MSHA panelist pointed out Tables III–4 and III–5 of the proposed preamble and identified six studies pertaining to miners that were listed in those tables. However, he placed no special weight on these studies and cited them only to illustrate the existence of epidemiologic studies reporting an elevated risk of lung cancer among miners.

With their post-hearing comments, the NMA and MARG submitted critiques by Dr. Peter Valberg and Dr. Jonathan Borak of six reports involving miners (see Footnote 42). Drs. Valberg and Borak both noted that the six studies reviewed lacked information on diesel exposure and were vulnerable to confounders and exposure misclassification. For these reasons, Dr. Valberg judged them ''particularly poor in identifying what specific role, if any, diesel exhaust plays in lung cancer for miners.'' He concluded that they do not ''implicate diesel exposure per se as

[42] In the proposed risk assessment, the studies identified as specifically investigating miners were Waxweiler *et al.* (1973) and Ahlman *et al.* (1991). At the Albuquerque public hearing, Mr. Bruce Watzman, representing the NMA, asked a member of the MSHA panel (Mr. Jon Kogut) to list six studies involving miners that he had cited earlier in the hearing and to identify those that were specific to miners. In both his response to Mr. Watzman, and in his earlier remarks, Mr. Kogut noted that the studies involving miners were listed in Tables III–4 and III–5. However, he inadvertently neglected to mention Ahlman *et al.* (op cit.) and Morabia *et al.* (1992). (The latter study addressed miners as a subgroup of a larger population.)

In his response to Mr. Watzman, Mr. Kogut cited Swanson *et al.* (1993) but not Burns and Swanson (1991), which he had mentioned earlier in the hearing in connection with the same study. These two reports are listed under a single entry in Table III–5 (Swanson *et al.*) because they both report findings based on the same body of data. Therefore, MSHA considers them to be two parts of the same study. The 5.03 odds ratio for mining machine operators mentioned by Mr. Kogut during the hearing was reported in Burns and Swanson (1991).

Only the six studies specified by Mr. Kogut in his response to Mr. Watzman were included in separate critiques by Dr. Peter Valberg and Dr. Jonathan Borak later submitted by the NMA and by MARG, respectively. Dr. Valberg did not address Burns and Swanson (1991), and he addressed a different report by Siemiatycki than the one listed in Table III–5 and cited during the hearing (*i.e.,* Siemiatycki *et al.,* 1988). Neither Dr. Valberg nor Dr. Borak addressed Ahlman *et al.* (op cit.) or Morabia *et al.* (op cit.). Also excluded were two additional miner-specific studies placed into the record on Feb. 12, 1999 (Fed. Reg. 64:29 at 59258). Mr. Kogut did not include them in his response to Mr. Watzman, or in his prior remarks, because he was referring only to studies listed in Tables III–4 and III–5 of the published proposals. Mr. Kogut also did not include a study specific to German potash miners submitted by NIOSH at a subsequent public hearing, and this too was left out of both critiques. A published version of the study (Säverin *et al.,* 1999) was placed into the record on June 30, 2000. All of the studies involving miners are in the public record and have been available for comment by interested parties throughout the posthearing comment periods.

[43] Some commenters suggested that MSHA ''overlooked'' a recently published study on NSW miners, Brown *et al.,* 1997. This study evaluated the occurrence of forms of cancer other than lung cancer in the same cohort studied by Christie *et al.* (1995).

[44] This study was published in two separate reports on the same body of data: Burns and Swanson (1991) and Swanson *et al.* (1993). Both published reports are listed in Table III–5 under the entry for Swanson *et al.*

strongly associated with lung cancer risk in miners.'' Similarly, Dr. Borak suggested that, since they do not relate adverse health effects in miners to any particular industrial exposure, ''the strongest conclusion that can be drawn from these six studies is that the miners in the studies had an increased risk of lung cancer.''

MSHA agrees with Drs. Valberg and Borak that none of the studies they reviewed provides direct evidence of a link between dpm exposure and the excess risk of lung cancer reported for miners. (A few disagreements on details of the individual studies will be discussed below). As MSHA said at the Albuquerque hearing, the lack of exposure information on miners in these studies led MSHA to rely more heavily on associations reported for other occupations. MSHA also noted the limitations of these studies in the proposed risk assessment. MSHA explicitly stated that other epidemiologic studies exist which, though not pertaining specifically to mining environments, contain better diesel exposure information and are less susceptible to confounding by extraneous risk factors.

Inconclusive as they may be on their own, however, even studies involving miners with only presumed or sporadic occupational diesel exposure can contribute something to the weight of evidence. They can do this by corroborating evidence of increased lung cancer risk for other occupations with likely diesel exposures and by providing results that are at least consistent with an increased risk of lung cancer among miners exposed to dpm. Moreover, two newer studies pertaining specifically to miners do contain dpm exposure assessments based on concurrent exposure measurements (Johnston *et al., op cit.;* Säverin *et al., op cit.*). The major limitations pointed out by Drs. Valberg and Borak with respect to other studies involving miners do not apply to these two studies.

Case-Control Studies

Five case-control studies, all of which adjusted for smoking, found elevated rates of lung cancer for miners, as shown in Table III–5. The results for miners in three of these studies (Benhamou *et al.,* 1988; Morabia *et al.,* 1992; Siemiatycki *et al.,* 1988) are given little weight, partly because of possible confounding by occupational exposure to radioactive gasses, asbestos, and silica dust. Also, Benhamou and Morabia did not verify occupational diesel exposure status for the miners. Siemiatycki performed a large number of multiple comparisons and reported that most of the miners ''were exposed to diesel exhaust for short periods of time,'' Lerchen *et al.* (1987) showed a marginally significant result for underground non-uranium miners, but cases and controls were not matched on date of birth or death, and the frequency of diesel exposure and exposure to known occupational carcinogens among these miners was not reported.

Burns and Swanson (1991)[45] reported elevated lung cancer risk for miners and especially mining machine operators, which the authors attributed to diesel exposure. Potential confounding by other carcinogens associated with mining make the results inconclusive, but the statistically significant odds ratio of 5.0 reported for mining machine operators is high enough to cause concern with respect to diesel exposures, especially in view of the significantly elevated risks reported in the same study for other diesel-exposed occupations. The authors noted that the ''occupation most likely to have high levels of continuous exposure to diesel exhaust and to experience that exposure in a confined area has the highest elevated risks: mining machine operators.''

Cohort Studies

As shown in Table III–4, MSHA identified six cohort studies reporting results for miners likely to have been exposed to dpm. An elevated risk of lung cancer was reported in five of these six studies. These results will be discussed chronologically.

Waxweiller (1973) investigated a cohort of underground and surface potash miners. The authors noted that potash ore ''is not embedded in siliceous rock'' and that the ''radon level in the air of potash mines is not significantly higher than in ambient air.'' Contrary to Dr. Valberg's review of this study, the number of lung cancer cases was reported to be slightly higher than expected, for both underground and surface miners, based on lung cancer rates in the general U.S. population (after adjustment for age, sex, race, and date of death). Although the excess was not statistically significant, the authors noted that lung cancer rates in the general population of New Mexico were about 25 percent lower than in the general U.S. population. They also noted that a higher than average percentage of the miners smoked and that this would ''tend to counterbalance'' the adjustment needed for geographic location. The authors did not, however, consider two other factors that would tend to obscure or deflate an excess risk of lung cancer, if it existed: (1) a healthy worker effect and (2) the absence of any occupational diesel exposure for a substantial percentage of the underground miners.

MSHA agrees with Dr. Valberg's conclusion that ''low statistical power and indeterminate diesel-exhaust exposure render this study inadequate for assessing the effect of diesel exhaust on lung-cancer risk in miners.'' However, given the lack of any adjustment for a healthy worker effect, and the likelihood that many of the underground miners were occupationally unexposed, MSHA views the slightly elevated risk reported in this study as consistent with other studies showing significantly greater increases in risk for exposed workers.

Boffetta *et al.* (1988) investigated mortality in a cohort of male volunteers who enrolled in a prospective study conducted by the American Cancer Society. Lung cancer mortality was analyzed in relation to self-reported diesel exhaust exposure and to employment in various occupations identified with diesel exhaust exposure, including mining. After adjusting for smoking patterns,[46] there was a statistically significant excess of 167 percent (RR = 2.67) in lung cancers among 2034 workers ever employed as miners, compared to workers never employed in occupations associated with diesel exposure. No analysis by type of mining was reported. Other findings reported from this study are discussed in the next subsection.

Although an adjustment was made for smoking patterns, the relative risk reported for mining did not control for exposures to radioactive gasses, silica dust, and asbestos. These lung carcinogens are probably present to a greater extent in mining environments than in most of the occupational environments used for comparison. Self-reported exposures to asbestos and stone dusts were taken into account in other parts of the study, but not in the calculation of excess lung cancer risks associated with specific occupations, including mining.

[45] This report is listed in Table III–5 under Swanson *et al.* (1993), which provides further analysis of the same body of data.

[46] During the public hearing on May 25, 1999, Mr. Mark Kaszniak of IMC Global incorrectly asserted that ''smoking was treated in a simplistic way in this study by using three categories: smokers, ex-smokers, and non-smokers.'' The study actually used five categories, dividing smokers into separate categories for 1–20 cigarettes per day, 21 or more cigarettes per day, and exclusively pipe and/or cigar smoking.

Several commenters reiterated two caveats expressed by the study's authors and noted in Table III–4. These are (1) that the study is susceptible to selection biases because participants volunteered and because the age-adjusted mortality rates differed between those who provided exposure information and those who did not; and (2) that all exposure information was self-reported with no quantitative measurements. Since these caveats are not specific to mining and pertain to most of the study's findings, they will be addressed when this study's overall results are described in the next subsection.

One commenter, however, (Mr. Mark Kaszniak of IMC Global) argued that selection bias due to unknown diesel exposure status played an especially important role in the RR calculated for miners. About 21 percent of all participants provided no diesel exposure information. Mr. Kaszniak noted that diesel exposure status was unknown for an even larger percentage of miners and suggested that the RR calculated for miners was, therefore, inflated. He presented the following argument:

> In the miner category, this [unknown diesel exposure status] accounted for 44.2% of the study participants, higher than any other occupation studied. This is important as this group experienced a higher mortality for all causes as well as lung cancer than the analyzed remainder of the cohort. If these persons had been included in the ''no exposure to diesel exhaust group,'' their inclusion would have lowered any risk estimates from diesel exposure because of their higher lung cancer rates. [IMC Global post-hearing comments]

This argument, which was endorsed by MARG, was apparently based on a misunderstanding of how the comparison groups used to generate the RR for mining were defined.[47] Actually, persons with unknown diesel exposure status were included among the miners, but excluded from the reference population. Including sometime miners with unknown diesel exposure status in the ''miners'' category would tend to mask or reduce any strong association that might exist between highly exposed miners and an increased risk of lung cancer. Excluding persons with unknown exposure status from the reference population had an opposing effect, since they happened to experience a higher rate of lung cancer than cohort members who said they were unexposed. Therefore, removing ''unknowns'' from the ''miner'' group and adding them to the reference group could conceivably shift the calculated RR for miners in either direction. However, the RR reported for persons with unknown diesel exposure status, compared to unexposed persons, was 1.4 (ibid., p. 412)—which is smaller than the 2.67 reported for miners. Therefore, it appears more likely that the RR for mining was deflated than inflated on account of persons with unknown exposure status.

Although confounders and selection effects may have contributed to the 2.67 RR reported for mining, MSHA believes this result was high enough to support a dpm effect, especially since elevated lung cancer rates were also reported for the three other occupations associated with diesel exhaust exposure. Dr. Borak stated without justification that ''[the] association between dpm and lung cancer was confounded by age, smoking, and other occupational exposures * * *.'' He ignored the well-documented adjustments for age and smoking. Although it does not provide strong or direct evidence that dpm exposure was responsible for any of the increased risk of lung cancer observed among miners, the RR for miners is consistent with evidence provided by the rest of the study results.

Ahlman *et al.* (1991) studied cohorts of 597 surface miners and 338 surface workers employed at two sulfide ore mines using diesel powered front-end loaders and haulage equipment. Both of these mines (one copper and one zinc) were regularly monitored for alpha energy concentrations (*i.e.*, due to radon progeny), which were at or below the Finish limit of 0.3 WL throughout the study period. The ore in both mines contained arsenic only as a trace element (less than 0.005 percent). Lung cancer rates in the two cohorts were compared to rates for males in the same province of Finland. Age-adjusted excess mortality was reported for both lung cancer and cardiovascular disease among the underground miners, but not among the surface workers. None of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on the alpha energy concentration measurements made for the two mines, the authors calculated that not all of the excess lung cancer for the underground miners was attributable to radon exposure. Based on a questionnaire, the authors found similar underground and surface age-specific smoking habits and alcohol consumption and determined that ''smoking alone cannot explain the difference in lung cancer mortality between the [underground] miners and surface workers.'' Due to the small size of the cohort, the excess lung cancer mortality for the underground miners was not statistically significant. However, the authors concluded that the portion of excess lung cancer not attributable to radon exposure could be explained by the combined effects of diesel exhaust and silica exposure. Three of the ten lung cancers reported for underground miners were experienced by conductors of diesel-powered ore trains.

Christie *et al.* (1994, 1995) studied mortality in a cohort of 23,630 male Australian (New South Wales, NSW) coal mine workers who entered the industry after 1972. Although the majority of these workers were underground miners, most of whom were presumably exposed to diesel emissions, the cohort included office workers and surface (''open cut'') miners. The cohort was followed up through 1992. After adjusting for age, death rates were lower than those in the general male population for all major causes except accidents. This included the mortality rate for all cancers as a group (Christie *et al.*, 1995, Table 1). Lower-than-normal incidence rates were also reported for cancers as a group and for lung cancer specifically (Christie *et al.*, 1994, Table 10).

The investigators noted that the workers included in the cohort were all subject to pre-employment physical examinations. They concluded that ''it is likely that the well known 'healthy worker' effect * * * was operating'' and that, instead of comparing to a general population, ''a more appropriate comparison group is Australian petroleum industry workers.'' (Christie *et al.*, 1995) In contrast to the comparison with the population of NSW, the all-cause standardized mortality ratio (SMR) for the cohort of coal miners was greater than for petroleum workers by a factor of over 20 percent—*i.e.*, 0.76 vs. 0.63 (ibid., p. 20). However, the investigators did not

[47] During the public hearing on May 25, 1999, Mr. Kaszniak stated his belief that, for miners, the ''relative risk calculation excluded that 44% of folks who did not respond to the questionnaire with regards to diesel exposure.'' Contrary to Mr. Kaszniak's belief, however, the ''miners'' on which the 2.67 RR was based included all 2034 cohort members who had ever been a miner, regardless of whether they had provided diesel exposure information (see Boffetta *et al.*, 1988, p. 409).

Furthermore, the 44.2-percent nonrespondent figure is not pertinent to potential selection bias in the RR calculation reported for miners. The group of 2034 ''sometime'' miners used in that calculation was 65 percent larger than the group of 1233 ''mainly'' miners to which the 44-percent nonrespondent rate applies. The reference group used for comparison in the calculation consisted of all cohort members ''with occupation different from those listed [*i.e.*, railroad workers, truck drivers, heavy equipment operators, and miners] and not exposed [to diesel exhaust].'' The overall nonrespondent rate for occupations in the reference group was about 21 percent (calculated by MSHA from Table VII of Boffetta *et al.*, 1988).

compare the cohort to petroleum workers specifically with respect to lung cancer or other causes of death. Nor did they adjust for a healthy worker effect or make any attempt to compare mortality or lung cancer rates among workers with varying degrees of diesel exposure within the cohort.

Despite the elevated SMR relative to petroleum workers, several commenters cited this study as evidence that exposure to diesel emissions was not causally associated with an increased risk of lung cancer (or with adverse health effects associated with fine particulates). These commenters apparently ignored the investigators' explanation that the low SMRs they reported were likely due to a healthy worker effect. Furthermore, since the cohort exhibited lower-than-normal mortality rates due to heart disease and non-cancerous respiratory disease, as well as to cancer, there may well have been less tobacco smoking in the cohort than in the general population. Therefore, it is reasonably likely that the age-adjusted lung cancer rate would have been elevated, if it had been adjusted for smoking and for a healthy worker effect based on mortality from causes other than accidents or respiratory disease. In addition, the cohort SMR for accidents (other than motor vehicle accidents) was significantly above that of the general population. Since the coal miners experienced an elevated rate of accidental death, they had a lower-than-normal chance to die from other causes or to develop lung cancer. The investigators made no attempt to adjust for the competing, elevated risk of death due to occupational accidents.

Given the lack of any adjustment for smoking, healthy worker effect, or the competing risk of accidental death, the utility of this study in evaluating health consequences of Dpm exposure is severely limited by its lack of any internal comparisons or comparisons to a comparable group of unexposed workers. Furthermore, even if such adjustments or comparisons were made, several other attributes of this study limit its usefulness for evaluating whether exposure to diesel emissions is associated with an increased risk of lung cancer. First, the study was designed in such a way as to allow inadequate latency for a substantial portion of the cohort. Although the cohort was followed up only through 1992, it includes workers who entered the workforce at the end of 1992. Therefore, there is no minimum duration of occupational exposure for members of the cohort. Approximately 30 percent of the cohort was employed in the industry for less than 10 years, and the maximum duration of employment and latency combined was 20 years. Second, average age for members of the cohort was only 40 to 50 years (Christie *et al.*, p. 7), and the rate of lung cancer was based on only 29 cases. The investigators acknowledged that ''it is a relatively young cohort'' and that ''this means a small number of cancers available for analysis, because cancer is more common with advancing age * * *.'' They further noted that ''* * * the number of cancers available for analysis is increasing very rapidly. As a consequence, every year that passes makes the cancer experience of the cohort more meaningful in statistical terms.'' (ibid., p. 27) Third, miners's work history was not tracked in detail, beyond identifying the first mine in which a worker was employed. Some of these workers may have been employed, for various lengths of time, in both underground and surface operations at very different levels of diesel exposure. Without detailed work histories, it is not possible to construct even semi-quantitative measures of diesel exposure for making internal comparisons within the cohort.

One commenter (MARG) claimed that this (NSW) study ''* * * reflects the latest and best scientific evidence, current technology, and the current health of miners'' and that it ''is not rational to predicate regulations for the year 2000 and beyond upon older scientific studies * * *.'' For the reasons stated above, MSHA believes, to the contrary, that the NSW study contributes little or no information on the potential health effects of long-term dpm exposures and that whatever information it does contribute does not extend to effects, such as cancer, expected in later life.

Furthermore, three even more recent studies are available that MSHA regards as far more informative for the purposes of the present risk assessment. Unlike the NSW study, these directly address dpm exposure and the risk of lung cancer. Two of these studies (Johnston *et al.*, 1997; Säverin *et al.*, 1999), both incorporating a quantitative dpm exposure assessment, were carried out specifically on mining cohorts and will be discussed next. The third (Brüske-Hohlfeld *et al.*, 1999) is a case-control study not restricted to miners and will be discussed in the following subsection. In accordance with MARG's emphasis on the timeliness of scientific studies, MSHA places considerable weight on the fact that all three—the most recent epidemiologic studies available—reported an association between diesel exposure and an increased risk of lung cancer.

Johnston *et al.* (1997) studied a cohort of 18,166 coal miners employed in ten British coal mines over a 30-year period. Six of these coal mines used diesel locomotives, and the other four were used for comparison. Historical NO_X and respirable dust concentration measurements were available, having routinely been collected for monitoring purposes. Two separate approaches were taken to estimate dpm exposures, leading to two different sets of estimates. The first approach was based on NO_X measurements, combined with estimated ratios between dpm and NO_X. The second approach was based on complex calculations involving measurements of total respirable dust, ash content, and the ratio of quartz to dust for diesel locomotive drivers compared to the ratio for face workers (ibid., Figure 4.1 and pp. 25–46). These calculations were used to estimate dpm exposure concentrations for the drivers, and the estimates were then combined with traveling times and dispersion rates to form estimates of dpm concentration levels for other occupational groups. In four of the six dieselized mines, the NO_X-based and dust-based estimates of dpm were in generally good agreement, and they were combined to form time-independent estimates of shift average dpm concentration for individual seams and occupational groups within each mine. In the fifth mine, the PFR measurements were judged unreliable for reasons extensively discussed in the report, so the NO_X-based estimates were used. There was no NO_X exposure data for the sixth mine, so they used dust-based estimates of dpm exposure.

Final estimates of shift-average dpm concentrations ranged from 44 $\mu g/m^3$ to 370 $\mu g/m^3$ for locomotive drivers and from 1.6 $\mu g/m^3$ to 40 $\mu g/m^3$ for non-drivers at various mines and work locations (ibid., Tables 8.3 and 8.6, respectively). These were combined with detailed work histories, obtained from employment records, to provide an individual estimate of cumulative dpm exposure for each miner in the cohort. Although most cohort members (including non-drivers) had estimated cumulative exposures less than 1 g-hr/m^3, some members had cumulative exposures that ranged as high as 11.6 g-hr/m^3 (ibid., Figure 9.1 and Table 9.1).

A statistical analysis (time-dependent proportional hazards regression) was performed to examine the relationship between lung cancer risk and each miner's estimated cumulative dpm exposure (unlagged and lagged by 15 years), attained age, smoking habit, mine, and cohort entry date. Smoking habit was represented by non-smoker, ex-smoker, and smoker categories, along with the average number of cigarettes smoked per day for the smokers. Pipe tobacco consumption was expressed by an equivalent number of cigarettes per day.

In their written comments, MARG and the NMA both mischaracterized the results of this study, apparently confusing it with a preliminary analysis of the same cohort. The preliminary analysis (one part of what Johnston *et al.* refer to as the ''wider mortality study'') was summarized in Section 1.2 (pp. 3–5) of the 105-page report at issue, which may account for the confusion by MARG and the NMA.[48]

Contrary to the MARG and NMA characterization, Johnston *et al.* found a positive, quantitative relationship between cumulative dpm exposure (lagged by 15 years) and an excess risk of lung cancer, after controlling for age, smoking habit, and cohort entry date. For each incremental g-hr/m^3 of cumulative occupational dpm exposure, the relative risk of lung cancer was estimated to increase by a factor of 22.7 percent. Adjusting for mine-to-mine differences that may account for a portion of the elevated risk reduced the estimated RR factor to 15.6 percent. Therefore, with the mine-specific adjustment, the estimated RR was 1.156 per g-hr/m^3 of cumulative dpm exposure. It follows that, based on the mine-adjusted model, the estimated RR for a specified cumulative exposure is 1.156 raised to a power equal to that exposure. For example, RR = $(1.156)^{3.84}$ = 1.74 for a cumulative dpm exposure of 3.84 g-hr/m^3, and RR = $(1.156)^{7.68}$ = 3.04 for a cumulative dpm exposure of 7.68 g-hr/m^3.[49] Estimates of RR based on the mine-unadjusted model would substitute 1.227 for 1.156 in these calculations.

Two limitations of this study weaken the evidence it presents of an increasing exposure-response relationship. First, although the exposure assessment is quantitative and carefully done, it is indirect and depends heavily on assumptions linking surrogate measurements to dpm exposure levels. The authors, however, analyzed sources of inaccuracy in the exposure assessment and concluded that ''the similarity between the estimated * * * [dpm] exposure concentrations derived by the two different methods give some degree of confidence in the accuracy of the final values * * *.'' (ibid., pp.71–75) Second, the highest estimated cumulative dpm exposures were clustered at a single coal mine, where the SMR was elevated relative to the regional norm. Therefore, as the authors pointed out, this one mine greatly influences the results and is a possible confounder in the study. The investigators also noted that this mine was ''* * * found to have generally the higher exposures to respirable quartz and low level radiation.'' Nevertheless, MSHA regards it likely that the relatively high dpm exposures at this mine were responsible for at least some of the excess mortality. There is no apparent way, however, to ascertain just how much of the excess mortality (including lung cancer) at this coal mine should be attributed to high occupational dpm exposures and how much to confounding factors distinguishing it (and the employees working there) from other mines in the study.

The RR estimates based on the mine-unadjusted model assume that the excess lung cancer observed in the cohort is entirely attributable to dpm exposures, smoking habits, and age distribution. If some of the excess lung cancer is attributed to other differences between mines, then the dpm effect is estimated by the lower RR based on the mine-adjusted model.

For purposes of comparison with the findings of Säverin *et al.* (1999), it will be useful to calculate the RR for a cumulative dpm exposure of 11.7 g-hr/m^3 (*i.e.*, the approximate equivalent of 4.9 mg-yr/m^3 TC).[50] At this exposure level, the mine-unadjusted model produces an estimated RR = $(1.227)^{11.7}$ = 11, and the mine-adjusted model produces an estimated RR = $(1.156)^{11.7}$ = 5.5.

Säverin *et al.* (1999) studied a cohort of male potash miners in Germany who had worked underground for at least one year after 1969, when the mines involved began converting to diesel powered vehicles and loading equipment. Members of the cohort were selected based on company medical records, which also provided bi-annual information on work location for each miner and, routinely after 1982, the miner's smoking habits. After excluding miners whose workplace histories could not be reconstructed from the medical records (5.5 percent) and miners lost to follow-up (1.9 percent), 5,536 miners remained in the cohort. Within this full cohort, the authors defined a sub-cohort consisting of 3,258 miners who had ''worked underground for at least ten years, held one single job during at least 80% of their underground time, and held not more than three underground jobs in total.''

The authors divided workplaces into high, medium, and low diesel exposure categories, respectively corresponding to production, maintenance, and workshop areas of the mine. Each of these three categories was assigned a representative respirable TC concentration, based on an average of measurements made in 1992. These averages were 390 µg/m^3 for production, 230 µg/m^3 for maintenance, and 120 µg/m^3 for workshop. Some commenters expressed concern about using average exposures from 1992 to represent exposure throughout the study. The authors justified using these measurement averages to represent exposure levels throughout the study period because ''the mining technology and the type of machinery used did not change substantially after 1970.'' This assumption was based on interviews with local engineers and industrial hygienists.

Thirty-one percent of the cohort consented to be interviewed, and information from these interviews was used to validate the work history and smoking data reconstructed from the medical records. The TC concentration assigned to each work location was combined with each miner's individual work history to form an estimate of cumulative exposure for each member of the cohort. Mean duration of exposure was 15 years. As of the end of follow-up in 1994, average age was 49 years, average time since first exposure was 19 years, and average cumulative exposure was 2.70 mg-y/m^3.

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[48] Since MARG and the NMA both stressed the importance of a quantitative exposure assessment, it is puzzling that they focused on a crude SMR from the preliminary analysis and ignored the quantitative results from the subsequent analysis. Johnston et al. noted that SMRs from the preliminary analysis were consistent ''with other studies of occupational cohorts where a healthy worker effect is apparent.'' But even the preliminary analysis explored a possible surrogate exposure-response relationship, rather than simply relying on SMRs. Unlike the analysis by Johnston et al., the preliminary analysis used travel time as a surrogate measure of dpm exposure and made no attempt to further quantify dpm exposure concentrations. (ibid., p. 5)

[49] Assuming an average dpm concentration of 200 µg/m^3 and 1920 work hours per year, 3.84 g-hr/m^3 and 7.68 g-hr/m^3 correspond to 10 and 20 years of occupational exposure, respectively.

[50] This value represents 20 years of cumulative exposure for the most highly exposed category of workers in the cohort studied by Säverin et al.

As explained elsewhere in this preamble, TC constitutes approximately 80 percent of total dpm. Therefore, the TC value of 4.9 mg-yr/m^3 presented by Säverin *et al.* must first be divided by 0.8 to produce a corresponding dpm value of 6.12 mg-yr/m^3. To convert this result to the units used by Johnston *et al.*, it is then multiplied by 1920 work hours per year and divided by 1000 mg/g to yield 11.7 g-hr/m^3. This is nearly identical to the maximum cumulative dpm exposure estimated for locomotive drivers in the study by Johnston *et al.* (See Johnston *et al., op cit.*, Table 9.1.)

The authors performed an analysis (within each TC exposure category) of smoking patterns compared with cumulative TC exposure. They also analyzed smoking misclassification as estimated by comparing information from the interviews with medical records. From these analyses, the authors determined that the cohort was homogeneous with respect to smoking and that a smoking adjustment was neither necessary nor desirable for internal comparisons. However, they did not entirely rule out the possibility that smoking effects may have biased the results to some extent. On the other hand, the authors concluded that asbestos exposure was minor and restricted to jobs in the workshop category, with negligible effects. The miners were not occupationally exposed to radon progeny, as documented by routine measurement records.

As compared to the general male population of East Germany, the cohort SMR for all causes combined was less than 0.6 at a 95-percent confidence level. The authors interpreted this as demonstrating a healthy worker effect, noting that ''underground workers are heavily selected for health and sturdiness, making any surface control group incomparable.'' Accordingly, they performed internal comparisons within the cohort of underground miners. The RR reported for lung cancer among miners in the high-exposure production category, compared to those in the low-exposure workshop category, was 2.17. The corresponding RR was not elevated for other cancers or for diseases of the circulatory system.

Two statistical methods were used to investigate the relationship between lung cancer RR and each miner's age and cumulative TC exposure: Poisson regression and time-dependent proportional hazards regression. These two statistical methods were applied to both the full cohort and the subcohort, yielding four different estimates characterizing the exposure-response relationship. Although a high confidence level was not achieved, all four of these results indicated that the RR increased with increasing cumulative TC exposure. For each incremental mg-yr/m^3 of occupational TC exposure, the relative risk of lung cancer was estimated to increase by the following multiplicative factor: [51]

Method	RR per mg-yr/m^3	
	Full cohort	Subcohort
Poisson	1.030	1.139
Proportional Hazards	1.112	1.225

Based on these estimates, the RR for a specified cumulative TC exposure (X) can be calculated by raising the tabled value to a power equal to X. For example, using the proportional hazards analysis of the subcohort, the RR for X = 3.5 mg-yr/m^3 is $(1.225)^{3.5} = 2.03$.[52]

The authors calculated the RR expected for a cumulative TC exposure of 4.9 mg-yr/m3, which corresponds to 20 years of occupational exposure for miners in the production category of the cohort. These miners were exposed for five hours per 8-hour shift at an average TC concentration of 390 µg/m.^{3} The resulting RR values were reported as follows:

Method	RR for 4.9 mg-yr/m^3	
	Full cohort	Subcohort
Poisson	1.16	1.89
Proportional Hazards	1.68	2.70

This study has two important limitations that weaken the evidence it presents of a positive correlation between cumulative TC exposure and the risk of lung cancer. These are (1) potential confounding due to tobacco smoking and (2) a significant probability (i.e., greater than 10 percent) that a correlation of the magnitude found could have arisen simply by chance, given that it were based on a relatively small number of lung cancer cases.

Although data on smoking habits were compiled from medical records for approximately 80 percent of the cohort, these data were not incorporated into the statistical regression models. The authors justified their exclusion of smoking from these models by showing that the likelihood of smoking was essentially unrelated to the cumulative TC exposure for cohort members. Based on the portion of the cohort that was interviewed, they also determined that the average number of cigarettes smoked per day was the same for smokers in the high and low TC exposure categories (production and workshop, respectively). However, these same interviews led them to question the accuracy of the smoking data that had been compiled from medical records. Despite the cohort's apparent homogeneity with respect to smoking, the authors noted that smoking was potentially such a strong confounder that ''even small inaccuracies in smoking data could cause effects comparable in size to the weak carcinogenic effect of diesel exhaust.'' Therefore, they excluded the smoking data from the analysis and stated they could not entirely rule out the possibility of a smoking bias. MSHA agrees with the authors of this report and the HEI Expert Panel (op cit.) that even a high degree of cohort homogeneity does not rule out the possibility of a spurious correlation due to residual smoking effects. Nevertheless, because of the cohort's homogeneity, the authors concluded that ''the results are unlikely to be substantially biased by confounding,'' and MSHA accepts this conclusion.

The second limitation of this study is related to the fact that the results are based on a total of only 38 cases of lung cancer for the full cohort and 21 cases for the subcohort. In their description of

[51] MSHA determined these values by calculating the antilog, to the base e, of each corresponding estimate of α reported by Säverin et al. (op cit.) in their Tables III and IV. The cumulative exposure unit of mg-yr/m^3 refers to the average TC concentration experienced over a year's worth of 8-hour shifts.

[52] This is the estimated risk relative not to miners in the workshop category but to a theoretical age-adjusted baseline risk for cohort members accumulating zero occupational TC exposure.

this study at the May 27, 1999, public hearing, NIOSH noted that the ''lack of [statistical] significance may be a result of the study having a small cohort (approximately 5,500 workers), a limited time from first exposure (average of 19 years), and a young population (average age of 49 years at the end of follow-up).'' More cases of lung cancer may be expected to occur within the cohort as its members grow older. The authors of the study addressed statistical significance as follows:

* * * the small number of lung cancer cases produced wide confidence intervals for all measures of effect and substantially limited the study power. We intend to extend the follow-up period in order to improve the statistical precision of the exposure-response relationship. [Säverin et al., op cit.]

Some commenters stated that due to these limitations, data from the Säverin et al. study should not be the basis of this rule. On the other hand, NIOSH commented that ''[d]espite the limitations discussed * * * the findings from the Säverin et al. (1999) study should be used as an alternative source of data for quantifying the possible lung cancer risks associated with Dpm exposures.'' As stated earlier, MSHA is not relying on any single study but, instead, basing its evaluation on the weight of evidence from all available data.

(iii) Best Available Epidemiologic Evidence. Based on the evaluation criteria described earlier, and after considering all the public comment that was submitted, MSHA has identified four cohort studies (including two from U.S.) and four case-control studies (including three from U.S.) that provide the best currently available epidemiologic evidence relating dpm exposure to an increased risk of lung cancer. Three of the 11 studies involving miners fall into this select group. MSHA considers the statistical significance of the combined evidence far more important than confidence levels for individual studies. Therefore, in choosing the eight most informative studies, MSHA placed less weight on statistical significance than on the other criteria. The basis for MSHA's selection of these eight studies is summarized as follows:

Study	Statistical Significance (at 95% Conf.)	Comparison groups	Exposure assessment	Controls on potential confounding
Boffetta et al. 1988 (cohort).	Yes	Internal Comparison	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking, and, in some analyses, for occupational exposures to asbestos, coal & stone dusts, coal tar & pitch, and gasoline exhaust.
Boffetta et al. 1990 (case-control).	No	Matched within hospital on smoking, age, year of interview.	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking habit and intensity, asbestos exposure, race, and education.
Brüske-Hohlfeld et al. 1999 (case-control).	Yes	Matched on sex, age, and region of residence of residence.	Total duration of occupational diesel exposure based on detailed job history.	Adjustments for current and past smoking patterns, cumulative amount smoked (packyears), and asbestos exposure.
Garshick et al. 1987 (case-control).	Yes	Matched within cohort on dates of birth and death.	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Adjustments for lifetime smoking and asbestos exposure.
Garshick et al. 1988, 1991 (cohort).	Yes	Internal Comparison	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Subjects with likely or possible asbestos exposure excluded from cohort. Cigarette smoking determined to be uncorrelated with diesel exposure within cohort.
Johnston et al. 1997 (cohort).	No (marginal)	Internal Comparison	Quantitative, based on surrogate exposure measurements and detailed employment records.	Adjustments for age, smoking habit & intensity, mine site, and cohort entry date.
Säverin et al. 1999 (cohort).	No	Internal Comparison	Quantitative, based on TC exposure measurements and detailed employment records.	Adjustment for age. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Steenland et al. 1990, 1992, 1998 (case-control).	Yes	Matached within cohort on date of death within 2 years.	Semi-quantitative, based on job history and subsequent EC measurements.	Adjustments for age, smoking, and asbestos exposure. Dietary covariates were tested and found not to confound the analysis.

Six entirely negative studies were identified earlier in this risk assessment. Several commenters objected to MSHA's treatment of the negative studies, indicating that they had been discounted without sufficient justification. To put this in proper perspective, the six negative studies should be compared to those MSHA has identified as the best available epidemiologic evidence, with respect to the same evaluation criteria. (It should be noted that the statistical significance of a negative study is best represented by its power.) In accordance with those criteria, MSHA discounts the evidentiary significance of these six studies for the following reasons:

Study	Power	Comparison groups	Exposure assessment	Controls on potential confounding
Bender et al. 1989 (cohort)	Relative small cohort (N=4849).	External comparison; No adjustment for healthy worker effect.	Job only: highway maintenance workers.	Disparate comparison groups with no smoking adjustment.

Study	Power	Comparison groups	Exposure assessment	Controls on potential confounding
Christie et al. 1996 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Industry only: combined all underground and surface workers at coal mines.	Disparate comparison groups with no smoking adjustment.
DeCoufle et al. 1977 (case-control).	Inadequate latency allowance.	Cases not matched with controls.	Job only: (1) Combined bus, taxi, and truck drivers; (2) locomotive engineers.	Age differences not taken into account.
Edling et al. 1987 (cohort)	Small cohort (N=694)	External comparison; No adjustment for healthy worker effect.	Job only: bus workers	Disparate comparison groups with no smoking adjustment.
Kaplan 1959 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Jobs classified by diesel exposure. No attempt to differentiate between diesel and coal-fired locomotives.	Disparate comparison groups with no smoking adjustment.
Waller 1981 (cohort)	Acceptable	External comparison; No adjustment for healthy worker effect; Selection bias due to excluding retirees from cohort.	Job only: bus workers	Disparate coparison groups with no smoking adjustment.

Other studies proposed as counter-evidence by some commenters will be addressed in the next subsection of this risk assessment.

The eight studies MSHA identified as representing the best available epidemiologic evidence all reported an elevated risk of lung cancer associated with diesel exposure. The results from these studies will now be reviewed, along with MSHA's response to public comments as appropriate.

Boffetta et al., 1988

The structure of this cohort study was summarized in the preceding subsection of this risk assessment. The following table contains the main results. The relative risks listed for duration of exposure were calculated with reference to all members of the cohort reporting no diesel exposure, regardless of occupation, and adjusted for age, smoking pattern, and other occupational exposures (asbestos, coal and stone dusts, coal tar and pitch, and gasoline exhausts). The relative risks listed for occupations were calculated for cohort members that ever worked in the occupation, compared to cohort members never working in any of the four occupations listed and reporting no diesel exposure. These four relative risks were adjusted for age and smoking pattern only. Smoking pattern was coded by 5 categories: never smoker; current 1–20 cigarettes per day; current 21 or more cigarettes per day; ex-smoker of cigarettes; current or past pipe and/or cigar smoker.

MAIN RESULTS FROM BOFFETTA ET AL., 1988

[RRs by duration adjusted for age, smoking, and other occupational exposures; Occupational RRs adjusted for age and smoking only]

Self-reported duration of exposure to diesel exhaust	Lung cancer RR	95-percent confidence interval
Years:		
1 to 15	1.05	0.80–1.39
16 or more	1.21	0.94–1.56
Occupation:		
Truck Drivers	1.24	0.93–1.66
Railroad Workers	1.59	0.94–2.69
Heavy Equipment Operators	2.60	1.12–6.06
Miners	2.67	1.63–4.37

In addition to comments (addressed earlier) on the RR for miners in this study, IMC Global submitted several comments pertaining to the RR calculated for persons who explicitly stated that they had been occupationally exposed to diesel emissions. This RR was 1.18 for persons reporting any exposure (regardless of duration) compared to all subjects reporting no exposure. MSHA considers the most important issue raised by IMC Global to be that 20.6 percent of all cohort members did not answer the question about occupational diesel exhaust exposure during their lifetimes, and these subjects experienced a higher age-adjusted mortality rate than the others. As the authors of this study acknowledged, this ''could introduce a substantial bias in the estimate of the association.'' (Boffetta et al., 1988, p. 412).

To show that the impact of this bias could indeed be substantial, the authors of the study addressed one extreme possibility, in which all ''unknowns'' were actually unexposed. Under this scenario, excluding the ''unknowns'' would have biased the calculated RR upward by a sufficient amount to explain the entire 18-percent excess in RR. This would not, however, explain the higher RR for persons reporting more than 16 years exposure, compared to the RR for persons reporting 1 to 15 years. Moreover, the authors did not discuss the opposite extreme: if all or most of the ''unknowns'' who experienced lung cancer were actually exposed, then excluding them would have biased the calculated RR downward. There is little basis for favoring one of these extremes over the other.

Another objection to this study raised by IMC Global was:

> All exposure information in the study was self-reported and not validated. The authors of the study have no quantitative data or measurements of actual diesel exhaust exposures.

MSHA agrees with IMC Global and other commenters that a lack of quantitative exposure measurements limits the strength of the evidence this study presents. MSHA believes, however, that the evidence presented is nevertheless substantial. The possibility of random classification errors due to self-reporting of exposures does not explain why persons reporting 16 or more years of exposure would experience a higher relative risk of lung cancer than persons reporting 1 to 15 years of exposure. This difference is not statistically significant, but random exposure misclassification would tend to make the effects of exposure less conspicuous. Nor can self-reporting explain why an elevated risk of lung cancer would be observed for four occupations commonly associated with diesel exposure.

Furthermore, the study's authors did perform a rough check on the accuracy of the cohort's exposure information. First, they confirmed that, after controlling for age, smoking, and other occupational exposures, a statistically significant relationship was found between excess lung cancer and the cohort's self-reported exposures to asbestos. Second they found no such association for self-reported exposure to pesticides and herbicides, which they considered unrelated to lung cancer (ibid., pp. 410–411).

IMC Global also commented that the ''* * * study may suffer from volunteer bias in that the cohort was healthier and less likely to be exposed to important risk factors, such as smoking or alcohol.'' They noted that this possibility ''is supported by the U.S. EPA in their draft Health Assessment Document for Diesel Emissions.''

The study's authors noted that enrollment in the cohort was nonrandom and that participants tended to be healthier and less exposed to various risk factors than the general population. These differences, however, would tend to reduce any relative risk for the cohort calculated in comparison to the external, general population. The authors pointed out that external comparisons were, therefore, inappropriate; but ''the internal comparisons upon which the foregoing analyses are based are not affected strongly by selection biases.'' (ibid.)

Although the 1999 EPA draft notes potential volunteer bias, it concludes: ''Given the fact that all diesel exhaust exposure occupations * * * showed elevated lung cancer risk, this study is suggestive of a causal association.''[53] (EPA, 1999, p. 7–13) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

Boffetta et al., 1990

This case-control study was based on 2,584 male hospital patients with histologically confirmed lung cancer, matched with 5099 male patients with no tobacco-related diseases. Cases and controls were matched within each of 18 hospitals by age (within two years) and year of interview. Information on each patient, including medical and smoking history, occupation, and alcohol and coffee consumption, was obtained at the time of diagnosis in the hospital, using a structured questionnaire. For smokers, smoking data included the number of cigarettes per day. Prior to 1985, only the patient's usual job was recorded. In 1985, the questionnaire was expanded to include up to five other jobs and the length of time worked in each job. After 1985, information was also obtained on dietary habits, vitamin consumption, and exposure to 45 groups of chemicals, including diesel exhaust.

The authors categorized all occupations into three groups, representing low, possible, and probable diesel exhaust exposure. The ''low exposure'' group was used as the reference category for calculating odds ratios for the ''possible'' and ''probable'' job groups. These occupational comparisons were based on the full cohort of patients, enrolled both before and after 1985. A total of 35 cases and 49 controls (all enrolled after the questionnaire was expanded in 1985) reported a history of diesel exposure. The reference category for self-reported diesel exposure consisted of a corresponding subset of 442 cases and 897 controls reporting no diesel exposure on the expanded questionnaire. The authors made three comparisons to rule out bias due to self-reporting of exposure: (1) No difference was found between the average number of jobs reported by cases and controls; (2) the association between self-reported asbestos exposure was in agreement with previously published estimates; and (3) no association was found for two exposures (pesticides and fuel pumping) considered unrelated to lung cancer (ibid., p. 584).

Stöber and Abel (1996) identified this study as being ''of eminent importance owing to the care taken in including the most influential confounding factors and analyses of dose-effect relationships.'' The main findings are presented in the following table. All of these results were obtained using logistic regression, factoring in the estimated effects of age, race, years of education, number of cigarettes per day, and asbestos exposure (yes or no). An elevated risk of lung cancer was reported for workers with more than 30 years of either self-reported or ''probable'' diesel exposure. The authors repeated the occupational analysis using ''ever'' rather than ''usual'' employment in jobs classified as ''probable'' exposure, with ''remarkably similar'' results (ibid., p. 584).

MAIN RESULTS FROM BOFFETTA ET AL., 1990

[Adjusted for age, race, education, smoking, and asbestos exposure]

Self-reported duration of exposure to diesel exhaust	Lung cancer odds ratio	95-percent confidence interval
Years:		
1 to 15	0.90	0.40–1.99
16 to 30	1.04	0.44–2.48
31 or more	2.39	0.87–6.57
Likelihood of Exposure:		
19 jobs with ''possible'' exposure	0.92	0.76–1.10
13 jobs with ''probable'' exposure	0.95	0.78–1.16
1 to 15 years in ''probable'' jobs	0.52	0.15–1.86
16 to 30 years in ''probable'' jobs	0.70	0.34–1.44
31 or more years in ''probable'' jobs	1.49	0.72–3.11

[53] In his review of this study for the NMA, Dr. Peter Valberg stated: ''This last sentence reveals EPA's bias; the RRs for truck drivers and railroad workers were not statistically elevated.'' Contrary to Dr. Valberg's statement, the RRs were greater than 1.0 and, therefore, were ''statistically elevated.'' Although the elevation for these two occupations was not statistically significant at a 95-percent confidence level, the EPA made no claim that it was. Under a null hypothesis of no real association, the probability should be ½ that the RR would exceed 1.0 for an occupation associated with diesel exposure. Therefore, under the null hypothesis, the probability that the RR would exceed 1.0 for all four such occupations is $(1/2)^4 = 0.06$. This corresponds to a 94-percent confidence level for rejecting the null hypothesis.

The study's authors noted that most U.S. trucks did not have diesel engines until the late 1950s or early 1960s and that many smaller trucks are still powered by gasoline engines. Therefore, they performed a separate analysis of truck drivers cross-classified by self-reported diesel exposure ''to compare presumptive diesel truck drivers with nondiesel drivers.'' After adjusting for smoking, the resulting OR for diesel drivers was 1.25, with a 95-percent confidence interval of 0.85 to 2.76 (*ibid.,* p. 585).

Brüske-Hohlfeld et al., 1999

This was a pooled analysis of two case-control studies on lung cancer in Germany. The data pool consisted of 3,498 male cases with histologically or cytologically confirmed lung cancer and 3,541 male controls randomly drawn from the general population. Cases and controls were matched for age and region of residence. For the pooled analysis, information on demographic characteristics, smoking, and detailed job and job-task history was collected by personal interviews with the cases and controls, using a standardized questionnaire.

Over their occupational lifetimes, cases and controls were employed in an average of 2.9 and 2.7 different jobs, respectively. Jobs considered to have had potential exposure to diesel exhaust were divided into four groups: Professional drivers (including trucks, buses, and taxis), other ''traffic-related'' jobs (including switchmen and operators of diesel locomotives or diesel forklift trucks), full-time drivers of farm tractors, and heavy equipment operators. Within these four groups, each episode of work in a particular job was classified as being exposed or not exposed to diesel exhaust, based on the written description of job tasks obtained during the interview. This exposure assessment was done without knowledge of the subject's case or control status. Each subject's lifetime duration of occupational exposure was compiled using only the jobs determined to have been diesel-exposed. There were 264 cases and 138 controls who accumulated diesel exposure exceeding 20 years, with 116 cases and 64 controls accumulating more than 30 years of occupational exposure.

For each case and control, detailed smoking histories from the questionnaire were used to establish smoking habit, including consumption of other tobacco products, cumulative smoking exposure (expressed as packyears), and years since quitting smoking. Cumulative asbestos exposure (expressed as the number of exposed working days) was assessed based on 17 job-specific questionnaires that supplemented the main questionnaire.

The main findings of this study, all adjusted for cumulative smoking and asbestos exposure, are presented in the following table. Although the odds ratio for West German professional drivers was a statistically significant 1.44, as shown, the odds ratio for East German professional drivers was not elevated. As a possible explanation, the authors noted that after 1960, the number of vehicles (cars, busses, and trucks) with diesel engines per unit area was about five times higher in West Germany than in East Germany. Also, the higher OR shown for professional drivers first exposed after 1955, compared to earlier years of first exposure, may have resulted from the higher density of diesel traffic in later years.

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Main results from Brüske-Hohlfeld et al., 1999

(controlled for age; adjusted for smoking and asbestos exposure)

Occupational Exposure to Diesel Exhaust	Lung Cancer Odds Ratio	95-Percent Confidence Interval
Any During Lifetime	1.43	1.23 - 1.67
West German Professional Drivers	*1.44*	*1.18 - 1.76*
First exposed before 1946	1.32	0.68 - 2.07
First exposed 1946 - 1955	1.49	0.96 - 1.88
First exposed after 1955	1.56	1.21 - 2.03
"Traffic-Related" Jobs other than Driving	*1.53*	*1.04-2.24*
4 to 10 years	1.18	0.6 - 2.4†
11 to 20 years	2.49	1.1 - 5.6†
More than 20 years	2.88	1.1 - 7.2†
Full-Time Drivers of Farm Tractors	*1.29*	*0.78 - 2.14*
11 to 20 years	1.51	0.4 - 3.8‡
21 to 30 years	3.67	1.0 - 13‡
More than 30 years	6.81	1.1 - 40‡
Heavy Equipment Operators	*2.31*	*1.44 - 3.70*
More than 20 years	4.30	statistically significant (interval not reported)

† Confidence limits estimated from Fig. 1 of Brüske-Hohlfeld et al. (1999).

‡ Confidence limits estimated from Fig. 2 of Brüske-Hohlfeld et al. (1999).

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As the authors noted, a strength of this study is the good statistical power resulting from having a significant number of workers exposed to diesel emissions for more than 30 years. Another strength is the statistical treatment of potential confounders, using quantitative measures of cumulative smoking and asbestos exposures.

Although they did not rely solely on job title, and differentiated between diesel-exposed and unexposed work periods, the authors identified limitations in the assessment of diesel exposure, ''under these circumstances leading to an odds ratio that is biased towards one and an underestimation of the true [relative] risk of lung cancer.'' A more quantitative assessment of diesel exposure would tend to remove this bias, thereby further elevating the relative risks. Therefore, the authors concluded that their study ''showed a statistically significant increase in lung cancer risk for workers occupationally exposed to [diesel exhaust] in Germany with the exception of professional drivers in East Germany.'' Garshick et al., 1987

This case-control study was based on 1,256 primary lung cancer deaths and 2,385 controls whose cause of death was not cancer, suicide, accident, or unknown. Cases and controls were drawn from records of the U.S. Railroad Retirement Board (RRB) and matched within 2.5 years of birth date and 31 days of death date. Selected jobs, with and without regular diesel exposure, were identified by a review of job titles and duties and classified as ''exposed'' or ''unexposed'' to diesel exhaust. For

39 jobs, this exposure classification was confirmed by personal sampling of current respirable dust concentrations, adjusted for cigarette smoke, at four different railroads. Jobs for which no personal sampling was available were classified based on similarities in location and activity to sampled jobs.

A detailed work history for each case and control was obtained from an annual report filed with the RRB. This was combined with the exposure classification for each job to estimate the lifetime total diesel exposure (expressed as ''diesel-years'') for each subject. Years spent not working for a railroad, or for which a job was not recorded, were considered to be unexposed. This amounted to 2.4% of the total worker-years from 1959 to death or retirement.

Because of the transition from steam to diesel locomotives in the 1950s, occupational lifetime exposures were accumulated beginning in 1959. Since many of the older workers retired not long after 1959 and received little or no diesel exposure, separate analyses were carried out for subjects above and below the age of 65 years at death. The group of younger workers was considered to be less susceptible to exposure misclassification.

Detailed smoking histories, including years smoked, cigarettes per day, and years between quitting and death, were obtained from next of kin. Based on job history, each case and control was also classified as having had regular, intermittent, or no occupational asbestos exposure.

The main results of this study, adjusted for smoking and asbestos exposure, are presented in the following table for workers aged less than 65 years at the time of their death. All of these results were obtained using logistic regression, conditioned on dates of birth and death. The odds ratio presented in the shaded cell for 20 years of unlagged exposure was derived from an analysis that modeled diesel-years as a continuous variable. All of the other odds ratios in the table were derived from analyses that modeled cumulative exposure categorically, using workers with less than five diesel-years of exposure as the reference group. Statistically significant elevations of lung cancer risk were reported for the younger workers with at least 20 diesel-years of exposure or at least 15 years accumulated five years prior to death. No elevated risk of lung cancer was observed for the older workers, who were 65 or more years old at the time of their death. The authors attributed this to the fact, mentioned above, that many of these older workers retired shortly after the transition to diesel-powered locomotives and, therefore, experienced little or no occupational diesel exposure. Based on the results for younger workers, they concluded that ''this study supports the hypothesis that occupational exposure to diesel exhaust increases lung cancer risk.''

MAIN RESULTS FROM GARSHICK ET AL., 1987, FOR WORKERS AGED LESS THAN 65 YEARS AT DEATH

[Controlled for dates of birth and death; adjusted for cigarette smoking and asbestos exposure]

Diesel exposure	Lung cancer odds ratio	95-percent confidence interval
No lag:		
0–4 diesel-years	1	N/A (reference group)
5–19 diesel-years	1.02	0.72–1.45
20 diesel-years (diesel exposure modeled as continuous variable)	1.41	1.06–1.88
20 or more diesel-years	1.64	1.18–2.29
Accumulated at least 5 years before death:		
0–4 diesel-years	1	N/A (reference group)
5–14 diesel-years	1.07	0.69– 1.66
15 or more diesel-years	1.43	1.06– 1.94

In its 1999 draft Health Assessment Document for Diesel Emissions, the U.S. EPA noted various limitations of this study but concluded that ''compared with previous studies [i.e., prior to 1987] * * *, [it] provides the most valid evidence that occupational diesel exhaust emission exposure increases the risk of lung cancer.'' (EPA, 1999, p. 7–33) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

The EMA objected to this study's determination of smoking frequency based on interviews with next of kin, stating that such determination ''generally results in an underestimate, as it has been shown that cigarette companies manufacture 60% more product than public surveys indicate are being smoked.''

A tendency to mischaracterize smoking frequency would have biased the study's reported results if the degree of under- or over-estimation varied systematically with diesel exposure. The EMA, however, submitted no evidence that the smoking under-estimate, if it existed at all, was in any way correlated with cumulative duration of diesel exposure. In the absence of such evidence, MSHA finds no reason to assume differential mis-reporting of smoking frequency.

Even more importantly, the EMA failed to distinguish between ''public surveys'' of the smokers themselves (who may be inclined to understate their habit) and interviews with next of kin. The investigators specifically addressed the accuracy of smoking data obtained from next of kin, citing two studies on the subject. Both studies reported a tendency for surrogate respondents to overestimate, rather than underestimate, cigarette consumption. The authors concluded that ''this could exaggerate the contribution of cigarette smoking to lung cancer risk if the next of kin of subjects dying of lung cancer were more likely to report smoking histories than were those of controls.'' (ibid, p.1246)

IMC Global, along with Cox (1997) objected to several methodological features of this study. MSHA's response to each of these criticisms appears immediately following a summary quotation from IMC Global's written comments:

(A) The regression models used to analyze the data assumed without justification that an excess risk at any exposure level implied an excess risk at all exposure levels.

The investigators did not extrapolate their regression models outside the range supported by the data. Furthermore, MSHA is using this study only for purposes of hazard identification at exposure levels at least as high as those experienced by workers in the study. Therefore, the possibility of a threshold effect at much lower levels is irrelevant.

(B) The regression model used did not specify that the exposure estimates were imperfect surrogates for true exposures. As a result, the regression coefficients do not bear any necessary relationship to the effects that they try to measure.

As noted by Cox (op cit.), random measurement errors for exposures in an univariate regression model will tend to bias results in the direction of no apparent association, thereby masking or reducing any apparent effects of exposure. The crux of Cox's criticism, however, is that, for statistical analysis of the type employed in this study, random errors in a mutivariate exposure (such as an interdependent combination of smoking, asbestos, and diesel exposure) can potentially bias results in either direction. This objection fails to consider the fact that a nearly identical regression result was obtained for the effect of diesel exposure when smoking and asbestos exposure were removed from the model: OR = 1.39 instead of 1.41. Furthermore, even with a multivariate exposure, measurement errors in the exposure being evaluated typically bias the estimate of relative risk downward toward a null result. Relative risk is biased upwards only when the various exposures are interrelated in a special way. No evidence was presented that the data of this study met the special conditions necessary for upward bias or that any such bias would be large enough to be of any practical significance.

(C) The * * * analysis used regression models without presenting diagnostics to show whether the models were appropriate for the data.

MSHA agrees that regression diagnostics are a valuable tool in assuring the validity of a statistical regression analysis. There is nothing at all unusual, however, about their not having been mentioned in the published report of this study. Regression diagnostics are rarely, if ever, published in epidemiologic studies making use of regression analysis. This does not imply that such diagnostics were not considered in the course of identifying an appropriate model or checking how well the data conform to a given model's underlying assumptions. Evaluation of the validity of any statistical analysis is (or should be) part of the peer-review process prior to publication.

(D) The * * * risk models assumed that 1959 was the effective year when DE exposure started for each worker. Thus, the analysis ignored the potentially large differences in pre-1959 exposures among workers. This modeling assumption makes it impossible to interpret the results of the study with confidence.

MSHA agrees that the lack of diesel exposure information on individual workers prior to 1959 represents an important limitation of this study. This limitation, along with a lack of quantitative exposure data even after 1959, may preclude using it to determine, with reasonable confidence, the shape or slope of a quantitative exposure-response relationship. Neither of these limitations, however, invalidates the study's finding of an elevated lung cancer risk for exposed workers. MSHA is not basing any quantitative risk assessment on this study and is relying on it, in conjunction with other evidence, only for purposes of hazard identification.

(E) The risk regression models * * * assume, without apparent justification, that all exposed individuals have identical dose-response model parameters (despite the potentially large differences in their pre-1959 exposure histories). This assumption was not tested against reasonable alternatives, *e.g.*, that individuals born in different years have different susceptibilities * * *

Cases and controls were matched on date of birth to within 2.5 years, and separate analyses were carried out for the two groups of younger and older workers. Furthermore, it is not true that the investigators performed no tests of reasonable alternatives even to the assumption that younger workers shared the same model parameters. They explored and tested potential interactions between smoking intensity and diesel exposure, with negative results. The presence of such interactions would have meant that the response to diesel exposure differed among individuals, depending on their smoking intensity.

One other objection that Cox (op cit.) raised specifically in connection with this study was apparently overlooked by IMC Global. To illustrate what he considered to be an improper evaluation of statistical significance when more than one hypothesis is tested in a study, Cox noted the finding that for workers aged less than 65 years at time of death, the odds ratio for lung cancer was significantly elevated at 20 diesel-years of exposure. He then asserted that this finding was merely

* * * an instance of a whole family of statements of the form ''Workers who were A years or younger at the time of death and who were exposed to diesel exhaust for Y years had a significantly increased relative odds ratios for lung cancer. The probability of at least one false positive occurring among the multiple hypotheses in this family corresponding to different combinations of A (*e.g.*, no more than 54, 59, 64, 69, 74, 79, etc. years old at death) and durations of exposure (*e.g.*, Y = 5, 10, 15, 20, 25, etc. years) is not limited to 5% when each combination of A and Y values is tested at a p = 5% significance level. For example, if 30 different (A, Y) combinations are considered, each independently having a 5% probability of a false positive (i.e., a reported 5% significance level), then the probability of at least one false positive occurring in the study as a whole is p = 1 − (1 − 0.05) 30 = 78%. This p-value for the whole study is more than 15 times greater than the reported significance level of 5%.

MSHA is evaluating the cumulative weight of evidence from many studies and is not relying on the level of statistical significance attached to any single finding or study viewed in isolation. Furthermore, Cox's analysis of the statistical impact of multiple comparisons or hypothesis tests is flawed on several counts, especially with regard to this study in particular. First, the analysis relies on a highly unrealistic assumption that when several hypotheses are tested within the same study, the probabilities of false positives are statistically independent. Second, Cox fails to distinguish between those hypotheses or comparisons suggested by exploration of the data and those motivated by prior considerations. Third, Cox ignores the fact that the result in question was based on a statistical regression analysis in which diesel exposure duration was modeled as a single continuous variable. Therefore, this particular result does not depend on multiple hypothesis-testing with respect to exposure duration. Fourth, and most importantly, Cox assumes that age and exposure duration were randomly picked for testing from a pool of interchangeable possibilities and that the only thing distinguishing the combination of ''65 years of age'' and ''20 diesel-years of exposure'' from other random combinations was that it happened to yield an apparently significant result. This is clearly not the case. The investigators divided workers into only two age groups and explained that this division was based on the history of dieselization in the railroad industry—not on the results of their data analysis. Similarly, the result for 20 diesel-years of exposure was not favored over shorter exposure times simply because 20 years yielded a significant result and the shorter times did not. Lengthy exposure and latency periods are required for the expression of increased lung cancer risks, and this justifies a focus on the longest exposure periods for which sufficient data are available.

Garshick et al., 1988; Garshick, 1991

In this study, the investigators assessed the risk of lung cancer in a cohort of 55,407 white male railroad workers, aged 40 to 64 years in 1959, who had begun railroad work between 1939 and 1949 and were employed in one of 39 jobs later surveyed for exposure. Workers whose job history indicated likely occupational exposure to asbestos were excluded. Based on the subsequent exposure survey, each of the 39 jobs represented in the cohort was classified as either exposed or unexposed to diesel emissions. The cohort was followed through 1980, and 1,694 cases of death due to lung cancer were identified.

As in the 1987 study by the same investigators, detailed railroad job histories from 1959 to date of death or retirement were obtained from RRB records and combined with the exposure classification for each job to provide the years of diesel exposure accumulated since 1959 for each worker in the cohort. Using workers classified as ''unexposed'' within the cohort to establish a baseline, time-dependent proportional hazards regression models were employed to evaluate the relative risk of lung cancer for exposed workers. Although the investigators believed they had excluded most workers with significant past asbestos exposures from the cohort, based on job codes, they considered it possible that some workers classified as hostlers or shop workers may have been included in the cohort even if occupationally exposed to asbestos. Therefore, they carried out statistical analyses with and without shop workers and hostlers included.

The main results of this study are presented in the following table. Statistically significant elevations of lung cancer risk were found regardless of whether or not shop workers and hostlers were included. The 1988 analysis adjusted for age in 1959, and the 1991 analysis adjusted, instead, for age at death or end of follow-up (i.e., end of 1980).[54] In the 1988 analysis, any work during a year counted as a diesel-year if the work was in a diesel-exposed job category, and the results from the 1991 analysis presented here are based on this same method of compiling exposure durations. Exposure durations excluded the year of death and the four prior years, thereby allowing for some latency in exposure effects. Results for the analysis excluding shop workers and hostlers were not presented in the 1991 report, but the report stated that ''similar results were obtained.'' Using either method of age adjustment, a statistically significant elevation of lung cancer risk was associated with each exposure duration category. Using ''attained age,'' however, there was no strong indication that risk increased with increasing exposure duration. The 1991 report concluded that ''there appears to be an effect of diesel exposure on lung cancer mortality'' but that ''because of weaknesses in exposure ascertainment * * *, the nature of the exposure-response relationship could not be found in this study.''

MAIN RESULTS FROM GARSHICK ET AL., 1988 AND GARSHICK, 1991

Exposure duration (diesel-years, last 5 years excluded)	Full cohort		Shopworkers & hostlers excluded	
	Relative risk	95% conf. int.	Relative risk	95% conf. int.
1–4	1.20	1.01–1.44	1.34	1.08–1.65
	1.31	1.09–1.57	N.R.	N.R.
5–9	1.24	1.06–1.44	1.33	1.12–1.58
	1.28	1.09–1.49	N.R.	N.R.
10–14	1.32	1.13–1.56	1.33	1.10–1.60
	1.19	1.002–1.41	N.R.	N.R.
15 or more	1.72	1.27–2.33	1.82	1.30–2.55
	1.40	1.03–1.90	N.R.	N.R.

Top entry within each cell is from 1988 analysis, adjusted for age in 1959. Bottom entry is from 1991 analysis, adjusted for age at death or end of follow-up (''attained age''). N.R. means ''not reported.''

Some commenters noted that removing the shop workers and hostlers from the analysis increased the relative risk estimates. Dr. Peter Valberg found this ''paradoxical,'' since workers in these categories had later been found to experience higher average levels of diesel exposure than other railroad workers.

This so-called paradox is likely to have resulted simply from exposure misclassification for a significant portion of the shop workers. The effect was explained by Garshick (1991) as follows:

> * * * shop workers who worked in the diesel repair shops shared job codes with workers in non-diesel shops where there was no diesel exhaust * * *. Apparent exposure as a shop worker based on the job code was then diluted with workers with the same job code but without true exposure, making it less likely to see an effect in the shop worker group. In addition, workers in the shop worker group of job codes tended to have less stable career paths * * * compared to the other diesel exposure categories.

So although many of the shopworkers may have been exposed to relatively high dpm concentrations, many others were among the lowest-exposed workers or were even unexposed because they spent their entire occupational lifetimes in unexposed locations. This could readily account for the increase in relative risks calculated when shop workers were excluded from the analysis.

Dr. Valberg also noted that, according to Crump (1999), mortality rates for cirrhosis of the liver and heart disease were significantly elevated for ''train riders,'' who were exposed to diesel emissions, as compared to other members of the cohort, who were less likely to be exposed. It is also the train riders who account, primarily, for the elevated risk of lung cancer associated with diesel exposure in the overall cohort. Dr. Valberg interpreted this as suggesting that ''lifestyle'' factors such as diet or smoking habits, rather than diesel exposure, were responsible for the increased risk of lung cancer observed among the diesel-exposed workers.

Dr. Valberg presented no evidence that, apart from diesel exposure, the train riders differed systematically from the other workers in their smoking habits or in other ways that would be expected to affect their risk of lung cancer. Therefore, MSHA views the suggestion of such a bias as speculative. Even if lifestyle factors associated with

[54] Also, the 1991 analysis excluded 12 members of the cohort due to discrepancies between work history and reported year of death, leaving 55,395 railroad workers included in the analysis.

train ridership were responsible for an increased risk of cirrhosis of the liver or heart disease, this would not necessarily mean that the same factors were also responsible for the increased risk of lung cancer. Still, it is hypothetically possible that systematic differences, other than diesel exposure, between train riders and other railroad workers could account for some or even all of the increased lung cancer risk. That is why MSHA does not rely on this, or any other, single study in isolation.

Some commenters, including the NMA, objected to this study on grounds that it failed to control for potentially confounding factors, principally smoking. The NMA stated that this ''has rendered its utility questionable at best.'' As explained earlier, there is more than one way in which a study can control for smoking or other potential confounders. One of the ways is to make sure that groups being compared do not differ with respect to the potential confounder. In this study, workers with likely asbestos exposure were excluded from the cohort, stability of workers within job categories was well documented, and similar results were reported when job categories subject to asbestos exposure misclassification were excluded. In their 1988 report, the investigators provided the following reasons to believe that smoking did not seriously affect their findings:

> * * * the cohort was selected to include only blue-collar workers of similar socioeconomic class, a known correlate of cigarette smoking * * *, in our case-control study [Garshick et al., 1987], when cigarette smoking was considered, there was little difference in the crude or adjusted estimates of diesel exhaust effects. Finally, in the group of 517 current railroad workers surveyed by us in 1982 * * *, we found no difference in cigarette smoking prevalence between workers with and without potential diesel exhaust exposure. [Garshick et al., 1988]

Since relative risks were based on internal comparisons, and the cohort appears to have been fairly homogeneous, MSHA regards it as unlikely that the association of lung cancer with diesel exposure in this study resulted entirely from uncontrolled asbestos or smoking effects. Nevertheless, MSHA recognizes that differential smoking patterns may have affected, in either direction, the degree of association reported in each of the exposure duration categories.

Cox (1997) re-analyzed the data of this study using exploratory, nonparametric statistical techniques. As quoted by IMC Global, Cox concluded that ''these methods show that DE [i.e., dpm] concentration has no positive causal association with lung cancer mortality risk.'' MSHA believes this quotation (taken from the abstract of Cox's article) overstates the findings of his analysis. At most, Cox confirmed the conclusion by Garshick (1991) that these data do not support a positive exposure-response relationship. Specifically, Cox determined that inter-relationships among cumulative diesel exposure, age in 1959, and retirement year make it ''impossible to prove causation by eliminating plausible rival hypotheses based on this dataset.'' (Cox, 1997; p. 826) Even if Cox's analysis were correct, it would not follow that there is no underlying causal connection between dpm exposure and lung cancer. It would merely mean that the data do not contain internal evidence implicating dpm exposure as the cause, rather than one or more of the variables with which exposure is correlated. Cox presented no evidence that any ''rival hypotheses'' were more plausible than causation by dpm exposure. Furthermore, it may simply be, as Garshick suggested, that an underlying exposure-response relationship is not evident ''because of weaknesses in exposure ascertainment.'' (Garshick, 1991, op cit.) None of this negates the fact that, after adjusting for either age in 1959 or ''attained'' age, lung cancer was significantly more prevalent among the exposed workers.

Along similar lines, many commenters pointed out that an HEI expert panel examined the data of this study (HEI, 1999) and found that it had very limited use for quantitative risk assessment (QRA). Several of these commenters mischaracterized the panel's findings. The NMA, for example, drew the following unjustified conclusion from the panel's report: ''In short, * * * the correct interpretation of the Garshick study is that any occupational increase in lung cancer among train workers was not due to diesel exposures.''

Contrary to the NMA's characterization, the HEI Expert Panel's report stated that the data are

> * * * consistent with findings of a weak association between death from lung cancer and occupational exposure to diesel exhaust. Although the secondary exposure-response analyses * * * are conflicting, the overall risk of lung cancer was elevated among diesel-exposed workers. [Ibid., p. 25]

The panel agreed with Garshick (1991) and Cox (1997) that the data of this study do not support a positive exposure-response relationship. Like Garshick and unlike Cox, however, the panel explicitly recognized that problems with the data could mask such a relationship and that this does not negate the statistically significant finding of elevated risk among exposed workers. Indeed, the panel even identified several factors, in addition to weak exposure assessment as suggested by Garshick, that could mask a positive relationship: unmeasured confounding variables such as cigarette smoking, previous occupational exposures, or other sources of pollution; a ''healthy worker survivor effect''; and differential misclassification or incomplete ascertainment of lung cancer deaths. (HEI, 1999; p. 32)

Positive exposure-response relationships based on these data were reported by the California EPA (OEHHA, 1998). MSHA recognizes that those findings were sensitive to various assumptions and that other investigators have obtained contrary results. The West Virginia Coal Association, paraphrasing Dr. Peter Valberg, concluded that although the two studies by Garshick et al. ''* * * may represent the best in the field, they fail to firmly support the proposition that lung cancer risk in workers derives from exposure to dpm.'' At least one commenter (IMC Global) apparently reached a considerably stronger conclusion that they were of no value whatsoever, and urged MSHA to ''discount their results and not consider them in this rulemaking.'' On the other hand, in response to the ANPRM, a consultant to the National Coal Association who was critical of all other studies available at the time acknowledged that these two:

> [* * * have successfully controlled for severally [sic] potentially important confounding factors * * *. Smoking represents so strong a potential confounding variable that its control must be nearly perfect if an observed association between cancer and diesel exhaust is * * * [inferred to be causal]. In this regard, two observations are relevant. First, both case-control [Garshick et al., 1987] and cohort [Garshick et al., 1988] study designs revealed consistent results. Second, an examination of smoking related causes of death other than lung cancer seemed to account for only a fraction of the association observed between diesel exposure and lung cancer. A high degree of success was apparently achieved in controlling for smoking as a potentially confounding variable. [Robert A. Michaels, RAM TRAC Corporation, submitted by National Coal Association].

To a limited extent, MSHA agrees with Dr. Valberg and the West Virginia Coal Association: these two studies—like every real-life epidemiologic study—are not ''firmly'' conclusive when viewed in isolation. Nevertheless, MSHA believes that they provide important contributions to the overall body of evidence. Whether or not they can be used to quantify an exposure-response relationship, these studies—among the most comprehensive and carefully controlled currently available—do show statistically significant increases in the risk of lung cancer among diesel-exposed workers.

Johnston et al. (1997)

Since it focused on miners, this study has already been summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The tabled relative risk estimates presented for cumulative exposures greater than 1000 mg-hr/m³ (i.e., 1 g-hr/m³) were calculated by MSHA based on the regression coefficients reported by the authors. The conversion from mg-hr/m³ to mg-yr/m³ assumes 1,920 occupational exposure hours per year. Although 6.1 mg-yr/m³ Dpm roughly equals the cumulative exposure estimated for the most highly exposed locomotive drivers in the study, the relative risk associated with this exposure level is presented primarily for purposes of comparison with findings of Saverin et al. (1999).

MAIN RESULTS FROM JOHNSTON ET AL., 1997

Cumulative dpm exposure	Mine-adjusted model (15-yr lag)		Mine-unadjusted model (15-yr lag)	
	Relative risk	95% conf. interval	Relative risk	95% conf. interval
1000 mg-hr/m³ (= 0.521 mg-yr/m³)	1.156	0.90–1.49	1.227	1.00–1.50.
1920 mg-hr/m³ (= 1 mg-yr/m³)	1.321	Not reported	1.479	Not reported
11,700 mg-hr/m³ ($\simeq$ 6.1 mg-yr/m³)	5.5	Not reported	11.0	Not reported

In its post-hearing comments, MARG acknowledged that this study ''found a 'weak association' between lung cancer and respiratory diesel particulate exposure'' but failed to note that the estimated relative risk increased with increasing exposure. MARG also stated that the association was ''deemed non-significant by the researchers'' and that ''no association was found among men with different exposures working in the same mines.'' Although the mine-adjusted model did not support 95-percent confidence for an increasing exposure-response relationship, the mine-unadjusted model yielded a statistically significant positive slope at this confidence level. Furthermore, since the mine-adjusted model adjusts for differences in lung cancer rates between mines, the fact that relative risk increased with increasing exposure under this model indicates (though not at a 95-percent confidence level) that the risk of lung cancer increased with exposure among men with different exposures working in the same mines.

Säverin et al. (1999)

Since this study, like the one by Johnston et al., was carried out on a cohort of miners, it too was summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The relative risk estimates and confidence intervals at the mean exposure level of 2.7 mg-yr/m³ TC (total carbon) were calculated by MSHA, based on values of α and corresponding confidence intervals presented in Tables III and IV of the published report (ibid., p. 420). The approximate equivalency between 4.9 mg-yr/m³ TC and 6.1 mg-yr/m³ Dpm assumes that, on average, TC comprises 80 percent of Dpm.

MAIN RESULTS FROM SAVERIN ET AL., 1999

	Relative risk	95% confidence interval
Highest compared to least exposed worker category	2.17	0.79–5.99

Cumulative total carbon exposure	Proportional hazards (Cox) Model *		Poisson mode *	
	Relative risk	95% conf. interval	Relative risk	95% conf. interval
2.7 mg-yr/m³ TC (i.e., cohort mean)	1.33 1.73	0.67–2.64 0.70–4.30	1.08 1.42	0.59–1.99 0.65–3.92
4.9 mg-yr/m³ TC ($\simeq$6.1 mg-yr/m³ dpm)	1.68 2.70	0.49–5.8 0.52–14.1	1.16 1.89	0.38–3.3 0.46–11.9

* Top entry in each cell is based on full cohort; bottom entry is based on subcohort, which was restricted to miners who worked underground at least ten years, with at least 80 percent of employment in same job, etc.

These results are not statistically significant at the conventional 95-percent confidence level. However, the authors noted that the relative risk calculated for the subcohort was consistently higher than that calculated for the full cohort. They also considered the subcohort to have a superior exposure assessment and a better latency allowance than the full cohort. According to the authors, these factors provide ''some assurance that the observed risk elevation was not entirely due to chance since improving the exposure assessment and allowing for latency effects should, in general, enhance exposure effects.''

Steenland et al., (1990, 1992, 1998)

The basis for the analyses in this series was a case-control study comparing the risk of lung cancer for diesel-exposed and unexposed workers who had belonged to the Teamsters Union for at least twenty years (Steenland et al., 1990). Drawing from union records, 996 cases of lung cancer were identified among more than 10,000 deaths in 1982 and 1983. For comparison to these cases, a total of 1,085 controls was selected (presumably at random) from the remaining deaths, restricted to those who died from causes other than lung cancer, bladder cancer, or motor vehicle accident. Information on work history, duration and intensity of cigarette smoking, diet, and asbestos exposure was obtained from next of kin. Detailed work histories were also obtained from pension applications on file with the Teamsters Union.

Both data sources were used to classify cases and controls according to a job category in which they had worked the longest. Based on the data obtained from next of kin, the job categories were diesel truck drivers, gasoline truck drivers, drivers of both truck types, truck mechanics, and dock workers. Based on the pension applications, the principal job categories were long-haul drivers, short-haul or city drivers, truck mechanics, and dock workers. Of the workers identified by next of kin as primarily diesel truck drivers, 90 percent were classified as long-haul drivers according to the Teamster data. The corresponding proportions were 82 percent for mechanics and 81 percent for dock workers. According to the investigators, most Teamsters had worked in only one exposed job category. However, because of the differences in job category definitions, and also because the next of kin data covered lifetimes whereas the pension applications covered only time in the Teamsters Union, the investigators found it problematic to fully evaluate the concordance between the two data sources.

In the 1990 report, separate analyses were conducted for each source of data used to compile work histories. The investigators noted that ''many trucking companies (where most study subjects worked) had completed most of the dieselization of their fleets by 1960, while independent drivers and nontrucking firms may have obtained diesel trucks later * * *'' Therefore, they specifically checked for associations between increased risk of lung cancer and occupational exposure after 1959 and, separately, after 1964. In the 1992 report, the investigators presented, for the Union's occupational categories used in the study, dpm exposure estimates based on subsequent measurements of submicrometer elemental carbon (EC) as reported by Zaebst et al. (1991). In the 1998 report, cumulative dpm exposure estimates for individual workers were compiled by combining the individual work histories obtained from the Union's records with the subsequently measured occupational exposure levels, along with an evaluation of historical changes in diesel engine emissions and patterns of diesel usage. Three alternative sets of cumulative exposure estimates were considered, based on alternative assumptions about the extent of improvement in diesel engine emissions between 1970 and 1990. A variety of statistical models and techniques were then employed to investigate the relationship between estimated cumulative dpm exposure (expressed as EC) and the risk of lung cancer. The authors pointed out that the results of these statistical analyses depended heavily on ''very broad assumptions'' used to generate the estimates of cumulative dpm exposure. While acknowledging this limitation, however, they also evaluated the sensitivity of their results to various changes in their assumptions and found these changes to have little impact on the results.

The investigators also identified and addressed several other limitations of this study as follows:

> (1) possible misclassification smoking habits by next of kin, (2) misclassification of exposure by next of kin, (3) a relatively small non-exposed group (n = 120) which by chance may have had a low lung cancer risk, and (4) lack of sufficient latency (time since first exposure) to observe a lung cancer excess. On the other hand, next-of-kin data on smoking have been shown to be reasonably accurate, non-differential misclassification of exposure * * * would only bias our findings toward * * * no association, and the trends of increased risk with increased duration of employment in certain jobs would persist even if the non-exposed group had a higher lung cancer risk. Finally, the lack of potential latency would only make any positive results more striking. (Steenland et al., 1990)

The main results from the three reports covering this study are summarized in the following table. All of the analyses were controlled for age, race, smoking (five categories), diet, and asbestos exposure as reported by next of kin. Odds ratios for the occupations listed were calculated relative to the odds of lung cancer for occupations other than truck driver (all types), mechanic, dock worker, or other potentially diesel exposed jobs (Steenland et al., 1990, Appendix A). The exposure-response analyses were carried out using logistic regression. Although the investigators performed analyses under three different assumptions for the rate of engine emissions (gm/mile) in 1970, they considered the intermediate value of 4.5 gm/mile to be their best estimate, and this is the value on which the results shown here are based. Under this assumption, cumulative occupational EC exposure for all workers in the study was estimated to range from 0.45 to 2,440 μg-yr/m^3, with a median value of 373 μg-yr/m^3. The estimates of relative risk (expressed as odds ratios) presented for EC exposures of 373 μg-yr/m^3, 1000 μg-yr/m^3, and 2450 μg-yr/m^3 were calculated by MSHA based on the regression coefficients reported by the authors for five-year lagged exposures (Steenland et al. 1998, Table II).

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Main results from Steenland et al., (1990, 1992, 1998)

Principal Occupation	Mean 1990 EC Concentration ($\mu g/m^3$)	Duration of Employment	Lung Cancer Odds Ratio	95-percent Conf. Interval
Diesel truck driver	N.A.	35 or more years*	1.89	1.04 - 3.42
Short-haul driver	5.4	18 or more years after 1959	1.79	0.94 - 3.42
Long-haul driver	5.1	18 or more years after 1959	1.55	0.97 - 2.47
		13 or more years after 1964	1.64	1.05 - 2.57
Truck mechanic	26.6	18 or more years after 1959	1.50	0.59 - 3.40
Cumulative Occupational Exposure (μg-yr/m^3, lagged 5 years)**			**Lung Cancer Odds Ratio**	**95-percent Conf. Interval**
EC	**TC ≈ 2•EC**	**dpm ≈ TC/0.8 ≈ 2.5•EC**		
0 - 169	0 - 338	0 - 422	1.08	0.72 - 1.63
169 - 257	338 - 514	422 - 642	1.10	0.74 - 1.65
257 - 331	514 - 662	642 - 827	1.36	0.90 - 2.04
more than 331	more than 662	more than 827	1.64	1.09 - 2.49
			Lung Cancer Odds Ratio‡	
		Logistic regression model ➜	**Simple Cum. Exposure**	**Log of Cum. Exposure**
373	746	932	1.16	1.41
1,000	2,000	2,500	1.48	1.66
2,450	4,900	6,100	2.59	1.93

*Although primary occupation was driving diesel trucks, employment duration includes years driving any type of truck.

**Conversions between EC, TC, and dpm assume that, on average, TC ≈ 2•EC and TC ≈ 0.8•dpm.

‡ Calculated by MSHA from regression coefficients presented by Steenland et al. (1990), Table II. Statistically significant regression coefficients reported for both models (95% Conf. level). Tabled results for Log(Cum. exposure) model have been adjusted for lifetime background exposure of 65 μg-yr/m^3 assumed in regression analysis.

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Under the assumption of a 4.5 gm/mile emissions rate in 1970, the cumulative EC exposure of 2450 μg-yr/m^3 ($\simeq$ 6.1 mg-yr/m^3 dpm) shown in the table closely corresponds to the upper limit of the range of data on which the regression analyses were based (Steenland et al., 1998, p. 224). However, the relative risks (i.e., odds ratios) calculated for this level of occupational exposure are presented primarily for purposes of comparison with the findings of Johnston et al. (1997) and Säverin et al. (1999). At a cumulative dpm exposure of approximately 6.1 mg-yr/m^3, it is evident that the Johnston models predict a far greater elevation in lung cancer risk than either the Šaverin or Steenland models. A possible explanation for this is that the Johnston data included exposures of up to 30 years in duration, and the statistical models showing an exposure-response relationship allowed for a 15-year lag in exposure effects. The other two studies were based on generally shorter diesel exposures and allowed less time for latent effects. In Subsection 3.b.ii(3) of this risk assessment, the quantitative results of these three studies will be further compared with respect to exposure levels found in underground mines.

Several commenters noted that the HEI Expert Panel (HEI, 1999) had identified uncertainties in the diesel exposure assessment as an important limitation of the exposure-response analyses by Steenland et al. (1998) and had recommended further investigation before the quantitative results of this study were accepted as conclusive. In addition, Navistar International Transportation (NITC) raised a number of objections to the methods by which diesel exposures were estimated for the period between 1949 and 1990 (NITC, 1999). In general, the thrust of these objections was that exposures to diesel engine emissions had been overestimated, while potentially relevant exposures to gasoline engine emissions had been underestimated and/or unduly discounted.[55]

As mentioned above, the investigators recognized that these analyses rely on ''broad assumptions rather than actual [concurrent] measurements,'' and they proposed that the ''results should be regarded with appropriate caution.'' While agreeing with both the investigators and the HEI Expert Panel that these results should be interpreted with appropriate caution, MSHA also agrees with the Panel ''* * * that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 39) In this context, MSHA considers it appropriate to regard the 1998 exposure-response analyses as contributing to the weight of evidence that dpm exposure increases the risk of lung cancer, even if the results are not conclusive when viewed in isolation.

Some commenters also noted that the HEI Expert Panel raised the possibility that the method for selecting controls in this study could potentially have biased the results in an unpredictable direction. Such bias could have occurred because deaths among some of the controls were likely due to diseases (such as cardiovascular disease) that shared some of the same risk factors (such as tobacco smoking) with lung cancer. The Panel presented hypothetical examples of how this might bias results in either direction. Although the possibility of such bias further demonstrates why the results of this study should be regarded with ''appropriate caution,'' it is important to distinguish between the mere possibility of a control-selection bias, evidence that such a bias actually exists in this particular study, and the further evidence required to show that such bias not only exists but is of sufficient magnitude to have produced seriously misleading results. Unlike the commenters who cited the HEI Expert Panel on this issue, the Panel itself clearly drew this distinction, stating that ''no direct evidence of such bias is apparent'' and emphasizing that ''even though these examples [presented in HEI (1999), Appendix D] could produce misleading results, it is important to note that they are only hypothetical examples. Whether or not such bias is present will require further examination.'' (HEI, 1999, pp. 37–38) As the HEI showed in its examples, such bias (if it exists) could lead to underestimating the association between lung cancer and dpm exposure, as well as to overestimating it. Therefore, in the absence of evidence that control-selection bias actually distorted the results of this study one way or the other, MSHA considers it prudent to accept the study's finding of an association at face value.

One commenter (MARG) noted that information on cigarette smoking, asbestos exposure, and diet in the trucking industry study was obtained from next of kin and stated that such information was ''likely to be unreliable.'' By increasing random variability in the data, such errors could widen the confidence intervals around an estimated odds ratio or reduce the confidence level at which a positive exposure-response relationship might be established. However, unless such errors were correlated with diesel exposure or lung cancer in such a way as to bias the results, they would not, on average, inflate the estimated degree of association between diesel exposure and an increased risk of ling cancer. The commenter provided no reason to suspect that errors with respect to these factors were in any way correlated with diesel exposure or with the development of lung cancer.

Some commenters pointed out that EC concentrations measured in 1990 for truck mechanics were higher, on average, than for truck drivers, but the mechanics, unlike the drivers, showed no evidence of increasing lung cancer risk with increasing duration of employment. NITC referred to this as a ''discrepancy'' in the data, assuming that ''cumulative exposure increases with duration of employment such that mechanics who have been employed for 18 or more years would have greater cumulative exposure than workers who have been employed for 1–11 years.'' (NITC, 1999)

Mechanics were included in the logistic regression analyses (Steenland et al., 1998) showing an increase in lung cancer risk with increasing cumulative exposure. These analyses pooled the data for all occupations by estimating exposure for each worker based on the worker's occupation and the particular years in which the worker was employed. There are at least three reasons why, for mechanics viewed as a separate group, an increase in lung cancer risk with increasing dpm exposure may not have been reflected by increasing duration of employment.

First, relatively few truck mechanics were available for analyzing the relationship between length of employment and the risk of lung cancer. Based on the union records, 50 cases and 37 controls were so classified; based on the next-of-kin data, 43 cases and 41 controls were more specifically classified as diesel truck mechanics (Steenland et al., 1990). In contrast, 609 cases and 604 controls were classified as long-haul drivers (union records). This was both the largest occupational category and the only one showing statistically significant evidence of increasing risk with increasing employment duration. The number of mechanics included in the study population may simply not have been sufficient to detect a pattern of increasing risk with increasing length of employment, even if such a pattern existed.

The second part of the explanation as to why mechanics did not exhibit a pattern similar to truck drivers could be that the data on mechanics were more subject to confounding. After noting that ''the risk for mechanics did not appear to increase consistently with duration of employment,'' Steenland et al. (1990) further noted that the mechanics may have been exposed to asbestos when working on brakes. The data used to adjust for asbestos exposure may have been inadequate to control for variability in asbestos exposure among the mechanics.

Third, as noted by NITC, the lung cancer risk for mechanics (adjusted for age, race, tobacco smoking, asbestos exposure, and diet) would be expected to increase with increasing duration of

[55] Many of the issues NITC raised in its critique of this study depend on a peculiar identification of dpm exclusively with elemental carbon. For example, NITC argued that ''more than 65 percent of the total carbon to which road drivers (and mechanics) were exposed consisted of organic (i.e., non-diesel) carbon, further suggesting that some other etiology caused or contributed to excess lung cancer mortality in these workers.'' (NITC, 1999, p. 16) Such lines of argument, which depend on identifying organic carbon as ''non-diesel,'' ignore the fact that dpm contains a large measure of organic carbon compounds (and also some sulfates), as well as elemental carbon. Any adverse health effects due to the organic carbon or sulfate constituents of dpm would nonetheless be due to dpm exposures.

employment only if the mechanics' cumulative dpm exposure corresponded to the length of their employment. None of the commenters raising this issue, however, provided any support for this assumption, which fails to consider the particular calendar years in which mechanics included in the study were employed. In compiling cumulative exposure for an individual worker, the investigators took into account historical changes in both diesel emissions and the proportion of trucks with diesel engines—so the exposure level assigned to each occupational category was not the same in each year. In general, workers included in the study neither began nor ended their employment in the same year. Consequently, workers with the same duration of employment in the same occupational category could be assigned different cumulative exposures, depending on when they were employed. Similarly, workers in the same occupational category who were assigned the same cumulative exposure may not have worked the same length of time in that occupation. Therefore, it should not be assumed that duration of employment corresponds very well to the cumulative exposure estimated for workers within any of the occupational categories. Furthermore, in the case of mechanics, there is an additional historical variable that is especially relevant to actual cumulative exposure but was not considered in formulating exposure estimates: the degree of ventilation or other means of protection within repair shops. Historical changes in shop design and work practices, as well as differences between shops, may have caused more exposure misclassification among mechanics than among long-haul or diesel truck drivers. Such misclassification would tend to further obscure any relationship between mechanics' risk of lung cancer and either duration of employment or cumulative exposure.

(iv) Counter-Evidence. Several commenters stated that, in the proposal, MSHA had dismissed or not adequately addressed epidemiology studies showing no association between lung cancer and exposures to diesel exhaust. For example, the EMA wrote:

> MSHA's discussion of the negative studies generally consists of arguments to explain why those studies should be dismissed. For example, MSHA states that, ''All of the studies showing negative or statistically insignificant positive associations . . . lacked good information about dpm exposure . . .'' or showed similar shortcomings. 63 Fed. Reg. at 17533. The statement about exposure information is only partially true, for, in fact, very few of any of the cited studies (the ''positive'' studies as well) included any exposure measurements, and none included concurrent exposures.

It should, first of all, be noted that the statement in question on dpm exposure referred to the issue of any diesel exposure—not to quantitative exposure measurements, which MSHA acknowledges are lacking in most of the available studies. In the absence of quantitative measurements, however, studies comparing workers known to have been occupationally exposed to unexposed workers are preferable to studies not containing such comparisons. Furthermore, two of the studies now available (and discussed above) utilize essentially concurrent exposure measurements, and both show a positive association (Johnston et al., 1997; Säverin *et al.,* 1999).

MSHA did not entirely ''dismiss'' the negative studies. They were included in both MSHA's tabulation (see Tables III–4 and III–5) and (if they met the inclusion criteria) in the two meta-analyses cited both here and in the proposal (Lipsett and Campleman, 1999, and Bhatia et al., 1998). As noted by the commenter, MSHA presented reasons (such as an inadequate latency allowance) for why negative studies may have failed to detect an association. Similarly MSHA gave reasons for giving less weight to some of the positive studies, such as Benhamou et al. (1988), Morabia et al. (1992), and Siemiatycki et al., 1988. Additional reasons for giving less weight to the six entirely negative studies have been tabulated above, under the heading of ''Best Available Epidemiologic Evidence.'' The most recent of these negative studies (Christie et al., 1994, 1995) is discussed in detail under the heading of ''Studies Involving Miners.''

One commenter (IMC Global) listed the following studies (all of which MSHA had considered in the proposed risk assessment) as ''examples of studies that reported negative associations between [dpm] exposure and lung cancer risk'':

- Waller (1981). This is one of the six negative studies discussed earlier. Results were likely to have been biased by excluding lung cancers occurring after retirement or resignation from employment with the London Transit Authority. Comparison was to a general population, and there was no adjustment for a healthy worker effect. Comparison groups were disparate, and there was no adjustment for possible differences in smoking frequency or intensity.
- Howe et al. (1983). Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risk for workers classified as ''possibly exposed'' or ''probably exposed'' to diesel exhaust. MSHA recognizes that these results may have been confounded by asbestos and coal dust exposures.
- Wong et al. (1985). The investigators reported a statistically insignificant deficit for lung cancer in the entire cohort and a statistically significant deficit for lung cancer in the less than 5-year duration group. However, since comparisons were to a general population, these deficits may be the result of a healthy worker effect, for which there was no adjustment. Because of the latency required for development of lung cancer, the result for ''less than 5-year duration'' is far less informative than the results for longer durations of employment and greater latency allowances. Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risks for ''normal'' retirees (SMR = 1.30) and for ''high exposure'' dozer operators with 15–19 years of union membership and a latency allowance of at least 20 years (SMR = 3.43).
- Edling et al. (1987). This is one of the six negative studies discussed earlier. The cohort consisted of only 694 bus workers and, therefore, lacked statistical power. Furthermore, comparison was to a general, external population with no adjustment for a healthy worker effect.
- Garshick (1988). The reason the commenter (IMC Global) gave for characterizing this study as negative was: ''That the sign of the association in this data set changes based on the models used suggests that the effect is not robust. It apparently reflects modeling assumptions more than data.'' Contrary to the commenter's characterization, however, the finding of increased lung cancer risk for workers classified as diesel-exposed did not change when different methods were used to analyze the data. What changed, depending on modeling assumptions, was the shape and direction of the exposure-response relationship among exposed workers (Cal-EPA, 1998; Stayner et al., 1998; Crump, 1999; HEI, 1999). MSHA agrees that the various exposure-response relationships that have been derived from this study are highly sensitive to data modeling assumptions. This includes assumptions about historical patterns of exposure, as well as assumptions related to technical aspects of the statistical analysis. However, as noted by the HEI Expert Panel, the study provides evidence of a

positive association between exposure and lung cancer despite the conflicting exposure-response analyses. Even though different assumptions and methods of analysis have led to different conclusions about the utility of this study for quantifying an exposure-response relationship, ''the overall risk of lung cancer was elevated among diesel-exposed workers'' (HEI, 1999, p. 25).

Another commenter (MARG) cited a number of studies (all of which had already been placed in the public record by MSHA) that, according to the commenter, ''reflect either negative health effects trends among miners or else failed to demonstrate a statistically significant positive trend correlated with dpm exposure.'' It should be noted that, as explained earlier, failure of an individual study to achieve statistical significance (i.e., a high confidence level for its results) does not necessarily prevent a study from contributing important information to a larger body of evidence. An epidemiologic study may fail to achieve statistical significance simply because it did not involve a sufficient number of subjects or because it did not allow for an adequate latency period. In addition to this general point, the following responses apply to the specific studies cited by the commenter.

• Ahlman et al. (1991). This study is discussed above, under the heading of ''Studies Involving Miners.'' MSHA agrees with the commenter that this study did not ''establish'' a relationship between diesel exposure and the excess risk of lung cancer reported among the miners involved. Contrary to the commenter's characterization, however, the evidence presented by this study does incrementally point in the direction of such a relationship. As mentioned earlier, none of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on measurements of the alpha energy concentration at the mines, and a comparison of smoking habits between underground and surface miners, the authors concluded that not all of the excess lung cancer for the underground miners was attributable to radon daughter exposures and/or smoking. A stronger conclusion may have been possible if the cohort had been larger.

• Ames et al. (1984). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter repeated MSHA's statement (in the proposed risk assessment) that the investigators had not detected any association of chronic respiratory effects with diesel exposure, but ignored MSHA's observation that the analysis had failed to consider baseline differences in lung function or symptom prevalence. Furthermore, as acknowledged by the investigators, diesel exposure levels in the study population were low.

• Ames et al. (1983). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Unlike the Australian mines studied by Christie et al. (1995), the coal mines included in this study were not extensively dieselized, and the investigators did not relate their findings to diesel exposures.

• Ames et al. (1982). As noted earlier under the heading of ''Acute Health Effects,'' this study, which did not attempt to evaluate cancer or other chronic health effects, detected no statistically significant relationship between diesel exposure and pulmonary function. However, the authors noted that this might have been due to the low concentrations of diesel emissions involved.

• Armstrong et al. (1979). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. As pointed out by the commenter, comparisons were to a general population. Therefore, they were subject to a healthy worker effect for which no adjustment was made. The commenter further stated that ''diesel emissions were not found to be related to increased health risks.'' However, diesel emissions were not mentioned in the report, and the investigators did not attempt to compare lung cancer rates in exposed and unexposed miners.

• Attfield et al (1982). MSHA has taken the results of this study into account, under the heading of ''Chronic Effects other than Cancer.''

• Attfield (1979). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Although the results were not conclusive at a high confidence level, miners occupationally exposed to diesel exhaust for five or more years exhibited an increase in various respiratory symptoms, as compared to miners exposed for less than five years.

• Boffetta et al. (1988). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' The commenter stated that ''the study obviously does not demonstrate risks from dpm exposure.'' If the word ''demonstrate'' is taken to mean ''conclusively prove,'' then MSHA would agree that the study, viewed in isolation, does not do this. As explained in the earlier discussion, however, MSHA considers this study to contribute to the weight of evidence that dpm exposure increases the risk of lung cancer.

• Costello et al. (1974). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Since comparisons were to a general population, they were subject to a healthy worker effect for which no adjustment was made. Diesel emissions were not mentioned in the report.

• Gamble and Jones (1983). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter did not address MSHA's observation that the method of statistical analysis used by the investigators may have masked an association of respiratory symptoms with diesel exposure.

• Glenn et al. (1983). As summarized by the commenter, this report reviewed NIOSH medical surveillance on miners exposed to dpm and found that ''* * * neither consistent nor obvious trends implicating diesel exhaust in the mining atmosphere were revealed.'' The authors noted that ''results were rather mixed,'' but also noted that ''levels of diesel exhaust contaminants were generally low,'' and that ''overall tenure in these diesel equipped mines was fairly short.'' MSHA acknowledges the commenter's emphasis on the report's 1983 conclusion: ''further research on this subject is needed.'' However, the authors also pointed out that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group. In the potash, salt and trona groups, these excesses were substantial.'' The miners included in the studies summarized by this report would not have been exposed to dpm for sufficient time to exhibit a possible increase in the risk of lung cancer.

• Johnston et al. (1997). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' MSHA disagrees with the commenter's assertion that ''the study does not support a health risk from dpm.'' This was not the conclusion drawn by the authors of the study. As explained in the earlier discussion, this study, one of the few containing quantitative estimates of cumulative dpm exposures, provides evidence of increasing lung cancer risk with increasing exposure.

• Jörgenson and Svensson (1970). MSHA discussed this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Contrary to the commenter's characterization, the investigators reported higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among the underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine.

• Kuempel (1995); Lidell (1973); Miller and Jacobsen (1985). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' these three studies were among the nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. The extent, if any, to which workers involved in these studies were occupationally exposed to diesel emissions was not documented, and diesel emissions were not mentioned in any of these reports.

• Morfeld et al. (1997). The commenter's summary of this study distorted the investigators' conclusions. Contrary to the commenter's characterization, this is one of eight studies that showed an increased risk of lung cancer for coal miners, as discussed later in this risk assessment under the heading of ''Mechanisms of Toxicity.'' For lung cancer, the relative SMR, which adjusts for the healthy worker effect, was 1.11. (The value of 0.70 cited by the commenter was the unadjusted SMR.) The authors acknowledged that the relative SMR obtained by the ''standard analysis'' (i.e., 1.11) was not statistically significant. However, the main object of the report was to demonstrate that the ''standard analysis'' is insufficient. The investigators presented evidence that the 1.11 value was biased downward by a ''healthy-worker-survivor-effect,'' thereby masking the actual exposure effects in these workers. They found that ''all the evidence points to the conclusion that a standard analysis suffers from a severe underestimate of the exposure effect on overall mortality, cancer mortality and lung cancer mortality.'' (Morfeld et al., 1997, p. 350)

• Reger (1982). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' As summarized by the commenter, ''diesel-exposed miners were found to have more cough and phlegm, and lower pulmonary function,'' but the author found that ''the evidence would not allow for the rejection of the hypothesis of health equality between exposed and non-exposed miners.'' The commenter failed to note, however, that miners in the dieselized mines, had worked underground for less than 5 years on average.

• Rockette (1977). This is one of eight studies, discussed under ''Mechanisms of Toxicity,'' showing an increased risk of lung cancer for coal miners. As described by the commenter, the author reported SMRs of 1.12 for respiratory cancers and 1.40 for stomach cancer. MSHA agrees with the commenter that ''the study does not establish a dpm-related health risk,'' but notes that dpm effects were not under investigation. Diesel emissions were not mentioned in the report, and, given the study period, the miners involved may not have been occupationally exposed to diesel exhaust.

• Waxweiler (1972). MSHA's discussion of this study appears earlier in this risk assessment, under ''Studies Involving Miners.'' As noted by the commenter, the slight excess in lung cancer, relative to the general population of New Mexico, was not statistically significant. The commenter failed to note, however, that no adjustment was made for a healthy worker effect and that a substantial percentage of the underground miners were not occupationally exposed to diesel emissions.

Summation. Limitations identified in both positive and negative studies include: lack of sufficient power, inappropriate comparison groups, exposure misclassification, statistically insignificant results, and potential confounders. As explained earlier, under ''Evaluation Criteria,'' weaknesses of the first three of these types can reasonably be expected, for the most part, to artificially decrease the apparent strength of any observed association between diesel exposure and increased risk of lung cancer. Statistical insignificance and potential confounders may, in the absence of evidence to the contrary, be regarded as neutral on average. The weaknesses that have been identified in these studies are not unique to epidemiologic studies involving lung cancer and diesel exhaust. They are sources of uncertainty in virtually all epidemiologic research.

Even when there is a strong possibility that the results of a study have been affected by confounding variables, it does not follow that the effect has been to inflate rather than deflate the results or that the study cannot contribute to the weight of evidence supporting a putative association. As cogently stated by Stöber and Abel (op cit., p. 4), ''* * * associations found in epidemiologic studies can always be, at least in part, attributed to confounding.'' Therefore, an objection grounded on potential confounding can always be raised against any epidemiologic study. It is well known that this same objection was, in the past, raised against epidemiologic studies linking lung cancer and radon exposure, lung cancer and asbestos dust exposure, and even lung cancer and tobacco smoking.

Some commenters, have now proposed that virtually every existing epidemiologic study relating lung cancer to dpm exposure be summarily discredited because of susceptibility to confounding or other perceived weaknesses. Given the practical difficulties of designing and executing an epidemiologic study, this is not so much an objection to any specific study as it is an attack on applied epidemiology in general. Indeed, in their review of these studies, Stöber and Abel (1996) conclude that

> In this field * * * epidemiology faces its limits (Taubes, 1995). * * * Many of these studies were doomed to failure from the very beginning.

For important ethical reasons, however, tightly controlled lung cancer experiments cannot be performed on humans. Therefore, despite their inherent limitations, MSHA must rely on the weight of evidence from epidemiologic studies, placing greatest weight on the most carefully designed and executed studies available.

(b) Bladder Cancer

With respect to cancers other than lung cancer, MSHA's review of the literature identified only bladder cancer as a possible candidate for a causal link to dpm. Cohen and Higgins (1995) identified and reviewed 14 epidemiologic case-control studies containing information related to dpm exposure and bladder cancer. All but one of these studies found elevated risks of bladder cancer among workers in jobs frequently associated with dpm exposure. Findings were statistically significant in at least four of the studies (statistical significance was not evaluated in three).

These studies point quite consistently toward an excess risk of bladder cancer among truck or bus drivers, railroad workers, and vehicle mechanics. However, the four available cohort studies do not support a conclusion that exposure to dpm is responsible for the excess risk of bladder cancer associated with these occupations. Furthermore, most of the case-control studies did not distinguish between exposure to diesel-powered equipment and exposure to gasoline-powered equipment for workers having the same occupation. When such a distinction was drawn, there was no evidence that the prevalence of bladder cancer was higher for workers exposed to the diesel-powered equipment.

This, along with the lack of corroboration from existing cohort studies, suggests that the excessive rates of bladder cancer observed may be a consequence of factors other than dpm exposure that are also associated with these occupations. For example, truck and bus drivers are subjected to vibrations while driving and may tend to have different dietary and sleeping habits than the general population. For these reasons, MSHA does not find that convincing evidence currently exists for a causal relationship between dpm exposure and bladder cancer. MSHA received no public comments objecting to this conclusion.

ii. Studies Based on Exposures to $PM_{2.5}$ in Ambient Air. Prior to 1990, the relationship between mortality and long-term exposure to particulate matter was generally investigated by means of cross-sectional studies, but unaddressed spatial confounders and other methodological problems inherent in such studies limited their usefulness (EPA, 1996).[56] Two more recent prospective cohort studies provide better evidence of a link between excess mortality rates and exposure to fine particulate, although some of the uncertainties here are greater than with the short-term studies conducted in single communities. The two studies are the ''Six Cities'' study (Dockery et al., 1993), and the American Cancer Society (ACS) study (Pope et al., 1995).[57] The first study followed about 8,000 adults in six U.S. cities over 14 years; the second looked at survival data for half a million adults in 151 U.S. cities for 7 years. After adjusting for potential confounders, including smoking habits, the studies considered differences in mortality rates between the most polluted and least polluted cities.

Both the Six Cities study and the ACS study found a significant association between chronically higher concentrations of $PM_{2.5}$ (which includes dpm) and age-adjusted total mortality.[58] The authors of the Six Cities Study concluded that the results suggest that exposures to fine particulate air pollution ''contributes to excess mortality in certain U.S. cities.'' The ACS study, which not only controlled for smoking habits and various occupational exposures, but also, to some extent, for passive exposure to tobacco smoke, found results qualitatively consistent with those of the Six Cities Study.[59] In the ACS study, however, the estimated increase in mortality associated with a given increase in fine particulate exposure was lower, though still statistically significant. In both studies, the largest increase observed was for cardiopulmonary mortality.

Both studies also showed an increased risk of lung cancer associated with increased exposure to fine particulate. Although the lung cancer results were not statistically significant, they are consistent with reports of an increased risk of lung cancer among workers occupationally exposed to diesel emissions (discussed above).

The few studies on associations between chronic $PM_{2.5}$ exposure and morbidity in adults show effects that are difficult to separate from measures of PM_{10} and measures of acid aerosols. The available studies, however, show positive associations between particulate air pollution and adverse health effects for those with pre-existing respiratory or cardiovascular disease. This is significant for miners occupationally exposed to fine particulates such as dpm because, as mentioned earlier, there is a large body of evidence showing that respiratory diseases classified as COPD are significantly more prevalent among miners than in the general population. It also appears that PM exposure may exacerbate existing respiratory infections and asthma, increasing the risk of severe outcomes in individuals who have such conditions (EPA, 1996).

d. Mechanisms of Toxicity

Four topics will be addressed in this section of the risk assessment: (i) the agent of toxicity, (ii) clearance and deposition of dpm, (iii) effects other than cancer, and (iv) lung cancer. The section on lung cancer will include discussions of the evidence from (1) genotoxicity studies (including bioavailability of genotoxins) and (2) animal studies.

i. Agent of Toxicity. As described in Part II of this preamble, the particulate fraction of diesel exhaust is made up of aggregated soot particles, vapor phase hydrocarbons, and sulfates. Each soot particle consists of an insoluble, elemental carbon core and an adsorbed, surface coating of relatively soluble organic compounds, such as polycyclic aromatic hydrocarbons (PAHs). Many of these organic carbon compounds are suspected or known mutagens and/or carcinogens. For example, nitrated PAHs, which are present in dpm, are potent mutagens in microbial and human cell systems, and some are known to be carcinogenic to animals (IPCS, 1996, pp. 100–105).

When released into an atmosphere, the soot particles formed during combustion tend to aggregate into larger particles. The total organic and elemental carbon in these soot particles accounts for approximately 80 percent of the dpm mass. The remaining 20 percent consists mainly of sulfates, such as H_2SO_4 (sulfuric acid).

Several laboratory animal studies have been performed to ascertain whether the effects of diesel exhaust are attributable specifically to the particulate fraction. (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). These studies compare the effects of chronic exposure to whole diesel exhaust with the effects of filtered exhaust containing no particles. The studies demonstrate that when the exhaust is sufficiently diluted to nullify the effects of gaseous irritants (NO_2 and SO_2), irritant vapors (aldehydes), CO, and other systemic toxicants, diesel particles are the prime etiologic agents of noncancer health effects. Exposure to dpm produced changes in the lung that were much more prominent than those evoked by the gaseous fraction alone. Marked differences in the effects of whole and filtered diesel exhaust were also evident from general toxicological

[56] Unlike *longitudinal studies,* which examine responses at given locations to changes in conditions over time, *cross-sectional studies* compare results from locations with different conditions at a given point in time.

[57] A third such study, the California Seventh Day Adventist study (Abbey et al., 1991), investigated only TSP, rather than fine particulate. It did not find significant excess mortality associated with chronic TSP exposures.

[58] The Six Cities study also found such relationships at elevated levels of PM_{10} and sulfates. The ACS study was designed to follow up on the fine particle results of the Six Cities Study, and also investigated sulfates separately. As explained earlier in this preamble, sulfates may be a significant constituent of dpm, depending on the type of diesel fuel used.

[59] The Six Cities study did not find a statistically significant increase in risk among non-smokers, suggesting that non-smokers might be less sensitive than smokers to adverse health effects from fine particulate exposures; however, the ACS study, with more statistical power, did find significantly increased risk even for non-smokers.

indices, such as body weight, lung weight, and pulmonary histopathology.

These studies show that, when the exhaust is sufficiently diluted, it is the particles that are primarily responsible for the toxicity observed. However, the available studies do not completely settle the question of whether the particles might act additively or synergistically with the gases in diesel exhaust. Possible additivity or interaction effects with the gaseous portion of diesel exhaust cannot be completely ruled out.

One commenter (MARG) raised an issue with regard to the agent of toxicity in diesel exhaust as follows:

> MSHA has not attempted to regulate exposure to suspected carcinogens contained in dpm, but has opted instead, in metal/non-metal mines, to regulate total carbon (''TC'') as a surrogate for diesel exhaust, without any evidence of adverse health effects from TC exposure. * * * Nor does the mere presence of suspected carcinogens, in minute quantities, in diesel exhaust require a 95 percent reduction of total diesel exhaust [sic] in coal mines. If there are small amounts of carcinogenic substances of concern in diesel exhaust, those substances, not TC, should be regulated directly on the basis of the risks (if any) posed by those substances in the quantities actually present in underground mines. [MARG]

First, it should be noted that the ''suspected carcinogens'' in diesel exhaust to which the commenter referred are part of the organic fraction of the total carbon. Therefore, limiting the concentration of airborne total carbon attributable to dpm, or removing the soot particles from the diesel exhaust by filtration, are both ways of effectively limiting exposures to these suspected carcinogens. Second, the commenter seems to have assumed that cancer is the only adverse health effect of concern and that the only agents in dpm that could cause cancer are the ''suspected carcinogens'' in the organic fraction. This not only ignores non-cancer health effects associated with exposures to dpm and other fine particles, but also the possibility (discussed below) that, with sufficient deposition and retention, soot particles themselves could promote or otherwise increase the risk of lung cancer—either directly or by stimulating the body's natural defenses against foreign substances.

The same commenter [MARG] also stated that ''* * * airborne carbon has not been shown to be harmful at levels currently established in MSHA's dust rules. If the problem is dpm, as MSHA asserts, then it is not rationally addressed by regulating airborne carbon.'' MSHA's intent is to limit dpm exposures in M/NM mines by regulating the submicrometer carbon from diesel emissions—not any and all airborne carbon. MSHA considers its approach a rational means of limiting dpm exposures because most of the dpm consists of carbon (approximately 80 percent by weight), and because using low sulfur diesel fuel will effectively reduce the sulfates comprising most of the remaining portion. The commenter offered no practical suggestion of a more direct, effective, and rational way of limiting airborne dpm concentrations in M/NM mines. Furthermore, direct evidence exists that the risk of lung cancer increases with increasing cumulative occupational exposure to dpm as measured by total carbon (Säverin *et al.,* 1999, discussed earlier in this risk assessment).

ii. Deposition, Clearance, and Retention. As suggested by Figure II–1 of this preamble, most of the aggregated particles making up dpm are no larger than one micrometer in diameter. Particles this small are able to penetrate into the deepest regions of the lungs, called *alveoli.* In the alveoli, the particles can mix with and be dispersed by a substance called *surfactant,* which is secreted by cells lining the alveolar surfaces.

The literature on deposition of fine particles in the respiratory tract was reviewed in Green and Watson (1995) and U.S. EPA (1996). The mechanisms responsible for the broad range of potential particle-related health effects varies depending on the site of deposition. Once deposited, the particles may be cleared from the lung, translocated into the interstitium, sequestered in the lymph nodes, metabolized, or be otherwise chemically or physically changed by various mechanisms. Clearance of dpm from the alveoli is important in the long-term effects of the particles on cells, since it may be more than two orders of magnitude slower than mucociliary clearance (IPCS, 1996).

IARC (1989) and IPCS (1996) reviewed factors affecting the deposition and clearance of dpm in the respiratory tracts of experimental animals. Inhaled PAHs adhering to the carbon core of dpm are cleared from the lung at a significantly slower rate than unattached PAHs. Furthermore, there is evidence that inhalation of whole dpm may increase the retention of subsequently inhaled PAHs. IARC (op cit.) suggested that this can happen when newly introduced PAHs bind to dpm particles that have been retained in the lung.

The evidence points to significant differences in deposition and clearance for different animal species (IPCS, 1996). Under equivalent exposure regimens, hamsters exhibited lower levels of retained dpm in their lungs than rats or mice and consequently less pulmonary function impairment and pulmonary pathology. These differences may result from a lower intake rate of dpm, lower deposition rate and/or more rapid clearance rate, or lung tissue that is less susceptible to the cytotoxicity of dpm. Observations of a decreased respiration in hamsters when exposed by inhalation favor lower intake and deposition rates.

Retardation of lung clearance, called ''overload'' is not specific to dpm and may be caused by inhaling, at a sufficiently high rate, dpm in combination with other respirable particles, such as mineral dusts typical of mining environments. The effect is characterized by (1) an overwhelming of normal clearance processes, (2) disproportionately high retention and loading of the lung with particles, compared to what occurs at lower particle inhalation rates, (3) various pathological responses; generally including chronic inflammation, epithelial hyperplasia and metaplasia, and pulmonary fibrosis; and sometimes including lung tumors.

In the proposed risk assessment, MSHA requested additional information, not already covered in the sources cited above, on fine particle deposition in the respiratory tract, especially as it might pertain to lung loading in miners exposed to a combination of diesel particulate and other dusts. In response to this request, NIOSH submitted a study that investigated rat lung responses to chronic inhalation of a combination of coal dust and diesel exhaust, compared to coal dust or dpm alone (Castranova et al., 1985). Although this report did not directly address deposition or clearance, the investigators reported that another phase of the study had shown that ''particulate clearance, as determined by particulate accumulation in the lung, is inhibited after two years of exposure to diesel exhaust but is not inhibited by exposure to coal dust.''

iii. Effects other than Cancer. A number of controlled animal studies have been undertaken to ascertain the toxic effects of exposure to diesel exhaust and its components. Watson and Green (1995) reviewed approximately 50 reports describing noncancerous effects in animals resulting from the inhalation of diesel exhaust. While most of the studies were conducted with rats or hamsters, some information was also available from studies conducted using cats, guinea pigs, and monkeys. The authors also correlated reported effects with different descriptors of dose, including both gravimetric and non-gravimetric (*e.g.,* particle surface area or volume) measures. From their review of these studies, Watson and Green concluded that:

(a) Animals exposed to diesel exhaust exhibit a number of noncancerous pulmonary effects, including chronic inflammation, epithelial cell hyperplasia, metaplasia, alterations in connective tissue, pulmonary fibrosis, and compromised pulmonary function.

(b) Cumulative weekly exposure to diesel exhaust of 70 to 80 mg• hr/m^3 or greater are associated with the presence of chronic inflammation, epithelial cell proliferation, and depressed alveolar clearance in chronically exposed rats.

(c) The extrapolation of responses in animals to noncancer endpoints in humans is uncertain. Rats were the most sensitive animal species studied.

Subsequent to the review by Watson and Green, there have been a number of animal studies on allergic immune responses to dpm. Takano et al. (1997) investigated the effects of dpm injected into mice through an intratracheal tube and found manifestations of allergic asthma, including enhanced antigen-induced airway inflammation, increased local expression of cytokine proteins, and increased production of antigen-specific immunoglobulins. The authors concluded that the study demonstrated dpm's enhancing effects on allergic asthma and that the results suggest that dpm is ''implicated in the increasing prevalence of allergic asthma in recent years.'' Similarly, Ichinose et al. (1997a) found that five different strains of mice injected intratracheally with dpm exhibited manifestations of allergic asthma, as expressed by enhanced airway inflammation, which were correlated with an increased production of antigen-specific immunoglobulin due to the dpm. The authors concluded that dpm enhances manifestations of allergic airway inflammation and that ''* * * the cause of individual differences in humans at the onset of allergic asthma may be related to differences in antigen-induced immune responses * * *.''

The mechanisms that may lead to adverse health effects in humans from inhaling fine particulates are not fully understood, but potential mechanisms that have been hypothesized for non-cancerous outcomes are summarized in Table III–6. A comprehensive review of the toxicity literature is provided in U.S. EPA (1996).

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Table III-6. — Hypothesized mechanisms of particulate toxicity[†]

Response	Description
Increased Airflow Obstruction	PM exposure may aggravate existing respiratory symptoms which feature airway obstruction. PM-induced airway narrowing or airway obstruction from increased mucous secretion may increase abnormal ventilation/perfusion ratios in the lung and create hypoxia. Hypoxia may lead to cardiac arrhythmias and other cardiac electrophysiologic responses that in turn may lead to ventricular fibrillation and ultimately cardiac arrest. For those experiencing airflow obstruction, increased airflow into non-obstructed areas of the lung may lead to increased particle deposition and subsequent deleterious effects on remaining lung tissue, further exacerbating existing disease processes. More frequent and severe symptoms may be present or more rapid loss of function.
Impaired Clearance	PM exposure may impair clearance by promoting hypersecretion of mucus which in turn results in plugging of airways. Alterations in clearance may also extend the time that particles or potentially harmful biogenic aerosols reside in the tracheobronchial region of the lung. Consequently alterations in clearance from either disturbance of the mucociliary escalator or of macrophage function may increase susceptibility to infection, produce an inflammatory response, or amplify the response to increased burdens of PM. Acid aerosols impair mucociliary clearance.
Altered Host Defense	Responses to an immunological challenge (e.g., infection), may enhance the subsequent response to inhalation of nonspecific material (e.g., PM). PM exposure may also act directly on macrophage function which may not only affect clearance of particles but also increase susceptibility and severity of infection by altering their immunological function. Therefore, depression or over-activation of the immune system, caused by exposure to PM, may be involved in the pathogenesis of lung disease. Decreased respiratory defense may result in increased risk of mortality from pneumonia and increased morbidity (e.g., infection).

Cardiovascular Perturbation	Pulmonary responses to PM exposure may include hypoxia, bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators that can contribute to cardiovascular perturbation. Inhaled particles could act at the level of the pulmonary vasculature by increasing pulmonary vascular resistance and further increase ventilation/perfusion abnormalities and hypoxia. Generalized hypoxia could result in pulmonary hypertension and interstitial edema that would impose further workload on the heart. In addition, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to increased risk of thrombus formation in the vascular system. Finally, direct stimulation by PM of respiratory receptors found throughout the respiratory tract may have direct cardiovascular effects (e.g., bradycardia, hypertension, arrhythmia, apnea and cardiac arrest).
Epithelial Lining Changes	PM or its pathophysiological reaction products may act at the alveolar capillary membrane by increasing the diffusion distances across the respiratory membrane (by increasing its thickness) and causing abnormal ventilation/perfusion ratios. Inflammation caused by PM may increase "leakiness" in pulmonary capillaries leading eventually to increased fluid transudation and possibly to interstitial edema in susceptible individuals. PM induced changes in the surfactant layer leading to increased surface tension would have the same effect.
Inflammatory Response	Diseases which increase susceptibility to PM toxicity involve inflammatory response (e.g., asthma, COPD, and infection). PM may induce or enhance inflammatory responses in the lung which may lead to increased permeability, diffusion abnormality, or increased risk of thrombus formation in vascular system. Inflammation from PM exposure may also decrease phagocytosis by alveolar macrophages and therefore reduce particle clearance. (See discussions above for other inflammatory effects from PM exposure.)

† This table was derived from information in EPA (1996) 11:179-185; 13:67-72; and Appendix D of EPA staff report.

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Deposition of particulates in the human respiratory tract may initiate events leading to increased airflow obstruction, impaired clearance, impaired host defenses, or increased epithelial permeability. Airflow obstruction can result from laryngeal constriction or bronchoconstriction secondary to stimulation of receptors in extrathoracic or intrathoracic airways. In addition to reflex airway narrowing, reflex or local stimulation of mucus secretion can lead to mucus hypersecretion and, eventually, to mucus plugging in small airways.

Pulmonary changes that contribute to cardiovascular responses include a variety of mechanisms that can lead to hypoxemia, including bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators. Hypoxia can lead to cardiac arrhythmias and other cardiac electrophysiologic responses that, in turn, may lead to ventricular fibrillation and ultimately cardiac arrest. Furthermore, many respiratory receptors have direct cardiovascular effects. For example, stimulation of C-fibers leads to bradycardia and hypertension, and stimulation of laryngeal receptors can result in hypertension, cardiac arrhythmia, bradycardia, apnea, and even cardiac arrest. Nasal receptor or pulmonary J-receptor stimulation can lead to vagally-mediated bradycardia and hypertension (Widdicombe, 1988).

Some commenters mistakenly attributed the sensory irritant effects of diesel exhaust entirely to its gaseous components. The mechanism by which constituents of dpm can cause sensory irritations in humans is much better understood than the mechanisms for other adverse health effects due to fine particulates. In essence, sensory irritants are ''scrubbed'' from air entering the upper respiratory tract, thereby preventing a portion from penetrating more deeply into the lower respiratory tract. However, the sensory irritants stimulate trigeminal nerve endings, which are located very close to the oro-nasal mucosa and also to the watery surfaces of the eye (cornea). This produces a burning, painful sensation. The intensity of the sensory irritant response is related to the irritant concentration and duration of exposure. Differences in relative potency are observed with different sensory irritants. Acrolein and formaldehyde are examples of highly potent sensory irritants which, along with others having low molecular weights (acids, aldehydes), are often found in the organic fraction of dpm (Nauss et al., 1995). They may be adsorbed onto the carbon-based core or released in a vapor phase. Thus, mixtures of sensory irritants in dpm may impinge upon the eyes and respiratory tract of miners and produce adverse health effects.

It is also important to note that mixtures of sensory irritants in dpm may produce responses that are not predicted solely on the basis of the individual chemical constituents. Instead, these irritants may interact at receptor sites to produce additive, synergistic, or antagonistic effects. For example, because of synergism, dpm containing a mixture of sensory irritants at relatively low concentrations may produce intense sensory responses (*i.e.,* responses far above those expected for the individual irritants). Therefore, the irritant effects of whole dpm cannot properly be evaluated by simply adding together the known effects of its individual components.

As part of its public comments on the proposed preamble, NIOSH submitted a study (Hahon et al., 1985) on the effects of diesel emissions on mice infected with influenza virus. The object of this study was to determine if exposure to diesel emissions (either alone or in combination with coal dust) could affect resistance to pulmonary infections. The investigators exposed groups of mice to either coal dust, diesel emissions, a combination of both, or filtered air (control group) for various durations, after which they were infected with influenza. Although not reflected by excess mortality, the severity of influenza infection was found to be more pronounced in mice previously exposed to diesel emissions than in control animals. The effect was not intensified by inhalation of coal dust in combination with those emissions.

In addition to possible acute toxicity of particles in the respiratory tract, chronic exposure to particles that deposit in the lung may induce inflammation. Inflammatory responses can lead to increased permeability and possibly diffusion abnormality. Furthermore, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to an increased risk of thrombus formation in the vascular system (Seaton, 1995). Persistent inflammation, or repeated cycles of acute lung injury and healing, can induce chronic lung injury. Retention of the particles may be associated with the initiation and/or progression of COPD.

Takenaka et al. (1995) investigated mechanisms by which dpm may act to cause allergenic effects in human cell cultures. The investigators reported that application of organic dpm extracts over a period of 10 to 14 days increased IgE production from the cells by a factor of up to 360 percent. They concluded that enhanced IgE production in the human airway resulting from the organic fraction of dpm may be an important factor in the increasing incidence of allergic airway disease. Similarly, Tsien et al. (1997) investigated the effects of the organic fraction of dpm on IgE production in human cell cultures and found that application of the organic extract doubled IgE production after three days in cells already producing IgE.

Sagai et al. (1996) investigated the potential role of dpm-induced oxygen radicals in causing pulmonary injuries. Repeated intratracheal instillation of dpm in mice caused marked infiltration of inflammatory cells, proliferation of goblet cells, increased mucus secretion, respiratory resistance, and airway constriction. The results indicated that oxygen radicals, induced by intratracheally instilled dpm, can cause responses characteristic of bronchial asthma.

Lovik et al. (1997) investigated inflammatory and systemic IgE responses to dpm, alone and in combination with the model allergen ovalbumin (OA), in mice. To determine whether it was the elemental carbon core or substances in the organic fraction of dpm that were responsible for observed allergenic effects, they compared the effects of whole dpm with those of carbon black (CB) particles of comparable size and specific surface area. Although the effects were slightly greater for dpm, both dpm and CB were found to cause significant, synergistic increases in allergenic responses to the OA, as expressed by inflammatory responses of the local lymph node and OA-specific IgE production. The investigators concluded that both dpm and CB synergistically enhance and prolong inflammatory responses in the lymph nodes that drain the site of allergen deposition. They further concluded that the elemental carbon core contributes substantially to the adjuvant activity of dpm.

Diaz-Sanchez et al. (1994, 1996, 1997) conducted a series of experiments on human subjects to investigate the effects of dpm on allergic inflammation as measured by IgE production. The studies by Takenaka et al. (op cit.) and Tsien et al. (op cit.) were also part of this series but were based on human cell cultures rather than live human volunteers. A principal objective of these experiments was to investigate the pathways and mechanisms by which dpm induces allergic inflammation. The investigators found that the organic fraction of dpm can enhance IgE production, but that the major polyaromatic hydrocarbon in this fraction (phenanthrene) can enhance IgE without causing inflammation. On the other hand, when human volunteers were sprayed intranasally with carbon particles lacking the organic compounds, the investigators found a large influx of cells in the nasal mucosa but no increase in IgE. These results suggest that while the organic portion of dpm is not necessary for causing irritation and local inflammation, it is the organic compounds that act on the immune system to promote an allergic response.

Salvi et al. (1999) investigated the impact of diesel exhaust on human airways and peripheral blood by exposing healthy volunteers to diesel exhaust at a concentration of 300 µg/m³ for one hour with intermittent exercise. Following exposure, they found significant evidence of acute inflammatory responses in airway lavage and also in the peripheral blood. Some commenters expressed a belief that the gaseous, rather than particulate, components of diesel exhaust caused these effects. The investigators noted that the inflammatory responses observed could not be attributed to NO_2 in the diesel exhaust because previous studies they had conducted, using a similar experimental protocol, had revealed no such responses in the airway tissues of volunteers exposed to a higher concentration of NO_2, for a longer duration, in the absence of dpm. They concluded that ''[i]t therefore seems more likely that the particulate component of DE is responsible.''

iv. *Lung Cancer.* (1) *Genotoxicity Studies.* Many studies have shown that diesel soot, or its organic component, can increase the likelihood of genetic mutations during the biological process of cell division and replication. A survey of the applicable scientific literature is provided in Shirnamé-Moré (1995). What makes this body of research relevant to the risk of lung cancer is that mutations in critical genes can sometimes initiate, promote, or advance a process of carcinogenesis.

The determination of genotoxicity has frequently been made by treating diesel soot with organic solvents such as dichloromethane and dimethyl sulfoxide. The solvent removes the organic compounds from the carbon core. After the solvent evaporates, the mutagenic potential of the extracted organic material is tested by applying it to bacterial, mammalian, or human cells propagated in a laboratory culture. In general, the results of these studies have shown that various components of the organic material can induce mutations and chromosomal aberrations.

One commenter (MARG) pointed out that ''even assuming diesel exhaust contains particular genotoxic substances, the bioavailability of these genotoxins has been questioned.'' As acknowledged in the proposed risk assessment, a critical issue is whether whole diesel particulate is mutagenic when dispersed by substances present in the lung. Since the laboratory procedure for extracting organic material with solvents bears little resemblance to the physiological environment of the lung, it is important to establish whether dpm as a whole is genotoxic, without solvent extraction. Early research indicated that this was not the case and, therefore, that the active genotoxic materials adhering to the carbon core of diesel particles might not be biologically damaging or even available to cells in the lung (Brooks *et al.*, 1980; King *et al.*, 1981; Siak *et al.*, 1981). A number of more recent research papers, however, have shown that dpm, without solvent extraction, can cause DNA damage when the soot is dispersed in the pulmonary surfactant that coats the surface of the alveoli (Wallace *et al.*, 1987; Keane *et al.*, 1991; Gu *et al.*, 1991; Gu *et al.*, 1992). From these studies, NIOSH concluded in 1992 that:

> * * * the solvent extract of diesel soot and the surfactant dispersion of diesel soot particles were found to be active in procaryotic cell and eukaryotic cell *in vitro* genotoxicity assays. The cited data indicate that respired diesel soot particles on the surface of the lung alveoli and respiratory bronchioles can be dispersed in the surfactant-rich aqueous phase lining the surfaces, and that genotoxic material associated with such dispersed soot particles is biologically available and genotoxically active. Therefore, this research demonstrates the biological availability of active genotoxic materials without organic solvent interaction. [Cover letter to NIOSH response to ANPRM, 1992].

If this conclusion is correct, it follows that dpm itself, and not only its organic extract, can cause genetic mutations when dispersed by a substance present in the lung.

One commenter (IMC Global) noted that Wallace *et al.* (1987) used aged dpm samples from scrapings inside an exhaust pipe and contended that this was not a realistic representation of dpm. The commenter further argued that the two studies cited by Gu *et al.* involved ''direct application of an unusually high concentration gradient'' that does not replicate normal conditions of dpm exposure.

MSHA agrees with this commenter's general point that conditions set up in such experiments do not duplicate actual exposure conditions. However, as a follow-up to the Wallace study, Keane *et al.* (op. cit.) demonstrated similar results with both exhaust pipe soot and particles obtained directly from an exhaust stream. With regard to the two Gu studies, MSHA recognizes that any well-controlled experiment serves only a limited purpose. Despite their limitations, however, these experiments provided valuable information. They avoided solvent extraction. By showing that solvent extraction is not a necessary condition of dpm mutagenicity, these studies provided incremental support to the hypothesis of bioavailability under more realistic conditions. This possibility was subsequently tested by a variety of other experiments, including experiments on live animals and humans.

For example, Sagai *et al.* (1993) showed that whole dpm produced active oxygen radicals in the trachea of live mice, but that dpm stripped of organic compounds did not. Whole dpm caused significant damage to the lungs and also high mortality at low doses. According to the investigators, most of the toxicity observed appeared to be due to the oxygen radicals, which can also have genotoxic effects. Subsequently, Ichinose *et al.* (1997b) examined the relationship between tumor response and the formation of oxygen radicals in the lungs of mice injected with dpm. The mice were treated with sufficiently high doses of dpm to produce tumors after 12 months. As in the earlier study, the investigators found that the dpm generated oxygen radicals, even in the absence of biologically activating systems (such as macrophages), and that these oxygen radicals were implicated in the lung toxicity of the dpm. The authors concluded that ''oxidative DNA damage induced by the repeated DEP [*i.e.*, dpm] treatment could be an important factor in enhancing the mutation rate leading to lung cancer.''

The formation of DNA adducts is an important indicator of genotoxicity and potential carcinogenicity. Adduct formation occurs when molecules, such as those in dpm, attach to the cellular DNA. These adducts can negatively affect DNA transcription and/or cellular duplication. If DNA adducts are not repaired, then a mutation or chromosomal aberration can occur during normal mitosis (*i.e.*, cell replication) eventually leading to cancer cell formation. IPCS (1996) contains a survey of animal experiments showing DNA adduct induction in the lungs of experimental animals exposed to diesel exhaust.[60] MSHA recognizes that such studies provide limited information regarding the bioavailability of organics, since positive results may well have been related to factors associated with lung particle overload. However, the bioavailability of genotoxic dpm components is also supported by human studies showing genotoxic effects of exposure to whole dpm. DNA adduct formation and/or mutations in blood cells following exposure to dpm, especially at levels insufficient to induce lung overload, can be presumed to result from organics diffusing into the blood.

Hemminki *et al.* (1994) found that DNA adducts were significantly elevated in lymphocytes of nonsmoking bus maintenance and truck terminal workers, as compared to a control group of hospital mechanics, with the highest adduct levels found among garage and forklift workers. Hou *et al.* (1995) reported significantly elevated levels of DNA adducts in lymphocytes of non-smoking diesel bus maintenance workers compared to a control group of unexposed workers. Similarly, Nielsen *et al.* (1996) found that DNA adducts were significantly increased in the blood and urine of bus garage workers and mechanics exposed to dpm as compared to a control group.

One commenter (IMC Global) acknowledged that ''the studies conducted by Hemminiki [Hemminiki et al., 1994] showed elevations in lymphocyte DNA adducts in garage workers, bus maintenance workers and diesel forklift drivers'' but argued that ''these elevations were at the borderline of statistical significance.'' Although results at a higher level of confidence would have been more persuasive, this does not negate the value of the evidence as it stands. Furthermore, statistical significance in an individual study becomes less of an issue when, as in this case, the results are corroborated by other studies.

IMC Global also acknowledged that the Nielsen study found significant differences in DNA adduct formation between diesel-exposed workers and controls but argued that ''the real source of genotoxins was unclear, and other sources of exposure, such as skin contact with lubricating oils could not be excluded.'' As is generally the case with studies involving human subjects, this study did not completely control for potential confounders. For this reason, MSHA considers it important that several human studies—not all subject to confounding by the same variables—found elevated adduct levels in diesel-exposed workers.

IMC Global cited another human study (Qu *et al.*, 1997) as casting doubt on the genotoxic effects of diesel exposure, even though this study (conducted on Australian coal miners) reported significant increases in DNA adducts immediately after a period of intense diesel exposure during a longwall move. As noted by the commenter, adduct levels of exposed miners and drivers were, prior to the longwall move, approximately 50% higher than for the unexposed control group; but differences by exposure category were not statistically significant. A more informative part of the study, however, consisted of comparing adducts in the same workers before and after a longwall move, which involved ''intensive use of heavy equipment, diesel powered in these mines, over a 2–3 week period.'' MSHA emphasizes that the comparison was made on the same workers, because doing so largely controlled for potentially confounding variables, such as smoking habits, that may be a factor when making comparisons between different persons. After the period of ''intensive'' exposure, statistically significant increases were observed in both total and individual adducts. Contrary to the commenter's characterization of this study, the investigators stated that their analysis ''provides results in which the authors have a high level of confidence.'' They concluded that ''given the * * * apparent increase in adducts during a period of intense DEE [*i.e.*, diesel exhaust emissions] exposures it would be prudent to pay particular attention to keeping exposures as low as possible, especially during LWCO [*i.e.*, 'longwall change out'] operations.'' Although the commenter submitted this study as counter-evidence, it actually provides significant, positive evidence that high dpm exposures in a mining environment can produce genotoxic effects.

The West Virginia Coal Association submitted an analysis by Dr. Peter Valberg, purporting to show that ''* * * the quantity of particle-bound mutagens that could potentially contact lung cells under human exposure scenarios is very small.'' According to Dr. Valberg's calculations, the dose of organic mutagens deposited in the lungs of a worker occupationally exposed (40 hours per week) to 500 µg/m³ of dpm would be equivalent in potency to smoking about one cigarette per month.[61] Dr. Valberg indicated that a person smoking at this level would generally be classified a nonsmoker, but he made no attempt to quantify the carcinogenic effects. Nor did he compare this exposure level with levels of exposures to environmental tobacco smoke that have been linked to lung cancer.

Since the commenter did not provide details of Dr. Valberg's calculation, MSHA was unable to verify its accuracy or evaluate the plausibility of key assumptions. However, even if the equivalence is approximately correct, using it to discount the possibility that dpm increases the risk of lung cancer relies on several questionable assumptions. Although their precise role in the analysis is unclear because it was not presented in detail, these assumptions apparently include:

(1) That there is a good correlation between genotoxicity dose-response and carcinogenicity dose-response. Although genotoxicity data can be very useful for identifying a carcinogenic hazard, carcinogenesis is a highly complex process that may involve the interaction of many mutagenic, physiological, and biochemical responses. Therefore, the shape and slope of a carcinogenic dose-response relationship cannot be readily predicted from a genotoxic dose-response relationship.

(2) That only the organic fraction of dpm contributes to carcinogenesis. This contradicts the findings reported by Ichinose *et al.* (1997b) and does not take into account the contribution that inflammation and active oxygen radicals induced by the inorganic carbon core of dpm may have in promoting lung cancers. Multiple routes of carcinogenesis may operate in human lungs—some requiring only the various organic mutagens in dpm and others involving induction of free radicals by the elemental carbon core, either alone or in combination with the organics.

(3) That the only mutagens in dpm are those that have been identified as mutagenic to bacteria and that the

[60] Some of these studies will be discussed in the next subsection of this risk assessment.

[61] The only details provided for this calculation pertained to adjusting 8-hour occupational exposures. Dr. Valberg adjusted the 500 µg/m³ concentration for an 8-hour occupational exposure to a supposedly equivalent 24-hour continuous concentration of 92 µg/m³. This adjustment ignored differences in breathing rates between periods of sleep, leisure activities, and heavy work. Even under the unrealistic assumption of homogeneous breathing rates, the calculation appears to be erroneous, since (500 µg/m³) × (40 hours/week) is nearly 30 percent greater than (92 µg/m³) × (168 hours/week). Also, Dr. Valberg stated that the calculation assumed a deposition fraction of 20 percent for dpm but did not state what deposition fraction was being assumed for the particles in cigarette smoke.

mutagenic constituents of dpm have all been identified. One of the most potent of all known mutagens (3-nitrobenzanthrone) was only recently isolated and identified in dpm (Enya *et al.*, 1997).

(4) That the mutagenic components of dpm have the same combined potency as those in cigarette smoke. This ignores the relative potency and amounts of the various mutagenic constituents. If the calculation did not take into account the relative amounts and potencies of all the individual mutagens in dpm and cigarette smoke, then it oversimplified the task of making such a comparison.

In sum, unlike the experimental findings of dpm genotoxicity discussed above, the analysis by Dr. Valberg is not based on empirical evidence from dpm experiments, and it appears to rely heavily on questionable assumptions. Moreover, the contention that active components of dpm are not available in sufficient quantities to cause significant mutagenic damage in humans appears to be directly contradicted by the empirical evidence of elevated DNA adduct levels in exposed workers (Hemminki *et al.*, 1994; Hou *et al.*, 1995; Nielsen *et al.*, 1996; Qu *et al.*, 1997).

(2) *Animal Inhalation Studies.* When dpm is inhaled, a number of adverse effects that may contribute to carcinogenesis are discernable by microscopic and biochemical analysis. For a comprehensive review of these effects, see Watson and Green (1995). In brief, these effects begin with phagocytosis, which is essentially an attack on the diesel particles by cells called alveolar macrophages. The macrophages engulf and ingest the diesel particles, subjecting them to detoxifying enzymes. Although this is a normal physiological response to the inhalation of foreign substances, the process can produce various chemical byproducts injurious to normal cells. In attacking the diesel particles, the activated macrophages release chemical agents that attract neutrophils (a type of white blood cell that destroys microorganisms) and additional alveolar macrophages. As the lung burden of diesel particles increases, aggregations of particle-laden macrophages form in alveoli adjacent to terminal bronchioles, the number of Type II cells lining particle-laden alveoli increases, and particles lodge within alveolar and peribronchial tissues and associated lymph nodes. The neutrophils and macrophages release mediators of inflammation and oxygen radicals, which have been implicated in causing various forms of chromosomal damage, genetic mutations, and malignant transformation of cells (Weitzman and Gordon, 1990). Eventually, the particle-laden macrophages are functionally altered, resulting in decreased viability and impaired phagocytosis and clearance of particles. This series of events may result in pulmonary inflammatory, fibrotic, or emphysematous lesions that can ultimately develop into cancerous tumors.

IARC (1989), Mauderly (1992), Busby and Newberne (1995), IPCS (1996), Cal-EPA (1998), and US EPA (1999) reviewed the scientific literature relating to excess lung cancers observed among laboratory animals chronically exposed to filtered and unfiltered diesel exhaust. The experimental data demonstrate that chronic exposure to whole diesel exhaust increases the risk of lung cancer in rats and that dpm is the causative agent. This carcinogenic effect has been confirmed in two strains of rats and in at least five laboratories. Experimental results for animal species other than the rat, however, are either inconclusive or, in the case of Syrian hamsters, suggestive of no carcinogenic effect. In two of three mouse studies reviewed by IARC (1989), lung tumor formation (including adenocarcinomas) was increased in the exposed animals as compared to concurrent controls; in the third study, the total incidence of lung tumors was not elevated compared to historical controls. Two more recent mouse studies (Heinrich et al., 1995; Mauderly et al., 1996) have both reported no statistically significant increase in lung cancer rates among exposed mice, as compared to contemporaneous controls. Monkeys exposed to diesel exhaust for two years did not develop lung tumors, but the short duration of exposure was judged inadequate for evaluating carcinogenicity in primates.

Bond et al. (1990a) investigated differences in peripheral lung DNA adduct formation among rats, hamsters, mice, and monkeys exposed to dpm at a concentration of 8100 μg/m³ for 12 weeks. Mice and hamsters showed no increase of DNA adducts in their peripheral lung tissue, whereas rats and monkeys showed a 60 to 80-percent increase. The increased prevalence of lung DNA adducts in monkeys suggests that, with respect to DNA adduct formation, the human lungs' response to dpm inhalation may more closely resemble that of rats than that of hamsters or mice.

The conflicting carcinogenic effects of chronic dpm inhalation reported in studies of rats, mice, and hamsters may be due to non-equivalent delivered doses or to differences in response among species. Indeed, monkey lungs have been reported to respond quite differently than rat lungs to both diesel exhaust and coal dust (Nikula, 1997). Therefore, the results from rat experiments do not, by themselves, establish that there is any excess risk due to dpm exposure for humans. However, the human epidemiologic and genotoxicity (DNA adduct) data indicate that humans comprise a species that, like rats, do suffer a carcinogenic response to dpm exposure. This would be consistent with the observation, mentioned above, that lung DNA adduct formation is increased among exposed rats but not among exposed hamsters or mice. Therefore, although MSHA recognizes that there are important differences between rats and humans (as there are also between rats and hamsters or mice), MSHA considers the rat studies relevant to an evaluation of human health risks.

Reactions similar to those observed in rats inhaling dpm have also been observed in rats inhaling fine particles with no organic component (Mauderly et al., 1994; Heinrich et al., 1994, 1995; Nikula et al., 1995). Rats exposed to titanium dioxide (TiO_2) or pure carbon (''carbon black'') particles, which are not considered to be genotoxic, exhibited similar pathological responses and developed lung cancers at about the same rate as rats exposed to whole diesel exhaust. Carbon black particles were used in these experiments because they are physically similar to the inorganic carbon core of dpm but have negligible amounts of organic compounds adsorbed to their surface. Therefore, at least in some species, it appears that the lung cancer toxicity of dpm may result largely from a biochemical response to the core particle itself rather than from specific, genotoxic effects of the adsorbed organic compounds.[62]

One commenter stated that, in the proposed risk assessment, MSHA had neglected three additional studies suggesting that lung cancer risks in animals inhaling diesel exhaust are unrelated to genotoxic mechanisms. One of these studies (Mauderly et al., 1996) did not pertain to questions of

[62] NIOSH commented as follows: ''Data cited by MSHA in support of this statement are not comparable. Rats were exposed to dpm at 4 mg/m³ for 2 years (Mauderly et al. 1987; Brightwell et al. 1989), in contrast to rats exposed to TiO_2 at 250 mg/m³ for two years [reference to article (Lee et al. 1985) not cited by MSHA]. It is not apparent that the overload mechanism that is proposed to be responsible for tumors in the TiO_2 exposed rats could also have been responsible for the tumors seen in the dpm exposed rats at 62-fold lower exposure concentrations.'' In the reports cited by MSHA, levels of TiO_2 and/or carbon black were commensurate with dpm levels.

genotoxicity but has been cited in the discussion of mouse studies above. The other two studies (Randerath et al., 1995 and Belinsky et al., 1995) were conducted as part of the cancer bioassay described in the 1994 article by Mauderly et al. (cited in the preceding paragraph). In the Randerath study, the investigators found that no DNA adducts specific to either diesel exhaust or carbon black were induced in the lungs of rats exposed to the corresponding substance. However, after three months of exposure, the total level of DNA adducts and the levels of some individual adducts were significantly higher in the diesel-exposed rats than in the controls. In contrast, multiple DNA adducts thought to be specific to diesel exhaust formed in the skin and lungs of mice treated topically with organic dpm extract. These results are consistent with the findings of Mauderly et al. (1994, op cit.). They imply that although the organic compounds of diesel exhaust are capable of damaging cellular DNA, they did not inflict such damage under the conditions of the inhalation experiment performed. The report noted that these results do not rule out the possibility of DNA damage by inhaled organics in ''other species or * * * [in] exposure situations in which the concentrations of diesel exhaust particles are much lower.'' In the Belinsky study, the investigators measured mutations in selected genes in the tumors of those rats that had developed lung cancer. This study did not succeed in elucidating the mechanisms by which dpm and carbon black cause lung tumors in rats. The authors concluded that ''until some of the genes involved in the carcinogenicity of diesel exhaust and carbon black are identified, a role for the organic compounds in tumor development cannot be excluded.''

The carbon-black and TiO_2 studies discussed above indicate that lung cancers in rats exposed to dpm may be induced by a mechanism that does not require the bioavailability of genotoxic organic compounds adsorbed on the elemental carbon particles. Some researchers have interpreted these studies as also suggesting that (1) the carcinogenic mechanism in rats depends on massive overloading of the lung and (2) that this may provide a mechanism of carcinogenesis involving a threshold effect specific to rats, which has not been observed in other rodents or in humans (Oberdörster, 1994; Watson and Valberg, 1996). Some commenters on the ANPRM cited the lack of a link between lung cancer and coal dust or carbon black exposure as evidence that carbon particles, by themselves, are not carcinogenic in humans. Coal mine dust, however, consists almost entirely of particles larger than those forming the carbon core of dpm or used in the carbon black and TiO_2 rat studies. Furthermore, although there have been nine studies reporting no excess risk of lung cancer among coal miners (Liddell, 1973; Costello et al., 1974; Armstrong et al., 1979; Rooke et al., 1979; Ames et al., 1983; Atuhaire et al., 1985; Miller and Jacobsen, 1985; Kuempel et al., 1995; Christie et al., 1995), eight studies have reported an elevated risk of lung cancer for those exposed to coal dust (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Correa et al., 1984; Levin et al., 1988; Morabia et al., 1992; Swanson et al., 1993; Morfeld et al., 1997). The positive results in five of these studies (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Morabia et al., 1992; Swanson et al., 1993) were statistically significant. Morabia et al. (op cit.) reported increased risk associated with duration of exposure, after adjusting for cigarette smoking, asbestos exposure, and geographic area. Furthermore, excess lung cancers have been reported among carbon black production workers (Hodgson and Jones, 1985; Siemiatycki, 1991; Parent et al., 1996). After a comprehensive evaluation of the available scientific evidence, the World Health Organization's International Agency for Research on Cancer concluded: ''Carbon black is possibly carcinogenic to humans (Group 2B).'' (IARC, 1996).

The carbon black and TiO_2 animal studies cited above do not prove there is a threshold below which dpm exposure poses no risk of causing lung cancer in humans. They also do not prove that dpm exposure has no incremental, genotoxic effects. Even if the genotoxic organic compounds in dpm were biologically unavailable and played no role in human carcinogenesis, this would not rule out the possibility of a genotoxic route to lung cancer (even for rats) due to the presence of the particles themselves. For example, as a byproduct of the biochemical response to the presence of particles in the alveoli, free oxidant radicals may be released as macrophages attempt to digest the particles. There is evidence that dpm can both induce production of reactive oxygen agents and also depress the activity of naturally occurring antioxidant enzymes (Mori, 1996; Ichinose et al., 1997; Sagai et al., 1993). Oxidants can induce carcinogenesis either by reacting directly with DNA, or by stimulating cell replication, or both (Weitzman and Gordon, 1990). Salvi et al. (1999) reported acute inflammatory responses in the airways of human exposed to dpm for one hour at a concentration of 300 µg/m³. Such inflammation is associated with the production of free radicals and could provide routes to lung cancer with even when normal lung clearance is occurring. It could also give rise to a ''quasi-threshold,'' or surge in response, corresponding to the exposure level at which the normal clearance rate becomes overwhelmed (lung overload).

Oxidant activity is not the only mechanism by which dpm could exert carcinogenic effects in the absence of mutagenic activity by its organic fraction. In its commentary on the Randerath study discussed above, the HEI's Health Review Committee suggested that dpm could both cause genetic damage by inducing free oxygen radicals and also enhance cell division by inducing cytokines or growth hormones:

> It is possible that diesel exhaust exerts its carcinogenic effects through a mechanism that does not involve direct genotoxicity (that is, formation of DNA adducts) but involves proliferative responses such as chronic inflammation and hyperplasia arising from high concentrations of particles deposited in the lungs of the exposed rats. * * * Phagocytes (macrophages and neutrophils) released during inflammatory reactions ''produce reactive oxygen species that can damage DNA. * * * Particles (with or without adsorbed PAHs) may thus induce oxidative DNA damage via oxygen free radicals. * * * Alternatively, activated phagocytes may release cytokines or growth factors that are known to increase cell division. Increased cell division has been implicated in cancer causation. * * * Thus, in addition to oxidative DNA damage, increased cell proliferation may be an important mechanism by which diesel exhaust and other insoluble particles induce pulmonary carcinogenesis in the rat. [Randerath et al., 1995, p. 55]

Even if lung overload were the primary or sole route by which dpm induced lung cancer, this would not mean that the high dpm concentrations observed in some mines are without hazard. It is noteworthy, moreover, that dpm exposure levels recorded in some mines have been almost as high as laboratory exposures administered to rats showing a clearly positive response. Intermittent, occupational exposure levels greater than about 500 µg/m³ dpm may overwhelm the human lung clearance mechanism (Nauss et al., 1995). Therefore, concentrations at the even higher levels currently observed in some mines could be expected to cause overload in some humans, possibly inducing lung cancer by a mechanism similar to what occurs in rats. In addition, a proportion of exposed individuals can always be expected to be more susceptible than normal to clearance impairments and lung overload. Inhalation at even moderate levels may significantly impair clearance, especially in susceptible individuals. Exposures to cigarette smoke and respirable mineral dusts may further depress clearance mechanisms and reduce the threshold for overload. Consequently, even at dpm concentrations far lower than 500 µg/m³ dpm, impaired clearance due to dpm inhalation may provide an important route to lung cancer in humans, especially if they are also inhaling cigarette smoke and other fine dusts simultaneously. (Hattis and Silver, 1992, Figures 9, 10, 11).

Furthermore, as suggested above, lung overload is not necessarily the only route to carcinogenesis in humans. Therefore, dpm concentrations too low to cause overload still may present a hazard. In humans exposed over a working lifetime to doses insufficient to cause overload, carcinogenic mechanisms unrelated to overload may operate, as indicated by the human epidemiologic studies and the data on human DNA adducts cited in the preceding subsection of this risk assessment. It is possible that overload provides the dominant route to lung cancer at high concentrations of fine particulate, while other mechanisms emerge as more relevant for humans under lower-level exposure conditions.

The NMA noted that, in 1998, the US EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that there is "no evidence that the organic fraction of soot played a role in rat tumorigenesis at any exposure level, and considerable evidence that it did not." According to the NMA, this showed "* * * it is the rat data—not the hamster data—that lacks relevance for human health assessment."

It must first be noted that, in MSHA's view, all of the experimental animal data on health effects has relevance for human health risk assessment—whether the evidence is positive or negative and even if the positive results cannot be used to quantify human risk. The finding that different mammalian species exhibit important differences in response is itself relevant for human risk assessment. Second, the passage quoted from CASAC pertains to the route for tumorigenesis in rats and does not discuss whether this does or does not have relevance to humans exposed at high levels. The context for the CASAC deliberations was ambient exposure conditions in the general environment, rather than the higher occupational exposures that might impair clearance rates in susceptible individuals. Third, the comment assumes that only a finding of tumorigenesis attributable to the organic portion of dpm would elucidate mechanisms of potential health effects in humans. This ignores the possibility that a mechanism promoting tumors, but not involving the organics, could operate in both rats and humans. Induction of free oxygen radicals is an example. Fourth, although there may be little or no evidence that organics contributed to rat tumorigenesis in the studies performed, there is evidence that the organics contributed to increases in DNA adduct formation. This kind of activity could have tumorigenic consequences in humans who may be exposed for periods far longer than a rat's 3-year lifetime and who, as a consequence, have more time to accumulate genetic damage from a variety of sources.

Bond et al. (1990b) and Wolff et al. (1990) investigated adduct formation in rats exposed to various concentrations of either dpm or carbon black for 12 weeks. At the highest concentration (10 mg/m³), DNA adduct levels in the lung were increased by exposure to either dpm or carbon black; but levels in the rats exposed to dpm were approximately 30 percent higher. Gallagher et al. (1994) exposed different groups of rats to diesel exhaust, carbon black, or TiO_2 and detected no significant difference in DNA adduct levels in the lung. However, the level of one type of adduct, thought to be derived from a PAH, was elevated in the dpm-exposed rats but not found in the control group or in rats exposed to carbon black or TiO_2.

These studies indicate that the inorganic carbon core of dpm is not the only possible agent of genetic damage in rats inhaling dpm. After a review of these and other studies involving DNA adducts, IPCS (1996) concluded that "Taken together, the studies of DNA adducts suggest that some organic chemicals in diesel exhaust can form DNA adducts in lung tissue and may play a role in the carcinogenic effects. * * *however, DNA adducts alone cannot explain the carcinogenicity of diesel exhaust, and other factors, such as chronic inflammation and cell proliferation, are also important."

Nauss et al. (1995, pp. 35–38) judged that the results observed in the carbon black and TiO_2 inhalation studies on rats do not preclude the possibility that the organic component of dpm has important genotoxic effects in humans. More generally, they also do not prove that lung overload is necessary for dpm-induced lung cancer. Because of the relatively high doses administered in some of the rat studies, it is conceivable that an overload phenomenon masked or even inhibited other potential cancer mechanisms. At dpm concentrations insufficient to impair clearance, carcinogenesis may have followed other routes, some possibly involving the organic compounds. At these lower concentrations, or among rats for which overload did not occur, tumor rates for dpm, carbon black, and TiO_2 may all have been too low to make statistically meaningful comparisons.

The NMA argued that "MSHA's contention that lung overload might "mask" tumor production by lower doses of dpm has been convincingly rebutted by recognized experts in the field," but provided no convincing explanation of why such masking could not occur. The NMA went on to say:

> The [CASAC] Panel viewed the premises that: a) a small tumor response at low exposure was overlooked due to statistical power; and b) soot-associated organic mutagens had a greater effect at low than at high exposure levels to be without foundation. In the absence of supporting evidence, the Panel did not view derivation of a quantitative estimate of human lung cancer risk from the low-level rat data as appropriate.

MSHA is not attempting to "derive a quantitative estimate of human lung cancer risk from the low-level rat data."

Dr. Peter Valberg, writing for the West Virginia Coal Association, provided the following argument for discounting the possibility of other carcinogenic mechanisms being masked by overload in the rat studies:

> Some regulatory agencies express concern about the mutagens bound to dpm. They hypothesize that, at high exposure levels, genotoxic mechanisms are overwhelmed (masked) by particle-overload conditions. However, they argue that at low-exposure concentrations, these organic compounds could represent a lung cancer risk. Tumor induction by mutagenic compounds would be characterized by a linear dose-response and should be detectable, given enough exposed rats. By using a "meta-analysis" type of approach and combining data from eight long-term rat inhalation studies, the lung tumor response can be analyzed. When all dpm-exposed rats from lifetime-exposure studies are combined, a threshold of response (noted above) occurs at approximately 600 µg/m³ continuous lifetime exposure (approximately 2,500 µg/m³ of occupational exposure). Additional statistical analysis of only those rats exposed to low concentrations of dpm confirms the absence of a tumorigenic effect below that threshold. Thus, even data in rats (the most sensitive laboratory species) do not support the hypothesis that particle-bound organics cause tumors.

MSHA finds that this analysis relies on several questionable and unsupported assumptions and that, for the following reasons, the possibility remains that organic compounds in inhaled dpm may, under the right exposure conditions, contribute to its carcinogenic effects:

(1) The absence of evidence for an organic carbon effect is not equivalent to evidence of the absence of such an effect. Dr. Valberg did not demonstrate that enough rats were exposed, at levels insufficient to cause overload, to ensure detection of a 30- to 40-percent increase in the risk of lung cancer. Also, the normal lifespan of a rat whose lung is not overloaded with particles may, because of the lower concentrations involved, provide insufficient time for the organic compounds to express carcinogenic effects. Furthermore, low bioavailability of the organics could further reduce the likelihood that a carcinogenic sequence of mutations would occur within a rat's relatively short lifespan (i.e., at particle concentrations too low to cause overload).

(2) If the primary mechanism for carcinogenesis requires a reduced clearance rate (due to overload), then acute exposures are important, and it may not be appropriate to represent equivalent hazards by spreading an 8-hour occupational exposures over a 24-hour period. For example, eight hours at 600 $\mu g/m^3$ would have different implications for lung clearance than 24 hours at 200 $\mu g/m^3$.

(3) Granting that the rat data cannot be used to extrapolate risk for humans, these data should also not be used to rule out mechanisms of carcinogenesis that may operate in humans but not in rats. Clearance, for example, may operate differently in humans than in rats, and there may be a gradual rather than abrupt change in human overload conditions with increasing exposure. Also, at least some of the organic compounds in dpm may be more biologically available to the human lung than to that of the rat.

(4) For experimental purposes, laboratory rats are deliberately bred to be homogeneous. This is done, in part, to deliberately minimize differences in response between individuals. Therefore, individual differences in the threshold for lung overload would tend to be masked in experiments on laboratory rats. It is likely that human populations would exhibit, to a far greater extent than laboratory rats, a range of susceptibilities to lung overload. Also some humans, unlike the laboratory rats in these experiments, place additional burdens on their lung clearance by smoking.

One commenter (MARG) concluded that ''[t]here is * * * no basis for extrapolating the rat results to human beings; the animal studies, taken together, do not justify MSHA's proposals.''

MSHA is neither extrapolating the rat results to make quantitative risk estimates for humans nor using them, in isolation, as a justification for these regulations. MSHA does regard it as significant, however, that the evidence for an increased risk of lung cancer due to chronic dpm inhalation comes from both human and animal studies. MSHA agrees that the quantitative results observed for rats in existing studies should not be extrapolated to humans. Nevertheless, the fact that high dpm exposures for two or three years can induce lung cancer in rats enhances the epidemiologic evidence that much longer exposures to miners, at concentrations of the same order of magnitude, could also induce lung cancers.

3. Characterization of Risk

After reviewing the evidence of adverse health effects associated with exposure to dpm, MSHA evaluated that evidence to ascertain whether exposure levels currently existing in mines warrant regulatory action pursuant to the Mine Act. The criteria for this evaluation are established by the Mine Act and related court decisions. Section 101(a)(6)(A) provides that:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

Based on court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that need to be addressed: (a) Whether health effects associated with dpm exposure constitute a ''material impairment'' to miner health or functional capacity; (b) whether exposed miners are at significant excess risk of incurring any of these material impairments; and (c) whether the rule will substantially reduce such risks.

Some commenters argued that the link between dpm exposure and material health impairments is questionable, and that MSHA should wait until additional scientific evidence becomes available before concluding that there are health risks due to such exposure warranting regulatory action. For example, MARG asserted that ''[c]ontrary to the suggestions in the [proposed] preamble, a link between dpm exposure and serious illness has never been established by reliable scientific evidence.''[63] MARG continued as follows:

> Precisely because the scientific evidence * * * is inconclusive at best, NIOSH and NCI are now conducting a * * * [study] to determine whether diesel exhaust is linked to illness, and if so, at what level of exposure. * * * MARG is also funding an independent parallel study.
>
> * * * Until data from the NIOSH/NCI study, and the parallel MARG study, are available, the answers to these important questions will not be known. Without credible answers to these and other questions, MSHA's regulatory proposals * * * are premature * * *.''

For reasons explained below, MSHA does not agree that the collective weight of scientific evidence is ''inconclusive at best.'' Furthermore, the criteria for evaluating the health effects evidence do not require scientific certainty. As noted by Justice Stevens in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straitjacket.'' [*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 100 S.Ct. 2844 (1980), hereinafter designated the ''Benzene'' case]. The Court recognized that regulation may be necessary even when scientific knowledge is not complete; and—

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. [Id. at 656].

[63] MARG supported this assertion by claiming that ''[t]he EPA reports which MSHA references in its preamble were found 'not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines' by EPA's Clean Air Scientific Advisory Committee. [reference to CASAC (1998)]'' Contrary to MARG's claim, CASAC (1998) did not review any of the 20 EPA documents MSHA cited in the proposed preamble. Instead, the document reviewed by CASAC (1998) was an unpublished draft of a health risk assessment on diesel exhaust (EPA, 1998), to which MSHA made no reference. Since MSHA has not relied in any way on this 1998 draft document, its ''scientific adequacy'' is entirely irrelevant to this rulemaking.

In response to the 1998 CASAC review, EPA modified its draft risk assessment (EPA, 1999), and CASAC subsequently reviewed the 1999 draft (CASAC, 2000). CASAC found the revised draft much improved over the previous version and agreed that even environmental exposure to diesel emissions is likely to increase the risk of lung cancer (CASAC, 2000). CASAC endorsed this conclusion for dpm concentrations in ambient air, which are lower, by a factor of more than 100, than the levels observed in some mines (see Fig. III–4).

Moreover, the statutory criteria for evaluating health effects do not require MSHA to wait for incontrovertible evidence. In fact, MSHA is required to set standards based on the ''best *available* evidence'' (emphasis added).

a. Material Impairments to Miners' Health or Functional Capacity

MSHA recognizes that there is considerable disagreement, among knowledgeable parties, in the interpretation of the overall body of scientific research and medical evidence related to human health effects of dpm exposures. One commenter for example, interpreted the collective evidence as follows:

> * * * the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health. * * * there is *clear* evidence that diesel particulate exposure can cause lung cancer (as well as other serious non-malignant diseases) among workers in a variety of occupational settings. While no body of scientific evidence is ever completely definitive, the evidence regarding diesel particulate is particularly strong * * *. [Michael Silverstein, MD, State of Washington Dept. of Labor and Industries]

Other commenters, including several national and regional organizations representing the mining industry, sharply disagreed with this interpretation. For example, one commenter stated that ''[i]n our opinion, the best available evidence does not provide substantial or credible support for the proposal.'' Several commenters argued that evidence from within the mining industry itself was especially weak.[64] A representative of one mining company that had been using diesel equipment for many years commented: ''[t]o date, the medical history of our employees does not indicate a single case of lung cancer, chronic illness, or material impairment of health due to exposure to diesel exhaust. This appears to be the established norm throughout the U.S. coal mining industry.'' This commenter, however, submitted no evidence comparing the rate of lung cancer or other material impairment among exposed miners to the rate for unexposed miners (or comparable workers) of similar age, smoking habits, and geographic location.

With due consideration to all oral and written testimony, comments, and evidence submitted during the rulemaking proceedings, MSHA conducted a review of the scientific literature cited in Part III.2. Based on the combined weight of the best available evidence, MSHA has concluded that underground miners exposed to current levels of dpm are at excess risk of incurring the following three kinds of material impairment: (i) Sensory irritations and respiratory symptoms (including allergenic responses); (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. The next three subsections will respectively explain MSHA's basis for linking these effects with dpm exposure.

i. Sensory Irritations and Respiratory Symptoms (including allergenic responses). Kahn et al. (1988), Battigelli (1965), Gamble et al. (1987a), and Rudell et al. (1996) identified a number of debilitating acute responses to diesel exhaust exposure. These responses included irritation of the eyes, nose and throat; headaches, nausea, and vomiting; chest tightness and wheeze. These symptoms were also reported by miners at the 1995 workshops and the public hearings held on these proceedings in 1998. In addition, Ulfvarson et al. (1987, 1990) reported evidence of reduced lung function in workers exposed to dpm for a single shift. The latter study supports attributing a portion of the reduction to the dpm in diesel exhaust. After reviewing this body of literature, Morgan et al. (1997) concluded ''it is apparent that exposure to diesel fumes in sufficient concentrations may lead to [transient] eye and nasal irritation'' and ''a transient decline of ventilatory capacity has been noted following such exposures.''

One commenter (Nevada Mining Association) acknowledged there was evidence that miners exposed to diesel exhaust experienced, as a possible consequence of their exposure, ''acute, short-term or 'transitory' irritation, such as watering eyes, in susceptible individuals * * *''; but asserted that ''[a]ddressing any such transient irritant effects does not require the Agency's sweeping, stringent PEL approach [in M/NM mines].''

Although there is evidence that such symptoms subside within one to three days of no occupational exposure, a miner who must be exposed to dpm day after day in order to earn a living may not have time to recover from such effects. Hence, the opportunity for a so-called ''reversible'' health effect to reverse itself may not be present for many miners. Furthermore, effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and can, in some cases, be seriously disabling. Also, workers experiencing sufficiently severe sensory irritations can be incapacitated or distracted as a result of their symptoms, thereby endangering themselves and other workers and increasing the risk of accidents. For these reasons, MSHA considers such irritations to constitute ''material impairments'' of health or functional capacity within the meaning of the Act, regardless of whether or not they are reversible. Further discussion of why MSHA believes reversible effects can constitute material impairments can be found above, in Subsection 2.a.2 of this risk assessment.

The best available evidence also points to more severe respiratory consequences of exposure to dpm. Significant statistical associations have been detected between acute environmental exposures to fine particulates and debilitating respiratory impairments in adults, as measured by lost work days, hospital admissions, and emergency room visits (see Table III–3). Short-term exposures to fine particulates, or to particulate air pollution in general, have been associated with significant increases in the risk of hospitalization for both pneumonia and COPD (EPA, 1996).

The risk of severe respiratory effects is exemplified by specific cases of persistent asthma linked to diesel exposure (Wade and Newman, 1993). Glenn et al. (1983) summarized results of NIOSH health evaluations among coal, salt, trona, and potash miners and reported that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group.'' There is persuasive evidence for a causal connection between dpm exposure and increased manifestations of allergic asthma and other allergic respiratory diseases, coming from recent experiments on animals and human cells (Takenaka et al., 1995; Lovik et al., 1997; Takano et al., 1997; Ichinose et al., 1997a). Based on controlled experiments on healthy human volunteers, Diaz-Sanchez et al. (1994, 1996, 1997), Peterson and Saxon (1996), and Salvi et al. (1999) reported significant increases in various markers of allergic response resulting from exposure to dpm.

Peterson and Saxon (1996) reviewed the scientific literature on the relationship between PAHs and other products of fossil fuel combustion found

[64] At the public hearing on May 11, 1999, a commenter representing MARG suggested there is evidence that miners exposed to dpm experience adverse health effects at lower-than-normal rates. According to this commenter, ''[s]ignificantly, the human studies conducted in the mining industry reveal a negative propensity for diesel particulate matter-related health effects.'' These studies drew comparisons against an external reference population and failed to adjust for the ''healthy worker effect.'' (See MSHA's discussion of this effect, especially as manifested in the study by Christie et al., 1995, in Subsection 2.c.i(2)(a) of this risk assessment.)

in dpm and trends in allergic respiratory disease. They found that the prevalences of allergic rhinitis (''hay fever'') and allergic asthma have significantly increased with the historical increase in fossil fuel combustion and that laboratory data support the hypothesis that certain organic compounds found in dpm ''* * * are an important factor in the long-term increases in the prevalence in allergic airway disease.'' Similarly, much of the research on allergenic responses to dpm was reviewed by Diaz-Sanchez (1997), who concluded that dpm pollution in the ambient environment ''may play an important role in the increased incidence of allergic airway disease.'' Morgan et al. (1997) noted that dpm ''* * * may be partly responsible for some of the exacerbations of asthma'' and that ''* * * it would be wise to err on the side of caution.'' Such health outcomes are clearly ''material impairments'' of health or functional capacity within the meaning of the Act.

ii. Premature Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes. The evidence from air pollution studies identifies death, largely from cardiovascular, cardiopulmonary, or respiratory causes, as an endpoint significantly associated with acute exposures to fine particulates ($PM_{2.5}$—see Table III–3). The weight of epidemiologic evidence indicates that short-term ambient exposure to particulate air pollution contributes to an increased risk of daily mortality (EPA, 1996). Time-series analyses strongly suggest a positive effect on daily mortality across the entire range of ambient particulate pollution levels. Relative risk estimates for daily mortality in relation to daily ambient particulate concentration are consistently positive and statistically significant across a variety of statistical modeling approaches and methods of adjustment for effects of relevant covariates such as season, weather, and co-pollutants. The mortality effects of acute exposures appear to be primarily attributable to combustion-related particles in $PM_{2.5}$ (such as dpm) and are especially pronounced for death due to pneumonia, COPD, and IHD (Schwartz et al., 1996). After thoroughly reviewing this body of evidence, the U.S. Environmental Protection Agency (EPA) concluded:

> It is extremely unlikely that study designs not yet employed, covariates not yet identified, or statistical techniques not yet developed could wholly negate the large and consistent body of epidemiologic evidence * * *. [EPA, 1996]

There is also substantial evidence of a relationship between chronic exposure to fine particulates ($PM_{2.5}$) and an excess (age-adjusted) risk of mortality, especially from cardiopulmonary diseases. The Six Cities and ACS studies of ambient air particulates both found a significant association between chronic exposure to fine particles and excess mortality. In some of the areas studied, $PM_{2.5}$ is composed primarily of dpm; and significant mortality and morbidity effects were also noted in those areas. In both studies, after adjusting for smoking habits, a statistically significant excess risk of cardiopulmonary mortality was found in the city with the highest average concentration of $PM_{2.5}$ as compared to the city with the lowest. Both studies also found excess deaths due to lung cancer in the cities with the higher average level of $PM_{2.5}$, but these results were not statistically significant (EPA, 1996). The EPA concluded that—

> * * * the chronic exposure studies, taken together, suggest there may be increases in mortality in disease categories that are consistent with long-term exposure to airborne particles and that at least some fraction of these deaths reflect cumulative PM impacts above and beyond those exerted by acute exposure events * * * There tends to be an increasing correlation of long-term mortality with PM indicators as they become more reflective of fine particle levels. [EPA, 1996]

Whether associated with acute or chronic exposures, the excess risk of death that has been linked to pollution of the air with fine particles like dpm is clearly a ''material impairment'' of health or functional capacity within the meaning of the Act.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that ''MSHA appears to regard all particulates smaller than 2.5 $\mu g/m^3$ as equivalent.'' He argued that ''dpm and other ultra-fine particulates represents only a small proportion of ambient particulate samples,'' that ''chronic cough, chronic phlegm, and chronic wheezing reflect mainly tracheobronchial effects,'' and that tracheobronchial deposition is highly dependent on particle size distribution.

No part of Dr. Borak's argument is directly relevant to MSHA's identification of the risk of death from cardiovascular, cardiopulmonary, or respiratory causes faced by miners exposed to high concentrations of dpm. First, MSHA does not regard all fine particulates as equivalent. However, dpm is a major constituent of $PM_{2.5}$ in many of the locations where increased mortality has been linked to $PM_{2.5}$ levels. MSHA regards dpm as presenting a risk by virtue of its comprising a type of $PM_{2.5}$. Second, the studies MSHA used to support the existence of this risk specifically implicate fine particles (i.e., $PM_{2.5}$), so the percentage of dpm in ''total suspended particulate emissions'' (which includes particles even larger than PM_{10}) is not relevant. Third, the chronic respiratory symptoms listed by Dr. Borak are not among the material impairments that MSHA has identified from the $PM_{2.5}$ studies. Much of the evidence pertaining to excess mortality is based on acute—not chronic—ambient exposures of relatively high intensity. In the preceding subsection of this risk assessment, MSHA identified various respiratory symptoms, including allergenic responses, but the evidence for these comes largely from studies on diesel emissions.

As discussed in Section 2.a.iii of this risk assessment, many miners smoke tobacco, and miners experience COPD at a significantly higher rate than the general population. This places many miners in two of the groups that EPA (1996) identified as being at greatest risk of premature mortality due to particulate exposures.

iii. Lung Cancer. It is clear that lung cancer constitutes a ''material impairment'' of health or functional capacity within the meaning of the Act. Therefore, the issue to be addressed in this section is whether there is sufficient evidence (i.e., enough to warrant regulatory action) that occupational exposure to dpm causes the risk of lung cancer to increase.

In the proposed risk assessment, MSHA noted that various national and international institutions and governmental agencies had already classified diesel exhaust or particulate as a probable human carcinogen. Considerable weight was also placed on two comprehensive meta-analyses of the epidemiologic literature, which had both found that the combined evidence supported a causal link. MSHA also acknowledged, however, that some reviewers of the evidence disagreed with MSHA's conclusion that, collectively, it strongly supports a causal connection. As examples of the opposing viewpoint, MSHA cited Stöber and Abel (1996), Watson and Valberg (1996), Cox (1997), Morgan et al. (1997), and Silverman (1998). As stated in the proposed risk assessment, MSHA considered the opinions of these reviewers and agreed that no individual study was perfect: even the strongest of the studies had limitations when viewed in isolation. MSHA nevertheless concluded (in the proposal) that the best available epidemiologic studies, supported by experimental data showing toxicity, collectively provide strong evidence that chronic dpm exposure (at occupational levels) actually does increase the risk of lung cancer in humans.

Although miners and labor representatives generally agreed with MSHA's interpretation of the collective evidence, many commenters representing the mining industry strongly objected to MSHA's conclusion. Some of these commenters also expressed dissatisfaction with MSHA's treatment, in the proposed risk assessment, of opposing interpretations of the collective evidence—saying that MSHA had dismissed these opposing views without sufficient explanation. Some commenters also submitted new critiques of the existing evidence and of the meta-analyses on which MSHA had relied. These commenters also emphasized the importance of two reports (CASAC, 1998 and HEI, 1999) that both became available after MSHA completed its proposed risk assessment.

MSHA has re-evaluated the scientific evidence relating lung cancer to diesel emissions in light of the comments, suggestions, and detailed critiques submitted during these proceedings. Although MSHA has not changed its conclusion that occupational dpm exposure increases the risk of lung cancer, MSHA believes that the public comments were extremely helpful in identifying areas of MSHA's discussion of lung cancer needing clarification, amplification, and/or additional supportive evidence.

Accordingly MSHA has re-organized this section of the risk assessment into five subsections. The first of these provides MSHA's summary of the collective epidemiologic evidence. Second is a description of results and conclusions from the only two existing peer-reviewed and published statistical meta-analyses of the epidemiologic studies: Bhatia et al. (1998) and Lipsett and Campleman (1999). The third subsection contains a discussion of potential systematic biases that might tend to shift all study results in the same direction. The fourth evaluates the overall weight of evidence for causality, considering not only the collective epidemiologic evidence but also the results of toxicity experiments. Within each of these first four subsections, MSHA will respond to the relevant issues and criticisms raised by commenters in these proceedings, as well as by other outside reviewers. The final subsection will describe general conclusions reached by other reviewers of this evidence, and present some responses by MSHA about opposing interpretations of the collective evidence.

(1) Summary of Collective Epidemiologic Evidence. As mentioned in Section III.2.c.i(2)(a) and listed in Tables III–4 and III–5, MSHA reviewed a total of 47 epidemiologic studies involving lung cancer and diesel exposure. Some degree of association between occupational dpm exposure and an excess rate of lung cancer was reported in 41 of these studies: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Section III.2.c.1(2)(a) explains MSHA's criteria for evaluating these studies, summarizes those on which MSHA places greatest weight, and explains why MSHA places little weight on the six studies reporting no increased risk of lung cancer for exposed workers. It also contains summaries of the studies involving miners, addresses criticisms of individual studies by commenters and reviewers, and discusses studies that, according to some commenters, suggest that dpm exposure does not increase the risk of lung cancer.

Here, as in the earlier, proposed version of the risk assessment, MSHA was careful to note and consider limitations of the individual studies. Several commenters interpreted this as demonstrating a corresponding weakness in the overall body of epidemiologic evidence. For example, one commenter [Energy West] observed that ''* * * by its own admission in the preamble * * * most of the evidence in [the epidemiologic] studies is relatively weak'' and argued that MSHA's conclusion was, therefore, unjustified.

It should first be noted that the three most recent epidemiologic studies became available too late for inclusion in the risk assessment as originally written. These three (Johnston et al., 1997; Säverin et al., 1999; Brüske-Hohlfeld, 1999) rank among the strongest eight studies available (see Section III.2.c.1(2)(a)) and do not have the same limitations identified in many of the other studies. Even so, MSHA recognizes that no single one of the existing epidemiologic studies, viewed in isolation, provides conclusive evidence of a causal connection between dpm exposure and an elevated risk of lung cancer in humans. Consistency and coherency of results, however, do provide such evidence. An appropriate analogy for the collective epidemiologic evidence is a braided steel cable, which is far stronger than any of the individual strands of wire making it up. Even the thinnest strands can contribute to the strength of the cable.

(a) Consistency of Epidemiologic Results

Although no epidemiologic study is flawless, studies of both cohort and case-control design have quite consistently shown that chronic exposure to diesel exhaust, in a variety of occupational circumstances, is associated with an increased risk of lung cancer. Furthermore, as explained earlier in this risk assessment, limitations such as small sample size, short latency, and (usually) exposure misclassification reduce the power of a study. These limitations make it more difficult to detect a relationship even when one exists. Therefore, the sheer number of studies showing a positive association readily distinguishes those studies criticized by Taubes (1995), where weak evidence is available from only a single study. With only rare exceptions, involving too few workers and/or observation periods too short to have a good chance of detecting excess cancer risk, the human studies have shown a greater risk of lung cancer among exposed workers than among comparable unexposed workers.

Moreover, the fact that 41 out of 47 studies showed an excess risk of lung cancer for exposed workers may itself be a significant result, even if the evidence in most of those 41 studies is relatively weak. Getting ''heads'' on a single flip of a coin, or two ''heads'' out of three flips, does not provide strong evidence that there is anything special about the coin. However, getting 41 ''heads'' in 47 flips would normally lead one to suspect that the coin was weighted in favor of heads. Similarly, results reported in the epidemiologic literature lead one to suspect that the underlying relationship between diesel exposure and an increased risk of lung cancer is indeed positive.

More formally, as MSHA pointed out in the earlier version of this risk assessment, the high proportion of positive studies is statistically significant according to the 2-tailed sign test. Under the ''null hypothesis'' that there is no systematic bias in one direction or the other, and assuming that the studies are independent, the probability of 41 or more out of 47 studies being either positive or negative is less than one per ten million. Therefore, the sign test rejects, at a very high confidence level, the null hypothesis that each study is equally likely to be positive or negative. This means that the collective results, showing increased risk for exposed workers, are statistically significant at a very high confidence level—regardless of the statistical significance of any individual study.

MSHA received no comments directly disputing its attribution of statistical significance to the collective epidemiologic evidence based the sign test. However, several commenters objected to the concept that a number of inconclusive studies can, when viewed collectively, provide stronger evidence than the studies considered in isolation. For example, the Engine Manufacturers Association (EMA) asserted that—

[j]ust because a number of studies reach the same conclusion does not make the collective sum of those studies stronger or more conclusive, particularly where the associations are admittedly weak and scientific difficulties exist in each. [EMA]

Similarly, IMC Global stated that

* * * IMC Global does not consider cancer studies with a relative risk of less than 2.0 as showing evidence of a casual relationship between dpm exposure and lung cancer. * * * Thus while MSHA states [in the proposed risk assessment; now updated to 41 out of 47] that 38 of 43 epidemiologic studies show some degree of association between occupational dpm exposures and lung cancer and considers that fact significant, IMC Global does not. [IMC Global]

Although MSHA agrees that even statistically significant consistency of epidemiologic results is not sufficient to establish causality, MSHA believes that consistency is an important part of establishing that a suspected association is causal.[65] Many of the commenters objecting to MSHA's emphasis on the collective evidence failed to distinguish the strength of evidence in each individual study from the strength of evidence in total.

Furthermore, weak evidence (from just one study) should not be confused with a weak effect. As Dr. James Weeks pointed out at the public hearing on Nov. 19, 1998, a 40-percent increase in lung cancer is a strong effect, even if it may be difficult to detect in an epidemiologic study.

Explicable differences, or heterogeneity, in the magnitudes of relative risk reported from different studies should not be confused with inconsistency of evidence. For example, as described by Silverman (1998), one of the available meta-analyses (Bhatia et al., 1998) ''examined the primary sources of heterogeneity among studies and found that a main source of heterogeneity is the variation in diesel exhaust exposure across different occupational groups.'' Figures III–5 and III–6, taken from Cohen and Higgins (1995), respectively show relative risks reported for the two occupations on which the most studies are available: railroad workers and truck drivers.

Each of these two charts compares results from studies that adjusted for smoking to results from studies that did not make such an adjustment. For each study, the point plotted is the estimated relative risk or odds ratio, and the horizontal line surrounding it represents a 95-percent confidence interval. If the left endpoint of a confidence interval exceeds 1.0, then the corresponding result is statistically significant at a 95-percent confidence level.

The two charts show that the risk of lung cancer has consistently been elevated for exposed workers and that the results are not significantly different within each occupational category. Differences in the magnitude and statistical significance of results within occupation are not surprising, since the groups studied differed in size, average exposure intensity and duration, and the time allotted for latent effects.

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[65] With respect to the IMC Global's blanket rejection of studies showing a relative risk less than 2.0, please see also the related discussions in Subsection 2.c.i(2)(a) above, under the heading of ''Potential Confounders,'' and in Subsection 3.a.iii(3) below, entitled ''Potential Systemic Biases.''

Figure III-5

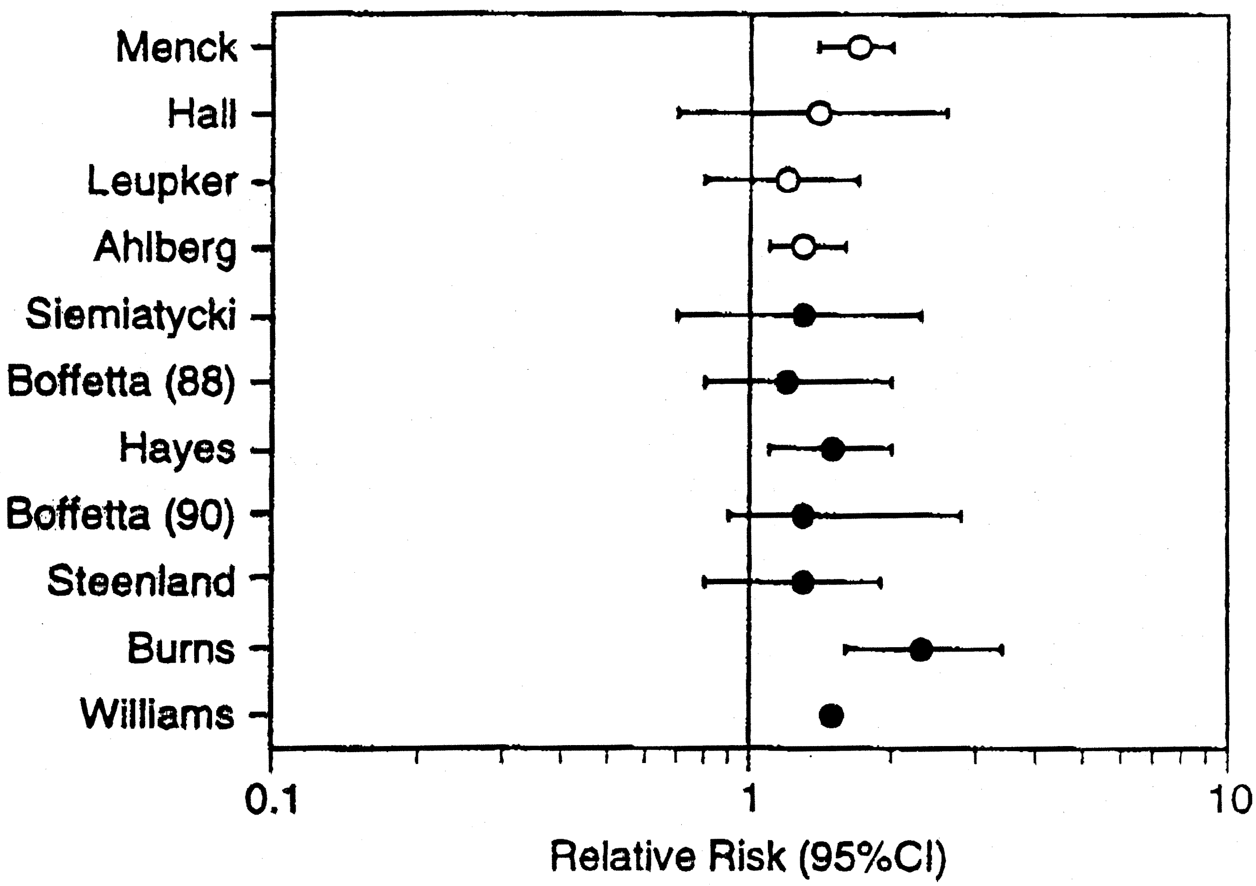

Figure , Lung cancer and exposure to diesel exhaust in truck drivers. ● = RR adjusted for cigarette smoking; ○ = RR not adjusted for cigarette smoking. For the study by Williams, CIs were not reported and could not be calculated. For the Steenland study, the data were gathered from union reports of long-haul truckers; for the Boffetta (1988) study, the data were self-reported by diesel truck drivers; and for the Siemiatycki study, they were self-reported by heavy-duty truck drivers (personal communication).

Figure III–6

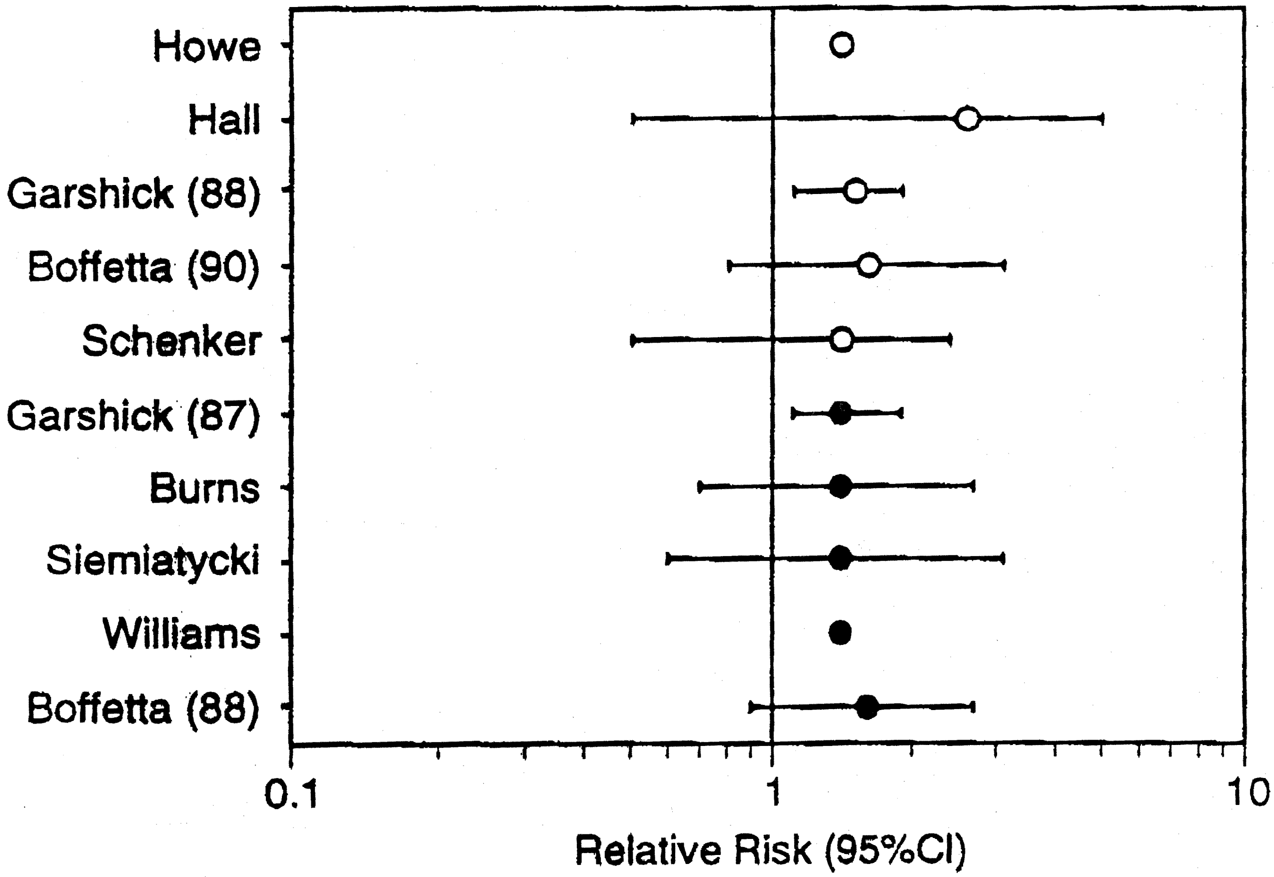

Figure **Lung cancer and exposure to diesel exhaust in railroad workers.** ● = RR adjusted for cigarette smoking; ○ = RR not adjusted for cigarette smoking. For the two studies by Howe and Williams, CIs were not reported and could not be calculated.

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As documented in Subsection 2.c.i(2)(a) of this risk assessment, all of the studies showing negative associations were either based on relatively short observation or follow-up periods, lacked good information about dpm exposure, involved low duration or intensity of dpm exposure, or, because of inadequate sample size or latency allowance, lacked the power to detect effects of the magnitude found in the ''positive'' studies. Boffetta et al. (1988, p. 404) noted that, in addition, studies failing to show a statistically significant association—

> * * * often had low power to detect any association, had insufficient latency periods, or compared incidence or mortality rates among workers to national rates only, resulting in possible biases caused by the ''healthy worker effect.''

Some commenters noted that limitations such as insufficient duration of exposure, inadequate latency allowance, small worker populations, exposure misclassification, and comparison to external populations with no adjustment for a healthy worker effect may explain why not all of the studies showed a statistically significant association between dpm exposure and an increased prevalence of lung cancer. According to these commenters, if an epidemiologic study shows a statistically significant result, this often occurs in spite of methodological weaknesses rather than because of them. MSHA agrees that limitations such as those listed make it more difficult to obtain a statistically significant result when a real relationship exists.

(b) Best Available Epidemiologic Evidence

As explained above, it is statistically significant that 41 of the 47 available epidemiologic studies reported an elevated risk of lung cancer for workers exposed to dpm. MSHA finds it even more informative, however, to examine the collective results of the eight studies identified in Section III.2.c.i(2)(a) as providing the best currently available epidemiologic evidence. These studies, selected using the criteria described earlier, are: Boffetta et al. (1988), Boffetta et al. (1990), Brüske-Hohlfeld et al. (1999), Garshick et al. (1987), Garshick et al. (1988, 1991), Johnston et al. (1997), Steenland et al. (90, 92, 98), and Säverin *et al.,* (1999). All eight of these studies reported an increased risk of lung cancer for workers with the longest diesel exposures and for those most likely to have been exposed, compared to unexposed workers. Tables showing the results from each of these studies are provided in Section III.2.c.1(2)(a).

The sign test of statistical significance can also be applied to the collective results of these eight studies. If there were no underlying association between exposure to diesel exhaust and an increased risk of lung cancer, or anything else systematically favoring a positive result, then there should be equal probabilities (equal to one-half) that any one of these eight studies would turn out positive or negative. Therefore, under the null hypothesis that positive and negative results are equally likely, the probability that all eight studies would show either a positive or a negative association is $(0.5)^8 = 0.0039$, or 0.39 percent. This shows that the collective results of the eight studies comprising the best available epidemiologic evidence are statistically significant at a confidence level exceeding 99 percent (i.e., $100 - 2 \times 0.39$).

When the risk of disease or death increases in response to higher cumulative exposures, this is described by a ''positive'' exposure-response relationship. Like consistency of results, the existence of a positive exposure-response relationship is important in establishing that the exposures in question actually cause an increase in risk. Among the eight studies MSHA has identified as comprising the best available epidemiologic evidence, there are five that provide evidence of increasing lung cancer risk with increasing cumulative exposure: Boffetta, et al. (1990), Brüske-Hohlfeld et al. (1999), Johnston et al. (1997), Säverin et al. (1999), and Steenland et al. (1990, 1992, 1998). The results supporting such a relationship are provided in the table accompanying discussion of each of these studies in Section III.2.c.i(2)(a).

Although some have interpreted the results from the two studies by Garshick et al. as also providing evidence of a positive exposure-response relationship (*e.g.,* Cal–EPA, 1998), this interpretation is highly sensitive to the statistical models and techniques used to analyze the data (HEI, 1999; Crump 1999). Therefore, for purposes of this risk assessment, MSHA is not relying on Garshick et al. (1987) or Garshick et. al (1988, 1991) to demonstrate the existence of a positive exposure-response relationship. MSHA used the study for purposes of hazard identification only. The Garshick studies contributed to the weight of evidence favoring a causal interpretation, since they show statistically significant excesses in lung cancer risk for the exposed workers.

The relative importance of the five studies identified in demonstrating the existence of a positive exposure-response relationship varies with the quality of exposure assessment. Boffetta *et al.* (1990) and Brüske-Hohlfeld *et al.* (1999) were able to show such a relationship based on the estimated duration of occupational exposure for exposed workers, but quantitative measures of exposure intensity (*i.e.*, dpm concentration) were unavailable. Although duration of exposure is frequently used as a surrogate of cumulative exposure, it is clearly preferable, as many commenters pointed out, to base estimates of cumulative exposure and exposure-response analyses on quantitative measurements of exposure levels combined with detailed work histories. Positive exposure-response relationships based on such data were reported in all three studies: Johnston *et al.* (1997), Steenland *et al.* (1998), and Säverin *et al.* (1999).

(c) Studies With Quantitative or Semiquantitative Exposure Assessments

Several commenters stressed the fact that most of the available epidemiologic studies contained little or no quantitative information on diesel exposures and that those studies containing such information (such as Steenland *et al.*, 1998) generated it using questionable assumptions. Some commenters also faulted MSHA for insufficiently addressing this issue. For example, one commenter stated:

> * * * the Agency fails to highlight the lack of acceptable (or any) exposure measurements concurrent with the 43 epidemiology studies cited in the Proposed Rule. * * * the lack of concurrent exposure data is a significant deficiency of the epidemiology studies at issue and is a major factor that prevents application of those epidemiology results to risk assessment. [EMA]

MSHA agrees that the nature and quality of exposure information should be an important consideration in evaluating the strength of epidemiologic evidence. That is why MSHA included exposure assessment as one of the criteria used to evaluate and rank studies in Section 2.c.1(2)(a) of this risk assessment. Two of the most recent studies, both conducted specifically on miners, utilize concurrent, quantitative exposure data and are included among the eight in MSHA's selection of best available epidemiologic evidence (Johnston *et al.*, 1997 and Säverin *et al.*, 1999). As a practical matter, however, epidemiologic studies rarely have concurrent exposure measurements; and, therefore, the commenter's line of reasoning would exclude nearly all of the available studies from this risk assessment—including all six of the negative studies. Since Section 101(a)(6) of the Mine Act requires MSHA to consider the ''best available evidence'' (emphasis added), MSHA has not excluded studies with less-than-ideal exposure assessments, but, instead, has taken the quality of exposure assessment into account when evaluating them. This approach is also consistent with the recognition by the HEI Expert Panel on Diesel Emissions and Lung Cancer that ''regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available'' (HEI, 1999; p.39).

The degree of quantification, however, is not the only relevant consideration in evaluating studies with respect to exposure assessment. MSHA also considered the likely effects of potential exposure misclassification. As expressed by another commenter:

> * * * [S]tudies that * * * have poor measures of exposure to diesel exhaust have problems in classification and will have weaker results. In the absence of information that misclassification is systematic or differential, in which case study results would be biased towards either positive or no-effect level, it is reasonable to assume that misclassification is random or nondifferentiated. If so, * * * study results are biased towards a risk ratio of 1.0, a ratio showing no association between diesel exhaust exposure and the occurrence of lung cancer. [Dr. James Weeks, representing UMWA]

In her review of Bhatia *et al.* (1998), Silverman (1998) proposed that ''[o]ne approach to assess the impact of misclassification would be to exclude studies without quantitative or semiquantitative exposure data.'' According to Dr. Silverman, this would leave only four studies among those considered by Dr. Bhatia: Garshick *et al.* (1988), Gustavsson *et al.* (1990), Steenland *et al.* (1992), and Emmelin *et al.* (1993).[66] All four of these studies showed higher rates of lung cancer for the workers estimated to have received the greatest cumulative exposure, as compared to workers who had accumulated little or no diesel exposure. Statistically significant results were reported in three of these four studies. Furthermore, the two more recent studies utilizing fully quantitative exposure assessments (Johnston *et al.*, 1997; Säverin *et al.*, 1999) were not evaluated or otherwise considered in the articles by Drs. Bhatia and Silverman. Like the other four studies, these too reported elevated rates of lung cancer for workers with the highest cumulative exposures. Specific results from all six of these studies are presented in Tables III–4 and III–5.

Once again, the sign test of statistical significance can be applied to the collective results of the four studies identified by Dr. Silverman plus the two more recent studies with quantitative exposure assessments. As before, under the null hypothesis of no underlying effect, the probability would equal one-half that any one of these six studies would turn out positive or negative. The probability that all six studies would show either a positive or a negative association would, under the null hypothesis, be $(0.5)^6 = 0.0156$, or 1.56 percent. This shows that the collective results of these six studies, showing an elevated risk of lung cancer for workers estimated to have the greatest cumulative exposure, are statistically significant at a confidence level exceeding 96 percent (i.e., $100 - 2 \times 1.56$).

As explained in the previous subsection, three studies showing evidence of increased risk with increasing exposure based on quantitative or semi-quantitative exposure assessments are included in MSHA's selection of best available epidemiologic evidence: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999). Not only do these studies provide consistent evidence of elevated lung cancer risk for exposed workers, they also each provide evidence of a positive exposure-response relationship—thereby significantly strengthening the case for causality.

(d) Studies Involving Miners

Eleven studies involving miners are summarized and discussed in Section 2.c.i(2)(a) of this risk assessment. Commenters' observations and criticisms pertaining to the individual studies in this group are also addressed in that section. Three of these studies are among the eight in MSHA's selection of best available epidemiologic evidence: (Boffetta et al., 1988; Johnston et al., 1997; Säverin et al., 1999). All three of these studies provide evidence of an increased risk of lung cancer for exposed miners. Although MSHA places less weight on the remaining eight studies, seven of them show some evidence of an excess lung cancer risk among the miners involved. The remaining study (Christie et al., 1995) reported a greater all-cause SMR for the coal miners involved than for a comparable population of petroleum workers but did not compare the miners to a comparable group of workers with respect to lung cancer.

The NMA submitted a review of six of these studies by Dr. Peter Valberg, who concluded that ''[t]hese articles do not implicate diesel exhaust, per se, as strongly associated with lung cancer in miners * * * The reviewed studies do not form a consistent and cohesive picture implicating diesel exhaust as a major risk factor for miners.'' Similarly, Dr. Jonathan Borak reviewed six of the studies on behalf of MARG and concluded:

> [T]he strongest conclusion that can be drawn from these six studies is that the miners in those studies had an increased risk of lung cancer. These studies cannot relate such increased [risk] to any particular industrial exposure, lifestyle or combination of such factors.

Apparently, neither Dr. Valberg nor Dr. Borak disputed MSHA's observation that the miners involved in the studies they reviewed exhibited, overall, an excess risk of lung cancer. It is possible that any excess risk found in epidemiologic studies may be due to extraneous unknown or uncontrolled risk factors (i.e., confounding variables). However, neither Drs. Valberg or Borak, nor the NMA or MARG, offered evidence, beyond a catalog of speculative possibilities, that the excess lung cancer risk for these miners was due to anything other than dpm exposure.

Nevertheless, MSHA agrees that the studies reviewed by Drs. Valberg and Borak do not, by themselves, conclusively implicate dpm exposure as the causal agent. Miners are frequently exposed to other occupational hazards associated with lung cancer, such as radon progeny, and it is not always possible to distinguish effects due to dpm exposure from effects due to these other occupational hazards. This is part of the reason why MSHA did not restrict its consideration of evidence to epidemiologic studies involving miners. What implicates exposure to diesel exhaust is the fact that diesel-exposed workers in a variety of different occupations, under a variety of different working conditions (including different types of mines), and in a variety of different geographical areas consistently exhibit an increased risk of lung cancer.

Drs. Valberg and Borak did not review the two studies that utilize quantitative dpm exposure assessments: Johnston et al. (1997) and Säverin et al. (1999). In recently received comments Dr. Valberg, writing for the NMA brought up four issues on the Säverin et al. 1999. These issues were potential exposure misclassification, potential flaws in the sampling method, potential smoker

[66] Emmelin *et al.* (1993) was considered but excluded from the meta-analysis by Bhatia *et al.* (1998) for reasons explained by the authors.

misclassification, and insufficient latency. Two of these issues have already been extensively discussed in section 2.c.i.2.a.ii and therefore will not be repeated here. Dr. Valberg suggested that the potential flaw in the sampling method would tend to over-estimate exposure and that there was insufficient latency. If, in fact, both of these issues are relevant, they would act to UNDERESTIMATE the lung cancer risk in this cohort instead of OVERESTIMATE it. MSHA regards these, along with Boffetta et al. (1988), Burns and Swanson (1991),[67] and Lerchen et al. (1987) to be the most informative of the available studies involving miners. Results on miners from these five studies are briefly summarized in the following table, with additional details provided in Section 2.c.1(2)(a) and Tables III–4 and III–5 of this risk assessment. The cumulative exposures at which relative risks from the Johnston and Säverin studies are presented are equivalent, assuming that TC constitutes 80 percent of total dpm. The cumulative dpm exposure of 6.1 mg-yr/m^3 is the multiplicative product of exposure duration and dpm concentration for the most highly exposed workers in each of these two studies.

[67] Listed in Table III–5 under Swanson et al., 1993.

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Results from best available studies involving miners.

Study	Mine Type	Exposure Assessment	Smoking Adjustm't	Result
Boffetta et al. (1988)	various	Occupational history	yes	RR = 2.67 for miners, compared to workers never employed in diesel -exposed occupations.†
Burns and Swanson (1991)	unknown	Occupational history	yes	OR = 5.03 for mining machinery operators.†
Johnston et al. (1997)	UG coal	Occupational history & indirect dpm measurements	yes	For cumulative dpm exposure = 6.12 mg-yr/m^3 : RR = 5.5 using mine-adjusted statistical model; RR= 11.0 using mine-unadjusted statistical model.
Lerchen et al. (1987)	various	Occupational history	yes	OR = 2.1 for underground non-uranium mining.
Säverin et al. (1999)	UG potash	Occupational history & TC measurements	smoking uncorrelated with TC within cohort	RR = 2.17 for most highly exposed group, compared to least exposed group. For cumulative TC exposure = 4.9 mg-yr/m^3 : RR = 1.16 to 2.70 depending on statistical model.

†Statistically significant at a 95-percent confidence level.

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Although MSHA places less weight on the studies by Burns and Swanson and by Lerchen than on the other three, it is significant that the five best available studies involving miners all support an increased risk of lung cancer attributable to dpm exposure.

(2) Meta-Analyses

MSHA recognizes that simply tabulating epidemiologic studies as positive or negative can sometimes be misleading. There are generally a variety of outcomes that could render a study positive or negative, some studies contain different analyses of related data sets, some studies involve multiple comparisons of various subgroups, and the studies differ widely in the reliability of their results. Therefore, MSHA is not limiting its assessment of the epidemiologic evidence to such a tabulation or relying only on the sign test described above. MSHA has also considered the results of two statistical meta-analyses covering most of the available studies (Lipsett and Campleman, 1999; Bhatia *et al.*, 1998). These meta-analyses weighted and pooled independent results from those studies meeting certain inclusion requirements to form overall estimates of relative risk for exposed workers based on the combined body of data. In addition to forming pooled estimates of the effect of diesel exposure, both meta-analyses analyzed sources of heterogeneity in the individual results and investigated but rejected publication bias as an explanation for the generally positive results reported. Both meta-analyses derived a statistically significant increase of 30 to 40 percent in the risk of lung cancer, attributable to occupational dpm exposure.

Lipsett and Campleman (1999) systematically analyzed and combined results from most of the studies summarized in Tables III–4 and III–5. Forty-seven studies published between 1957 and 1995 were identified for initial consideration. Some studies were excluded from the pooled analysis because they did not allow for a period of at least 10 years for the development of clinically detectable lung cancer. Others were excluded because of bias resulting from incomplete ascertainment of lung cancer cases in cohort studies or because they examined the same cohort population as another study. One study was excluded because standard errors could not be calculated from the data presented. The remaining 30 studies, contributing a total of 39 separate estimates of exposure effect (for distinct occupational groups within studies), were analyzed using a random-effects analysis of variance (ANOVA) model.

Potential effects of publication bias (*i.e.*, the likelihood that papers with positive results may be more likely to be published than those with negative results) were investigated by plotting the logarithm of relative risk estimated from each study against its estimated precision, as expressed by the inverse of its standard error. According to the authors, the resulting ''funnel plot'' was generally consistent with the absence of significant publication bias, although there were relatively few small-scale, statistically insignificant studies. The investigators performed a further check of potential publication bias by comparing results of the included studies with the only relevant unpublished report that became available to them during the course of their analysis. Smoking-adjusted relative risks for several diesel-exposed occupations in the unpublished study were, according to the investigators, consistent with those found in the studies included in the meta-analysis.

Each of the 39 separate estimates of exposure effect was weighted by a factor proportional to its estimated precision. Sources of heterogeneity in results were investigated by subset analysis—using categorical variables to characterize each study's design, target population (general or industry-specific), occupational group, source of control or reference population, latency, duration of exposure, method of ascertaining occupation, location (North America or Europe), covariate adjustments (age, smoking, and/or asbestos exposure), and absence or presence of a clear healthy worker effect (as manifested by lower than expected all-cause mortality in the occupational population under study).

Sensitivity analyses were conducted to evaluate the sensitivity of results to inclusion criteria and to various assumptions used in the analysis. This included (1) substitution of excluded ''redundant'' studies of the same cohort population for the included studies and (2) exclusion of studies involving questionable exposure to dpm. An influence analysis was also conducted to examine the effect of dropping one study at a time, to determine if any individual study had a disproportionate effect on results of the ANOVA.

The pooled relative risk from all 39 exposure effects (estimated from 30 studies) was RR = 1.33, with a 95-percent confidence interval (CI) extending from 1.21 to 1.46. For the subgroup of 13 smoking-adjusted exposure effects (nine studies) from populations ''most likely to have had substantial exposure'' to dpm, the pooled effect was RR = 1.47, with a CI from 1.29 to 1.67. Based on the all of the various analyses they conducted, the authors concluded:

> Although substantial heterogeneity existed in the initial pooled analysis, stratification on several factors substantially reduced heterogeneity, producing subsets of studies with increased relative risk estimates that persisted through various influence and sensitivity analyses. * * *
>
> In studies that adjusted for confounding by cigarette smoking, not only did the positive association between diesel exhaust exposure and lung cancer persist but the pooled risk estimate showed a modest increase, with little evidence of heterogeneity.
>
> * * * [T]his meta-analysis provides quantitative evidence consistent with several prior reviews, which have concluded that the epidemiologic evidence supports a causal relationship between occupational exposure to diesel exhaust and lung cancer. [Lipsett and Campleman, 1999]

The other meta-analysis was conducted by Bhatia *et al.* (1998) on epidemiologic studies published in peer-reviewed journals between 1957 and 1993. In this analysis, studies were excluded if actual work with diesel equipment ''could not be confirmed or reliably inferred'' or if an inadequate latency period was allowed for cancer to develop, as indicated by less than 10 years from time of first exposure to end of follow-up. Studies of miners were also excluded, because of potential exposure to radon and silica. Likewise, studies were excluded if they exhibited selection bias or examined the same cohort population as a study published later. A total of 29 independent results on exposure effects from 23 published studies were identified as meeting the inclusion criteria.

To address potential publication bias, the investigators identified several unpublished studies on truck drivers and noted that elevated risks for exposed workers observed in these studies were similar to those in the published studies utilized. Based on this and a ''funnel plot'' for the included studies, the authors concluded that there was no indication of publication bias.

After assigning each of the 29 separate estimates of exposure effect a weight proportional to its estimated precision, Bhatia *et al.* (1998) used a fixed-effects ANOVA model to calculate pooled relative risks based on the following groupings: all 29 results; all case-control studies; all cohort studies; cohort studies using internal reference populations; cohort studies making external comparisons; studies adjusted for smoking; studies not adjusted for smoking; and studies grouped by occupation (railroad workers, equipment operators, truck drivers, and bus workers). Elevated risks of lung cancer were shown for exposed workers overall and within every individual group of studies analyzed. A positive duration-response relationship was observed in those studies presenting results according to employment duration. The weighted, pooled estimates of relative risk were identical for case-control and cohort studies and nearly identical for studies with or without smoking adjustments.

The pooled relative risk from all 29 exposure effects (estimated from 23 studies) was RR = 1.33, with a 95-percent confidence interval (CI), adjusted for heterogeneity, extending from 1.24 to 1.44. For just the smoking-adjusted studies, it was 1.35 (CI: 1.20 to 1.52); and for cohort studies making internal comparisons, it was 1.43 (CI: 1.29 to 1.58). Based on their evaluation of the all the analyses on various subgroups, Bhatia *et al.* (1998) concluded that the elevated risk of lung cancer observed among exposed workers was unlikely to be due to chance, that confounding from smoking was unlikely to explain all of the excess risk, and that ''this meta-analysis supports a causal association between increased risks for lung cancer and exposure to diesel exhaust.''

The pooled relative risks estimated in both meta-analyses equal 1.33 and exceed 1.4 for studies making internal comparisons, or comparisons to similar groups of workers. Both meta-analyses found these results to be statistically significant, meaning that they cannot be explained merely by random or unexplained variability in the risk of lung cancer that occurs among both exposed and unexposed workers. Although both meta-analyses relied, by necessity, on an overlapping selection of studies, the inclusion criteria were different and some studies included in one meta-analysis were excluded from the other. They used different statistical models for deriving a pooled estimate of relative risk, as well as different means of analyzing heterogeneity of effects. Nevertheless, they derived the same estimate of the overall exposure effect and found similar sources of heterogeneity in the results from individual studies.[68] One commenter observed that—

> Lung cancer relative risks for occupational ''control groups'' vary over a range from 0.4 to 2.7 * * *. Therefore, the level of relative risks being reported in the dpm epidemiology fall within this level of natural variation. [IMC Global]

This argument is refuted by the statistical significance of the elevation in risk detected in both meta-analyses in combination with the analyses accounting for heterogeneity of exposure effects.

The EMA objected that MSHA's focus on these two meta-analyses ''presents an incomplete picture because the counter-arguments of Silverman (1998) were not discussed in the same detail.'' IMC global also faulted MSHA for dismissing Dr. Silverman's views without adequate explanation.

In her review,[69] Dr. Silverman characterized Bhatia *et al.* (1998) as a ''careful meta-analysis'' and acknowledged that it ''add[s] to the credibility that diesel exhaust is carcinogenic * * *.'' She also explicitly endorsed several of its most important conclusions. For example, Dr. Silverman stated that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' She suggested, however, that Bhatia *et al.* (1998) ''ultimately do not resolve the question of causality.'' (Silverman, 1998)

Dr. Silverman imposed an extremely high standard for what is needed to ultimately resolve the question of causality. The precise question she posed, along with her answer, was as follows:

> Has science proven causality *beyond any reasonable doubt?* Probably not. [Silverman, 1998, emphasis added.]

Neither the Mine Act nor applicable case law requires MSHA to prove causality ''beyond any reasonable doubt.'' The burden of proof that Dr. Silverman would require to close the case and terminate research is not the same burden of proof that the Mine Act requires to warrant protection of miners subjected to far higher levels of a probable carcinogen than any other occupational group. In this risk assessment, MSHA is evaluating the collective weight of the best available evidence—not seeking proof ''beyond any reasonable doubt.''[70]

The EMA objected to MSHA's reliance on the two meta-analyses because of ''* * * serious deficiencies in each'' but did not, in MSHA's opinion, identify any such deficiencies. The EMA pointed out that ''most of the original studies in each were the same, and the few that were not common to each were not of significance to the outcome of either meta-analysis.'' MSHA does not regard this as a deficiency. Since the object of both meta-analyses was to analyze the available epidemiologic evidence linking dpm exposure with lung cancer, using defensible inclusion criteria, it is quite understandable that they would rely on overlapping information. The principal differences were in the types and methods of statistical analysis used, rather than in the data subjected to analysis; and MSHA considers it informative that different approaches yielded very similar results and conclusions. It is noteworthy, moreover, that both of the meta-analyses explicitly addressed the EMA's concern by performing analyses on various different sub-groupings of the available studies. The sensitivity of results to the inclusion criteria was also explicitly investigated and considered. MSHA believes that the conclusions of these meta-analyses did not depend on unreasonable inclusion or exclusion criteria.

The EMA also argued that—

> [a] meta-analysis cannot compensate for basic deficiencies in the studies used to create the meta-analysis, and this fact is not clearly stated by MSHA. Instead, MSHA follows the tack of the meta-analysis authors, who claim that the meta-analysis somehow overcomes deficiencies of the individual studies selected and presents a stronger case. This is simply not true. [EMA]

MSHA agrees that a meta-analysis cannot correct for all deficiencies that may be present in individual studies. It

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[68] Several commenters suggested that because the two meta-analyses both received direct or indirect funding from the same governmental agency, they were not independently conducted. These commenters speculated that Dr. Allan Smith, a co-author of Cal-EPA (1998) and Bhatia *et al.* (1998), contributed to both meta-analyses. Although an earlier version of Lipsett and Campleman (1999) appeared as an appendix to Cal-EPA (1998), commenters provided no evidence that Dr. Smith contributed anything to that appendix. Dr. Smith is not listed as a co-author of Lipsett and Campleman (1999).

[69] Silverman (1998) reviewed Bhatia *et al.* (1998) but not Lipsett and Campleman (1999) or the earlier version of that meta-analysis (Lipsett and Alexeeff, 1998) cited in MSHA's proposed preamble.

[70] It is noteworthy that, in describing research underway that might resolve the issue of causality, Dr. Silverman stressed the need for studies with quantitative exposure measurements and stated that ''underground miners may, in fact, be the most attractive group for study because their exposure to diesel exhaust is at least five times greater than that of previously studied occupational groups.'' (Silverman, 1998) She then mentioned a study on underground miners in Germany that had recently been initiated. The study of German underground potash miners (Säverin *et al.*, 1999), published after Dr. Silverman's article, utilizes quantitative exposure measurements and is included in MSHA's selection of best available epidemiologic evidence (see Section 3.a.iii(1)(a) of this risk assessment). MSHA also includes in that selection another underground miner study utilizing quantitative exposure measurements (Johnston *et al.*, 1997). The 1997 study was available prior to Dr. Silverman's article but is not listed among her references.

can, however, correct for certain types of deficiencies. For example, individual studies may lack statistical power because of small study populations. By pooling results from several such studies, a meta-analysis may achieve a level of statistical significance not attainable by the individual studies. Furthermore, both of the meta-analyses used well-defined inclusion criteria to screen out those studies with the most severe deficiencies. In addition, they both found that it was the more rigorous and technically more valid studies that reported the strongest associations between excess lung cancer and dpm exposure. They also performed separate analyses that ruled out inflationary effects of such ''deficiencies'' as lack of a smoking adjustment. For example, Lipsett and Campleman (1999) reported a pooled RR = 1.43 for 20 smoking-adjusted results, as compared to a pooled RR = 1.25 for 19 results with no smoking adjustment.

IMC Global and MARG submitted five specific criticisms of the meta-analyses, to which MSHA will respond in turn.

(1) Publication Bias

> * * * both studies * * * rely only on published studies. * * * the authors rely on statistical analysis in an attempt to uncover possible publication bias. * * * the only safeguard to protect against possible publication bias is to seek out unpublished results * * *. [IMC Global]

Both meta-analyses compared the results of published and unpublished studies and found them to be similar. Bhatia *et al.* (1998) found several unpublished studies of lung cancer among truck drivers that ''* * * were not included in our analysis; however the risk ratios of these studies are similar to the [sic] those in published studies among truck drivers.'' (Bhatia *et al.*, p. 90) Lipsett and Campleman (1999) checked ''[s]moking-adjusted relative risks for several diesel-exposed occupations'' in an unpublished report on U.S. veterans and found them ''* * * consistent with those reported here.'' They remarked that ''although publication bias cannot be completely ruled out, it is an unlikely explanation for our findings.'' (Lipsett and Campleman, p. 1015) In addition to comparing results directly against unpublished studies, both meta-analyses used the statistical method of ''funnel plots'' as an indirect means of checking for the existence of significant publication bias. It should also be noted that MSHA did not exclude unpublished studies from this risk assessment.

(2) Selection Bias

> * * * [the] meta-analyses have to provide a much more convincing rationale as to why all miners were excluded even when the confounders that are mentioned are not likely or important, for example in studies conducted in potash and salt mines. * * * IMC Global sees no reason why the older studies of potash workers [Waxweiler *et al.*, 1973] and more recent studies on New South Wales coal miners [Christie *et al.*, 1995] should not be included * * *. [IMC Global]
>
> Studies were selectively included or excluded, without good or sufficient explanation. [MARG]

Contrary to the commenters' characterization, both meta-analyses listed each study excluded from the analysis of pooled relative risk and gave a good reason for its exclusion. For example, both meta-analyses excluded studies that failed to allow for a minimum 10-year latency period for lung cancer to develop after first exposure. With respect to the exclusion of all studies on miners, Bhatia *et al.* (1998) pointed out that ''[s]ince studies of miners often indicate higher relative risks for lung cancer than those considered in this meta-analysis, this was a conservative exclusion.'' Even if studies on miners had been considered, Waxweiler *et al.* (1973) and Christie *et al.* (1995) would have been excluded from both meta-analyses because of their failure to meet the 10-year minimum latency requirement.

(3) Lack of Actual Exposure Data

> * * * [N]ondifferential exposure or disease misclassification can sometimes produce bias away from the null * * * Thus, tests for heterogeneity performed in both these meta-analyses won't detect or correct this problem. [IMC Global]

Lipsett and Campleman acknowledged that ''[e]xposure misclassification is a problem common to all studies of cancer and diesel emissions. In no case were there direct measurements of historical diesel exhaust exposures of the subjects.'' However, as Dr. Silverman pointed out in her review, ''* * * this bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates toward the null value. Thus the summary RR of 1.33 may be an underestimate of the true lung cancer effect associated with diesel exposure.'' (Silverman, 1998)

(4) Smoking as a Confounder

> * * * The use of data manipulation and modeling adjustments in both these meta-analyses cannot rectify the flaws in the initial studies. [IMC Global]
>
> * * * misclassification of this exposure [cigarette smoking] could result in residual confounding of individual studies and, consequently, meta-analyses, of those studies. [MARG]

Contrary to the commenter's suggestion, neither of the meta-analyses made any attempt to manipulate or adjust the data in order to rectify what the commenter regards as ''flaws'' in the way smoking or other potential confounders were treated in the initial studies. Both meta-analyses, however, compared the pooled RR for studies with a smoking adjustment to the pooled RR for studies without any such adjustment. Both meta-analysis calculated a pooled RR for the smoking-adjusted studies greater than or equal to that for the unadjusted studies. In addition, Bhatia *et al.* (1998) analyzed the impact of the smoking adjustment for the subgroup of studies reporting results both with and without such an adjustment and found that the ''small reduction in the pooled RR estimates would not be consistent with a major effect from residual confounding.'' Dr. Silverman concluded that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' (Silverman, 1998)

(5) Inadequate Control in the Underlying Studies for Diet

> As noted by Lipsett and Campleman, ''Diet may also confound the diesel-lung cancer association.'' The researchers also caution that this risk factor was not controlled for in the nearly 50 diesel studies they examined. [MARG]

Since inhalation is the primary route of dpm exposure, and the lung is the primary target organ, MSHA considers potential dietary confounding to be of minor importance in the diesel-lung cancer association. Lipsett and Campleman acknowledged that diet might be a relevant consideration for long-haul truck drivers, but stated that ''diet would probably not be an important confounder in studies of other occupations, particularly those using internal or other occupationally active reference populations.'' Studies making internal comparisons, or comparisons to similar groups of workers, are unlikely to be seriously confounded by dietary differences, because the groups of workers being compared are likely to have very similar dietary habits, on average. The pooled relative risk for cohort studies making comparisons internally or to other active workers was 1.48 (95% CI = 1.28 to 1.70). (Lipsett and Campleman, 1999, Table 3) This was considerably higher than the pooled RRs for studies making comparisons against regional or national populations, where dietary differences (and also differences with respect to other potential confounders) would be more important.

(3) Potential Systematic Biases

Citing failure to account for dietary differences as an example, some commenters argued that the meta-analyses may simply propagate weaknesses shared by the individual studies. These commenters contended that many of the studies MSHA considered in this risk assessment share methodological similarities and that, therefore, a ''deficiency'' causing bias in one study would probably also bias many other studies in the same direction. According to these commenters, no matter how great a majority of studies report a 30- to 40-percent increase in the risk of lung cancer for exposed workers, the possibility of systematic bias prevents the collective evidence from being strong or sufficient.

Although this point has some theoretical foundation, it has no basis in fact for the particular body of epidemiologic evidence relating lung cancer to diesel exposure. The studies considered were carried out by many different researchers, in different countries, using different methods, and involving a variety of different occupations. Elevated risk was found in cohort as well as case-control studies, and in studies explicitly adjusting for potential confounders as well as studies relying on internal comparisons within homogeneous populations. The possibility that systematic bias explains these results is also rendered less plausible by results from studies of a radically different type: the elevated risk of lung cancer associated with chronic environmental exposures to $PM_{2.5}$ (Dockery *et al.* 1993; Pope *et al.*, 1995).

Furthermore, the commenters advancing this argument presented no evidence that the studies shared any deficiencies of a type that would systematically shift results in the direction of showing a spurious association. As explained in Subsection 2.c.i(2)(a), exposure misclassification, healthy worker effect, and low power due to insufficient latency generally have the opposite effect—systematically diluting and masking results. Although many studies may share a similar susceptibility to bias by dietary differences or residual smoking effects,[71] there is no reason to expect that such effects will consistently bias results in the same direction, across all occupations and geographic regions.

Associations between dpm exposure and excess lung cancer are evident in a wide variety of occupational and geographical contexts, and it is unlikely that all (or most) would be biased in the same direction by lifestyle effects. There is no reason to suppose that, in nearly all of these studies, exposed subjects were more likely than unexposed subjects to have lifestyles (apart from their occupations) that increased their risk of lung cancer. On the other hand, exposures to other occupational carcinogens, such as asbestos dust, radon progeny, and silica, could systematically cause studies in which they are not taken into account to exhibit spurious associations between lung cancer and occupational diesel exhaust exposures. Silica dust and radon progeny are frequently present in mining environments (though not usually in potash mines), and this was the reason that studies on miners were excluded from the two meta-analyses.

IMC Global argued that because of the possibility of being misled by systematic biases, epidemiologic evidence can be used to identify only those hazards that, at a minimum, double the risk of disease (i.e., RR ≥ 2.0). IMC Global explained this viewpoint by quoting an epidemiologist as follows:

> * * * [E]pidemiologic methods can only yield valid documentation of large relative risks. Relative risks of low magnitude (say, less than 2) are virtually beyond the resolving power of the epidemiologic microscope. We can seldom demonstrably eliminate all sources of bias, and we can never exclude the possibility of unidentified and uncontrolled confounding. If many studies—preferably based on different methods—are nevertheless congruent in producing markedly elevated relative risks, we can set our misgivings aside. If however, many studies produce only modest increases, those increases may well be due to the same biases in all the studies. [Dr. Samuel Shapiro, quoted by IMC Global]

It is important to note that, unlike IMC Global, Dr. Shapiro did not suggest that results of RR < 2.0 be counted as ''negative.'' He contended only that low RRs do not completely rule out the possibility of a spurious association due to unidentified or uncontrolled confounding. More importantly, however, this restriction would allow workers to be exposed to significant risks and is, therefore, unacceptable for regulatory purposes. For purposes of protecting miners from lung cancer, certainty is not required; and an increase in the relative risk of less than 100 percent can increase the absolute risk of lung cancer by a clearly unacceptable amount. For example, if the baseline risk of lung cancer is six per thousand, then increasing it by 33 percent amounts to an increase of two per thousand for exposed workers.

IMC Global went on to argue that—

> * * * only a few of these studies have relative risks that exceed 2.0, and some of the studies that do exceed 2.0 exhibit biases that make them unsuitable for rulemaking purposes in our opinion. * * * Thus, in IMC Global's opinion, the epidemiologic evidence demonstrates an artificial association that can be explained through common biases probably due to smoking habits and lifestyle factors. [IMC Global]

This line of reasoning leaps from the *possibility* that systematic biases might account for observed results to a conclusion that they actually do so. Furthermore, after proposing to allow for possible biases by requiring that only relative risks in excess of 2.0 be counted as positive evidence, IMC global has ignored its own criterion and discounted results greater than 2.0 for the same reason. Contrary to IMC Global's claim that ''only a few of the studies have relative risks that exceed 2.0,'' Tables III–4 and III–5 show 23 separate results greater than 2.0, applying to independent categories of workers in 18 different studies.

According to Stöber and Abel (1996), the potential confounding effects of smoking are so strong that ''residual smoking effects'' could explain even statistically significant results observed in studies where smoking was explicitly taken into account. MSHA agrees that variable exposures to non-diesel lung carcinogens, including relatively small errors in smoking classification, could bias individual studies. However, the potential confounding effect of tobacco smoke and other carcinogens can cut in either direction. Spurious positive associations of dpm exposure with lung cancer would arise only if the group exposed to dpm had a greater exposure to these confounders than the unexposed control group used for comparison. If, on the contrary, the control group happened to be more exposed to confounders, then this would tend to make the association between dpm exposure and lung cancer appear negative. Therefore, although smoking effects could potentially distort the results of any single study, this effect could reasonably be expected to make only about half the studies that were explicitly adjusted for smoking come out positive. Smoking is unlikely to have been responsible for finding an excess prevalence of lung cancer in 17 out of 18 studies in which a smoking adjustment was applied. Based on a 2-tailed sign test, this possibility can be

[71] The term ''residual smoking effects'' refers to the potentially confounding effects of smoking that may remain after a smoking adjustment has been made.

rejected at a confidence level greater than 99.9 percent.

Even in the 29 studies for which no smoking adjustment was made, tobacco smoke and other carcinogens were important confounders only to the extent that the populations exposed and unexposed to diesel exhaust differed systematically with respect to these other exposures. Twenty-four of these studies, however, reported some degree of excess lung cancer risk for the diesel-exposed workers. This result could be attributed to other occupational carcinogens only in the unlikely event that, in nearly all of these studies, diesel-exposed workers happened to be more highly exposed to these other carcinogens than the control groups of workers unexposed to diesel.

Like IMC Global, Stöber and Abel (1996) do not, in MSHA's opinion, adequately distinguish between a *possible* bias and an *actual* one. Potential biases due to extraneous risk factors are unlikely to account for a significant part of the excess risk in all studies showing an association. Excess rates of lung cancer were associated with dpm exposure in all epidemiologic studies of sufficient size and scope to detect such an excess. Although it is possible, in any individual study, that the potentially confounding effects of differential exposure to tobacco smoke or other carcinogens could account for the observed elevation in risk otherwise attributable to diesel exposure, it is unlikely that such effects would give rise to positive associations in 41 out of 47 studies. As stated by Cohen and Higgins (1995):

> * * * elevations [of lung cancer] do not appear to be fully explicable by confounding due to cigarette smoking or other sources of bias. Therefore, at present, exposure to diesel exhaust provides the most reasonable explanation for these elevations. The association is most apparent in studies of occupational cohorts, in which assessment of exposure is better and more detailed analyses have been performed. The largest relative risks are often seen in the categories of most probable, most intense, or longest duration of exposure. In general population studies, in which exposure prevalence is low and misclassification of exposure poses a particularly serious potential bias in the direction of observing no effect of exposure, most studies indicate increased risk, albeit with considerable imprecision. [Cohen and Higgins (1995), p. 269].

Several commenters identified publication bias as another possible explanation for the heavy preponderance of studies showing an elevated risk of lung cancer for exposed workers. As described earlier, both of the available meta-analyses investigated and rejected the hypothesis of significant publication bias affecting the overall results. This was based on both a statistical technique using "funnel plots" and a direct comparison between results of published and unpublished studies. Commenters presented no evidence that publication bias actually exists in this case. After the 1988 NIOSH and 1989 IARC determinations that diesel exhaust was a "potential" or "probable" human carcinogen, negative results would have been of considerable interest, and, in the absence of any evidence specifically applying to dpm studies, there is no reason to assume they would not have been published.

(4) Causality

MSHA must draw its conclusions based on the weight of evidence. In the absence of any statistical evidence for differential confounding or significant publication bias, the weight of epidemiologic evidence strongly favors a causal connection. On the one side, it is evident that virtually all of the studies that adjusted for smoking and other known confounders, or controlled for them by comparing against similar groups of workers, showed positive associations (i.e., relative risk or odds ratio > 1.0). Also on this side of the balance are all eight of the studies MSHA identified as comprising the best available human evidence. These include three studies reporting positive exposure-response relationships based on quantitative dpm exposure assessments: two recent studies specifically on underground miners (one coal and one potash) and one on trucking industry workers.[72] On the other side of the balance is the possibility that publication bias or other systematic biases may have been responsible for some unknown portion of the overall 30- to 40-percent elevation in lung cancer risk observed—a possibility that, while conceivable, is based on speculation. After considering other viewpoints (addressed here and in the next subsection), MSHA has accepted what in its view is the far more likely alternative: that the vast majority of epidemiologic studies showed an elevated risk in association with occupational exposures to diesel exhaust because such exposures cause the risk of lung cancer to increase. The toxicity experiments discussed in Subsection 2.d.iv of this risk assessment support the causal interpretation that MSHA has placed on the associations observed in epidemiologic studies.

In this risk assessment, MSHA is basing its conclusions primarily on epidemiologic studies. However, the results obtained from animal studies confirm that diesel exhaust can increase the risk of lung cancer in some species and help show that dpm (rather than the gaseous fraction of diesel exhaust) is the causal agent. The fact that dpm has been proven to cause lung cancer in laboratory rats only under conditions of lung overload does not make the rat studies irrelevant to miners. The very high dpm concentrations currently observed in some mines could impair or even overwhelm lung clearance for miners already burdened by respirable mineral dusts, thereby inducing lung cancer by a mechanism similar to what occurs in rats (Nauss et al., 1995). It must also be noted, however, that most of the human studies show an increased risk of lung cancer at dpm levels lower than what might be expected to cause overload. Therefore, the human studies suggest that overload is not a necessary condition for dpm to induce or promote lung cancer among humans. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. Animal studies provide evidence that inhalation of dpm has related effects, such as induction of free oxygen radicals, that could promote the development of human lung cancers by mechanisms not requiring lung overload. (See Sec. III.2.d.iv(2).)

Similarly, the weight of genotoxicity evidence helps support a causal interpretation of the associations observed in the epidemiologic studies. This evidence shows that dpm dispersed by alveolar surfactant can have mutagenic effects, thereby providing a genotoxic route to carcinogenesis that is independent of overloading the lung with particles. After a comprehensive review of the evidence, IPCS (1996) concluded that both the particle core and the associated organic materials have biological activity. The biological availability of carcinogens present in the organic portion of dpm may, however, differ significantly in different species. Chemical byproducts of phagocytosis, which occurs even when the lung is not overloaded, may provide another genotoxic route. Inhalation of diesel emissions has been shown to cause DNA adduct formation in peripheral lung cells of rats and monkeys, and increased levels of human DNA adducts have been found in association with occupational exposures. (See Sec. III.2.d.iv(1)) None of this evidence

[72] These studies (respectively: Johnston et al., 1997; Säverin et al., 1999; Steenland et al., 1998) are discussed in detail in Subsection 2.c.i(2)(a) of this risk assessment.

suggests that a lung cancer threshold exists for humans exposed to dpm, despite its importance in the rat model. Nor does this evidence suggest that lung overload is necessary for dpm to induce lung cancer in humans. Indeed, lung overload may be only one of many mechanisms through which lung cancer is produced in humans.

Results from the epidemiologic studies, the animal studies, and the genotoxicity studies are coherent and mutually supportive. After considering all these results, MSHA has concluded that the epidemiologic studies, supported by the experimental data establishing the plausibility of a causal connection, provide strong evidence that chronic occupational dpm exposure increases the risk of lung cancer in humans.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that MSHA's determination that results from the epidemiologic and toxicity studies were ''coherent and mutually reinforcing'' involved circular reasoning. He supported this assertion by incorrectly attributing to MSHA the view that ''most of the individual [epidemiologic] studies are not very good'' and that their suggestion of an association between dpm and lung cancer is ''made credible in light of the animal data.'' To complete his argument that MSHA relied on circular reasoning, Dr. Borak then suggested that the epidemiologic data provided MSHA's sole basis for considering the animal data relevant to humans. In a similar vein, Kennecott Minerals claimed there was an ''absence of toxicological support for epidemiologic findings that are themselves inconclusive.''

Contrary to Dr. Borak's assertion, MSHA has not characterized most of the epidemiologic studies as ''not very good.'' Nor has MSHA suggested that the epidemiologic evidence would not be credible or plausible in the absence of supporting animal data. As Dr. Borak correctly noted, MSHA acknowledged that ''none of the existing human studies is perfect'' and that ''no single one of the existing epidemiological studies, viewed in isolation, provides conclusive evidence of a causal connection * * *.'' That a study is not ''perfect,'' however, does not imply that it is ''not very good.'' MSHA's position has consistently been that, as demonstrated by the two available meta-analyses, the collective epidemiologic evidence is not merely credible but statistically significant and indicative of a causal association. Although MSHA views the toxicity data as supporting and reinforcing the epidemiologic evidence, MSHA believes that the collective epidemiologic evidence is highly credible in its own right.

Furthermore, MSHA does not consider the animal data relevant to humans simply because of the positive epidemiologic evidence. The animal evidence is also credible in its own right. As MSHA has repeatedly pointed out, dust concentrations in some mines have been measured at levels of the same order of magnitude as those found to have caused lung cancer in rats. Such high exposures, especially when combined with occupational exposures to respirable mineral dusts and exposures to particles in tobacco smoke, could overload the human lung and promote lung cancer by a mechanism similar to that hypothesized for rats. (Hattis and Silver, 1992, Figures 9, 10, 11). Also, many of the animal experiments have elucidated genotoxic effects that, while apparently not responsible for the excess lung cancers observed for rats, may be responsible for some or all of the excess risk reported for humans.

MSHA has not relied on circular reasoning. If either the animal data or the toxicity data had failed to show any link between dpm and effects implicated in the induction or promotion of lung cancer, then MSHA's conclusion would have been weakened. The existence of experimental evidence confirming that there is such a link is not imaginary and is logically independent of the epidemiologic evidence. Therefore, contrary to Dr. Borak's characterization, the ''coherency and reinforcement'' arising from the epidemiologic, animal, and genotoxicity data are not the product of circular reasoning. A more apt description is that the three sources of evidence, like three legs of a tripod, support the same conclusion.

Many commenters argued that a causal connection between dpm exposure and an increased human risk of lung cancer should not be inferred unless there is epidemiologic evidence showing a positive exposure-response relationship based on quantitative measures of cumulative dpm exposure. MSHA does not agree that a quantitative exposure-response relationship is essential in establishing causality. Such a relationship is only one of several factors, such as consistency and biological plausibility, that epidemiologists examine to provide evidence of causality. As mentioned earlier, however, there are three studies providing quantitative exposure-response relationships. One of these studies (Steenland et al., 1998) controlled for age, race, smoking, diet, and asbestos exposure, but relied on ''broad assumptions'' to estimate historical exposure levels from later measurements. Two of the studies, however, (Johnston et al., 1997, and Säverin et al., 1999) utilized measurements that were either contemporaneous with the exposures (Johnston) or that were made under conditions very similar to those under which the exposures took place (Säverin). Both of these studies were conducted on underground miners. The Säverin study used exposure measurements of total carbon (TC). All three of the studies combined exposure measurements for each job with detailed occupational histories to form estimates of cumulative dpm exposure; and all three reported evidence of increasing lung cancer risk with increasing cumulative exposure.

Several commenters, expressing and endorsing the views of Dr. Peter Valberg, incorrectly asserted that the epidemiologic results obtained across different occupational categories were inconsistent with a biologically plausible exposure-response relationship. For example, MARG argued that—

> It is biologically implausible that, if dpm were (causally) increasing lung cancer risk by 50% for a low exposure (say, truck drivers), then the lung cancer risk produced by dpm exposure in more heavily exposed worker populations (railroad shop workers) would fall in this same range of added risk. The added lung-cancer risk for bus garage workers is half that of either railroad workers or truck drivers, but dpm concentrations are considerably higher. [MARG]

Earlier, MARG had argued to the contrary that, due to their lack of concurrent exposure measurements, these studies could not reliably be used for hazard identification. MARG then attempted to use them to perform the rather more difficult task of making quantitative comparisons of relative risk. If cumulative exposures are unknown, as MARG argued elsewhere, then there is little basis for comparing responses at different cumulative exposures.

In an analysis submitted by the West Virginia Coal Association, Dr. Valberg extended this argument to miners as follows:

> * * * If dpm concentrations for truck drivers is in the range of 5–50 $\mu g/m^3$, then we can assign the 0.49 excess risk (Bhatia's meta-analysis result) to the 5–50 $\mu g/m^3$ exposure. Hence, dpm concentrations for miners in the range of 100–2,000 $\mu g/m^3$ should have yielded excess risks forty times larger, meaning that the RR for exposed miners would be expected to be about 21 (i.e., 1 + 19.6), whereas reported risk estimates are less than 3 (range from 0.74

2.67). Such an utter lack of concordance argues against a causal role for dpm in the reported epidemiologic associations.

Based on a similar line of reasoning, IMC Global asserted that ''* * * the assumptions that MSHA used to develop [Figure III–4] * * * do not do make sense in the context of a dose-response relationship between lung cancer and dpm exposure.'' This was one of the reasons IMC Global gave for objecting to MSHA's comparison (in Section III.1.d) of exposure levels measured for miners to those reported for different occupations. IMC Global proposed that, as a consequence of this argument, MSHA should delete this comparison from its risk assessment.

MSHA sees three major flaws in Dr. Valberg's argument and rejects it for the following reasons:

(1) The argument glosses over the important distinction between exposure concentrations (intensity) and cumulative exposure (dose). Total cumulative exposure is the product of intensity and duration of exposure. Depending on duration, high intensity exposure may result in similar (or even lower) cumulative exposure than low intensity exposure. Furthermore, different industries, in different nations, introduced diesel equipment at different times. The studies being considered were carried out in a variety of different countries and covered a variety of different historical periods. Therefore, the same number of years in different studies can correspond to very different durations of occupational exposure.

Many of the miners in the studies Dr. Valberg considered may have been occupationally exposed to dpm for relatively short periods of time or even not at all. Various forms of exposure misclassification would tend to obscure any exposure-response relationship across industries. Such obscuring would result from both exposure misclassification within individual studies and also variability in the degree of exposure misclassification in different industries.

Furthermore, the exposure levels or intensities assigned to the various occupations would not necessarily be proportional to cumulative exposures, even if the average number of years of exposure were the same. Different job conditions, such as longer-than-average work hours, could have major, variable impacts on cumulative exposures. For example, lower dpm concentrations have been measured for truck drivers than for other occupationally-exposed workers. But as a group, the truck drivers who were studied, due to their work conditions, may have been in their trucks for longer than the standard 40-hour work week and therefore have larger cumulative dpm exposures. These truck drivers commonly congregated in parking areas and slept in their trucks with the engines idling, thereby disproportionately increasing their cumulative dpm exposures compared to miners and other types of workers.

(2) The commenters advancing this argument assumed that an exposure-response relationship spanning occupations at different levels of exposure intensity would take the form of a straight line. This assumption is unwarranted, since carcinogens do not necessarily follow such a simple pattern across a broad range of exposure levels. There is little basis for assuming that the relationship between cumulative dpm exposures and the relative risk of lung cancer would appear as a straight line when plotted against exposure levels that may differ by a factor of 100. Steenland et al. (1998) reported a better statistical ''fit'' to the data using a model based on the logarithm of cumulative exposure as compared to simple cumulative exposure. Even across the relatively limited range of exposures within the trucking industry, the logarithmic exposure model exhibits pronounced curvature towards the horizontal at the higher cumulative exposures (Steenland et al., 1998, Fig. 5). If this model is extrapolated out to the much higher exposures currently found in underground mining, then (as shown in Subsection 3.b.ii(3)(b) of this risk assessment) it diverges even more from a straight-line model. Toxicological evidence of curvature in the dose-response relationship has also been reported (Ichinose et al., 1997b, p. 190).

Furthermore, the exposure-response pattern may depend on other aspects of exposure, besides how much is accumulated. For example, the National Research Council (NRC) has adopted a risk model for radon-induced lung cancer in which the relative risk (RR) at any age depends on both accumulated exposure and the rate (reflecting the intensity of exposure) at which total exposure was accumulated. In this model, which was derived empirically from the epidemiologic data, exposures accumulated over long time periods at relatively low rates result in a greater risk of lung cancer than the same total exposures accumulated over shorter time periods at relatively higher rates (NRC, 1999). A similar effect for dpm could cause apparent anomalies in the pattern of relative risks observed for occupations ranked simply with respect to the intensity of their average exposures.

(3) Mean exposures and relative risks reported for miners involved in the available studies were mischaracterized. Although dpm levels as high as 2000 $\mu g/m^3$ have been measured in some mines, the levels at most mines surveyed by MSHA were substantially lower (see Figures III–1 and III–2). The average levels MSHA measured at underground mines were 808 $\mu g/m^3$ and 644 $\mu g/m^3$ for M/NM and coal mines using diesel equipment for face haulage, respectively (Table III–1). However, these were not necessarily the levels experienced by miners involved in the available studies. The mean TC exposure concentration reported by Säverin et al. (1999), for work locations having the highest mean concentration, was 390 $\mu g/m^3$—corresponding to a mean dpm concentration of about 490 $\mu g/m^3$. In the only other study involving miners for which exposure measurements were available, Johnston et al. (1997) reported dpm concentrations for the most highly exposed category of workers (locomotive drivers), ranging from 44 $\mu g/m^3$ to 370 $\mu g/m^3$. Therefore, the mean dpm concentration experienced by the most highly exposed miners involved in these two studies was not ''forty times larger'' than the level imputed to truck drivers, but closer to seven times larger.[73] Applying Dr. Valberg's procedure, this yields an ''expected'' relative risk of about 4.4 for the underground miners who happened to work at mines included in these particular studies (1 + 7×(0.49)). Miners exposed at higher levels would, of course, face a greater risk.

Dr. Valberg asserted that the highest relative risk reported for miners was 2.67 (from Boffetta et al., 1988). Dr. Valberg failed to note, however, that the upper 95-percent confidence limit for miners' relative risk in this study was 4.37, so that this result hardly qualifies as an ''utter lack of concordance'' with the 4.4 ''expected'' value for miners. Furthermore, even higher relative risks for miners have been reported in other studies. Burns and Swanson (1991) reported 5.0 for operators of mining machinery, with an upper 95-percent confidence limit of 16.9. The relative risk estimated for the most highly exposed miners in the study by Johnston et al. (1997) was either 5.5 or 11.0, depending on the statistical model used. These results appear to be quite consistent with the data for truck drivers.

[73] The estimate of seven times larger dpm exposure in miners is the result of averaging data from Säverin et al. (1999) with data from Johnston et al. (1997) and comparing the combined average miner dpm exposure to the average truck driver dpm exposure.

(5) Other Interpretations of the Evidence

After reviewing the same body of scientific evidence as MSHA, Dr. Peter Valberg came to a very different conclusion with respect to the likelihood of causality:

> Flawed methodology (lack of adequate control for smoking); values for relative risks (''RR'') that are low and often not statistically elevated above 1.0; inadequate treatment of sources of variability; reliance on multiple comparisons; and inadequate control over how authors choose to define dpm exposure surrogates (that is, job category within a profession, cumulative years of work, age at time of exposure, etc.), all undermine the assignment of causality to dpm exposure.

On the other hand, many scientific organizations and governmental agencies have reviewed the available epidemiologic and toxicological evidence for carcinogenicity and, in accordance with MSHA's conclusion, identified dpm as a probable human carcinogen—at levels far lower than those measured in some mines—or placed it in a comparable category. These include:

YEAR

2000 National Toxicology Program (NTP);
1999 (tentative) U.S. Environmental Protection Agency (EPA)
1998 (tentative) (American Conference of Governmental Industrial Hygienists (ACGIH); Currently on Y2K NIC list. Probable vote in 10/2000.
1998 California Environmental Protection Agency (Cal-EPA);
1998 Federal Republic of Germany;
1996 International Programme on Chemical Safety (IPCS), a joint venture of the World Health Organization, the International Labour Organization, and the United Nations Environment Programme;
1989 International Agency for Research on Cancer (IARC);
1988 National Institute for Occupational Safety and Health (NIOSH).

Nevertheless, several commenters strongly objected to MSHA's conclusion, claiming that the evidence was obviously inadequate and citing scientific authorities who, they claimed, rejected MSHA's inference of a causal connection. In some cases, views were inaccurately attributed to these authorities, and misleading quotations were presented out of context. For example, the Nevada Mining Association stated that its own review of the scientific literature led to—

> * * * the only reasonable conclusion possible: there is no scientific consensus that there is a causal link between dpm exposure and lung cancer. The HEI [1999 Expert Panel] report concludes that the causal link between diesel exhaust and lung cancer remains unproven, and that further study and analysis are clearly required. [Nevada Mining Assoc.]

Although HEI (1999) recommended further study and analysis for purposes of quantitative risk assessment, the report contains no findings or conclusions about the ''causal link.'' To the contrary, the report explicitly states that the panel ''* * * was not charged to evaluate either the broad toxicologic or epidemiologic literature concerning exposure to diesel exhaust and lung cancer for hazard identification purposes, which has been done by others.'' (HEI, 1999, p. 1) Furthermore, the HEI panel ''* * * recognize[d] that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 20)

MARG, along with the Nevada Mining Association and several other commenters, mischaracterized the Expert Panel's findings as extending beyond the subject matter of the report. This report was limited to evaluating the suitability of the data compiled by Garshick et al. (1987, 1988) and Steenland et al. (1990, 1992, 1998) for quantitative risk assessment. Contrary to the characterization by these commenters, HEI's Expert Panel explicitly stated:

> [The Panel] was not charged to evaluate the broad toxicologic or epidemiologic literature for hazard identification purposes, which has been done by others. State, national, and international agencies have all reviewed the broader animal and human evidence for carcinogenicity and, in either their draft or final reports, have all identified diesel exhaust as [a] probable human carcinogen or placed it in a comparable category.'' [HEI, 1999, p. 1]

The Panel then identified most of the organizations and governmental institutions listed above (HEI, 1999, p. 8).

One commenter (MARG) also grossly misrepresented HEI (1999) as having stated that ''the available epidemiologic work has 'study design flaws, including uncontrolled, confounding and lack of exposure measures, leading to a lack of convincing evidence.' '' (MARG post-hearing comments) The opinion falsely attributed to HEI was taken from a sentence in which HEI's Diesel Epidemiology Expert Panel was describing opinions expressed in ''[s]ome reviews critical of these data.'' (HEI, 1999, p. 10) The Panel did not suggest that these opinions were shared by HEI or by any members of the Panel. In fact, the cited passage came at the end of a paragraph in which the Panel cited a larger number of other review articles that had ''discusse[d] this literature in depth'' and had expressed no such opinions. In the same paragraph, the Panel confirmed that ''[t]he epidemiologic studies generally show higher risks of lung cancer among persons occupationally exposed to diesel exhaust than among persons who have not been exposed, or who have been exposed to lower levels or for shorter periods of time.'' (HEI, 1999, p. 10)

Several commenters noted that the U.S. EPA's Clean Air Scientific Advisory Committee (CASAC) issued a report (CASAC, 1998) critical of the EPA's 1998 draft Health Assessment Document for Diesel Emissions (EPA, 1998) and rejecting some of its conclusions. After the HEI (1999) Expert Panel report was published, the EPA distributed a revised draft of its Health Assessment Document (EPA, 1999). In the 1999 draft, the EPA characterized human exposures to diesel exhaust as ''highly likely'' to be carcinogenic to humans at ambient (i.e., environmental) exposure levels. After reviewing this draft, CASAC endorsed a conclusion that, at ambient levels, diesel exhaust is likely to be carcinogenic to humans. Although CASAC voted to recommend that the designation in the EPA document be changed from ''highly likely'' to ''likely,'' this change was recommended specifically for ambient rather than occupational exposures. The CASAC report states that ''[a]lthough there was mixed opinion regarding the characterization of diesel emissions as 'highly likely' to be a human carcinogen, the majority of the Panel did not agree that there was sufficient confidence (i.e., evidence) to use the descriptor 'highly' *in regard to environmental exposures.''* (CASAC, 2000, emphasis added)

MSHA recognizes that not everyone who has reviewed the literature on lung cancer and diesel exposure agrees about the collective weight of the evidence it presents or about its implications for regulatory decisions. IMC Global, for example, stated:

> After independently reviewing most [of the] * * * epidemiologic studies, the literature reviews and the two meta-analyzes, IMC Global believes * * * MSHA has misrepresented the epidemiologic evidence in the Proposed Rule. The best conclusion that we can reach based on our review of this information is that different reputable studies reach conflicting conclusions * * *. [IMC Global]

IMC Global continued by expressing concern that MSHA had ''dismissed'' opposing arguments critical of the positive studies, especially ''regarding lack of statistical significance; small magnitudes of relative risk * * *; and the impact of confounding factors, especially smoking * * *. [IMC Global]''

MSHA has addressed these three issues, as they relate to the evaluation of individual studies, in Section 2.c.i(2)(a) of this preamble. The argument that confounding factors such as smoking may have been systematically responsible for the positive results was discussed above, under the heading of ''Potential Systematic Biases.'' Statistical significance of the collective evidence is not the same thing as statistical significance of individual studies. Application of the sign test, as described Subsection 3.a.iii(1) above, is one way that MSHA has addressed statistical significance of the collective evidence. Another approach was also described above, under the heading of ''Meta-Analyses.''

IMC Global quoted Morgan et al. (1997) as concluding that ''[a]lthough there have been a number of papers suggesting that diesel fumes may act as a carcinogen, the weight of the evidence is against this hypothesis.'' This conclusion was based largely on the authors' contention, shared by IMC Global, that the epidemiologic results were inconsistent and of insufficient strength (i.e., RR < 2.0) to rule out spurious associations due to potential confounders. MSHA, on the other hand, interprets the epidemiologic studies as remarkably consistent, given their various limitations, and has argued that the strength of evidence from individual studies is less important than the strength of evidence from all studies combined. Dr. Debra Silverman has referred to the ''striking consistency'' of this evidence. (Silverman, 1998)

Ironically, Morgan et al. point out many of the very limitations in individual studies that may actually explain why the studies do not yield entirely equivalent results. The 1997 Morgan article was written before the meta-analyses became available and resolved many, if not all, of the apparent inconsistencies in the epidemiologic results. Since none of the existing human studies is perfect and many contain important limitations, it is not surprising that reported results differ in magnitude and statistical significance. The meta-analyses described earlier showed that the more powerful and carefully designed studies tended to show greater degrees of association. MSHA has addressed the joint issues of consistency and strength of association above, under the heading of ''Consistency of Epidemiologic Evidence.''

The Engine Manufacturers Association (EMA) quoted Cox (1997) as concluding: ''* * * there is no demonstrated biological basis for expecting increased risk at low to moderate levels of [diesel] exposure.'' (Cox, 1997, as quoted by EMA] The EMA, however, prematurely terminated this quotation. The quoted sentence continues: ''* * * low to moderate levels of exposure (those that do not lead to lasting soot deposits, chronic irritation, and perhaps GSH enzyme depletion in the lung).'' MSHA does not regard concentrations of dpm exceeding 200 $\mu g/m^3$ as ''low to moderate,'' and the EMA presented no evidence that the effects Dr. Cox listed do not occur at the high exposure levels observed at some mines. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. The deleted caveat ending the quotation is especially important in a mining context, since mine atmospheres generally contain respirable mineral dusts that may diminish clearance rates and contribute to meeting thresholds for chronic irritation and inflammation leading to oxidative damage. Based on miners' testimony at the public hearings and workshops, there is, in fact, reason to believe that exposed miners experience lasting soot deposits and chronic irritation as a result of their exposures.

With respect to the epidemiologic evidence, the EMA quoted Dr. Cox as concluding: ''* * * among studies that demonstrate an increased relative risk, it appears plausible that uncontrolled biases in study design and data analysis methods can explain the statistical increases in relative risk without there being a true causal increase.'' (Cox, 1997, quoted by EMA) Dr. Cox refers to non-causal explanations for positive epidemiologic results as ''threats to causal inference.'' In considering Dr. Cox's discussion of the evidence, it is important to bear in mind that his purpose was ''* * * not to establish that any (or all) of these threats do explain away the apparent positive associations between [dpm] and lung cancer risk * * * but only to point out that they plausibly could * * *.'' (Cox, 1997, p. 813) Dr. Cox's stated intent was to identify non-causal characteristics of positive studies that could potentially ''explain away'' the positive results. This is a relatively simple exercise that could misleadingly be applied to even the strongest of epidemiologic studies. As stated earlier, no epidemiologic study is perfect, and it is always possible that unknown or uncontrolled risk factors may have given rise to a spurious association. Neither the EMA nor Dr. Cox pointed out however, that there are characteristics common to the negative studies that plausibly explain why they came out negative: insufficient latency allowance, nondifferential exposure misclassification, inappropriate comparison groups (including healthy worker effect, negative confounding by smoking or other variables. A similar approach could also be used to explain why many of the positive studies did not exhibit stronger associations. As observed by Dr. Silverman, ''an unidentified negative confounder may have produced bias across studies, systematically diluting RRs.''

b. Significance of the Risk of Material Impairment to Miners

The fact that there is substantial and persuasive evidence that dpm exposure can materially impair miner health in several ways does not imply that miners will necessarily suffer such impairments at a significant rate. This section will consider the significance of the risk faced by miners exposed to dpm.

i. Meaning of Significant Risk

(1) Legal Requirements

The benzene case, cited earlier in this risk assessment, provides the starting point for MSHA's analysis of this issue. Soon after its enactment in 1970, OSHA adopted a ''consensus'' standard for exposure to benzene, as authorized by the OSH Act. The standard set an average exposure limit of 10 parts per million over an 8-hour workday. The consensus standard had been established over time to deal with concerns about poisoning from this substance (448 U.S. 607, 617). Several years later, NIOSH recommended that OSHA alter the standard to take into account evidence suggesting that benzene was also a carcinogen. (*Id.* at 619 et seq.). Although the ''evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best,'' OSHA was operating under a policy that there was no safe exposure level to a carcinogen. (*Id.*, at 631). Once the evidence was adequate to reach a conclusion that a substance was a carcinogen, the policy required the agency to set the limit at the lowest level feasible for the industry. (*Id.* at 613). Accordingly, the Agency proposed lowering the permissible exposure limit to 1 ppm.

The Supreme Court rejected this approach. Noting that the OSH Act requires ''safe or healthful employment,'' the court stated that—

> * * * 'safe' is not the equivalent of 'risk-free' * * * a workplace can hardly be considered ''unsafe'' unless it threatens the

workers with a significant risk of harm. Therefore, before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. [*Id.*, at 642, italics in original].

The court went on to explain that it is the Agency that determines how to make such a threshold finding:

First, the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as ''unsafe.'' [*Id.*, at 655].

The court noted that the Agency's ''* * * determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' (*Id.*, note 62).

Some commenters contended that the concept of significant risk, as enunciated by the Supreme Court in the Benzene case, requires support by a quantitative dose-response relationship. For example, one commenter argued as follows:

* * * OSHA had contended in * * * [the benzene] case that ''because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response curve at this time''. 448 U.S. at 632–633. The court rejected the Agency's attempt to support a standard based upon speculation that ''the benefits to be derived from lowering'' the permissible exposure level from 10 to 1 ppm were 'likely' to be 'appreciable'.'' 448 U.S. at 654.

One year after the Benzene case, the Court in American Textile Mfr's Inst. v. Donovan, 452 U.S. 490 (1981), upheld OSHA's ''cotton dust'' standard for which a dose-response curve had been established by the Agency. The Court relied upon the existence of such data to find that OSHA had complied with the Benzene mandate, stating: ''In making its assessment of significant risk, OSHA relied on dose-response curve data * * * It is difficult to imagine what else the agency could do to comply with this Court's decision in the Benzene case.'' *Id.* at 505, n. 25. See also *Public Citizen Research Group* v. *Tyson,* 796 F. 2d 1479, 1496, 1499 (D.C. Cir. 1986) (where a dose response curve was constructed for the ethylene oxide standard and the agency [had] gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk); *United Steelworkers of America* v. *Marshall,* 647 F. 2d 1189, 1248 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981) (where in promulgating a new lead standard ''OSHA amassed voluminous evidence of the specific harmful effects of lead at particular blood levels and correlated these blood lead levels with air lead levels''). [NMA]

A dose-response relationship has been established between exposure to $PM_{2.5}$ (of which dpm is a major constituent) and the risk of death from cardiovascular, cardiopulmonary, or respiratory causes (Schwartz et al.,1996; EPA, 1996). Furthermore, three different epidemiologic studies, including two carried out specifically on mine workers, have reported evidence of a quantitative relationship between dpm exposure and the risk of lung cancer (Johnston et al., 1997, Steenland et al., 1998, Säverin et al., 1999). However, the Secretary has carefully reviewed the legal references provided by the commenters and finds there is no requirement in the law that the determination of significant risk be based on such a relationship. The cited court rulings appear to describe sufficient means of establishing a significant risk, rather than necessary ones. Indeed, as stated earlier in this section, the Benzene court explained that:

* * * the requirement that a ''significant'' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a ''significant'' risk. * * * the Agency has no duty to calculate the exact probability of harm * * *.

The Agency has set forth the evidence and rationale behind its decision to propose a rule restricting miner exposure to dpm, obtained an independent peer review of its assessment of that evidence, published the evidence and tentative conclusions for public comment, held hearings, kept the record open for further comments for months after the hearings, and re-opened the record so that stakeholders could comment on the most recent evidence available. Throughout these proceedings, the Agency has carefully considered all public comments concerning the evidence of adverse health effects resulting from occupational dpm exposures. Based on that extensive record, and the considerations noted in this section, the Agency is authorized under the statute and relevant precedents to act on this matter—despite the fact that a more conclusive or definitively established exposure-response relationship might help address remaining doubts among some members of the mining community.

As the Supreme Court pointed out in the benzene case, the appropriate definition of significance also depends on policy considerations of the Agency involved. In the case of MSHA, those policy considerations include special attention to the history of extraordinary occupational risks leading to the Mine Act. That history is intertwined with the toll to the mining community of silicosis and coal workers' pneumoconiosis (CWP or ''black lung''), along with billions of dollars in Federal expenditures.

(2) Standards and Guidelines for Risk Assessment

Several commenters suggested that this risk assessment, as originally proposed, deviated from established risk assessment guidelines, because it did not provide a sufficiently quantitative basis for evaluating the significance of miners's risks due to their dpm exposures. One of these commenters (Dr. Jonathan Borak) maintained that a determination of significant risk based on a ''qualitative'' assessment ''has no statistical meaning.''

MSHA recognizes that a risk assessment should strive to provide as high a degree of quantification and certainty as is possible, given the best available scientific evidence. However, in order to best protect miners' health, it is not prudent to insist on a ''perfect'' risk assessment. Nor is it prudent to delay assessing potentially grave risks simply because the available data may be insufficient for an ideal risk assessment. The need for regulatory agencies to act in the face of uncertainty was recognized by the HEI's Diesel Epidemiology Expert Panel as follows: ''The Panel recognizes that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999) When there is good, qualitative evidence—such as the sight and smell of heavy smoke—that one's house is on fire, an inference of significant risk may be statistically meaningful even without quantitative measurements of the smoke's density and composition.

Moreover, as will be demonstrated below, the question of whether a quantitative assessment is or is not essential is, in this case, moot: this risk assessment does, in fact, provide a quantitative evaluation of how significant the risk is for miners occupationally exposed to dpm.

ii. Significance of Risk for Underground Miners Exposed to dpm

An important measure of the significance of a risk is the likelihood that an adverse effect actually will occur. A key factor in the significance of risks that dpm presents to miners is the very high dpm concentrations to which a number of those miners are currently exposed—compared to ambient atmospheric levels in even the most polluted urban environments, and to workers in diesel-related occupations for which positive epidemiologic results have been reported. Figure III–4 compared the range of median dpm exposure levels measured for mine workers at various mines to the range of medians estimated for other occupations, as well as to ambient environmental levels. Figure III–7 presents a similar comparison, based on the highest mean dpm level observed at any individual mine, the highest mean level reported for any occupational group other than mining, and the highest monthly mean concentration of dpm estimated for ambient air at any site in the Los Angeles basin.[74] As shown in Figure III–7, underground miners are currently exposed at mean levels up to 10 times higher than the highest mean exposure reported for other occupations, and up to 100 times higher than the highest mean environmental level even after adjusting the environmental level upwards to reflect an equivalent occupational exposure.

Given the significant increases in mortality and other acute health effects associated with increments of 25 μg/m^3 in fine particulate concentration (see Table III–3), the relative risk of acute effects for some miners (especially those already suffering respiratory problems) appears to be extremely high. Acute responses to dpm exposures have been detected in studies of stevedores, whose exposures were likely to have been less than one tenth the exposure of some miners on the job. Likewise, the risk of lung cancer due to dpm exposure would appear to be far greater for those underground miners who are exposed at such high levels than for other workers or general urban populations.

[74] For comparability with occupational lifetime exposure levels, the environmental ambient air concentration has been multiplied by a factor of approximately 4.7. This factor reflects a 45-year occupational lifetime with 240 working days per year, as opposed to a 70-year environmental lifetime with 365-days per year, and assumes that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day.

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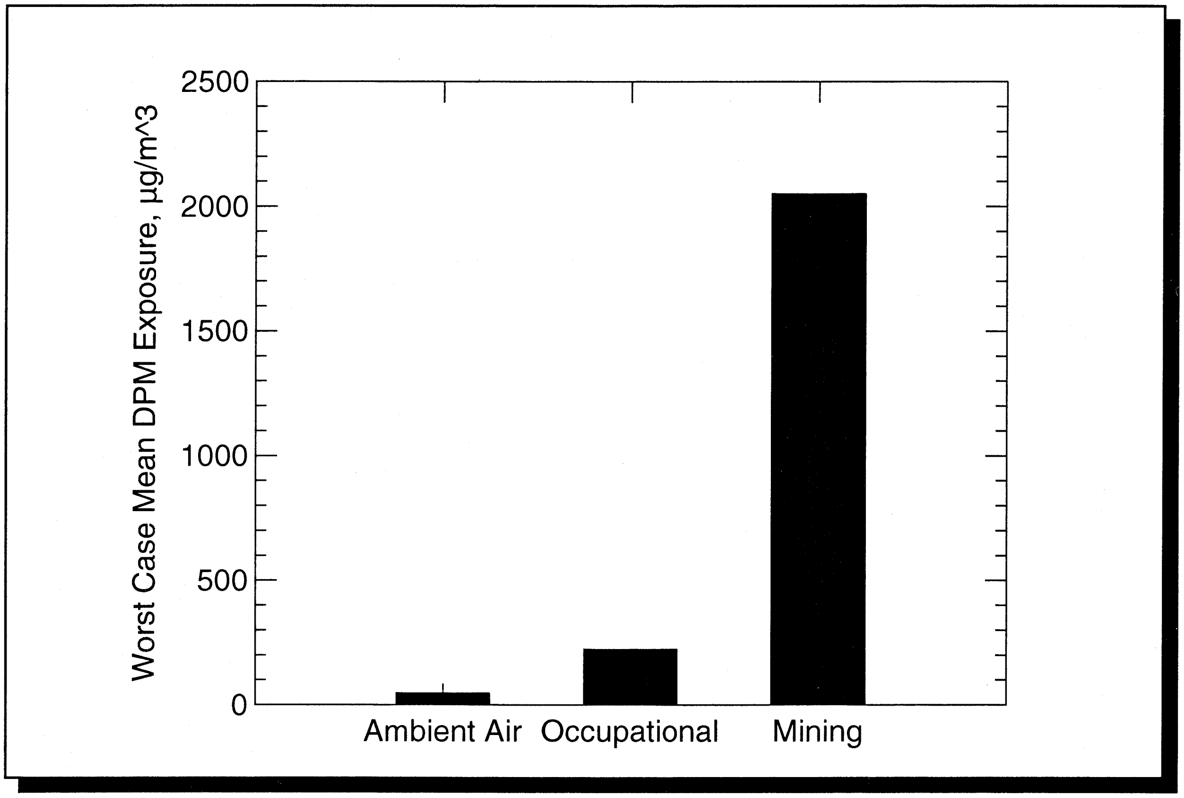

Figure III-7. — Worst case observed or reported mean diesel particulate exposure concentrations for urban ambient air, occupations other than mining, and mining. Worst case for mining is mean dpm measured within an underground mine. Worst case for occupations other than mining is mean respirable particulate matter, other than cigarette smoke, reported for railroad workers classified as hostlers (Woskie et al., 1988). Worst case for ambient air is mean estimated for peak months at most heavily polluted site in Los Angeles area (Cass and Gray, 1995), multiplied by 4.7 to adjust for comparability with occupational lifetime exposure levels. For additional information on means and ranges see Section III.1.d.

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Several commenters asserted that current dpm exposures in underground mines are lower than they were when MSHA conducted its field surveys and that MSHA had not taken this into account when assessing the significance of dpm risk to miners. A related comment was that MSHA had not designed its sampling studies to provide a statistically representative cross section of the entire industry but had nevertheless used the results in concluding that the risk to underground miners was significant.

In accordance with § 101.(a)(6) of the Mine Act, MSHA is basing this risk assessment on the best available evidence. None of the commenters provided evidence that dpm levels in underground metal/nonmetal mines had declined significantly since MSHA's field studies, or provided quantitative estimates of any purported decline in average dpm concentrations, or submitted data that would better represent the range of dpm concentrations to which underground miners are typically exposed at the present time. Although MSHA's field studies were not designed to be statistically representative in a way that can be readily quantified, they were performed at locations selected, according to MSHA's best engineering judgement, to be typical of the type of diesel equipment used. Furthermore, as will be shown below, MSHA's evaluation of the significance of risks presented to underground metal/nonmetal miners by their dpm exposures does not rely on the highest levels, or even the average levels, that MSHA has measured. As documented in Section 1.d of this risk assessment, some of the highest of MSHA's measurements were made as recently as 1996–1997. It is important to note, as is shown below, the cancer risks of dpm exposure are clearly significant even at a concentration of 300 $\mu g/m^3$—less than half of the average level that MSHA observed in its field studies. Therefore, MSHA believes that a reduction in exposure of more than 50 percent in the last couple of years is highly implausible.

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A number of other governmental and nongovernmental bodies have concluded that, even at the far lower levels evident in other occupational environments or in ambient air, the health risks of dpm exposure are of sufficient significance that exposure should be limited:

(1) In 1988, after a thorough review of the scientific literature, the National Institute for Occupational Safety and Health (NIOSH) recommended that diesel exhaust be controlled to the *lowest feasible exposure level.* The document did not contain a recommended exposure limit.

(2) In 1996, the Federal Republic of Germany classified dpm as "probably carcinogenic for humans" and established legally binding technical limits on dpm concentrations in occupational environments. The classification requires that the "best available technology" be used for emission reduction. The technical concentration limits, applying to all workplaces except coal mines, are the lowest limits thought to be feasible in Germany with current technology. Expressed as limits on elemental carbon (EC), they are: 300 $\mu g/m^3$ for tunneling and non-coal mining; 100 $\mu g/m^3$ for all other workplaces (except coal mines).

(3) An ad hoc committee of the Canada Centre for Mineral and Energy Technology (CANMET) has recommended that a limit of 500 $\mu g/m^3$ RCD be adopted as a goal for underground mining environments.

(4) The International Programme on Chemical Safety (IPCS), which is a joint venture of the World Health Organization, the International Labour Organisation, and the United Nations Environment Programme, performed a comprehensive evaluation of the scientific evidence linking diesel exhaust with adverse health effects (IPCS, 1996). IPCS concluded that inhalation of diesel exhaust is of concern with respect to both neoplastic and non-neoplastic diseases and that the particulate phase appears to have the greatest effect on health. As a result of this evaluation, the IPCS recommended that "in the occupational environment, good work practices should be encouraged, and adequate ventilation must be provided to prevent excessive exposure."

(5) In light of the significant health risks associated with environmental exposures to fine particulates ($PM_{2.5}$), in 1997 the U.S. Environmental Protection Agency revised national air quality standards regulating PM to include $PM_{2.5}$ in the ambient air. Diesel particulate matter was a major constituent of $PM_{2.5}$ in many of the areas forming the basis of the EPA's health risk assessment. (EPA, 1996)

(6) In 1998, the California Environmental Protection Agency identified dpm as a toxic air contaminant, as defined in their Health and Safety Code, Section 39655. According to that section, a toxic air contaminant is an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health. This conclusion, unanimously adopted by the California Air Resources Board and its Scientific Review Panel on Toxic Air Contaminants, initiates a process of evaluating strategies for reducing dpm concentrations in California's ambient air.

(7) In 1999, the American Conference of Governmental Industrial Hygienists (ACGIH) proposed a Threshold Limit Value of 50 $\mu g/m^3$ for the dpm component of diesel exhaust and placed dpm on its Notice of Intended Changes. This ACGIH proposal was based on a determination that occupational exposure levels exceeding 50 $\mu g/m^3$ would present a significant "incremental" or excess risk of lung cancer.

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Earlier in this risk assessment, MSHA identified three types of material impairment that can result from occupational exposures to dpm. The next three subsections present the Agency's evaluation of how much of a risk there is that miners occupationally exposed to dpm will actually incur such consequences. Each part addresses the risk of incurring one of the three types of material impairment identified earlier.

(1) Sensory Irritations and Respiratory Symptoms (Including Allergenic Responses)

It is evident from the direct testimony of numerous miners working near diesel equipment that their exposures pose a significant risk of severe sensory irritations and respiratory symptoms. This was underscored during the workshops and public hearings by several miners who noted that such effects occurred immediately and consistently after episodes of intense exposure (Section 2.b.i). There is also persuasive experimental evidence that exposure at levels found in underground mines frequently cause eye and nose irritation (Rudell et al., 1996) and pulmonary inflammation (Salvi et al., 1999). Section 2.a.ii and 3.a.i of this risk assessment explain why these effects constitute ''material impairments'' under the Mine Act and why they threaten miners' safety as well as health. Therefore, it is clear that even short-term exposures to excessive concentrations of dpm pose significant risks.

MSHA's quantitative evaluation of how significant the risks of sensory irritations and respiratory symptoms are for miners is limited, by the quantitative evidence available, to acute respiratory symptoms linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. MSHA recognizes that, for miners exposed to dpm, this type of risk cannot be quantified with great confidence or precision based on the available evidence. This is because $PM_{2.5}$ is not solely comprised of dpm and also because miners, as a group, have different demographic and health characteristics from the general populations involved in the relevant studies. However, MSHA believes that the quantitative evidence suffices to establish a lower bound on the significance of this type of risk to miners exposed to dpm. Even at this lower bound, which is likely to substantially underestimate the degree of risk, the probability that a miner's occupational exposure to dpm will cause adverse respiratory effects is clearly significant.

As shown in Table III–3, the risk of acute lower respiratory tract symptoms has been reported to increase, at a 95-percent confidence level, by 15 to 82 percent (RR = 1.15 to 1.82) for each incremental increase of 20 µg/m³ in the concentration of $PM_{2.5}$ in the ambient air. This means that the relative risk estimated for a given $PM_{2.5}$ concentration ranges between $(1.15)^k$ and $(1.82)^k$, where k = the concentration of $PM_{2.5}$ divided by 20 µg/m³. For example, for a $PM_{2.5}$ concentration of 40 µg/m³, the RR is estimated to be between $(1.15)^2$ and $(1.82)^2$, or 1.32 to 3.31. MSHA believes that part of the reason why the range is so wide is that the composition of $PM_{2.5}$ varied in the data from which the estimates were derived.

MSHA acknowledges that there are substantial uncertainties involved in converting 24-hour environmental exposures to 8-hour occupational exposures. However, since mining often involves vigorous physical activity (thereby increasing breathing depth and frequency) and sleep is characterized by reduced respiration, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. If it is assumed that the acute respiratory effects of inhaling dpm at a concentration of 60 µg/m³ over an 8-hour workshift are at least as great as those at a concentration of 20 µg/m³ over a 24-hour period, then it is possible to estimate a lower bound on the relative risk of such effects.

Based solely on the fact that dpm consists almost entirely of particles much smaller than 2.5 micrometers in diameter, the dpm would be expected to penetrate the lower respiratory tract at least as effectively as $PM_{2.5}$. Also, given the complex chemical composition of dpm, and its generation within a confined space, there is no reason to suspect that dpm in an underground mining environment is less potent than ambient $PM_{2.5}$ in inducing respiratory symptoms. Under these assumptions, a short-term environmental exposure to $PM_{2.5}$ at a concentration of 20 µg/m³ would correspond to a short-term occupational exposure to dpm at a concentration of 60 µg/m³. Consequently, the RR at an occupational exposure level of Y µg/m³ would equal the RR calculated for an ambient exposure level of 20×(Y/60) µg/m³. For example, the relative risk (RR) of acute lower respiratory symptoms at an occupational exposure level of 300 µg/m³ dpm would, at a minimum, correspond to the RR at an ambient exposure level equal to 5×20 µg/m³ $PM_{2.5}$. (See Table III–3) A dpm concentration of 300 µg/m³ happens to be the level at which Salvi et al. (1999) found a marked pulmonary inflammatory response in healthy human volunteers after just one hour of exposure.

Under these assumptions, the risk of lower respiratory tract symptoms for a miner exposed to dpm for a full shift at a concentration of 300 µg/m³ or more, would be at least twice the risk of ambient exposure (i.e., RR = $(1.15)^5$ = 2.01). This would imply that for miners exposed to dpm at or above this level, the risk of acute lower respiratory symptoms would double, at a minimum. The Secretary considers such an increase in risk to be clearly significant.

(2) Premature Death From Cardiovascular, Cardiopulmonary, or Respiratory Causes

As in the case of respiratory symptoms, the nature of the best available evidence limits MSHA's quantitative evaluation of how large an excess risk of premature death, due to causes other than lung cancer, there is for miners exposed to dpm. As before, this evidence consists of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. Therefore, the analysis is subject to similar uncertainties. However, also as before, MSHA believes that the quantitative evidence suffices to place a lower bound on the increase in risk of premature mortality for miners occupationally exposed to dpm. As will be shown below, even this lower bound, which is likely to substantially underestimate the degree of increase, indicates that a miner's occupational exposure to dpm has a clearly significant impact on the likelihood of premature death.

Schwartz et al. (1996) found an average increase of 1.5 percent in daily mortality associated with each increment of 10 µg/m³ in the daily concentration of fine particulates. Higher increases were estimated specifically for ischemic heart disease (IHD: 2.1 percent), chronic obstructive pulmonary disease (COPD: 3.3 percent), and pneumonia (4.0 percent). The corresponding 95-percent confidence intervals for the three specific estimates were, respectively, 1.4% to 2.8%, 1.0% to 5.7%, and 1.8% to 6.2%, per increment of 10 µg/m³ in daily $PM_{2.5}$ exposure. Within the range of dust concentrations studied, the response appeared to be linear, with no threshold. The investigators checked for but did not find any consistent or statistically stable relationship between increased mortality and the atmospheric concentration of ''course'' respirable particles—i.e., those with aerodynamic diameter greater than 2.5 micrometers but less than 10 micrometers.

As explained earlier, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. Therefore, under the same assumptions made in the previous subsection, the 24-hour average concentrations of $PM_{2.5}$ measured by Schwartz et al. are no more potent, in their impact on mortality risk, than eight-hour average concentrations that are three times as high. As discussed in Section 2.a.iii of this risk assessment, underground miners may be less, equally, or more susceptible than the general population to the acute mortality effects of fine particulates such as dpm. However, miners who smoke tobacco and/or suffer various respiratory ailments fall into groups identified as likely to be especially sensitive (EPA, 1996). Consequently, for such miners occupationally exposed to dpm, the relative risk of each type of premature mortality would be at least equal to the corresponding lower 95-percent confidence limit specified above.

Therefore, MSHA estimates that, on average, each increment of 30 $\mu g/m^3$ in the dpm concentration to which miners are exposed increases the risk of premature death due to IHD, COPD, and pneumonia by a factor of at least 1.4 percent, 1.0 percent, and 1.8 percent, respectively. As noted earlier, these estimates are based on the evidence of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. A lower bound on the increased risk expected at an occupational dpm concentration greater than 30 $\mu g/m^3$, is obtained by raising the relative risks equivalent to these factors (i.e., 1.014, 1.01, and 1.018) to a power, k, equal to the ratio of the concentration to 30 $\mu g/m^3$. For a concentration of 300 $\mu g/m^3$, k = 10; so MSHA estimates the lower bounds on relative risk to be: $(1.014)^{10} = 1.149$ for IHD; $(1.01)^{10} = 1.105$ for COPD; and $(1.018)^{10} = 1.195$ for pneumonia. This means that for miners exposed to dpm at or above this level, MSHA expects the risks to increase by at least 14.9 percent for IHD, 10.5 percent for COPD, and 19.5 percent for pneumonia. The Secretary considers increases of this magnitude to be clearly significant, since the causes of death to which they apply are not rare among miners.

(3) Lung Cancer

In contrast to the two types of risk discussed above, the available epidemiologic data can be used to relate the risk of lung cancer directly to dpm exposures. Therefore, the significance of the lung cancer risk can be evaluated without having to make assumptions about the relative potency of dpm compared to the remaining constituents of $PM_{2.5}$. This removes an important source of uncertainty present in the other two evaluations.

There are two different ways in which the significance of the lung cancer risk may be evaluated. The first way is based on the relative risk of lung cancer observed in the best available epidemiologic studies involving miners (identified as such in Subsections 3.a.iii(1) (b) and (d) of this risk assessment). As will be explained below, this approach leads to an estimated tripling of lung cancer risk for miners exposed to dpm, compared to a baseline risk for unexposed miners. The second way is to calculate the lung cancer risk expected at exposure levels MSHA has observed in underground mines, assuming a specified occupational lifetime and using the exposure-response relationships estimated for underground miners by Johnston et al. (1997) and Säverin et al. (1999). As will be explained further below, this second approach yields a wide range of estimates, depending on which exposure-response relationship and statistical model is used. All of the estimates, however, show at least a doubling of baseline lung cancer risk, assuming dpm exposure for a 45-year occupational lifetime at the average concentration MSHA has observed. Most of the estimates are much higher than this. If the exposure-response relationship estimated for workers in the trucking industry by Steenland et al. (1998) is extrapolated to the much higher exposure levels for miners, the resulting estimates fall within the range established by the two mine-specific studies, thereby providing a degree of corroboration. Since lung cancer is not a rare disease, the Secretary considers even the very lowest estimate—a doubling of baseline risk—to represent a clearly significant risk.

Both of these methods provide quantitative estimates of the degree by which miners' risk of lung cancer is increased by their occupational dpm exposures. The estimate based on exposure-response relationships is more refined, in that it ties the increased risk of lung cancer to specific levels of cumulative dpm exposure. However, this added refinement comes at the price of an additional source of uncertainty: the accuracy of the exposure-response relationship used to calculate the estimate. This additional uncertainty is reflected, in MSHA's evaluation, by a broad range of relative risk estimates, corresponding to the range of exposure-response relationships derived using different statistical models and epidemiologic data. The next two subsections present the details of MSHA's two approaches to analyzing lung cancer risk for miners exposed to dpm, along with MSHA's responses to the relevant public comments.

(a) Risk Assessment Based on Studies Involving Miners

As one commenter pointed out, the epidemiologic evidence showing an elevated risk of lung cancer for exposed workers is mostly based on occupations estimated to experience far lower exposure levels, on average, than those observed in many underground mines:

> * * *[U]nderground coal, metal and non-metal miners face a significant risk of lung cancer from occupational exposure to diesel particulate. Numerous epidemiologic studies of workers exposed to levels far below those experienced by coal, metal and non-metal miners have found the risk for exposed workers to be 30–50% greater than for unexposed workers. [Washington State Dept. of Labor and Industries]

Indeed, although MSHA recognizes that results from animal studies should be extrapolated to humans with caution, it is noteworthy that dpm exposure levels recorded in some underground mines (see Figures III–1 and III–2) have been well within the exposure range that produced tumors in rats (Nauss et al., 1995).

Both existing meta-analyses of the human studies relating dpm exposure and lung cancer excluded studies on miners but presented evidence showing that, averaged across all other occupations, dpm exposure is responsible for an increase of about 40 percent in lung cancer risk (See Section 3.a.iii(2) of this risk assessment). Even a 40-percent increase in the risk of lung cancer would clearly be significant, since this would amount to more than two cases of lung cancer per year per thousand miners at risk, and to an even greater risk for smoking miners. The best available evidence, however, indicates (1) that exposure levels in underground mines generally exceed exposures for occupations included in the meta-analyses and (2) that lung cancer risks for exposed miners are elevated to a greater extent than for other occupations.

As Dr. Valberg and other commenters pointed out, the epidemiologic studies used in the meta-analyses involved much lower exposure levels than those depicted for mines in Figures III–1 and III–2. The studies supporting a 40-percent excess risk of lung cancer were conducted on populations whose average exposure is estimated to be less than 200 µg/m³—less than one tenth the average concentration MSHA observed in some underground mines. More specifically, average exposure levels in the two most extensively studied industries—trucking (including loading dock workers) and railroads—have been reported to be far below the levels observed in underground mining environments. For workers at docks employing diesel forklifts—the occupational group estimated to be most highly exposed within the trucking industry—the highest average dpm concentration reported was about 55 µg/m³ EC at an individual dock (NIOSH, 1990). As explained in Subsection 1.d of this risk assessment, this corresponds to less than 150 µg/m³ of dpm, on average. Published dpm measurements for railworkers have generally also been less than 150 µg/m³ (measured as respirable particulate matter other than cigarette smoke). The reported mean of 224 µg/m³ for hostlers displayed in Figure III–7 represents only the worst-case occupational subgroup (Woskie et al., 1988). In contrast, in the study on underground potash miners by Säverin et al. (1999), the mean TC concentration measured for production areas was 390 µg/m³—corresponding to a mean dpm concentration of about 490 µg/m³. As shown in Table III–1, the mean dpm exposure level MSHA observed in underground production areas and haulageways was 644 µg/m³ for coal mines and 808 µg/m³ for M/NM.

In accordance with the higher exposure levels for underground miners, the five studies identified in Section III.3.a.iii(1)(d) as comprising the best available epidemiologic evidence on miners all show that the risk of lung cancer increased for occupationally exposed miners by substantially more than 40 percent. The following table presents the relative risk (RR) of lung cancer for miners in these studies, along with the geometric mean based on all five studies:

Study	Relative risk of lung cancer
Boffetta et al., 1988	2.67
Burns & Swanson, 1991	5.03
Johnston et al., 1997 (mine-adjusted model applied at highest cumulative exposure)	5.50
Lerchen et al., 1987	2.1
Säverin et al., 1999 (highest vs least exposed)	2.17
geometric mean	3.2

As shown in this table, the estimated RR based on these five studies is 3.2 for miners exposed to dpm. In other words, the risk of lung cancer for the highly exposed miners is estimated to be 3.2 times that of a comparable group of occupationally unexposed workers. The geometric mean RR remains 3.2 if the two studies on which MSHA places less weight (by Burns & Swanson and by Lerchen) are excluded from the calculation. This represents a 220-percent increase in the risk of lung cancer for exposed miners, in contrast to the 40-percent increase estimated, on average, for other occupationally exposed workers. The Secretary believes that a 40-percent increase in the risk of lung cancer already exceeds, by a wide margin, the threshold for a clearly significant risk. However, a 220-percent increase to more than three times the baseline rate is obviously of even greater concern.

Some commenters questioned whether increased lung cancer risks of this magnitude were plausible, since they were not aware of any unusually high lung cancer rates among workers at mines with which they were familiar and which used diesel equipment. There are several reasons why an elevated risk of lung cancer might not currently be conspicuous among U.S. miners exposed to dpm. Lung cancer not only may require a latency period of 30 or more years to develop, but it may also not develop until beyond the normal retirement age of 65 years. Cases of lung cancer developing after retirement may not all be known to members of the mining community. Also, in a population that includes many tobacco smokers, it may be difficult to discern cases of lung cancer specifically attributable to dpm exposure when they first begin to become prevalent. Two commenters expressed some of the relevant considerations as follows. Although they were referring to coal miners, the same points apply to M/NM miners.

> Because the latency period for lung cancer is so long, and diesel-powered equipment has only been used extensively in U.S. coal mines for about 25 years, the epidemic may well be progressing unnoticed. [UMWA]
>
> If dpm exposure will cause cancer, there is a huge population of miners here in the West that have already been exposed. Considering the latency periods indicated by MSHA, these miners should be beginning to develop cancers. [Canyon Fuels]

(b) Risk Assessment Based on Miners' Cumulative Exposure

Although it is evident that underground miners currently face a significant risk of lung cancer due to their occupational exposure to dpm, there are certain advantages in utilizing an exposure-response relationship to quantify the degree of risk at specific levels of cumulative exposure. As some commenters pointed out, for example, dpm exposure levels may change over time due to changes in diesel fuel and engine design. The extent and patterns of diesel equipment usage within mines also has changed significantly during the past 25 years, and this has affected dpm exposure levels as well. Furthermore, exposure levels at the mines involved in epidemiologic studies were not necessarily typical or representative of exposure levels at mines in general. A quantitative exposure-response relationship provides an estimate of the risk at any specified level of cumulative exposure. Therefore, using such a relationship to assess risk under current or anticipated conditions factors in whatever differences in exposure levels may be relevant, including those due to historical changes.

(i) Exposure-Response Relationships from Studies Outside Mining

Stayner et al. (1998) summarized quantitative risk assessments based on exposure-response relationships for dpm published through 1998. These assessments were broadly divided into those based on human studies and those based on animal studies. Depending on the particular studies, assumptions, statistical models, and methods of assessment used, estimates of the exact degree of risk varied widely even within each broad category. However, as presented in Tables III and IV of Stayner et al. (1998), all of the very different approaches and methods published through 1998 produced results indicating that levels of dpm exposure measured at some underground mines present an unacceptably high risk of lung cancer for miners—a risk significantly greater than the risk they would experience without the dpm exposure.[75]

[75] In comments submitted by MARG, Dr. Jonathan Borak asserted that MSHA had ''misrepresented the findings of a critical study'' by stating that all methods showed an ''unacceptably high risk'' at exposure levels found at some mines. Dr. Borak claimed that Stayner et al. (1998) had described an analysis by Crump et al. ''that reached an opposite conclusion.'' Dr. Borak failed to distinguish between a finding of high risk and a finding of changes in that risk corresponding to changes in estimated exposures. The findings to which Dr. Borak referred pertained only to the exposure-response relationship within the group of exposed workers. Garshick (1981), Crump (1999), and HEI (1999) all noted that the risk of lung cancer was nevertheless elevated among the exposed workers, compared to unexposed workers in the same cohort,

Continued

Quantitative risk estimates based on the human studies were generally higher than those based on analyses of the rat inhalation studies. As indicated by Tables 3 and 4 of Stayner et al. (1998), a working lifetime of exposure to dpm at 500 µg/m³ yielded estimates of excess lung cancer risk ranging from about 1 to 200 excess cases of lung cancer per thousand workers based on the rat inhalation studies and from about 50 to 800 per thousand based on the epidemiologic assessments. Stayner et al. (1998) concluded their report by stating:

The risk estimates derived from these different models vary by approximately three orders of magnitude, and there are substantial uncertainties surrounding each of these approaches. Nonetheless, the results from applying these methods are consistent in predicting relatively large risks of lung cancer for miners who have long-term exposures to high concentrations of DEP [i.e., dpm]. This is not surprising given the fact that miners may be exposed to DEP [dpm] concentrations that are similar to those that induced lung cancer in rats and mice, and substantially higher than the exposure concentrations in the positive epidemiologic studies of other worker populations.

Restricting attention to the exposure-response relationships derived from human data, Table IV of Stayner et al. (1998) presented estimates of excess lung cancer risk based on exposure-response relationships derived from four different studies: Waller (1981) as analyzed by Harris (1983); Garshick et al. (1987) as analyzed by Smith and Stayner (1991); Garshick et al. (1988) as analyzed by California EPA (1998); and Steenland et al. (1998). Harris (1983) represented upper bounds on risk; and all of the other estimates represented the most likely value for risk, given the particular data and statistical modeling assumptions on which the estimate was based. Three different ranges of estimates were presented from the California EPA analysis, corresponding to various statistical models and assumptions about historical changes in dpm exposure among the railroad workers involved. As mentioned above and in the proposed version of this risk assessment, the low end of the range of estimates was 50 lung cancers per 1000 workers occupationally exposed at 500 µg/m³ for a 45-year working lifetime. This estimate was one of those based on railroad worker data from Garshick et al. (1988).

Several commenters objected to MSHA's reliance on any of the exposure-response relationships derived from the data compiled by Garshick et al. (1987) or Garshick et al. (1988). These objections were based on re-analyses of these data by Crump (1999) and HEI (1999), using different statistical methods and assumptions from those used by Cal-EPA (1998). For example, the NMA quoted HEI (1999) as concluding:

At present, the railroad worker cohort study * * * has very limited utility for QRA [quantitative risk assessment] of lifetime lung cancer risk from exposure to ambient levels of diesel exhaust * * * [NMA, quoting HEI (1999)]

From this, the NMA argued as follows:

What then is the relevance of this data to the proceedings at issue? Simply put, there is no relevance. The leading epidemiologist [sic], including Dr. Garshick himself, now agree that the data are inappropriate for conducting risk assessment. [NMA]

MSHA notes that the HEI (1999) conclusion cited by the NMA referred to quantitative risk assessments at ambient, not occupational, exposure levels. Also, HEI (1999) did not apply its approach (i.e., investigating the correlation between exposure and relative risk within separate job categories) to the Armitage-Doll model employed by Cal-EPA in some of its analyses. (Results using this model were among those summarized in Table IV of Stayner et al., 1998). Therefore, the statistical findings on which HEI (1999) based its conclusion do not apply to exposure-response relationships estimated using the Armitage-Doll model. Furthermore, although HEI concluded that the railroad worker data have ''very limited utility for *QRA * * * at ambient levels*'' [emphasis added], this does not mean, even if true, that these data have ''no relevance'' to this risk assessment, as the NMA asserted. Even if they do not reliably establish an exposure-response relationship suitable for use in a quantitative risk assessment, these data still show that the risk of lung cancer was significantly elevated among exposed workers. This is the only way in which MSHA is now using these data in this risk assessment.

In the proposed risk assessment, MSHA did not rely directly on the railroad worker data but did refer to the lowest published quantitative estimate of risk, which happened, as of 1998, to be based on those data. MSHA's reasoning was that, even based on the lowest published estimate, the excess risk of lung cancer attributable to dpm exposure was clearly sufficient to warrant regulation. If risk assessments derived from the railroad worker data are eliminated from consideration, the lowest estimate remaining in Table IV of Stayner et al. (1998) is obviously even higher than the one that MSHA used to make this determination in the proposed risk assessment. This estimate (based on one of the analyses performed by Steenland et al., 1998) is 89 excess cases of lung cancer per year per thousand workers exposed at 500 µg/m³ for a 45-year working lifetime.

HEI (1999) also evaluated the use of the Steenland data for quantitative risk assessment, but did not perform any independent statistical analysis of the data compiled in that study. Some commenters pointed out HEI's reiteration of the cautionary remark by Steenland et al. (1998) that their exposure assessment depended on ''broad assumptions.'' The HEI report did not rule out the use of these data for quantitative risk assessment but suggested that additional statistical analyses and evaluations were desirable, along with further development of exposure estimates using alternative assumptions. MSHA has addressed comments on various aspects of the analysis by Steenland et al., including the exposure assumptions, in Section 2.c.i(2)(a) of this risk assessment.

One commenter noted that Steenland et al. (1998) had recognized the limitations of their analysis and had, therefore, advised that the results ''should be viewed as exploratory.'' The commenter then asserted that MSHA had nevertheless used these results as ''the basis for a major regulatory standard'' and that ''[t]his alone is sufficient to demonstrate that MSHA's proposal lacks the necessary scientific support.'' [Kennecott Minerals]

The Secretary does not accept the premise that MSHA should exclude ''exploratory'' results from its risk assessment, even if it is granted that those results depend on broad assumptions possibly requiring further research and validation before they are widely accepted by the scientific community. Steenland et al. (1998) estimated risks associated with specific cumulative exposures, based on estimates of historical exposure patterns combined with data originally described by Steenland et al., 1990 and 1992. Regardless of whether the cumulative exposure estimates used by Steenland et al. (1998) are sufficiently reliable to permit pinpointing the risk of lung cancer at any given exposure level, the quantitative analysis indicates that as cumulative exposure increases, so does the risk. Therefore, the 1998 analysis adds significantly to the weight of evidence supporting a causal

and they all identified reasons why the data used in this study might fail to detect a positive exposure-response relationship among the exposed workers.

relationship. However, MSHA did not use or propose to use exposure-response estimates derived by Steenland et al. (1998) as the sole basis for any regulatory standard.

The exposure-response relationships presented by Steenland et al. were derived from exposures estimated to be far below those found in underground mines. As Stayner et al. (1998) point out, questions are introduced by extrapolating an exposure-response relationship beyond the exposures used to determine the relationship. The uncertainties implicit in such extrapolation are demonstrated by comparing results from two statistical models based on five-year lagged exposures—one using simple cumulative exposure and the other using the natural logarithm of cumulative exposure (Steenland et al., 1998, Table II).

Assuming that, on average, EC comprises 40 percent of total dpm,[76] the formula for calculating a relative risk (RR) using Steenland's simple cumulative exposure model is RR = exp(0.4×0.389×CumExp), where CumExp is occupationally accumulated dpm exposure (expressed in mg-yr/m³), ignoring the most recent five years. Again assuming EC=0.4×dpm, the corresponding formula using Steenland's Log(CumExp) model is: RR = exp(0.1803×(Log(0.4×1000×CumExp + BG) − Log(BG))), still ignoring occupational dpm exposure in the most recent five years.[77]

The risk estimates from these two models are similar at the cumulative exposure levels estimated for workers involved in the study, but the projected risks diverge markedly at the higher exposures projected for underground miners exposed to dpm for a 45-year occupational lifetime. For example, a cumulative dpm exposure of 2.5 mg-yr/m³ (i.e., 45 years of occupational exposure at an average dpm concentration of about 55.6 µg/m³) is within the range of cumulative exposures from which these exposure-response relationships were estimated. At this level of cumulative exposure, the models (both lagged five years) yield relative risk estimates of 1.48 (based on simple cumulative exposure) and 1.64 (based on the logarithm of cumulative exposure, with BG=70 µg-yr/m³). On the other hand, 45 years of occupational exposure at an average dpm concentration of 808 µg/m³ amounts to a cumulative dpm exposure of 36,360 µg-yr/m³, or about 36.4 mg-yr/m³. At this level, which lies well beyond the range of data used by Steenland et al. (1998), the simple and logarithmic exposure models produce relative risk estimates of about 300 and 2.6, respectively.

Despite the divergence of these two models at high levels of cumulative exposure, they can provide a useful check of excess lung cancer risks estimated using exposure-response relationships developed from other studies. For highly exposed miners, the Steenland models both produce estimates of lung cancer risk within the range established by the two miner studies discussed below. This corroborates the upper and lower limits on such risk as estimated by the various statistical models used in those two studies.

(ii) Exposure-Response Relationships from Studies on Miners

As described in Section 2.c.i(2)(a) of this risk assessment, two epidemiologic studies, both conducted on underground miners, provide exposure-response relationships based on fully quantitative dpm exposure assessments. Johnston et al. (1997) conducted their study on a cohort of 18,166 underground coal miners, and Säverin et al. (1999) conducted theirs on a cohort of 5,536 underground potash miners. Each of these studies developed a number of possible exposure-response relationships, depending on the statistical model used for analysis and, in the case of Saverin et al. (1999), inclusion criteria for the cohort analyzed. For purposes of this risk assessment, MSHA has converted the units of cumulative exposure in all of these exposure-response relationships to mg-yr/m³.

Two exposure-response relationships derived by Johnston et al. (1997) are used in this risk assessment, based on a ''mine-adjusted'' and a ''mine-unadjusted'' statistical model. In both of these models, cumulative dpm exposure is lagged by 15 years.[78] This reflects the long latency period required for development of lung cancer and means that the most recent 15 years of exposure are ignored when the relative risk of lung cancer is estimated. The exposure-response relationships, as reported by the investigators, were expressed in terms of g-hr/m³ of cumulative dpm exposure. MSHA has converted the exposure units to mg-yr/m³ by assuming 1920 work hours per year.

Two different methods of statistical analysis were applied by Saüverin et al. (1999) to both the full cohort and to a subcohort of 3,258 miners who had worked underground, in relatively stable jobs, for at least ten years. Thus, the investigators developed a total of four possible exposure-response relationships from this study. Since they were based on measurements of total carbon (TC), these exposure-response relationships were expressed in terms mg-yr/m³ of cumulative TC exposure. MSHA has converted the exposure units to mg-yr/m³ of cumulative dpm exposure by assuming that, on average, TC comprises 80 percent of total dpm.

The following table summarizes the exposure-response relationships obtained from these two studies. Each of the quantitative relationships is specified by the unit relative risk (RR) per mg-yr/m³ of cumulative dpm exposure. To calculate the relative risk estimated for a given cumulative dpm exposure (CE), it is necessary to raise the unit RR to a power equal to CE. For example, if the unit RR is 1.11 and CE = 20, then the estimated relative risk is $(1.11)^{20}$ = 8.1. Therefore, the estimated relative risk of lung cancer increases as CE increases. For the two Johnston models, CE does not include exposure accumulated during the 15 years immediately prior to the time in a miner's life at which the relative risk is calculated.

[76] The assumption is that, on average, EC = TC/2 and TC = 0.8×dpm.

[77] BG, expressed in µg-yr/m³, accounts for an assumed background (i.e., non-occupational) EC exposure level of 1.0 µg/m³. At age 70, after a 45-year worklife and an additional 5-year lag after retirement, BG is assumed to equal 70 µg-yr/m³. ''Log'' refers to the natural logarithm, and ''exp'' refers to the antilogarithm of the subsequent quantity.

[78] The 15-year lagged mine-unadjusted and mine-adjusted models are respectively denoted by M/03 and M/06 in Table 11.2 of Johnston et al. (1997). As explained earlier, the individual mines considered in this study differed significantly with respect to both dpm exposures and lung cancer experience. The investigators could not determine exactly how much, if any, of the increased lung cancer risk associated with dpm exposure depends on other, unknown factors differentiating the individual mines. The mine-adjusted model allocates a significant number of the lung cancers otherwise attributable to dpm exposure to the ''norm'' for specific mines. Therefore, if the differences in lung cancer prevalence between mines is actually due to corresponding differences in mean dpm exposure, then this model will mask a significant portion of the risk due to dpm exposure. After adjusting for miners' age and smoking habits, the mine-unadjusted model attributes differences in the prevalence of lung cancer between mines to corresponding differences in mean dpm exposure. However, the mine-adjusted model has the advantage of taking into account differences between mines with respect to potentially confounding factors, such as radon progeny and silica levels.

EXPOSURE-RESPONSE RELATIONSHIPS OBTAINED FROM TWO STUDIES ON UNDERGROUND MINERS.

Study and statistical model	Unit RR per mg-yr/m³ dpm
Säverin et al. (1999)[1]:	
Poisson, full cohort	1.024
Cox, full cohort	1.089
Poisson, subcohort	1.110
Cox, subcohort	1.176
Johnston et al. (1997)[2]:	
15-year lag, mine-adjusted	1.321
15-year lag, mine-unadjusted	1.479

[1] Unit RR calculated from Tables III and IV, assuming TC = 0.8×dpm.

[2] Unit RR calculated from Table 11.2, assuming 1920 work hours per year.

For example, suppose a miner is occupationally exposed to dpm at an average level of 500 µg/m³. Then each year of occupational exposure would contribute 0.5 mg-yr/m³ to the miner's cumulative dpm exposure. Suppose also that this miner's occupational exposure begins at age 45 and continues for 20 years until retirement at age 65. Consequently, at or above age 65, this hypothetical miner would have accumulated a total of 10 mg-yr/m³ of occupational dpm exposure. According to the Säverin-Cox-subcohort model, the relative risk estimated for this miner after retirement is $RR = (1.176)^{10} = 5.1$. This means that, at or above age 65, the retired miner's risk of lung cancer is estimated (by this model) to be about five times that of another retired miner having the same age and smoking history but no occupational dpm exposure.

Since the two Johnston models exclude exposure within the last 15 years, it is instructive to calculate the relative risk using these models for the same hypothetical retiree at age 75. Since this miner retired at age 65, immediately after 20 years of occupational exposure, the cumulative exposure used in applying the Johnston models must be reduced by the 2.5 mg-yr/m³ accumulated from age 60 to age 65. Therefore, according to the Johnston mine-adjusted model, the relative risk estimated for this retired miner at age 75 is $RR = (1.321)^{7.5} = 8.1$. At age 80 or above, however, this model predicts that the relative risk would increase to $RR = (1.321)^{10} = 16.2$.

The six exposure-response relationships obtained from these two studies establish a range of quantitative risk estimates corresponding to a given level of cumulative dpm exposure. This range provides lower and upper limits on the risk of lung cancer for workers exposed at the given level, relative to similar workers who were not occupationally exposed. The lower limit of this range is established by Säverin's full cohort Poisson model. Therefore, the lowest estimate of relative risk after 45 years of occupational dpm exposure is $RR = (1.024)^{45\times0.644} = 2.0$ at a mean concentration of 644 µg/m³ or $RR = (1.024)^{45\times0.808} = 2.4$ at mean concentration of 808 µg/m³. These exposure levels correspond to the averages presented in Table III–1 for underground coal and underground M/NM mines, respectively.

A relative risk of 2.0 amounts to a doubling of the baseline lung cancer risk, and all of the models project relative risks of at least 2.0 after 45 years of exposure at these levels. Therefore, MSHA expects that underground miners exposed to dpm at these levels for a full 45-year occupational lifetime would, at a minimum, experience lung cancer at a rate twice that of unexposed but otherwise similar miners. Five of the six statistical models, however, predict a relative risk much greater than 2.0 after 45 years at a mean dpm concentration of 644 µg/m³. The second-lowest estimate of relative risk, for example, is $RR = (1.089)^{45\times0.644} = 11.8$, predicted by Säverin's full cohort Cox model.[79]

In the next subsection of this risk assessment, relative risks will be combined with baseline lung cancer and mortality data to estimate the lifetime probability of dying from lung cancer due to occupational dpm exposure.

(iii) Excess Risk at Specific dpm Exposure Levels. The ''excess risk'' discussed in this subsection refers to the lifetime probability of dying from lung cancer resulting from occupational exposure to dpm for 45 years. This probability is expressed as the expected excess number of lung cancer deaths per thousand miners occupationally exposed to dpm at a specified level. The excess is calculated relative to baseline, age-specific lung cancer mortality rates taken from standard mortality tables. In order to properly estimate this excess, it is necessary to calculate, at each year of life after occupational exposure begins, the expected number of persons surviving to that age with and without dpm exposure at the specified level. At each age, standard actuarial adjustments must be made in the number of survivors to account for the risk of dying from causes other than lung cancer.

Table III–7 shows the excess risk of death from lung cancer estimated across the range of exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). Estimates based on the 5-year lagged models from Steenland et al. (1998) fall within this range and are included for comparison. Based on each of the eight statistical models, the excess risk was estimated at four levels of dpm exposure: 200 µg/m³, 500 µg/m³, 644 µg/m³ (the mean dpm concentration observed by MSHA at underground coal mines, as shown in Table III–1), and 808 µg/m³ (the mean dpm concentration observed by MSHA at underground M/NM mines, as shown in Table III–1).

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[79] Some commenters contended that MSHA cannot establish a reliable exposure-response relationship because of potential interferences in MSHA's dpm concentration measurements. More specifically, some of these commenters claimed that MSHA's dpm measurements in underground coal mines were significantly inflated by submicrometer coal dust.

As explained in Subsection 1.a of this risk assessment, the sampling device MSHA used to measure dpm in underground coal mines was designed specifically to allow for the submicrometer fraction of coal dust. Both the size-selective and RCD methods are reasonably accurate when dpm concentrations exceed 300 µg/m³. Moreover, neither of these methods was used to establish the exposure-response relationships presented by Säverin et al. (1999) or Johnston *et al.* (1997).

Table III-7. — Lifetime excess risk of lung cancer mortality at specific dpm exposure levels.

Study and Statistical Model	Excess Lung Cancer Deaths per 1000 Occupationally Exposed Workers†			
	200 µg/m³	500 µg/m³	644 µg/m³	808 µg/m³
Säverin et al. (1999)				
Poisson, full cohort	15	44	61	83
Cox, full cohort	70	280	422	577
Poisson, subcohort	93	391	563	693
Cox, subcohort	182	677	761	802
Steenland et al. (1998)				
5-year lag, log of cumulative exposure	67	89	95	101
5-year lag, simple cumulative exposure	159	620	721	771
Johnston et al. (1997)				
15-year lag, mine-adjusted	313	724	770	800
15-year lag, mine-unadjusted	513	783	811	830

† Assumes 45-year occupational exposure at 1920 hours per year from age 20 to retirement at age 65. Lifetime risk of lung cancer adjusted for competing risk of death from other causes and calculated through age 85. Baseline lung cancer and overall mortality rates from NCHS (1996).

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All of the estimates in Table III–7 assume that occupational exposure begins at age 20 and continues until retirement at age 65. Excess risks were calculated through age 85 as in Table IV of Stayner et al. (1998). Table III–7 differs from Table IV of Stayner et al. in that results from Johnston et al. and Säverin et al. are substituted for results based on the two studies by Garshick et al. Nevertheless, at 500 μg/m³, the range of excess risks shown in Table III–7 is nearly identical to the range (50 to 810 μg/m³) presented in Table IV of Stayner et al. (1998).

MSHA considers the exposure levels shown in Table III–1 to be typical of current conditions in underground coal mines using diesel face equipment. At the mean dpm concentration observed by MSHA at underground M/NM mines (808 μg/m³), the eight estimates range from 83 to 830 excess lung cancer deaths per 1000 affected miners. At the mean dpm concentration observed by MSHA at underground coal mines (644 μg/m³), the estimates range from 61 to 811 excess lung cancer deaths per 1000 affected miners. MSHA recognizes that these risk estimates involved extrapolation beyond the exposure experience of the miner cohorts in Säverin et al. (1999) and Johnston et al. (1997). However, the degree of extrapolation was less for those two studies than the extrapolation that was necessary for the diesel-exposed truck drivers in Steenland et al. The lowest excess lung cancer risk in dpm exposed miners found in Table III–7 is 61/1000 per 45-year working lifetime. Based on the quantitative rule of thumb established in the benzene case, this estimate indicates a clearly significant risk of lung cancer attributable to dpm exposure at current levels. [*Industrial Union* vs. *American Petroleum;* 448 U.S. 607, 100 S.Ct. 2844 (1980)].

c. The Rule's Expected Impact on Risk

MSHA strongly disagrees with the views of some commenters who asserted that the proposed rules would provide no known or quantifiable health benefit to mine workers. On the contrary, MSHA's assessment of the best available evidence indicates that reducing the very high exposures currently existing in underground mines will significantly reduce the risk of three different kinds of material impairment to miners: (1) Acute sensory irritations and respiratory symptoms (including allergenic responses); (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (3) lung cancer. Furthermore, as will be shown below, the reduction in lung cancer risk expected as a result of the rule can readily be quantified based on the estimates of excess risk at exposure levels given in Table III–7.

Using exposure-response relationships and assumptions described in Subsections 3.b.ii(1) and 3.b.ii(2) of this risk assessment, MSHA estimated lower bounds on the significance of risks faced by miners occupationally exposed to dpm with respect to (1) acute sensory irritations and respiratory symptoms or (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. MSHA expects the rules to significantly and substantially reduce all three kinds of risk. However, MSHA is unable, based on currently available data, to quantify with confidence the reductions expected for the first two kinds. A 24-hour exposure at 20 μg/m³ may not have the same short-term effects as an 8-hour exposure at 60 μg/m³. Furthermore, this concentration is only 30 percent of the maximum dpm concentration that MSHA expects once the rules are fully implemented and represents an even smaller fraction of average dpm concentrations many underground miners currently experience. It is unclear whether the same incremental effects on acute respiratory symptoms and premature mortality would apply at the much higher exposure levels found in underground mines. Additionally, as MSHA suggested in the proposed preamble and several commenters repeated, the toxicity of dpm and $PM_{2.5}$ may differ because of differences in composition. Finally, underground miners as a group may differ significantly from the populations for which the $PM_{2.5}$ exposure-response relationships were derived.

Therefore, MSHA's quantitative assessment of the rule's impact on risk is restricted to its expected impact on the third kind of risk—the risk of lung cancer. The rule will limit dpm concentrations to which miners in underground M/NM mines are exposed. The rule will limit these dpm concentrations to approximately 200 μg/m³ by limiting the measured concentration of total carbon to 160 μg/m³. Assuming that, in the absence of this rule, underground M/NM miners would be occupationally exposed to dpm for 45 years at a mean level of 808 μg/m³, the following table contains the estimated reductions in lifetime risk expected to result from full implementation of the rule, based on the various exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). These estimates were obtained by calculating the difference between the corresponding estimates of excess lung cancer mortality, at 808 μg/m³ and 200 μg/m³, shown in Table III–7. The Regulatory Impact Analysis (RIA), presented later in this preamble, contains further quantitative discussion of the benefits anticipated from this rule.

REDUCTION IN LIFETIME RISK OF LUNG CANCER MORTALITY EXPECTED AS RESULT OF REDUCING EXPOSURE LEVEL FROM 808 μG/M³ TO 200 μG/M³.

Study and statistical model	Expected reduction in lung cancer deaths per 1000 affected miners[1]
Säverin et al. (1999):	
Poisson, full cohort	68
Cox, full cohort	507
Poisson, subcohort	600
Cox, subcohort	620
Johnston et al. (1997):	
15-year lag, mine-adjusted	487
15-year lag, mine-unadjusted	317

[1] Calculated from Table III–7.

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain even after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that, due to monetary costs and technological limitations, the underground M/NM mining sector as a whole cannot feasibly reduce dpm concentrations further at this time.

4. Conclusions

MSHA has carefully considered all of the evidence and public comment submitted during these proceedings to determine whether dpm exposures, at levels observed in some mines, present miners with significant health risks. This information was evaluated in light of the legal requirements governing regulatory action under the Mine Act. Particular attention was paid to issues and questions raised by the mining community in response to the Agency's ANPRM and NPRM and during workshops on dpm held in 1995. Based on its review of the record as a whole, the agency has determined that the best available evidence warrants the following conclusions:

1. Exposure to dpm can materially impair miner health or functional capacity. These material impairments include acute sensory irritations and respiratory symptoms (including allergenic responses); premature death

from cardiovascular, cardiopulmonary, or respiratory causes; and lung cancer.

2. At dpm levels currently observed in underground mines, many miners are presently at significant risk of incurring these material impairments due to their occupational exposures to dpm over a working lifetime.

3. By reducing dpm concentrations in underground mines, the rule will substantially reduce the risks of material impairment faced by underground miners exposed to dpm at current levels.

In its response to MSHA's proposals, the NMA endorsed these conclusions to a certain extent, as follows:

> The members of NMA have come to recognize that it would be prudent to limit miners' exposure to the constituents of diesel exhaust in the underground environment. [NMA]

A number of commenters, however, urged MSHA to defer rulemaking for either the coal or M/NM sector, or both, until results were available from the NCI/NIOSH study currently underway. For example, referring to the M/NM proposal, one commenter stated:

> Vulcan agrees with MSHA that underground miner dpm exposure needs to be addressed by mine operators. Vulcan agrees with MSHA that a permissible exposure level (PEL) should be established, but disagrees that adequate information is currently available to set a PEL. [Vulcan Materials]

MSHA believes that expeditious rulemaking, in both underground mining sectors, is necessary for the following reasons:

(1) The NCI/NIOSH study currently in progress will eventually provide additional information on lung cancer mortality. Non-cancer health effects, such as sensory irritations, respiratory symptoms, or premature death from cardiovascular, cardiopulmonary, or respiratory causes will not be addressed. MSHA believes that these non-cancer effects constitute material impairments.

(2) NIOSH itself has recommended that, ''* * * given the length of time to complete this study and the current state of knowledge regarding dpm exposures and health effects in miners,'' MSHA should ''proceed with rulemaking based on the evidence currently available as presented in this FR notice.'' [NIOSH testimony by Paul Schulte, dated 5/27/99]

(3) Given the very high exposure levels measured at some underground mines, miners should not be required to serve as human guinea pigs in order to remove all doubts about the excess risks of dpm exposures in underground mines. While additional studies are in progress, miners should be protected by reducing dpm concentrations to a level more nearly commensurate with exposures in other industries.

Referring to some commenters' position that further scientific study was necessary before regulatory action could be justified, a miner at one of the dpm workshops held in 1995 said:

> * * * if I understand the Mine Act, it requires MSHA to set the rules based on the best set of available evidence, not possible evidence * * * Is it going to take us 10 more years before we kill out, or are we going to do something now * * *? (dpm Workshop; Beckley, WV, 1995).

Similar concern with the risk of waiting for additional scientific evidence was expressed by another miner, who testified:

> * * * I got the indication that the diesel studies in rats could no way be compared to humans because their lungs are not the same * * * But * * * if we don't set the limits, if you remember probably last year when these reports come out how the government used human guinea pigs for radiation, shots, and all this, and aren't we doing the same thing by using coal miners as guinea pigs to set the value? (dpm Workshop; Beckley, WV, 1995).

MSHA shares these sentiments. That is why MSHA considers it imperative to protect miners based on the weight of existing evidence, rather than to wait for the results of additional studies.

IV. Section by Section Discussion of Final Rule

This part of the preamble describes the provisions of the final rule on a section-by-section basis. As appropriate, this part references discussions in other parts of this preamble: in particular, the background discussions on measurement methods and controls in part II, and the feasibility discussions in part V.

The final rule would add nine new sections to 30 CFR Part 57 immediately following § 57.5015. It would not amend any existing sections of that part.

Many provisions of the final rule are identical to the proposed rule, but some provisions have been changed. The following table provides a quick overview of the key changes:

Section	Final rule (changes from proposal)
57.5060	When specified conditions have been met and various precautions have been taken (including use of proper PPE), miners performing certain inspection, maintenance and repair activities may be granted permission from MSHA to work in certain areas where miners normally work and travel, but where the dpm concentration limit is exceeded (not authorized in proposed rule)
57.5061	Compliance sampling must always be done with submicrometer impactor (unspecified in proposed rule)
57.5067	Engines meeting the applicable EPA requirements as per a table provided in the rule may be introduced underground after rule's effective date (under proposal, only MSHA approved engines were so allowed)

Section 57.5060 Limit on Concentration of Diesel Particulate Matter

Summary. This section of the final rule limits the concentration of dpm in underground metal and nonmetal mines. It has six subsections.

Subsection (a) provides that 18 months after the date of promulgation, dpm concentrations would be limited by restricting total carbon to 400 micrograms per cubic meter of air ($400_{TC}\mu g/m^3$). The reason why the concentration limit for dpm is expressed in terms of total carbon is explained below. A total carbon limit of $400_{TC}\mu g/m^3$ is the equivalent of about 500 micrograms per cubic meter of air of dpm ($500_{DPM}\mu g/m^3$). This limit would apply only for a period of 42 months; accordingly, it is sometimes referred to in this preamble as the ''interim'' concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (b) provides that five years after the date of promulgation, the concentration limit would be reduced, restricting total carbon to 160 micrograms per cubic meter of air ($160_{TC}\mu g/m^3$, or about $200_{DPM}\mu g/m^3$). This is sometimes referred to in this preamble as the ''final'' concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (c) provides for a special extension of up to two additional years in order for a mine to comply with the final concentration limit. This special extension is only available when the mine operator can establish that the final concentration limit cannot be met within the five years allotted due to technological constraints. The final rule establishes the information that must be contained in the application for an extension, the procedure to follow to make application, and the conditions that must be observed during the special extension period. Subsection (c) of the final rule refers to this extension as ''special'' because the final rule provides all mines in this sector with an extension of time (five years) to meet the final concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (d) provides that under certain conditions, a miner engaged in inspection, repair or maintenance activities in certain areas of a mine may work in concentrations of dpm in excess of the applicable concentration limit. Among the conditions that must be met in order for such work to be permitted is the use of proper personal protective equipment. This exception was not included in the proposed rule.

Subsection (e) provides that apart from the extraordinary circumstances where the use of such controls may be authorized under subsections (c) and (d), an operator must not utilize personal protective equipment to comply with either the interim or final concentration limit. The wording in the final rule clarifies the intent of the proposed rule, and accommodates new subsection (d).

Subsection (f) provides that an operator must not utilize administrative controls to comply with either the interim or final concentration limit. The proposed rule included the same requirement, but in the final rule this has been separated into a separate paragraph.

General Comments. Some commenters questioned MSHA's rationale for establishing concentration limits at this time. They pointed out that a large scale study by NIOSH of the health risks of dpm exposure is still on-going. Accordingly, they accused MSHA of acting prematurely, and urged delaying implementation of any limits until the health risks of dpm exposure are fully quantified. MSHA was also challenged to justify the specific numerical values chosen for the limits; several commenters suggested that these limits are based on unsubstantiated and unquantified health risks, and that therefore, the levels chosen cannot be justified. But another commenter suggested that the health risks are sufficiently documented to justify even lower limits than were contained in the proposed rule. This commenter suggested 100 µg and 50 µg for the interim and final limits, respectively. As these comments involve questions about the risk to underground metal and nonmetal miners, they are addressed in Part III of this preamble.

Some commenters also objected to the proposed concentration limits because they argued that MSHA lacked evidence that the limits were technologically feasible and economically feasible, and some objected to the use of unvalidated simulations to demonstrate the feasibility of compliance. An alternative to concentration limits was proposed wherein mine operators would ''Examine and adopt technically and economically feasible methods of preventing potentially hazardous or irritating exposure to diesel exhaust.'' But another commenter argued that the metal and nonmetal industry could feasibly meet even lower concentration limits than those proposed. And another suggested that a concentration limit alone will not adequately protect miner health because, given the freedom to choose control options, mine operators may elect to boost ventilation rather than cut emissions. As these comments concern feasibility, they are generally discussed in part V of this preamble.

A number of commenters argued that MSHA should allow operators considerable additional flexibility dealing with dpm. Some felt operators should be left complete flexibility on controls, and that a concentration limit at all was inappropriate. Others argued that the range of operator choice of controls should include personal protective equipment as well as administrative controls. These comments are discussed below in connection with this section (§ 57.5060).

Still other commenters argued that concentration limits should not be proposed, or should be much higher, because they argue MSHA lacks a method to measure dpm concentrations in underground metal and nonmetal mines that provides the accuracy, consistency, and reliability that are needed for compliance determinations. These comments are discussed in this part in connection with § 57.5061.

Another commenter expressed concern about the interplay between this rule and those already in effect for diesel gases. This commenter expressed concern that, in addition to complying with the interim and final dpm concentration limits, mine operators would be required to comply with a concentration limit that considers the additive effect of diesel particulate matter and the principal gaseous emissions from a diesel engine (carbon monoxide, carbon dioxide, nitric oxide, and nitrogen dioxide).

MSHA's risk assessment in part III does not specifically evaluate the possible additive effects of diesel particulate matter and diesel gases. Accordingly, the agency does not at this time have a basis upon which to enforce either the interim or final dpm concentration limit in combination with any other substance or substances, including diesel exhaust gases. MSHA will, of course, continue to enforce the limits applicable to diesel gases, but this enforcement will be separate from the enforcement of the dpm concentration limits under the final dpm rule. The Agency understands that Canada does consider the additive effect of diesel exhaust gases and particulate, and will notify the mining community if it decides to look into this matter further based upon additional information.

Finally, the Agency notes it received only two comments on a related matter on which it specifically sought comment—whether to establish an ''Action Level'' for dpm (63FR 58119). An ''Action Level'' is a defined contaminant level (usually one-half of the compliance limit) which, if exceeded, triggers actions that must be taken to effectuate control of the contaminant. In the preamble to the proposed rule, MSHA noted it had considered the possibility of establishing an Action Level because the dpm concentration at which exposure does not result in adverse health effects is not known at this time. If an Action Level were in place and compliance sampling results exceeded this level, certain remedial steps, or ''best practices,'' would have to be initiated by management to reduce exposures, such as limits on fuel type, idling, and engine maintenance—whatever steps MSHA determined would be feasible at the Action Level for this sector as a whole. One comment that addressed this approach recommended against establishing an Action Level because the commenter was of the view that no limits at all could be justified at this time based on available health risk data. The other commenter suggested that an Action Level should be adopted in lieu of a rule incorporating a concentration limit requiring mandatory compliance.

After further consideration, MSHA determined it does not have enough information to proceed with an Action Level at this time, although it notes that the concept of an Action Level is well recognized in occupational health protection and included in many other standards. Furthermore, MSHA determined that these ''best practices'' are technologically and economically feasible for all mines, so there is no reason to withhold their implementation until an Action Level is reached. The rationale for requiring these ''best practices'' is discussed in more detail later in this section under ''Meeting the concentration limit: operator choice of controls.''

Concentration limit expressed as an ''average eight-hour equivalent full shift airborne concentration.'' MSHA recognizes that work shifts longer than eight hours are common in the underground metal and nonmetal mining industry. It is for this reason that MSHA expressed its concentration limit as an ''average eight-hour equivalent full shift airborne concentration.'' Health-related standards for airborne contaminants are typically established on the basis of an eight-hour work shift. Standard industrial hygiene practice, and MSHA's past practice for metal and nonmetal health sampling, involve adjusting the actual measured concentration of an airborne contaminant to an eight-hour equivalent concentration when work shifts are longer than eight hours. This adjusts an exposure occurring over an extended workshift (*e.g.,* 10 or 12 hours) to enable a valid comparison to an established exposure limit that is based on an 8-hr workshift.

The mathematical formula for making this adjustment is thoroughly described in the MSHA Metal and Nonmetal Health Inspection Procedures Handbook. This formula is as follows:

$$\frac{\text{Contaminant mass}}{(\text{sampling pump flow rate}) \times (480 \text{ minutes}) \times (0.001 \text{ m}^3/\text{l})}$$

When the sampling pump flow rate is expressed in units of liters per minute, the formula results in a contaminant concentration expressed in units of mg or µg per cubic meter. The factor of 480 minutes is used regardless of actual shift duration so as to adjust the actual concentration to an eight-hour equivalent concentration that can be appropriately compared to a standard limit.

MSHA specifically asked for comment on whether a more explicit definition is required in this regard (63 FR 58183). The agency did not receive any such suggestions. However, it is apparent that the term may be confusing to some. For example, one commenter observed that ''miners working overtime hours would be exposed to more dpm than miners on a normal eight-hour shift,'' and that a formula to determine eight-hour equivalency should be included. Another commenter expressed concern that the final rule would place a restriction on the number of hours or overtime hours miners could work.

MSHA disagrees with these interpretations of the rule. The only impact of the rule relative to work hours is the aforementioned determination of ''average eight-hour equivalent full shift airborne concentration'' for dpm-exposed miners whose work shifts exceed eight hours. Although the Agency has no suggestions for a more clear formulation, it will endeavor to clarify this matter further for operators in its compliance guide.

Dpm concentration limits expressed in terms of total carbon. The purpose of the interim and final concentration limits is to limit the amount of diesel particulate matter; but the limit is being expressed in terms of a restriction on the amount of total carbon. The reason for this involves the measurement method that MSHA intends to utilize to determine the concentration of dpm. As discussed in connection with § 57.5061(a), the final rule specifies that MSHA will use a sampling and analytical method developed by NIOSH (NIOSH Method 5040) to measure dpm concentrations for compliance purposes. Using NIOSH's analytical method, the amount of total carbon (TC) contained in a dpm sample from any underground metal and nonmetal mine can be determined; the method does not directly yield the amount of dpm in a particular sample. However, as explained in detail in Part II of this preamble, TC represents approximately 80–85 percent of the total mass of dpm emitted in the exhaust of a diesel engine. The remaining 15–20 percent consists of sulfates and the various elements bound up with the organic carbon to form the adsorbed hydrocarbons. Using the lower boundary of this range, limiting the concentration of total carbon to 400 micrograms per cubic meter (400_{TC} µg/m^3) effectively limits the concentration of whole diesel particulate to about 500 $_{DPM}$ µg/m^3. Similarly, limiting the concentration of total carbon to 160_{TC} µg/m^3 effectively limits the concentration of whole diesel particulate to about 200_{DPM} µg/m^3. Expressing the concentration limit in terms of total carbon enables miners, mine operators and inspectors to directly compare a measurement result with the applicable limit.

Where the concentration limit applies. The concentration limits—both interim and final—would apply *only* in areas where miners normally work or travel. The purpose of this restriction is to ensure that mine operators do not have to monitor and control dpm concentrations in areas where miners do not normally work or travel—*e.g.,* abandoned areas of a mine where, for example, the roof may not be monitored for safety or ventilation may not be provided. At the same time, it should be noted that the interim and final concentration limits apply in any and all areas of a mine where miners *normally* work or travel—not just where miners might be present at any particular time.

MSHA generally intends for inspectors to determine which portions of a given mine are subject to the concentration limit based on whether normal work or travel activities routinely do, or could occur there, whether areas are designated as ''abandoned'' on mine maps, whether areas are made ''off limits'' through the use of signs or barricades, etc.

MSHA has, however, in the final rule (§ 57.5060(d)), explicitly authorized the Secretary, upon making certain findings and ensuring that certain protections are in place for miners, to allow miners engaged in certain inspection, maintenance or repair activities to work in areas of a mine which are considered areas in which miners normally work or travel but that exceed the concentration limits. These situations are discussed immediately below.

Exception: Specific mining activities which may be conducted in areas which exceed the concentration limit. Although feasible engineering and work practice controls were found to exist for most underground metal and nonmetal mining situations, MSHA did determine that certain maintenance and repair activities might have to be performed in areas where feasible engineering and work practice controls may not be capable of maintaining the dpm concentration at or below the applicable concentration limit. Therefore, in the final rule, § 57.5060(d) under certain conditions permits miners to work in areas where the concentration limit is exceeded, and only when specified precautions have been implemented to protect affected miners. As explained in detail below, principal among these precautions is the use by all affected miners, of proper personal protective equipment (*i.e.*, respiratory protection devices) within the context of a comprehensive respiratory protection program.

More specifically, § 57.5060(d)(1) permits, with the pre-approval of the Secretary, employees engaged in inspection, maintenance, or repair activities to work in concentrations of dpm exceeding the applicable limit if they are protected by appropriate respiratory protective equipment. This provision applies only to miners performing the identified activities, and only when certain mandatory protections are implemented. If respiratory protective equipment is used, the final rule requires implementation of a respiratory protection program consistent with the minimum requirements established in § 56/57.5005 (a) and (b), which address such factors as selection, maintenance, training, fitting, supervision, and cleaning. These requirements include by reference, the elements of a minimally acceptable respiratory protection program as delineated in the American National Standard on ''Practices For Respiratory Protection'' (ANSI Z88.2–1969).

The rule specifies that areas for which a request to allow employees to work in areas that exceed the concentration limit are limited to—areas where miners work or travel infrequently or for brief periods of time for equipment or mine inspection; areas where miners otherwise work exclusively inside of enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; and in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are also used for access into, or egress from an underground mine.

The standard applies in areas of the mine where miners ''normally'' work or travel. Normally does not equate to frequency, but rather to the nature of the area. Areas where miners work or travel infrequently are treated by the rule no differently than areas where miners work or travel frequently. For example, if a remote pump is checked on a weekly basis, the area in which that pump is located would be considered an area where miners normally work or travel, even though the area is visited infrequently.

Approval to allow miners to work in areas that exceed the concentration limit would be contingent on the Secretary determining that engineering controls are not feasible, and that adequate safeguards would be employed by the mine operator to prevent hazardous exposure to dpm. The final rule requires mine operators to submit a plan to the Secretary to justify the infeasibility of engineering controls, and to explain the circumstances of the job, the location where work will be performed, resulting dpm exposures, and controls to be used, including, but not necessarily limited to personal protective equipment.

In order for MSHA to determine the reasonableness of a mine operator's request for approval under 5060(d), certain details regarding the work need to be provided. These include the types of inspection, maintenance or repair activities planned, the locations of such activities, the dpm concentrations at these locations, the reasons why engineering controls would not be feasible, the anticipated frequency of these activities, the anticipated number of miners involved, and the safeguards the mine operator will employ to minimize dpm exposures. These factors will tend to change over time as the mine develops, as new equipment or procedures are introduced, as ventilation system parameters change, etc. MSHA believes that an annual updating of these factors is necessary to insure that approval is granted only where justified by the actual circumstances.

In essence, this exemption allows the use of personal protective equipment as a substitute for engineering controls under a limited number of circumstances. Many commenters suggested MSHA permit the use of PPE much more broadly in lieu of engineering controls; MSHA's review and reaction to these comments is discussed below.

One commenter, a mine operator, agreed with MSHA's approach that stresses engineering controls first and foremost. The commenter stated that, ''engineering controls, as close to the source of the diesel emission as possible, must be the first line of DPM exposure control.'' The commenter further suggested that, ''The proposed rule should allow personal protective equipment to be used as a last resort. The proposed rule should require written documentation explaining how the mine determined the appropriate exposure controls. This written documentation should clearly explain why engineering controls, commonly used in industry to control diesel emissions, are not technically or economically feasible.''

Although MSHA has embraced the commenter's basic idea of requiring written documentation when personal protective equipment is proposed as an alternative to engineering controls, the final rule includes other necessary safeguards to insure that this option is used only when absolutely necessary and that appropriate steps are taken to insure that respirator wearers are adequately protected. The final rule requires such plans to identify, at a minimum, the types of anticipated inspection, maintenance, and repair activities that must be performed for which there are no feasible engineering controls sufficient to comply with the concentration limit, the locations where such activities could take place, the concentration of dpm in these locations, the reasons why engineering controls are not feasible, the anticipated frequency of such activities, the anticipated duration of such activities, the anticipated number of miners involved in such activities, and the safeguards that will be employed to limit miner exposure to dpm, including, but not limited to the use of respiratory protective equipment.

The final rule requires mine operators to utilize all feasible engineering and work practice controls, however, the exception under subsection (d) permits such controls to be supplemented with respirator use in certain limited situations where reliance solely on feasible engineering and work practice controls would be inadequate to control exposures below the applicable concentration limit. The proposal's prohibition on administrative controls under any and all circumstances is retained in the final rule in subsection (e).

Examples of situations where MSHA believes engineering controls might not be feasible include cleaning up a roof fall in an exhaust air course, replacing a conveyor belt idler in a conveyor tunnel that is carrying exhaust air, or shaft inspection in an exhaust air shaft. The provisions of subsection (d) are not intended to suggest that MSHA believes these and similar activities should automatically be considered exempt from the requirement to utilize engineering and work practice controls to comply with the concentration limit. Rather, MSHA recognizes that under certain site specific circumstances, feasible engineering and work practice controls alone may not be capable of achieving compliance with the concentration limit. Therefore, MSHA agrees that respirator use should be permitted if the applications are sufficiently justified and approved in advance.

MSHA does not intend that plans submitted for advance approval need to identify specifically and individually every activity for which advance approval is sought. The intent is that plans must identify, in a generic sense, the types of activities and related circumstances as can reasonably be anticipated, sufficient to enable the Secretary to determine whether advance approval is warranted.

Meeting the concentration limit: operator choice of engineering controls. The final rule contemplates that an operator of an underground metal or nonmetal mine have considerable discretion over the controls utilized to bring down dpm concentrations to the interim and final concentration limits. For example, an operator could filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, use traffic controls, or use a variety of other readily available controls. A combination of several control measures, including both engineering controls and work practices, may be necessary, depending on site specific conditions.

MSHA intends for engineering controls to refer to controls that remove the dpm hazard by applying such methods as substitution, isolation, enclosure, and ventilation. MSHA intends for work practice controls to refer to specified changes in the way work tasks are performed that reduce or eliminate a hazard, such as traffic controls (speed limits, one-way travel, etc.), prohibiting unnecessary engine idling, or designating areas that are off-limits for diesel equipment operations. As discussed below, the final rule does not permit utilization of administrative controls as a means of complying with the dpm concentration limit. In the context of this rule, MSHA intends for administrative controls to refer to controls that limit a miner's exposure to dpm by distributing the exposure among other miners through various work scheduling and worker rotation practices.

Some commenters asserted that implementation of certain dpm control measures may create other, unrelated health or safety problems. One example given concerned the complications and safety trade-offs of increasing ventilation to control dpm concentrations. The increased ventilation would tend to dry out roadways, causing increased problems with respirable silica bearing dust exposure. This problem, would, in turn, require application of greater amounts of water on the roadways for dust control, which, in turn, would create traction problems for vehicles. Increased ventilation might also accelerate the drying out of certain roof strata, creating roof control problems. Another commenter worried that enclosed cabs can reduce an equipment operator's field-of-view, and dirt or glare on windows can obscure visibility, possibly creating safety problems.

MSHA acknowledges that dpm control measures need to be selected and implemented carefully, both to insure they achieve the desired effect on dpm concentrations, and to minimize or avoid undesirable effects on other aspects of the mine's health and safety environment. In most cases, implementation of a given control will not have any undesirable effects. In other isolated cases, the undesirable effects of a given control can most likely be negated through additional work practice controls or other measures. For example, the increased application of water on roadways to reduce dust control problems caused by higher ventilation rates may require that equipment be operated at slower speeds. Roof control problems resulting from the accelerated drying out of strata may require a reassessment of the mine's roof control plan, such as its roof bolting practices. Vehicle operator field-of-view and visibility problems could be addressed by instituting new traffic controls, requiring slower speeds, and use of window washers. For these reasons, MSHA does not wish to explicitly deny operators a particular type of engineering control because in some circumstances an adjustment to customary mining practices may have to be made.

Because information on available controls has been described in other parts of this preamble (part II and part V), further discussion is not provided here. Mine operators are also directed to the MSHA ''estimator'' model to help them determine which control or combination of controls would be best able to produce the reduction in dpm concentrations necessary to comply with the appropriate concentration limit. The ''estimator'' mathematically calculates the effect of any combination of engineering and ventilation controls on existing dpm concentrations in a given production area of a mine. This model is in the form of a spreadsheet template permitting instant display of outcomes as inputs are altered. The model and some examples illustrating its potential utility are described in Part V of this preamble.

Several commenters expressed disappointment that the proposal did not embrace what they sometimes referred to as ''MSHA's toolbox approach.'' In some cases, this appears to mean the commenters want operators to have the flexibility to use personal protective equipment and administrative controls, as well as engineering and work practice controls, to meet the required concentration limits. In other cases, however, it appears the commenters meant that MSHA should allow them the discretion not only to choose the controls they wish, but to choose whether or not to use controls at all. In other words, to these commenters, the ''toolbox approach'' means voluntary implementation of controls without enforcement of a concentration limit.

By way of background, in 1997, MSHA published a pocket-sized handbook called, ''Practical Ways to Reduce Exposure to Diesel Exhaust in Mining—-A Toolbox.'' This handbook describes and discusses a variety of emission control equipment, methods, and strategies, both in terms of laboratory emissions testing and in-mine experience. The rationale for a ''toolbox approach'' to controlling diesel emissions is explained in the handbook. ''A toolbox offers a choice of tools, each with a specific purpose. One tool after another may be used to find a solution to a problem, or several tools may be tried at the same time.* * * Reducing exposure to diesel emissions lends itself to a toolbox approach because no single method or approach to reducing exposure may be suitable for every situation.'' Since its publication, this handbook, which is referred to simply as the ''MSHA toolbox'' or ''toolbox'' has become quite well known and is widely used in the mining industry.

Commenters who urged MSHA to adopt a ''toolbox approach'' in its rulemaking praised the approach taken in MSHA's publication, and indicated that they had successfully implemented some of the control strategies discussed. They urged MSHA to maintain this flexibility. One commenter suggested that, ''The toolbox is just simply best practices, if you would. If we're doing this, this, and this, then we're doing all we can without enforcement.* * * That's what a toolbox is. A toolbox is not an enforcement tool.''

The MSHA Toolbox was issued before this rulemaking, in which, after considering all the evidence, MSHA has concluded that miners are at significant risk of material impairment at the concentration levels still found in underground metal and nonmetal mines. When MSHA makes such a finding, it is required to act to protect miners to the extent feasible. MSHA has concluded that requiring operators to comply with a concentration limit using engineering controls is necessary to protect miners and feasible for the mining industry as a whole, while still providing underground metal and nonmetal mine operators with maximum flexibility to address this problem. Thus, MSHA believes the final rule does incorporate the ''toolbox approach'' by allowing mine operators to choose, from among numerous alternatives, the mix of control measures most suitable for the site specific conditions at a given mine—provided that the controls bring exposures down to the required limit.

MSHA has determined that certain types of controls discussed in the toolbox—PPE and administrative controls—are not considered acceptable ways to meet a concentration limit. PPE does not reduce the concentrations of a contaminant in the environment, though such equipment does offer limited protection to miners who must work in areas where the applicable concentration limit cannot be achieved using feasible engineering or work practice controls. The rule permits PPE to be used to protect miners in those limited situations where it permits work to take place despite dpm concentrations in excess of the concentration limit (special extension of time to meet final concentration limit under paragraph (c), discussed below, and special permission to perform inspection, maintenance and repair activities in areas that exceed the concentration limit under paragraph (d), discussed above.) Administrative controls (*e.g.,* limiting the hours worked by a particular miner in a high concentration area) simply spread risk among miners. The reasons for MSHA's position in this regard are discussed in detail below.

MSHA has also determined that certain other types of dpm control measures discussed in the toolbox must be implemented at all underground metal and nonmetal mines that use diesel equipment, regardless of the dpm concentration level, to minimize miner risks. These ''best practices'' include such requirements as low sulfur content diesel fuel, limits on unnecessary idling of diesel engines, maintenance standards, and a requirement for newly introduced engines to be MSHA approved or meet certain EPA standards. MSHA's rationale for why it is mandating such ''best practices'' is summarized below. Further detail is provided in the preamble to the proposal (63FR 58119), and in the sections of this Part which discuss the individual practices themselves (diesel fuel (§ 57.5065(a)), maintenance (§ 57.5066), and engines that are MSHA approved or meet EPA standards (§ 57.5067).

In the proposal, MSHA explained that it had considered implementing an ''Action Level'' for dpm, possibly at a level one-half of the final concentration limit, or 80_{TC} µg/m^3 because the dpm concentration at which exposure does not result in adverse health effects is not known at this time. Under this approach, when dpm levels exceeded the Action Level, implementation of certain ''best practice'' controls, such as limits on fuel types, idling, and engine maintenance would have been required. However, this approach was not incorporated into the proposal, nor has it been incorporated into the final rule. MSHA determined it does not have enough information to proceed with an Action Level at this time, although it notes that the concept of an Action Level is well recognized in occupational health protection and included in many other standards. Instead, MSHA determined that these ''best practices'' would be required for all mines at all times.

MSHA followed this course for several reasons, including: (1) Sampling by both mine operators and MSHA would have been much more frequent under an approach incorporating an Action Level; (2) tracking equipment maintenance requirements would have been much more complicated, as diesel equipment could move from an area of the mine where the dpm concentration was less that the Action Level, to another area where the Action Level had been exceeded; (3) these ''best practices'' are already in place, and have proven to be workable and practical in coal mines; (4) given the history of lung problems associated with the mining industry, and considering that these practices were determined to be economically and technologically feasible for the industry as a whole, a more protective course seemed prudent; and (5) a number of the work practices appear to have significant benefits, such as improving the efficiency of maintenance operations.

One commenter suggested that other ''best practices'' related to mine ventilation should be mandated in the final rule. This commenter recommended requiring mine operators to provide details on the design and operating parameters of auxiliary ventilation systems, that they be required to utilize an appropriate air measurement and recording program, and that they properly attend to uncontrolled recirculations and leakages. MSHA believes that existing ventilation regulations adequately address these concerns, and that mine operators, in utilizing a ''toolbox approach'' to implement dpm control measures, have the option of incorporating ventilation system improvements if they are judged to be feasible, practical, desirable, and appropriate to the site specific conditions at a given mine. Thus, MSHA did not include a mandate to use such ventilation ''best practices'' in the final rule.

Concentration limit: time to meet. As noted, the dpm limitation requires metal and nonmetal mines to reduce total carbon concentrations in areas where miners normally work or travel to 160 micrograms per cubic meter of air (equating to about 200 micrograms of dpm per cubic meter of air.) § 57.5060 provides for an extension of time for underground metal and nonmetal mines to meet the concentration limit. Mines do not have to meet any limit for the first 18 months after the final rule is promulgated. Instead, this period will be used to provide compliance assistance to the metal and nonmetal mining community to ensure it understands how to measure and control diesel particulate matter concentrations in individual operations. Moreover, the rule provides all mines in this sector an extension of three and a half additional years to meet the final concentration limit established by § 57.5060(b). During this extension, however, all mines will have to bring total carbon concentrations down to 400 micrograms per cubic meter, equating to a limit of 500 micrograms per cubic meter in dpm.

Comments on the implementation schedule for the concentration limits focused on the technological and economic feasibility of complying within the time frames established. Commenters expressed the view that the rule is technology forcing, and that the mining sector of the economy is too small to justify the expense by manufacturers (mining equipment, diesel engines, aftertreatment devices, etc.) to develop the necessary products to enable mine operators to fully comply by the deadlines contained in the final rule.

MSHA provided these phase-in times for meeting the interim and final concentration limits after carefully reviewing comments on the economic and technological feasibility of requiring all mines in this sector to meet the applicable limits using available controls. This review is presented in Part V of this preamble. MSHA has studied a number of metal and nonmetal mines in which it believed dpm might be particularly difficult to control. The Agency has concluded that in combination with the ''best practices'' required under other provisions of the final rule (§§ 57.5065, 57.5066 and 57.5067), engineering and work practice controls are available that can bring dpm concentrations in all underground metal and nonmetal mines down to or below 400_{TC} µg/m³ within 18 months. Moreover, the Agency has concluded that controls are available to bring dpm concentrations in all underground metal and nonmetal mines down to or below 160_{TC} µg/m³ within 5 years. The Agency has concluded that it is not feasible to require this sector, as a whole, to lower dpm concentrations further, or to implement the required controls more swiftly.

Despite its conclusions on the feasibility of these timeframes for the underground metal and nonmetal industry as a whole, MSHA has included a provision in the final rule to allow an additional two years for mines experiencing difficulty in complying due to technological problems. A discussion of this special extension follows.

Special extension. Pursuant to § 5060(c), an operator may request more than five years to comply with the final concentration limit only in the case of technological problems. In light of the risks to miners posed by dpm, however, the Agency has concluded that the economic constraints of a particular operator are not an adequate basis for a further extension of time for that operator, and the final rule does not provide for any extension grounded in economic concerns. Moreover, if it is technologically feasible for an operator to reduce dpm concentrations to the final limit within the established five year compliance period, no extension would be permitted even if a more cost effective solution might be available in the future for that operator.

However, the Agency has determined that if an operator can actually demonstrate that there is no technological solution that could reduce the concentration of dpm to 160_{TC} µg/m³ within five years, a special extension would be warranted.

Extension application. § 57.5060(c)(1) provides that if an operator of an underground metal or nonmetal mine can demonstrate that there is no combination of controls that can, due to technological constraints, be implemented within five years to reduce the concentration of dpm to the limit, MSHA may approve an application for an extension of time to comply.

Such a special extension is available only once, and is limited to 2 years. In this regard, MSHA does not anticipate that an extension will automatically last 2 years, and the agency will closely scrutinize applications to determine how much time is really required to implement a technological solution. To obtain a special extension, an operator must show that diesel powered equipment was used in the mine prior to publication of the rule, demonstrate that there is no off-the-shelf technology available to reduce dpm to the limit specified in § 57.5060, and establish the lowest concentration of dpm attainable. In this regard, the Agency reiterates that cost is not a consideration; thus, simply because a more cost-effective solution will become available in the future is not an acceptable reason for an extension.

One commenter questioned whether it is reasonable to limit mine operators to one special extension when the necessary technology to comply with the concentration limits does not exist today. This commenter suggests a five to ten year compliance schedule is more realistic to allow time to develop the technology and to phase in the replacement of equipment. MSHA believes that very few, if any, underground metal and nonmetal mining operations should need a special extension, based on the feasibility information discussed in part V of this preamble. Despite this information, the final rule makes specific provision for a special extension for the very few mines that might experience technical problems that cannot be foreseen at this time. In the unlikely event any mines experience such technical problems, MSHA believes that a two year extension, in addition to the five years granted in the final rule for all mines, will be sufficient for them to achieve compliance.

The final rule further requires that to establish the lowest achievable concentration, the operator must provide sampling data obtained using NIOSH Method 5040 (the method MSHA will use when determining concentrations for compliance purposes; this sampling method is further discussed in connection with § 57.5061(a)).

The application would also require the mine operator to specify the actions that are to be taken to ''maintain the lowest concentration of diesel particulate achievable'' (such as ensuring strict adherence to an established control plan) and to minimize miner exposure to dpm (*e.g.,* such as providing and requiring the use of suitable respirators at mines or areas of mines under extension). MSHA's intent is to ensure that personal protective equipment is permitted only as a last and temporary resort to bridge the gap between what can be accomplished with engineering and work practice controls and the concentration limit. It is not the Agency's intent that personal protective equipment be permitted during the extension period as a substitute for engineering and work practice controls that can be implemented immediately.

Filing, posting and approval of extension application. The final rule requires that an application for an extension be filed no later than 6 months (180 days) in advance of the date of the final concentration limit (160_{TC} µg/m³), and a copy of the extension be posted at the mine site for the duration of the extension period. In addition, a copy of the application would also have to be provided to the designated representative of the miners.

The application must be approved by MSHA before it becomes effective. While pre-approval of plans is not the norm in this sector, an exception to the final concentration limit cannot be provided without careful scrutiny. Moreover in some cases, the examination of the application may enable MSHA to point out to the operator the availability of solutions not considered to date. MSHA notes that it received no comments on this requirement for pre-approval.

While the final rule is not explicit on the point, it is MSHA's intent (as set forth in the preamble to the proposed rule, 63 FR 58184) that primary responsibility for processing of the operator's application for an extension will rest with MSHA's District Managers. This ensures familiarity with the mine conditions, and provides an opportunity to consult with miners as well. At the same time, MSHA recognizes that District Managers may not have the expertise required to keep fully abreast of the latest technologies and of solutions being used in similar mines elsewhere in the country. Accordingly, and again consistent with the preamble to the proposed rule, the Agency intends to establish, within its Technical Support Directorate a special panel to consult on these issues and to provide assistance and guidance to its District Managers. In the preamble to the proposed rule (63 FR 58184) the Agency requested comment on whether further specifics regarding this approach to approving applications for special extensions should be incorporated into the final rule, however, no such comments were received.

The rule specifies that a mine operator shall comply with the terms of any approved application for a special extension, and provides that a copy of the approved application be posted at the mine site for the duration of the application.

Personal protective equipment and administrative controls. In the proposal, mine operators were expressly forbidden to use personal protective equipment (*e.g.,* respirators) or administrative controls (*e.g.,* job rotation) to comply with either the interim or final dpm concentration limit. MSHA's rationale for these provisions was that limiting individual miner exposure through the use of respirators or job rotation would not reduce the airborne concentrations of dpm in the mine. Rather, in the proposal, MSHA chose to incorporate the widely accepted industrial hygiene concept of ''hierarchy of controls'' which places the highest priority on eliminating or minimizing hazards at the source through implementation of engineering and work practice controls.

The ''hierarchy of controls'' paradigm regards administrative controls and the use of personal protective equipment to be inherently inferior methods of controlling contaminant exposures in the workplace. Support for this position is virtually universal in the field of industrial hygiene. *Patty's Industrial Hygiene and Toxicology* (Vol I, General Principles) states, ''Evidence of the importance of engineering control of the work environment among the various alternative solutions to industrial hygiene problems is found in every current industrial hygiene text: all list the possible solutions in priority fashion as engineering controls, administrative controls, and as a last resort, use of personal protective equipment.'' The National Safety Council's *Fundamentals of Industrial Hygiene* states, ''Engineering controls should be used as the first line of defense against workplace hazards whenever feasible. Such built-in protection, inherent in the design of a process, is preferable to a method that depends on continual human implementation or intervention.''

This text goes on to describe administrative controls as, ''not as satisfactory as engineering controls,'' and notes that such controls ''have been criticized by some as a means of spreading exposures instead of reducing or eliminating the exposure.'' This latter statement is particularly relevant to dpm, and to carcinogens in general, because administrative controls, such as job rotation, result in placing more workers at risk. Among the reasons *Patty's Industrial Hygiene and Toxicology* recommends that a given chemical should not be controlled by administrative reduction of exposure time is that it may be a carcinogen.

In the proposed rule, MSHA prohibited administrative controls as an acceptable dpm control method because they fail to eliminate the exposure hazard and result in placing more miners at risk. Since MSHA determined that compliance with the interim and final dpm concentration limits was feasible for the underground metal and nonmetal mining industry as a whole using exclusively engineering and work practice controls, the Agency logically chose to prohibit personal protective equipment as a compliance option as well.

In the Preamble to the proposed rule, MSHA stated that it intended that the normal meaning be given to the terms personal protective equipment and administrative controls, and asked for comment as to whether more specificity would be useful. MSHA noted that it assumed the mining community understands, for example, that an environmentally controlled cab for a piece of equipment is an engineering control and not a piece of personal protective equipment.

Numerous commenters took issue with the proposal's prohibition on administrative controls and personal protective equipment as compliance options. They noted that both administrative controls and personal protective equipment are accepted industrial hygiene exposure control methods that should be permitted under the rule. Most commenters agreed that engineering controls would be the preferred option for reducing an occupational health exposure, but that engineering controls sufficient to reduce dpm concentrations below the applicable concentration limit might not be the most cost-effective approach, and more importantly, that engineering controls may not be feasible in all situations. They argued that prohibiting administrative controls and personal protective equipment would, as a result, place mine operators in an impossible compliance dilemma.

It is significant to note that the commenters did not disagree with MSHA's fundamental reasoning for using the ''hierarchy of controls'' concept as the basis for prohibiting administrative controls and personal protective equipment. Likewise, there was no direct disagreement with MSHA's endorsement of the widely accepted industrial hygiene principle that administrative controls are inappropriate in the case of exposure to carcinogens because job rotation will expose more miners to the hazard.

Rather, commenters argued that administrative controls and personal protective equipment should be permitted simply to give mine operators greater flexibility in dealing cost effectively with a workplace contaminant, and because certain situations exist where no feasible engineering control would be available to enable compliance with the concentration limit.

Regarding the question of affording greater operator flexibility, a typical commenter observed that, ''If MSHA's goal is protection of miners, in the context of a viable and profitable industry, it should encourage flexible control approaches to the control of dpm exposure, and not penalize operators for using all effective means available—including administrative controls and PPE.'' Another commenter asked MSHA to, ''reconsider the use of personal protective equipment as a cost effective solution when appropriate.'' MSHA responds to these comments by noting that it did incorporate compliance flexibility into the requirements for this rule. As noted earlier under the discussion on ''Meeting the concentration limit: operator choice of engineering controls,'' mine operators do have considerable freedom to choose the control, or combination of controls necessary to achieve and maintain compliance with the applicable concentration limit in their mines. However, this freedom is not total, particularly with respect to administrative controls and personal protective equipment. Operator flexibility, convenience, or cost effectiveness are not acceptable bases for permitting dpm control methods that are widely acknowledged to be inherently inferior to engineering and work practice controls.

Regarding the question of the feasibility of controls, several commenters argued that there are situations where engineering controls are either economically infeasible, technologically infeasible, or both. Some typical examples of these comments include a mining company that objected to, ''the Agency's continued downgrading of administrative controls and the use of personal protective equipment in favor of considerably more expensive, presently infeasible, engineering controls.'' Another commenter complained that, ''the standard must be attained with engineering controls alone,'' and that, ''personal protective equipment and other means cannot be used even where compliance with engineering controls is not feasible.'' Still another commenter observed that, ''The proposal is not [economically or technologically] feasible for metal mines * * * which are designed specifically for use of diesel equipment. In these mining scenarios, use of electric equipment is not cost-effective, and elimination of diesel equipment would eliminate the process for which the mines were designed.''

The question of economic feasibility will be discussed separately from the question of technological feasibility. MSHA acknowledges that administrative controls or the use of personal protective equipment may be less costly than engineering or work practice controls in certain situations. However, a difference in cost between two approaches is simply that—a difference in cost. MSHA does not regard a cost difference per se as prima facia proof that an approach is economically infeasible simply because a less expensive alternative exists.

Commenters also questioned MSHA's compliance cost estimates, asserting that compliance costs will actually be much higher. MSHA's compliance cost estimates are discussed in the REA. However, in answer to this comment, MSHA determined that exclusive reliance on engineering and work practice controls are economically feasible for the underground metal and nonmetal mining industry as a whole (with the exception of the situations addressed in § 57.5050(d)). Thus, MSHA rejects the argument that administrative controls and the use of personal protective equipment should be permitted based on consideration for economic feasibility.

Regarding the question of the technological feasibility of engineering and work practice controls, the high number of comments addressing this issue suggested that the underground metal and nonmetal mining industry considered it to be of vital importance. Despite their number, however, none of these comments identified specific equipment or mining situations where exclusive reliance on engineering or work practice controls to achieve and maintain compliance with the applicable dpm concentration limit would be impossible due to technological infeasibility.

In the preamble to the proposed rule, MSHA provided extensive information on how mine operators might use a computer program known as the ''Estimator'' to conduct assessments of controls that might be necessary to deal with problems in individual mines, and requested comments based on such specific information. The comments that were received were critical of the ''Estimator'' because it produces an estimate of average dpm concentration in a given area, not the specific concentration that might exist at a specified sampling location; and because its accuracy depends on the quality of the input data, which is suspect due to the perceived inherent inaccuracy of the dpm sampling methods which must be used to obtain the input data.

Regarding the first criticism, MSHA notes that the average dpm concentration in a given area, which is the output obtained from the ''Estimator,'' is a more accurate indicator of the potential dpm hazard than a specific concentration that might exist at a specified sampling location. Since compliance is based on a shift weighted average concentration produced by diesel equipment that is normally in constant motion throughout the shift, the average dpm concentration in a given area is a better predictor of compliance or noncompliance than a determination of specific concentration that might exist at a specified sampling location. It might also be advisable to consider relocating a miner who, by virtue of their specific work location, is thought to be at risk of being exposed to a concentration of dpm that is greater than the average for that area (for example, move the miner from being in the direct line of the exhaust stream). Finally, MSHA notes that the ''Estimator'' is just that, a means of *estimating* dpm concentration. It was never claimed that this model could predict dpm concentrations with pinpoint accuracy. However, in verification testing of the model, MSHA has observed good agreement between predicted and measured dpm concentrations (as discussed in part II, section 3 of this preamble).

Regarding the second criticism, MSHA notes that users have the option of inputting actual dpm data, or estimating such values. If users desire to input in-mine measurements of dpm concentrations, MSHA is confident that dpm sampling and analysis using the NIOSH Method 5040, as described elsewhere in this preamble, will accurately represent actual dpm concentrations.

Nonetheless, MSHA reevaluated the feasibility of engineering and work practice controls as the exclusive means of complying with the applicable dpm concentration limits. This reevaluation identified potential compliance problems related to performing certain inspection, repair, and maintenance work if only engineering and work practice controls were permitted as means of achieving compliance. Therefore, the Agency has adjusted the final rule to allow such work, when sufficiently justified and preapproved by the Secretary, to be performed using personal protective equipment as a supplement to engineering and work practice controls. But apart from these very limited situations, the Agency has concluded that the use of engineering controls to meet the concentration limit is both economically and technologically feasible for the underground mining industry as a whole, and in light of the health risks to miners, and the superiority of engineering controls, the Agency has concluded that they (and not PPE or administrative controls) must be utilized to meet the concentration limit.

57.5061 Compliance Determinations

Summary. This section of the final rule establishes the criteria for determining compliance with the concentration limits. It has three subsections.

Subsection (a) provides for compliance sampling to be performed by MSHA directly, requires that such compliance sampling be done in accordance with the other requirements of this section, and further provides that a single such sample will be adequate to establish a violation. This is consistent with the proposed rule.

Subsection (b) provides that MSHA will collect dpm samples using a respirable dust sampler equipped with a submicrometer impactor, and analyze such samples for the amount of total carbon (TC) using NIOSH Method 5040 (or by using any method of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of dpm in underground metal and nonmetal mines). This is like the proposed rule except that the final rule explicitly requires a submicrometer impactor to be used in collecting all dpm compliance samples in underground metal and nonmetal mines.

Subsection (c) provides for MSHA inspectors to determine the appropriate sampling strategy for compliance determinations—personal sampling, occupational sampling, or area sampling—based on the circumstances of the particular exposure or exposures to be evaluated. This provision was not explicitly stated in the proposed rule; it was, however, stated in the preamble to the proposed rule as MSHA's intent. The final rule makes explicit MSHA's discretion in this regard.

As discussed in more detail in Part II, section 3, an important factor in the agency's decision as to which sampling practice to utilize in a particular situation, and how the sampling should be conducted (*e.g.,* how far away from a smoker or source of oil mist), is a careful review of other sources of total carbon in the environment to be sampled which could cast doubt on whether the sample result was based solely on the amount of dpm present. MSHA will provide guidance in this regard to metal and nonmetal inspectors and the mining community—based on the information noted already in Part II, section 3 of this preamble, such new information as may be developed, and continued experience in this regard—so as to avoid wasting the limited resources of the Agency and its counsel, the Mine Safety and Health Review Commission, and the underground metal and nonmetal mining community by taking compliance samples whose validity is questionable.

Numerous comments were received on this section—addressing the validity of single samples for determining compliance with an occupational health standard; the accuracy, precision, appropriateness, and practicality of using the NIOSH Method 5040 for determining dpm concentrations for enforcement purposes; and the legitimacy of using area sampling to determine compliance with a health standard. These comments, and MSHA's response to them, are discussed below.

Single sample compliance determination. Pursuant to § 57.5061(a), a single dpm sample showing that the applicable TC concentration limit has been exceeded on any individual shift will constitute a citable violation. Such a violation will also trigger further action pursuant to § 57.5062, as discussed below in connection with that section.

As is standard practice with other health compliance measurements, MSHA intends to account for normal variability in the sampling and analytical process by allowing a margin of error in the sampling result before issuing a citation. This margin of error will be based on the accuracy of the sampling and analytical method (Method 5040) used to measure the total carbon (TC) concentration in the mine environment, after correcting for potential interferences.

The variability associated with Method 5040, as expressed by the relative standard deviation (RSD), decreases with increased load on the filter. Based on a laboratory experiment, NIOSH has determined that, at a TC concentration as low as 23 µg/m^3, the variability associated with an 8-hour sample using Method 5040 and a pump flow rate of 2.0 L/min is approximately 8.5 percent. (NIOSH Manual of Analytical Methods, Method 5040, Issue 2, 1998)

MSHA will issue a citation for exceeding the applicable concentration limit only when such a citation can be issued at a confidence level of at least 95 percent. Each measurement made for purposes of compliance determination may be adjusted, if necessary, to compensate for any expected biases due to interferences such as tobacco smoke and oil mist. To account for sampling and analytical variability associated with Method 5040, the adjusted measurement will then be compared to the appropriate level established in § 57.5060 multiplied by an ''error factor.'' The error factor will be calculated so as to achieve the required 95-percent confidence that a violation has actually occurred. Based on the standard normal distribution for measurement errors, this will be 1 + 1.645 times the variability of the sampling and analytical method, as expressed by its RSD.

For example, assuming the 8.5-percent limit on the RSD established by NIOSH under laboratory conditions, the error factor would be $1 + 1.645 \times .085 = 1.14$. Suppose MSHA takes a sample during the interim period when the limit is 400_{TC} µg/m^3. Then, if expected interferences are negligible, MSHA would cite noncompliance only if the TC measurement exceeded $1.14 \times 400 = 456$ µg/m^3.

MSHA recognizes that measurement uncertainty may be higher for samples collected under mining conditions than under laboratory conditions. Therefore, MSHA intends to base the margin of error required to achieve a 95-percent confidence level for all noncompliance determinations on samples collected under field conditions. The Agency anticipates that the sampling and analytical error factor will be somewhere between 1.1 and 1.2. The Agency will, however, be governed by the actual data obtained to establish an appropriate margin of error.

Several comments were received regarding the value of the error factor for dpm sampling using NIOSH Method 5040. One commenter asserted that it will be impossible to establish a meaningful error factor, stating, ''* * * there is insufficient information available to quantify the margin of error with any level of certainty.'' Another commenter expressed confusion with respect to the various ways in which measurement uncertainty was quantified in the proposal. This commenter argued as follows:

> MSHA states on page 58116 that the 5040 Method meets NIOSH's accuracy criteria that measurements come within 25% of the concentration at least 95% of the time. This standard is for a known particle size distribution in a laboratory setting, not a mine environment. Then on page 58184 states that, ''the variability associated with the Method 5040 to be approximately 6% (one relative standard deviation)''! These do not compare! Then it states MSHA will issue a citation if the measured value was 10% over the established level! There is a contradiction somewhere in the MSHA proposal—how can MSHA take 25% NIOSH laboratory criteria and shrink it to 6% in a mining environment?

This commenter has apparently misunderstood the NIOSH Accuracy Criterion. Any unbiased method for which the RSD is known to be less than 12.75 percent meets the criterion, because any RSD less than 12.75 percent implies (assuming no measurement bias) that measurements will come within 25 percent of the true value at least 95 percent of the time. An RSD of 6 percent meets the NIOSH accuracy criterion, simply because 6 percent is less than 12.75 percent. In order to achieve 95-percent confidence that a specific measurement demonstrates noncompliance, a 6-percent RSD would, nevertheless, have to be multiplied by a 1-tailed 95-percent confidence coefficient of 1.645, yielding the 10-percent adjustment to which the commenter was referring. Therefore, these quantities are internally consistent. As stated earlier, however, MSHA intends to base its estimate of the RSD on data appropriate for field conditions in underground mining environments.

Another commenter suggested that the NIOSH Method 5040 is prone to excessive errors because it is ''complex and requires highly skilled technicians.'' The inherent capacity of the method to produce accurate results was criticized by one commenter who stated, ''* * * it is not possible to evaluate the accuracy of the method. In fact, the method has been shown to produce massive errors when side-by-side samples and control filters are analyzed. Even blank filters produce high and widely-varying readings for TC.''

Based on MSHA's extensive experience using NIOSH Method 5040 and related sampling practices, the Agency is confident that such sampling and analysis will meet or exceed MSHA's accuracy criteria. This is discussed in detail in Part II, section 3, and later in this section under ''Using NIOSH Method 5040 for compliance determinations.''

Regarding the issue of uncertainty in the sampling and analytical process for field measurements, MSHA has not yet completed its determination of an appropriate error factor for this method. As noted above, MSHA will determine an appropriate factor and apply it when enforcing the applicable compliance limit. As a matter of general practice, however, the Agency does not include error factors in occupational health rules, since the accuracy of measurement methods may change over time. When this determination is made, the error factor, along with its derivation, will be promptly communicated to the underground metal and nonmetal mining industry through the appropriate channels.

MSHA recognizes that in recent years courts have closely scrutinized Agency actions to ensure they are consistent with the requirements of the Administrative Procedures Act and, in MSHA's case, with the requirements of the Mine Safety and Health Act as well. Courts have held that certain actions, traditionally regarded as enforcement policies issued at an agency's discretion, require notice and comment and even the development of feasibility analyses. MSHA has carefully considered its obligations in light of these precedents and has concluded that the determination of a margin of error to be allowed before issuing a citation remains among the type of actions left to Agency discretion. To require the Agency to go through rulemaking each time such an error factor is established or updated based upon improved sampling or analytical methods would not serve the best interests of the mining community. Therefore, MSHA wishes to emphasize that the Agency does not regard the determination of an appropriate margin of error as a necessary part of this rulemaking, but rather as strictly a matter of enforcement policy. As noted explicitly in the rule, the Agency is retaining discretion to switch to better techniques should NIOSH certify that they provide "equal or improved accuracy for the measurement of diesel particulate matter in" underground metal and nonmetal mines. (§ 57.5061(b))

Notwithstanding its decision not to be explicit in this standard about the error factor to be used, MSHA recognizes the strong interest the underground metal and nonmetal mining community has in this issue and will ensure the matter is fully discussed with that community before the concentration limits are scheduled to go into effect. In working with this community on diesel particulate matter controls (see the history of this rulemaking in Part II of this preamble), the Agency has repeatedly demonstrated its commitment to good communications in this regard—*e.g.,* the workshops, the advance and final circulation of the diesel toolbox, the use of the Agency's web site and direct notification in appropriate cases.

As explained elsewhere in this preamble, MSHA has determined that it is feasible for underground M/NM mines to maintain dpm concentrations at or below the limits specified in § 57.5060 on each and every shift, everywhere that miners normally work or travel, with the exception of the circumstances defined in § 57.5060(d). Therefore, MSHA will protect miners' health to the maximum extent feasible by citing a violation whenever a single sample demonstrates that the limit has been exceeded on a full shift at any appropriate sampling location. This single-sample enforcement strategy is consistent with all other occupational health enforcement practices in the metal and nonmetal sector. As per long-standing policy in this sector, single out-of-compliance samples for dust (*e.g.,* silica-bearing respirable dust, total nuisance particulate, etc.), gas (*e.g.,* CO, NO_2, solvent vapors, etc.), mist (*e.g.,* cutting oil mist, spray paint, etc.), fume (*e.g.,* welding fumes, fumes from melting furnaces, etc.), and noise are all considered citable violations of the respective standards. Nevertheless, the Agency decided it would be best, in this rulemaking, to avoid any possible ambiguity in this regard by explicitly stating in the rule itself that a single sample by the Agency would provide the basis for a citation. MSHA highlighted this matter in the preamble of its proposed rule (63 FR 58117, part of Question and Answer 12).

Some commenters suggested that MSHA should collect numerous samples and base noncompliance determinations on the average value of all samples collected. These commenters argued that a single sample is not a statistically valid representation of the subject's "typical" or "normal" exposure to the contaminant. The commenters noted that a single sample, if taken on a randomly selected work day, could result in an unusually high measurement (unusual with respect to a "typical" or "normal" day). Therefore, a single sample could give rise to a noncompliance determination, even if the environment being sampled is in compliance on most shifts. These commenters contended that such a sample was "unrepresentative" of typical exposure concentrations and should not, therefore, be used as a basis for a noncompliance determination.

MSHA recognizes that the day-to-day exposure of a miner will not be constant and that on some days the sample collected over a single shift may be lower than the miner's long term average and on other days higher. However, MSHA has several compelling reasons for considering noncompliance on any individual shift to be a citable violation of the dpm concentration limit.

First, MSHA has identified significant risks associated with short-term dpm exposures (i.e., exposures over a 24-hour period). As documented in Part III of this preamble, adverse health effects associated with short-term exposures include (1) acute sensory irritations and respiratory symptoms (including allergenic responses) and (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. These risks alone would fully justify enforcing the concentration limits established in § 57.5060 on each and every shift.

Second, the concentration limits that MSHA has established are not expected to fully protect miners from these risks or from the excess risk of lung cancer associated with chronic dpm exposure. Instead, they are based on what can be feasibly achieved at this time to control dpm. By requiring compliance with the concentration limit on each shift measurement, it is MSHA's intent to protect miners to the maximum extent feasible.

Third, it is not MSHA's objective, when sampling for compliance determination purposes, to estimate average dpm concentrations for any period greater than the shift sampled or for any mine location other than the location sampled. Some commenters confused the objective of estimating cumulative exposures for purposes of risk assessment with the objective of limiting cumulative exposures for purposes of risk management. MSHA's objective is to limit exposures to protect miners against both short- and long-term effects. It is not practical for MSHA to track miners' cumulative exposures over an occupational lifetime. Therefore, as a practical matter of enforcement policy, MSHA can best protect miners from both the health risks associated with acute exposures and from the excess lung cancer risk due to chronic dpm exposure by limiting exposure on each shift wherever miners normally work or travel.

In addition, MSHA wants to emphasize that compliance limits in the metal and nonmetal sector, whether personal exposure limits or concentration limits, apply to every individual work shift. Every full-shift exposure, not just the typical, or "average" exposure, must be in compliance with the limit. Basing compliance on the typical, or "average" shift would permit frequent or sustained exposures to the contaminant at concentrations significantly higher than the compliance limit.

Although MSHA's dpm compliance limit was not derived from any corresponding ACGIH TLV©, the explanation of the proper interpretation and application of TLV©'s provided in the 1999 TLV©'s and BEI©'s booklet (American Conference of Governmental Industrial Hygienists, 1999), is relevant to this discussion. Compliance limits are specifically intended to be applied over a conventional eight-hour work day and forty-hour workweek, and not to the average exposure received during a series of consecutive work shifts or workweek. Although an allowance is made in some instances for calculating exposures on the basis of a workweek average concentration, MSHA believes such an exception should not apply to dpm because of (1) the seriousness of associated health risks (such as lung cancer and premature death from cardiovascular, cardiopulmonary, or respiratory causes) and (2) the significant risk of adverse health effects associated with short-term exposures).

The only circumstance in which a single, out-of-compliance sample would not be used as the basis for a non-compliance determination is if the sample itself were considered invalid; for example, an inspector following an improper sampling procedure. MSHA is of course concerned primarily with the health and safety of miners so the magnitude of any citation for a single out-of compliance sample will take into account the actual risk posed to miners.

MSHA's policy on health inspections requires inspectors to rigorously follow established sampling procedures to ensure the validity of samples collected. As a practical matter, MSHA will not sample for diesel particulate at the tailpipe of any diesel powered equipment in metal and nonmetal underground mines. As discussed below, MSHA's sampling strategy for determining operator compliance is established in paragraph (c) of Section 57.5062. That section specifically states that MSHA will conduct personal sampling, occupational sampling, and/or area sampling, depending upon the circumstances of the particular exposure. Because MSHA has an environmental exposure limit, MSHA is interested in obtaining the level of diesel particulate in the environment where miners normally work or travel. In the alternative, MSHA may conduct personal sampling where circumstances necessitate it. For example, if a mine operator has a miner working inside a cab and there are no other workers in that area working outside the cab, MSHA will conduct personal sampling of the cab operator and not conduct environmental sampling outside the cab in the same area of the mine. Moreover, MSHA's sampling would be conducted inside the cab rather than outside the cab. On the other hand, if there are miners working outside the enclosed cab, MSHA will sample the environment to determine the level of exposure to dpm for these miners. Also, if an operator has a miner who is operating a shuttle car, and that miner is replaced by another miner during that shift, MSHA intends to place the sampler on the shuttle car in the vicinity of the miner and not at the tailpipe. However, in no case will area sampling be performed closer than five feet to a piece of operating diesel equipment, and no tailpipe sampling will be performed to determine compliance with any concentration limit.

Among other precautions, sampling equipment is maintained and operated in strict accordance with manufacturer recommendations, and pumps are calibrated before and after samples are collected. Sampling media are blank-corrected, and all laboratory handling and analytic procedures are in accordance with AIHA laboratory certification. Sample integrity is ensured through chain-of-custody seals. If any breach in procedure occurs, all affected samples are invalidated.

In order to assure compliance with the limit, mine operators need to implement controls sufficient to ensure that the entire range of concentration values is always safely below the compliance limit. The purpose of both MSHA sampling and mine operator monitoring is to verify, on an on-going basis, that this limit is always met on every shift.

When mine operators implement effective engineering controls, the range of the concentration values becomes narrower so that once control of dpm is demonstrated, it is unlikely that the concentration limit will be exceeded.

MSHA believes the same justification for determining noncompliance based on a single sample applies to dpm as to other contaminants and noise. Therefore, MSHA has retained the provision permitting a noncompliance determination to be based on a single sample.

Using NIOSH Method 5040 for compliance determinations. Pursuant to paragraph (b) of section 5061 of the final rule, MSHA will collect dpm samples for compliance using a respirable dust sampler equipped with a submicrometer impactor, and analyze such samples for the amount of total carbon using NIOSH Method 5040 (or by using any method of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy) for the measurement of dpm in underground metal and nonmetal mines. As noted above, this is like the proposed rule except that the final rule explicitly requires that a submicrometer impactor be used in collecting all dpm compliance samples in underground metal and nonmetal mines.

Section 3 of part II of this preamble discusses alternative methods for measuring dpm concentrations, and reviews the many comments MSHA received on this topic. As noted in that discussion, methods other than NIOSH Method 5040 do not at this time provide the accuracy required to support compliance determinations at the concentration levels required to be achieved under this rule. Moreover, after a careful review of the comments and hearing record, the available technical information submitted in response to MSHA's proposed rule, and the results of studies performed by agency experts to ascertain the veracity of those comments and submissions, MSHA has determined that NIOSH method 5040 provides an accurate method of determining the total carbon content of a sample collected in any underground metal or nonmetal mine when a submicron impactor is used with the otherwise prescribed sampling procedure, and when sampling strategies avoid sampling under circumstances that could compromise the integrity of the analytical process. Accordingly, MSHA will use this method for determining TC concentrations for compliance purposes, and the rule has been specifically amended to require that such samples be taken with a submicron impactor.

As indicated in the discussion of the proposed rule (p. 58129), utilizing the submicron impactor—a device that limits particles entering the sampler to those less than 0.9 micron in size when operated at a flow rate of 1.7 LPM—does cause a reduction in the amount of dpm that can enter the sampler, since some dpm is larger than 0.9 microns. Thus, in making this amendment, MSHA recognizes that underground metal and nonmetal miners will be exposed to more dpm than will be ascertained by these compliance measurements. However, for the reasons noted in section 3 of Part II, MSHA has determined that requiring use of the impactor is the only way to ensure that certain potential interferences (sources of total carbon other than dpm) are avoided at this time. Thus, to ensure the integrity of the sampling method, the agency has determined that it must use such an impactor.

One commenter suggested that, in addition to basing concentration limit compliance determinations on samples collected pursuant to § 57.5061, samples collected and analyzed in accordance with § 7.89 should also be used as a basis for compliance determinations. Section 57.5061 is the compliance determination for the ambient concentrations in the mine. Based on the ventilation being supplied, the number of engines being used, the condition of the engines, the duty cycle of the machines, the sample will show if the mine is in compliance with the dpm standard. Section 7.89 is the laboratory test for the diesel in engine in the lab to measure the raw dpm from the engine. The § 7.89 test data is used to calculate the particulate index for a single engine. Section 7.89 data can give the mine operator an idea of the dpm being emitted from the single engine and can use this data in the ''Estimator'' to calculate an estimated dpm ambient concentration. However, as explained elsewhere in the preamble, this is an estimate to set up proper ventilation when adding other pieces of equipment or deciding on which engine to buy. The section 7.89 dpm concentration does not take into account the duty cycle of the engine. Section 7.89 tests all engines on a specific test cycle. Section 7.89 test data can only be used to estimate dpm, cannot be used to know exactly what the concentration is in a mine at any given time. The test in 57.5061 is used for that determination. MSHA believes this procedure is inappropriate for determining compliance with the concentration limits and provision for doing so has not been included in the final rule.

Sampling strategy—personal, occupational, and area sampling. Subsection (c) of section 5061 provides for MSHA inspectors to determine the appropriate sampling strategy for compliance determinations: personal sampling (attaching a sampler to an individual miner within the miner's breathing zone), area sampling (sampling at a fixed location where miners normally work or travel), or occupational sampling (locating the sampler on a piece of equipment where a miner may work).

Personal sampling is well understood in the metal and nonmetal sector because it is commonly used by MSHA to determine compliance with TLV©'s for silica-bearing respirable dust, welding fumes, and other airborne contaminants. Area sampling is less well known in this sector, but it is used by MSHA for compliance determinations in some situations, such as where miners are exposed to a contaminant having a ceiling limit. Occupational sampling is not well known in the metal and nonmetal sector because it is not currently used by MSHA for compliance determinations in this sector. However, MSHA does employ occupational sampling in the coal sector for compliance determinations.

Occupational sampling is a method which measures the exposure of an occupation to a given contaminant, as opposed to personal sampling, which measures the exposure of an individual, or area sampling, which measures the contaminant concentration at a fixed location throughout the working shift. All three methods determine contaminant concentration on a shift weighted average basis (see previous discussion of ''Concentration limit expressed as an average eight hour equivalent full shift airborne concentration'' under § 57.5060). In occupational sampling, a full-shift sample is collected from the working environment of the occupation. The sampling apparatus (sample pump, size selection devices, sample filter, etc.) remains in the environment of the work position being sampled rather than with the individual miner, even when miners change positions or alternate duties during the shift.

A very common example of where occupational sampling would be the appropriate sampling method is where the sampling objective is to determine the full shift exposure of the operator of a particular piece of equipment, but where two or more individuals alternate operating the equipment. Personal sampling would capture both the exposure received while the equipment is being operated, as well as the exposure received while performing other duties. Area sampling would be limited to measuring the contaminant concentration in the general area where the equipment is operated, but would not capture the operator's exposure. In this example, occupational sampling, with the sample apparatus remaining in the cab or operator's compartment of the equipment throughout the shift, would be the only sampling method that could satisfy the sampling objective.

As noted above, the provision for utilizing either personal sampling, area sampling, or occupational sampling was not explicitly stated in the proposed rule. It was, however, clearly stated in the preamble to the proposed rule as MSHA's intent; indeed, a specific Question and Answer was devoted to the topic. (63 FR 58117, Question and Answer 14; the topic is further explored at 63 FR 58185). Moreover, in explaining its adoption of a ''concentration limit'', MSHA noted that its intention was to emulate the approach taken with coal mine dust, where inspectors have similar discretion (63 FR 58184) in the preamble to the proposal). Accordingly, the mining community was fully informed in this regard. The topic was the subject of considerable discussion at the hearings and received considerable comment.

After evaluating the comments, and reviewing the verification data on possible interferences discussed in Part II of this preamble, MSHA determined that its proposed position in this regard should be explicitly incorporated into the final rule. At the same time, as a result of the comments, the Agency has refined its thinking as to when various types of sampling would be appropriate. The Agency will provide further information in this regard in its compliance guide, but is using this opportunity to inform the underground metal and nonmetal mining community of its current views on how it will initially approach this matter.

Numerous commenters expressed concern about the proposed rule's provision for using either personal sampling or area sampling for determining compliance with the concentration limit for dpm. They pointed out that area sampling was a departure from previous enforcement practice in metal and nonmetal mines. They also questioned whether it was appropriate to use area sampling to determine compliance when there may be no one exposed (or very limited miner exposure) to dpm at the time and in the location where the area sample is taken, as well as in situations where miners work in enclosed cabs with filtered breathing air, and in other areas where engineering controls are not feasible. One commenter also argued that sampling at a fixed location (area sampling) and then equating the results with a personal exposure was invalid.

Commenters also asserted that the superiority of personal sampling for quantifying worker exposures is a commonly accepted industrial hygiene principle. Some commenters noted that in underground mines which use mobile diesel equipment, the positions of diesel-powered vehicles with respect to intake and return air streams vary from hour to hour. Therefore, they asserted, it is virtually impossible to obtain meaningful information from stationary instruments. One commenter stated that area sampling was appropriate as a screening tool to determine whether personal sampling would be warranted, or to evaluate the effectiveness of controls, but that it should not be used to determine compliance with a mandatory limit.

In responding to these comments, MSHA would like to emphasize to the metal and nonmetal mining community, as it did in the preamble to the proposed rule, that while the concept of a concentration limit is new for this sector, it is a well established concept in the mining industry, and has been implemented for many years with respect to coal dust. Questions about whether a particular sampling method are appropriate in a given situation have been raised and resolved many times.

Moreover, the courts have upheld MSHA's use of area sampling for enforcing compliance. In a 1982 decision (*American Mining Congress* v. *Secretary of Labor,* Nos. 80–1581 and 80–2166), the U.S. Court of Appeals, Tenth Circuit ruled that the decision to employ area sampling for respirable dust compliance determinations was a reasonable exercise of MSHA's discretion and authority. The court stated:

> ''Nothing in the record supports the conclusion that either type of sampling provides a perfect measure of exposure to respirable dust. Since there is no perfect sampling method, the Secretary has discretion to adopt any sampling method that approximates exposure with reasonable accuracy. The Secretary is not required to impose an arguably superior sampling method as long as the one he imposes is reasonably calculated to prevent excessive exposure to respirable dust. On this record, the difference between area and personal sampling is not shown to be so great as to make Secretary's choice of an area sampling program irrational. Keeping in mind that our task is not to determine which method is better, we hold that the Secretary's choice of area sampling over personal sampling is not legally arbitrary and capricious.''
>
> ''We are not unmindful that area sampling may effectively require lower dust levels than might be required under a personal sampling program.''
>
> ''The fact that in theory the regulation may require operators to maintain a dust level below [the limit] in its person-by-person impact does not render the regulation arbitrary and capricious. We repeat that all proposed sampling methods are less than perfect and are designed to provide only estimates of actual exposure. Since measurement error is inherent in all sampling, the very fact that Congress authorized a sampling program indicates that it intended some error to be tolerated in enforcement of the dust standard. The method selected by the Secretary, while perhaps more burdensome in its impact on mine operators than other methods, is not beyond the scope of his discretion.''

In addition to affirming MSHA's discretion to employ area sampling on the basis that it can be ''reasonably calculated to prevent excessive exposure,'' the court also observed that area sampling can be considered superior to personal sampling for enforcement purposes:

> ''The area sampling program has several advantages over a personal sampling program. The most important advantage is that area sampling not only measures the concentration of respirable dust, it allows identification and thus control of dust generation sources. Control of dust at the source will obviously contribute to reducing the level of personal exposure. By contrast, the results of personal samples do not allow identification of dust sources due to the movement of miners through various areas of the mine during the course of a working shift. Thus, while a personal sampling system makes possible the identification of discrete individuals who have been overexposed, it does nothing to ensure reduction of dust generation because the source of the dust cannot be determined. Therefore, it clearly appears that area sampling can rationally be found to be superior to personal sampling as a means of enforcing (as opposed to merely measuring) compliance with [the standard].''

Although this decision relates specifically to respirable dust, it is clear that the Court of Appeals did not find that area sampling is inherently unreliable. Moreover, the logic expressed by the Court in describing the application of area sampling to respirable coal mine dust applies equally to dpm. Both are solid particulates that are produced from discrete sources during mining and are transported via the mine's ventilation system and inhaled by miners.

Accordingly, the fact that some in the metal and nonmetal sector, or some not engaged in mining at all, may not be familiar with this approach does not make it invalid or inappropriate.

Implementation by MSHA of its discretion. For the reasons noted above, MSHA has determined that personal sampling, occupational sampling, and area sampling are all viable sampling methods, and that inspectors should have the discretion to utilize whichever sampling strategy is appropriate in a given situation to determine compliance with the concentration limit for dpm. Accordingly, all three approaches are permitted in the final rule.

The Agency will provide further information about how these approaches should be used for dpm sampling in its compliance guide; however, it is using this opportunity to inform the underground metal and nonmetal mining community of its current views on some common situations.

For example, one commenter noted that an area sample could be taken adjacent to where a piece of diesel equipment was accelerating at low RPM, which is the time that an engine is working at its lowest efficiency. This commenter expressed concern that such a sample could indicate that the applicable dpm concentration was exceeded, even though the duty cycle as a whole for that equipment might be in compliance. MSHA believes this situation shouldn't result in a violation, because such an area sample would be taken for an entire shift, not just for the short time period when the piece of diesel equipment passes by the sampler.

Moreover, MSHA recognizes that it would not provide an accurate measure of the concentration of dpm to place a sampler in the area immediately around a machine's tailpipe when no workers would be in that location for any great length of time. An area sample would not be taken in that manner. But if a worker were assigned to work in a location on or immediately adjacent to diesel equipment, a personal or occupational sample might well be appropriate to determine if the limit is being exceeded for that worker or for such occupation.

Similarly, the agency would not consider it appropriate to conduct area sampling for compliance determinations in areas where dpm exposures, if any, would be infrequent and brief; in areas where miners work exclusively inside enclosed cabs; and in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are also used for access into, or egress from an underground mine.

Examples of the first situation would be work areas that are visited infrequently and briefly, such as a remote pump that needs to be checked weekly, or a remote area where roof conditions need to be inspected at periodic intervals. These areas would clearly be subject to the concentration limit because miners ''normally work or travel'' there. Area sampling in such areas would be inconsistent with the regulation's intent to, '' * * * limit the concentration of [dpm] to which miners are exposed * * *,'' because exposure would occur for only a few minutes per week, or possibly less.

Examples of the second situation would be production areas or haulageways where the only miners present work inside of enclosed and isolated cabs with appropriate filtration of breathing air, and underground crushing stations where crusher operator booths or similar fixed structures are provided with appropriately filtered breathing air. Area sampling outside such cabs or structures, which would have been permitted under the proposed rule, would be inconsistent with the regulation's intent to, '' * * * limit the concentration of [dpm] to which miners are exposed * * *,'' because miners in these areas are not exposed; they are already protected by an accepted engineering control. This approach is consistent with MSHA's intent as stated in the preamble to the proposed rule (63 FR 58184). It also reflects MSHA's awareness that enclosed cabs may provide many other important health and safety benefits, such as reducing noise exposure and reducing exposure to silica bearing respirable dust.

However, as a result of the comments concerning whether NIOSH method 5040 can effectively be used to determine compliance when miners are smoking, the agency recognizes that it faces a particular difficulty in sampling miners when they smoke inside an enclosed cab or booth, whether such sampling is area, occupational, or personal. As noted in Part II, section 3, MSHA has verified that sampling using NIOSH method 5040 immediately adjacent to smokers can undermine the validity of the sample result—since some of the total carbon detected may be from the smoke). While MSHA can generally avoid this problem by not sampling immediately near smokers, as discussed in that section of this preamble, it does face a problem when the area to be sampled is an enclosed cab or booth: it can neither sample inside nor outside an enclosed cab or booth if the subject miner smokes. The Agency intends to address this problem by obtaining the concurrence of the miner not to smoke while sampling the environment of the cab.

MSHA is troubled that, under certain circumstances, it will need to rely on miners voluntarily refraining from smoking in order to perform compliance sampling for dpm. Since miners are usually free to choose to smoke if they wish, this need to rely on the voluntarily cooperation of miners could seriously limit the agency's ability to sample when and where it desires. Though MSHA has determined that sampling of nonsmokers would usually be unaffected by the presence of smokers elsewhere in the mine, there will be situations where sampling of a specifically targeted area, occupation, or person would be prevented due to the presence of a smoker at that immediate location. Therefore, MSHA intends to continue to search for a means to reliably measure dpm concentrations despite the presence of cigarette, cigar, and pipe smoke in close proximity to the sampling equipment.

As noted in Part II, section 3, MSHA has determined that samples analyzed only for elemental carbon are unaffected by the presence of cigarette smoke. At this time, however, MSHA cannot limit its analysis to elemental carbon, because no consistent quantitative relationship has been established between elemental carbon concentration and the concentration of whole dpm.

MSHA intends to implement any newly developed sampling procedure and/or analytical method that is capable of directly or indirectly measuring the concentration of whole dpm in the presence of cigarette, cigar, and pipe smoke, provided such procedure and/or method is determined by NIOSH to provide equal or improved accuracy compared to the NIOSH Method 5040. If MSHA decides that such a change in sampling procedure and/or analytic method should be adopted, the agency will utilize standard communication channels to provide specific notification of its intention in this regard to the underground metal and nonmetal mining industry. However, MSHA wishes to be clear that, in accordance with § 57.5061(b), implementing such a change does not require new rulemaking.

Examples of the third situation include return or exhaust air courses that are shafts, inclines, slopes, adits, tunnels, etc. which terminate on the surface, but which are also used for mine access or egress by mine personnel.

Since the purpose of a return or exhaust air course is to collect and remove contaminated air from the mine, one would expect such an air course could contain high dpm levels. However, being a major travelway, one would naturally consider them to be areas ''where miners normally work or travel.'' As miners travel into the mine at the beginning of the shift and out of the mine at the end of the shift through these mine openings, relatively brief exposures to potentially high dpm levels could be expected. Full shift area sampling in such a location would likely indicate dpm levels in excess of the concentration limit. Should area sampling in such an air course result in a determination of noncompliance (which would be highly likely), the mine operator would be required to implement a change of some kind to bring the area into compliance, such as requiring that miners use a different access to the mine that is an intake or neutral air course, or that the ventilation system would need to be changed so that the access in question is no longer a return or exhaust air course. Since neither of these options may be feasible, the operator would be placed in an impossible compliance situation.

In such situations, MSHA believes that it would not be appropriate to use area sampling; rather, personal sampling would be more appropriate. Personal sampling would capture the exposure as miners travel into the mine at the beginning of the shift and depart at the end of the shift. Since the exposure time is brief, overexposure on a full-shift basis would be unlikely (assuming dpm levels in the working places are in compliance). Also, since exposure time is brief, the health risk associated with the exposure would be minimal.

It should be noted, however, that miners whose jobs require them to spend significant periods of time in these areas would continue to be at risk of overexposure if the dpm levels are high. For example, a haulage truck driver that spends much of the shift driving in and out of the mine through exhaust air hauling material to a surface dump point or crusher may need to be protected with an enclosed cab that is provided with filtered breathing air. Personal sampling on miners who engage in such activities would reveal the problem.

Another situation requiring clarification as to MSHA's intended compliance sampling procedures concerns miners who perform multiple work tasks during a shift. If a miner's work on a given shift includes a task or tasks for which the sampling procedures would not provide an accurate measurement of the dpm, MSHA would not use that measurement for the basis of a compliance determination. An example would be a miner who begins the shift operating a diesel-powered loader, and who finishes the shift operating a jack leg drill equipped with an in-line oil bowl. While operating the loader, MSHA would consider a personal or occupational sampling procedure to be acceptable for obtaining an accurate measurement for compliance purposes. However, as noted in Section II, MSHA would not consider personal or occupational sampling to be acceptable for sampling a miner who is operating a jack leg drill equipped with an in-line oil bowl, because there is the potential that oil mist emitted from the drill may be collected on the sample filter causing an inaccurate measurement of dpm to be made.

In this case, full shift area sampling would be performed at a location where the oil mist would not interfere with the measurement of dpm. If the drilling operation takes place in a different location from the loading operation (a different stope, for example), MSHA would consider full shift area sampling in both locations, if appropriate.

However, if no source of dpm is present at the drilling location, the inspector would probably choose to sample only the location where the loader is operating.

The agency considered whether it would be appropriate to deal with these situations through an amendment of the rule, and decided this would not be appropriate. The specific facts in a specific situation should determine the appropriateness of the sampling approach; trying to lock down this situation or that in the rule would prove very complex and restrict the flexibility to react to developments in the industry. The rule reserves to MSHA the flexibility to adjust the use of sampling approaches for any situation where use of one or another method might not be appropriate.

At the same time, the Agency wishes to make it clear that in putting explicitly into the rule that the Agency can use any of the three methods specified, it intends by that action to ensure that any policy that would broadly restrict the use of one or another of these methods would have to be the subject of new rulemaking. Thus, for example, any policy to significantly restrict the use of area sampling to enforce compliance with this rule would have to be the subject of new rulemaking action, as the availability of that method was a key consideration in MSHA's decision that it could implement a concentration limit.

Section 57.5062 Diesel Particulate Matter Control Plan

Under the final rule, a determination of noncompliance with either the interim or final concentration limit prescribed by § 57.5060 would trigger two requirements: first, the operator must establish a diesel particulate matter control plan (dpm control plan) meeting certain basic requirements—or modify the plan if one is already in effect; and second, the operator must demonstrate that the new or modified plan will be effective in controlling the concentration of dpm to the applicable concentration limit. The final rule also sets forth a number of other specific details about such plans, and states that failure of an operator to comply with the provisions of a plan or to conduct required verification sampling will be a violation of Part 57 without regard for the concentration of dpm that may be present. In all respects, this section of the final rule is essentially the same as in the proposed rule.

Only a few comments were directed specifically at § 57.5062. Some of those were supportive of the concept, such as the remark by one mine operator that, ''Generally, the Diesel Particulate Matter Control Plan (DPMCP) contained in § 57.5062 is well conceived.'' One commenter noted that once a plan is in place, failure to abide by its provisions is a citable violation, even if dpm levels are below the applicable concentration limit. Another commenter recommended that rather than a single out-of-compliance sample triggering the requirement to implement a plan, the provisions of § 57.5062 should not be triggered unless there is a significant history of non-compliance with the limit. Another commenter questioned why a determination of non-compliance requires MSHA to obtain only one non-compliant sample, whereas proof of operator compliance (both with respect to § 57.5062 and § 57.5071) requires multiple operator samples. A commenter also observed that a single sample is not ''statistically significant or representative and cannot determine if the mine is out of compliance.'' The same commenter argued that the requirements for documenting dpm control plan effectiveness were unnecessary, burdensome, and duplicated other MSHA requirements.

Triggering plan. Under the final rule, a single out-of-compliance dpm sample constitutes a citable violation of the applicable concentration limit and triggers the requirement to implement a diesel particulate matter control plan. As noted above, one commenter recommended that a diesel particulate matter control plan should not be required unless a mine has a significant history of non-compliance with the applicable dpm concentration limit. MSHA disagrees with the commenter's position because MSHA does consider a single sample to be a valid means of determining compliance (see discussion under § 57.5060 on single sample), and because a ''significant history of non-compliance'' at a given mine, would almost certainly be accompanied by significant, prolonged, and repeated exposure of miners to dpm levels in excess of the applicable concentration limit. Such exposures cannot be tolerated. When sampling indicates non-compliance, remedial action consisting of the implementation of a dpm control plan, or modification of an existing plan, must be initiated without delay. This will insure a timely reduction in dpm levels, and will help prevent dpm levels from rising above the applicable concentration limit in the future.

No advance approval of plans required. § 57.5062 will maintain the Agency's metal and nonmetal mine plan tradition by not invoking a formal plan approval process. That is, the plan would not require advance approval of the MSHA District Manager. As noted in the discussion of § 57.5060(c) and (d), MSHA is requiring advance approval for an operator to obtain a special extension of up to 2 years to meet the final concentration limit, and/or to allow miners performing inspection, maintenance or repair work to conduct such activities in areas that exceed the concentration limit. But a plan required because the limit has been exceeded need not obtain such advance approval.

In the preamble to the proposal for this Part, MSHA requested comment from the mining industry as to whether dpm control plans should require pre-approval by the Agency (p. 58119). The only comment received was in support of the Agency's proposal that such plans not require pre-approval.

A dpm control plan would, however, have to meet certain requirements set forth in the final rule, and as noted in the preamble to the proposed rule, it would be a violation of § 57.5062 if MSHA determines that the operator has failed to adequately address each of the plan's required elements.

Moreover, as discussed subsequently in connection with paragraph (f) of this section, once in place, a dpm control plan becomes law for that mine, and an operator must comply with it.

Elements of plan. Under § 57.5062(b), a dpm control plan must describe the controls the operator will utilize to maintain the concentration of diesel particulate matter to the applicable limit specified by § 57.5060. The plan must also include a list of diesel-powered units maintained by the mine operator, together with information about any unit's emission control device and the parameters of any other methods used to control the concentration of diesel particulate matter.

Relationship to ventilation plan. At the discretion of the operator, the dpm control plan may be consolidated with the ventilation plan required by § 57.8520.

Demonstration of plan effectiveness. The final rule would require monitoring to verify that the dpm control plans are actually effective in reducing dpm concentrations in the mine to the applicable concentration limit. Because the dpm control plan was initiated as a result of a compliance action, the final rule would require the use of the same measurement method used by MSHA in compliance determinations—total carbon using NIOSH method 5040—to conduct verification sampling. As a result, mine operators who are required to establish a dpm control plan would need to acquire the necessary sampling equipment to conduct the verification sampling, or arrange for such sampling to be conducted for them. As noted in Part II, the necessary sampling equipment is commercially available.

MSHA recognizes concerns about the commercial availability of the sampling equipment for NIOSH Method 5040. It is important that operators know whether they are in compliance with the standard. MSHA understands that the equipment will be available before this standard is in effect. MSHA will not use any equipment for sampling for compliance with this standard that is not commercially available. If the equipment is not commercially available by the effective date of the standard it is MSHA's intention not to enforce the dpm levels in the standard until the sampling equipment is available.

Effectiveness must be demonstrated by ''sufficient'' monitoring to confirm that the plan or amended plan will control the concentration of diesel particulate to the applicable limit under conditions that can be ''reasonably anticipated'' in the mine.

The final rule, like the proposed rule, does not specify that any defined number of samples must be taken—the intent is that the sampling provide a fair picture of whether the plan or amended plan is working. Instead, as indicated in the preamble to the proposed rule, MSHA will determine compliance with this obligation based on a review of the situation involved. While an MSHA compliance sample may be an indicator that the operator has not fulfilled the obligation under this section to undertake monitoring ''sufficient'' to verify plan effectiveness, it would not be conclusive on that point.

One commenter questioned the fairness of holding operators responsible for verifying plan effectiveness, the need for documentation to verify that plans will control dpm to the applicable limit, and for the requirement that such documentation must be provided upon request by MSHA. This commenter suggested that mine operators are already required to show compliance with air quality standards under § 57.5002, and that further documentation relating to the diesel particulate matter control plan therefore duplicates existing requirements.

While it is true that § 57.5002 requires mine operators to conduct ''dust, gas, mist, and fume surveys'' as frequently as necessary to determine the adequacy of control measures, this regulation does not specifically address diesel particulate matter, nor does it specify that dpm concentrations must be determined using the NIOSH Method 5040 (as is required in § 57.5062(c)). Thus, compliance with § 57.5002 will not insure compliance with the intent of § 57.5062. Section 57.5062(c) also requires that mine operators demonstrate that dpm concentrations will be controlled to applicable limits, not only under current conditions (*i.e.*, that a compliant sample be obtained), but also under reasonably anticipated conditions in the future.

MSHA disagrees with the commenter's suggestion that ''rigorous enforcement of existing TLV©'s and air quality rules, and * * * utilization of recommendations in the 'Diesel Toolbox''' will result in ''adequate safety levels.'' The 1973 Threshold Limit Values© or TLV©'s (the TLV©'s incorporated by reference in § 57.5001, and therefore currently enforceable in underground metal and nonmetal mines) do not include a limit of any kind for dpm. It is interesting to note that, as indicated in Table II–2 of Part II, section 5, the TLV©'s enforced by MSHA are derived from recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH). That organization has recently proposed a limit for dpm (ACGIH Notice of Intended Changes for 1999) of $50_{DPM}\mu g/m^3$, well below what is being established by this rule. As noted in Part V of this preamble, MSHA has concluded that $50_{DPM}\mu g/m^3$ is an unreasonably low limit for dpm concentration in underground metal and nonmetal mines because MSHA's technological and economic feasibility assessment indicate that this level cannot be achieved using feasible control measures.

If a diesel particulate matter control plan is in effect, the final rule specifies that monitoring must be ''sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine.'' Again, as conditions and circumstances in the mine change, the mine operator must demonstrate, on a continuing basis, through sampling results using NIOSH Method 5040, that compliance with the applicable concentration limit is consistently achieved.

MSHA believes that dpm control requires a holistic approach. A piecemeal solution to a dpm problem may result in shifting an overexposure from one area to another, but not eliminating the problem entirely. If an overexposure in one part of the mine is addressed by re-routing more ventilation air to that area, it means another part of the mine will have to give up some air, possibly causing an overexposure there. If an overexposure in one part of the mine is addressed by exchanging a dirty machine for a clean machine, it means the dirty machine is still polluting somewhere else. In these examples, the actions taken may simply move an overexposure to a different location, or they may result in overall compliance. The only way of knowing for sure whether the problem has actually been solved, is to consider the effects of a given action on the mine as a whole. That is what the regulation requires. MSHA does expect operators will focus their control plans on the areas of the mine in which dpm presents a hazard to miners.

The reason that MSHA can determine non-compliance based on a single sample whereas mine operators need multiple samples to demonstrate compliance is due to the fundamental difference between proving non-compliance versus proving compliance. For example, proving that at least one non-compliance condition exists somewhere in a mine requires only one non-compliant sample result. Proving conditions are fully compliant everywhere in a mine all the time requires more than one compliant sample result. The actual number of compliant samples necessary to prove that every location in the mine is fully compliant all the time would have to be determined, but it would rarely, if ever, be only one.

The differences between determining non-compliance versus determining compliance are incorporated into standard industrial hygiene practice. For example, regarding the evaluation of the exposure of a worker over a single day by means of a full-period measurement (which is MSHA's compliance sampling approach), *Patty's Industrial Hygiene and Toxicology* (3rd Edition, 1994) states, ''In that case, the error variance is determined by only the sampling and analytical error, and confidence limits tend to be quite narrow.'' By appropriately accounting for sampling and analytic errors, MSHA will assure, at the 95% confidence level, that an out-of-compliance sample accurately reflects an out-of-compliance condition in the mine.

This contrasts with the mine operator's need to verify compliance. *Patty's* states, ''Usually, however, our concern is with the totality of a workers exposure, and we wish to use the data collected to make inferences about other times not sampled. There is little choice; unless the universe of all exposure occasions is measured, we must ''sample,'' that is, make statements about, the whole based on measurement of some parts.''

''The American Industrial Hygiene Association has addressed the issue of appropriate sample size (Hawkins et al., 1991) and recommends in the range of 6–10 random samples per homogeneous exposure group. Fewer than 6 leaves a lot of uncertainty and more than 10 results in only marginal improvement in accuracy. Also, it is usually possible to make a reasonable approximation of the exposure distribution with 10 samples although a rigorous goodness-of-fit test often requires 30 or more.'' Although a single sample is not adequate to demonstrate compliance, MSHA does not specify in the final rule, a minimum number of samples that will constitute adequate verification of compliance in all cases. It is the mine operator's responsibility to determine the appropriate level of sampling effort and explain the rationale in the diesel particulate matter control plan.

Like the final rule, the proposed rule provided that verification sampling would be conducted under conditions that can be ''reasonably anticipated'' in the mine. The Agency very specifically solicited comment on ''whether, and how, it should define the term 'reasonably anticipated.' '' (63 FR 58185) The agency noted that with respect to coal dust, the Dust Advisory Committee recommended that ''MSHA should define the range of production values which must be maintained during sampling to verify the plan. This value should be sufficiently close to maximum anticipated production.'' (MSHA, 1996) For dpm, the Agency suggested, the equivalent approach might be based on worst-case operating conditions of the diesel equipment—*e.g.,* all equipment is being operated simultaneously with the least ventilation. No comments were received on this point.

Recordkeeping retention and access. Pursuant to section 5062(b), a copy of the current dpm control plan is to be maintained at the mine site during the duration of the plan and for one year thereafter. Section 5062(c) requires that verification sample results be retained for 5 years. And, section 5062(d) provides that both the control plan and sampling records verifying effectiveness be made available for review, upon request, by the authorized representative of the Secretary, the Secretary of Health and Human Services, and/or the authorized representative of miners. Upon request of the District Manager or the authorized representative of miners, a copy of these records is to be provided by the operator.

Duration. The final rule requires the dpm control plan to remain in effect for three years from the date of the violation resulting in the establishment/modification of the plan. Section 57.5062(e)(1) and (e)(2). MSHA has concluded that operators have sufficient time under the final rule to come into compliance with the concentration limits; if a problem exists, maintaining a plan in effect long enough to ensure that daily mine practices really change is an important safeguard. MSHA noted its view in this regard in the preamble to the proposed rule; no comments were received on this point.

Modification during plan lifetime. If a diesel particulate matter control plan is already in effect at a mine, section 57.5062(a) requires the mine operator to modify the current plan upon a subsequent violation of section 57.5060, and to demonstrate the effectiveness of the modified plan.

Section 57.5062(e)(3) would require the mine operator to independently initiate the modification of an existing dpm control plan to reflect changes in mining equipment and/or the mine environment, and requires the operator to demonstrate the effectiveness of the modified plan.

It should also be noted that a mine operator, based on dpm sampling data or other information or analysis, may at any time, modify the provisions of a dpm control plan to make it less restrictive, provided sufficient sampling data confirm the plan's continuing effectiveness in controlling dpm to compliant levels. A modification made in this manner does not affect the 3-year duration of the plan (end date unaffected). These plans made by the operator do not require advance approval by MSHA.

Compliance with plan requirements. Section 57.5062(f) states that failure by a mine operator to comply with the provisions of a diesel particulate matter control plan is a violation of the rule, regardless of the concentration of dpm that may be present at any time. Once an underground metal or nonmetal mine operator adopts a dpm control plan, it is considered law for the mine. Section 57.5062(f) specifically provides that MSHA would not need to establish (by sampling) that an operator is currently in violation of the applicable concentration limit under § 57.5060 in order to determine (by observation) that an operator has failed to comply with any requirement of the mine's dpm control plan.

One commenter observed that, ''It does seem odd * * * that § 57.5062(f) contemplates that the mere failure to adhere to the [dpm control plan] itself is deemed a violation of the regulation—irrespective of the fact that the exposure to dpm may indeed be less than the [concentration limit].''

MSHA's rationale for making a mine's dpm control plan law for that mine derives from the rule's approach to setting control requirements. MSHA recognizes that every mine faces a unique set of conditions and circumstances relating to equipment, engines, emission controls, ventilation, etc. that would make uniform dpm control requirements across the entire underground metal and nonmetal mining industry unworkable, impractical, and ineffective. Hence, the final rule, with just a few exceptions, permits mine operators considerable freedom to select the mix of dpm control options they believe are necessary to comply with the applicable concentration limit. An operator can filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, or use a variety of other readily available controls, all without consulting with, or seeking approval from MSHA.

However, if MSHA sampling indicates non-compliance with the applicable concentration limit, the rule requires the operator reduce to writing his or her specific plans for controlling dpm to the concentration limit and to adhere to that plan. MSHA considers miner exposure to dpm, a probable carcinogen, as a very serious matter, and has not established that exposures, even at the concentration limit, are safe. That is why a single non-compliant sample triggers the requirement for a compliance plan. The plan lays out the minimum steps the operator has determined must be followed in that mine to insure compliance. Failure to adhere to the requirements of the operator-developed plan must thus be viewed as a failure to take actions that are necessary for compliance with the concentration limit.

Because of the importance of adhering strictly to an effective dpm control plan, a means of enforcing such adherence is necessary. The plan is made law for that mine so that its provisions can be enforced by MSHA. The plan need not be approved by the MSHA District Manager, but it is, nonetheless, law for that mine, and any violation of the plan is therefore a violation of the regulation. As discussed above, an operator is free to modify a dpm control plan to make it less restrictive at any time during its life, and as often as desired, as long as sufficient sampling data confirm the plan's continuing effectiveness in controlling dpm to compliant levels. MSHA is of course concerned primarily with the health and safety of miners so the magnitude of any citation for a violation of the plan will take into account the actual risk posed to miners.

With respect to the required diesel particulate matter control plan, the mine operator is essentially telling MSHA what steps are necessary for that mine to comply with the applicable concentration limit. If MSHA observes a violation of the plan, it is only reasonable and proper for MSHA to conclude that full compliance is therefore not possible. If enforcement of the provisions of the dpm control plan depended upon obtaining an out-of-compliance dpm sample, plan enforcement would be greatly diminished, both in terms of timeliness and effectiveness. If such a sample were taken, and found to be out of compliance, implementation of needed corrective measures would be delayed because MSHA could not require the mine operator to take remedial actions until the sample results were obtained from the analytic laboratory, which could involve several weeks of time. If such a sample were taken, and found to be in compliance, that fact would not constitute conclusive evidence that the plan as a whole was fully effective (see earlier discussion on the need for multiple samples to establish continuing compliance). Thus, while providing inconclusive information at best, such a sampling outcome would prevent MSHA from enforcing a provision of the plan. Regardless of sampling outcome, it is important to remember that a violation of the plan means the mine operator did not adhere to the very requirements that were represented to MSHA by the operator as being necessary for compliance.

It should also be noted that MSHA already has similar enforcement authority relative to various other plans that are required in the underground metal and nonmetal sector. Mine operators are required to prepare plans for such purposes as escape and evacuation, rock bursts, ventilation, and training. MSHA has the authority to enforce the provisions of these plans without first verifying that the observed violation has caused an immediate outcome which itself, is prohibited by regulation. There is also ample precedent for citing health-related violations without sampling, such as § 58.620 on drill dust control, and § 57.5005 on respiratory protection.

The mine operator is required to modify dpm control plans to reflect changes in mining equipment or circumstances. The mine operator is also required to modify dpm control plans if the plan proves to be inadequate, as evidenced by a subsequent non-compliance determination during the three year period that the plan is in effect. In either case, the modifications to the original plan become law for that mine, and violations are subject to enforcement action by MSHA regardless of dpm concentration.

It is also important to remember that dpm levels are determined by the complex interaction of numerous factors, such as equipment type, engine size, type, and horsepower, duty cycles, engine maintenance, equipment operator training and work practices, fuel and fuel additives, the characteristics and performance of exhaust filtering systems, mine ventilation flows, and many others. Effectively controlling dpm levels throughout a mine requires a systematic approach that acknowledges the interrelationships and interactions between these factors to produce the desired end result, which is compliance with the applicable concentration limit. A determination of non-compliance indicates that the system of controls has failed. Thus, an effective permanent solution requires a comprehensive approach which not only corrects the immediate cause of the non-compliance (an out-of-tune engine, for example), but also addresses the underlying system failure (deficient maintenance management, inadequate dpm monitoring, ineffective equipment operator training, failure to tag equipment believed to require maintenance, etc.).

The implementation of a dpm control plan avoids piecemeal solutions that result in a repetitive pattern of mines being in and out of compliance without ever coming to grips with underlying problems. The required elements of a dpm control plan force a comprehensive approach, and facilitate effective, permanent solutions to systemic failures. The three year duration of such plans insures that the necessary system changes become institutionalized and integrated into daily mine practices. This, in turn, will increase the chances that mines will be in compliance with the applicable concentration limit on a continuous, on-going basis.

MSHA recognizes that some operators may want to supplement the compliance plans required by the regulation with additional internal instructions that provide supplementary protection—i.e., to achieve concentration levels below those required. MSHA does not want to discourage such supplemental plans; indeed, it would like to encourage them. Accordingly, MSHA will, upon request, work closely with mine operators to help avoid confusion by mine and Agency personnel between required compliance plans that contain the minimum elements considered essential to achieve compliance (and whose provisions are therefore enforceable by MSHA) and non-required supplemental plans that contain elements the mine operator wishes to implement as a matter of company policy (but whose provisions are not enforceable by MSHA).

Section 57.5065 Fueling Practices

Summary. This section of the final rule establishes the requirements for fueling practices in underground metal and nonmetal mines. Unlike the proposed rule, the final rule has two subsections.

Subsection (a) limits the amount of sulfur that may be contained in diesel fuel used to power equipment in underground areas, and requires mine operators to maintain purchase records that verify the sulfur content of the fuel they use.

Subsection (b) requires that fuel additives used in underground diesel-powered equipment be restricted to those registered by the U.S. Environmental Protection Agency.

These subsections of the final rule have not been changed from the proposed rule.

The practices being required by these two subsections are accepted industry practices to reduce dpm emissions. They are among the methods for reducing dpm explicitly included in MSHA's toolbox publication, and were made requirements for underground coal mines as part of MSHA's diesel equipment rulemaking. They are among the ''best practices'' for reducing dpm emissions that MSHA has determined are technologically and economically feasible for all underground metal and nonmetal mines. Part II of this preamble contains some background information on these practices together with information about the rules currently applicable in underground coal mines.

Low-sulfur fuel. In the final rule, § 57.5065(a) would require underground metal and nonmetal mine operators to use only low-sulfur fuel having a sulfur content of no greater than 0.05 percent. This requirement is identical to that currently required for diesel equipment used in underground coal mines [30 CFR 75.1901(a)]. Both number 1 and number 2 diesel fuel meeting the sulfur content requirement of this rule are commercially available.

Sulfur content can have a significant effect on diesel emissions. Use of low-sulfur diesel fuel reduces the sulfate fraction of dpm matter emissions, and reduces objectionable odors associated with diesel exhaust.

Another major benefit of using low-sulfur fuel is that the reduction of sulfur allows oxidation catalysts to perform properly. Some diesel emission aftertreatment devices, such as catalytic converters and catalyzed particulate traps, are ''poisoned'' with fuels having high-sulfur content (greater than 0.05 percent sulfur). MSHA believes the use of these aftertreatment devices is important to the mining industry because they will be necessary for many mines to meet the specified concentration limits. The requirement to use low-sulfur fuel will allow these devices to be used without additional adverse effects caused by the high-sulfur fuel.

Several commenters questioned why low-sulfur fuel was mandated, even for operators who could meet the applicable concentration limit using other means. MSHA responds by noting that the use of low-sulfur fuel is one of the ''best practices'' that MSHA requires all mines to follow, regardless of current dpm levels. Further elaboration on the rationale for mandating these ''best practices'' was included in the preamble to the proposed rule (63 FR 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed ''Meeting the concentration limit, operator choice of engineering controls.'' As noted in those discussions, MSHA is required by statute to reduce a significant risk to the extent feasible; the use of low-sulfur fuel is feasible, has not created any problems in the underground coal sector where it is required as a result of the diesel equipment rule, and its use will reduce dpm emissions from underground engines.

In the preamble to the proposal (63 FR 58186), MSHA indicated it did not believe a requirement mandating the use of low-sulfur fuel will add additional compliance costs. Several commenters contradicted this conclusion, arguing that the provision requiring low-sulfur fuel would have an adverse cost impact. One commenter supplied actual cost figures that showed their fuel costs increased over $18,000 per year after they switched to low-sulfur fuel. However, it is significant to note that this increase is quite small on both a cost per gallon of fuel basis (less than $0.03 per gallon), and a cost per ton basis (about $0.008 per ton), and that this mine had already made the switch to low-sulfur fuel, apparently because they perceived that the benefits justified the small additional expense.

As discussed in the Section IV of the PRIA, MSHA determined that the cost difference between high-sulfur and low-sulfur diesel fuel was less than $0.02 per gallon in many parts of the country, and in some areas, there was no difference at all, or a slight cost advantage to using low-sulfur fuel. Fuel used in over-the-road diesel engines is currently required by EPA regulations to meet the same 0.05% sulfur content limit that is being implemented for underground metal and nonmetal mines. Because over-the-road diesel engines represent the bulk of the diesel fuel market, such low-sulfur fuel is already readily available throughout the country. EPA has proposed regulations that would further reduce allowable fuel sulfur content to 0.0015% for over-the-road diesel engines. Current MSHA regulations limit the sulfur content of diesel fuel used in underground coal mines to 0.05%, and the availability of this fuel in remote coal mining areas has not been a problem for coal mine operators. As discussed above, MSHA has determined, based on extensive study of the metal and nonmetal mining industry, that compliance with the rule is economically feasible for the industry as a whole. Thus, although the provision requiring use of only low-sulfur fuel may, in some instances, result in a small cost increase for some operators, MSHA estimates that on average, the overall measurable impact is negligible. When they are measurable, it is because the mine is located in an area where heating fuel has relatively large market share compared to diesel fuel used for vehicles. This circumstance is unrelated to mine size. Most mines are not located in these regions and there is no evidence that small mines are disproportionately concentrated in these regions.

Fuel additives. Paragraph (b) of this section requires mine operators to use only diesel fuel additives that have been registered by the Environmental Protection Agency (40 CFR Part 79). Again, this rule is consistent with current requirements for diesel equipment used in underground coal mines [30 CFR 75.1901(c)], and is another of the ''best practices'' that MSHA considers to be feasible for all underground metal and nonmetal mines. The restricted use of additives would ensure that diesel particulate concentrations would not be inadvertently increased, while also protecting miners against the emission of other toxic contaminants. MSHA has published Program Information Bulletin No. P97–10, issued on May 5, 1997, that discusses the fuel additives list. The requirements of this paragraph do not place an undue burden on mine operators because operators need only verify with their fuel suppliers or distributors that the additive purchased is included on the EPA registration list. To assist mine operators in this regard, EPA's Internet site contains a current listing of additives registered with EPA. This site can be accessed at the following address: http://www.epa.gov/oms/regs/fuels/additive/web-dies.txt. No commenters objected to this requirement.

Idling practices. Proposed paragraph (c) of § 57.5021 would have prohibited idling of mobile diesel-powered equipment, except as required for normal mining operations. After further consideration of all comments received during the comment period, as well as testimony presented at the public hearings, MSHA has decided to delete this requirement from the final rule. Therefore, the final rule does not contain a restriction for operators on idling diesel-powered equipment. MSHA does, however, recommend as a best practice that mine operators do not allow miners to idle diesel-powered equipment unnecessarily.

Although commenters generally agreed with MSHA's statement in the proposal that this requirement would aid in the reduction of dpm concentrations at the mine, they pointed out that the total amount of diesel particulate matter emitted from this single source might have little effect on the levels of dpm in the overall mining environment. Also, several commenters questioned the need for an idling restriction in light of the proposed concentration limits established in the regulation. Additionally, another commenter indicated that the provision was not necessary because mine operators, in an effort to comply with the applicable concentration limits, would be forced to institute work rules to this effect anyway. Moreover, as pointed out by commenters, nothing in the regulatory language prohibits operators from voluntarily restricting idling at the mine, eliminating the need to include this provision. Accordingly, we have deleted proposed paragraph (c) from the final rule.

Section 57.5066 Maintenance standards.

Summary. This section of the final rule establishes maintenance standards for diesel-powered equipment operated in underground areas of metal and nonmetal mines. It has three subsections.

Subsection (a) addresses maintenance of diesel engines, emission related components, and emission or particulate control devices.

Subsection (b) institutes a mandatory procedure by which diesel equipment operators must be authorized and required to tag equipment they believe requires maintenance in order to comply with subsection (a) above, for mine operators to insure that equipment so tagged is promptly examined, and for mine operators to retain a log of tagged equipment and the corresponding equipment examinations.

Subsection (c) requires that persons maintaining diesel equipment in underground metal and nonmetal mines be appropriately qualified by virtue of training or experience, and that mine operators must retain evidence of the competence of such persons.

The provisions of this section in the final rule are unchanged from the proposal.

Maintain Approved engines in approved condition. § 57.5066(a)(1) requires that mine operators maintain any approved diesel engine in ''approved'' condition. Under MSHA's approval requirements, engine approval is tied to the use of certain parts and engine specifications. When these parts or specifications are changed (i.e., an incorrect part is used, or the engine timing is incorrectly set), the engine is no longer considered by MSHA to be in approved condition.

Often, engine exhaust emissions will deteriorate when this occurs. Maintaining approved engines in their approved condition will ensure near-original performance of an engine, and maximize vehicle productivity and engine life, while keeping exhaust emissions at approved levels. The maintenance requirements for approved engines in this rule are already applicable to underground coal mines. 30 CFR 75.1914.

Thus in practice, with respect to approved engines, mine maintenance personnel will have to maintain the following engine systems in near original condition: air intake, cooling, lubrication, fuel injection and exhaust. These systems shall be maintained on a regularly scheduled basis to keep the system in its ''approved'' condition and thus operating at its expected efficiency.

One of the best ways to ensure these standards are observed is to implement a proper maintenance program in the mine—but the final rule would not require operators to do this. A good program should include compliance with manufacturers' recommended maintenance schedules, maintenance of accurate records and the use of proper maintenance procedures. MSHA's diesel toolbox provides more information about the practices that should be followed in maintaining diesel engines in mines.

Maintain emissions related components of non-approved engines to manufacturer specifications. For any non-approved diesel engine, paragraph (a)(2) requires mine operators to maintain the emissions related components to manufacturer specifications.

The term ''emission related components,'' refers to the parts of the engine that directly affect the emission characteristics of the raw exhaust. These are basically the same components which MSHA examines for ''approved'' engines. They are the piston, intake and exhaust valves, cylinder head, injector, fuel injection pump, governor, turbo charger, after cooler, injection timing and fuel pump calibration.

Engine manufacturers are required to build engines in a manner that ensures continued compliance with EPA emissions levels and to establish specifications for adjusting and maintaining these engines to the engine manufacturer's specifications to ensure that the engines continue to perform properly and emit acceptable levels of emissions.

As it indicated in the preamble to the proposed rule, the Agency does not intend that this requirement could be misconstrued as establishing the basis for ''picky'' citations. It is not MSHA's intent that engines be torn down and the engine components be compared against the specifications in manufacturer maintenance manuals (63 FR 58187). Primarily, the Agency is interested in ensuring that engines are maintained in accordance with the schedule recommended by the manufacturer. However, if it becomes evident that the engines are not being maintained to the correct specifications or are being rebuilt in a configuration not in line with manufacturers' specifications or approval requirements, an inspector may ask to see the manuals to confirm that the right manuals are being used, or call in MSHA experts to examine an engine to confirm whether basic specifications are being properly observed.

This explanation of MSHA's intent relative to its enforcement of this provision was included in the Preamble to the proposed rule, accompanied by an invitation for comment from the mining industry to suggest alternative ways to rephrase this requirement so the Agency has a basis for ensuring compliance while minimizing the opportunity for overprescriptiveness (63 FR 58187). However, no such suggestions were received.

Maintain emission or Particulate Control Devices in effective operating condition. Paragraph (a)(3) requires that any emission or particulate control device installed on diesel-powered equipment be maintained in effective operating condition. Depending on the type of devices installed on an engine, this would involve having trained personnel perform such basic tasks as regularly cleaning aftertreatment filters, using methods recommended by the manufacturer for that purpose, or inserting appropriate replacement filters when required, checking for and repairing any exhaust system leaks, and other appropriate actions. This explanation of MSHA's intent relative to subsection (a)(3) was contained in the preamble to the proposed rule (63 FR 58187). One comment was received on this subsection from a commenter who submitted a complete regulatory alternative to MSHA's proposed dpm rule. The section of this regulatory alternative that corresponds to subsection (a)(3) of both the proposed and final rules reads as follows: ''Emission related components of diesel powered equipment shall be maintained in effective operating condition.'' This alternative language is functionally identical to both the proposed and final rules. It incorporates the phrase ''Emission related components of diesel powered equipment * * *,'' whereas the rules incorporate the phrase, ''Any emission or particulate control device installed on the equipment * * *,'' however, the requirement that such equipment, ''shall be maintained in effective operating condition,'' is identical. Therefore, MSHA concluded that no change from the proposal was necessary.

Ensuring equipment that may be out of compliance with maintenance standards is attended to—Tagging. Section 57.5066(b)(1) of the final rule requires underground metal and nonmetal mine operators to authorize and require miners operating diesel powered equipment to affix a visible and dated tag to the equipment at any time the equipment operator ''notes any evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section.'' Moreover, § 57.5066 (b)(2) requires that the equipment be ''promptly'' examined by a person authorized by the mine operator to maintain diesel equipment, and prohibits removal of the tag until such examination has been completed. Section 57.5066 (b)(3) requires a log to be retained of all equipment tagged.

In proposing this approach, MSHA noted its view that tagging would provide an effective and efficient method of alerting all mine personnel that a piece of equipment needs to be checked by qualified service personnel for possible emission problems, and that such a check is performed in a timely way (63 FR 58187).

The agency noted that the presence of a tag serves as a caution sign to miners working on or near the equipment, as well as a reminder to mine management, as the equipment moves from task to task throughout the mine. While the equipment is not barred from service, operators would be expected to use common sense and not use it in locations in which diesel particulate concentrations are known to be high.

The agency noted it was not requiring that equipment tagged for potential emission problems be automatically taken out of service. The rule is not, therefore, directly comparable to a ''tag-out'' requirement such as OSHA's requirement for automatic powered machinery, nor is it as stringent as MSHA's requirement to remove from service certain equipment ''when defects make continued operation hazardous to persons'' (see 30 CFR 57.14100). In the Preamble to the proposed rule, MSHA indicated that it did not think there was a need for something as stringent as these requirements because, although exposure to dpm emissions does pose a serious health hazard for miners, the existence or scope of an equipment problem cannot be determined until the equipment is examined or tested by a person competent to assess the situation. Moreover, the danger is not as immediate as, for example, an explosive hazard.

In the preamble to the proposed rule, MSHA also provided additional insights into how this approach would be implemented. It noted, for example, that the tag may be affixed because the equipment operator detects a problem through a visual exam conducted before the equipment is started, or because of a problem that comes to the attention of the equipment operator during mining operations, (i.e., black smoke while the equipment is under normal load, rough idling, unusual noises, backfiring, etc.) MSHA also noted it had not defined the term ''promptly'' with respect to how quickly tagged equipment must be examined by a qualified person, and sought comment on whether it should define this term—for example, by limiting the number of shifts it could operate before the required examination is performed (63 FR 58187).

The equipment tagging requirement was the subject of numerous comments. Most commenters were concerned that equipment operators would be authorized and required to make judgements about equipment function (and malfunction) for which they are unqualified, namely, to tag equipment they believe requires maintenance due to a problem related to dpm emissions. The commenters argued that, although equipment operators may be highly skilled in operating equipment, they are not necessarily qualified to make judgements concerning equipment maintenance requirements. Even though the regulation would not require tagged equipment to be removed from service, the commenters were concerned that such tags would cause unnecessary ''scurrying about of mechanics'' whose time could be more productively spent performing actual needed maintenance, rather than reacting to tags affixed for reasons that might be dubious, at best.

Commenters noted that, in addition to unnecessary maintenance inspections and the possibility of unnecessarily removing equipment from service, this requirement could result in a safety hazard if a tag affixed under § 57.14100(c) is mistaken for a tag affixed under § 57.5066(b)(1). The former addresses safety defects that ''make continued operation hazardous to persons,'' and it requires the equipment to be immediately removed from service. The latter relates to dpm emissions, and does not require the piece of equipment to be removed from service. If a tag under § 57.14100(c) is mistaken for a tag under § 57.5066(b)(1), the affected equipment would be allowed to remain in service, exposing the operator, and possibly others, to potentially dangerous conditions.

Some commenters suggested that the tagging requirement in the final rule was completely unnecessary because its intent is already satisfied by existing § 57.14100, and that for the sake of simplicity, § 57.5066(b)(1) should be eliminated. Another commenter noted that § 57.5066(b)(1) was unnecessary because mine operators already have effective mechanisms in place to identify and correct maintenance problems on diesel equipment, including emissions-related problems. Another commenter worried that a citation could be issued if an inspector believes an operator failed to tag a piece of diesel equipment with a ''smoky'' exhaust, even if the operator believes the exhaust is within the normal range. Several commenters speculated that disgruntled employees would deliberately shut down equipment by tagging it for an emissions check.

Several commenters suggested alternative requirements, including incorporating emissions checks into the pre-shift equipment inspection required under § 57.14100(a), requiring equipment operators to either inform their supervisors of any suspected emissions-related problems or note any suspected emissions-related problems in a log book provided in every piece of equipment for that purpose, and requiring the mine operator to insure that a qualified person examines any piece of equipment for which an emissions-related problem has been identified.

MSHA has considered these comments, and determined that the requirements contained in the proposal are both necessary, and more protective than the alternatives suggested by the commenters. For these reasons, the requirements contained in the proposal have been retained without change in the final rule.

MSHA believes that, since equipment operators spend more time running the equipment than other employees (such as mechanics), and are present when the equipment functions under the widest range of operating conditions, they are often better able to detect emissions-related problems than are mechanics. For this reason, the final rule requires that equipment operators be authorized and required to affix a visible and dated tag if they note any evidence that the equipment may need maintenance in order to comply with the rule's maintenance requirements. Even though equipment operators may not be trained or qualified as diesel mechanics, they often know the difference between normal and abnormal equipment performance, especially as it relates to diesel particulate matter generation, which is often plainly visible or apparent (i.e., black smoke while the equipment is under normal load, rough idling, unusual noises, backfiring, etc.).

MSHA acknowledges that an equipment operator's judgement should not necessarily be relied upon to remove a piece of diesel equipment from service, precisely because equipment operators are not specifically trained or qualified to make such a judgement. Accordingly, the final rule does not require equipment operators to be granted this authority; only that they be granted authority to visibly identify a potential problem machine by affixing a tag. It is then the responsibility of the mine operator to appropriately respond to the presence of a tag. Note that the response by the mine operator need not be immediate, nor does it necessarily require the affected equipment to be removed from service, as some commenters feared. Mine operators have the authority to establish work rules and procedures to prevent equipment from being removed from service unnecessarily. Equipment operators and mechanics simply need to be trained as to their respective authority and responsibility under this section; namely, that equipment operators need to tag equipment suspected of requiring maintenance attention, and that qualified mechanics need to follow up to determine if a problem actually exists, and if so, what corrective maintenance work is needed.

It is highly unlikely that a tag intended to indicate a suspected emissions-related problems, if properly designed, would be confused with a tag intended to indicate a safety problem as per § 57.14100(c). Such tags could be differentiated by size, color, or other obvious visual characteristics so that mistaking one for the other would be virtually impossible. As noted below, the final rule allows mine operators the freedom to develop a design that suits their circumstances. In contrast, a design mandated by MSHA might be too similar to a given mine's existing § 57.14100(c) safety tag.

MSHA believes that the equipment tagging requirements of § 57.14100(c) and § 57.5066(b)(1) are inherently and significantly different, to the extent that the § 57.14100(c) requirement, even if modified to include health hazards, could not achieve the desired effect of § 57.5066(b)(1). The purpose of § 57.14100(c) is to immediately remove equipment from service if it poses a safety hazard, whereas the purpose of § 57.5066(b)(1) is to identify a potential emissions-related problem that might require maintenance, but does not justify immediate removal from service. Another important difference is that examinations under § 57.14100(c) occur before a piece of equipment is placed in operation on that shift, whereas § 57.5066(b)(1) applies throughout a work shift. These fundamental differences would make any attempt to combine the rules overly complicated, which would defeat the commenter's purpose of simplifying the rule.

As discussed above, MSHA believes that equipment operators should be authorized and required to note emissions-related deficiencies at all times during a work shift, and not be limited to making such observations during a pre-shift equipment inspection or before the equipment is placed into operation. Some emissions-related problems may not become apparent until after the equipment has been fully engaged for some time in heavy duty cycle activities. If the only time emissions-related deficiencies could be identified is before the equipment is placed into operation, the mine operator might never learn about such problems, or the corresponding notification might be unnecessarily delayed.

MSHA acknowledges that many underground metal and nonmetal mine operators utilize effective maintenance programs to identify and correct emissions-related problems in a timely manner. However, MSHA believes that §§ 57.5066(b)(1) and (2) are ''best practices'' that should be implemented at all mines. At mines that already have an effective program, this provision would serve as a complementary element. At mines that have no effective program, this provision would create an important safeguard. Further elaboration on the rationale for mandating these ''best practices'' was included in the preamble to the proposal (p. 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed ''Meeting the concentration limit, operator choice of engineering controls.''

The tagging provision of § 57.5066(b) requires judgement on the parts of both the equipment operator and the MSHA inspector. There is no absolute standard which precisely defines the physical proof that constitutes, ''evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section.'' Thus, MSHA inspectors will be guided by a standard of reasonableness, based on an equipment operator's ability to differentiate normal emissions from grossly abnormal emissions. MSHA does not expect operators to tag equipment whenever there is a minor aberration or excursion from an optimum or perfect emissions condition, or that an inspector should make a fine distinction between emissions that are ''slightly too smoky'' versus ''barely acceptable.'' However, MSHA inspectors will not ignore an operator's failure to tag a piece of equipment suffering from a serious emissions-related problem that is so obvious as to suggest the mine operator is indifferent to, or even discourages such tagging.

MSHA believes that disgruntled employees' attempts to shut down equipment by affixing tags indicating possible emissions-related problems can be effectively controlled and prevented by mine operators through work rules and procedures, and employee discipline policies. Mine operators should treat the inappropriate exercise of this provision by a disgruntled employee no differently than any other disruptive or malicious behavior. In addition to being preventable, MSHA believes the inappropriate tagging of equipment would have minimal impact on mining operations because tagged equipment need not be immediately removed from service. The maintenance examination that is triggered by a tag might not take place until the next shift or the shift after, and if there is truly nothing wrong with the equipment, it would be obvious to the mechanic performing the examination, and would therefore only require a few minutes of a mechanic's time.

MSHA considers the provision for tagging equipment to be preferable to a system which permits equipment operators to simply notify their supervisor of a suspected emissions-related problem, because the presence of a tag serves as a caution sign to other miners working on or near the equipment, as well as a reminder to mine management that this piece of equipment needs to be examined. Simply informing the supervisor does not provide this ongoing visual indicator or reminder, and as miners and equipment are reassigned to different jobs in different parts of a mine, information that is communicated verbally can be easily forgotten. A major advantage of tagging is that the tag goes with the equipment throughout the mine, alerting all who come in contact with it of the potential dpm emissions problem. In this sense, tagging requirements are particularly valuable for mobile equipment that travels from place to place throughout the shift, and may have multiple operators over the course of several shifts.

Design of the tag. MSHA proposed that the design of the tag be left to the discretion of the mine operator, with the exception that the tag must be able to be marked with a date. MSHA sought comment on ''whether some or all elements of the tag should be standardized to ensure its purpose is met''.

Several commenters suggested that MSHA should design the tag to be used for indicating equipment suspected of needing emissions-related maintenance.

As noted above, the final rule leaves this decision to the discretion of the mine operator. Since the design of tags required under § 57.14100(c) is left to the discretion of the operator, it would be impossible for MSHA to insure that any mandated design for a tag under § 57.5066(b)(1) would be easily distinguishable from an existing § 57.14100(c) tag. However, MSHA strongly urges mine operators to adopt a design for their § 57.5066(b)(1) tags that is easily distinguishable from the design of their § 57.14100(c) tags, using, for example, different sizes, colors, or other obvious visual characteristics.

Time to inspect equipment. As noted above, MSHA sought specific comment on whether to define the term ''promptly.'' One commenter referred to ''promptly examined'' as, ''whatever that is,'' indicating they believed the term ''promptly examined'' is too vague. Another commenter suggested that a definite time period for examining equipment should be specified; namely, ''by the end of the next shift.'' However, another commenter agreed with MSHA that equipment tagged by an operator should be, ''promptly examined'' by an authorized diesel maintenance person. Another commenter proposed that, ''the required examination be conducted during normally scheduled maintenance cycles.''

The final rule, like the proposal, does not define the term ''promptly''. Operating and maintenance practices vary from mine to mine to such an extent that a proscriptive requirement mandating a specific time period within which an examination must be completed may be infeasibly short for some operators and unnecessarily long for other operators. However, MSHA's intent is that mine operators will insure such examinations are performed without undue delay. If a tag is affixed during a given shift, it would not be unreasonable to complete that shift before the maintenance examination. If no qualified mechanic is scheduled to work on the following shift, the equipment could be operated during that shift as well. However, if a qualified mechanic was scheduled to work on the next shift, the examination would be required before the equipment was used.

Tagged Equipment Log. Section 57.5066(b)(3) requires a log to be retained of all equipment tagged. Moreover, the log must include the date the equipment is tagged, the date the tagged equipment is examined, the name of the person making the examination, and the action taken as a result of the examination. Records in the log about a particular incident must be retained for at least one year after the equipment is tagged.

MSHA does not expect the log to be burdensome to the mine operator or mechanic examining or testing the engine. Based on MSHA's experience, it is common practice to maintain a log when equipment is serviced or repaired, consistent with any good maintenance program. The records of the tagging and servicing, although basic, provide mine operators, miners and MSHA with a history that will help in determining whether a maintenance program is being effectively implemented, and whether emissions-related components on the equipment are being maintained in a proper and timely fashion.

Several comments addressing the equipment log were received. Proposed revisions generally retained the requirement for an equipment log, but varied as to who would maintain the log (equipment operators, mechanics or supervisors), and how long they should be kept (one year versus until the condition is examined and remedied). It was also suggested that all record keeping could be accomplished under ''existing mobile equipment examination standards and maintenance work order systems,'' and that additional standards were therefore not needed.

MSHA has concluded that the requirements in the proposal relative to tagged equipment logs are essential to effectively controlling dpm, and have therefore been retained in the final rule without change. They enable both the mine operator and MSHA to track emissions-related problems on equipment, and the actions taken by the mine operator to resolve the problems that occur. The logs are also important because they provide a written record documenting when equipment was tagged, and how the mine operator responded.

The log creates an accountability chain that clearly indicates the date the equipment was tagged, the date the tagged equipment was examined, the name of the person making the examination, and the action taken as a result of the examination. Without the written record, MSHA would be unable to ascertain the extent to which mine operators respond in a timely and appropriate manner to emissions-related problems on diesel equipment. The one-year record retention requirement is necessary so that MSHA can review the emissions-related maintenance history on a given piece of equipment over a meaningful time period. This will enable MSHA to judge the mine operator's on-going commitment to proper and timely maintenance of these components. If the log were kept only until a given maintenance operation was completed, MSHA's opportunity to assess the mine operator's on-going responsiveness to emissions-related problems would be limited to the few chance occasions where a piece of equipment is tagged during an MSHA inspection of the mine.

These requirements are protective to miners because they force mine operators to address dpm emissions problems through a systematic and effective program. The combination of equipment tagging and logging helps insure problems will be identified and resolved quickly. If either or both requirements were eliminated, mine operators would be less likely to receive timely notice of a potential problem, and once notified, would be less motivated to promptly initiate the required examination and corrective measures.

Persons qualified to perform maintenance. Section 57.5066(c) requires that persons who maintain diesel equipment in underground metal and nonmetal mines be ''qualified,'' by virtue of training or experience, to ensure the maintenance standards of § 57.5066(a) are observed. Paragraph (c) also requires that an operator retain appropriate evidence of ''the competence of any person to perform specific maintenance tasks'' in compliance with the requirement's maintenance standards for one year.

The requirements being established in this regard are not as stringent as those in effect for the maintenance of diesel powered equipment in underground coal mines. Operators of underground coal mines where diesel-powered equipment is used are required, as of November 25, 1997, to establish programs to ensure that persons who perform maintenance, tests, examinations and repairs on diesel-powered equipment are qualified (30 CFR 75.1915). The unique conditions in underground coal mines require the use of specialized equipment. Accordingly, the persons who maintain this equipment generally must be appropriately qualified.

If repairs and adjustments to diesel engines used in underground metal and nonmetal mines are to be done properly, personnel performing such tasks must be properly trained. MSHA does not believe, however, that the qualifications required to perform this work in underground metal and nonmetal mines necessarily require the same level of training as is required for similar work in underground coal mines. Under the final rule, the training required would be that which is commensurate with the maintenance task involved. If examining and, if necessary, changing a filter or air cleaner is all that is required, a miner who has been shown how to do these tasks would be qualified by virtue of training or experience to do those tasks. For more detailed work, specialized training or additional experience would be required. Training by a manufacturer's representative, completion of a general diesel engine maintenance course, or practical experience performing such repairs could also serve as evidence of having the qualifications to perform the service.

In practice, the appropriateness of the training or experience of the maintenance personnel will be revealed by the performance of the equipment, both the diesel engine itself and any emission aftertreatment devices. If MSHA finds a situation where maintenance appears to be shoddy, where the log indicates an engine has been in for repair with more frequency than should be required, or where repairs have damaged engine approval status or emission control effectiveness, MSHA would ask the operator to provide evidence that the person(s) who worked on the equipment was properly qualified by virtue of training or experience.

It is MSHA's intent that equipment sent off-site for maintenance and repair is also subject to the requirement that the personnel performing the work be qualified by virtue of training or experience for the task involved. It is not MSHA's intent that a mine operator have to examine the training and experience record of off-site mechanics, but a mine operator will be expected to observe the same kind of caution as one would observe with a personal vehicle—*e.g.,* selecting the proper kind of shop for the nature of the work involved, and considering prior direct experience with the quality of the shop's work.

One commenter objected to the requirement that mine operators must retain evidence of the competence of such workers for one year after any applicable maintenance task is completed. MSHA believes the provision is important because the evidence retained by the mine operator is the only means by which MSHA can judge compliance with the competency requirement.

Another commenter recommended this provision be dropped from the final rule because it is unnecessary. This commenter argued that it is in a mine operator's self interest to employ only qualified diesel mechanics to perform maintenance on equipment that is critical to the productive capacity of the mine. Another commenter stated that the rule is unnecessary because they already keep a file on mechanic training. MSHA believes this provision is important because not all mine operators are as careful in employing only qualified persons to maintain the emissions-related components of their diesel equipment. For mine operators that do, this requirement should not be burdensome. For mine operators that don't, this requirement will prevent unqualified persons from performing improper maintenance procedures on this equipment, thereby preventing this equipment from generating potentially excessive diesel emissions.

Another commenter recommended that the final rule should include minimum qualifications for persons responsible for ventilation at underground metal and nonmetal mines. The recommendation applied to mines employing greater than 20 miners, and suggested that the minimum qualification should be a mining engineering degree from an accredited university having a program that includes training in the theory and practice of underground metal and nonmetal mine ventilation, and that qualified persons should also have some minimum level of operating experience in this field. MSHA believes that its existing ventilation regulations and this final dpm rule are appropriately performance oriented regarding the use of mine ventilation as a dpm control measure. Mine operators who rely on ventilation will be judged by MSHA according to their success in complying with the final concentration limit. Therefore, the final rule has not been changed to require persons who are responsible for ventilation at mines employing more than 20 miners to meet any minimum qualifications.

Section 57.5067 Engines

The final rule requires that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine in the future have to either be engines approved by MSHA under part 7 or part 36 or engines that meet or exceed the applicable dpm emission requirements of the EPA explicitly incorporated into a table in the rule. This requirement takes effect 60 days after the date this rule is promulgated. Only engines approved by MSHA as permissible can be used in areas of the mine where permissible diesel equipment is required. The composition of the existing fleet in an underground metal and nonmetal mine is not impacted by this part of the final rule. However, after the rule's effective date, any engine introduced into the underground areas of the mine must be either MSHA approved or meet the applicable EPA requirements. The term ''introduced'' is explicitly defined in the final rule to eliminate uncertainty regarding MSHA's intent. Engines that are introduced means engines in newly purchased equipment, engines in used equipment brought into the mine, or replacement engines that have a different serial number than the engine it is replacing. The term introduced does not include engines that were previously part of the mine inventory and rebuilt.

The final rule reflects a change from the proposed rule. The proposed rule would have required that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine in the future would have to have been approved by MSHA under Part 7 or Part 36. As discussed below, after reviewing the comments on this topic, MSHA concluded that it could accomplish the same goal, while providing operators with considerable extra flexibility, by permitting engines compliant with applicable EPA standards as an alternative to MSHA approved engines.

Table § 57.5067–1 in the final rule lists the applicable EPA dpm standards for diesel engines. The EPA standards represent the dpm emission limits set by EPA for light duty vehicles, light duty trucks, heavy duty highway engines, and nonroad engines. MSHA believes that all engines used in underground M/NM mines would come from these categories. MSHA chose the current on-highway dpm standards that have been in effect since 1994 for any commercially available on-highway vehicle. For nonroad, MSHA mainly used the EPA tier 1 standards that have been in effect starting in 1996 through 2000.

MSHA did notice one gap in the EPA nonroad standards. For engines in the 50 to 175 horsepower range, EPA did not list a dpm standard for tier 1. A tier 2 standard is listed in the final rule table for this reason. Full EPA implementation of the tier 2 standard for this horsepower range will become effective in 2003 for engines from 50–100 horsepower and in 2004 for engines 100 to 175 horsepower. However, MSHA believes that engines in this horsepower range are available now to meet the standard. MSHA has approved many engines under part 7 in this horsepower range that would meet the standard, and engine manufacturers are also producing other engine models in this horsepower range that meet the standard. The dpm requirement is the same for this engine horsepower range as was specified for engines in light duty vehicles in the coal final rule. Therefore, MSHA does not believe that mine operators will have problems introducing engines that meet any of the requirements of this section.

Several commenters questioned the need for engine restrictions at all if the applicable concentration limit could be achieved through other means. The rationale for this requirement is to promote the gradual turnover of the existing fleet to better, less-polluting engines, thereby reducing dpm concentrations and attendant health risks. Without this requirement, there would be no constraint on the introduction of engines that are inherently higher polluting into underground metal and nonmetal mines. Such engines, regardless of the level of maintenance they receive, produce significantly higher dpm emissions than the low polluting engines mandated in the final rule. MSHA acknowledges that older, high polluting engines will eventually be replaced with low polluting engines through the normal equipment turnover process, because EPA emission requirements (and similar requirements imposed by foreign regulatory bodies) will make high polluting engines increasingly difficult for manufacturers to sell for any application. Even if a mine operator wanted to continue using high polluting engines, such engines will become more and more scarce over time. But in light of the risks of dpm exposure to miners, and the history of the underground mining industry to bring old engines underground and keep them operating for a long period of time, MSHA has concluded that a rule is required to bring about the transition to newer engines more quickly than would otherwise be the case. MSHA considers the gradual introduction of cleaner engines to be one of the ''best practices'' that is feasible for all underground metal and nonmetal mines. Further elaboration on the rationale for mandating these ''best practices'' was included in the preamble to the proposal (63 FR 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed ''Meeting the concentration limit, operator choice of engineering controls.''

Other commenters recommended that EPA certification be an acceptable alternative to MSHA approval. As noted above, after considering the matter, MSHA agrees that engines certified as meeting applicable EPA standards would provide an acceptable level of protection to miner health comparable to that which can be achieved by requiring MSHA approved engines. (For detailed information about the various ''tiers'' of EPA engine requirements, and the various types of engine categories, please see Part II, section 5). Therefore, under the final rule, engines meeting or exceeding applicable particulate emission requirements of the Environmental Protection Agency (as listed in the table in § 57.5067(b)) are an acceptable alternative to engines approved by MSHA as nonpermissible under subpart E of Part 7 of this title. This change in the final rule will provide mine operators with a wider choice of acceptable engines, and may reduce compliance costs.

MSHA is developing a program that will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA approval programs for engines used in off-road applications. MSHA will continue to issue approvals for mining engines, but the application process will be abbreviated. Many of the provisions of part 7 are intended to ensure that engines continue to be manufactured in the same configuration and with the same emissions as the engine tested by MSHA. Procedures within the EPA approval programs reach the same end. Additionally, EPA has the resources and the regulatory authority to conduct an extensive quality assurance program to monitor emissions from production engines. In addition to streamlining the application process, MSHA will establish a program under which the engine emission tests conducted for EPA approval will satisfy the part 7 testing requirements. The test cycles under which emissions are tested for both MSHA and EPA are identical, and the gaseous emission results from the EPA tests can be used to establish the ventilating air quantity that appears on the engine approval plate and is referenced in mine ventilation regulations. MSHA will announce the specifics of the program when it is finalized. A listing of MSHA approved nonpermissible engines has been provided on MSHA's Internet web site. This listing can be accessed at the following address: http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM.

Many underground metal and nonmetal mines are accustomed to employing front end loaders, haulage trucks, and other production equipment that is developed for, and primarily marketed to the surface mining and construction industries. Likewise, where conditions permit, underground metal and nonmetal mines often employ support vehicles such as pickup trucks, sport utility vehicles, and other small to medium sized trucks that are developed for, and primarily marketed to the surface over-the-road market. Mine operators employ this equipment because it is significantly less costly than purpose-built underground mining equipment, which has special mine-duty features and is produced in relatively low volume.

The engines in newly manufactured surface off-road equipment and over-the-road vehicles are already required to comply with EPA dpm emission regulations. EPA regulations are fashioned in a Tier structure whereby engines in designated horsepower ranges are required to meet increasingly stringent emissions levels. By changing the final rule as indicated above to accept engines meeting or exceeding applicable particulate emission requirements of the EPA, MSHA is, in essence, allowing mine operators to continue the long-standing and cost-effective practice of employing standard off-road equipment and over-the-road vehicles underground (if they are equipped with engines meeting the appropriate EPA requirements), without requiring potentially costly retrofits of approved engines. This change will enable mine operators and mine workers to gain the added benefits of engines that incorporate the most recent emission reducing technology.

Laboratory testing to certify that an engine meets the applicable EPA particulate matter limit or MSHA approval requirements is not the responsibility of the mine operator. MSHA approved engines carry an approval plate so they are easy to distinguish. Engines produced after the date indicated in the Table incorporated into 5067(b) will meet the EPA requirements for the listed category of engines.

Engines in diesel-powered ambulances and fire-fighting equipment are exempted from these requirements. This exemption is identical with that in the rule for diesel-powered equipment in underground coal mines. The rationale for this exemption is that the usage of these vehicles and equipment is so limited that their contribution to overall dpm levels in a mine is negligible. MSHA wishes to caution mine operators, however, that this exemption is intended to apply only to equipment that is used exclusively as an ambulance or fire fighting equipment. This exemption does not apply to vehicles and equipment that are normally used for other purposes, but serve as an ambulance or fire fighting equipment in the event of an accident or mine emergency.

Section 57.5070 Miner Training

Section 57.5070 requires any miner ''who can reasonably be expected to be exposed to diesel emissions'' be trained annually in: (a) The health risks associated with dpm exposure; (b) the methods used in the mine to control dpm concentrations; (c) identification of the personnel responsible for maintaining those controls; and (d) actions miners must take to ensure the controls operate as intended. The final rule is the same as that proposed, and is identical to the rule being established for underground coal miners through MSHA's rulemaking limiting dpm concentrations in underground coal mines.

The purpose of these requirements is to promote miner awareness. Exposure to diesel particulate is associated with a number of harmful effects as discussed in Part III of this preamble, and the safe level is unknown. Miners who work in mines where they are exposed to this risk ought to be reminded of the hazard often enough to make them active and committed partners in implementing actions that will reduce that risk.

The training need only be provided to miners who can reasonably be expected to be exposed at the mine. The training is to be provided by operators; hence, it is to be without fee to the miner.

The rule places no constraints on the operator as to how to accomplish this training. MSHA believes that the required training can be provided at minimal cost and minimal disruption. The proposal would not require any special qualifications for instructors, nor would it specify the hours of instruction.

Instruction could take place at safety meetings before the shift begins. Devoting one of those meetings to the topic of dpm would be a very easy way to convey the necessary information. Simply providing miners with a copy of MSHA's ''Toolbox'' and, a copy of the plan, if a control plan is in effect for the mine, and reviewing these documents, can cover several of the training requirements. One-on-one discussions that cover the required topics are another approach that can be used.

Operators could also choose to include a discussion on diesel particulate matter emissions in their Part 48 training, provided the plan is approved by MSHA. There is no existing requirement that Part 48 training include a discussion of the hazards and control of diesel emissions. While mine operators are free to cover additional topics during the Part 48 training sessions, the topics that must be covered during the required time frame may make it impracticable to cover the additional material on dpm. Where adequate time is available at mines using diesel-powered equipment, operators would be free to include the dpm instruction in their Part 48 training plans. Since inclusion of dpm-related training in Part 48 training plans is not explicitly prohibited in the final rule, MSHA does not believe special language is required to permit this practice.

The final rule does not require the mine operator to separately certify the completion of the dpm training, but some evidence that the training took place would have to be produced upon request. A serial log with the employee's signature is an acceptable practice. To assist mine operators with this training requirement, it is MSHA's intent to develop an instructor's guide and corresponding training materials.

A few comments were received on § 57.5070, including the suggestion that such training be included under Part 48, and the opposing view that such training be independent of Part 48. Arguments in favor of including the training under Part 48 focused on the need to simplify the rule by not requiring separate diesel particulate emissions training and training recordkeeping. Arguments opposed focused on the difficulty of including more subject matter into a Part 48 training plan that is already overfilled. It was also noted that Part 48 training requires MSHA-certified instructors. By separating Part 48 training from the training required under § 57.5070, mine operators would have greater flexibility in choosing instructors.

MSHA believes the final rule satisfies both positions because inclusion of the specified diesel particulate emissions training topics under Part 48 training is neither required nor prohibited. Mine operators wishing to incorporate diesel emissions training in their Part 48 training plan are free to do so, whereas those wishing to conduct diesel emissions training separate from Part 48 training are equally free to choose that option. MSHA believes it is significant that none of the commenters discounted the importance of providing dpm-exposed miners with such training; their comments only addressed the mechanics of how such training should be delivered.

In its preamble to the proposed rule, MSHA specifically invited comment as to whether special language should be included in the final rule that would expressly permit required dpm training to be incorporated into Part 48 training. Only one commenter responded, expressing the view that special language was not necessary. Therefore, MSHA did not change this provision in the final rule.

Another commenter suggested that training required under § 57.5070 incorporate mandatory coverage of underground metal and nonmetal mine ventilation, that such training address auxiliary ventilation and the use of elementary ventilation measurement instruments, and that similar training be mandatory for first and second line supervisors.

MSHA agrees that ventilation is an important topic and that ventilation can have a significant effect on dpm concentrations underground. However, MSHA believes it would be inappropriate to specify the content of dpm-related miner training to the level of detail suggested by the commenter. Since MSHA allows mine operators considerable freedom to choose dpm control measures, MSHA expects significant variability from mine to mine in the mix of controls selected. For example, some mines may rely heavily on ventilation to comply with the applicable concentration limit, but other mines may rely more on enclosed cabs or diesel particulate filters. As a result, the most important training subject or subjects at one mine could be quite different at another mine.

By requiring training in the health risks associated with dpm exposure, the methods used in the mine to control dpm concentrations, identification of the personnel responsible for maintaining those controls, and the actions miners must take to ensure the controls operate as intended, MSHA believes it has established performance-based training requirements that are applicable to all mines.

As with the proposed rule, the final rule does not require the mine operator to separately certify the completion of dpm training, but some evidence that the training took place will have to be produced upon MSHA request. In this regard, as noted in the preamble to the proposed rule, a serial log with the employee's signature is an acceptable practice. Nevertheless, some commenters complained that the recordkeeping requirements in the training provisions are burdensome, and don't reduce diesel emissions. MSHA believes that dpm training is an essential element of a comprehensive dpm control program because miners who are fully informed are more apt to become active and committed partners in implementing an effective dpm control strategy. In this way, training can have an indirect, yet substantive and positive influence on reducing dpm exposure. The corresponding recordkeeping requirements are important, because the records are the means by which MSHA can insure that the mine operator is complying with the training requirements.

As noted in the preamble to the proposed rule, to assist mine operators with this training requirement, it is MSHA's intent to develop an instruction outline that mine operators can use as a guide for training personnel. Instruction materials will be provided with the outline.

Section 57.5071 Environmental Monitoring

The final rule requires mine operators to monitor as often as necessary to effectively evaluate, under conditions that can be reasonably anticipated in the mine—(1) whether the concentration of dpm in an area where miners normally work or travel exceeds the applicable concentration limit; and (2) the average full shift airborne concentration at any position or on any person designated by the Secretary. This section also requires operators to provide affected miners and their representatives with notice and an opportunity to observe monitoring, to initiate corrective action by the next work shift should monitoring reveal a violation and to promptly complete such action, and requires certain posting and recordkeeping. The final rule is the same as the proposed rule.

Operator's Monitoring Responsibility. Section 57.5071(a) requires mine operators to monitor the underground mine environment to insure dpm concentrations are within compliance limits wherever the limits apply. Sampling, which could be area sampling, personal sampling, or occupational sampling, is required as often as necessary to ''effectively determine''—under conditions that can be reasonably anticipated in the mine—(1) whether the dpm concentration in any area of the mine where miners normally work or travel exceeds the applicable limit; and (2) the average full shift airborne concentration at any position or on any person designated by the Secretary.

This requirement is similar to existing § 57.5002 which requires mine operators to conduct dust, gas, mist, and fume surveys as frequently as necessary to determine the adequacy of control measures, and to existing § 62.110(a) and (b) which requires mine operators to measure each miner's noise dose sufficient to determine continuing compliance with the established noise limits. Under § 57.5071(a), mine operators are required to monitor dpm concentrations in much the same way they are already required to monitor dust, gas, mist, fume, and noise.

There are three important aspects of this operator monitoring requirement.

First, the responsibility for dpm monitoring rests with the mine operator, not with MSHA. Mine operators cannot rely on MSHA inspectors to conduct dpm monitoring whenever and wherever necessary to ensure compliance with the applicable dpm concentration limit. The purpose of operator monitoring is to determine continuing compliance, whereas the purpose of MSHA sampling is to identify non-compliance. MSHA sampling is neither intended for, nor capable of determining continued compliance.

Second, the information gathered through operator monitoring is to be used by the operator to determine whether action is necessary to maintain compliance anywhere the applicable concentration limits apply in the mine. Gathering dpm concentration data, though necessary, is not the final goal in itself. The reason for gathering this information is so it can be used by the mine operator to assess the effectiveness of dpm control measures. Sampling results which indicate non-compliance should prompt the mine operator to initiate whatever actions are required (i.e., implementation of appropriate engineering controls and work practices) to achieve compliance wherever the applicable concentration limits apply.

Third, this requirement ensures special attention will be focused on locations or persons known to MSHA to have a significant potential for overexposure to dpm.

The obligation of operators to ''effectively determine'' dpm concentrations in a mine is a separate obligation from that to keep dpm levels below the established limit, and can be the basis of a separate citation from MSHA. The final rule is performance-oriented in that the regularity and methodology used to make this evaluation are not specified. However, MSHA expects mine operators to sample with such frequency that they and the miners working at the mine site are aware of dpm levels in their work environment. In this regard, MSHA's own measurements will assist the Agency in verifying the effectiveness of an operator's monitoring program. If an operator is ''effectively determining'' the concentration of dpm at designated positions, for example, MSHA would not expect to regularly record concentrations above the limit when it samples at that location. If MSHA does find such a problem, it will investigate to determine how frequently an operator is sampling, where the operator is sampling, and what methodology is being used, so as to determine whether the obligation in this section is being fulfilled. (See previous discussion in this Part in the portion of § 57.5062 that addressed ''Demonstration of plan effectiveness'' for further information on the number of samples required to demonstrate continuing compliance.)

Operator Monitoring Methods. The final rule requires that full-shift diesel particulate concentrations be determined during periods of normal production or normal work activity in areas where miners work or travel. The rule does not specify a particular monitoring method or frequency; rather, the rule is performance-oriented. Operators may, at their discretion, conduct their monitoring using the same sampling and analytical method as MSHA, or they may use any other method that enables that mine to ''effectively determine'' the concentrations of dpm.

As required by § 57.5061, MSHA will collect samples using a respirable dust sampler equipped with a submicrometer impactor, and use NIOSH Method 5040, the sampling and analytical method that NIOSH has developed for accurately determining the concentration of total carbon, to determine compliance. Operators who must comply with the terms of a diesel particulate control plan pursuant to § 57.5062 must, as noted in the requirements of that section, use the same sampling and analytical method as MSHA to verify plan effectiveness; monitoring performed for that purpose would probably meet the obligation under § 5071 if it is done with enough sufficiency to meet the obligation under § 57.5062(c). But the method may not be necessary to effectively determine dpm in some mines for purposes of § 57.5071(a). For example, dpm measurements in limestone, potash and salt mines could be determined using the RCD method, since there are no large carbonaceous particles present that would interfere with the analysis. For hydrated minerals such as gypsum and trona, a two-step RCD method would be necessary, wherein the first step would elevate the temperature of the sample sufficient to cause dehydration (105 °C). The sample is then reweighed, and the conventional RCD analysis procedure is followed. Such estimates can be useful in determining the effectiveness of controls and where more refined measurements may be required.

Of course, mine operators using the RCD or size-selective methods to monitor their diesel particulate concentrations would have to convert the results to a TC equivalent to ascertain their compliance status. At the present time, MSHA has no conversion tables for this purpose, however a simple conversion approach would be to adjust the sampling result to the corresponding estimated whole dpm concentration, then multiply that value by 0.8. In most cases, the other methods will provide a good indication of whether controls are working and whether further action is required.

Part II of this preamble provides information on monitoring methods and their constraints, and on laboratory and sampler availability.

One commenter observed that area sampling outside of an enclosed cab would defeat the purpose of installing the cab, and would diminish the status of such a cab, which is a recognized engineering control, to that of personal protective equipment, which is prohibited under the rule. MSHA agrees that area sampling is inappropriate where miners are protected by enclosed cabs with filtered breathing air and no other miners are required to work in the area outside of the cab. As discussed under section 5061(c)(3), area sampling by MSHA for compliance purposes would not be conducted outside of an enclosed cab unless miners are working in the area outside of such cabs, and MSHA would urge operators to follow the same approach. Also, as noted in discussing that section, personal sampling within cabs operated by smokers should only be conducted if the equipment operator agrees not to smoke during the sampling period.

Observation of Monitoring. Section 103(c) of the Mine Act requires that:

> The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act. Such regulations shall provide miners or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof.

In accordance with this legal requirement, § 57.5071(b) of the final rule requires a mine operator to provide affected miners and their representatives with an opportunity to observe exposure monitoring required by this section. Mine operators must give prior notice of the date and time of intended monitoring so that affected miners and their representatives can exercise their right to observe the monitoring if they so choose.

Comments addressing § 57.5071(b) questioned the meaning of the terms ''miner's representative'' and ''affected miners,'' and objected to paying miners to observe dpm monitoring.

MSHA intends for miner's representative to mean any authorized representative of the miners. A representative of the miners could, but does not necessarily have to be, a representative of a certified union. Limiting representatives of miners to certified unions is a violation of the Mine Act and departs from previous MSHA practice.

MSHA intends for affected miners to mean the miners that are potentially exposed to the diesel particulate matter being monitored. The commenter suggested that this provision ''* * * leaves too much for interpretation. How many employees may observe? For how long?'' Consistent with the Mine Act, MSHA does not intend to limit the number of miners who may observe dpm monitoring, however, such miners need not be paid if, as a result of observing the monitoring, they are not performing their jobs.

Corrective Action if Concentration Is Exceeded. Section 57.5071(c) provides that if any monitoring performed under this section indicates that the applicable dpm concentration limit has been exceeded, an operator shall initiate corrective action by the next work shift, promptly post a notice of the corrective action being taken and promptly complete such corrective action.

The Agency wishes to emphasize that operator monitoring of dpm concentrations would not take the place of MSHA sampling for compliance purposes; rather, this requirement is designed to ensure the operator checks dpm concentrations on a more regular basis than is possible for MSHA to do. Paragraph (c) provides that if sampling results indicate the concentration limit has been exceeded in an area of a mine, an operator would initiate corrective action by the next work shift and promptly complete such action. Paragraph (c) does not require an operator to establish a dpm control plan. The establishment of a dpm control plan is triggered by a non-compliance determination based on sampling conducted by the Secretary.

In certain types of cases (*e.g.,* 30 CFR 75.323), MSHA has required that when monitoring detects a hazardous level of a substance, miners must be immediately withdrawn from an area until abatement action has been completed. Although MSHA did not include such a requirement in the final rule, MSHA in its proposal did solicit comment from the mining industry concerning this practice, especially in light of the evidence presented on the various risks posed by exposure to diesel particulate, including material presented in the preamble to the proposal that acute short-term increases in exposure can pose significant risks to miner health. The comments that were received in response to this solicitation were opposed to a provision requiring immediate withdrawal.

The agency also specifically asked for comments on three other points (63 FR 58189, 58190). First, the agency noted that it welcomed comments as to what guidance to provide with respect to corrective actions required where an operator is not using the total carbon analytical method. Second, the agency noted it welcomed comment as to whether personal notice of corrective action would be more appropriate than posting, given the health risks involved. Third, the agency solicited comment on whether clarification of the proposed requirement was needed in light of the fact that operators using more complex analytical procedures (*e.g.,* the total carbon method) may not receive the results for some time period after the posting has taken place.

No comments addressing these points were received.

Posting of Sample Results. Section 57.5071(d)(1) requires that monitoring results be posted on the mine bulletin board within 15 days of receipt, and remain posted for 30 days. A copy of the results must also be provided to the authorized miners' representative. Posting of the results will ensure that miners are kept aware of the hazard so they can actively participate in efforts to control dpm.

Comments that addressed this paragraph recommended that sampling results should not be given to the representative of the miners because this information is private, and recommended that mine operators should not be cited for posting sampling results that exceed the applicable concentration limit.

MSHA disagrees with the assertion that dpm sampling results are private, and therefore, such results should not be given the representative of the miners. The Mine Act clearly states that miners or their representatives have a legal right to access to exposure monitoring information.

Regarding the question of MSHA issuing a citation based on a mine operator posting sampling results that exceed the applicable concentration limit, it is not MSHA's intent to issue a citation under these circumstances. If such sampling indicates that dpm levels exceed the applicable concentration limit, a citation may be issued if the mine operator fails to initiate corrective action by the next work shift, as required under § 57.5071(c). However, mine operator sampling results that exceed the applicable limit is not, by itself, a violation.

MSHA recognizes that this is an important point, and reiterates that, as indicated in § 57.5061, MSHA itself is to conduct compliance sampling.

Retention of Sample Results. Section 57.5071(d)(2) requires that records of the sampling method and the sample results themselves be retained by mine operators for five years. This is because the results from a monitoring program can provide insight as to the effectiveness of controls over time, and provide a history of occupational exposures at the mine.

In the preamble to the proposed rule, MSHA welcomed comments on the sample retention period appropriate for the risks involved. None were received.

In the preamble to the proposed rule, MSHA also asked for comments regarding the advisability of instituting a system of medical surveillance of miners exposed to dpm to identify miners suffering ill effects of dpm exposure, and the subsequent medical removal of miners who are determined to be suffering such ill effects. The comments received in response to this request suggested that medical surveillance for excessive dpm exposure is not feasible at this time because the appropriate biological tests or markers do not exist. One commenter observed that they were, ''* * * unaware of any recognized or generally accepted examinations or tests for detecting whether miners are suffering from ill effects as a result of diesel particulate or exhaust exposure. This view is supported by EPA's Health Assessment Document for Diesel Emissions which states, 'There is no single medical test to determine if DP exposure has occurred. Many symptoms of episodic DP exposure are similar to symptoms caused by other agents or, in some cases, onset of a common cold. Invasive sampling of particle deposits in the upper respiratory tract or lung could be done, yet such particles may not be readily distinguishable from particulate matter from other sources' [EPA, 1998].'' MSHA agrees with these commenters that appropriate medical testing protocols are not currently available. Therefore, provision for neither medical surveillance nor medical removal protections have been incorporated into the final rule.

Section 57.5075 Diesel Particulate Records

Various recordkeeping requirements are set forth in the provisions of the final rule. For the convenience of the mining community, these requirements are also listed in a table entitled ''Diesel Particulate Recordkeeping Requirements,'' which can be found in § 57.5075(a). Each row involves a record that must be kept. The section requiring the record be kept is noted, along with the retention time.

This approach—having a summary table of recordkeeping requirements included in various sections of the rule—is identical to that taken in the proposed rule. MSHA indicated in the preamble to the proposed rule that it would welcome input from the mining community as to whether it liked this approach or found it duplicative or confusing, however, no comments were received.

Location of Records. Section 57.5075(b)(1) provides that any record which is required to be retained at the mine site may be retained elsewhere if it is immediately accessible from the mine site by electronic transmission. Compliance records need to be accessible to an inspector so they can be viewed during the course of an inspection, as the information in the records may determine how the inspection proceeds. If the mine site has a fax machine or computer terminal, there is no reason why the records cannot be maintained elsewhere. MSHA's approach in this regard is consistent with Office of Management and Budget Circular A–130.

One commenter, though supporting the concept of off-site electronic records storage, questioned MSHA's intent relative to the term ''immediately accessible.'' As noted above, MSHA intends that records maintained off-site be made available to an MSHA inspector so the information can be used to guide inspection decisions. Thus, undue delay in retrieving this information from off site electronic storage would impede an inspection, and would not be permitted. If the records are maintained in hardcopy form at an off-site location, and considering the time required to contact off-site personnel to request the records, for those personnel to locate and remove the records from the files, and to fax the records to the mine site, a delay of one or two hours would not be unreasonable. If records are maintained in an off-site electronic database, it is reasonable to assume they could be electronically transmitted to the mine site even faster; perhaps one hour or less.

These time frames are in contrast to the requirement in MSHA's new noise regulation for noise records to be accessible to the MSHA inspector, but not ''immediately accessible.'' The guideline established in the Preamble to the final noise rule states that records must be provided to the MSHA inspector within one business day or less (p. 49625).

The commenter notes further that, ''Even with Y2K compliant systems, computer and electronic transmission equipment is not 100% reliable, especially in remote mining environments.'' MSHA agrees that an insistence on 100% reliability of computer and electronic transmission equipment is unreasonable. However, MSHA will not accept chronic computer or electronic transmission problems as a justification for the repeated denial of timely access to the required records. If chronic computer or electronic transmission problems make ''immediate'' access to records problematic, such records would have to be kept at the mine site.

Records Access. Section 57.5075(b) also covers records access. Consistent with the statute, upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators are to promptly provide access to any record listed in the table in this section. A miner, former miner, or, with the miner's or former miner's written consent, a personal representative of a miner, is to have access to any exposure record required to be maintained pursuant to § 57.5071 to the extent the information pertains to the miner or former miner. Upon request, the operator must provide the first copy of such record at no cost. Whenever an operator ceases to do business, that operator would be required to transfer all records required to be maintained by this part to any successor operator.

General Effective Date of Part 57. The rule provides that unless otherwise specified, its provisions take effect 60 days after the date of promulgation of the final rule. Thus, for example, the requirements to implement certain work practice controls (*e.g.,* fuel type) go into effect 60 days after the final rule is published.

A number of provisions of the final rule contain separate effective dates that provide more time for technical support. For example, the initial concentration limit for underground metal and nonmetal mines would be delayed for 18 months.

A general outline of effective dates is summarized in Part I of this preamble.

Additionally, the paperwork provisions will not become effective until approved by the Office of Management and Budget.

V. Adequacy of Protection and Feasibility of Final Rule; Alternatives Considered

The Mine Act requires that in promulgating a standard, the Secretary, based on the best available evidence, shall attain the highest degree of health and safety protection for the miner with feasibility a consideration.

Overview. This part begins with a summary of the pertinent legal requirements, followed by a general profile of the economic health and prospects of the metal and nonmetal mining industry.

The final rule establishes a concentration limit for dpm, supplemented by monitoring and training requirements. An operator in the metal and nonmetal sector would have the flexibility to choose any type or combination of engineering controls to keep dpm levels at or below the concentration limit. This part evaluates the final rule to ascertain if, as required by the statute, it achieves the highest degree of protection for underground metal and nonmetal miners that is feasible, both technologically and economically, for underground metal and nonmetal mine operators to provide.

Several regulatory alternatives to the final rule were also reviewed by MSHA in light of the record. The Agency has concluded that compliance with these alternatives either provide less protection than the feasible approach being adopted, or are not technologically or economically feasible for the underground metal and nonmetal industry as a whole at this time.

Pertinent Legal Requirements. Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) states that MSHA's promulgation of health standards must:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary of Labor (Secretary), in promulgating mandatory standards pertaining to toxic materials or harmful physical agents, base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration.

In relation to feasibility, the legislative history of the Mine Act states that:

> * * *Section further provides that ''other considerations'' in the setting of health standards are ''the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.'' While feasibility of the standard may be taken into consideration with respect to engineering controls, this factor should have a substantially less significant role. Thus, the Secretary may appropriately consider the state of the engineering art in industry at the time the standard is promulgated. However, as the circuit courts of appeal have recognized, occupational safety and health statutes should be viewed as ''technology-forcing'' legislation, and a proposed health standard should not be rejected as infeasible when the necessary technology looms in today's horizon. *AFL-CIO* v. *Brennan,* 530 F.2d 109 (1975); *Society of the Plastics Industry* v. *OSHA,* 509 F.2d 1301, *cert. denied,* 427 U.S. 992 (1975).

Similarly, information on the economic impact of a health standard which is provided to the Secretary of Labor at a hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of [this section], the Committee wishes to emphasize that it rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure. S. Rep. No. 95–181, 95th Cong., 1st Sess. 21 (1977).

Court decisions have clarified the meaning of feasibility. The Supreme Court, in *American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 101 S.Ct. 2478 (1981), defined the word ''feasible'' as ''capable of being done, executed, or effected.'' The Court stated that a standard would not be considered economically feasible if an entire industry's competitive structure was threatened. According to the Court, the appropriate inquiry into a standard's economic feasibility is whether the standard is capable of being achieved.

Courts do not expect hard and precise predictions from agencies regarding feasibility. Congress intended for the ''arbitrary and capricious standard'' to be applied in judicial review of MSHA rulemaking (S.Rep. No. 95–181, at 21.) Under this standard, MSHA need only base its predictions on reasonable inferences drawn from the existing facts. MSHA is required to produce reasonable assessment of the likely range of costs that a new standard will have on an industry. The agency must also show that a reasonable probability exists that the typical firm in an industry will be able to develop and install controls that will meet the standard. See, *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 91 S.Ct. 814 (1971); *Baltimore Gas & Electric Co.* v. *NRDC*, 462 U.S. 87 103 S.Ct. 2246, (1983); *Motor Vehicle Manufacturers Assn.* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 103 S.Ct. 2856 (1983); *International Ladies' Garment Workers' Union* v. *Donovan*, 722 F.2d 795, 232 U.S. App. D.C. 309 (1983), *cert. denied*, 469 U.S. 820 (1984); *Bowen* v. *American Hospital Assn.*, 476 U.S. 610, 106 S.Ct. 2101 (1986).

In developing a health standard, MSHA must also show that modern technology has at least conceived some industrial strategies or devices that are likely to be capable of meeting the standard, and which industry is generally capable of adopting. *United Steelworkers of America* v. *Marshall*, 647 F.2d 1189, 1272 (1980). If only the most technologically advanced companies in an industry are capable of meeting the standard, then that would be sufficient demonstration of feasibility (this would be true even if only some of the operations met the standard for some of the time). *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825, (3d Cir. 1978); see also, *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (1974).

Industry Profile. This industry profile provides background information about the structure and economic characteristics of the mining industry. It provides data on the number of mines, their size, the number of employees, and the diesel powered equipment used.

The Structure of the Metal/Nonmetal Mining Industry. MSHA divides the mining industry into two major segments based on commodity: (1) Coal mines and (2) metal and nonmetal (M/NM) mines. These segments are further divided based on type of operation (*e.g.,* underground mines or surface mines). MSHA maintains its own data on mine type, size, and employment, and the Agency also collects data on the number of independent contractors and contractor employees by major industry segment.

MSHA categorizes mines by size based on employment. For the past 20 years, for rulemaking purposes, MSHA has consistently defined a small mine to be one that employs fewer than 20 workers and a large mine to be one that employs 20 or more workers. To comply with the requirements of the Small

Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), however, an agency must use the Small Business Administration's (SBA's) criteria for a small entity-¾ for mining, 500 or fewer employees ¾ when determining a rule's economic impact.

Table V–1 presents the total number of small and large mines and the corresponding number of miners, excluding contractors, for the M/NM mining segment. The M/NM mining segment consists of metal mines (copper, iron ore, gold, silver, etc.) and nonmetal mines (stone including granite, limestone, dolomite, sandstone, slate, and marble; sand and gravel; and others such as clays, potash, soda ash, salt, talc, and pyrophyllite.) As Table II–1 indicates, 98 percent of all M/NM mines are surface mines, and these mines employ some 90 percent of all M/NM miners, excluding office workers. Table V–2 presents corresponding data on the number of independent contractors and their employees working in the M/NM mining segment.

TABLE V–1.—DISTRIBUTION OF M/NM MINE OPERATIONS AND EMPLOYMENT (EXCLUDING CONTRACTORS) BY MINE TYPE AND SIZE [a]

Size of M/NM mine [b]	Mine type			
	Underground	Surface	Office workers	Total M/NM
Fewer than 20 employees:				
Mines	134	9,635	....	9,769
Employees	1,054	54,356	9,160	64,570
20 to 500 employees:				
Mines	124	1,419	....	1,543
Employees	11,299	79,675	15,040	106,014
Over 500 employees:				
Mines	7	18	....	25
Employees	4,594	16,836	3,543	24,973
All M/NM mines:				
Mines	265	11,072	....	11,337
Employees	16,947	150,867	27,743	195,557

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CM441/CM935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1997 Closeout Edition) Table 2, p. 6.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

TABLE V–2.—DISTRIBUTION OF M/NM CONTRACTORS AND CONTRACTOR EMPLOYMENT BY SIZE OF OPERATION [a]

Size of contractors [b]	Contractors			
	Underground	Surface	Office workers	Total
Fewer than 20 employees:				
Mines	399	2,783	....	3,182
Employees	1,717	14,155	649	16,521
20 to 500 employees:				
Mines	36	349	....	384
Employees	1,639	17,979	802	20,420
Over 500 employees:				
Mines	....	3	....	3
Employees	....	2,560	105	2,665
Total contractors:				
Mines	434	3,135	....	3,569
Employees	3,356	34,694	1,556	39,606

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CT441/CT935LA cycle 1998/198. Data for total office workers from Mine Injury and Worktime Quarterly (1998 Closeout Edition) Table 6, p. 21.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

The M/NM mining sector consists of about 80 different commodities including industrial minerals. There were 11,337 M/NM mines in the U.S. in 1998, of which 9,769 (86%) were small mines and 1,568 (14%) were large mines, using MSHA's traditional definition of small and large mines. Based on SBA's definition, however, only 25 M/NM mines (0.2%) were large mines.[1]

The data in Table V–1 indicate that employment at M/NM mines in 1998 was 195,557, of which 64,570 workers (33%) were employed by small mines and 130,987 miners (67%) were employed by large mines, using MSHA's definition. Based on SBA's definition, however, 170,584 workers (87%) were employed by small mines and 24,973 workers (13%) were employed by large mines. Using MSHA's definition, the average employment is 7 workers at a small M/NM mine and 84 workers at a

[1] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

large M/NM mine.[2] Using SBA's definition, there are an average of 15 workers in each small M/NM mine and 888 workers in each large M/NM mine.

Metal Mining. There are about 24 metal commodities mined in the U.S. Underground metal mines use a few basic mining methods, such as room and pillar and block caving. The larger mines rely more heavily on hydraulic drills and track-mounted haulage, and the smaller underground metal mines rely more heavily on hand-held pneumatic drills

Surface metal mines normally include drilling, blasting, and hauling; such processes are typical in all surface mines, irrespective of commodity types. Surface metal mines in the U.S. rank among some of the largest mines in the world.

Metal mines constitute 3 percent of all M/NM mines and employ 23 percent of all M/NM miners. Under MSHA's traditional definition of a small mine, 45 percent of metal mines are small, and these mines employ 2 percent of all miners working in metal mines. Using SBA's definition, 94 percent of metal mines are small, and they employ 53 percent of all miners working in metal mines.[3]

Stone Mining. In the stone mining subsector, there are eight different stone commodities, of which seven are further classified as either dimension stone or crushed and broken stone. Stone mining in the U.S. is predominantly by quarrying, with only a few slight variations. Crushed stone mines typically drill and blast, while dimension stone mines generally use channel burners, drills, or wire saws. Diesel powered-haulage is used to transfer the broken rock from the quarry to the mill where crushing and sizing are done.

Stone mines constitute 33 percent of all M/NM mines, and they employ 41 percent of all M/NM miners. Using MSHA's definition of a small mine, 71 percent of stone mines are small, and these mines employ 29 percent of all miners working in stone mines. Using SBA's definition, 99.9 percent of stone mines are small, and they employ 99 percent of all miners working in stone mines.[4]

Sand & Gravel Mining. Sand and gravel, for construction, is generally extracted from surface deposits using dredges or draglines. Further preparation involves washing and screening. As in other surface mining operations, sand and gravel uses diesel-driven machines, such as front-end loaders, trucks, and bulldozers, for haulage. The preparation of industrial sand and silica flour involves the use of crushers, ball mills, vibrating screens, and classifiers.

The sand and gravel subsector represents the single largest commodity group in the U.S. mining industry when the number of mining operations is being considered. Sand and gravel mines comprise 57 percent of all M/NM mines, and they employ 22 percent of all M/NM miners. Using MSHA's definition of a small mine, 95 percent of sand and gravel mines are small, and these mines employ 76 percent of all miners working in sand and gravel mines. Using SBA's definition, almost 100 percent of sand and gravel mines are small, and they employ approximately 42,800 miners.[5]

Other Nonmetal Mining. For enforcement and statistical purposes, MSHA separates stone and sand and gravel mining from other nonmetal mining. There are about 35 other nonmetal commodities, not including stone, and sand and gravel. Nonmetal mining uses a wide variety of underground mining methods such as continuous mining (similar to coal mining), in-situ retorting, block caving, and room and pillar. The mining method is dependent on the geologic characteristics of the ore and host rock. Some nonmetal operations use kilns and dryers in ore processing. Ore crushing and milling are processes common to both nonmetal and metal mining.

As with underground mining, there is a wide range of mining methods utilized in extracting minerals by surface mining. In addition to drilling and blasting, other mining methods, such as evaporation and dredging, are also utilized, depending on the ore formation.

''Other'' nonmetal mines comprise 7 percent of all M/NM mines, and they employ 14 percent of all M/NM miners. Using MSHA's definition of a small mine, 66 percent of other nonmetal mines are small, and they employ 12 percent of all miners working in these nonmetal mines. Using SBA's definition, 99 percent of other nonmetal mines are small, and they employ 92 percent of all miners working in these nonmetal mines.[6]

Economic Characteristics of the Metal/nonmetal Mining Industry. The value of all M/NM mining output in 1998 was estimated at $40 billion.[7] Metal mines, which include copper, gold, iron, lead, silver, tin, and zinc mines, contributed $17.8 billion. Nonmetal production was valued at $22.2 billion: $9.0 billion from stone mining, $5.2 billion from sand and gravel, and $8 billion from other nonmetals such as potash, clay, and salt.

The end uses of M/NM mining output are diverse. For example, iron and aluminum are used to produce vehicles and other heavy duty equipment, as well as consumer goods such as household equipment and soft drink cans. Other metals, such as uranium and titanium, have more limited uses. Nonmetals, like cement, are used in construction while salt is used as a food additive and for road deicing in the winter. Soda ash, phosphate rock, and potash also have a wide variety of commercial uses. Stone and sand and gravel are used in numerous industries and extensively in the construction industry.

A detailed economic picture of the M/NM mining industry is difficult to develop because most mines are either privately held corporations or sole proprietorships, or subsidiaries of publicly owned companies. Privately held corporations and sole proprietorships are not required to make their financial data available to the public. Parent companies are not required to separate financial data for subsidiaries in their reports to the Securities and Exchange Commission. As a result, financial data are available for only a few M/NM companies, and these data are not representative of the entire industry.

Adequacy of Miner Protection Provided by the Final Rule in Underground Metal and Nonmetal Mines. In evaluating the rule for this purpose, it should be remembered that MSHA has measured dpm concentrations in this sector as high as $5,570_{DPM}$ µg/m^3—a mean of 808_{DPM} µg/m^3. See Table III–1 and Figure III–2 in part III of the preamble. As discussed in detail in part III of the preamble, these concentrations place underground metal and nonmetal miners at significant risk of material impairment of their health,

[2] U.S. Department of Labor, MSHA, 1998 final MIS data CM441 cycle 1998/198.

[3] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[4] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[5] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[6] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[7] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998,* July 1999, pp. 3, 6, 142, 158, and 160.

and it does not appear there is any lower boundary to the risk. Accordingly, in accordance with the statute, the Agency has to set a standard which reduces these concentrations as much as is both technologically and economically feasible for this sector as a whole.

Specifically, the standard establishes a concentration limit on dpm. The concentration limit is the equivalent of about 200_{DPM} µg/m³ (as explained in Part IV, in the rule the concentration limit is expressed in terms of a restriction on the amount of total carbon because of the measurement system which MSHA will utilize for compliance sampling).

Alternatives considered. In order to ensure that the maximum protection that is feasible for the underground mining industry as a whole is being provided, the Agency has considered three alternatives that would provide greater protection: a lower concentration limit, a significantly shorter implementation period, and requiring certain categories of metal and nonmetal equipment to be filtered in addition to observing a concentration limit. In addition, the agency has considered whether the approach it is taking in underground coal mines would be feasible in this sector. Specific alternatives and approaches suggested by industry and labor are discussed in detail in part IV.

(1) *Establish a lower concentration limit for underground metal/nonmetal mines.* Based on the Agency's risk assessment, a lower concentration limit would provide more miner protection. The Agency has concluded, however, that at this time it would not be feasible for the underground metal and nonmetal sector to reach a lower concentration limit. The problem is not technological feasibility, but rather economic feasibility.

Technological feasibility of lower limit. In evaluating whether a lower concentration limit is technologically feasible for this sector, MSHA considered several examples of real-world situations. These examples, and a detailed description of the methodology by which they were developed, were published in the preamble to the proposed rule (65 FR 58198 *et seq.*). The examples were based on data about equipment and ventilation from several actual underground metal and nonmetal mines: a salt mine; an underground limestone mine that operates two completely different shifts, one for production, and one for support; and a multi-level underground gold mine. The data was placed into a computer model to estimate the ambient dpm that would remain in a mine section after the application of a particular combination of control technologies. The details of this computer model, referred to as ''The Estimator'', has subsequently been published in the literature (Haney and Saseen, *Mining Engineering,* April 2000). The results for the salt and limestone mines were written up in detail and placed into MSHA's record, with actual mine identifiers removed; the study of the underground gold mine is based on information supplied by inspectors, and all available data was presented in the preamble to the proposed rule.

MSHA had picked these mines because the Agency originally thought the conditions there were such that these mines would have great difficulty in controlling dpm concentrations. As the results indicated, however, even in these apparently difficult situations the concentration of dpm could be lowered to well below 200_{DPM} µg/m³ with readily available control techniques. Moreover as noted above, MSHA can adopt a rule which is not feasible for every mine; the standard is that the rule be feasible for the industry as a whole.

MSHA did receive comments on the Estimator. However, no specific examples of its application were received nor comments taking issue with the examples discussed above. Specific comments received on the Estimator are addressed in part IV.

Economic feasibility of lower concentration limit. MSHA estimates that it will cost the underground metal and nonmetal industry about $25.1 million a year to comply with a concentration limit of 160_{TC} µg/m³ (200_{DPM} µg/m³). For an average underground metal and nonmetal dieselized mine that uses diesel powered equipment, this amounts to about $128,000 per year.

The assumptions used in preparing the cost estimates for the final review are discussed in detail in the Agency's REA. They are based on a careful review of the evidence on the capabilities of various controls, and a careful review of an economic analysis submitted on behalf of several industry associations. That analysis estimated costs to be three times as high as MSHA's initial estimate. MSHA's analysis and the industry analysis agree on many of their assumptions; however, MSHA believes the industry analysis to be an overestimation primarily because it failed to properly optimize.

In general, MSHA has concluded that:

- The interim standard of 400_{TC} µg/m³ (500_{DPM} µg/m³) will be met primarily through the use of filters, but with cabs and ventilation in certain instances; and
- The final standard of 160_{TC} µg/m³ (200_{DPM} µg/m³) will be met through the use of more filters, ventilation changes, and the turnover in equipment and engines to less polluting models that will have occurred by the time the final standard goes into effect.

Based on its cost estimates, the Agency has concluded that this sector would not find it economically feasible to reduce dpm concentrations to a lower limit at this time. The incremental cost of additional controls would rise sharply if the industry were required to reach a substantially lower concentration level. It would begin to be necessary to retrofit cabs on equipment that was not designed with cabs and/or did not have off-the-shelf parts—at a cost per unit nearly three times as great as the costs for more limited retrofitting of suitably designed equipment. Additional ventilation improvements (*e.g.,* new shafts) could easily run into the millions of dollars—compared with the $300,000 estimate for more limited ''major system improvements'' used in the cost analysis. Additional replacement of engines beyond the natural turnover included in the baseline could run as high as $27,500 for the engine itself, with additional costs possibly as high as $65,000 for equipment modifications and installation.

(2) *Significantly shorten the phase-in time to reach the final concentration limit in underground metal/nonmetal mines.* Under the rule, there is a phase-in period for a dpm concentration limit. Operators have 18 months to reduce dpm concentrations in areas of the mine where miners work or travel to 400_{TC} µg/m³ (500_{DPM} µg/m³), and up to 60 months in all to reduce dpm concentrations in those areas to 160_{TC} µg/m³ (200_{DPM} µg/m³).

MSHA has established this phase-in period because it has concluded that it is economically infeasible for the underground metal and nonmetal mining industry as a whole to implement the requirements sooner. The costs of the rule would increase significantly were the final concentration limit to become effective significantly sooner. For example, the turnover of the fleet to less polluting engines would not be as complete by the time the final limit goes into effect; hence, operators would be required to purchase new engines ahead of schedule. Moreover, a substantial portion of the costs to implement these provisions were calculated using a 5-year discounting process to reflect the phase-in schedule.

Technological feasibility problems might also be more frequent with a quicker implementation schedule. The rule includes a provision for a special time extension to deal with unique situations; shortening the normal time frame available to this sector would tend to increase the frequency upon which operators would have to apply for such extensions.

Accordingly, MSHA has concluded that, for the underground metal and nonmetal sector as a whole, a significantly accelerated approach would not be feasible.

(3) *In addition to a concentration limit, require certain types of equipment to utilize an 80% efficiency filter.* This approach would help reduce dpm concentrations in localized areas of a mine, and ensure that problems with ventilation controls will have less of an impact on miner exposures. Most filters can meet the 80% requirement. The requirement could be applied: (a) just to loading and hauling equipment (*e.g.,* trucks and loaders); (b) to the equipment in (a) plus equipment used in the production process (*e.g.,* drills, powered trucks); (c) to the equipment in (a) and (b) and also direct support equipment (*e.g.,* scalers, lube trucks, generators, compressors and pumps); or (d) to all equipment except personnel carriers and supply trucks.

Such an approach would limit operator flexibility on controls—the broader the requirement, the less the flexibility. And it would increase expense, since the most efficient way to achieve compliance with the concentration limit might well be another type of control (*e.g.,* new engine, cab, ventilation, etc.). Accordingly, MSHA has determined that this approach would be infeasible for this sector at this time.

(4) *In lieu of a concentration limit, require certain types of equipment to reach tailpipe limits.* In the underground coal sector, MSHA is requiring various categories of equipment to meet specific tailpipe limits. Compliance with these limits is determined through laboratory tests of engines and control devices. This approach avoids questions about MSHA in-mine compliance sampling which have been the focus of much discussion in coal mining. Accordingly, MSHA considered requiring a similar approach in underground metal and nonmetal mines. However, the agency determined that this would not be practical, because the engines in the current fleet are not approved; hence, the agency lacks information on their emission rates, a key piece of information needed to implement a tailpipe standard. Moreover, in many cases a cab or ventilation change might be a more effective solution to a localized dpm concentration in an underground metal and nonmetal mine than a change in the engine or emission control device—and perhaps less expensive for equipment of this size. One of the advantages of a concentration limit is the flexibility of controls that the operator can apply to meet the limit.

Feasibility of the final rule for underground metal and nonmetal mining sector. The Agency has carefully considered both the technological and economic feasibility of the rule being promulgated for the underground metal and nonmetal mining sector as a whole.

Technological feasibility of final rule. There are arguably two separate issues with respect to technological feasibility—(a) the existence of technology that can accurately and reliably measure dpm concentration levels in all types of underground metal and nonmetal mines; and (b) the existence of control mechanisms that can bring dpm concentrations down to the proposed limit in all types of underground metal and nonmetal mines. Both have been addressed elsewhere in this preamble.

The first of these questions, concerning measurement, is reviewed in considerable detail in section 3 of Part II and in the discussion of section 57.5061 of the rule in Part IV. For the reasons set forth in those discussions, MSHA has concluded that with the use of a submicrometer sampler as required by the final rule, and with a sampling strategy that avoids the inteferences which can compromise individual samples in certain situations, it does have a technologically feasible measurement method that operators and the agency can use to determine if the limits established by the standard are in fact being met.

The second of these questions, concerning controls, is discussed earlier in this part [See ''(1) *Establish a lower concentration limit for underground metal/nonmetal mines*'']. MSHA has performed various studies which suggest that even in the most difficult situations, it is technologically feasible for operators to meet the rule's final concentration limit. In fact, these studies suggest it is technologically feasible for operators in this sector to reduce their dpm concentrations to an even lower concentration limit. In addition, as discussed in section 6 of Part II of this preamble, considerable progress has been made in recent years on the effectiveness of filters and cabs. MSHA very carefully reviewed this information with reference to the kinds of engines and equipment found in underground metal and nonmetal mines, and their ventilation, and is confident that the final rule is technologically feasible.

Although the agency has reached this conclusion, and moreover knows of no mine that cannot accomplish the required reductions in the permitted time, it has nevertheless retained in the final rule a provision that any underground metal or nonmetal mine may have up to an additional two years to install the required controls should it find that there are unforseen technological barriers to timely completion. A detailed discussion of the requirements for obtaining approval for such an extension of time to comply is provided in part IV of the preamble.

Economic Feasibility. MSHA estimates that the rule would cost the underground metal and nonmetal sector about $25.1 million a year even with the extended phase-in time. The costs per underground dieselized metal or nonmetal mine are estimated to be about $128,000 annually. The yearly cost of the final rule represents about 0.67 percent of yearly industry revenue. MSHA uses a one-percent ''screen'' of costs relative to revenues as a presumptive benchmark of economic feasibility. Therefore, since the cost of the rule is less than one percent of revenues, MSHA anticipates that (subject to contrary evidence) the rule is economically feasible for the dieselized underground M/NM mining sector as a whole. Note, however, that the costs are sufficiently close to one percent of revenues that the rule could threaten the economic viability of affected mines on the economic margin and that more costly regulatory alternative could conceivably threaten the economic viability of a substantial fraction of this mining sector.

As explained in the REA, nearly all ($24.1 million) of the anticipated yearly costs would be investments in equipment to meet the interim and final concentration limits. While operators have complete flexibility as to what controls to use to meet the concentration limits, the Agency based its cost estimates on the assumption that operators will ultimately need the following to get to the final concentration limit: (a) Fifty percent of the fleet will have new engines (these new engines do not impact cost of the rule). It is expected that the new engines will be more expensive and technologically superior to the ones that they replace. One aspect of this technological superiority will be substantially lower DPM emissions. It does not follow, however, that the greater expense of these engines is an impact of this rule. Mine operators will not replace existing engines with the same type or model of engine. New engine technology makes engines much more efficient and productive than existing older engines. Particularly on larger equipment, greater productivity makes new engines an attractive investment that will pay back the greater costs. Moreover, due to EPA regulations which will limit DPM emissions from engines used in surface construction, surface mining, and over-the-road trucks (the major markets for heavy duty diesel engines), the market for low tech, ''dirtier'' engines will dry up. Underground mine operators will thus purchase high tech, cleaner engines because they will be the only engines available for purchase.

(b) One hundred percent of the production equipment and about fifty percent of the support equipment will be equipped with filters; (c) about thirty percent of all equipment will need to be equipped with environmentally controlled cabs; (d) twenty three percent of the mines will need new ventilation systems (fans and motors): (e) forty percent of the mines will need new motors on these fans; and (f) thirty two percent of the mines will need major ventilation upgrades.

The Agency is taking a number of steps to mitigate the impact of the rule for the underground metal and nonmetal sector, particularly on the smallest mines in this sector. These are described in detail in the Agency's Regulatory Flexibility Analysis, which the Agency is required to prepare under the Regulatory Flexibility Act in connection with the impact of the rule on small entities. (The regulatory flexibility analysis can be found in part VI of this preamble, or packaged with the Agency's REA.)

Based on its cost estimates, the Agency has concluded that this sector would not find it economically feasible to reduce dpm concentrations to a lower limit at this time. These assumptions and the rationale behind them are discussed in greater detail in the beginning of Chapter IV of the Regulatory Economic Analysis.

After a careful review of the information about this sector available from the industry economic profile, and the other obligations of this sector under the Mine Act, MSHA has concluded that a reasonable probability exists that the typical firm in this sector will be able at this time to afford the controls that will be necessary to meet the proposed standard.

Conclusion: metal and nonmetal mining sector. Based on the best evidence available at this time, the Agency has concluded that the final rule for the underground metal and nonmetal sector meets the statutory requirement that the Secretary attain the highest degree of health and safety protection for the miners in that sector, with feasibility a consideration.

VI. Regulatory Impact Analyses

This part of the preamble reviews several impact analyses which the Agency is required to provide in connection with its final rulemaking. The full text of these analyses can be found in the Agency's Regulatory Economic Analysis (REA).

(A) Costs and Benefits: Executive Order 12866

In accordance with Executive Order 12866, MSHA has prepared a Regulatory Economic Analysis (REA) of the estimated costs and benefits associated with the final rule for the underground metal and nonmetal mining sector.

The key conclusions of the REA are summarized, together with cost tables, in part I of this preamble (see Item number 7). The complete REA is part of the record of this rulemaking, and is available from MSHA.

The Agency considers this rulemaking ''significant'' under section 3(f) of Executive Order 12866, and has so designated the rule in its semiannual regulatory agenda (RIN 1219–AA74). However, based upon the REA, MSHA has determined that the final rule does not constitute an ''economically significant'' regulatory action pursuant to section 3(f)(1) of Executive Order 12866.

(B) Regulatory Flexibility Act (RFA)

Introduction

In accordance with section 605 of the Regulatory Flexibility Act of 1980 as amended, MSHA has analyzed the impact of the final rule on small businesses. Further, MSHA has made a determination with respect to whether or not it can certify that this final rule will not have a significant economic impact on a substantial number of small entities that are affected by this rulemaking. Under the Small Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), MSHA must include a factual basis for this certification. If the final rule does have a significant economic impact on a substantial number of small entities, then the Agency must develop a final regulatory flexibility analysis.

The Agency has, as required by law (5 U.S.C. 605), developed a final regulatory flexibility analysis which is set forth Chapter V of the REA. In addition to a succinct statement of the objectives of the final rule and other information required by the Regulatory Flexibility Act, the analysis reviews alternatives considered by the Agency with an eye toward minimizing the economic impact on small business entities.

Definition of a Small Mine

Under the RFA, in analyzing the impact of a rule on small entities, MSHA must use the Small Business Administration (SBA) definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not taken such an action, and hence is required to use the SBA definition.

The SBA defines a small entity in the mining industry as an establishment with 500 or fewer employees (13 CFR 121.201). Of the 196 underground M/NM mines that use diesel powered equipment and are therefore affected by this rulemaking, 189 (or all but 7) fall into this category and hence can be viewed as sharing the special regulatory concerns that the RFA was designed to address.

Traditionally, the Agency has also looked at the impacts of its rules on a subset of mines with 500 or fewer employees ¾ those with fewer than 20 employees, which the mining community refers to as ''small mines.'' The way these small mines perform mining operations is generally recognized as being different from the way larger mines operate. These small mines differ from larger mines not only in the number of employees, but also, among other things, in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. Therefore, their costs of complying with MSHA rules and the impact of MSHA rules on them will also tend to be different. It is for this reason that ''small mines,'' as traditionally defined by the mining community, are of special concern to MSHA.

This analysis complies with the legal requirements of the RFA for an analysis of the impacts on ''small entities'' while continuing MSHA's traditional look at ''small mines.'' MSHA concludes that the final rule would not have a significant economic impact on small entities, as defined by SBA, *when considered as a group.* However, MSHA has determined that the final rule arguably would have a significant economic impact on a subset of small entities that are covered by this rulemaking. That subset is small underground M/NM mines as traditionally defined by MSHA, those mines with fewer than 20 employees. This subset of affected mines constitutes a substantial number of small entities.

Screening Analysis

General Approach. The Agency's analysis of impacts on ''small entities'' begins with a ''screening'' analysis. The screening compares the estimated compliance costs of a rule for small entities in the sector affected by the rule to the estimated revenues for those small entities. When estimated compliance costs are less than 1 percent of the estimated revenues (for the size categories considered), the Agency believes it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed 1 percent of revenues, it tends to indicate that further analysis may be warranted.

Derivation of Costs and Revenues. The compliance costs presented here were previously introduced in Chapter IV of the REA along with an explanation of how they were derived. Table VI–1 summarizes the total yearly cost of the final rule by mine size.

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TABLE VI-1: Total Yearly Compliance Costs for M/NM Mine Operators by Mine Size Class

Requirement	Total Yearly Industry Cost By Mine Size Class		
	Under 20 Employees	20 to 500 Employees	Over 500 Employees
Section 57.5060(a)&(b) DPM Concentration Limits	$3,909,865	$17,068,073	$3,215,869
Section 57.5067 Newly Introduced Engines	$ -	$ 2,848	$ 712
Section 57.5060(c) Extension Application	$ 148	$ 401	$ 36
Section 57.5060(d) Respirator Protection	$ 67,247	$ 285,690	$ 17,855
Section 57.5062 DPM Control Plans	$ 1,408	$ 6,336	$ 704
Section 57.5066(c) Maintenance Training	$ 894	$ 2,384	$ 468
Section 57.5066(b) Tagging and Examination	$ 1,769	$ 6,178	$ 1,948
Section 57.5070 Miner Health Training	$ 5,226	$ 74,189	$ 42,005
Section 57.5071 Environmental Monitoring	$ 106,425	$ 297,213	$ 31,008
Section 57.5075 Diesel Particulate Records	$ 204	$ 1,639	$ 943
TOTAL COST	$4,093,186	$17,744,951	$3,311,548
COST PER MINE	$ 53,158	$ 158,437	$ 473,078

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Data on underground M/NM mines published by the U.S. Geological Survey [1] were used for tonnage and value of underground M/NM mines. These data, however, are not disaggregated by mine size class. MSHA collects data, by mine size, on both average employees and employee hours.[2] MSHA has used these data to estimate revenues by mine size class.

MSHA has assumed that tonnage is proportional to employee hours. This assumption (rather than proportionality with employees) implicitly adjusts for different shift lengths associated with different sizes of mines. MSHA has also assumed that all underground M/NM mines use diesel powered equipment.[3] Using these assumptions, MSHA has computed the percentages of employee hours of all underground M/NM mines that are accounted for by each size class. MSHA estimates that these percentages of total revenues are accounted for by the different mine size classes.

Results of the Screening Analysis. The final rule applies to underground M/NM mines that use diesel-powered equipment. Table VI–1 shows that the estimated yearly cost of the final rule as a percentage of yearly revenues is about 0.8 percent for the affected underground M/NM mines with 500 or fewer employees.

However, for a subset of affected underground M/NM mines, those with fewer than 20 employees, estimated yearly costs are equal to about 2.16 percent of yearly revenues for this subset of mines. The economic impact on these small mines, which constitute a substantial number of small entities affected by the final rule, is larger than one percent of their revenues. MSHA therefore cannot certify that the final rule would not have a significant impact on a substantial number of small entities.

The Agency has prepared a final regulatory flexibility analysis, as required by law, which explains the steps MSHA has taken to minimize the burden on these small entities and justifies the costs placed on them.

TABLE VI–2.—ESTIMATED YEARLY COSTS OF FINAL RULE RELATIVE TO YEARLY REVENUES FOR UNDERGROUND COAL MINES THAT USE DIESEL-POWERED EQUIPMENT

Mine size	Final rule yearly costs (In thousands)	Revenues[a] (In thousands)	Costs as Percentage of revenues
<20 emp.	$4,093	$189,305	2.16
≤500 emp.	21,837	2,745,137	0.80

[a] Source: Mine Safety and Health Administration, Office of Injury and Employment Information, Denver, Colorado. 1999, and U.S. Department of Energy, Energy Information Agency, *Annual Energy Review 1998,* DOE/EIA0384(98), July 1999, p.203.

Final Regulatory Flexibility Analysis

As indicated above, the estimated yearly cost of the final rule on a subset of small entities, those with fewer than 20 employees, is 2.16 percent of yearly revenue. This percentage is just over twice the value (1.0 percent) below which MSHA could say with reasonable confidence that the final rule does not have a significant economic impact on a substantial number of small entities. Accordingly, MSHA has prepared a final regulatory flexibility analysis.

Need for, and Objectives of, the Rule

Need. The rule is needed because underground miners in mines that use diesel powered equipment are currently exposed to extremely high concentrations of diesel particulate matter (DPM). Based on MSHA field studies, median DPM concentrations to which underground miners are exposed range up to 200 times as high as average environmental exposures in the most heavily polluted urban areas and up to 10 times as high as median exposures estimated for the most heavily exposed workers in any occupational group other than underground miners.

The available scientific information indicates that miners exposed to the extremely high DPM concentrations found in underground mines are at significant excess risk of experiencing three kinds of material impairment to their health:

- Increased risk of lung cancer has been linked to chronic occupational DPM exposure.
- Increased acute risk of death from cardiovascular, cardiopulmonary, or respiratory causes has been linked to short or long term DPM exposures.
- Sensory irritations and respiratory symptoms can result from even short term DPM exposures. Besides being potentially debilitating, such effects can distract miners from their responsibilities in ways that could pose safety hazards for everyone in the mine.

Although definitive dose-response relationships have not yet been established (especially for the acute effects), the best available evidence indicates that the risks are substantial.

Objective. The objective of the rule is to lower DPM exposures in underground M/NM mines to concentrations similar to the worst levels to which other occupational groups are exposed. By doing so, the rule is designed substantially to lower the health risks associated with DPM. Expected benefits include an estimated minimum of 8.5 lung cancer deaths avoided per year.

Significant Issues Raised in Response to the Initial RFA

Comments. The principal issue raised in comments on the PREA was that, for a variety of reasons, MSHA had substantially understated the costs of controlling DPM. The implication of these comments was that the rule was economically infeasible. The most comprehensive comments along these lines were by Head,[4] who argued (among other things) that MSHA had made the following errors and omissions in its analysis:

- MSHA had (according to Head) understated the numbers of machines and mines affected, including:

[1] U.S. Geological Survey, ''Mineral Industry Surveys: Mining and Quarrying Trends, 1998 Annual Review, April 2000.

[2] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[3] This assumption ignores the fact that some very small mines do not use diesel powered equipment. MSHA believes, however, that these mines are generally very small (even among the mines with fewer than 20 employees) and that many of them operate only intermittently. Thus they account for employee hours proportionately far less than their numbers. Accordingly, MSHA believes that the most accurate way to interpret the data is to disregard the fact that these mines do not use diesel powered equipment.

[4] H. John Head, Principal Mining Engineer, Harding Lawson Associates, ''Review of Economic and Technical Feasibility of Compliance Issues Related to: Department of Labor—MSHA, 30 CFR Part 57—Proposed Rule for Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners,'' Report prepared under contract with the National Mining Association, July 21, 1999.

- Understatement of the number of diesel units in underground M/NM mines by more than 50 percent, and
- Understatement of the number of ventilation upgrades needed by 20 percent to 40 percent
- MSHA had understated a number of costs, including:
- Understatement of the cost of replacement engines by up to one third,
- Understatement of the costs of filters on larger engines by 20 percent, and
- Understatement of the costs of vehicle cabs by about 60 percent.
- MSHA had omitted some costs entirely, including:
- Installation costs of retrofitting new engines in old equipment, which ran as high as three times the costs of the engines themselves, and
- Major ventilation improvements needed by about one third of the mines.

Based on his own numbers, Head estimated compliance costs to be three times as high as MSHA's estimate of the cost of the proposed rule of $19.2 million.

Analytical Assessment of Issues. MSHA considered the comments and reviewed its assessment of costs very carefully. The assessment focused on Head's comments, since his exposition was detailed enough for analysis of the basis of his estimates. MSHA responded in a variety of ways, which are summarized below.

The key to the issue of the number of diesel units affected by the rule was how one interpreted the number. MSHA resolved this issue by recognizing that not all diesel powered equipment would be affected in the same manner. In fact, the machines in Head's total count should be grouped into three categories: active, spares, and disused. Active diesel powered equipment (essentially MSHA's original count) needs to be fitted for everyday use. Spare equipment needs to be controlled for occasional use as back-up. Disused equipment is essentially not affected by the rule. A shift in the principal control strategy from engine replacement to ceramic filters (discussed further below) made these distinctions operational. With ceramic filters, both active and spare equipment can be fitted with filters (a relatively inexpensive operation), but filters need to be regenerated and changed (which encompasses most of the costs) only to the extent that the equipment is actually used.

MSHA believes that Head was simply wrong about the number of mines needing upgrades to their ventilation systems. Head appeared to believe that MSHA's count was arbitrary, and the basis for his proposed number was obscure. In fact, MSHA has based its count on mine-specific data on the existence and rate of air flow of ventilation systems. Thus, MSHA retained its original count.

MSHA's review of comments on costs produced different conclusions for different specific costs:

- MSHA accepted and used Head's estimate of costs of ceramic filters.
- MSHA does not entirely agree with Head's estimates of costs of new engines. Moreover, expensive new engines are technologically advanced and tend to produce substantial gains in productivity and savings in operating costs, which Head did not consider. The issue of engine costs became irrelevant, however, under a strategy of filters as the first-used control device.
- MSHA's re-examination of the costs of cabs indicated that MSHA's cost estimate is appropriate for equipment for which equipment manufacturers can provide off-the-shelf kits for retrofitting equipment, and Head's cost estimate is appropriate for equipment for which cabs have to be custom designed and retrofitted. Since the rule does not mandate cabs and MSHA expects cabs to be used on a relatively small proportion of equipment, however, MSHA believes that mine operators will not retrofit equipment for which cabs would need to be custom designed. Accordingly, MSHA has retained its original cost estimate.
- Head concurred with MSHA on the costs of ventilation improvements. While these costs appear to be an appropriate average estimate for M/NM mines as a whole, there is a distinct possibility that they may be too high for very small M/NM mines.[5] In the context of regulatory flexibility analysis, MSHA considers these cost estimates to be fairly conservative.

MSHA agrees that certain costs were omitted, but the conclusions of MSHA's reconsideration of these costs also vary with the cost:

- MSHA has accepted Head's estimates for major ventilation improvements and has included them in the analysis of costs.
- Head's comment that MSHA had omitted the costs of retrofitting new engines in old equipment is correct, although MSHA does not agree with the size of Head's cost estimates. The key issue, however, is that the strategy of relying primarily on filters does not entail retrofitting engines. Thus Head's comment is not germane.

Concentration Limits and the Toolbox. This standard for underground M/NM mines is a performance standard, with an interim DPM concentration limit of 500 micrograms/m³, followed by a final DPM concentration limit of 200 micrograms/m³. The rule encourages mine operators to use any combination of a ''toolbox'' of measures to meet these concentration limits. For cost estimation purposes, however, it is necessary to assume a specific set and sequence of control measures. Specifically, in the PREA MSHA assumed that:

- The interim standard would be met by replacing engines, installing oxidation catalytic converters, and improving ventilation; and
- The final standard would be met by adding cabs and filters.

Both the general strategy and the specific proportions of diesel powered equipment to be controlled by each measure were based on an optimizing approach, in which the most cost-effective additional measures were selected for additional DPM reductions at each stage.

In his comments, Head exactly replicated MSHA's assumptions about how many pieces of each kind of diesel equipment would be controlled, how they would be controlled, and the sequence in which controls would be used. Although his cost estimates differed substantially from MSHA's, Head made no attempt to optimize the use of DPM control ''tools'' from the toolbox.

Substantially the most important of Head's changes is to make filters much cheaper, relative to engine replacement. At the same time, data collected by MSHA since publication of the PREA indicate that filters are more effective than was previously understood. This finding has further enhanced the cost-effectiveness of filters, relative to engine replacement. These changes in information have caused MSHA to go back to the toolbox and rethink the optimized compliance strategy. The revised compliance strategy, upon which MSHA bases the revised estimates of compliance costs, reverses the two most widely used measures from the toolbox. MSHA now anticipates that:

- The interim DPM standard of 500 micrograms/m³ will be met with filters, cabs, and ventilation; and
- The final DPM standard of 200 micrograms/m³ will be met with more filters, ventilation, and such turnover in

[5] The issue is further complicated by the fact that mines that are ''small'' in terms of employment vary considerably among commodities and mining techniques in their physical size and ventilation requirements. Accordingly, MSHA has not attempted to make a separate cost estimate of ventilation improvement costs for ''small'' M/NM minas as a group.

equipment and engines as will have occurred in the baseline.

This new approach uses the same toolbox and optimization strategy that was used in the PREA. Since relative costs are different, however, the tools used and costs estimated are quite different. The effects on costs is substantial. Most of the difference between Head's cost estimate and the cost estimate in the REA is attributable to this change in strategy.

Changes in the Rule. Because the rule is a performance standard that uses a tool-box approach, most modifications that MSHA made in response to comments involved changes in the mix of tools within the framework of the rule, rather than changes in the rule per se. MSHA did make one significant change in the rule itself, however, by allowing compliance with listed EPA standards as a substitute for MSHA approval of new engines. Because most engines used in underground M/NM mining equipment are essentially the same engines used on the surface, which fall under EPA regulations, MSHA believes that virtually all new engines used in mining equipment will meet EPA standards. Therefore, this change resulted in eliminating a cost of approval that was estimated in the PREA to average $2,500 per new engine.

Small Entities to Which the Rule Will Apply

For the purposes of this regulatory flexibility analysis, the working definition of ''small'' is MSHA's definition of fewer than 20 employees. (Although SBREFA requires use of the SBA's definition, the impacts on mines with 500 or fewer employees as a whole are not economically significant.) Correspondingly, one element of a regulatory flexibility analysis involves developing a more focused definition of ''small.''

There are 77 M/NM mines that are ''small'' by this definition. These mines fall in four commodity groups:

- Stone is the largest group, accounting for 54 small underground M/NM mines that use diesel equipment (70 percent). These mines include limestone (46 mines), marble (5 mines), lime (2 mines), and granite (1 mine).
- Precious metals account for 10 small underground M/NM mines that use diesel equipment (13 percent). Most of these (9 mines) are gold mines; one mines both gold and silver.
- Other metals account for 4 small underground M/NM mines that use diesel equipment (5 percent). These mines include zinc (2 mines), copper (1 mine), and a combination of copper and zinc (1 mine).
- The other 9 small underground M/NM mines that use diesel equipment (12 percent) are a miscellany that includes shale (3 mines) as well as calcite, clay, gemstone, perlite, sand (industrial), and talc (1 mine each).

Collectively, these 77 mines have estimated revenues of $189.3 million, or an average of $2.46 million per mine. The estimated total costs of the rule are $4.1 million, or an average of $53,160 per mine. Estimated costs of the rule are 2.16 percent of estimated revenues.

Costs by Commodity Group and Mine Size. Table VI–3 shows the estimated yearly cost by size class for each commodity group in M/NM mines. Costs for Section 57.5060(a) and Section 57.5060(b) were recalculated for each commodity group, based on the diesel powered equipment and air flow of the mines in each commodity group. All other costs were very small, probabilistically distributed among mines, and/or essentially constant for all mines or for all mines in a size class. For these costs, the average cost per mine in each size class (from Table VI–1) was used, as very little precision was lost through this simpler estimation procedure. Table VI–3 shows a fair degree of variation among commodity groups.

- For mines with fewer than 20 employees, the average cost per mine is estimated to be $53,158, and estimated costs per mine for commodity groups range from $31,500 to $60,500, with:
- Costs above average for stone mines ($60,500) and base metal ($54,400), and
- Costs below average for other M/NM mines ($31,500) and gold mines ($34,600).
- For mines with 20 to 500 employees, the average cost per mine is estimated to be $158,437, and estimated costs per mine for commodity groups range from $102,100 to $201,700, with:
- Costs above average for base metal mines ($201,700) and gold mines ($171,900),
- Costs roughly average for stone mines ($150,900) and evaporates mines ($149,100), and
- Costs below average for other M/NM mines ($102,100).
- For mines with over 500 employees, the average cost per mine is estimated to be $473,078, and estimated costs per mine for commodity groups range from $291,800 to $660,300, with:
- Costs above average for gold mines ($660,300) and base metal mines ($592,300), and
- Costs below average for evaporates mines ($291,800) and stone mines ($298,000).

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Table VI-3: Yearly Compliance Costs by Commodity Group and Mine Size

Commodity Group	Mine Size	Total Yearly Industry Cost	Yearly Cost per Mine
Stone[a]	Under 20	$ 3,258,360	$ 60,340
	20 to 500	$ 6,330,996	$ 150,738
	Over 500	$ 297,691	$ 297,691
	All Mines	$ 9,887,047	$ 101,928
Precious Metals[b]	Under 20	$ 345,240	$ 34,524
	20 to 500	$ 3,263,782	$ 171,778
	Over 500	$ 659,978	$ 659,987
	All Mines	$ 4,269,000	$ 142,300
Other Metals[c]	Under 20	$ 217,104	$ 54,276
	20 to 500	$ 5,039,700	$ 201,588
	Over 500	$ 1,775,991	$ 591,997
	All Mines	$ 7,032,795	$ 219,775
Evaporates[d]	20 to 500	$ 3,724,100	$ 148,964
	Over 500	$ 582,990	$ 291,495
	All Mines	$ 4,307,090	$ 159,522
Other[e]	Under 20	$ 282,357	$ 31,373
	20 to 500	$ 101,950	$ 101,950
	All Mines	$ 384,307	$ 38,431

[a] Granite, lime, limestone, marble, and sandstone.

[b] Gold, Platinum, and silver.

[c] Copper, iron ore, lead, molybdenum, uranium, and zinc.

[d] Gypsum, potash, salt, and trona.

[e] Borate, calcite, clay, gemstones, perlite, sand (industrial), shale, and talc.

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Thus by overall commodity group:

- Compliance costs are relatively high in gold mines (except for small mines) and base metal mines,
- Compliance costs are relatively low in evaporates mines and other M/NM mines, and
- Compliance costs of stone mines show no consistent pattern relative to average costs for all M/NM mines.

The differences in cost per mine appear to be attributable to the interaction of three characteristics of the mines, which are included in Table VI–4:

- The percentage of mines that need new ventilation systems;
- The number of diesel powered machines per mine; and
- The proportion of diesel powered equipment that is large production equipment.

Table VI-4: Factors Contributing to Variability of Yearly Compliance Costs Across Commodity Groups

Commodity Group	Mine Size	Machines per Mine				Percent Needing Ventilation Improvements	
		Production		Sup.	Total		
		>150 h.p.	≤150 h.p.			New System	New Motor
Stone	Under 20	4.3	0.5	4.4	9.2	44%	30%
	20 to 500	8.5	1.0	7.6	17.1	33%	31%
	Over 500	16.0	1.0	23.0	40.0	0%	100%
	All Mines	6.3	0.7	6.0	12.9	39%	31%
Gold	Under 20	0.4	1.2	0.8	2.4	40%	40%
	20 to 500	6.6	5.8	11.7	24.1	0%	68%
	Over 500	26.0	12.0	95.0	133.0	0%	0%
	All Mines	5.2	4.5	10.9	20.5	13%	57%
Base Metal	Under 20	3.5	1.0	6.2	10.7	25%	50%
	20 to 500	10.3	2.8	16.6	29.8	0%	48%
	Over 500	17.3	29.3	68.0	114.7	0%	33%
	All Mines	10.1	5.1	20.2	35.3	3%	47%
Evaporate	20 to 500	5.2	4.6	21.1	30.9	4%	40%
	Over 500	1.5	11.5	80.0	93.0	0%	0%
	All Mines	4.9	5.1	25.5	35.5	4%	41%
Other	Under 20	1.2	0.8	0.2	2.2	11%	67%
	20 to 500	0.0	15.0	0.0	15.0	0%	100%
	All Mines	1.1	2.2	0.2	3.5	10%	70%

These three characteristics interact in somewhat different ways in the different mine size classes:

• For mines with fewer than 20 employees, the cost per mine is:

• Relatively high (or just above average) in commodity groups where two or all three of these factors have relatively high values, and

• Relatively low when two of these factors have relatively low values.

• For mines with 20 to 500 employees, the cost per mine is:

• Relatively high in commodity groups where the number of machines per mine and the proportion of machines that are large production equipment are both relatively large,

• Average when one of these two factors is relatively high and the other is relatively small, and

• Relatively low when all three of the factors have relatively low values.

• For mines with over 500 employees (none of which need new ventilation systems), the cost per mine is:

• Relatively high in commodity groups where the number of machines per mine is relatively large, and

• Relatively low when the number of machines per mine or the proportion of machines that are large production equipment is relatively small.

Impacts on Small Mines by Commodity Group. The available data are not adequate to support a realistic estimate of impacts on small underground M/NM mines by commodity group, since revenues of individual commodities cannot be allocated to different size classes of mine. The analysis of costs per mine suggests, however, that stone is the only commodity group with impacts much above average. The costs per small stone mine are 13.6 percent higher than the average for all small underground M/NM mines. Impacts on small underground mines in other M/NM commodity groups appear to be about average or less.

Projected Reporting, Recordkeeping, and Other Requirements of the Rule

The rule requires several types of records and reports. Plans are required in conjunction with respirator use and DPM control if the concentration levels are violated, and these must be posted and provided to various parties. An extension may be applied for. Maintenance training, miner health training, and respirator training must be logged. Environmental monitoring results must be recorded and provided to miners upon request. While there are a number of reporting and recordkeeping requirements, however, each one is straightforward, and most are no more than the simplest form of documentation. Thus the total cost of recordkeeping is only about 0.35 percent of the compliance costs for small mines.

The principal source of costs of the rule is controls to reduce the DPM concentrations in underground mines. MSHA has adopted a flexible ''toolbox'' approach that allows mine operators to select the controls that will be most cost-effective for their mines. MSHA has based its cost estimates on extensive use of ceramic filters, less widespread use of cabs on equipment, and ventilation upgrades. MSHA also assumes that new diesel engines introduced into the mines as part of the baseline turnover of the fleet and its engines will be relatively clean and will contribute to reduced DPM levels. These control costs account for an estimated 95.6 percent of the yearly compliance costs of small mines. Of these costs, ventilation costs (47.1 percent) and filter costs (46.3 percent) account for nearly half each, while the cost of cabs (6.6 percent) is relatively minor.

Only two other requirements impose costs of any size. Environmental monitoring accounts for about 2.6 percent of the estimated compliance costs of small mines. Occasional use of respirators (equipment, training, inspection, etc.) accounts for about 1.6 percent of estimated compliance costs. Maintenance training and miner health training account for less than 0.2 percent of compliance costs. The non-control requirements of the rule are quite modest.

Steps Taken to Minimize Impacts on Small Entities

Constraints of the Mine Safety and Health Act. The Federal Mine Safety and Health Act of 1977 was enacted to protect miners. MSHA has always read the Act to prohibit discriminating among miners by providing different degrees of protection that varied systematically with the size of the mine in which they worked. Accordingly, the Mine Safety and Health Act rules out certain classes of regulatory flexibility alternatives, particularly exemption of small mines, but also any alternative that would result in systematically higher allowable DPM concentration levels in small mines. Because over 95 percent of the yearly costs to be incurred by small mines are directly related to protection, there is little scope for distinct provisions for small mines.

Built-In Flexibility. To minimize impacts on small entities, MSHA has taken steps to build as much flexibility into the rule itself as possible. The rule itself is a performance standard that allows mine operators to meet the DPM concentration limits with their own choice of ''tools.'' While MSHA has selected a specific set of tools for the cost analysis, MSHA expects that operators of specific mines probably will often be able to come into compliance at lower costs by using a mix of techniques tailored to that specific mine.

Other parts of the rule provide similar flexibility. Training and recordkeeping requirements indicate the information to be imparted or retained, for example, but they do not spell out how this is to be done. Much of the reporting is required only upon request, rather than routinely. Where a requirement (*e.g.,* MSHA approval of new engines) appeared to be relatively expensive, MSHA added an alternative (compliance with listed EPA standards).

Phasing in over five years is another element that MSHA has incorporated to minimize impacts (albeit for all mines, not just for small ones). This not only defers costs, it allows impacts to be reduced in a number of ways. Mine operators can spread major expenses out to avoid a capital crunch. To a great degree, mine operators will be able to take advantage of the natural turnover of their fleets, rather than doing extensive (and more expensive) retrofitting. In extreme cases, if a mine is quite marginal and/or is likely to shut down in a few years anyway, the five-year phase-in allows an orderly closure that minimizes impacts.

Low Risk of Short-Term Closures. Ultimately, the issue of concern related to impacts whether mines may be forced to close. When costs are a significant but relatively small fraction of revenues (or profits), however, it is especially difficult to determine whether closure is an impact resulting from the rule or a baseline event that would have happened anyway. Given the fact that profits fluctuate widely over time, even the presence of losses is not necessarily a good indicator of whether businesses will recover or fail. In many cases where a business does fail, the true impact of a regulation is not causing its failure but rather hastening its failure. Because of the phasing of this rule, it affords an opportunity to consider the potential for hastening the failure of a small mine.

If a mine is likely to close within five to seven years without the regulation, the impacts of the rule are different from the above analysis. In order to stay open for five years, a mine need only comply with the interim DPM concentration level. To this end, it needs to incur the costs of:

- Control costs necessary for Section 57.5060(a); [6]
- Respirator protection costs of Section 57.5060(d); [7]
- DPM control plan costs of Section 57.5062; [8]
- Maintenance training, tagging, and examination costs of Section 57.5066(b) and Section 57.5066(c);[9]
- Miner Health Training costs of Section 57.5071; [10]
- Environmental monitoring costs of Section 57.5071; [11] and
- DPM record costs of Section 57.5075. [12]

Thus the yearly costs for small mines, amortized over 5 years at an annual discount rate of 7.0 percent, would be $1,554,086, or an average of $20,183 per mine. This is 0.82 percent of annual revenue, which is below the threshold for a significant economic impact. This is not the type of impact that would force a mine to close sooner rather than later. The conclusion is that any closure impacts would be mild and would occur foreseeably over time, rather than abruptly.

Compliance Assistance

The Agency plans to provide extensive compliance assistance to the mining community. MSHA intends to focus these efforts on smaller metal and nonmetal operators, including training them to measure DPM concentrations, providing technical assistance on available controls, and establishing a system for addressing compliance inquiries from small businesses. The Agency will also issue a compliance guide, continue its current efforts to disseminate educational materials and software, and hold workshops to inform the mining community.

In conclusion, MSHA believes that it has taken all of the steps consistent with the Mine Safety and Health Act that could substantially reduce the impacts of this rule on small entities.

(C) Alternatives Considered

MSHA did explore a variety of alternatives in its Initial Regulatory Flexibility Analysis. See 63 FR 58212. For example, it looked at a regulatory approach that would have focused on limiting workers exposure rather than limiting particulate concentration. Under such an approach, operators would have been able to use administrative controls and respiratory protection equipment to reduce diesel particulate exposure. For the reasons explained in that Initial Analysis, the Agency declined to take such an approach. For MSHA's response to comments on the specific topics of administrative controls and respiratory protection equipment, see Part IV's discussion of 57.5060(e) and 57.5060(f).

(D) Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, the final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector of more than $100 million.

(E) Paperwork Reduction Act of 1995

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95). The final rule will impose two types of paperwork burden hours on underground M/NM mine operators that use diesel powered equipment. First, there are burden hours that will occur *only* in the first year the rule is in effect (hereafter known as first year burden hours). Second, there are burden hours that will occur *every* year that the rule is in effect, starting with the first year (hereafter known as "annual" burden hours).

In the first year, mine operators will incur 3,571 burden hours and associated burden costs of about $171,926. After the first year, mine operators will incur 526 burden hours annually and associated costs of about $21,871.

We have submitted a copy of this final rule to OMB for its review and approval of these information collections. Interested persons are requested to send comments regarding this information collection, including suggestions for reducing this burden, to the Office of Information and Regulatory Affairs, OMB New Executive Office Building, 725 17th St., NW, Rm. 10235, Washington, DC 20503, Attn: Desk Officer for MSHA. Submit written comments on the information collection not later than 60 days after date of publication in the **Federal Register**.

Our paperwork submission summarized above is explained in detail in the REA. The REA includes the estimated costs and assumptions for each final paperwork requirement related to this final rule. A copy of the REA is available from us. These paperwork requirements have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1995. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

(F) National Environmental Protection Act

The National Environmental Policy Act (NEPA) of 1969 requires each Federal agency to consider the environmental effects of final actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the environment. MSHA has reviewed the final rule in accordance with NEPA requirements (42 U.S.C. 4321 et. seq.), the regulations of the Council of Environmental Quality (40 CFR Part 1500), and the Department of Labor's NEPA procedures (29 CFR Part 11). As a result of this review, MSHA has determined that this rule will have no significant environmental impact.

(G) Executive Order 12360 Governmental Actions and Interference With Constitutionally Protected Property Rights

This final rule is not subject to Executive Order 12360, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

(H) Executive Order 13045 Protection of Children From Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, MSHA has evaluated the environmental health and safety effects of the final rule on children. The Agency has determined that the rule will not have an adverse impact on children.

(I) Executive Order 12988 (Civil Justice)

The Agency has reviewed Executive Order 12988, Civil Justice Reform, and determined that the final rule will not unduly burden the Federal court system. The rule has been written so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

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[6] These controls include ceramic filters and cabs, but not ventilation (which MSHA did not estimate to be necessary for the interim DPM level. These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $1,119,800 for filters and $150,437 for cabs.

[7] These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $164,845.

[8] Annual costs are $1,408.

[9] These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $5,681.

[10] Annual costs are $5,226.

[11] Annual costs are $106,425.

[12] Annual costs are $204.

(J) Executive Order 13084 Consultation and Coordination With Indian Tribal Governments

MSHA certifies that the final rule will not impose substantial direct compliance costs on Indian tribal governments.

(K) Executive Order 13132 (Federalism)

MSHA has reviewed the final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''federalism implications.'' The final rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

VII. References

Abbey, David, *et al.,* ''Ambient Air Pollution and Cancer in California Seventh-day Adventists,'' *Archives of Environmental Health,* 96(5):271–280, September/October 1991.

Ahlberg, J., *et al.,* ''Cancer and Professional Drivers-A Problem-Oriented Study of Records,'' Läkartidningen, 78(15):1545–1546, 1981.

Ahlman, Kaj, *et al.,* ''Mortality Among Sulfide Ore Miners,'' *American Journal of Industrial Medicine,* 19:603–617, 1991.

American Conference of Governmental Industrial Hygienists, Diesel Exhaust (Particulate and Particulate Adsorbed Component) September 20, 1998.

American Federation of Labor and Congress of Industrial Organizations v. *Occupational Safety and Health Administration,* 965 F.2d 962 (11th Cir., 1992).

American Federation of Labor and Congress of Industrial Organizations v. *Peter J. Brennan, Secretary of Labor,* 530 F.2d 109 (3rd Cir., 1975).

American Iron and Steel Institute et al., v. *Occupational Safety and Health Administration,* 577 F.2d 825 (3rd Cir., 1978).

American Mining Congress, public comment submitted in response to MSHA's January 5, 1992 ANPRM, #87–0–21,Executive Summary, page 1 and Appendix A, July 10, 1992.

American Textile Manufacturers Institute, Inc. et al., v. *Donovan, Secretary of Labor, et al.,* 452 U.S. 490, 101 S.Ct. 2478 (1981).

American Trucking Associations, Inc. et al., v. *United States Environmental Protection Agency,* 175 F.3d 1027 (D.C. Cir. 1999).

American Trucking Associations, Inc. et al., v. United States Environmental Protection Agency, No. 97–1440 and 97–1441 consolidated cases, June 28, 1999.

Ames, Richard G., *et al.,* ''Chronic Respiratory Effects of Exposure to Diesel Emissions in Coal Mines,'' *Archives of Environmental Health,* 39(6):389–394, November/December 1984.

Ames, Richard G., *et al.,* ''Does Coal Mine Dust Present a Risk for Lung Cancer? A Case-Control Study of U.S. Coal Miners,'' *Archives of Environmental Health,* 38(6):331–333, November/December 1983.

Ames, Richard G., *et al.,* ''Acute Respiratory Effects of Exposure to Diesel Emissions in Coal Miners,'' *American Review of Respiratory Disease,* 125:39–42, 1982.

Armstrong, B.K., *et al.,* ''Mortality in Gold and Coal Miners in Western Australia with Special Reference to Lung Cancer,'' *British Journal of Industrial Medicine,* 36:199–205, 1979.

Attfield, M.D., *et al.,* ''Exposure to Diesel Fumes and Dust at Six Potash Mines,'' *Annals of Occupational Hygiene,* 26:817–831, 1982.

Attfield, M.D., ''The Effect of Exposure to Silica and Diesel Exhaust in Underground Metal and Nonmetal Miners,'' in *Proceedings of an American Council of Governmental Industrial Hygienists Topical Symposium: Industrial Hygiene for Mining and Tunneling,* 1979.

Atuhaire, L.K., M.J. Campbell, A.L. Cochrane, M. Jones, F. Moore, ''Mortality of Men in the Rhondda Fach 1950–80,'' *British Journal of Industrial Medicine,* 42:741–745, 1985.

Bagley, Susan T., *et al.,* ''Characterization of Fuel and Aftertreatment Device Effects on Diesel Emissions,'' Health Effects Institute, Research Report Number 76, September 1996.

Balarajan, R., and M.E. McDowall, ''Professional Drivers in London: A Mortality Study,'' *British Journal of Industrial Medicine,* 45:483–486, 1988.

Baltimore Gas and Electric Co., et al., v. *Natural Resources Defense Council,* 462 U.S. 87, 103 S.Ct. 2246, (1983).

Battigelli, M.C., ''Effects of Diesel Exhaust,'' *Archives of Environmental Health,* 10:165–167, February 1965.

Battigelli, M.C., *et al.,* ''Environmental and Clinical Investigation of Workmen Exposed to Diesel Exhaust in Railroad Engine Houses,'' *Industrial Medicine and Surgery,* 33:121–1243, 1964.

Becklake, M.R., ''Occupational Exposures and Chronic Airways Disease,'' in Rom, W.R., *Environmental and Occupational Medicine,* 2nd Ed., Little Brown and Co., pp. 453–464,1992.

Becklake, M.R., ''Occupational Exposures: Evidence for a Causal Association with Chronic Obstructive Pulmonary Disease,'' *American Review of Respiratory Disease,* 140:S85–S91, 1989.

Belinsky, SA et al., Pulmonary Toxicity of Inhaled Diesel Exhaust and Carbon Black in Chronically Exposed Rats. Part III: Examination of Possible Target genes, HEI Report #68, Cambridge, MA Health effects Institute, 1995.

Bender, Alan, *et al.,* ''Minnesota Highway Maintenance Worker Study: Cancer Mortality,'' *American Journal of Industrial Medicine,* 15:545–556, 1989.

Benhamou, Simone, *et al.,* ''Occupational Risk Factors of Lung Cancer in a French Case-Control Study,'' *British Journal of Industrial Medicine,* 45:231–233, 1988.

Bhatia, Rajiv, *et al.,* ''Diesel Exhaust Exposure and Lung Cancer,'' *Journal of Epidemiology,* 9:84–91, January 1998.

Birch, M.E. and R.A. Cary, ''Elemental Carbon-Based Method for Monitoring Occupational Exposures to Particulate Diesel Exhaust,'' *Aerosol Science and Technology,* 25:221–241, 1996.

Boffetta, Paolo, *et al.,* ''Diesel Exhaust Exposure and Mortality Among Males in the American Cancer Society Prospective Study,'' *American Journal of Industrial Medicine,* 14:403–415, 1988.

Bond, J.A., *et al.,* ''The Role of DNA Adducts in Diesel Exhaust-Induced Pulmonary Carcinogenesis,'' in Mendelsohn, J.L. and R.J., Albertini, eds., *Mutation and the Environment Part C: Somatic and Heritable Mutation, Adduction, and Epidemiology,* Wiley-Liss, pp. 259–269, 1990.

Bond J. A., *et al.* (1990 b) ''Concentration- and time-dependent formation of DNA adducts in lungs of rats exposed to diesel exhaust.'' *Toxicology* 60:127–135.

Bowen, Otis R., Secretary of Heath and Human Services v. *American Hospital Association, et al.,* 476 U.S. 610, 106 S.Ct. 2101 (1986).

Brightwell, J., *et al.,* ''Neoplastic and Functional Changes in Rodents After Chronic Inhalation of Engine Exhaust Emissions,'' Elsevier Science Publisher B.V. (Biomedical Division), *Carcinogenic and Mutagenic Effects of Diesel Engine Exhaust,* pp. 471–485, 1986.

Brooks, A.L., *et al.,* ''Biological Availability of Mutagenic ChemicalsAssociated with Diesel Exhaust Particles,'' in *Health Effects of Diesel Engine Emissions* (Pepelko, W. E., R.M. Danner, N.A. Clarke, eds.) pp. 345–358, EPA/600/9–80/57a, U.S. Environmental Protection Agency, Cincinnati, OH, 1980.

Bruske-Hohlfeld, I. et al., ''Lung Cancer Risk in Male Workers Occupationally Exposed to Diesel Motor Emissions in Germany,'' *American Journal of Industrial Medicine,* 36:405–414, 1999.

Buiatti, E., *et al.,* ''A Case Control Study of Lung Cancer in Florence, Italy. I Occupational Risk Factors,'' *Journal of Epidemiology and Community Health,* 39:244–250, 1985.

Burns, Patricia, and G. Marie Swanson, ''The Occupational Cancer Incidence Surveillance Study (OCISS): Risk of Lung Cancer by Usual Occupation and Industry in the Detroit Metropolitan Area,'' *American Journal of Industrial Medicine,* 19:655–671, 1991.

Busby, William F. and Paul M. Newberne, ''Diesel Emissions and Other Substances with Animal Carcinogenicity,'' in *Diesel Exhaust: A Critical Analysis of Emissions, Exposure, and Health Effects,* Health Effects Institute, Cambridge, MA, pp. 187–220, 1995.

California Environmental Protection Agency, Health and Safety Code, California Air Pollution Control Laws, Division 26, Air Resources, Section 39655.

Canada Centre for Mineral and Energy Technology (CANMET), ''Diesel Emissions Exposure Reduction in Mines,'' by Don Dainty, *Canadian Ad hoc Diesel Committee Proceedings of the DEEP Conference,* Toronto, Ontario, November 6–7, 1996.

Cantrell, Bruce *et al.,* ''*Pollutant Levels in Underground Coal Mines Using Diesel Equipment*,'' Proceedings of the 6th U.S. Mine Ventilation Symposium, Salt Lake City, UT, 1993.

Cantrell, Bruce and Kenneth Rubow, ''Measurement of Diesel Exhaust Aerosol In

Underground Coal Mines'' *U.S. Bureau of Mines Information Circular 9324*, pp. 11–17, 1992.

Cantrell, Bruce and Kenneth Rubow, ''Diesel Exhaust Aerosol Measurements In Underground Metal and Nonmetal Mines,'' *U.S. Bureau of Mines Information Circular 9324*, pp. 18–23, 1992.

Cass, G.R., and H.A. Gray, ''Regional Emissions and Atmospheric Concentrations of Diesel Engine Particulate Matter: Los Angeles as a Case Study,'' in *Diesel Exhaust: A Critical Analysis of Emissions, Exposure, and Health Effects,* pp. 127–137, Health Effects Institute, Cambridge, MA, 1995.

Castranova, V., et al., ''The Response of Rat Alveolar Macrophages to Chronic Inhalation of Coal Dust and/or Diesel Exhaust,'' *Environmental Research,* 36:405–419, 1985.

Centers for Disease Control, Mine Health Research Advisory Committee Diesel Subgroup and X-Ray Surveillance Subgroup; Open Meetings; 49 FR 37174, September 21, 1984.

Christie et al. (1995), Mortality in the New South Wales Coal Industry, 1973–1992, Medical Journal of Australia 163:19–21.

Citizens to Preserve Overton Park, Inc., et al., v. *John A. Volpe, Secretary, Department of Transportation, et al.,* 401 U.S. 402,91 S.Ct. 814 (1971).

Clean Air Act Amendments of 1990, January 23, 1990.

Clean Air Scientific Advisory Committee, ''Review of EPA's Health Assessment Document for Diesel Emissions, (EPA 600/8–90/057D),'' February 2000.

Coggon, David, *et al.,* ''Use of Job-Exposure Matrix in an Occupational Analysis of Lung and Bladder Cancers on the Basis of Death Certificates,'' *Journal of the National Cancer Institute,* 72(1):61–65, January 1984.

Cohen, A.J. and M.W.P. Higgins, ''Health Effects of Diesel Exhaust: Epidemiology,'' in *Diesel Exhaust: A Critical Analysis of Emissions, Exposures, and Health Effects*, Health Effects Institute, Cambridge, MA, pp. 251–292, 1995.

Correa, P., *et al.,* ''The Causes of Lung Cancer in Louisiana,'' in Mizell, M. and Correa, P. (eds.) *Lung Cancer: Causes and Prevention*, Deerfield Beach: Verlag Cheine International, pp. 73–82, 1984.

Costello, J., *et al.,* ''Mortality from Lung Cancer in U.S. Coal Miners, *American Journal of Public Health*, 64(3):222–224, 1974.

Cox, L.A., ''Does Diesel Exhaust Cause Human Lung Cancer,'' *Risk Analysis*, 17(6):807–829, December 1997.

Crump, KS (1999) Lung cancer mortality and diesel exhaust: Reanalysis of a retrospective cohort study of U.S. railroad workers. Inhalation Toxicology 11:101–107.

DCL International Inc., ''Mine-X Sootfilters,'' Operation and Maintenance Guide, Toronto, Ontario, Canada.

Dahmann, Dirk, *et al.,* ''Diesel Engine Emissions in Workplace-Atmospheres in Germany,'' *Occupational Hygiene*, 3:255–262, 1996.

Damber, L. and L.G. Larsson, ''Professional Driving, Smoking, and Lung Cancer: A Case Referent Study,'' *British Journal of Industrial Medicine*, 42:246–252, 1985.

Dawson, S.V., *et al.,* ''*Health Risk Assessment for Diesel Exhaust*,'' (public and SRP review draft) California Environmental Protection Agency, Air Resources Board, Office of Environmental Health Assessment, February 23, 1998.

DeCoufle, Pierre, *et al.,* ''A Retrospective Survey of Cancer in Relation to Occupation,'' *NIOSH Research Report*, DHEW, (NIOSH) Publication No. 77–178, 1977.

Diaz-Sanchez, D., ''The Role of Diesel Exhaust Particles and Their Associated Polyaromatic Hydrocarbons in the Induction of Allergic Airway Disease,'' *Allergy*, 52:52–56, 1997.

Diaz-Sanchez, D., *et al.,* ''Combined Diesel Exhaust Particle and Ragweed Allergen Challenge Markedly Enhances Human In Vivo Nasal Ragweed-Specific IgE and Skews Cytokine Production to a T Helper Cell 2-Type Pattern,'' *Journal of Immunology*, 158:2406–2413, 1997.

Diaz-Sanchez, D., *et al.,* ''Enhanced Nasal Cytokine Production in Human Beings After In Vivo Challenge with Diesel Exhaust Particles,'' *Journal of Allergy Clinical Immunology*, 98:114–123, 1996.

Diaz-Sanchez, D., *et al.,* ''Diesel Exhaust Particles Induce Local IgE Production in Vivo and Alter the Pattern of IgE Messenger RNA Isoforms,'' *Journal of Clinical Investigation*, 94(4):1417–1425, 1994.

Diesel Emission Control-Sulfur Effects (DECSE) Program, Phase 1 Interim Data Report No. 4: Diesel Particulate Filters-Final Report, (Sponsored by the U.S. Department of Energy, Engine Manufacturers Association, Manufacturers of Emission Controls Association), January 2000.

Dockery, Douglas, *et al.,* ''An Association Between Air Pollution and Mortality in Six U.S. Cities,'' *New England Journal of Medicine*, 24:1753–1759, 1993.

Dubrow, Robert, and David Wegman, ''Cancer and Occupation in Massachusetts: A Death Certificate Study,'' *American Journal of Industrial Medicine*, 6:207–230, 1984.

Dusseldorp, A., *et al.,* ''Association of PM_{10} and Airborne Iron with Respiratory Health of Adults Living Near a Steel Factory,'' *American Journal of Respiratory and Critical Care Medicine*, 152:1932–1939,1995.

Edling, Christer, *et al.,* ''Mortality Among Personnel Exposed to Diesel Exhaust,'' *International Archives of Occupational and Environmental Health*, 59:559–565, 1987.

Ellington, Ray, Public Testimony, presented at the ''Workshop on Miners'' Exposure to Diesel Particulate,'' Salt Lake City, Utah, October 12–13, 1995.

Emmelin, Anders, *et al.,* ''Diesel Exhaust Exposure and Smoking: A Case Referent Study of Lung Cancer Among Swedish Dock Workers,'' *Journal of Epidemiology*, 4:237–244, 1993.

Engine Manufacturers Association v. *EPA*, 88 F.3d 1075, 319 U.S. App.D.C. 12 (1996).

Enterline, P.E., ''A Review of Mortality Data for American Coal Miners,'' *Annals New York Academy of Sciences*, 200:260–272, 1972.

Enya, Takeji, *et al.,* ''3 Nitrobenzanthrone, a Powerful Bacterial Mutagen and Suspected Human Carcinogen Found in Diesel Exhaust and Airborne Particulates,'' *Environmental Science and Technology*, 31:2772–2776, 1997.

EPA, Health Assessment Document for Diesel Emissions, Office of Research and Development, SAB Review Draft, EPA–600/8–90/057D, November 1999.

EPA, Air Pollution; Tier 2 Motor Vehicle Emission Standards and Gasoline Sulphur Control Requirements; Diesel Fuel Quality Control; Proposed Rule, 40 CFR Parts 80, 85 and 86, 64 FR 26003, May 13, 1999.

EPA, Control of Air Pollution from New Motor Vehicles; Compliance Programs for New Light-Duty Vehicles and Light-Duty Trucks; Final Rule, 40 CFR Part 9 et al., 64 FR 23906, May 4, 1999.

EPA, Control of Emissions of Air Pollution From Nonroad Diesel Engines; Final Rule, 40 CFR Parts 9, 86, and 89, October 23, 1998.

EPA, Emission Standards for Locomotives and Locomotive Engines; Final Rule, 40 CFR Parts 85, 89, and 92, 63 FR 18978, April 16, 1998.

EPA, 40 CFR Part 86, Control of Air Pollution from New and In-Use Motor Vehicles and New and In-Use Motor Vehicle Engines: Certification and Test Procedures.

EPA, 40 CFR Part 85, Control of Air Pollution from Motor Vehicles and Motor Vehicle Engines.

EPA, 40 CFR Part 80, Regulation of Fuels and Fuel Additives.

EPA, Control of Emissions of Air Pollution from Highway Heavy-Duty Engines; Final Rule, 62 FR 54693, 40 CFR Parts 9 and 86, October 21, 1997.

EPA, Control of Emissions of Air Pollution from Nonroad Diesel Engines; Proposed Rule, 40 CFR Parts 9, 86, and 89, 62 FR 50151, September 24, 1997.

EPA, National Ambient Air Quality Standards for Particulate Matter, Final Rule, 40 CFR Part 50, 62 FR 38651, July 18, 1997.

EPA, Office of Air & Radiation, Office of Air Quality Planning & Standards, *Fact Sheet,* EPA's Revised Particulate Matter Standards, July 17, 1997.

EPA, ''PM–2.5 Composition and Sources,'' Office of Air Quality Planning and Standards, June 16, 1997.

EPA, Emission Standards for Locomotives and Locomotive Engines; Proposed Rule, 40 CFR Parts 85, 89, and 92, 62 FR 6366, February 11, 1997.

EPA, *Environmental Fact Sheet,* ''Statement of Principles for Nonroad Diesel Engines,'' EPA 420–F–96–015, September 1996.

EPA, *Fact Sheet,* ''Emission Control Potential for Heavy-Duty Diesel Engines,'' EPA 420-F–95–009(b), 1996.

EPA, *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information,* OAQPS Staff Paper, EPA–452/R–96–013, July 1996.

EPA, Control of Emissions of Air Pollution from Highway Heavy-Duty Engines, Proposed Rule, 40 CFR Part 86, 61 FR 33421, June 27, 1996.

EPA, *Air Quality Criteria for Particulate Matter, Volumes I–III,* EPA/600/P–95/001aF/001bF/001cF, April 1996.

EPA, Determination of Significance for Nonroad Sources and Emission Standards for New Nonroad Compression-Ignition Engine At or Above 37 Kilowatts; Final Rule, 40 CFR Parts 9 and 89, 59 FR 31306, June 17, 1994.

EPA, Fuels and Fuel Additives Registration Regulations, Final Rule, 40 CFR Part 79, 59 FR 33042, June 27, 1994.

EPA, *The Plain English Guide to the Clean Air Act,* EPA 400–K–93–001, April 1993.

EPA, Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines: Gaseous and Particulate Emission Regulations for 1994 and Later Model Year Light-Duty Vehicles and Light-Duty Trucks; Final Rule, 40 CFR Part 86, 56 FR 25724, June 5, 1991.

EPA, Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines and Fuel Economy of Motor Vehicles: Emissions Certification and Test Procedures, Fuel Economy Test Procedures: Technical Amendments; Final Rule, Parts 86 and 600, 40 CFR 86.088–11, Emission Standards for 1988 and Later Model Year Diesel Heavy-Duty Engines, 52 FR 47853, December 16, 1987.

EPA, *Second Addendum to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of Newly Available Health Effects Information,* EPA Report No. EPA–600/8–86–020F, December 1986.

EPA, Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Final Rule, 40 CFR 86.085–11, Part 86, Emission Standards for 1984 and Later Model Year Diesel Heavy-Duty Engines, 48 FR 52183, November 16, 1983.

Federal Institute for Occupational Safety and Health, ''Cohort Study on the Effect of Diesel Motor Emission on Lung Cancer Mortality in Potash Mining,'' Unpublished Cohort Study in German, NIH Library Translation, NIH–98–120.

Financial Times, ''Survey of World Motor Industry (2),'' March 5, 1996.

Firket, J., ''Fog Along the Meuse Valley,'' *Transactions of the Faraday Society,* 32:1192–1197, 1931.

French, Ian W., ''An Annotated Bibliography Relative to the Health Implications of Exposure of Underground Mine Workers to Diesel Exhaust Emissions (Contract 16SQ.23440–6–9095),'' Report to the Department of Energy, Mines and Resources, Ottawa, Canada, Dec. 11, 1978.

Fritz, Steven G., ''Exhaust Emissions from a Caterpillar 3306 PCNA Mining Engine Equipped with a Jeffrey Exhaust Filter System,'' Southwest Research Institute, Final Report, prepared for MSHA, February 2000.

Gallagher, J., *et al.,* ''Formation of DNA Adducts in Rat Lung Following Chronic Inhalation of Diesel Emissions, Carbon Black and Titanium Dioxide Particles,'' *Carcinogenesis,* 15(7):1291–1299, 1994.

Gamble, John, *et al.,* Epidemiological-Environmental Study of Diesel Bus Garage Workers: Acute Effects of NO_2 and Respirable Particulate on the Respiratory System,'' *Environmental Research,* 42:201–214, 1987(a).

Gamble, John, *et al.,* ''Epidemiological-Environmental Study of Diesel Bus Garage Workers: Chronic Effects of Diesel Exhaust on the Respiratory System,'' *Environmental Research,* 44:6–17, 1987(b).

Gamble, John, and William Jones, ''Respiratory Effects of Diesel Exhaust in Salt Miners,'' *American Review of Respiratory Disease,* 128:369–394, 1983.

Gamble, John, *et al.,* ''Acute Changes in Pulmonary Function in Salt Miners,'' in *Proceedings of an American Council of Governmental Industrial Hygienist Topical Symposium: Industrial Hygiene for Mining and Tunneling,* Denver, CO, November 6–7, 1978.

Gangel, M.K. and E.D. Dainty, ''Ambient Measurement of Diesel Particulate Matter and Respirable Combustible Dust in Canadian Mines,'' *Proceedings of the 6th U.S. Mine Ventilation Symposium (Bhaskar, R., ed.)* pp. 83–89, Society for Mining, Metallurgy, and Exploration, Littleton, CO., 1993.

Garshick, Eric, M.D., letter to U.S. EPA, August 15, 1991.

Garshick, Eric, *et al.,* ''A Retrospective Cohort Study of Lung Cancer and Diesel Exhaust Exposure in Railroad Workers,'' *American Review of Respiratory Disease,* 137:820–825, 1988.

Garshick, Eric, *et al.,* ''A Case-Control Study of Lung Cancer and Diesel Exhaust Exposure in Railroad Workers,'' *American Review of Respiratory Disease,* 135:1242–1248, 1987.

Gautam, Mridul, Public Testimony, presented at the ''Workshop on Miners' Exposure to Diesel Particulate,'' Beckley, West Virginia, September 12–13, 1995.

Glenn, R., et al., ''Respiratory health effects in relation to underground diesel use,'' Proceeding of VI International Pneumoconiosis Conference, 1983.

Green, Gareth M. and Ann Y. Watson, ''Relation Between Exposure to Diesel Emissions and Dose to the Lung,'' in Diesel Exhaust: A Critical Analysis of Emissions, Exposure, and Health Effects, Health Effects Institute, pp. 167–184, Cambridge, MA, 1995.

Gu, Zu-Wei, *et al., Induction of Unscheduled DNA Synthesis in V79 Cells by Diesel Emission Particles Dispersed in Simulated Pulmonary Surfactant,* Division of Respiratory Disease Studies, NIOSH, Morgantown, West Virginia, 1991.

Gu, Zu-Wei, *et al.,* ''Micronucleus Induction and Phagocytosis in Mammalian Cells Treated with Diesel Emission Particles,'' *Mutation Research,* 279:55–60, 1992.

Gubéran, E., *et al.,* ''Increased Risk for Lung Cancer and for Cancer of the Gastrointestinal Tract Among Geneva Professional Drivers,'' *British Journal of Industrial Medicine,* 49:337–344, 1992.

Gushee, David, ''Heavy Duty Diesel Engines and Their Fuel: Can They Survive Clean Air Regulations?'' Congressional Reference Service, The Library of Congress, 95–961 ENR, September 11, 1995.

Gustafsson, Lennart, *et al.,* ''Mortality and Cancer Incidence Among Swedish Dock Workers—A Retrospective Cohort Study,'' *Scandinavian Journal of Work, Environment and Health*, 12:22–26, 1986.

Gustavsson, Per, *et al.*, ''Lung Cancer and Exposure to Diesel Exhaust Among Bus Garage Workers,'' *Scandinavian Journal of Work, Environment and Health*, 16:348–354, 1990.

Hahon, Nicholas, et al., ''Influenza Virus Infection in Mice after Exposure to Coal Dust and Diesel Engine Emissions,'' *Environmental Research*, 37:44–60, 1985.

Hall, Nancy, and Ernst Wynder, ''Diesel Exhaust Exposure and Lung Cancer: A Case-Control Study,'' *Environmental Research,* 34:77–86, 1984.

Haney, Robert, and Saseen, George, ''Estimation of Diesel Particulate Concentrations in Underground Mines,'' *Mining Engineering,* Volume 52, Number 5, April 2000.

Haney, Robert, George Saseen, and Robert Waytulonis, ''An Overview of Diesel Particulate Control Technology in the U.S. Mining Industry,'' *Appl. Occup. Environ. Hyg.*, (12)12, December 1997.

Haney, Robert, ''Diesel Particulate Exposures in Underground Mines,'' *Mining Engineering,* 173:176, February 1992.

Hansen, Eva S., ''A Follow-up Study on the Mortality of Truck Drivers,'' *American Journal of Industrial Medicine,* 23:811–821, 1993.

Harris, Jeffrey E., ''Diesel Emissions and Lung Cancer,'' *Society for Risk Analysis,* Vol. 3, No. 2, 1983.

Hattis, Dale, and Silver, Ken, ''Projection of Human Lung Cancer Risks for Diesel Particulates from Animal Data—Effects of Using Measures of Internal vs External Dose, and Possible Interactions with Smoking,'' Submitted by CENTED University, in response to ANPRM, #87–0–18, May 20, 1992.

Hayes, Richard, *et al.*, ''Lung Cancer in Motor Exhaust-Related Occupations,'' *American Journal of Industrial Medicine,* 16:685–695, 1989.

Health Effects Institute, ''Diesel Emissions and Lung Cancer: Epidemiology and Quantitative Risk Assessment,'' A Special Report of the Institute's Diesel Epidemiology Expert Panel, June 1999.

Heinrich, Uwe, *et al.*, ''Chronic Inhalation Exposure of Wistar Rats and Two Different Strains of Mice to Diesel Engine Exhaust, Carbon Black, and Titanium Dioxide,'' *Inhalation Toxicology,* 7:533–556, 1995.

Heinrich, Uwe, ''Carcinogenic Effects of Solid Particles,'' 1994.

Heinrich, Uwe, *et al.*, ''Inhalation Exposure of Rats to Tar/Pitch Condensation Aerosol or Carbon Black Alone or in Combination with Irritant Gases,'' 1994.

Heinrich, Uwe, *et al.,* ''Chronic Effects on the Respiratory Tract of Hamsters, Mice and Rats after Long-term Inhalation of High Concentrations of Filtered and Unfiltered Diesel Engine Emissions,'' *Journal of Applied Toxicology,* (6)6:383–395, 1986.

Hemminki, Kari, *et al.,* ''DNA Adducts Among Personnel Servicing and Loading Diesel Vehicles,'' *Carcinogenesis,* 15(4):767–769, 1994.

Hodgson, J.T. and R.D. Jones, ''A Mortality Study of Carbon Black Workers Employed at Five United Kingdom Factories Between 1947 and 1980,'' *Archives of Environmental Health,* 40(5):261–268, September/October 1985.

Holtz, John, *Safety with Mobile Diesel-Powered Equipment Underground,* United States Department of Interior, Bureau of Mines, Report of Investigations No. 5616, 1960.

Hou, S.M., et al., ''Relationship between hprt mutant frequency, aromatic DNA adducts and genotypes for GSTM1 and NAT2 in bus maintenance workers,'' *Carcinogenesis,* 16:1913–1917, 1995.

Howe, Geoffrey R., *et al.,* ''Cancer Mortality (1965–77) in Relation to Diesel Fume and

Coal Exposure in a Cohort of Retired Railway Workers,'' *Journal of the National Cancer Institute,* Vol. 70, No. 6, June 1983.

Hricko, Andrea, Deputy Assistant Secretary for MSHA, ''Workshop on Diesel Exhaust: Considerations in the Use of Epidemiologic Data for Quantitative Cancer Risk Assessments,'' San Francisco, California, January 29, 1996.

Inco Limited, public comment submitted in response to MSHA's January 1992 ANPRM, 87–0–5, April 16, 1992.

Industrial Union Department, AFL-CIO v. *American Petroleum Institute et al.,* No. 78–911, 448 U.S. 607, 100 S.Ct. 2844 (1980).

Industrial Union Department, AFL-CIO v. *James D. Hodgson,* 499 F.2d 467 (1974).

Ichinose, Takamichi, *et al.,* ''Murine Strain Differences in Allergic Airway Inflammation and Immunoglobulin Production by a Combination of Antigen and Diesel Exhaust Particles,'' Toxicology, 122:183–192, 1997a.

Ichinose, et al., ''Lung Carcinogenesis and Formation of in Mice by Diesel Exhaust Particles'' *Carcinogenesis,* 18:185–192, 1997b.

Interagency Task Group Report (MSHA, NIOSH, BOM) ''The Health and Safety Implications of the Use of Diesel-Powered Equipment in Underground Coal Mines,'' 1986.

International Agency for Research on Cancer, ''Diesel and Gasoline Engine Exhausts,'' in: IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Vol. 46, Lyon, France, 1989(b).

International Agency for Research on Cancer, ''Printing Processes and Printing Inks, Carbon Black and some Nitro Compounds,'' IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Human, Volume 65.

International Ladies' Garment Workers' Union, et al., v. *Raymond J. Donovan, et al.,* 722 F.2d 795, 232 U.S. App. D.C. 309 (1983).

International Programme on Chemical Safety, Environmental Health Criteria 171, *Diesel Fuel and Exhaust Emissions,* World Health Organization, Geneva, 1996.

International Union, United Mine Workers of America v. *Cynthia Metzler et al.,* U.S. D.C. Circuit Court of Appeals, #97–1109, February 1997.

Iwai, Kazuro, et al., ''Long-Term Inhalation Studies of Diesel Exhaust on F344 SPF Rats. Incidence of Lung Cancer and Lymphoma'' in *Carcinogenic and Mutagenic Effects of Diesel Exhaust,* Elsevier Science B.V. (Biomedical Division), 1986.

Jacobsen, Michael, *et al., Respiratory Infections in Coal Miners Exposed to Nitrogen Oxides,* Health Effects Institute Research Report 18, 1988.

Johnston, A.M, et al. (1997), Investigation of the possible association between exposure to diesel exhaust particulates in British coal mines and lung cancer. Institute of Occupational Medicine (IOM), Report TM/97/08 (Edinburgh, Scotland).

Jörgenson, Harold, and Äke Svensson, ''Studies on Pulmonary Function and Respiratory Tract Symptoms of Workers in an Iron Ore Mine Where Diesel Trucks are Used Underground,'' *Journal of Occupational Medicine,* Volume 12, No. 9, September 1970.

Kahn, Geralynn, *et al.,* ''Acute Overexposure to Diesel Exhaust: Report of 13 Cases,'' *American Journal of Industrial Medicine,* 13:405–406, 1988.

Kaplan, Isadore, ''Relationship of Noxious Gases to Carcinoma of the Lung in Railroad Workers,'' *Journal of the American Medical Association,* Vol. 171, No. 15, 1959.

Keane, M.J., *et al.,* ''Genotoxicity of Diesel-Exhaust Particles Dispersed in Simulated Pulmonary Surfactant,'' *Mutation Research,* 260:233–238, 1991.

King, Leon, *et al.,* ''Evaluation of the Release of Mutagens from Diesel Particles in the Presence of Physiological Fluids,'' *Environmental Mutagenesis,* 3:109–121, 1981.

Kittleson and Khalek, 1999.

Kuempel, E.D., L.T. Stayner, M.D. Attfield, C.R. Buncher, ''Exposure-Response Analysis of Mortality Among Coal Miners in the United States,'' *American Journal of Medicine,* 28:167–184, 1995.

Lambert, B., *et al.,* ''Analysis of Mutation at the hprt Locus in Human T Lymphocytes,'' *Toxicology Letters,* 82–83:323–333, 1995.

Lerchen, Mary, *et al.,* ''Lung Cancer and Occupation in New Mexico,'' *Journal of the National Cancer Institute,* 79(4):639–645, October 1987.

Leupker, Russell, and Michelle Smith, ''Mortality in Unionized Truck Drivers,'' *Journal of Occupational Medicine,* Vol. 20, No. 10, October 1978.

Levin, L.I., *et al.,* ''Occupation and Lung Cancer in Shanghai: A Case-Control Study,'' *British Journal of Industrial Medicine,* 45:450–458, 1988.

Liddell, F.D.K., ''Mortality of British Coal Miners in 1961,'' *British Journal of Industrial Medicine,* 30:15–24, 1973.

Lindsay, Joan, *et al.,* ''The Canadian Labour Force Ten Percent Sample Study: Cancer Mortality Among Men, 1965–1979,'' *Journal of Occupational and Environmental Medicine,* Vol. 35, No. 4, 1993.

Lipsett, M. and G. Alexeeff, ''Quantitative Meta-Analysis on the Relationship of Occupational Exposure to Diesel Exhaust and Lung Cancer,'' Appendix C of *Health Risk Assessment for Diesel Exhaust,* (public and SRP review draft) California Environmental Protection Agency, Air Resources Board, Office of Environmental Health Assessment, February 23, 1998.

Lipsett M., and Campleman, Susan, ''Occupational Exposure to Diesel Exhaust and Lung Cancer: A Meta-Analysis,'' *American Journal of Public Health,* (89) 1009–1017, July 1999.

Lovik, Martinus, *et al.,* ''Diesel Exhaust Particles and Carbon Black Have Adjuvant Activity on the Local Lymph Node Response and Systemic IgE Production to Ovalbumin,'' *Toxicology,* 121:165–178, 1997.

Majewski, W. Addy, ''The Nature of Diesel Nanoparticles May Require Rethinking of Particulate Matter Standards,'' *Diesel Progress,* pp. 106–109, June 1998.

Martin, A.E., ''Mortality and Morbidity Statistics and Air Pollution,'' *Proceedings of the Royal Society of Medicine,* 57:969–975, 1964.

Marrecau, Willy, and Peter Klaus, ''Diesel Wire Mesh Particulate Filter'' presentation at the Mining Emission Diesel Conference, Toronto, Ontario, Canada, November 3–4, 1999.

Mayer, Ing, A., et al., ''Verified Particulate Trap Systems for Diesel Engines-Filter List,'' Swiss Agency for the Environment, Forests and Landscape, Version 1, August 1999.

Mayer, Ing, A., et al., ''Effectiveness of Particulate Traps on Construction Site Engines: VERT Final Measurements,'' DieselNet Technical Report, March 1999.

Mayer, Ing, A., ''VERT: Curtailing Emissions of Diesel Engines in Tunnel Sites,'' April 1998.

Mauderly JL, et al., Diesel Exhaust is not a pulmonary carcinogen in CD–1 mice exposed under conditions carcinogenic to F344 rats. *Fundam Appl Toxicol* 1996; 30:233–242.

Mauderly, Joe L., *et al.,* ''Pulmonary Toxicity of Inhaled Diesel Exhaust and Carbon Black in Chronically Exposed Rats, Part I, Neoplastic and Nonneoplastic Lung Lesions,'' *Research Report Number 68,* Health Effects Institute, Cambridge, MA, October 1994.

Mauderly, Joe L., ''Toxicological and Epidemiological Evidence for Health Risks from Inhaled Engine Emissions,'' presented at the Risk Assessment of Urban Air; Emissions, Exposure, Risk Identification and Risk Quantification Conference held in Stockholm, Sweden, May 31-June 5, 1992.

Mauderly, Joe L., ''Diesel Exhaust,'' *Environmental Toxicants: Human Exposures and Their Health Effects,* Chapter 5, 1992.

McAteer, J. Davitt, Assistant Secretary for Mine Safety and Health, MSHA, Letter to Diesel Particulate Workshop Participants, July 24, 1995.

McElroy, G.E., ''Engineering Factors in the Ventilation of Metal Mines,'' U.S. Department of the Interior, Bureau of Mines, Bulletin 385, 1935.

McKinnon, Dale, Public Testimony, presented at the ''Workshop on Miners' Exposure to Diesel Particulate,'' Beckley, West Virginia, September 12–13, 1995.

Menck, Herman, and Brian Henderson, ''Occupational Differences in Rates of Lung Cancer,'' *Journal of Occupational Medicine,* Vol.18, No. 12, December 1976.

Miller, B.G., and M. Jacobsen, ''Dust Exposure, Pneumoconiosis, and Mortality of Coal Miners,'' *British Journal of Industrial Medicine,* 42:723–733, 1985.

Milne, K.L., *et al.,* ''Lung Cancer and Occupation in Alameda County: A Death Certificate Case-Control Study,'' *American Journal of Industrial Medicine,* 4:565–575, 1983.

Morabia, A., *et al.,* ''Lung Cancer and Occupation: Results of a Multicentre Case-Control Study,'' *British Journal of Industrial Medicine,* 49:721–727, 1992.

Morfeld, P., K. Lampert, H. Ziegler, C. Stegmaier, G. Dhom, C. Piekarski, ''Overall Mortality and Cancer Mortality of Coal Miners: Attempts to Adjust for Healthy Worker Selection Effects,'' *Annals of Occupational Hygiene,* 41(Supplement 1):346–351, 1997.

Morgan, W.K.C., ''Health Effects of Diesel Emissions,'' *Annals of Occupational Hygiene,* 41(6):643–658, December 1997.

Mori, Y., *et al.,* ''Inhibition of Catalase Activity in Vitro by Diesel Exhaust

Particles,'' *Journal of Toxicology and Environmental Health,* 47(2):125–134, 1996.

Morton International, public comment submitted in response to MSHA's January 1992 ANPRM, 87–0–11, July 10, 1992.

Motor Vehicle Manufacturers Association of the United States, Inc., v. *State Farm Mutual Automobile Insurance Company et al.,* 463 U.S. 29, 103 S.Ct. 2856 (1983).

MSHA, Results of Tests to Determine Interference on Diesel Particulate Matter Measurements from Carbonate Dust, May 19, 2000.

MSHA, Results of Tests to Determine Interference on Diesel Particulate Matter Measurements from Cigarette Smoke, March 14, 2000.

MSHA, Jackleg Drill Diesel Particulate Evaluation Carlin Mine, Newmont Mining Corporation, (Mine I.D. No. 26 02271, Carlin, Nevada), March 15, 2000.

MSHA, Sampling for Diesel Particulate Interferences Barrick Goldstrike Mines, Incorporated, (Mine I.D. No. 26 01089, Elko, Nevada), March 15, 2000.

MSHA, ''Diesel Particulate Evaluation at a Crusher and Sample Preparation Room South Area, Newmont Mining Corporation, (Mine I.D. No. 26 00500, Carlin, Nevada), March 15, 2000.

MSHA, Diesel Particulate Study at the Homestake Mine, Homestake Mining Company, (Mine I.D. No. 39 00055, Lead, South Dakota), March 15, 2000.

MSHA, Sampling Results of the Diesel Particulate Study Conducted at the Viburnum #28 Mine, The Doe Run Company, (Mine I.D. No. 23–00494), Viburnum, Missouri, October 24, 1997.

MSHA, Sampling Results of the Diesel Particulate Study Conducted at the Plattville Galena Mine, Conco, Western Stone Company, (Mine I.D. No. 11–02931), North Aurora, Illinois, May 20, 1997.

MSHA, Sampling Results of the Diesel Particulate Study Conducted at the Cleveland Mine, AKZO Nobel Salt, Inc., (Mine I.D. 33–01994), Cleveland, Ohio, May 7, 1997.

MSHA, Health Standards for Occupational Noise Exposure in Coal, Metal and Nonmetal Mines; Proposed Rule, 30 CFR Parts 56, 57, 62, 70 and 71, 61 FR 66348, December 17, 1996.

MSHA, Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines; Final Rule, 30 CFR Parts 7, *et al.*, 61 FR 55412, October 25, 1996.

MSHA, Division of Mining Information Systems, Coal 1996-Size Group Report, MSHA/DMIS, CM–441, (Quarters 1–4, 1996).

MSHA, ''Workshop on Miners' Exposure to Diesel Particulate,'' Transcript, Salt Lake City, Utah, October 12–13, 1995.

MSHA, ''Workshop on Miners' Exposure to Diesel Particulate,'' Transcript, Mt. Vernon, Illinois, October 6, 1995.

MSHA, ''Workshop on Miners' Exposure to Diesel Particulate,'' Transcript, Beckley, West Virginia, September 12–13, 1995.

MSHA, Permissible Exposure Limit for Diesel Particulate; Advance Notice of Proposed Rulemaking, 30 CFR Parts 56 and 72, 57 FR 500, January 6, 1992.

MSHA, Respirable Coal Mine Dust and Diesel Particulate Survey Conducted at Kinney Branch No. 5 Mine, Kinney Branch Coal Company, Pikeville, Kentucky, April 13, 1990.

MSHA, Approval Requirements for Diesel-Powered Machines and Approval Exposure Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines; Proposed Rules, 54 FR 40950, October 4, 1989.

MSHA, Air Quality, Chemical Substances and Respiratory Protection Standards; Proposed Rule, 30 CFR Part 56 *et al.*, 54 FR 35760, August 29, 1989.

MSHA, Report of the Mine Safety and Health Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines,'' July 1988.

MSHA, Notice of Establishment of Advisory Committee, 52 FR 37381, October 6, 1987.

MSHA, Policy Memorandum, 81–19MM, August 5, 1981.

Muscat, Joshua and Wynder, Ernst, ''Diesel Engine and Lung Cancer: An Unproven Association,'' *Environmental Health Perspectives,* 103:9–812–818, 1995.

National Coal Association, public comment prepared by Robert A. Michaels, RAM TRAC Corporation, #87–0–10, July 10, 1992.

National Center for Health Statistics, *Vital Statistics of the United States 1992, Vol. II -Mortality Part A;* National Center for Health Statistics, U.S. Dept. of Health and Human Services, 1996.

National Research Council, Health Effects of Exposure to Radon: (BEIR VI), Board on Radiation Effects Research, 1999.

National Research Council, ''*Understanding Risk: Informing Decisions in a Democratic Society,*'' Stern, Paul and Harvey Fineberg, eds., Summary, pp. 1–10, Committee on Risk Characterization, National Press, 1996.

Nauss, K.M., *et al.,* ''Critical Issues in Assessing the Carcinogenicity of Diesel Exhaust: A Synthesis of Current Knowledge,'' in *Diesel Exhaust: A Critical Analysis of Emissions, Exposures, and Health Effects,* pp. 1–61, Health Effects Institute, Cambridge, MA, April, 1995.

Navistar International Transportation Corp., ''An Analysis of the Suitability of Steenland et al., for Conducting Quantitative Risk Assessment of Diesel Exhaust,'' June 4, 1999.

Needham, John, ''Heavy Duty Diesel Technology for the Mid 90's and Beyond-Worldwide Perspective, Ricardo Consulting Engineers Ltd., paper presented at the SAE TOPTEC Conference, April 27–28, 1993.

Newmont Gold Company, comments, EPA docket number A–95–54, IV–D–2346, March 11, 1997.

Nielsen, P.S., *et al.,* ''Biomonitoring of Diesel Exhaust-Exposed Workers. DNA and Hemoglobin Adducts and Urinary 1-Hydroxypyrene as Markers of Exposure,'' *Toxicology Letters,* 86:27–37, July 1996.

Nikula, K.J., *et al.,* ''Lung Tissue Responses and Sites of Particle Retention Differ Between Rats and Cynomolgus Monkeys Exposed Chronically to Diesel Exhaust and Coal Dust,'' *Fundamental and Applied Toxicology,* 37:37–53, 1997.

Nikula, K. J., *et al.,* ''Comparative Pulmonary Toxicities and Carcinogenicities of Chronically Inhaled Diesel Exhaust and Carbon Black in F344 Rats,'' *Fundamental and Applied Toxicology,* 25:80–94, 1995.

NIOSH, *Criteria for a Recommended Standard, Occupational Exposure to Respirable Coal Mine Dust,* U.S. Department of Health and Human Services, September 1995.

NIOSH Analytical Method 5040, Elemental Carbon, December 14, 1994.

NIOSH, U.S. Department of Health and Human Services, public comment in response to MSHA 1992 ANPRM, #87–OFED–2, July 10, 1992.

NIOSH, Health Hazard Evaluation Report: Yellow Freight Systems, Inc., *NIOSH Report No. HHE HETA 90–088–2110,* 1990.

NIOSH, *Current Intelligence Bulletin No. 50,* ''Carcinogenic Effects of Exposure to Diesel Exhaust,'' U.S. Department of Health and Human Services, (NIOSH) Publication No. 88–116, August 1988.

Oberdörster, Gunter, *et al.,* ''Increased Pulmonary Toxicity of Inhaled Ultra Fine Particles: Due to Lung Overload Alone?,'' *Annals of Occupational Hygiene,* Vol. 38, Supplement 1, pp. 295–302, 1994.

Oberdörster, Gunter, *et al.,* ''Correlation between Particle Size, In Vivo Particle Persistence, and Lung Injury,'' *Environmental Health Perspectives,* 102:173–179, 1994.

Official Journal of European Countries, Information and Notices, C–123, Volume 40, April 21, 1997.

Office of Management and Budget, *Circular A–130,* February 8, 1996.

Ohio General Assembly, Ohio Revised Code, Chapter 1567: Mine Equipment, Safety Procedures. Section 1567.35, Bill Number: Amended. Sub. S.B. 162, Effective Date: October 29, 1999.

OSHA, Air Contaminants; Final Rule, 29 CFR Part 1910, 54 FR 2332, January 19, 1989.

Oxman, Andrew D., *et al.,* ''Occupational Dust Exposure and Chronic Obstructive Pulmonary Disease: A Systematic Overview of the Evidence,'' *American Review of Respiratory Disease,* Vol. 148, pp. 38–48, 1993.

Paas, Norbert, Public testimony presented at the ''Workshop on Miners' Exposure to Diesel Particulate,'' Beckley, West Virginia, September 12–13, 1995.

Parent, M.E., *et al.,* ''Case-Control Study of Exposure to Carbon Black in the Occupational Setting and Risk of Lung Cancer,'' *American Journal of Industrial Medicine,* 30(3):285–292, 1996.

Pennsylvania, The General Assembly of Pennsylvania, Senate Bill No. 1643, Article II–A, Section 203–A, Exhaust Emission Controls, July 22, 1996.

Perry, G.B., *et al.,* ''Effects of Particulate Air Pollution on Asthmatics,'' *American Journal of Public Health*, 73(1):50–56, January 1983.

Peterson, Brett, and Andrew Saxon, ''Global Increases in Allergic Respiratory Disease: The Possible Role of Diesel Exhaust Particles,'' *Annals of Allergy, Asthma, and Immunology,* 77:263–270, 1996.

Pfluger, D. H. and C. E. Minder, ''A Mortality Study of Lung Cancer Among Swiss Professional Drivers: Accounting for the Smoking Related Fraction by a

Multivariate Approach,'' *Soz Präventivmed,* 39:372–378, 1994.

Pope, C. A., *et al.,* ''Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults,'' *American Journal of Respiratory and Critical Care Medicine,* 151:669–674, 1995.

Pope, C.A. and R.E. Kanner, ''Acute Effects of PM_{10} Pollution on Pulmonary Function of Smokers with Mild to Chronic Obstructive Pulmonary Disease,'' *American Review of Respiratory Disease,* 47:1336–1340, 1993.

Purdham, James, *et al.,* ''Environmental and Medical Assessment of Stevedores Employed in Ferry Operations,'' *App. Ind. Hyg.,* Vol. 2, No. 3, May 1987.

Qu, Shu-Xin, *et al.,* ''DNA adducts in miners: Association with Exposures to Diesel Engine Emissions,'' *Biomarkers,* 2:95–102 1997.

Randerath K., et al., Pulmonary Toxicity of Inhaled Diesel Exhaust and Carbon Black in Chronically Exposed Rats. Part II: DNA Damage (HEI Research Report #68) Cambridge: Health Effects Institute, 1995.

Raffle, P.A., ''The Health of the Worker,'' *British Journal of Industrial Medicine*, 14:73–80, 1957.

Rafnsson, Vilhjalmur, and Holmfriour Gunnarsdottir, ''Mortality Among Professional Drivers,'' *Scandinavian Journal of Work, Environment and Health*, 17:312–317, 1991.

Reger, R., *et al.*, ''Coal Miners Exposed to Diesel Exhaust Emissions,'' *Annals of Occupational Hygiene*, Vol. 26, Nos. 1–4, pp. 799–815, 1982.

Rice, George S., ''Notes on Testing the Explosibility of Coal Dusts and a Proposal to Have an International Test Method,'' U.S. Department of the Interior, Bureau of Mines, Information Circular 6878, March 1936.

Rockette, H.E., ''Cause Specific Mortality of Coal Miners,'' *Journal of Occupational Medicine*, 19:795–801, 1977.

Rooke, G.B., F.G. Ward, A.N. Dempsey, J.B. Dowler, C.J. Whitaker, ''Carcinoma of the Lung in Lancashire Coal Miners,'' *Thorax*, 34:229–233, 1979.

Rudell, B., *et al.*, ''Effects on Symptoms and Lung Function in Humans Experimentally Exposed to Diesel Exhaust,'' *Occupational and Environmental Medicine*, 53:658–662, 1996.

Rushton, L., *et al.*, ''Epidemiological Survey of Maintenance Workers in London Transport Executive Bus Garages and Chiswick Works,'' *British Journal of Industrial Medicine*, 40:340–345, 1983.

Sagai, M., *et al.*, ''Biological Effects of Diesel Exhaust Particles. I. In Vitro Production of Superoxide and In Vivo Toxicity in Mouse,'' *Free Radical Biology & Medicine*, 14:37–47, January 1993.

Salvi, Sundeep, *et al.*, ''Acute Inflammatory Responses in the Airways and Peripheral Blood After Short-Term Exposure to Diesel Exhaust in Healthy Human Volunteers,'' *Am. J. Respir. Care Med.* 159:702–709, 1999.

Samet, Jonathan, and Thomas Burke, Peer Review of MSHA's Revised Draft Risk Assessment on Miners' Exposure to Diesel Particulate Matter, November 10, 1997.

Sauerteig, Jaime, ''The Future of the Diesel Engine in Tomorrow's Environment,'' paper presented at the SAE TOPTEC Conference, May 23–24, 1995.

Säverin, R. *et al*. ''Diesel Exhaust and Lung Cancer Mortality in Potash Mining,'' *American Journal of Industrial Medicine*, 36:415–422, 1999.

Schrenk, H.H., *et al.*, ''Air Pollution in Donora, PA. Epidemiology of the Unusual Smog Episode of October 1948,'' Preliminary Report, *Public Health Bulletin No. 306*, Public Health Service, Bureau of State Services, 1949.

Schenker, M.B., *et al.*, ''Markers of Exposure to Diesel Exhaust in Railroad Workers,'' *Research Report No. 33*, Health Effects Institute, Cambridge, MA, 1990.

Schenker, M.B., *et al.*, ''Diesel Exposure and Mortality Among Railway Workers: Results of a Pilot Study,'' *British Journal of Industrial Medicine*, 41:320–327, 1984.

Schwartz, J., *et al.*, ''Is Daily Mortality Associated Specifically with Fine Particles,'' *Journal of the Air & Waste Management Association*, 46(10):927–939, October 1996.

Seaton, Anthony, *et al.*, ''Particulate Air Pollution and Acute Health Effects,'' *Lancet*, 345(8943):176–178, January 1995.

Shea, Quinlan J., ''New Dirt on a Very Old Problem: Particulate Matter NAAQS,'' *Mining Voice*, Nov/Dec 1995.

Shirnamé-Moré, Lata, ''Genotoxicity of Diesel Emissions, Part I: Mutagenicity and Other Genetic Effects'' in *Diesel Exhaust: A Critical Analysis of Emissions, Exposure, and Health Effects,* pp. 223–242, Health Effects Institute, Cambridge, MA, 1995.

Siak, J.S., *et al.*, ''Diesel Particulate Extracts in Bacterial Test Systems,'' Biomedical Science Department, General Motors Research Laboratories, Warren, Michigan, 1981.

Siemiatycki, Jack, *Risk Factors for Cancer in the Workplace*, CRC Press, (Boca Raton, Florida) 1991.

Siemiatycki, Jack, *et al.*, ''Associations Between Several Sites of Cancer and Ten Types of Exhaust and Combustion Products,'' *Scandinavian Journal of Work, Environment and Health*, 14:79–90, 1988.

Silverman, Debra T., ''Is Diesel Exhaust a Human Lung Carcinogen?'', *Epidemiology*, 9:4–6, 1998.

Society of Automotive Engineers, *Diesel Exhaust Aftertreatment 1995*, SP–1073, February 1995.

Society of Automotive Engineers, *Developments in Diesel Particulate Control*, SP–735, 1988.

Society of Automotive Engineers, *Characterization of Heavy-Duty Diesel Gaseous and Particulate Emissions, and Effects of Fuel Composition*, 0148–7191, 1979.

Society of the Plastics Industry, v. *Occupational Safety and Health Administration*, 509 F.2d 1301, decided January 31, 1975, stay denied March 31, 1975.

Stayner, L., *et al.*, ''Predicted Lung Cancer Risk Among Miners Exposed to Diesel Exhaust Particles,'' *American Journal of Industrial Medicine*, 1998.

Steenland, K. *et al.*, Diesel Exhaust and Lung Cancer in the Trucking Industry: Exposure-Response Analyses and Risk Assessment, *American Journal of Industrial Medicine*, 34:220–228, 1998.

Steenland, K., *et al.*, ''Exposure to Diesel Exhaust in the Trucking Industry and Possible Relationships with Lung Cancer,'' *American Journal of Industrial Medicine*, 21:887–890, 1992.

Steenland, Kyle, *et al.*, ''Case-Control Study of Lung Cancer and Truck Driving in the Teamsters Union,'' *American Journal of Public Health*, 80(6): 670–674, 1990.

Stöber, Werner and Urich R. Abel, ''Lung Cancer Due to Diesel Soot Particles in Ambient Air? A Critical Appraisal of Epidemiological Studies Addressing This Question,'' *International Archives of Occupational and Environmental Health*, 68 (Suppl):S3–S61, 1996.

Swanson, G. Marie, C. S. Lin and P. B. Burns, ''Diversity in the Association Between Occupation and Lung Cancer Among Black and White Men,'' *Cancer Epidemiology, Biomarkers & Prevention*, 2:313–320, July/August 1993.

Takano, Hiroshisa, *et al.*, ''Diesel Exhaust Particles Enhance Antigen-Induced Airway Inflammation and Local Cytokine Expression in Mice,'' *American Journal of Respiratory and Critical Care Medicine*, 156:36–42, 1997.

Takenaka, Hiroshi, *et al.*, ''Enhanced Human IgE Production Results from Exposure to the Aromatic Hydrocarbons from Diesel Exhaust: Direct Effects on B-Cell IgE Production,'' *J Allergy Clin Immunol*, 95–103–115, 1995.

Taubes, G., ''Epidemiology Faces Its Limits,'' (editorial), *Science*, 269:164–169, July 1995.

Tomb, Thomas, and R.A. Haney, ''Results of Underground Mine Studies to Assess Diesel Particulate Exposures and Control Technologies,'' *Mining Engineering*, pp. 276–279, March 1995.

Tsien, Albert, *et al.*, ''The Organic Component of Diesel Exhaust Particles and Phenanthrene, a Major Polyaromatic Hydrocarbon Constituent, Enhances IgE Production by IgE-Secreting EBV-Transformed Human B Cells in Vitro,'' *Toxicology and Applied Pharmacology*, 142:256–263, 1997.

Ulfvarson, Ulf, and Rolf Alexandersson, ''Reduction in Adverse Effect on Pulmonary Function After Exposure to Filtered Diesel Exhaust,'' *American Journal of Industrial Medicine*, 17:341–347, 1990.

Ulfvarson, Ulf, *et al.*, ''Effects of Exposure to Vehicle Exhaust on Health,'' *Scandinavian Journal of Work, Environment and Health*, 13:505–512, 1987.

United States Code, Title 5, Government Organization and Employees, Section 605, Avoidance of Duplicative or Unnecessary Analyses.

United States Code, Title 29, Labor, Section 654(a)(1) and 655(c), Duties of Employers and Employees.

United States Department of Energy, Energy Information Administration, DOE/EIA–0384(96), *Annual Energy Review 1996*, pp. 205 and 209, July 1997.

United States Department of the Interior, Bureau of Mines, ''Evaluation of a Disposable Diesel Exhaust Filter for Permissible Mining Machines,'' *Report of Investigations No. 9508*, 1994.

United States Department of the Interior, Bureau of Mines, ''Evaluation of Catalyzed

Diesel Particulate Filters Used in an Underground Metal Mine'', *Report of Investigations No. 9478*, 1993.

United States Department of the Interior, Bureau of Mines, ''In-Service Performance of Catalyzed Ceramic Wall-Flow Diesel Particulate Filters,'' in *Diesels in Underground Coal Mines: Measurement and Control of Particulate Emissions, Information Circular No. 9324*, 1992.

United States Department of the Interior, Bureau of Mines, ''Diesel in Underground Mines: Measurement and Control of Particulate Emissions,'' *Information Circular No. 9324*, 1992.

United States Department of the Interior, Bureau of Mines, public comment submitted in response to MSHA's January 1992 ANPRM, 87–OFED–1, July 7, 1992.

United States Department of the Interior, Bureau of Mines, ''Fuel Additive and Engine Operation Effects on Diesel Soot Emissions,'' *Information Circular No. 9238*, 1990.

United States Department of the Interior, Bureau of Mines, *Relationship of Underground Diesel Engine Maintenance to Emissions, Vol. I and II*, contract H–0292009, 1979.

United States Department of the Interior, United States Geological Survey, USDI/ USGS, *Mineral Commodity Summaries 1997*, February 1997.

United Steelworkers of America, AFL–CIO–CLC v. *F. Ray Marshall*, 647 F.2d 1189 (1980).

Valberg, Peter A. and Ann Y. Watson, ''Analysis of Diesel-Exhaust Unit-Risk Estimates Derived from Animal Bioassays,'' *Regulatory Toxicology and Pharmacology*, 24:30–44, 1996.

VERT (Verminderung der Emissionen von Realmaschinen in Tunnelbau), ''Efficiency of Diesel Particulate Traps, VERT-Certification Test, Average 4 Operation Points, ISO 8187,'' March 23, 2000.

Vuk, Carl, Martin Jones, and John Johnson, *The Measurement and Analysis of the Physical Character of Diesel Particulate Emissions*, Society of Automotive Engineers, Automotive Engineering Congress and Exposition, Detroit, Michigan, February 23–27, 1976.

Wade, J.F., and L.S. Newman, ''Diesel Asthma. Reactive Airways Disease Following Overexposure to Locomotive Exhaust,'' *Journal of Occupational Medicine*, 35(2):149–154, February 1993.

Wallace, William, *et al.*, ''Mutagenicity of Diesel Exhaust Particles and Oil Shale Particles Dispersed in Lecithin Surfactant,'' *Journal of Toxicology and Environmental Health*, 21:163–171, 1987.

Waller, R.E., ''Trends in Lung Cancer in London in Relation to Exposure to Diesel Fumes,'' *Environment International*, 5:479–483, 1981.

Watson, Ann Y. and Gareth M. Green, ''Noncancer Effects of Diesel Emissions: Animal Studies,'' in *Diesel Exhaust: A Critical Analysis of Emissions, Exposure, and Health Effects*, pp. 141–164, Health Effects Institute, Cambridge, MA 1995.

Watts, Winthrop, F., ''Assessment of Occupational Exposure to Diesel Emissions,'' in *Diesel Exhaust: A Critical Analysis of Emissions, Exposure, and Health Effects*, pp. 109–123, Health Effects Institute, Cambridge, MA., 1995.

Watts, Winthrop, F., *et al.*, ''Diesel Exhaust Aerosol Levels in Underground Coal Mines,'' U.S. Bureau of Mines, *Information Circular No. 9324*, pp. 31–39, 1992.

Watts, Winthrop, F., *et al.*, ''Control of Diesel Particulate Matter in Underground Coal Mines,'' United States Department of Interior, Bureau of Mines, *Report of Investigations No. 9276*, 1989.

Waxweiler, Richard, *et al.*, ''Mortality of Potash Workers,'' *Journal of Occupational Medicine*, Vol. 15, No. 6, June 1973.

Weitzman, Sigmund A. and Leo Gordon, ''Inflammation and Cancer: Role of Phagocyte-Generated Oxidants in Carcinogenesis,'' *Blood*, 76(4):655–663, August 15, 1990.

West Virginia House Bill No. 2890, May 5, 1997.

White House Press Release, Office of the Vice President, ''Vice President Gore Announces Joint Industry-Government Research Plan to Produce the World's Cleanest Diesels,'' July 23, 1997.

Widdicombe, J. *et al.*, ''Nerve Receptors of the Upper Airway,'' in Matthew, O.P. and G. Sant' Ambrogio, eds., *Respiratory Function of the Upper Airway*, pp. 193–231, 1988.

Williams, Roger, *et al.*, ''Associations of Cancer Site and Typewith Occupation and Industry From the Third National Cancer Survey Interview,'' *Journal of the National Cancer Institute*, Vol. 59, No. 4, October 1977.

Wolff, Ronald K., *et al.* Pulmonary inflamation and DNA adducts in rats inhaling diesel exhaust or carbon black. *Inhalation Toxicology*, 2:241–254, 1990.

Wong, O., ''Mortality Among Members of a Heavy Construction Equipment Operators Union with Potential Exposure to Diesel Exhaust Emissions,'' *British Journal of Industrial Medicine*, 42:435–448, 1985.

Woskie, Susan R., *et al.*, ''Estimation of the Diesel Exhaust Exposures of Railroad Workers: I. Current Exposures,'' *American Journal of Industrial Medicine*, 13:381–394, 1988.

Woskie, Susan R., *et al.*, ''Estimation of the Diesel Exhaust Exposures of Railroad Workers: II. National and Historical Exposures,'' *American Journal of Industrial Medicine*, 13:395–404, 1988.

Zaebst, D.D., *et al.*, ''Quantitative Determination of Trucking Industry Workers' Exposures to Diesel Exhaust Particles,'' *American Industrial Hygiene Association Journal*, (52), December 1991.

Supplementary References

Below is a list of supplemental references that MSHA reviewed and considered in the development of the proposed rule. These documents are not specifically cited in the preamble discussion, but are applicable to MSHA's findings:

Bice, D.E., *et al.*, ''Effects of Inhaled Diesel Exhaust on Immune Responses after Lung Immunization,'' *Fundamental and Applied Toxicology*, 5:1075–1086, 1985.

California Environmental Protection Agency, Air Resources Board, News Release, ''ARB Identifies Diesel Particulate Emissions as a Toxic Air Contaminant,'' August 27, 1998.

Fischer, Torkel, and Bolli Bjarnason, ''Sensitizing and Irritant Properties of 3 Environmental Classes of Diesel Oil and Their Indicator Dyes,'' *Contact Dermatitis*, 34:309–315, 1996.

Frew, A.J., and S.S. Salvi, ''Diesel Exhaust Particles and Respiratory Allergy,'' *Clinical and Experimental Allergy*, 27:237–239, 1997.

Fujimaki, Hidekazu, *et al.*, ''Intranasal Instillation of Diesel Exhaust Particles and Antigen in Mice Modulated Cytokine Productions in Cervical Lymph Node Cells,'' *International Archives of Allergy and Immunology*, 108:268–273, 1995.

Fujimaki, Hidekazu, *et al.*, ''IL–4 Production in Mediastinal Lymph Node Cells in Mice Intratracheally Instilled with Diesel Exhaust Particles and Antigen,'' *Toxicology*, 92:261–268, 1994.

Fujimaki, Hidekazu, *et al.*, ''Inhalation of Diesel Exhaust Enhances Antigen-Specific IgE Antibody Production in Mice,'' *Toxicology*, 116:227–233, 1997.

Ikeda, Masahiko, *et al.*, ''Impairment of Endothelium-Dependent Relaxation by Diesel Exhaust Particles in Rat Thoracic Aorta,'' *Japanese Journal of Pharmacology*, 68:183–189, 1995.

Muranaka, Masaharu, *et al.*, ''Adjuvant Activity of Diesel-Exhaust Particles for the Production of IgE Antibody in Mice,'' *J Allergy Clin Immunology*, 77:616–623, 1986.

Northridge, Mary, ''Diesel Exhaust Exposure Among Adolescents in Harlem: A Community-Driven Study,'' *American Journal of Public Health*, (89) 998–1002, July 1999.

Scientific Review Panel, Findings on the Report on Diesel Exhaust as a Toxic air Contaminant, as adopted at the Panel's April 22, 1998 meeting.

Stayner, Leslie, ''Protecting Public Health in the Face of Uncertain Risks: The Example of Diesel Exhaust,'' American Journal of Public Health, (89) 991–993, July 1999.

Takafuji, Shigeru, *et al.*, ''Diesel-Exhaust Particulates Inoculated by the Intranasal Route Have an Adjuvant Activity for IgE Production in Mice,'' *J Allergy Clin Immunol*, 79:639–645, 1987.

Terada, Nobushisa, *et al.*, ''Diesel Exhaust Particulates Enhance Eosinophil Adhesion to Nasal Epithelial Cells and Cause Degranulation,'' *International Archives of Allergy and Immunology*, 114:167–174, 1997.

Yang, Hui-Min, *et al.*, ''Effects of Diesel Exhaust Particles on the Release of Interleukin-1 and Tumor Necrosis Factor-Alpha from Rat Alveolar Macrophages,'' *Experimental Lung Research*, 23:269–284, 1997.

List of Subjects in 30 CFR Part 57

Metal and nonmetal, Mine safety and health, Underground mines, Diesel particulate matter.

Dated: January 8, 2001.

Robert A. Elam,

Acting Assistant Secretary for Mine Safety and Health.

Chapter I of Title 30 of the Code of Federal Regulations is hereby amended as follows:

PART 57—[AMENDED]

1. The authority citation for Part 57 continues to read as follows:

Authority: 30 U.S.C. 811, 957, 961.

2. The heading of Subpart D of Part 57 is revised to read as follows:

Subpart D—Air Quality, Radiation, Physical Agents, and Diesel Particulate Matter

3. A new undesignated center heading and §§ 57.5060 through 56.5075 are added to subpart D.

DIESEL PARTICULATE MATTER—UNDERGROUND ONLY

Sec.

DIESEL PARTICULATE MATTER—UNDERGROUND ONLY

§ 57.5060 Limit on concentration of diesel particulate matter.

(a) After July 19, 2002 and until January 19, 2006, any mine operator covered by this part must limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 400 micrograms per cubic meter of air (400_{TC} µg/m^3).

(b) After January 19, 2006, any mine operator covered by this part must limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 160 micrograms per cubic meter of air (160_{TC} µg/m^3).

(c)(1) If, as a result of technological constraints, a mine requires additional time to come into compliance with the limit specified in paragraph (b) of this section, the operator of the mine may file an application with the Secretary for a special extension.

(2) No mine may be granted more than one special extension, nor may the time otherwise available under this section to a mine to comply with the limit specified in paragraph (b) be extended by more than two years.

(3) The application for a special extension may be approved, and the additional time authorized, only if the application includes information adequate for the Secretary to ascertain:

(i) That diesel-powered equipment was used in the mine prior to October 29, 1998;

(ii) That there is no combination of controls that can, due to technological constraints, bring the mine into full compliance with the limit specified in paragraph (b) within the time otherwise specified in this section;

(iii) The lowest achievable concentration of diesel particulate, as demonstrated by data collected under conditions that are representative of mine conditions using the method specified in § 57.5061; and

(iv) The actions the operator will take during the duration of the extension to:

(A) Maintain the lowest concentration of diesel particulate; and

(B) Minimize the exposure of miners to diesel particulate.

(4) The Secretary may approve an application for a special extension only if:

(i) The mine operator files, the application at least 180 days prior to the date the mine must be in full compliance with the limit established by paragraph (b) of this section; and

(ii) The application certifies that the operator has posted one copy of the application, at the mine site for 30 days prior to the date of application, and has provided another copy to the authorized representative of miners.

(5) A mine operator must comply with the terms of any approved application for a special extension, and post a copy of an approved application for a special extension at the mine site for the duration of the special extension period.

(d)(1) Mine operators may permit miners engaged in inspection, maintenance, or repair activities, and only in such activities, with the advance approval of the Secretary under the circumstances and conditions defined in paragraphs (d)(2) through (d)(4) of this section, to work in concentrations of diesel particulate matter exceeding the applicable concentration limit under paragraph (a) or (b) of this section.

(2) The Secretary will only provide advance approval:

(i) For inspection, maintenance or repair activities to be conducted:

(A) In areas where miners work or travel infrequently or for brief periods of time;

(B) In areas where miners otherwise work exclusively inside of enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; or

(C) In shafts, inclines, slopes, adits, tunnels and similar workings that the operator designates as return or exhaust air courses and that miners use for access into the mine or egress from the mine;

(ii) When the Secretary determines that it is not feasible to reduce the concentration of dpm in the areas where the inspection, maintenance or repair activities are to be conducted to those otherwise applicable under paragraph (a) or (b) of this section; and

(iii) When the Secretary determines that the mine operator will employ adequate safeguards to minimize the dpm exposure of the miners.

(3) The Secretary's determinations under paragraph (d)(2) of this section will be based on evaluating a plan prepared and submitted by the operator no less than 60 days before the commencement of any inspection, maintenance or repair activities. The mine operator must certify in the plan that one copy of the application has been posted at the mine site for 30 days prior to the date of submission, and another copy has been provided to the authorized representative of miners. The plan must identify, at a minimum, the types of anticipated inspection, maintenance, and repair activities that must be performed for which engineering controls sufficient to comply with the concentration limit are not feasible, the locations where such activities could take place, the concentration of dpm in these locations, the reasons why engineering controls are not feasible, the anticipated frequency and duration of such activities, the anticipated number of miners involved in such activities, and the safeguards that the operator will employ to limit miner exposure to dpm, including, but not limited to the use of respiratory protective equipment. The approved plan must include a program for selection, maintenance, training, fitting, supervision, cleaning and use of personal protective equipment and must meet the minimum requirements established in § 57.5005 (a) and (b).

(4) An advance approval by the Secretary for employees to engage in inspection, maintenance, or repair activities will be valid for no more than one year. A mine operator must comply with the conditions of the approved plan [which was the basis of the approval], and must post a copy of the approved plan at the mine site for the duration of its applicability.

(e) Other than pursuant to the conditions required in paragraphs (c) or (d) of this section, an operator must not utilize personal protective equipment to comply with the requirements of either paragraph (a) or paragraph (b) of this section.

(f) An operator must not utilize administrative controls to comply with the requirements of this section.

§ 57.5061 Compliance determinations.

(a) A single sample collected and analyzed by the Secretary in accordance with the requirements of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect samples of diesel particulate matter by using a respirable dust sampler equipped with a submicrometer impactor and analyze the samples for the amount of total carbon using the method described in NIOSH Analytical Method 5040, except that the Secretary also may use any methods of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of diesel particulate matter. Copies of the NIOSH 5040 Analytical Method are available by contacting MSHA's, Pittsburgh Safety and Health Technology Center, P.O. Box 18233, Cochrans Mill Road, Pittsburgh, PA 15236.

(c) The Secretary will determine the appropriate sampling strategy for compliance determination, utilizing personal sampling, occupational sampling, and/or area sampling, based on the circumstances of the particular exposure.

§ 57.5062 Diesel particulate matter control plan.

(a) In the event of a violation by the operator of an underground metal or nonmetal mine of the applicable concentration limit established by § 57.5060, the operator, in accordance with the requirements of this section, must—

(1) Establish a diesel particulate matter control plan for the mine if one is not already in effect, or modify the existing diesel particulate matter control plan, and

(2) Demonstrate that the new or modified diesel particulate matter control plan controls the concentration of diesel particulate matter to the applicable concentration limit specified in § 57.5060.

(b) A diesel particulate control plan must describe the controls the operator will utilize to maintain the concentration of diesel particulate matter to the applicable limit specified by § 57.5060. The plan also must include a list of diesel-powered units maintained by the mine operator, information about any unit's emission control device, and the parameters of any other methods used to control the concentration of diesel particulate matter. The operator may consolidate the plan with the ventilation plan required by § 57.8520. The operator must retain a copy of the current diesel particulate matter control plan at the mine site during its duration and for one year thereafter.

(c) An operator must demonstrate plan effectiveness by monitoring, using the measurement method specified by § 57.5061(b), sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine. The operator must retain a copy of each verification sample result at the mine site for five years. The operator monitoring must be in addition to, and not in lieu of, any sampling by the Secretary pursuant to § 57.5061.

(d) The records required by paragraphs (b) and (c) of this section must be available for review upon request by the authorized representative of the Secretary, the authorized representative of the Secretary of Health and Human Services, or the authorized representative of miners. In addition, upon request by the District Manager or the authorized representative of miners, the operator must provide a copy of any records required to be maintained pursuant to paragraph (b) or (c) of this section.

(e)(1) A control plan established as a result of this section must remain in effect for 3 years from the date of the violation which caused it to be established, except as provided in paragraph (e)(3) of this section.

(2) A modified control plan established as a result of this section must remain in effect for 3 years from the date of the violation which caused the plan to be modified, except as provided in paragraph (e)(3) of this section.

(3) An operator must modify a diesel particulate matter control plan during its duration as required to reflect changes in mining equipment or circumstances. Upon request from the Secretary, an operator must demonstrate the effectiveness of the modified plan by monitoring, using the measurement method specified by § 57.5061, sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine.

(f) The Secretary will consider an operator's failure to comply with the provisions of the diesel particulate matter control plan in effect at a mine or to conduct required verification sampling to be a violation of this part without regard for the concentration of diesel particulate matter that may be present at any time.

§ 57.5065 Fueling and idling practices.

(a) Diesel fuel used to power equipment in underground areas must not have a sulfur content greater than 0.05 percent. The operator must retain purchase records that demonstrate compliance with this requirement for one year after the date of purchase.

(b) The operator must only use fuel additives registered by the U.S. Environmental Protection Agency in diesel powered equipment operated in underground areas.

(c) Idling of mobile diesel-powered equipment in underground areas is prohibited except as required for normal mining operations.

§ 57.5066 Maintenance standards.

(a) Any diesel powered equipment operated at any time in underground areas must meet the following maintenance standards:

(1) The operator must maintain any approved engine in approved condition;

(2) The operator must maintain the emission related components of any non-approved engine to manufacturer specifications; and

(3) The operator must maintain any emission or particulate control device installed on the equipment in effective operating condition.

(b)(1) A mine operator must authorize and require each miner operating diesel powered equipment underground to affix a visible and dated tag to the equipment at any time the miner notes any evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section.

(2) A mine operator must ensure that any equipment tagged pursuant to this section is promptly examined by a person authorized by the mine operator to maintain diesel equipment, and that the affixed tag not be removed until the examination has been completed.

(3) A mine operator must retain a log of any equipment tagged pursuant to this section. The log must include the date the equipment is tagged, the date the equipment is examined, the name of the person examining the equipment, and any action taken as a result of the examination. The operator must retain the information in the log for one year

after the date the tagged equipment was examined.

(c) Persons authorized by a mine operator to maintain diesel equipment covered by paragraph (a) of this section must be qualified, by virtue of training or experience, to ensure that the maintenance standards of paragraph (a) of this section are observed. An operator must retain appropriate evidence of the competence of any person to perform specific maintenance tasks in compliance with those standards for one year after the date of any maintenance, and upon request must provide the documentation to the authorized representative of the Secretary.

§ 57.5067 Engines.

(a) Any diesel engine introduced into an underground area of a mine covered by this part after March 20, 2001, other than an engine in an ambulance or fire fighting equipment which is utilized in accordance with mine fire fighting and evacuation plans, must either:

(1) Have affixed a plate evidencing approval of the engine pursuant to subpart E of Part 7 of this title or pursuant to Part 36 of this title; or

(2) Meet or exceed the applicable particulate matter emission requirements of the Environmental Protection Administration listed in Table 57.5067–1, as follows:

TABLE 57.5067–1

EPA requirement	EPA category	PM limit
40 CFR 86.094–8(a)(1)(i)(A)(2)	light duty vehicle	0.1 g/mile.
40 CFR 86.094–9(a)(1)(i)(A)(2)	light duty truck	0.1 g/mile.
40 CFR 86.094–11(a)(1)(iv)(B)	heavy duty highway engine	0.1 g/bhp-hr.
40 CFR 89.112(a)	nonroad (tier, power range)	varies by power range:
	tier 1 kW<8 (hp<11)	1.0 g/kW-hr (0.75 g/bhp-hr).
	tier 1 8≤kW<19 (11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 1 19≤kW<37 (25≤hp<50)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 2 37≤kW<75 (50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr).
	tier 2 75≤kW<130 (100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr).
	tier 1 130≤kW<225 (175≤hp<300)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 225≤kW<450 (300≤hp<600)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 450≤kW<560 (600≤hp<750)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 kW≥560 (hp≥750)	0.54 g/kW-hr (0.40 g/bhp-hr).

Notes:
"g" means grams.
"hp" means horsepower.
"g/bhp-hr" means grams/brake horsepower-hour.
"kW" means kilowatt.
"g/kW-hr" means grams/kilowatt-hour.

(b) For purposes of paragraph (a):

(1) The term "introduced" means any engine added to the underground inventory of engines of the mine in question, including:

(i) An engine in newly purchased equipment;

(ii) An engine in used equipment brought into the mine; and

(iii) A replacement engine that has a different serial number than the engine it is replacing; but

(2) The term "introduced" does not include engines that were previously part of the mine inventory and rebuilt.

§ 57.5070 Miner training.

(a) Mine operators must provide annual training to all miners at a mine covered by this part who can reasonably be expected to be exposed to diesel emissions on that property. The training must include—

(1) The health risks associated with exposure to diesel particulate matter;

(2) The methods used in the mine to control diesel particulate matter concentrations;

(3) Identification of the personnel responsible for maintaining those controls; and

(4) Actions miners must take to ensure the controls operate as intended.

(b) An operator must retain a record at the mine site of the training required by this section for one year after completion of the training.

§ 57.5071 Environmental monitoring.

(a) Mine operators must monitor as often as necessary to effectively determine, under conditions that can be reasonably anticipated in the mine—

(1) Whether the concentration of diesel particulate matter in any area of the mine where miners normally work or travel exceeds the applicable limit specified in § 57.5060; and

(2) The average full shift airborne concentration of diesel particulate matter at any position or on any person designated by the Secretary.

(b) The mine operator must provide affected miners and their representatives with an opportunity to observe exposure monitoring required by this section. Mine operators must give prior notice to affected miners and their representatives of the date and time of intended monitoring.

(c) If any monitoring performed under this section indicates that the applicable concentration limit established by § 57.5060 has been exceeded, an operator must promptly post notice of the corrective action being taken, initiate corrective action by the next work shift, and promptly complete such corrective action.

(d)(1) The results of monitoring for diesel particulate matter, including any results received by a mine operator from sampling performed by the Secretary, must be posted on the mine bulletin board within 15 days of receipt and must remain posted for 30 days. The operator must provide a copy of the results to the authorized representative of miners.

(2) The mine operator must retain for five years (from the date of sampling), the results of any samples the operator collected as a result of monitoring under this section, and information about the sampling method used for obtaining the samples.

§ 57.5075 Diesel particulate records.

(a) The table entitled "Diesel Particulate Recordkeeping Requirements" lists the records the operator must retain pursuant to §§ 57.5060 through 57.5071, and the duration for which particular records need to be retained. The table follows:

DIESEL PARTICULATE RECORDKEEPING REQUIREMENTS

Record	Section reference	Retention time
1. Approved application for extension of time to comply with final concentration limit.	§ 57.5060(c)	1 year beyond duration of extension.
2. Approved plan for miners to perform inspection, maintenance or repair actions in areas exceeding the concentration limit.	§ 57.5060(d)	For duration of plan.
3. Control plan	§ 57.5062(b)	1 year beyond duration of plan.
4. Compliance plan verification sample results	§ 57.5062(c)	5 years from sample date.
5. Purchase records noting sulfur content of diesel fuel.	§ 57.5065(a)	1 year beyond date of purchase.
6. Maintenance log	§ 57.5066(b)	1 year after date any equipment is tagged.
7. Evidence of competence to perform maintenance.	§ 57.5066(c)	1 year after date maintenance performed.
8. Annual training provided to potentially exposed miners.	§ 57.5070(b)	1 year beyond date training completed.
9. Sampling method used to effectively evaluate mine particulate concentration, and sample results.	§ 57.5071(d)	5 years from sample date.

(b)(1) Any record listed in this section which is required to be retained at the mine site may, notwithstanding such requirement, be retained elsewhere if the mine operator can immediately access the record from the mine site by electronic transmission.

(2) Upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators must promptly provide access to any record listed in the table in this section.

(3) An operator must provide access to a miner, former miner, or, with the miner's or former miner's written consent, a personal representative of a miner, to any record required to be maintained pursuant to § 57.5071 to the extent the information pertains to the miner or former miner. The operator must provide the first copy of a requested record at no cost, and any additional copies at reasonable cost.

(4) Whenever an operator ceases to do business, that operator must transfer all records required to be maintained by this part, or a copy thereof, to any successor operator who must maintain them for the required period.

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