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Federal Register

Tuesday
December 10, 1985

Briefings on How To Use the Federal Register—
For information on briefings in Philadelphia, PA and Washington, DC, see announcement on the inside cover of this issue.

Selected Subjects

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Federal Aviation Administration

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Federal Reserve System

Benzene
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Cemeteries
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Crop Insurance
Federal Crop Insurance Corporation

Endangered and Threatened Species
Fish and Wildlife Service

Fisheries
National Oceanic and Atmospheric Administration

Food Additives
Food Safety and Inspection Service

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Selected Subjects

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Questions and requests for specific information may be directed to the telephone numbers listed under INFORMATION AND ASSISTANCE in the READER AIDS section of this issue.

How To Cite This Publication: Use the volume number and the page number. Example: 50 FR 12345.

Formaldehyde
Occupational Safety and Health Administration

Freedom of Information
Securities and Exchange Commission

Government Procurement
Agency for International Development
General Services Administration

Grant Programs—Housing and Community Development
Housing And Urban Development Department

Loan Programs—Agriculture
Commodity Credit Corporation

Navigation (Water)
Engineers Corps

Privacy Act
Nuclear Regulatory Commission

Radio Broadcasting
Federal Communications Commission

Recreation and Recreation Areas
Land Management Bureau

Securities
Federal Reserve System

Seizures and Forfeitures
Customs Service

Surface Mining
Surface Mining Reclamation and Enforcement Office

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 2 1/2 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

PHILADELPHIA, PA

WHEN: Dec. 17; at 1 pm.
Dec. 18; at 9 am. (identical session)

WHERE: Room 3306/10,
William J. Green, Jr., Federal Building,
600 Arch Street, Philadelphia, PA.

RESERVATIONS: Laura Lewis,
Philadelphia Federal Information Center,
215-597-1709

WASHINGTON, DC

WHEN: January 17; at 9 am.

WHERE: Office of the Federal Register,
First Floor Conference Room,
1100 L Street NW., Washington, DC.

RESERVATIONS: Howard Landon 202-523-5227
Melanie Williams 202-523-5229 (TDD)

NOTE: There will be a sign language interpreter for hearing impaired persons at the Washington, DC briefing.

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Presidential Documents

Title 3—

The President

Proclamation 5417 of December 5, 1985

National Consumers Week, 1986

By the President of the United States of America

A Proclamation

Because ours is a free society, we Americans are blessed with many choices. We can choose to live where we want. We can choose our education and our vocation. We are free to speak our minds, to worship God as our conscience prompts us, and to choose our political affiliation. And nowhere else in the world is there a wider variety of goods and services from which to choose, thanks to an open marketplace and the freedom to produce and purchase. This bountiful marketplace has provided us with a standard of living that is the marvel and envy of the world.

The outlook for the future is even brighter. The regulatory reform of recent years is spawning innovation and reinvigorated competition; by opening new markets, it has resulted in even more choices for consumers. This gives buyers both a new opportunity and a new responsibility to make informed decisions about the quality and value of products and services offered for sale.

To make responsible decisions in our dynamic and abundant economy, consumers need both information and education if they are to reap the full benefits of the marketplace. They need information, the facts about the goods and services; they need to be educated so they can analyze those facts before making a purchase. This will enable them to make wise choices whether they are shopping for food, shelter, clothing, transportation, recreation, health care, entertainment, and so on. Prudent, informed, discriminating consumers put pressure on suppliers to keep improving products and services while devising production efficiencies that will permit them to keep their prices competitive.

In light of the central role of the consumer in our free economy, it is especially appropriate to recognize that relationship during National Consumers Week, 1986. The slogan for 1986, "Consumers Rate Quality," acknowledges that consumers, by seeking quality and value, set the standards of acceptability for products and services by "voting" with their marketplace dollars, rewarding efficient producers of better quality products and performance. It is also a ringing declaration that consumers are entitled to and can insist on honest value for their hard-earned income.

Indeed, American businessmen and women are becoming aware that the broadened competition of a global marketplace necessitates attention to quality if they are to succeed. They must do more than just build better products—they must strive to improve marketing, sales, warranties, and service. Quality demands efficient management, productive use of human resources, and responsiveness to consumer needs and preferences.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim the week beginning April 20, 1986, as National Consumers Week. I urge businesses, educators, community organizations, labor unions, the media, government leaders, and consumers to recognize the pursuit of quality and excellence in every aspect of our lives, and to contribute to consumer and economic awareness during this week.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of December, in the year of our Lord nineteen hundred and eighty-five, and of the Independence of the United States of America the two hundred and tenth.

Ronald Reagan

[FR Doc. 85-29394
Filed 12-6-85; 4:24 pm]
Billing code 3195-01-M

Presidential Documents

Proclamation 5418 of December 6, 1985

National Community College Month, 1986

By the President of the United States of America

A Proclamation

The more than thirteen hundred community, technical, and junior colleges, public and private, in the United States have contributed enormously to the richness and availability of American higher education. Nearly half of all undergraduate college students in the Nation today are enrolled in such institutions.

By providing educational opportunities at costs and locations accessible to all who are qualified, community, technical, and junior colleges have greatly enhanced the opportunity for every ambitious student, young or old, to enter a postsecondary school program. As community-based institutions, these schools provide varied programs and offer specialized training for more than one thousand occupations.

In recognition of the important contribution of community, technical, and junior colleges to our total educational system, the Congress, by Senate Joint Resolution 158, has designated the month of February 1986 as "National Community College Month" and authorized and requested the President to issue a proclamation in observance of this event.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim the month of February 1986 as National Community College Month. I ask all Americans to observe this month with appropriate activities that express recognition of the significant contribution these institutions are making to the strength, vitality, and prosperity of our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of December, in the year of our Lord nineteen hundred and eighty-five, and of the Independence of the United States of America the two hundred and tenth.

Ronald Reagan

[FR Doc. 85-28385
Filed 12-6-85; 4:25 pm]
Billing code 3195-01-M

Presidential Documents

Presidential Determination No. 86-03 of November 25, 1985

Determination Pursuant to Section 620E(e) of the Foreign Assistance Act of 1961, as Amended

Memorandum for the Secretary of State

Pursuant to section 620E(e) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2375(e), I hereby certify that Pakistan does not possess a nuclear explosive device and that the proposed United States assistance program will reduce significantly the risk that Pakistan will possess a nuclear explosive device.

You or your delegatee are authorized and directed to publish this determination and certification in the **Federal Register.**

Ronald Reagan

THE WHITE HOUSE,
Washington, November 25, 1985

[FR Doc. 85-29396
Filed 12-6-85; 4:26 pm]
Billing code 3195-01-M

Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 403

[Docket No. 2991S]

Peach Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice of extension of sales closing date.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) herewith gives notice of the extension of the sales closing date for accepting applications for peach crop insurance in all counties wherein such insurance is offered, effective for the 1985 crop year only. This action is necessary because the policy for insuring peaches has recently been provided to agents leaving an insufficient amount of time for marketing purposes. Therefore, additional time for applications to be accepted is being provided accordingly. The intended effect of this notice is to advise all interested parties of the extension of the sales closing date and to comply with the provisions of the peach crop insurance regulations with respect to the Manager's authority to extend sales closing dates.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, D.C., 20250, telephone (202) 447-3325.

SUPPLEMENTARY INFORMATION: Under the provisions contained in 7 CFR 403.7, the closing date for accepting applications for peach crop insurance in all counties is November 20.

Because of the delay in providing agents with current policy provisions resulting in a foreshortened marketing period, FCIC is extending the sales closing date in all counties where peach crop insurance is offered.

Under the provisions of 7 CFR 403.7, the sales closing date for accepting applications may be extended by placing the extended date on file in the service office and by publishing a notice in the **Federal Register** upon determination that no adverse selectivity will result from such extension. If adverse conditions develop during such period, FCIC will immediately discontinue acceptance of applications.

Notice

Accordingly, pursuant to the authority contained in 7 CFR 403.7, the Federal Crop Insurance Corporation herewith gives notice that the sales closing date for accepting applications for peach insurance in all counties where such insurance is offered, is hereby extended through the close of business on December 20, effective for the 1985 crop year only.

Authority: Secs. 506, 516, Pub. L. 75-430, 52 Stat. 73, 77, as amended (7 U.S.C. 1506, 1516).

Done in Washington, D.C., on November 26, 1985.

Edward Hews,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 85-29200 Filed 12-9-85; 8:45 am]
BILLING CODE 3410-08-M

7 CFR Parts 404 and 408

[Docket No. 2989S]

Western and Eastern U.S. Apple Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice of extension of sales closing date.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) herewith gives notice of the extension of the sales closing date for accepting applications for apple crop insurance in all counties wherein such insurance is offered, effective for the 1985 crop year only. This action is necessary because the policy for insuring apples has recently been provided to agents leaving an insufficient amount of time for marketing purposes. Therefore, additional time for applications to be accepted is being provided accordingly. The intended effect of this notice is to advise all interested parties of the extension of the sales closing date and to comply with the provisions of the apple crop insurance regulations with respect to the Manager's authority to extend sales closing dates.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, D.C., 20250, telephone (202) 447-3325.

SUPPLEMENTARY INFORMATION: Under the provisions contained in 7 CFR 404.7 and 408.7, the closing date for accepting applications for apple crop insurance in all counties is November 20.

Because of the delay in providing agents with current policy provisions resulting in a foreshortened marketing period, FCIC is extending the sales closing date in all counties where apple crop insurance is offered.

Under the provisions of 7 CFR 404.7 and 408.7, the sales closing date for accepting applications may be extended by placing the extended date on file in the service office and by publishing a notice in the **Federal Register** upon determination that no adverse selectivity will result from such extension. If adverse conditions develop during such period, FCIC will immediately discontinue acceptance of applications.

Notice

Accordingly, pursuant to the authority contained in 7 CFR 404.7 and 408.7, the Federal Crop Insurance Corporation herewith gives notice that the sales closing date for accepting applications for apple insurance in all counties where such insurance is offered, is hereby extended through the close of business on December 20, effective for the 1985 crop year only.

Authority: Secs. 506, 516, Pub. L. 75-430, 52 Stat. 73, 77, as amended (7 U.S.C. 1506, 1516).

Done in Washington, D.C., on November 26, 1985.

Edward Hews,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 85-29201 Filed 12-9-85; 8:45 am]
BILLING CODE 3410-08-M

7 CFR Part 450

[Docket No. 2355SA]

Prune Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) hereby issues a new Part 450 in Chapter IV of Title 7 of the Code of Federal Regulations to prescribe procedures for insuring prunes effective for the 1986 and succeeding crop years. The intended effect of this rule is to provide insurance for prunes in response to many requests from producers and processors for such insurance protection as approved by the Board of Directors of FCIC. The authority for the promulgation of this rule is contained in the Federal Crop Insurance Act, as amended.

EFFECTIVE DATE: January 9, 1986.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (202) 447-3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512-1. This action constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is May 15, 1989.

Merritt W. Sprague, Manager, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. -based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under Number 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

On Tuesday, February 26, 1985, FCIC published a notice of proposed rulemaking in the **Federal Register** at 50 FR 7783, issuing a new Part 450 in Chapter IV of Title 7 of the Code of Federal Regulations to be known as 7 CFR Part 450—Prune Crop Insurance Regulations. The public was given 60 days in which to submit written comments, data, and opinions on the proposed rule.

No comments were received in direct response to this proposed rule. However, on September 4–5, 1985, the Board of Directors, FCIC held informal meetings in Hearing Room B, Interstate Commerce Commission Building, Washington, DC, for the purpose of receiving comments from interested parties on the Actual Production History (APH) method of insurance. This concept was included in the proposed rule.

The APH concept of yield guarantees establishes a direct relationship between proven production capability of the individual insured producer, and the insurance guarantee or the premium rates. It requires the insured producer to submit annual records of insured production as a condition of continued insurability.

Comments on the proposed regulation were received from six representatives of the private insurance industry, one member of Congress, fifteen insurance agents, four representatives of special interest groups, and five farmers.

The comments generally opposed the proposed requirement that insureds furnish annual records of insured production as a condition of continued insurability under the APH program for the establishment of yield guarantees.

Those in opposition to the proposed regulation generally argued that they would decrease the marketability of crop insurance by making the resulting insurance offer less attractive to potential purchasers. Many predicted a substantial level of cancellation by current contract holders if the proposed regulation became effective.

Argument against the proposed requirement for records submission as a condition of continued insurance eligibility included: (1) Many farmers would not be willing to furnish records establishing annual production unless they have a loss and a potential indemnity; (2) an economic incentive like a reduced future yield guarantee is preferable to cancellation; and (3) the APH system as a whole is cumbersome, complex, and more difficult to administer than an area coverage plan.

Many commentators recommended that FCIC develop a plan to offer reduced insurance guarantees when a producer failed to voluntarily furnish records. Most comments supported the APH concept as a means of making an equitable insurance offer to the better producers of an area; however, many of the same group requested simplification of program procedures. Several comments recommended the establishment of a new method to reduce the impact of severe loss years upon yield guarantees for the future. A few comments recommended a return to an area coverage program as a means of retaining the participation of those whose recent production has not equaled former area coverage guarantees.

The comments received were fully considered in arriving at the decision on the proposed rule.

The rationale for the initial adoption of the APH concept was to correct the problem of adverse selection inherent in the previous area coverage plans of insurance. Adverse selection occurs when the best insurance offer is made to the highest risk producer and the poorest insurance offer is made to the lowest risk producer. It is characterized by having insured clients with higher than average risk expectations without commensurate higher premium rates. Adverse selection results in higher than expected losses and ultimately in higher premium rates and thus, over the long term, severely limits participation levels.

Adverse selection is best addressed by establishing a direct relationship between proven production capability of individual producers and their insurance guarantee and premium rates. The APH program accomplishes this objective.

Records of production are basic to a yield protection program of insurance. There is no logical alternative to requiring records if such program is to succeed over an extended period of time. The APH concept, linking records to guarantees, is clearly preferable to any extension of the area coverage concept. The latter can only lead to further aggravation of adverse selection. The ultimate result is the program serving only the lowest producing farmers on the highest risk land.

The premise that farmers will choose to cancel insurance participation in

preference to furnishing annual records of production after the close of harvest or marketing season is rejected. The need to have such records of production for other business purposes, including for share rent settlement purposes, for financial statements in the event of the use of borrowed funds for operations, and for the submission of income tax returns, combined with the need of such records for farm management purposes, make such records readily available for most producers. The records are available. No legitimate reason exists for failure to support a requested yield guarantee by furnishing production records.

If the sole reason for unwillingness to submit records of production lies in the fact that such submission will result in a lower than otherwise obtainable yield guarantee for the future, then the producer is seeking to be overinsured in relation to his proven capability. While past performance is not an absolute guarantee of future yield expectations, it is the best indicator which can be measured objectively.

The FCIC would be violating its public trust if it were not to use the best system possible to establish yield guarantees which fairly reflect yield expectations. Considering the administrative changes to procedure which are to be implemented, the objections to the APH program raised in the comments have been fully and fairly considered and are regarded as an insufficient basis for reversal of previous proposed regulations.

FCIC, in response to requests from the producers and the participating insurance industry, has taken administrative action to ease the burden of keeping the required records and to address problems in program administration.

Therefore, with the exception of minor changes in language and format, the proposed rule is hereby adopted as a final rule.

List of Subjects in 7 CFR Part 450

Crop insurance, Prunes.

Final rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation hereby issues a new Part 450 in Chapter IV of Title 7 of the Code of Federal Regulations to be known as 7 CFR Part 450—Prune Crop Insurance Regulations, effective for the 1986 and succeeding crop years. Part 450 is added to read as follows:

PART 450—PRUNE CROP INSURANCE REGULATIONS

Subpart—Regulations for the 1986 and Succeeding Crop Years

Sec.

450.1 Availability of prune crop insurance.
450.2 Premium rates, production guarantees, coverage levels, and prices at which indemnities shall be computed.
450.3 OMB control numbers.
450.4 Creditors.
450.5 Good faith reliance on misrepresentation.
450.6 The contract.
450.7 The application and policy.

Authority: Secs. 506, 516, Pub. L. 75–430, 52 Stat. 73, 77, as amended (7 U.S.C. 1506, 1516).

Subpart—Regulations for the 1986 and Succeeding Crop Years

§ 450.1 Availability of prune crop insurance.

Insurance shall be offered under the provisions of this subpart on prunes in counties within the limits prescribed by and in accordance with the provisions of the Federal Crop Insurance Act, as amended. The counties shall be designated by the Manager of the Corporation from those approved by the Board of Directors of the Corporation.

§ 450.2 Premium rates, production guarantees, coverage levels, and prices at which indemnities shall be computed.

(a) The Manager shall establish premium rates, production guarantees, coverage levels, and prices at which indemnities shall be computed for prunes which will be included in the actuarial table on file in the applicable service offices for the county and which may be changed from year to year.

(b) At the time the application for insurance is made, the applicant will elect a coverage level and price at which indemnities will be computed from among those levels and prices contained in the actuarial table for the crop year.

§ 450.3 OMB control numbers.

OMB control numbers are contained in Subpart H of Part 400, Title 7 CFR.

§ 450.4 Creditors.

An interest of a person in an insured crop existing by virtue of a lien, mortgage, garnishment, levy, execution, bankruptcy, involuntary transfer or other similar interest shall not entitle the holder of the interest to any benefit under the contract.

§ 450.5 Good faith reliance on misrepresentation.

Notwithstanding any other provision of the prune insurance contract, whenever: (a) An insured under a contract of crop insurance entered into under these regulations, as a result of a misrepresentation or other erroneous action or advice by an agent or employee of the Corporation: (1) Is indebted to the Corporation for additional premiums; or (2) has suffered a loss to a crop which is not insured or for which the insured is not entitled to an indemnity because of failure to comply with the terms of the insurance contract, but which the insured believed to be insured, or believed the terms of the insurance contract to have been complied with or waived; and (b) the Board of Directors of the Corporation, or the Manager in cases involving not more than $100,000.00, finds that: (1) An agent or employee of the Corporation did in fact make such misrepresentation or take other erroneous action or give erroneous advice; (2) said insured relied thereon in good faith; and (3) to require the payment of the additional premiums or to deny such insured's entitlement to the indemnity would not be fair and equitable, such insured shall be granted relief the same as if otherwise entitled thereto. Requests for relief under this section must be submitted to the Corporation in writing.

§ 450.6 The contract.

The insurance contract shall become effective upon the acceptance by the Corporation of a duly executed application for insurance on a form prescribed by the Corporation. The contract shall cover the prune crop as provided in the policy. The contract shall consist of the application, the policy, and the county actuarial table. Any changes made in the contract shall not affect its continuity from year to year. The forms referred to in the contract are available at the applicable service offices.

§ 450.7 The application and policy.

(a) Application for insurance on a form prescribed by the Corporation may be made by any person to cover such person's share in the prune crop as landlord, owner-operator, or tenant. The application shall be submitted to the Corporation at the service office on or before the applicable sales closing date on file in the service office.

(b) The Corporation may discontinue the acceptance of applications in any county upon its determination that the insurance risk is excessive, and also, for the same reason, may reject any individual application. The Manager of the Corporation is authorized in any crop year to extend the sales closing date for submitting applications in any county, by placing the extended date on file in the applicable service offices and

publishing a notice in the **Federal Register** upon the Manager's determination that no adverse selectivity will result during the extended period. However, if adverse conditions should develop during such period, the Corporation will immediately discontinue the acceptance of applications.

(c) In accordance with the provisions governing changes in the contract contained in policies issued under FCIC regulations for the 1986 and succeeding crop years, a contract in the form provided for in this subpart will come into effect as a continuation of a prune contract issued under such prior regulations, without the filing of a new application.

(d) The application for the 1986 and succeeding crop years is found at Subpart D of Part 400—General Administrative Regulations (7 CFR 400.37 and 400.38) and may be amended from time to time for subsequent crop years. The provisions of the Prune Crop Insurance Policy for the 1986 and succeeding crop years are as follows:

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

Prune—Crop Insurance Policy

(This is a continuous contract. Refer to Section 15.)

Agreement to Insure: We will provide the insurance described in this policy in return for the premium and your compliance with all applicable provisions.

Throughout this policy, "you" and "your" refer to the insured shown on the accepted Application and "we," "us" and "our" refer to the Federal Crop Insurance Corporation.

Terms and Conditions

1. Causes of loss.

a. The insurance provided is against unavoidable loss of production resulting from the following causes occurring within the insurance period:

(1) Adverse weather conditions;

(2) Fire;

(3) Wildlife;

(4) Earthquake;

(5) Volcanic eruption;

(6) Direct Mediterranean Fruit Fly damage; or

(7) If applicable, failure of the irrigation water supply due to an unavoidable cause occurring after insurance attaches;

unless those causes are excepted, excluded, or limited by the actuarial table or section 9e(4).

b. We will not insure against any loss of production due to:

(1) The neglect, mismanagement or wrongdoing by you, any member of your household, your tenants or employees;

(2) The failure to follow recognized good prune farming practices;

(3) The failure to follow recognized good prune irrigation practice;

(4) The failure or breakdown of irrigation equipment or facilities;

(5) The impoundment of water by any governmental, public or private dam or reservoir project; or

(6) Any cause not specified in section 1a as an insured loss.

2. Crop, acreage, and share insured.

a. The crop insured will be any of the varieties of prune plums ("prunes") which are grown for the production of dried prunes on insured acreage and for which a guarantee and premium rate are provided by the actuarial table.

b. The acreage insured for each crop year will be prunes grown on insurable acreage as designated by the actuarial table and in which you have a share, as reported by you or as determined by us, whichever we elect.

c. The insured share is your share as landlord, owner-operator, or tenant in the insured prunes at the time insurance attaches. However, only for the purpose of determining the amount of indemnity, your share will not exceed your share on the earlier of:

(1) The time of loss; or

(2) The beginning of harvest.

d. We do not insure any acreage:

(1) Which is not irrigated except where provided by the actuarial table, or for which adequate facilities and water are not available at the time insurance attaches to carry out a good prune irrigation practice;

(2) On which the trees have not reached the seventh growing season after being set out unless we agree in writing to insure such acreage;

(3) Planted with a vine or tree crop other than prunes;

(4) Which we inspect and consider not acceptable; or

(5) A variety of prunes not established as adapted to the area or excluded by the actuarial table.

e. We may limit the insured acreage to any acreage limitation established under any Act of Congress, if we advise you of the limit prior to the date insurance attaches.

3. Report of acreage, share, and practice.

You must report on our form:

a. All the acreage of prunes in the county in which you have a share;

b. The practice; and

c. Your share at the time insurance attaches.

You must designate separately any acreage that is not insurable. You must report if you do not have a share in any prunes grown in the county. This report must be submitted annually on or before March 1. All indemnities may be determined on the basis of information you submit on this report. If you do not submit this report by the reporting date, we may elect to determine, by unit, the insured acreage, share, and practice or we may deny liability on any unit. Any report submitted by you may be revised only upon our approval. By applying for prune crop insurance, you authorize us to examine records maintained by the Prune Marketing Committee, if applicable, or prune packer for the purpose of determining or verifying your production and acreage.

4. Production guarantees, coverage levels, and prices for computing indemnities.

a. The production guarantees, coverage levels, and prices for computing indemnities are contained in the actuarial table.

b. If the number of bearing trees (seventh growing season and older) is reduced more than 10 percent from the preceding calendar year as a result of damage occurring within that year, the production guarantee will be reduced 1 percent (through adjustment to your average yield) for each 1 percent reduction in excess of 10 percent.

c. Coverage level 2 will apply if you do not elect a coverage level.

d. You may change the coverage level and price election on or before the sales closing date as established by the actuarial table for submitting applications for the crop year.

5. Annual premium.

a. The annual premium is earned and payable on the date insurance attaches. The amount is computed by multiplying the production guarantee times the price election, times the premium rate, times the insured acreage, times your share on the date insurance attaches.

b. Interest will accrue at the rate of one and one-half percent (1½%) simple interest per calendar month, or any part thereof, on any unpaid premium balance starting on the first day of the month following the first premium billing date.

6. Deductions for debt.

Any unpaid amount due us may be deducted from any indemnity payable to you or from any loan or payment due you under any Act of Congress or program administered by the United States Department of Agriculture or its Agencies.

7. Insurance period.

Insurance attaches for each crop year on March 1 and ends at the earliest of:

a. Total destruction of the prunes;

b. The date harvest of the prunes (by variety) should have started;

c. Harvest of the prunes;

d. Final adjustment of a loss;

e. October 1 in California; or

f. October 15 in Oregon.

8. Notice of damage or loss.

a. In case of damage or probable loss:

(1) You must give us written notice of:

(a) The dates of damage; and

(b) The causes of damage.

(2) You must give us written notice if during the period before harvest, the prunes on any unit are damaged and you decide not to further care for or harvest any part of them.

(3) You must give us notice at least 15 days before the beginning of harvest if you anticipate a loss on any unit.

(4) If probable loss or damage is determined within 15 days of or during harvest, immediate notice must be given.

(5) If you are going to claim an indemnity on any unit, you must give us notice not later than 72 hours:

(a) After total destruction of the prunes;

(b) Discontinuance of harvest on the unit; or

(c) Before harvest would normally start if any acreage on the unit is not to be harvested.

(6) Unless notice has been given under subsection (5) above, and in addition to the other notices required by this section, if you are going to claim an indemnity on any unit, you must give us notice not later than 10 days after the earliest of:

(a) Harvest of the unit;
(b) October 1 of the crop year in California; or
(c) October 15 of the crop year in Oregon.

b. You must obtain written consent from us before you destroy any of the prunes which are not to be harvested.

c. We may reject any claim for indemnity if you fail to comply with any of the requirements of this section or section 9.

9. Claim for indemnity.

a. Any claim for indemnity on a unit must be submitted to us on our form not later than 60 days after the earliest of:

(1) Total destruction of the prunes on the unit;
(2) Harvest of the unit;
(3) October 1 of the crop year in California; or
(4) October 15 of the crop year in Oregon.

b. We will not pay any indemnity unless you:

(1) Establish the total production of prunes on the unit and that any loss of production has been directly caused by one or more of the insured causes during the insurance period;

(2) Authorize us in writing to examine and obtain any records pertaining to the production and marketing of the insured prunes under this contract from the prune packer Prune Marketing Committee, if applicable, or prune packer; and

(3) Furnish all information we require concerning the loss.

c. The indemnity will be determined on each unit by:

(1) Multiplying the insured acreage by the production guarantee;

(2) Subtracting therefrom the total production of prunes to be counted [see section 9e];

(3) Multiplying the remainder by the price election; and

(4) Multiplying this result by your share.

d. If the information reported by you under section 3 of the policy results in a lower premium than the actual premium determined to be due, the production guarantee on the unit will be computed on the information reported, but all production from insurable acreage, whether or not reported as insurable, will count against the production guarantee.

e. The total production to be counted for a unit will include all harvested and appraised production on a natural condition prune basis which grades substandard or better.

(1) Any production of substandard prunes which results from damage by insurable causes will be adjusted by:

(a) Dividing the value per ton of such prunes by the market price per ton of standard prunes (of the same size count); and

(b) Multiplying the result by the number of tons of such prunes.

(2) Appraised production to be counted will include:

(a) Potential production lost due to uninsured causes and failure to follow recognized good prune farming practices;

(b) Not less than the guarantee for any acreage which is abandoned, damaged solely by an uninsured cause, or destroyed by you without our consent; and

(c) Any unharvested production.

(3) Any appraisal we have made on insured acreage will be considered production to count unless such appraised production is:

(a) Not harvested before the harvest of prunes becomes general in the county;

(b) Further damaged by an insured cause and reappraised by us; or

(c) Harvested.

(4) If you elect to exclude hail and fire as insured causes of loss and the prunes are damaged by hail or fire, appraisals will be made in accordance with Form FCI–78, "Request to Exclude Hail and Fire".

f. You must not abandon any acreage to us.

g. You may not sue us unless you have complied with all policy provisions. If a claim is denied, you may sue us in the United States District Court under the provisions of 7 U.S.C. 1508(c). You must bring suit within 12 months of the date notice of denial is received by you.

h. We have a policy for paying your indemnity within 30 days of our approval of your claim, or entry of a final judgment against us. We will, in no instance, be liable for the payment of damages, attorney's fees, or other charges in connection with any claim for indemnity, whether we approve or disapprove such claim. We will, however, pay simple interest computed on the net indemnity ultimately found to be due by us or by a final judgment from and including the 61st day after the date you sign, date, and submit to us the properly completed claim for indemnity form, if the reason for our failure to timely pay is not due to your failure to provide information or other material necessary for the computation or payment of the indemnity. The interest rate will be that established by the Secretary of the Treasury under Section 12 of the Contract Disputes Act of 1978 (41 U.S.C. 611), and published in the Federal Register semiannually on or about January 1 and July 1. The interest rate to be paid on any indemnity will vary with the rate announced by the Secretary of the Treasury.

i. If you die, disappear, or are judicially declared incompetent, or if you are an entity other than an individual and such entity is dissolved after insurance attaches for any crop year, any indemnity will be paid to the persons we determine to be beneficially entitled thereto.

j. If you have other fire insurance, fire damage occurs during the insurance period, and you have not elected to exclude fire insurance from this policy, we will be liable for loss due to fire only for the smaller of the amount:

(1) Of indemnity determined pursuant to this contract without regard to any other insurance; or

(2) By which the loss from fire exceeds the indemnity paid or payable under such other insurance.

For the purpose of this section, the amount of loss from fire will be the difference between the fair market value for the production on the unit before the fire and after the fire.

10. Concealment or fraud.

We may void the contract on all crops insured without affecting your liability for premiums or waiving any right, including the right to collect any amount due us if, at any time, you have concealed or misrepresented any material fact or committed any fraud relating to the contract. Such voidance will be effective as of the beginning of the crop year with respect to which such act or omission occurred.

11. Transfer of right to idemnity on insured share.

If you transfer any part of your share during the crop year, you may transfer your right to an indemnity. The transfer must be on our form and approved by us. We may collect the premium from either you or your transferee or both. The transferee will have all rights and responsibilities under the contract.

12. Assignment of indemnity.

You may assign to another party your right to an indemnity for the crop year, only on our form and with our approval. The assignee will have the right to submit the loss notices and forms required by the contract.

13. Subrogation. (Recovery of loss from a third party.)

Because you may be able to recover all or a part of your loss from someone other than us, you must do all you can to preserve any such right. If we pay you for your loss, then your right of recovery will at our option belong to us. If we recover more than we paid you plus our expenses, the excess will be paid to you.

14. Records and access to farm.

You must keep, for two years after the time of loss, records of the harvesting, storage, shipment, sale or other disposition of all prunes produced on each unit, including separate records showing the same information for production from any uninsured acreage. Failure to keep and maintain such records may, at our option, result in cancellation of the contract prior to the crop year to which the records apply, assignment of production to units by us, or a determination that no indemnity is due. Any person designated by us will have access to such records and the farm for purposes related to the contract.

15. Life of contract: Cancellation and termination.

a. This contract will be in effect for the crop year specified on the application and may not be canceled by you for such crop year. Thereafter, the contract will continue in force for each succeeding crop year unless canceled or terminated as provided in this section.

b. This contract may be canceled by either you or us for any succeeding crop year by giving written notice on or before the cancellation date preceding such crop year.

c. Prior to the cancellation date you must:

(1) Furnish to the Corporation satisfactory production records for the crop year or the contract will be cancelled for the next crop year; or

(2) Show to our satisfaction that the records are not available because of conditions beyond your control, such as fire, flood or other natural disaster. (If this subsection (2) applies, the Field Actuarial Office may assign a yield for the year for which the records are unavailable).

d. This contract will terminate as to any crop year if any amount due us on this or any other contract with you is not paid on or before the termination date preceding such

crop year for the contract on which the amount is due. The date of payment of the amount due if deducted from:

(1) An indemnity claim will be the date you sign the claim; or

(2) Payment under another program administered by the United States Department of Agriculture will be the date both such payment and setoff are approved.

e. The cancellation and termination dates are January 31.

f. If you die or are judicially declared incompetent, or if you are an entity other than an individual and such entity is dissolved, the contract will terminate as of the date of death, judicial declaration, or dissolution. If such event occurs after insurance attaches for any crop year, the contract will continue in force through the crop year and terminate at the end thereof. Death of a partner in a partnership will dissolve the partnership unless the partnership agreement provides otherwise. If two or more persons having a joint interest are insured jointly, death of one of the persons will dissolve the joint entity.

g. The contract will terminate if no premium is earned for 5 consecutive years.

16. Contract changes.

We may change any terms and provisions of the contract from year to year. If your price election at which indemnities are computed is no longer offered, the actuarial table will provide the price election which you are deemed to have elected. All contract changes will be available at your service office by October 31 preceding the cancellation date. Acceptance of any change will be conclusively presumed in the absence of notice from you to cancel the contract.

17. Meaning of terms.

For the purposes of prune crop insurance:

a. "Actuarial table" means the forms and related material for the crop year approved by us which are available for public inspection in your service office, and which show the production guarantees, coverage levels, premium rates, prices for computing indemnities, practices, insurable and uninsurable acreage, and related information regarding prune insurance in the county.

b. "Average yield" means the yield established from your production records, which is approved by us and shown on our form.

c. "Contiguous land" means land which is touching at any point, except that land which is separated by only a public or private right-of-way will be considered contiguous.

d. "County" means the county shown on the application and any additional land located in a local producing are bordering on the county, as shown by the actuarial table.

e. "Crop year" means the period beginning with the date insurance attaches and extending through the normal harvest time and designated by the calendar year in which the prunes are normally harvested.

f. "Direct Mediterranean Fruit Fly damage" means the actual physical damage to the prunes on the unit which causes such prunes to be unmarketable and will not include unmarketability of such prunes as a direct result of a quarantine, boycott, or refusal to accept the prunes by any entity without regard to actual physical damage to such prunes.

g. "Harvest" means picking of the prunes from the trees or ground either by hand or machine for the purpose of removal from the orchard.

h. "Insurable acreage" means the land classified as insurable by us and shown as such by the actuarial table.

i. "Insured" means the person who submitted the application accepted by us.

j. "Market price for standard prunes" means the price per ton shown on the processor's settlement sheet for each size count of standard prunes.

k. "Natural condition prunes" means prunes in the condition in which they normally come from a dry yard or dehydrator.

l. "Person" means an individual, partnership, association, corporation, estate, trust, or other legal entity, and wherever applicable, a State, a political subdivision of a State, or any agency thereof.

m. "Service office" means the office servicing your contract as shown on the application for insurance or such other approved office as may be selected by you or designated by us.

n. "Standard prunes" means any natural conditioned prunes:

(1) Grading C or better in accordance with U.S. Standards for grades of dried prunes; or

(2) Which conform to the grading specifications currently regulating the handling of dried prunes in States where Federal Marketing Orders for dried prunes are applicable.

o. "Substandard prunes" mean any natural condition prunes failing to meet the applicable grading specifications for standard prunes.

p. "Tenant" means a person who rents land from another person for a share of the prunes or a share of the proceeds therefrom.

q. "Unit" means all insurable acreage of prunes in the county located on contiguous land on the data insurance attaches for the crop year:

(1) In which you have a 100 percent share; or

(2) Which is owned by one entity and operated by another entity on a share basis.

Land rented for cash, a fixed commodity payment, or any consideration other than a share in the prunes on such land will be considered as owned by the lessee. Land which would otherwise be one unit may be divided according to applicable guidelines on files in your service office. Units will be determined when the acreage is reported. Errors in reporting units may be corrected by us to conform to applicable guidelines when adjusting a loss. We may consider any acreage and share thereof reported by or for your spouse or child or any member of your household to be your bona fide share or the bona fide share of any other person having an interest therein.

18. Descriptive headings.

The descriptive headings of the various policy terms and conditions are formulated for convenience only and are not intended to affect the construction or meaning of any of the provisions of the contract.

19. Determinations.

All determinations required by the policy will be made by us. If you disagree with our determinations, you may obtain reconsiderations of or appeal those determinations in accordance with Appeal Regulations.

20. Notices.

All notices required to be given by you must be in writing and received by your service office within the designated time unless otherwise provided by the notice requirement. Notices required to be given immediately may be by telephone or in person and confirmed in writing. Time of the notice will be determined by the time of our receipt of the written notice.

Done in Washington, DC, on October 29, 1985.

Edward Hews,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 85-29233 Filed 12-9-85; 8:45 am]

BILLING CODE 3410-08-M

Commodity Credit Corporation

7 CFR Part 1446

General Regulations Governing 1982 Through 1985 Crops Peanut Warehouse Storage Loans and Handler Operations (Amendment 2)

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: An interim rule published at 49 FR 37729 amending regulations in 7 CFR Part 1446 with respect to the 1984 and 1985 crops of peanuts is adopted as a final rule without change except for a minor revision in the definition of "fragmented peanuts" contained in the regulations. The interim rule addressed the handling of quota peanuts designated as replacements for additional peanuts substituted into the U.S. market, the allowance of a tolerance for certain screen sizes for handlers substituting quota and additional peanuts, the offset of losses in marketing pools for quota peanuts, and the definitions in the regulations of "net weight," "fragmented peanuts," "peanut products," and "raw peanuts."

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: David L. Kincannon (ASCS), 202-382-0152. A Final Regulatory Impact Analysis has been prepared and is available upon request.

SUPPLEMENTARY INFORMATION: This Final Rule has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Departmental Regulation No. 1512-1 and has been classified "not major." It has been determined that the provisions of this rule will not result in: (1) An

annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State and local governments, or geographical regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The title and number of the Federal assistance program to which this rule applies are: Commodity Loans and Purchases, 10.051, as found in the Catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this rule since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment. In addition, this action will not adversely affect environmental factors such as wildlife habitat, water quality, air quality, or land use and appearance. Therefore, neither an environmental assessment nor an Environmental Impact Statement is needed.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983).

CCC published an interim rule in the Federal Register (49 FR 37729) which amended the CCC peanut handler regulations and warehouse-stored peanut price support loan regulations codified at 7 CFR 1446.50 *et seq.* The interim rule revised these regulations with respect to: (1) The handling of quota peanuts which are substituted for contract additional peanuts used in the domestic edible market; (2) offsets of losses in marketing pools for quota loan peanuts; and (3) the definitions of net weight, fragmented peanuts, peanut products, and raw peanuts.

Comments

A. Substitution of Quota and Additional Peanuts

The regulations found at 7 CFR 1446.58(d) provided that if quota and additional peanuts were substituted for one another, they must be of the same grade and screen size. The interim rule amended § 1446.58(d) to allow a variance tolerance of 1 percent of the export obligation of certain screen sizes.

Three comments generally supported the tolerance concept, but one of these comments suggested that the tolerance should apply to all screen sizes. In addition, ten comments suggested that the tolerance should be increased to 5 percent for those screen sizes for which the tolerance is allowed. These ten comments suggested that a 1-percent tolerance would not justify the administrative effort needed for enforcement purposes. In addition, two comments were received which opposed the allowance of any tolerance. These commenters suggested that the allowance of a tolerance would: (1) Work to the disadvantage of some handlers; (2) release handlers from penalties which would otherwise be due as the result of unwise marketing decisions; and (3) delay the settlement of peanut price accounting pools under which gains from sales of peanuts pledged as collateral for price support loans are distributed to peanut producers.

It has been determined that amendments made to § 1446.58(d) with respect to the tolerance should be adopted as a final rule without change for the reasons set out in the supplementary information published with that rule. The limitations on the tolerance avoid having the tolerance serve as a source of disadvantage to other handlers. The enforcement of the tolerance is not expected to be administratively burdensome to CCC, for area marketing associations or handlers, nor is it expected that the tolerance will delay settling peanut price support pools.

B. Fragmented Peanuts

The interim rule amended the definition of "fragmented peanuts" found at 7 CFR 1446.52(u) by adopting by reference the definition of fragmented peanuts promulgated by the Peanut Administrative Committee (PAC) for PAC marketing agreements.

One commenter objected to the adoption in the CCC regulations of the PAC definition of fragmented peanuts since that definition could change from year to year without rulemaking. Traditionally CCC regulations governing peanut handler operations and peanut warehouse-stored price support loans have followed the PAC definition of fragmented peanuts by repetition rather than by incorporation by reference. If CCC determines that the definition of fragmented peanuts for program purposes should differ from that promulgated by PAC, CCC can amend its regulations accordingly. However, there is currently no basis for a difference in definition. Accordingly, the definition of "fragmented peanuts" as set forth in the interim rule has been adopted as a final rule without change except for a minor revision for purposes of clarity only.

C. Raw Peanuts

The interim rule amended the definition of "raw peanuts" found at 7 CFR 1446.52(mm) to include in that definition pressed peanuts and any other classification of peanuts which is approved by CCC if certain conditions are met.

One commenter questioned the inclusion of pressed peanuts in this definition. However, pressed peanuts are a form of blanched peanuts, i.e., they are blanched peanuts with a percentage of the oil removed. As a result, it has been determined that pressed peanuts, like blanched peanuts, should be classified as "raw peanuts" rather than "peanut products." A second commenter complained that revising the definition of "raw peanuts" to include "any other classification of peanuts as designated by CCC which have not passed through any other processing operations" permits CCC to treat additional classifications of peanuts as "raw peanuts" without further rulemaking. However, it is felt that CCC needs flexibility in handling hybrid classifications of peanuts as the need arises. In addition, this revision in the definition of raw peanuts applies only to classifications of peanuts which have not undergone other processing operations. Accordingly the definition of "raw peanuts" as set forth in the interim rule has been adopted as a final rule without change.

D. Net Gains

The interim rule amended the regulations at 7 CFR 1446.61 to make it clear that gains from certain additional peanut loan pools must be used to offset losses from quota peanut loan pools.

One commenter recommended that the application of net gains from the sale of additional peanuts pledged as collateral for price support loans should be limited to losses on an equivalent quantity of quota peanuts. As indicated in the supplementary information to the interim rule, section 108A of the Agricultural Act of 1949 provides that any distribution of net gains otherwise attributable to additional peanuts from the sale of such peanuts in the pool for domestic food and related uses shall be used to offset any losses with respect to the disposition of all peanuts in the pool for quota peanuts. In view of this

statutory requirement, the recommendation submitted by the commenter cannot be adopted.

Conclusion

No comments were received with respect to other amendments to the regulations which were made by the provisions of the interim rule. After reviewing the comments received, it has been determined that the amendments made by the interim rule should be adopted as a final rule without change except as indicated.

List of Subjects in 7 CFR Part 1446

Loan Programs—Agriculture, Peanuts, Price Support Programs, Warehouses.

Final Rule

PART 1446—[AMENDED]

Accordingly, the interim rule published at 49 FR 37729 is hereby adopted as a final rule without change, except that 7 CFR 1446.52(u) is revised to read as follows:

§ 1446.52 Definitions.

* * * * *

(u) *Fragmented peanuts.* Peanuts qualifying as fragmented peanuts under the definitions contained in the outgoing quality regulations of the Peanut Marketing Agreement (No. 146) which are applicable for the crop year in which the peanuts were produced.

* * * * *

Signed at Washington, DC, on December 3, 1985.

Everett Rank,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 85-29208 Filed 12-9-85; 8:45 am]

BILLING CODE 3410-05-M

Food Safety and Inspection Service

9 CFR Parts 318 and 381

[Docket No. 85-006F]

Monoammonium Glutamate in Meat and Poultry Food Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service has been petitioned to amend the Federal meat and poultry products inspection regulations to permit the use of monoammonium glutamate as a flavor enhancer in meat and poultry food products. The Food and Drug Administration (FDA) lists monoammonium glutamate as a multiple purpose food substance which is generally recognized as safe (GRAS) when used in accordance with good manufacturing practice (21 CFR 182.1500). The administrator has determined that it is appropriate to add monoammonium glutamate to the list of acceptable flavor enhancers used in foods under the Agency's procedural regulation for the approval of added substances (9 CFR 318.7(a)(2) and 381.147(f)(2)).

EFFECTIVE DATE: February 10, 1986.

ADDRESS: Post-promulgation comments concerning this final rule may be addressed to the Department of Agriculture, Food Safety and Inspection Service, ATTN: Hearing Clerk, 14th and Independence SW., Washington, DC 20250, (202-447-8545). (See also "Comments" under "Supplementary Information.")

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Jones, Chief, Standards Branch, Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447-7503.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined that this final rule is not a "major rule" under Executive Order 12291. It will not result in an annual effect on the economy of $100 million or more. There will be no major increase in costs or prices to consumers; to individual industries; to Federal, State, or local government agencies; or to geographic regions. This final rule will not have a significant adverse effect on competition, employment, investment, productivity, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This final rule provides for the use of monammonium glutamate as a flavor enhancer in meat and poultry food products. Current Federal meat and poultry products regulations do not provide for the use of monoammonium glutamate. Industry will benefit from this action by gaining the ability to use an alternative flavor enhancer, and the public will benefit through introduction into the food supply of a safe and functional food ingredient which may help reduce the sodium content of food products.

Effect on Small Entities

The Administrator has determined that this action will not have a significant economic impact upon a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). This final rule will impose no new compliance or reporting requirements on industry. The promulgation of this rule merely authorizes the discretionary use of monammonium glutamate in meat and poultry food products.

Comments

This is a final rule consistent with the provisions of § 318.7 of the Federal meat inspection regulations and § 381.147 of the Federal poultry products inspection regulations. As such, comments have not been solicited. However, interested persons may inform the Department of any available data which may raise questions about this action within the 60 day period between publication and the effective date of this final rule.

Background

The Henkel Corporation has petitioned the Agency to approve the use of monoammonium glutamate as a flavor enhancer in "various" meat and poultry food products, in amounts "sufficient for purpose." The petitioner's request is based on current USDA provisions which authorize the discretionary use of monosodium glutamate. (9 CFR 318.7 and 381.147).

The petitioner maintains that monoammonium glutamate has been shown to be an effective flavor enhancer in various meat and poultry food products, and has the same technical effect as monosodium glutamate. The use of monoammonium glutamate as a flavor enhancer may also be effective in reducing the sodium content of foods.

In the **Federal Register** of July 19, 1983 (48 FR 32749), the Agency published a final rule on new procedures for the approval of certain added substances in meat and poultry products. Under that rule, applicants are required to show (1) that a proposed added substance has been previously approved by FDA for use in meat or meat food products as a food additive, color additive, or as a substance generally recognized as safe (GRAS), and (2) that the substance is listed in Title 21 of the Code of Federal Regulations, Parts 73, 74, 81, 172, 173, 182, or 184. Once this is established, the use of the added substance will be permitted upon a further determination by the Administrator that (1) its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the stated technical effect, and (2) that the substance will not render the product adulterated, misbranded, or otherwise not in compliance with the Federal meat

Inspection Act or the Poultry Products Inspection Act.

The FDA lists monoammonium glutamate as a multiple purpose GRAS food substance when used in accordance with good manufacturing practice (21 CFR 182.1500).

The Administrator concurs with FDA's conclusions regarding the safety of this substance for its proposed use, provided that the addition of monoammonium glutamate in meat or poultry products is declared in the product label under existing provisions of the Federal meat inspection regulations (9 CFR 317.2(f)), or the Federal poultry products inspection regulations (9 CFR 381.118(a)). He further finds that information provided by the petitioner and other data available to the Agency indicate that (1) the proposed use of this substance is functional and suitable for meat and poultry products, (2) the substance would be used at the lowest level necessary to accomplish its intended technical effect, and (3) the use of this substance will not render the products in which it is used adulterated, misbranded, or otherwise not in accordance with requirements of the Federal Meat Inspection Act and the Poultry Products Inspection Act.

Therefore, the Agency is amending the Federal meat and poultry inspection regulations to include monoammonium glutamate in the table of approved substances contained in Title 9, Parts 318 and 381, Code of Federal Regulations.

Indexing Terms: Following are the indexing terms for this regulation.

List of Subjects

9 CFR Part 318

Food additives, Food labeling, Meat and poultry products, Preparation of products.

9 CFR Part 381

Food additives, Food labeling, Poultry and poultry products, Preparation of products.

For reasons explained in the preamble, Part 318, Subchapter A, Chapter III of Title 9, Code of Federal Regulations, and Part 381, Subchapter C, Chapter III of Title 9, Code of Federal Regulations are amended as set forth below.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS [AMENDED]

9 CFR Part 318 is amended as follows:

1. The authority citation for Part 318 continues to read as follows:

Authority: 34 Stat. 1260, 81 Stat. 584, as amended (21 U.S.C. 601 *et seq.*); 72 Stat. 862, 92 Stat. 1069, as amended (7 U.S.C. 1901 *et seq.*); 76 Stat. 663 (7 U.S.C. 450 *et seq.*), unless otherwise noted.

2. In Part 318, the chart in § 318.7(c)(4) is amended to add a new substance under the class of substances entitled "Flavoring agents; protectors and developers" immediately following the entry for monosodium glutamate to read as follows:

§ 318.7 Approval of substances for use in the preparation of products.

* * * * *

(c) * * *

(4) * * *

Class of substance	Substance	Purpose	Products	Amount
	Monoammonium glutamate.	do	do	do.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS [AMENDED]

9 CFR Part 381 is amended as follows:

1. The authority citation for Part 381 continues to read as follows:

Authority: 71 Stat. 441, 82 Stat. 791, as amended, 21 U.S.C. 451 *et seq.*; 76 Stat. 663 (7 U.S.C. 450 *et seq.*), unless otherwise noted.

2. In Part 381, the table in § 381.147(f)(4) is amended to add a new substance under the class of substances entitled "Flavoring agents; protectors and developers" immediately following the entry for monosodium glutamate to read as follows:

§ 381.147 Restrictions on the use of substances in poultry products.

* * * * *

(f) * * *

(4) * * *

Class of substance	Substance	Purpose	Products	Amount
	Monoammonium glutamate.	do	do	do.

Done at Washington, D.C., on: November 15, 1985.

Donald L. Houston,

Administrator, Food Safety and Inspection Service.

[FR Doc. 85-29207 Filed 12-9-85; 8:45 am]

BILLING CODE 3410-DM-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 9

Miscellaneous Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations pertaining to public records to indicate that Executive Order 12356 governs classified documents and to remove references to a now defunct NRC Committee. These amendments are necessary to inform the public of these administrative changes to NRC regulations.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301-492-7086.

SUPPLEMENTARY INFORMATION: On December 16, 1982, the NRC published a final rule (47 FR 15624) which amended its regulations to incorporate into 10 CFR Part 9, Appendix A, references to Executive Order 12356, that covers the original and derivative classification, downgrading, declassification, and safeguarding of national security information. Inadvertently overlooked at that time was a corresponding amendment to § 9.61. The NRC is now amending its regulations to incorporate The Executive Order into § 9.61.

Appendix A, originally added to Part 9 on August 3, 1972 (37 FR 15624), is now being removed from Part 9 because the NRC Classification Review Committee no longer exists and the considerations addressed in Appendix A will now be incorporated into § 9.61.

Because these are amendments dealing with agency practice and procedures, the notice provisions of the Administrative Procedure Act do not apply pursuant to 5 U.S.C. 553(b)(A). The amendments are effective upon publication in the **Federal Register.** Good cause exists to dispense with the usual 30-day delay in the effective date because the amendments are of a minor and administrative nature dealing solely with agency procedures.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR

51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.)

List of Subjects in 10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 9.

PART 9—PUBLIC RECORDS

1. The authority citation for Part 9 is revised to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Subpart A also issued under 5 U.S.C. 552 and 31 U.S.C. 9701. Subpart B also issued under 5 U.S.C. 552a. Subpart C also issued under 5 U.S.C. 552b.

2. In § 9.61, paragraph (b)(1) is revised to read as follows:

§ 9.61 Procedures for processing requests for records exempt in whole or in part.

* * * * *

(b) * * *

(1) *Information classified pursuant to Executive Order 12356 and exempted pursuant to 5 U.S.C. 552a(k)(1).*

(i) Requested information classified by NRC will be reviewed by the responsible official of the NRC to determine whether it continues to warrant classification under the criteria of section 1.3 of Executive Order 12356.

(ii) Information which no longer warrants classification under these criteria shall be declassified and made available to the individual. If the requested information has been classified by another agency, the responsible official of the NRC will request the classifying agency to review the information to ascertain if classification is still warranted. If the information continues to warrant classification, the individual shall be advised that the information sought is classified, that it has been reviewed and continues to warrant classification, and that it has been exempted from access pursuant to 5 U.S.C. 552a(k)(1).

3. Appendix A is removed.

Dated at Bethesda, Maryland this 3d day of December 1985.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

[FR Doc. 85-29251 Filed 12-9-85; 8:45 am]

BILLING CODE 7590-01-M

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Regulation D; Docket No. R-0561]

Depository Institutions; Reserve Requirement Ratios

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending 12 CFR Part 204 (Regulation D—Reserve Requirements of Depository Institutions): (1) To increase the amount of transaction accounts subject to a reserve requirement ratio of three percent, as required by section 19(b)(2)(C), of the Federal Reserve Act (12 U.S.C. 461(b)(2)(C)), from $29.8 million to $31.7 million; and (2) to increase the amount of reservable liabilities of each depository institution that is subject to a reserve requirement of zero percent, as required by section 19(b)(11)(B) of the Federal Reserve Act (12 U.S.C. 461(b)(11)(B)), from $2.4 million to $2.6 million. The Board is also changing the basis of the reporting cutoff level (currently $25 million in "total deposits"), which is used to separate weekly reporters from quarterly reporters, from "total deposits" to "total deposits and other reservable liabilities."

EFFECTIVE DATE: December 31, 1985.

FOR FURTHER INFORMATION CONTACT: Oliver I. Ireland, Associate General Counsel (202/452-3625), or John Harry Jorgenson, Senior Attorney (202/452-3778), Legal Division, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Section 19(b)(2) of the Federal Reserve Act requires each depository institution to maintain with the Federal Reserve System reserves against its transaction accounts and nonpersonal time deposits, as prescribed by Board regulations. The initial reserve requirements imposed under section 19(b)(2) were set at three percent for each depository institution's total transaction accounts of $25 million or less and at 13 percent on total transaction accounts above $25 million. Section 19(b)(2) further provides that the Board shall issue a regulation before December 31 of each year that adjusts for the next calendar year the total dollar amount of the transaction account tranche against which reserves must be maintained at a ratio of three percent. The increase in the tranche is to be 80 percent of the percentage increase in total transaction accounts for all depository institutions determined as of June 30 of each year.

Currently, the amount of the low reserve tranche on transaction accounts is $29.8 million. The growth in the total net transaction accounts of all depository institutions from June 30, 1984, to June 30, 1985, was 8.1 percent (from $396.6 billion to $428.9 billion). In accordance with section 19(b)(2), the Board is amending Regulation D to increase the amount of the low reserve tranche for transaction accounts for 1986 by $1.9 million to $31.7 million.

Section 19(b)(11)(A) of the Federal Reserve Act provides that $2 million of reservable liabilities[1] of each depository institution shall be subject to a zero percent reserve requirement. Section 19(b)(11)(A) permits each depository institution, in accordance with the rules and regulations of the Board, to designate the reservable liabilities to which this reserve requirement exemption is to apply. However, if transaction accounts are designated, only those that would otherwise be subject to a three percent reserve requirement (*i.e.*, transaction accounts within the low reserve requirement tranche) may be so designated.

Section 19(b)(11)(B) of the Federal Reserve Act provides that the Board shall issue a regulation before December 31 of each year, adjusting for the next calendar year the dollar amount of reservable liabilities exempt from reserve requirements. The change in the amount is to be made only if the total reservable liabilities held at all depository institutions increases from one year to the next. The percentage increase in the exemption is to be 80 percent of the percentage increase in total reservable liabilities of all depository institutions determined as of June 30 each year. The growth in total reservable liabilities of all depository institutions from June 30, 1984, to June 30, 1985, was 8.5 percent (from $855.5 billion to $928.0 billion). In accordance with section 19(b)(11), the Board is amending Regulation D to increase the amount of the reserve requirement

[1] Reservable liabilities include transaction accounts, nonpersonal time deposits, and Eurocurrency liabilities as defined in section 19(b)(5) of the Federal Reserve Act.

exemption for 1986 by $0.2 million to $2.6 million.

As a result, the effect of these amendments is to modify the low reserve tranche (which is $31.7 million, effective January 1, 1986) to apply a zero percent reserve requirement on the first $2.6 million of transaction accounts (effective January 1, 1986) and a three percent reserve requirement on the remainder of the low reserve tranche. Any excess of this zero percent reserve requirement tranche remaining after applying it to transaction accounts will then be applied to nonpersonal time deposits with maturities of less than 1½ years or to Eurocurrency liabilities, both of which are subject to a reserve requirement ratio of three percent.

The tranche adjustment and the reservable liabilities exemption adjustment for weekly reporting institutions will be effective starting with the reserve computation period beginning on December 31, 1985, and with the corresponding reserve maintenance periods beginning January 2, 1986, for net transaction accounts, and on January 30, 1986, for other reservable liabilities. For institutions that report quarterly, the tranche adjustment and the exemption will be effective with the computation period beginning on December 17, 1985, and with the reserve maintenance period beginning January 16, 1986. In addition, all entities currently submitting Form FR 2900 will continue to submit reports to the Federal Reserve under current reporting procedures.

In order to reduce the reporting burden for small institutions, the Board established a deposit reporting cutoff level (currently $25 million in "total deposits") to determine deposit reporting frequency. In March of 1985, the Board decided to index this reporting cutoff level equal to 80 percent of the annual rate of increase of "total deposits" at all depository institutions. Institutions are screened during the second quarter of each year to determine reporting frequency beginning the following September.

All U.S. branches and agencies of foreign banks and all Edge and Agreement Corporations, regardless of size, and all other institutions with reservable liabilities in excess of the exemption level amount prescribed by section 19(b)(11) of the Federal Reserve Act and with at least $25 million in "total deposits" are required to file weekly the Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900). Depository institutions with reservable liabilities in excess of the exemption level amount but with "total deposits" less than $25 million may file the FR 2900 quarterly. Institutions that obtain funds from non-U.S. sources or that have foreign branches or international banking facilities are required to file the Report of Certain Eurocurrency Transactions (FR 2950) on the same frequency. The reporting cutoff level is also used to determine whether an institution with reservable liabilities at or below the exemption level amount must file the Quarterly Report of Selected Deposits, Vault Cash, and Reservable Liabilities (FR 2910q) or the Annual Report of Total Deposits and Reservable Liabilities (FR 2910a).

In order to ensure accurate reporting of reservable nondeposit liabilities, the Board has determined that the reporting cutoff level will be based on "total deposits" *plus* "other reservable liabilities." Thus, beginning with the screening in the second quarter of 1986, the cuttoff level of $25 million (indexed annually) will be measured by "total deposits" (which is the sum of gross transaction deposits, savings accounts, and time deposits) plus "other reservable liabilities" (which is the sum of reservable obligations of affiliates, ineligible acceptance liabilities, and net Eurocurrency liabilities).

Finally, the Board may require a depository institution to report on a weekly basis, regardless of the cutoff level, if the institution manipulates its "total deposits and other reservable liabilities" in order to qualify for quarterly reporting. Similarly, any depository institution that reports quarterly may be required to report weekly and to maintain appropriate reserve balances with its Reserve Bank if, during its computation period, it understates its usual reservable liabilities or it overstates the deductions allowed in computing required reserve balances.

The provisions of 5 U.S.C. 553(b) relating to notice and public participation have not been followed in connection with the adoption of these amendments because the amendments involve adjustments prescribed by statute and an interpretative statement reaffirming the Board's policy concerning reporting practices. Accordingly, the Board believes that notice and public participation is unnecessary and contrary to the public interest.

List of Subjects in 12 CFR Part 204

Banks, Banking; Currency; Federal Reserve System; Penalties and reporting requirements.

PART 204—[AMENDED]

Effective December 31, 1985, pursuant to the Board's authority under section 19 of the Federal Reserve Act, 12 U.S.C. 461 *et seq.*, 12 CFR Part 204 is amended by revising paragraph (a) of § 204.9 to read as follows:

§ 204.9 Reserve requirement ratios.

(a)(1) *Reserve percentages.* The following reserve ratios are prescribed for all depository institutions, Edge and Agreement Corporations, and United States branches and agencies of foreign banks:

Category: Net transaction accounts	Reserve requirement
$0 to $31.7 million	3 percent of amount.
Over $31.7 million	$951,000 plus 12 percent of amount over $31.7 million.

Nonpersonal time deposits

By original maturity (or notice period):

Less than 1½ years (percent)	3
1½ years or more (percent)	0
Eurocurrency liabilities (percent)	3

(2) *Exemption from reserve requirements.* Each depository institution, Edge or Agreement Corporation, and U.S. branch or agency of a foreign bank is subject to a zero percent reserve requirement on an amount of its transaction accounts suject to the low reserve tranche in paragraph (a)(1), nonpersonal time deposits, or Eurocurrency liabilities or any combination thereof not in excess of $2.6 million determined in accordance with section 204.3(a)(3) of this Part.

* * * * *

By order of the Board of Governors of the Federal Reserve System, December 4, 1985.

William W. Wiles,

Secretary of the Board.

[FR Doc. 85-29185 Filed 12-9-85; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 85-AGL-21]

Establishment of Transition Area; Pickneyville, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The nature of this action is to establish the Pickneyville, Illinois, transition area to accommodate a new NDB Runway 18 instrument approach

procedure to Pickneyville-DuQuoin Airport.

The intended effect of this action is to ensure segregation of the aircraft using approach procedures in instrument conditions from other aircraft operating under visual weather conditions in controlled airspace.

EFFECTIVE DATE: 0901 G.m.t., March 13, 1986.

FOR FURTHER INFORMATION CONTACT: Edward R. Heaps, Airspace, Procedures, and Automation Branch, Air Traffic Division, AGL-530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694-7360.

SUPPLEMENTARY INFORMATION:

History

On Friday, October 4, 1985, the Federal Aviation Administration (FAA) proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish the Pickneyville, Illinois, transition area (50 FR 40564).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6 dated January 2, 1985.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations establishes the Pickneyville, Illinois, transition area to accommodate a new NDB Runway 18 instrument approach procedure to Pickneyville-DuQuoin Airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Transition areas.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration (FAA) proposes to amend Part 71 of the FAR (14 CFR Part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. By amending § 71.181 as follows:

Pickneyville, Illinois [New]

That airspace extending upward from 700 feet above the surface, within a 5 mile radius of Pickneyville-DuQuoin Airport (lat. 37°58'39" N., long. 89°21'31" W.) and within 3 miles each side of the Pickneyville NDB 006° bearing extending from the 5 mile radius area to 8.5 miles north of the airport.

Issued in Des Plaines, Illinois, on November 26, 1985.

Monte R. Belger,

Acting Director, Great Lakes Region.

[FR Doc. 85-29172 Filed 12-9-85; 8:45 am]

BILLING CODE 4910-13-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 34-22684]

Freedom of Information Act; Public Reference Facilities in Regional Offices of the Commission

AGENCY: Securities and Exchange Commission.

ACTION: Adoption of Rule Amendments.

SUMMARY: The Commission is adopting amendments to the rule which requires certain categories of records to be maintained on file for reference by members of the public in regional offices other than New York and Chicago. Because of the increasing availability of information through private sector services, Commission resource limitations and changes in the needs of the public for information, certain filings will no longer be maintained for public use in these offices. Various reference materials generated by the agency concerning Commission activities will continue to be available.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Jonathan G. Katz, (202) 272-7440, Director, Office of Consumer Affairs and Information Services, Securities and Exchange Commission, 450 5th Street, N.W., Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION: The Commission is adopting amendments to rule 80(c)(1)(ii) of the Commission's regulations regarding information and requests (17 CFR 200.80(c)(1)(ii)), by which regional offices other than those in New York and Chicago would no longer be required to maintain certain regional firm information. The Commission's regional offices in New York and Chicago have public reference facilities containing microform records of all public filings made with the Commission. Present Commission regulations (*See* 17 CFR 200.80(c)(1)(ii)) also require regional offices to maintain certain documents on file and available for public reference, principally the public filings of all registered companies headquartered in the region, broker/dealer and investment adviser applications and Regulation A filings by firms within each respective region.

Most regional offices other than New York and Chicago do not have adequate staff resources or facilities to accommodate public access to these records. Some of the items are no longer available in all regional offices or are maintained for very limited periods of time. There is not significant public interest in reference facilities which specialize only in information on companies headquartered in a given region.

For these reasons, regional offices other than those in New York and Chicago will no longer be required to maintain for public access the reports by entities headquartered in the region. Such records will be available through the Commission's Public Reference Branch in Washington, DC, or through any of a number of private firms offering such information to the public. The Commission believes that these changes will have no significant impact on any substantial number of small entities. It seems that there is little or no utilization of those services proposed to be eliminated. The *SEC Docket*, *SEC News Digest* and other Commission publications will be made available for public access in the regional offices. Availability of other reference materials in the regional offices will be left to the discretion of each regional administrator.

The amendment does not affect the maintenance of microform records at the New York and Chicago regional offices which will continue to make available

copies of all filings with the Commission, nor does the amendment affect the availability of records through the Commission's Public Reference Branch in Washington, D.C. The Commission will simultaneously update its regulations to reflect the closing of public reference facilities at the Los Angeles Regional Office. The proposing release indicated that the Commission intended to delete references to the Los Angeles facilities contained at 200.80(c)(1) and 200.80(c)(1)(iii). In addition to these references the Commission is also deleting similar references at 200.80(c)(1)(i) and 200.310. No additional notice or comment is necessary because these deletions fall within the scope of the proposing release. The original amendments were proposed in Securities Exchange Act Release No. 34-22243 [50 FR 30858 (July 30, 1985)]. No coments on the proposed amendments were received during the prescribed thirty day comment period. All of these amendments are designed to reflect current information access practices in the regional offices. Therefore, the Commission finds good cause for making the changes effective upon publication.

Regulatory Flexibility Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Chairman of the Commission has previously certified that the proposed amendments to Rule 80(c)(1)(ii) of the Commission's regulations regarding information and requests (17 CFR 200.80(c)(1)(ii)) will not, if adopted, have a significant economic impact on a substantial number of small entities. No comments were received on the certification. The amendments to Rule 80(c)(1)(i) and Rule 310, not mentioned in the proposing release, do not affect the basis or scope of the certification.

Lists of Subjects in 17 CFR Part 200

Administrative practice and procedure, Freedom of Information, Privacy, Securities,

Statutory Basis and Text of Amendment

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Pursuant to the Securities Exchange Act and particularly section 23(a) thereof, 15 U.S.C. 78w(a), the Commission is amending Part 200 of Title 17, Chapter II, of the Code of Federal Regulations as follows:

1. The authority citation for Part 200 Subpart D continues to read as follows:

Authority: 80 Stat. 383, as amended, 31 Stat. 54, secs. 19, 23, 48 Stat. 85, 901, as amended, sec. 20, 49 Stat. 833, sec. 319, 53 Stat. 1173, secs. 38, 211, 54 Stat. 841, 855; 5 U.S.C. 552, 15 U.S.C. 77s 78w, 79t, 77sss, 80a-37, 80b-11.

Section 200.80 also issued under 5 U.S.C. 78d-1 78d-2; Pub. L. 93-502; Pub. L. 93-579; 15 U.S.C. 78a et. seq., as amended by Pub. L. 84-29 and by secs. 11a, 15, 19 and 23 of Pub. L. 98-38 (15 U.S.C. 78k-l, 78o, 78s and 78w); 11 U.S.C. 901, 1109(a).

2. In §200.80 by revising the second sentence of paragraph (c)(1), introductory text; the second sentence of paragraph (c)(1)(i); paragraph (c)(1)(ii); and paragraph (c)(1)(iii), introductory text, as indicated.

§ 200.80 Commission records and information.

* * * * *

(c)(1) * * * Coin-operated machines, which are available to requesters on a self-service basis, can be used to make immediate copies up to 8½ by 14 inches in size of materials that are available for inspection in the Washington, D.C., New York and Chicago offices.

(i) * * * In addition, upon request, such records will be sent to the Commission's regional offices in New York or Chicago for inspection in the public reference facilities at those offices, if the records are not needed by the Commission or the staff in connection with the performance of official duties.

* * * * *

(ii) All regional offices of the Commission have available for public examination the materials set forth in paragraph (a)(2) of this section and the *SEC Docket, SEC News Digest* and other SEC publications. Blank forms as well as other general information about the operations of the Commission described in paragraph (a)(1) of this section may also be available at particular regional offices.

(iii) In the New York and Chicago regional offices, microfiche of all recent registration statements filed pursuant to the Securities Act of 1933, registration statements and periodic reports filed pursuant to the Investment Company Act from 1969 to date are available for inspection and reproduction.

* * * * *

3. In § 200.310 by revising the fourth sentence in paragraph (a) to read as follows:

§ 200.310 Fees.

(a) * * * In addition, copying machines are provided for public reference facilities in the Commission's Washington, DC, New York and Chicago Offices.

* * * * *

By the Commission.

John Wheeler,

Secretary.

December 4, 1985.

FR Doc. 85-29275 Filed 12-9-85; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 162 and 171

[T.D. 85-195]

Fines; Penalties; Forfeiture Procedures

AGENCY: U.S. Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations relating to the disposal of property seized and forfeited for violations of the Customs laws. The document results from provisons of the Comprehensive Crime Control Act of 1984 and the Tariff and Trade Act of 1984, which made changes to the Tariff Act of 1930 concerning the disposition of seized property. The amendments include revisions to both the administrative petitioning process and the summary forfeiture process.

EFFECTIVE DATE: January 9, 1986.

FOR FURTHER INFORMATION CONTACT: James S. Demb, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229 (202-556-5746).

SUPPLEMENTARY INFORMATION:

Background

Sections 311-323 and 2304 of the Comprehensive Crime Control Act of 1984 (Pub. L. 98-473) and section 213 of the Tariff and Trade Act of 1984 (Pub. L. 98-573), made various changes to the Tariff Act of 1930 with regard to the forfeiture and disposition of property seized by Customs. These changes include the expanded use of administrative forfeiture proceedings to permit the Government to perfect title to seized property more quickly, without having to resort to lengthy judicial proceedings; the transfer of forfeited property to other federal agencies and state or local law enforcement agencies which participated in the seizure of the property; and more expedited procedures for the disposition of seized property. These changes are intended to reduce Customs costs for seizure and storage of seized property and the processing of penalty and forfeiture

cases resulting from the seizure of the property.

To aid in the expeditious processing of these cases, this document amends Parts 162 and 171, Customs Reguations (19 CFR Parts 162, 171), to reduce the amount of time property is held in Customs custody, thus reducing the costs of seizure and storage. Specific changes include: (1) Reducing the petitioning time in seizure cases from 60 days to 30 days; (2) authorizing expedied destruction or other disposition of low-value property under seizure when cost of storage of the property are disproportionate to its value; (3) changing requirements for publication of administrative forfeiture notices so as to reduce seizure costs; (4) further restricting the granting of extensions of time to file petitions for relief; and (5) increasing the district director's authority to accept payment of the appraised value of seized property from $50,000 to $100,000, inclusive.

These changes were proposed in a notice published in the **Federal Register** on June 27, 1985 (50 FR 26588). Nine comments were received in response to the notice. A discussion of these comments and our responses follow.

Discussion of Comments

Comments: Several commenters opposed reducing the petition filing time from 60 days to 30 days in both property seizure and foreiture cases and in non-foreiture cases. They also object to restricting the allowance of extensions of time to file petitions for relief. They contend that the combination of both reducing the petition filing time and limiting the district director's authority to grant extensions would work substantial administrative injustice and hardship for petitioners.

One commenter states that, in the context of a property seizure case, these changes would result in many administrative or judicial forfeiture proceedings when the matter should properly be resolved by release of the property upon payment of its appraised value and/or administrative remission or mitigation under section 618, Tariff Act of 1930, as amended (19 U.S.C. 1618). Another commenter believes that these amendments will be interpreted by Customs officers as authority for the wholesale institution of administrative forfeitures or referrals to the U.S. attorney even if a petition is under consideration.

Response: Customs believes that these changes are necessary to allow for the institution of summary forfeiture proceedings in cases involving conveyances either carrying or facilitating the transportation of controlled substances. In such cases, a transporting conveyance would not be released to a petitioner but would instead be summarily forfeited. However, in certain cases, a petitioner could be awarded the proceeds from the sale of a conveyance following its forfeiture.

Comment: One commenter argues that, in a non-seizure case, the events triggering the penalty notice may have occurred two or three years before and consulting stored records and gathering information in light of personnel changes would be difficult to accomplish in 30 days. This commenter suggests that the time to respond be increased to 90 days. Another commenter believes that large corporate importers and exporters will suffer the greatest harm due to the changes because it takes two to three weeks from the time a penalty notice is mailed from Customs for it to be routed to the proper party responsible for handling such matters. This would leave only one or two weeks to draft and submit a responsive petition.

Most commenters feel that the proposed reduction in time to respond to Customs notices would cause substantial difficulties in those cases involving complicated facts, legal issues and/or numerous entries. The commenters indicate that cases of this nature often require substantial research and investigation in order to meaningfully respond to Customs allegations. Consequently, they are opposed to reducing the time to respond in these complex cases, and are generally opposed to limiting the authority of Customs personnel to grant extensions of time to respond. One commenter indicates that he believes a general rule should be promulgated which would permit an automatic extension in the event new counsel is retained by the petitioner during the response period. Another commenter is of the opinion that in cases where less than 180 days remain before the statute of limitations may be asserted as a defense, the minimum response time should be not less than 14 days from the date of receipt of the notice, rather than the current 7-day minimum.

Response: Customs is of the opinion that in the vast majority of cases, 30 days from the mailing date of the violation penalty notice is a reasonable period of time to respond with a petition. Customs does not agree that extensions of time to petition are warranted in every case where new counsel is retained or in cases where internal corporate structure precludes immediate delivery of the violation notice. Further, it has been legally established in the case of *U.S. v. Ross*, 574 F. Supp. 1067 (1983) that a 7-day response period is not unreasonable in cases where the statute of limitations may be asserted as a defense in less than 180 days.

However, Customs recognizes that certain cases may require more time in order to adequately respond to the violation/penalty notice. Consequently, the proposed language of § 171.15, Customs Regulations, has been revised to afford the district director the discretion to grant the alleged violator a 60-day response period (i.e., 60 days from the mailing date of the violation notice) in such cases. In the event the alleged violator disagrees with the district director's determination that the violation notice response period is limited to 30 days, amended § 171.15 provides for a direct appeal to the Director, Entry Procedures and Penalties Division, Customs Headquarters, within 7 days from the mailing date of the violation/penalty notice (a copy of the appeal must be sent to the district director). Section 171.15 states that this appeal does not automatically operate to extend the period specified by the district director, and that the appeal is submitted at the risk of the alleged violator. If the Director, Entry Procedures and Penalties Division, denies the appeal, the alleged violator must submit his petition within the original time period required by the district director. In any seizure case involving or related to controlled substances, however, Customs believes that no extension should be granted absent a demonstration of extraordinary circumstances justifying additional time beyond the required 30 days. Both § 162.32(a) and § 171.12, Customs Regulations, have been amended to cross reference § 171.15 regarding cases where additional time to respond is afforded the alleged violator.

Comment: One commenter states that clerks should not be used to decide legal questions, especially when the decision results in a sizeable penalty. Instead, the commenter suggests that decisions of this nature should be made by attorneys if matters of law are raised.

Response: Although this suggestion is beyond the scope of these regulatory amendments, Customs notes that district personnel are provided extensive training with respect to the issuance of notices of fines, penalties and forfeitures, and that in cases where sizeable penalties are assessed, the mitigation decisions issued by Customs are made by attorneys.

Comment: One commenter disagrees with raising the value of property that

must be forfeited by newspaper publication from $250 to $2,500. This commenter believes that $2,500 is too high a figure because Customs is not always aware of all the claimants. Therefore, the amount should be $1,000; the same as the limit for an informal entry.

Response: Customs has determined that raising the limit from $250 to $2,500 will provide great savings in publication costs without jeopardizing claimants' interests in goods subject to forfeiture. Customs believes that the posting of a list of goods subject to forfeiture (valued at under $2,500) at the local customhouse will provide sufficient notice to those interested claimants.

Comment: One commenter suggests that Customs should provide more information in both the prepenalty and penalty processes such as copies of audit reports, reports of investigation, baggage declarations and Customs entries instead of forcing a respondent to make Freedom of Information requests.

Response: This matter, although beyond the scope of these regulatory changes, is presently under consideration and instructions will be sent to Customs field officers in the near future to allow petitioners greater access to information.

Comment: One commenter recommended the following three specific changes in § 162.32: (1) Exempting penalties associated with a seizure from the "required collection action" and referring the matters simultaneously if judicial forfeiture is required; (2) replacing the words "mailing date" with "date of the notice"; and (3) omitting the word "is" from the italicized heading to § 162.32(c).

Response: We do not agree with the commenter's second recommendation. Maintaining the mailing date as the date from which the 30-day response period is determined is advantageous to petitioners since it allows them more time in which to prepare a response.

Customs agrees with the commenter's first and third suggestions and will incorporate these changes in § 162.32.

After consideration of all the comments received in response to the notice and further review of the matter, it has been determined to adopt the proposal with the modifications discussed.

Executive Order 12291

This regulation is not a "major rule" as defined by section 1(b) of E.O. 12291. Accordingly, a regulatory impact analysis is not required.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this document because the amendments will not have a significant economic impact on a substantial number of small entities. Accordingly, it is certified that the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Drafting Information

The principal author of this document was Susan Terranova, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Parts 162 and 171

Administrative practice and procedure, Penalties, Seizures and forfeitures.

Amendments to the Regulations

Parts 162 and 171, Customs Regulations (19 CFR Parts 162 and 171), are amended as set forth below.

PART 162—RECORDKEEPING, INSPECTION, SEARCH, AND SEIZURE

1. The authority citation for Part 162 continues to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1624.

Section 162.32 also issued under 19 U.S.C. 1603, 1610.

Section 162.44 also issued under 19 U.S.C. 1614.

Section 162.46 also issued under 19 U.S.C. 1609, 1611.

2. Section 162.32 is revised to read as follows:

§ 162.32 Where petition for relief not filed.

(a) *Fines, penalties and forfeitures.* If any person who is liable for a fine, penalty, or claim for a monetary amount, or who has an interest in property subject to forfeiture, fails to petition for relief as set forth in Part 171 of this chapter, or fails to pay the fine or penalty within 30 days from the mailing date of the violation/penalty notice provided in § 162.31 (unless additional time is authorized for filing a petition, as set forth in Part 171 of this chapter) the district director, shall, after any required collection action is complete, refer any fine or penalty case promptly to the U.S. attorney, or the Department of Justice if the penalty was assessed under section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592). In the case of property subject to forfeiture, the district director, where appropriate, shall complete administrative forfeiture proceedings or shall refer the matter promptly to the U.S. attorney, or the Department of Justice if the case arose under section 592, in accordance with the provisions of subparagraph (c) below, unless the Commissioner of Customs expressly authorizes other action.

(b) *Institution of forefeiture proceedings before completion of administrative procedures.* Nothing in these regulations is intended to prevent the institution of forfeiture proceedings before completion of the administrative remission or mitigation procedures pursuant to section 618, Tariff Act of 1930, as amended (19 U.S.C. 1618).

(c) *Seized property not eligible for administrative forfeiture.* If the seized property is not eligible for administrative forfeiture, and neither a petition for relief in accordance with Part 171 of this chapter, nor an offer to pay the domestic value as provided for in section 162.44, is made within 30 days (unless additional time has been authorized under Part 171 of this chapter), the district director shall refer the case promptly to the U.S. attorney for the judicial district in which the seizure was made, or the Department of Justice if the penalty was assessed under section 592.

3. Section 162.44 is amended by revising paragraph (a) and (b)(1)(i) to read as follows:

§ 162.44 Release on payment of appraised value.

(a) *Value exceeding $100,000.* Any offer to pay the appraised domestic value of seized property in order to obtain the immediate release of the property which was seized under the Customs laws or laws administered by Customs and exceeding $100,000 in appraised domestic value, or which was seized under the navigation laws, shall be in writing, addressed to the Commissioner of Customs, and signed by the claimant or his attorney. It shall be submitted in duplicate to the district director for the district in which the property was seized. Proof of ownership shall be submitted with the application if the facts in the case make such action necessary.

(b) *Value not over $100,000—(1) Authority to accept offer.* The district director is authorized to accept a written offer pursuant to § 614, Tariff Act of 1930, as amended (19 U.S.C. 1614), to pay the appraised domestic value of property seized under the Customs laws and to release such property if:

(i) The appraised domestic value of the seized property does not exceed $100,000.

* * * * *

4. The heading and paragraphs (b)(1) and (c) of § 162.45 are revised to read as follows:

§ 162.45 Summary forfeiture: Property other than Schedule 1 controlled substances. Notice of seizure and sale.

* * * * *

(b) *Publication.* (1) If the appraised value of any property in one seizure from one person other than Schedule 1 controlled substances (as defined in 21 U.S.C. 802(6) and 812) exceeds $2,500, the notice shall be published in a newspaper in the Customs district and the judicial district in which the property was seized for at least three successive weeks. All known parties-in-interest shall be notified of the newspaper and expected dates of publication of such notice.

* * * * *

(c) *Delay of publication.* Publication of the notice of seizure and intent to summarily forfeit and dispose of property eligible for such treatment may be delayed for a period not to exceed 30 days in those cases where the district director has reason to believe that a petition for administrative relief in accord with Part 171 of this chapter will be filed.

5. The heading and paragraph (d) of § 162.46 are revised to read as follows:

§ 162.46 Summary forfeiture: Disposition of goods.

* * * * *

(d) *Destruction.* (1) If, after summary forfeiture of property is completed, it appears that the net proceeds of sale will not be sufficient to pay the costs of sale, the district director may order destruction of the property. Any vessel or vehicle summarily forfeited for violation of any law respecting the Customs revenue may be destroyed in lieu of the sale thereof when such destruction is authorized by the Commissioner of Customs to protect the revenue.

(2) If the expense of keeping any vessel, vehicle, aircraft, merchandise or baggage is disproportionate to the value thereof, and such value is less than $1,000, destruction or other appropriate disposition of such property may proceed forthwith.

* * * * *

6. The heading and first sentence of § 162.48 are revised to read as follows:

§ 162.48 Summary sale of perishable and other property.

Seized property which is perishable or otherwise enumerated in section 612, Tariff Act of 1930, as amended (19 U.S.C. 1612), and is covered by the provisions of section 607, Tariff Act of 1930, as amended (19 U.S.C. 1607), shall be advertised for sale and sold at public auction at the earliest possible date. * * *

7. Paragraph (b) of § 162.78 is revised to read as follows:

§ 162.78 Presentations responding to prepenalty notice.

(a) * * *

(b) *Extensions.* If at least 1 year remains before the statute of limitations may be asserted as a defense, the district director, upon written request, may extend the time for filing a written presentation, or making an oral presentation, or both, for any of the reasons given in Part 171 of this chapter (except for the reason described in § 171.15(a)(4)), relating to extensions of time for filing petitions for relief. In addition, an extension may be granted if, upon the request of the alleged violator, the Commissioner of Customs determines that the case involves an issue which is a proper matter for submission to Customs Headquarters under the internal advice procedures of § 177.11(b)(2) of this chapter. Other extensions may be authorized only by Headquarters.

* * * * *

Part 171, Customs Regulations (19 CFR Part 171), is amended as set forth below.

PART 171—FINES, PENALTIES AND FORFEITURES

1. The authority citation for Part 171 continues to read as follows:

Authority: 19 U.S.C. 66, 1592, 1618, 1624.

2. Section 171.12 is revised to read as follows:

§ 171.12 Filing of Petition.

(a) *Where filed.* A petition for relief shall be filed with the district director for the district in which the property was seized or the fine or penalty imposed.

(b) *When filed.* Unless additional time has been authorized as provided in § 171.15, petitions for relief shall be filed within 30 days from the date of the mailing of the notice of fine, penalty, or forfeiture incurred.

(c) *Number of copies.* The petition shall be filed in triplicate.

(d) *Exception for certain cases.* If a penalty is assessed under section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592), and fewer than 180 days remain from the date of the penalty notice before the statute of limitations may be asserted as a defense, the district director may specify in the notice a reasonable period of time shorter than 30 days but not less than 7 days, for the filing of a petition for relief.

3. Section 171.15 is added to read as follows:

§ 171.15 Extensions of time for filing petition.

(a) *Extension of time for filing petition or supplemental petition for relief.* If there is at least 1 year before the statute of limitations may be asserted as a defense, a district director may extend the time for filing a petition (or establish a 60-day response period pursuant to subparagraph (4) below) or supplemental petition, upon the request of a person who is or may be liable for a fine or penalty, or who has an interest in property subject to forfeiture, in the following situations:

(1) The person is incapacitated and unable to prepare or to assist in the preparation of a petition.

(2) The person is absent from the U.S. for 20 days or more during the specified period for filing the petition for relief.

(3) Evidence necessary to file an effective petition is not immediately available. Evidence is not immediately available if, for example, it:

(i) Is in the possession of a foreign source and must be procured from same.

(ii) Requires that a request of any Government agency be complied with, provided that any such request is not frivolous and is made in accordance with law.

(4) The case involves a complex legal or factual problem. Examples of the type of problem are the need to examine voluminous records (e.g., Customs entries, purchase orders, invoices and the like) to learn the facts on which to base a petition, or the need to determine legal responsibilities in a case involving numerous parties or numerous violations. In such cases, the district director, on his own initiative, may specify in the violation/penalty notice that a 60-day response period from the date of the mailing of the notice is warranted. If, in such cases, the district director concludes that only a 30-day response period is warranted and so indicates in the violation/penalty notice, the person charged with responding shall have 7 days from the date of the mailing of the notice to appeal the decision of the district director to the Director, Entry Procedures and Penalties Division, Customs Headquarters. If an appeal is taken, a copy of the appeal must be furnished to the district director who issued the notice, and the original forwarded to the Director, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Ave., NW., Washington, DC 20229. Such appeals should clearly set forth the reasons why the particular case

warrants an extension beyond the 30-day period. If the appeal is granted, the Director, Entry Procedures and Penalties Division, will notify both the district director and the person charged with responding of the time period allotted for response. In no case will the filing of an appeal under this paragraph toll the 30-day period of time specified by the district director in the violation/penalty notice.

(5) There is an occurrence of some act of God which makes compliance with petitioning time limits impossible.

(6) In any seizure case involved or related to controlled substances, no extensions of time to respond shall be granted absent a demonstration of extraordinary circumstances justifying additional time beyond the 30-day period.

(7) Any other situation in which the district director determines that an extension of time for filing a petition is justified.

(b) *Retention of new counsel insufficient reason to grant extension.* As a general rule, the mere fact that counsel has just been retained, or new counsel appointed or selected, without another enumerated reason, will be insufficient reason to grant an extension of petitioning time.

4. Paragraphs (a) and (c)(2) of § 171.33 are revised to read as follows:

§ 171.33 Supplemental petitions for relief.

(a) *Time and place of filing.* If the petitioner is not satisfied with a decision of the district director or the Commissioner of Customs, a supplemental petition may be filed with the district director. Such a petition shall be filed either:

(1) Within 30 days from the date of notice to the petitioner of the decision from which further relief is requested if no effective period is prescribed in the decision; or

(2) Within the time prescribed in the decision from which further relief is requested as the effective period of the decision.

* * * * *

(c) *Second supplemental petition.*

(1) * * *

(2) A second supplemental petition will not be considered except in one of the following circumstances:

(i) If it is filed within 2 years from the date of notice to the petitioner of the decision on the first supplemental petition;

(ii) If it is filed within 30 days following an administrative or judicial decision with respect to the entries involved in the penalty case which reduces the loss of duties upon which the mitigated penalty amount was based; or

(iii) If the deciding official in his discretion determines that the acceptance of a second supplemental petition is warranted.

William von Raab,

Commissioner of Customs.

Approved: November 18, 1985.

David D. Queen,

Assistant Secretary of the Treasury.

[FR Doc. 85-29138 Filed 12-9-85; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Oxfendazole and Trichlorfon Paste

AGENCY: Food and Drug Administration; HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Syntex Agribusiness, Inc., providing for safe and effective oral use of a paste containing oxfendazole and trichlorfon as an anthelmintic and boticide in horses.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, filed NADA 136-740 providing for oral administration to horses by dose syringe of a paste containing fenbendazole and trichlorfon. The Combination drug is indicated for removal of certain large roundworms, pinworms, large and small strongyles, and bots. The NADA is approved, and the regulations are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(ii) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environment impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 520 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. By adding new § 520.1631 to read as follows:

§ 520.1631 Oxfendazole and trichlorfon paste.

(a) *Specifications.* Each gram of paste contains 28.5 milligrams oxfendazole and 454.5 milligrams trichlorfon.

(b) *Sponsor.* See 000033 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2.5 milligrams of oxfendazole and 40 milligrams of trichlorfon per kilogram of body weight.

(2) *Indications for use.* The drug is used in horses for removal of bots (*Gasterophilus intestinalis*, 2nd and 3rd instars; *G. nasalis*, 3rd instar) and the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), pinworms (*Oxyuris equi*), adult and 4th stage larvae; large strongyles (*Strongylue edentatus, S. vulgaris*, and *S. equinus*); and small strongyles.

(3) *Limitations.* Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water before use is unnecessary. Administer with caution to sick or debilitated horses. Not for use in horses intended for food. Do not administer to mares during the last month of pregnancy. Trichlorfon is a cholinesterase inhibitor. Do not use this product in animals simultaneously with, or within a few days before or after treatment with or exposure to, cholinesterase-inhibiting

drugs, pesticides, or chemicals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: December 2, 1985.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 85-29204 Filed 12-9-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Tylosin Injection

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Medico Industries, Inc., providing for safe and effective intramuscular use of tylosin injection in cattle and swine. The drug is indicated for use in cattle for treating bovine respiratory complex, foot rot, calf diphtheria, and metritis. It is indicated for use in swine for treating arthritis, pneumonia, erysipelas, and dysentery.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Charles E. Haines, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: Medico Industries, Inc., Elkan Estates, P.O. Box 338, Elwood, KS 66024, filed NADA 138-955 providing for intramuscular use of tylosin injection in: (1) Beef cattle and nonlactating dairy cattle for treating bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Corynebacterium pyogenes;* foot rot (necrotic pododermatitis) and calf diptheria caused by *Fusobacterium necrophorum* and metritis caused by *Corynebacterium pyogenes;* and (2) swine for treating swine arthritis caused by *Mycoplasma hyosynoviae;* swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae;* swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed. The NADA provides data and information establishing bioequivalency between the subject drug and a similar drug that was evaluated as effective by the National Academy of Sciences/National Research Council (NAS/NRC) and concurred by FDA (46 FR 48642; October 2, 1981). The NADA is approved and the regulations are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegatged to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 522 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. In § 522.2640a by revising paragraph (b) to read as follows:

§ 522.2640a Tylosin injection.

* * * * *

(b) *Sponsors.* (1) See No. 000986 in § 510.600(c) of this chapter for use in paragraph (e)(1), (2), and (3) of this section.

(2) See No. 015562 in § 510.600(c) of this chapter for use as in paragraph (e)(1) and (2) of this section.

* * * * *

Dated: December 3, 1985.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 85-29205 Filed 12-9-85; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin and Sulfamethazine

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for J&R Specialty Supply Co. The NADA provides for manufacture of premixes containing 5, 10, 20, or 40 grams per pound each of tylosin and sulfamethazine for use in making finished swine feeds.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: J&R Specialty Supply Co., 310 Second Ave. SW., P.O. Box 506, Waseca, MN 56093, is the sponsor of NADA 138-454 submitted on its behalf by Elanco Products Co. The NADA provides for the manufacture of premixes containing 5, 10, 20, or 40 grams per pound each of tylosin (as tylosin phosphate) and sulfamethazine intended for use in making finished swine feeds. The resulting feeds are for use in maintaining weight gains and feed efficiency in the presence of atrophic rhinitis, lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis, preventing swine dysentery (vibrionic), and controlling swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*). The NADA is approved and the regulations are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of

safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

§ 558.630 [Amended]

2. Section 558.630, *Tylosin and sulfamethazine*, is amended in paragraph (b)(10) by inserting numerically the number "049768".

Dated: December 2, 1985.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 85-29203 Filed 12-9-85; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 1020

[Docket No. 82N-0274]

Retrospective Review of the Performance Standard for Diagnostic X-Ray Equipment; Availability of Report

Correction

In FR Doc. 85-26832 beginning on page 46646 in the issue of Tuesday, November 12, 1985, make the following correction on page 46646:

In the second column, in the second complete paragraph, in the sixth and seventh lines the CFR cite should read "21 CFR 1020.30-32".

BILLING CODE 1505-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Approval of Permanent Program Amendment From the Commonwealth of Kentucky Under the Surface Mining Control and Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: OSM is announcing the approval of a program amendment to the Kentucky permanent regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment establishes a program for the training, examination and certification of blasters, and amends performance standards for the use of explosives.

Kentucky submitted the proposed program amendment on December 4, 1984. OSM published a notice in the **Federal Register** on January 3, 1985 (50 FR 283) announcing receipt of the amendment and inviting public comment on its adequacy. The public comment period ended February 4, 1985. Since no one requested an opportunity to testify, the public hearing scheduled for January 28, 1985, was not held.

Kentucky submitted modifications to the amendment on May 22, 1985. OSM reopened the public comment period for 15 days to allow consideration of the modifications by the public (July 18, 1985, 50 FR 29235). After providing opportunity for public comment and conducting a thorough review of the program amendment, the Director has determined that the amendment meets the requirements of SMCRA and the Federal regulations, and is approving it. The Federal rules at 30 CFR Part 917 codifying decisions concerning the Kentucky program are being amended to implement this action.

This final rule is being made effective immediately to expedite the State program amendment process and encourage States to conform their programs with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: W.H. Tipton, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 340 Legion Drive, Suite 28, Lexington, Kentucky 40504, Telephone: (606) 233-7327.

SUPPLEMENTARY INFORMATION:

I. Background

On December 30, 1981, Kentucky resubmitted its proposed regulatory program to OSM. The Kentucky program was conditionally approved by the Secretary of the Interior subject to the correction of 12 minor deficiencies. The approval was effective upon publication of the notice of conditional approval in the May 18, 1982 **Federal Register** (47 FR 21404-21435). Information pertinent to the general background, revisions, modifications, and amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval of the Kentucky program can be found in the May 18, 1982 **Federal Register.**

II. Submission of Program Amendments

On December 4, 1984, Kentucky submitted to OSM pursuant to 30 CFR 732.17, an amendment to the Kentucky regulatory program to establish a blaster training and certification program and amend performance standards for use of explosives.

On January 3, 1985, OSM published a notice in the **Federal Register** (50 FR 283) announcing receipt of the amendment and inviting public comment. The public comment period ended February 4, 1985. A public hearing scheduled for January 28, 1985, was not held because no one expressed a desire to testify. On May 22, 1985, Kentucky submitted additional information on the amendment. The additional information consisted of further modifications to the Kentucky Administrative Regulations (KAR) at 405 KAR 7:070, 16:120 and 18:120, concerning blaster certification and use of explosives. OSM announced a reopening of the public comment period for 15 days in the July 18, 1985 **Federal Register** (50 FR 29235) to allow for public review and comment on the modifications to the amendment.

In regard to the blaster certification program, on March 4, 1983, OSM issued final rules effective April 14, 1983, establishing the Federal standards for the training and certification of blasters at 30 CFR Part 850 (48 FR 9486). Section 850.12 of these regulations stipulates that the regulatory authority in each State with an approved program under SMCRA shall develop and adopt a program to examine and certify all persons who are directly responsible for the use of explosives in a surface coal mining operation within 12 months after approval of a State program or within 12 months after publication date of OSM's rules at 30 CFR Part 850, whichever is

later. In the case of Kentucky's program, the applicable date is 12 months after the publication date of OSM's rule, or March 4, 1984.

On January 20, 1984, Kentucky advised OSM that it would be unable to meet the March 4 deadline. Kentucky requested and received a nine month extension of the deadline to December 4, 1984 (49 FR 21926, May 24, 1984). Kentucky has submitted the proposed blaster training and certification program in compliance with the extended deadline.

In regard to the proposed regulatory amendment to the performance standards for use of explosives, Kentucky proposed changes at 405 KAR 16:120 and 18:120 pertaining to use of explosives.

III. Director's Findings

A. General Findings

The Director finds, in accordance with SMCRA and 30 CFR 732.15 and 732.17, that the program amendment concerning blaster certification and use of explosives, submitted by Kentucky on December 4, 1984, as modified on May 22, 1985, meets the requirements of SMCRA and 30 CFR Chapter VII. Only those areas of particular interest are discussed below in the specific findings. Discussion of only those provisions for which findings are made does not imply any deficiency in any provision not discussed. The amended provisions are cited at the end of this notice in the amendatory lanaguage for 30 CFR 917.15.

B. Specific Findings

Blaster Certification Program

1. The Director finds that the proposed Kentucky rules for certification of blasters at 405 KAR 7:070 sections 1 through 7 and 11 contain all the requirements found in 30 CFR Part 850 and are no less effective than the Federal requirements. The Kentucky rules contain requirements for certification, including training and a written examination in all topics covered in the Federal rule, and proof of experience in the form of letters of reference. They contain requirements for issuance and renewal of certification, suspension and revocation of certification, protection of certification, and conditions for maintaining certification which the Director finds no less effective than the Federal requirements.

2. Kentucky rule 405 KAR 7:070 section 8 provides that persons who are certified under an OSM certification program or a State blaster certification program approved by OSM, shall be certified in Kentucky without being required to demonstrate training, to supply letters of reference, or to pass the written examination. In the preamble to the Federal rules on blaster certification, OSM endorsed the concept of State reciprocity, saying that this "should be facilitated by the State programs review and approval process, under which all States with approved programs must conform with the rules adopted today and the Act." (48 FR 9488, March 4, 1983). Therefore, the Director finds this section of the Kentucky rules no less effective than the Federal rules.

3. Section 9 of 405 KAR 7:070 provides for reinstatement of revoked certification after the term of certification has passed, if certain procedures are followed. Although there is no Federal counterpart to this rule, it is logical for the State to establish procedures for reinstatement of revoked certification, and the Director finds these procedures are not inconsistent with the Federal requirements.

4. Section 10 of 405 KAR 7:070 provides for the Kentucky Natural Resources and Environmental Protection Cabinet to enter into agreements with the Kentucky Department of Mines and Minerals to administer all or part of this regulation. OSM stated in the preamble of its March 4, 1983 **Federal Register** publication of blaster certification rules, that "OSM is placing the responsibility on the regulatory authority to determine qualifications of the personnel responsible for implementing the certification program and does not believe it is necessary to prescribe the manner in which it is done." (48 FR 9488). The Director finds that the Kentucky Department of Mines and Minerals would be capable of administering the Kentucky blaster certification rules and that this would not render the program less effective than the Federal program.

5. OSM has completed a review of the course material proposed for use in Kentucky's training courses and has reviewed copies of representative examinations to be used to satisfy the written examination requirement and has found these materials to satisfactorily comply with State and Federal program requirements. During the course of this review, Kentucky officials explained that licensed blasters in the State have already been tested in the "use of explosives" topics and will only be tested in areas not previously covered in order to qualify for certification under the Kentucky blaster program. OSM then reviewed the previous test and the supplemental test and has determined that, along with the requirement at 405 KAR 7:070 section 4 that certified blasters retake the entire examination every three years in order to be recertified, this aspect of the program is no less effective than the Federal provisions. Therefore, the Director finds the Kentucky training course and certification examination no less effective than required by the Federal rules in 30 CFR Part 850.

Use of Explosives

6. Kentucky rules 16:120 and 18:120 section 1 contain all the general requirements for use of explosives contained in the Federal counterpart sections, 30 CFR 816.61 and 817.61, except for the counterpart to 30 CFR 816.61(c)(2) and 817.61(c)(2) which require blasters to carry their certifications during blasting. This requirement is found in the rules for Kentucky blaster certification in 405 KAR 7:070 section 7(1). Therefore, the Director finds the Kentucky requirements no less effective than the Federal requirements.

7. The rules in section 2 of 405 KAR 16:120 and 18:120 on preblasting surveys contain all the requirements found in 30 CFR 816.62 and 817.62. The Director therefore, finds the Kentucky rules no less effective than the Federal rules.

8. Section 3 of 405 KAR 16:120 contains requirements for public notice of blasting schedule, including the contents of the schedule, which the Director finds no less effective than 30 CFR 816.64 (b) and (c).

9. Section 4 of 405 KAR 16:120 and section 3 of 405 KAR 18:120 contain surface blasting requirements. Section 4, subsection (1), of 405 KAR 16:120 and Section 3, subsection (1) of 405 KAR 18:120 contain all requirements found in 30 CFR 816.64(a) and 30 CFR 817.64(a), respectively, plus a requirement for a valid permit to use a charge weight of explosives in excess of 40,000 pounds in any blast. Subsection 2, Warnings, and subsection 3, Access control, contain all requirements found in 30 CFR 816.66 and 817.66 concerning blasting signs, warnings and access control. The Kentucky rules reference 405 KAR 16:030 and 18:030, section 6, for warning signs. Those sections contain requirements similar to and no less effective than the Federal requirements for blasting signs in 30 CFR 816.66(a) and 817.66(a).

Subsections 4, 5, 6, 7, and 8 of 405 KAR 16:120 section 4 and of 405 18:120 section 3, section 5 of 405 KAR 16:120 and section 4 of 405 KAR 18:120, contain requirements similar to Federal rules 30 CFR 816.67 and 817.67. The topics covered in these rules include airblast levels, flyrock, prevention of adverse

impacts, ground vibration and seismographic measurements. The amendments in section 6 of 405 KAR 16:120 and section 5 of 405 KAR 18:120 render those rules no less effective than the Federal rules at 30 CFR 816.68 and 817.68 concerning records of blasing operations.

The Director finds that the amendments to 405 KAR 16:120 sections 4, 5, and 6 and 405 KAR 18:020 sections 3, 4, and 5 are consistent with the Federal counterparts and no less effective than the Federal requirements.

IV. Disposition of Public Comments

Comments were submitted by Thomas J. FitzGerald on behalf of the Kentucky Governmental Accountability Project of the Kentucky Resources Council and the Cumberland Chapter of the Sierra Club.

Blaster Certification Program

The commenter said that Kentucky's proposed blaster certification program appears to meet, in large part, the requirements of the Federal rules. The commenter suggested a change to 405 KAR 7:070 section 5(7) to provide that the Cabinet may suspend or revoke certification of a blaster who "handles or uses explosives while under the influence of alcohol, narcotics or other dangerous drugs, or unlawfully uses same in the workplace." Kentucky has added this language to 405 KAR 7:070 section 5(7) in its May 22, 1985 submission of the modified amendments.

The commenter wanted it made clear that the Cabinet cannot wholly transfer primary responsibility for implementation of the Kentucky rules, and that the transfer of responsibilities should not adversely affect the public's ability to request an inspection. The commenter also asked that it be made clear in the Memorandum of Agreement that the certification test shall cover, at a minimum, the topics in 450 KAR 7:070, section 2(5).

In the March 4, 1983 **Federal Register** publication of Federal blaster certification rules, OSM stated in the preamble to these rules that "OSM is placing the responsibility on the regulatory authority to determine qualifications of the personnel responsible for implementing the certification program * * *" (48 FR 9488). The Director, OSM has found that the Kentucky Department of Mines and Minerals would be capable of administering the Kentucky blaster certification rules. Transfer of administration of the rules to the Department of Mines and Minerals does not relieve the Kentucky Natural Resources and Environmental Cabinet (NREPC) from responsibility for ensuring tht the rules are implemented as written. OSM has examined a representative certification test and has found that all required topics are covered in the test.

The commeter said that use of the Department of Mines and Minerals to implement the blaster certification program should be temporary and that the NREPC shoud develop "in house" capability to administer the program. As stated above, OSM has provided, in the preamble of its rules, for the regulatory authority to determine who is qualified to implement the program. Therefore, the Director does not require that the NREPC develop such "in house" capabilities.

Use of Explosives

The commenter said the Kentucky should not delete the word "pre-blasting" before "damage" in proposed 16:120 and 18:120 section 2(3). The May 22, 1985 submission modifying the submission to which the commenter refers does not delete the word "preblasting" before "damage" in those sections.

The commenter said that 405 KAR 16:120 and 18:120 section 2(4) should require that the written report of a preblast survey be *promptly* provided to the person requesting the survey and to the NREPC. In its May 22, 1985 submission modifying the proposed amendment, Kentucky has added the word "promptly" to the requirement that the report be provided to those parties.

The commenter stated that the "use of the vector-sum formula for measuring peak particle velocity is permissible provided that the same maximum allowable component limit is applied, since it should ensure conservative limits when using the vector sum instruments."

The Kentucky rules at 405 KAR 16:120 section 4(7)(b) and 405 KAR 18:120 section 3(7)(b) establish maximum peak particle velocity limits, and do not establish separate limits for use with the vector sum formula. OSM assumes, therefore, that these same limits will apply. This would be in keeping with the language in the preamble to OSM's March 8, 1983 rules on use of explosives which states: "* * * OSM has allowed, but does not require, the use of vector-sum units * * * The values listed for acceptable vector sum limits are identical for component limits, insuring conservative results when using a vector sum instrument." (48 FR 9800).

The commenter said that the use of the phrase "areas affected by surface operations and facilities" rather than "permit area" in 405 KAR 18:120 to define the rights of the public to preblast surveys and notice of proposed blasting, does not satisfy Federal rule requirements. The commenter stated that the Federal rules use the term "permit area" and this includes shadow areas above underground workings, which the Kentucky phrase would not.

Although the Federal rules do use the term "permit area," the Federal definition of "permit area" at 30 CFR 701.5 does not necessarily include shadow areas above underground workings, since the definition limits the permit area to land "required to be covered by the operator's performance bond * * *" including all disturbed areas. Bonds are not required for "shadow areas" if no reclamation is planned for those areas. Therefore, the Director has determined that the Kentucky rule is no less effective than the Federal rule.

V. Director's Decision

The Director, based on the above findings, is approving the amendments to the Kentucky program submitted on December 4, 1984 and modified on May 22, 1985. the Director is amending Part 917 of 30 CFR Chapter VII to reflect approval of the above State program modifications.

VI. Additional Determinations

1. *Compliance with the National Environmental Policy Act:* The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. *Executive Order No. 12291 and the Regulatory Flexibility Act:* On August 28, 1981, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a Regulatory Impact Analysis and Regulatory review by OSM.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

3. *Paperwork Reduction Act:* This rule does not contain information collection requirements which require approval by

the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 917

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: December 4, 1985.

Gary Bennethum,

Acting Deputy Director, Operations and Technical Services, Office of Surface Mining.

PART 917—KENTUCKY

30 CFR Part 917 is amended as follows.

1. The authority citation for Part 917 continues to read as follows:

Authority: Pub. L. 95-87, Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*).

2. 30 CFR 917.15 is amended by adding a new paragraph (n) as follows:

§ 917.15 Approval of amendments to State Regulatory Program.

* * * * *

(n) The following amendments submitted to OSM on December 4, 1984, and modified on May 22, 1985 are approved effective December 10, 1985: Kentucky's blaster certification program, as contained in the Kentucky regulations at 405 KAR 7:070 and in the Kentucky blaster training program and examination; and revisions to the Kentucky regulations governing use of explosives at 405 KAR 16:120 and 18:120.

3. 30 CFR 917.16 is amended by removing and reserving paragraph (a) as follows:

§ 917.16 Required program amendments.

(a) [Reserved]

* * * * *

[FR Doc. 85-29210 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-05-M

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30 CFR Part 936

Approval of Amendment to the Oklahoma Regulatory Program Under the Surface Mining Control and Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: OSM is announcing the approval of a program amendment submitted by Oklahoma as an amendment to the State's permanent regulatory program (hereinafter referred to as the Oklahoma program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

On July 16, 1985, the State of Oklahoma submitted to OSM an amendment to its approved permanent regulatory program. The proposed program amendment consists of language amending the Oklahoma Coal Reclamation Act. The amendment creates a new nine member Oklahoma Mining Commission which will replace the previous 10 member State Mining Board. The amendment specifies length of terms, specific area of representation for each Commission member, and duties and responsibilities of the Commission.

The amendment also creates a new position, that of Director, Oklahoma Department of Mines who serves as chief executive officer in the absence of the Chief Mine Inspector. The amendment also identifies the duties and responsibilities of the Director and interaction between the Director and the Mining Commission.

OSM published a notice in the **Federal Register** on October 29, 1985, announcing receipt of the amendment and inviting public comment on the adequacy of proposed amendment. The public comment period ended November 29, 1985.

After providing opportunity for public comment and conducting a thorough review of the program amendment, the Director has determined that the amendment meets the requirements of SMCRA and the Federal regulations and is approving it. The Federal rules at 30 CFR Part 936 codifying decisions concerning the Oklahoma program are being amended to implement this action.

This final rule is being made effective January 1, 1986, to coincide with the revised State statute effective date.

EFFECTIVE DATE: January 1, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. James H. Moncrief, Director, Tulsa Field Office, Room 3432, 333 West Fourth Street, Tulsa, Oklahoma 74103, Telephone: (918) 581-7927.

SUPPLEMENTARY INFORMATION:

I. Background

The Oklahoma program was conditionally approved by the Secretary of the Interior on January 19, 1981, (46 FR 4910). Information pertinent to the general background, revisions, modifications and amendments to the proposed permanent program submission as well as the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Oklahoma program can be found in the January 19, 1981 **Federal Register** (46 FR 4910), in the April 2, 1982 **Federal Register** (47 FR 14152), in the May 4, 1983 **Federal Register** (48 FR 20050) and the August 28, 1984 **Federal Register** (49 FR 34000).

II. Submission of Revisions

On July 16, 1985, Oklahoma submitted to OSM an amendment to its approved permanent regulatory program establishing a new nine member Mining Commission which will provide policy direction for the Oklahoma Department of Mines (ODM). The statute also establishes the position of the Director of ODM. The amendment submitted by Oklahoma for the Director's approval is an amendment to the Oklahoma Coal Reclamation Act, Senate Bill 332. The amendment, signed on July 8, 1985, by the Governor of Oklahoma shall become effective on January 1, 1986.

The act identifies the responsibilities and duties of the Oklahoma Mining Commission. It creates the position of Director, who shall be the chief executive officer of ODM in the absence of an appointed Chief Mine Inspector and shall be appointed by the Oklahoma Mining Commission. The act amends 45 O.S. 1981, sections 1, 2, 4, 5 and 6.

The October 29, 1985 **Federal Register** (50 FR 43726) announced receipt of the amendment and opened a public comment period, which closed on November 29, 1985. In that same notice, OSM announced that a public hearing would be held only if requested. No requests were received for a hearing, therefore no hearing was held.

III. Director's Findings

In accordance with SMCRA and 30 CFR 732.15 and 732.17, the Director finds that the program amendment to revise the Oklahoma Coal Reclamation Act as signed by the Governor of Oklahoma on July 8, 1985, and submitted to OSM on July 16, 1985, renders the Oklahoma program no less effective than the Federal regulations and no less stringent than SMCRA.

The amendment, consisting of enrolled Senate Bill No. 332, as enacted on July 8, 1985, creates a nine-member commission to be the policy determining agency for ODM and creates a position of Director of ODM who shall be the chief executive officer of ODM in the absence of an appointed Chief Mine Inspector. Further, the amendment sets forth the composition, terms, duties and reporting responsibilities of the Oklahoma Mining Commission and identifies the duties and responsibilities of the Director of ODM.

The act also revises and establishes criteria for certain miners, specifically for certified surface blasters.

The Director finds that the revisions to the Oklahoma Coal Reclamation Act

meet the requirements of SMCRA and the Federal regulations.

IV. Public Comments

Pursuant to section 503(b) of SMCRA and 30 CFR 732.17(h)(10)(i), of those Federal agencies invited to comment, none chose to do so. No additional public comments were received.

The disclosure of Federal agency comments is made pursuant to section 503(b) of SMCRA and 30 CFR 732.17(h)(10)(i).

V. Director's Decision

The Director, based on the above finding, is approving the July 16, 1985 amendment to the Oklahoma program. The Director is amending Part 936 of 30 CFR Chapter VII to reflect approval of the above program modification. It should be noted that while the Director is approving the amendment which contains provisions relevant to blaster certification, the approval does not constitute approval of the Oklahoma amendment to establish a blaster certification program in accordance with 30 CFR Part 850. An amendment from the State to establish a blaster certification program is being handled through a separate rulemaking. See 50 FR 43724, October 29, 1985.

1. *Compliance with the National Environmental Policy Act:* The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. *Executive Order No. 12291 and the Regulatory Flexibility Act:* On August 28, 1981, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a Regulatory Impact Analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

3. *Paperwork Reduction Act:* This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 936

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: December 4, 1985.

Gary Bennethum,

Acting Deputy Director, Operations and Technical Services.

PART 936—OKLAHOMA

30 CFR Part 936 is amended as follows:

1. The authority citation for Part 936 continues to read as follows:

Authority: Sec. 503, Pub. L. 95-87, 91 Stat. 407 (30 U.S.C. 1253), unless otherwise noted.

2. 30 CFR 936.15 is amended by adding a new paragraph (e) as follows:

§ 936.15 Approval of regulatory program amendments.

* * * * *

(e) The following amendment submitted July 16, 1985, is approved effective January 1, 1986: Revisions to Oklahoma statute at 45 O.S. 1981, as amended by Enrolled Senate Bill No. 332, and signed by the Governor on July 8, 1985.

[FR Doc. 85-29209 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

33 CFR Part 334

Naval Restricted Area in the Pacific Ocean at San Clemente Island, CA

AGENCY: Army Corps of Engineers, DOD.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers is establishing a naval restricted area in the Pacific Ocean at San Clemente Island, California, in the vicinity of West Cove. The restricted area prohibits vessels from anchoring in that designated area for the protection of the Navy's submarine cables.

EFFECTIVE DATE: January 9, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. Glenn Lukos at (213) 894-5606 or Mr. Ralph T. Eppard at (202) 272-0199.

SUPPLEMENTARY INFORMATION: The Corps of Engineers is establishing a restricted area in the vicinity of West Cove, San Clemente Island, California. This restricted area does not affect normal vessel traffic in the area except with regard to a prohibition on anchoring. The Corps of Engineers published this proposal in the Notice of Proposed Rulemaking section of the **Federal Register** on September 3, 1985, and invited comments for a 30-day period ending on October 3, 1985 (50 FR 35573). No comments were received, however, it was observed that the proposed rule contained coordinates listed as longitude, followed by latitude which conventionally should be stated as latitude followed by longitude. The coordinates were correct as published and accordingly the reversal is made in this final rule.

On October 22, 1985, the Department of the Army consolidated the danger zone regulations in Part 204, and the restricted area/prohibited area regulations in Part 207 into a new Part 334. Proposed § 207.614a is renumbered to be § 334.921 in accordance with the new numbering system.

Note.—This regulation is issued with respect to a military function of the Defense Department, is not a major rule within the meaning of Executive Order 12291, and accordingly, the provisions of Executive Order 12291 do not apply. The Department of the Army certifies that this regulation would not have a significant economic impact on a substantial number of entities and thus does not require preparation of regulatory flexibility analysis.

List of Subjects in 33 CFR Part 334

Navigation, Navigation (Water), Water transportation, Waterways.

Accordingly, 33 CFR Part 334 is amended as follows:

PART 334—NAVIGATION REGULATIONS

1. The authority for Part 334 continues to read as follows:

Authority: 40 Stat. 266; 33 U.S.C. 1.

2. Section 334.921 is added to read as follows:

§ 334.921 Pacific Ocean at San Clemente Island, Cal.; naval restricted area.

(a) *The area.* All waters between the northern and southern boundaries of the area known as West Cove seaward approximately four miles.

The northern boundary is defined by the coordinates:

33°00'52" N. 118°36'18" W.
32°59'30" N. 118°37'30" W.
32°59'20" N. 118°38'38" W.

The southern boundary is defined by the coordinates:

33°00'40" N. 118°35'27" W.
32°58'30" N. 118°36'40" W.
32°57'45" N. 118°38'36" W.

(b) *The regulation.* (1) The use of this area for anchorage is prohibited to all craft at all times.

(2) The regulations in this section shall be enforced by the Commander, Naval Base, San Diego, and such agencies as he/she shall designate.

Dated: November 21, 1985.
Approved:

Robert K. Dawson,

Acting Assistant Secretary of the Army (Civil Works).

[FR Doc. 85-29189 Filed 12-9-85; 8:45 am]

BILLING CODE 3710-08-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 2740 and 2910

[Circular No. 2573]

Recreation and Public Purposes Act Conveyances; Amendments Regulations

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rulemaking.

SUMMARY: The Recreation and Public Purposes Act, as amended, provides the major avenue through which public lands are transferred, by conveyance or lease, to the States or their political subdivisions and to nonprofit corporations and associations. The Act provides procedures for the transfer of public lands for recreational and public purpose uses. This final rulemaking makes a number of amendments in the existing regulations to facilitate acquisitions of public lands by States, State instrumentalities and subdivisions, including counties and municipalities for recreational or public purpose uses. The final rulemaking does not affect the procedures as they relate to nonprofit corporations or associations.

EFFECTIVE DATE: January 9, 1986.

ADDRESS: Suggestions or inquiries should be sent to: Director (320), Bureau of Land Management, 1800 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Robert C. Nauert, (202) 343-8693; or Robert C. Bruce, (202) 343-8735.

SUPPLEMENTARY INFORMATION: Proposed rulemaking was published in the **Federal Register** on September 28, 1982 (47 FR 42684), with a 60-day comment period. Comments were received from ten different sources, six from Federal agencies, three from States and one from an environmental group.

The general comments on the proposed rulemaking expressed the view that the proposed rulemaking would make a number of improvements in the existing regulations and would facilitate speedier action on applications for public lands for recreational and public use purposes under the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 et seq.).

The majority of the comments on the proposed rulemaking were directed at specific provisions. Those sections that received comments and the comments on them will be discussed individually.

The new definition of the term "public purpose" set out in the proposed rulemaking drew numerous comments. Most ot the comments objected to the inclusion of the word "morals" in the definition. Most of the comments expressed the view that the inclusion of the word "morals" raised the implication that the Federal Government intended to regulate the morals of the public. The word was included in the regulations, not for the purpose of regulating the public's morals, but to cover such public purposes as use of public lands for police and public safety facilities, etc. Because the word is not really necessary to the definition and the uses for police and public safety facilities are clarified in the totally revised term "public purposes" in the final rulemaking, the word "morals" is no longer used.

Several comments raised the point that the term "conveyance" appeared several times in existing regulations and in the proposed rulemaking and that it was used in a way that made its meaning subject to some confusion. The comments questioned what constituted a conveyance, was it a sale or was it also a lease. Another comment made the point that transfers for recreation purposes that were made at no monetary consideration were not sales but were some other form of conveyance. The suggestions made in the comments were given careful consideration and the final rulemaking contains a new definition of the term "conveyance." In addition, the final rulemaking deletes from the proposed rulemaking the word "sale" and substitutes for it the word conveyance for clarification.

Several comments expressed the view that the changes in the policy section made by the proposed rulemaking were not clear as to the types of uses that were not permitted by the Recreation and Public Purposes Act and those uses that were more appropriately authorized under other authorities. The paragraph of the policy section covering uses has been rewritten by the final rulemaking to clarify the types of uses that are not permissible under the Act. This paragraph in the final rulemaking also requires that uses requiring development of the public lands for recreational or public purposes will require the conveyee to commit to a development plan or program before the lease or conveyance is granted.

Other comments on the policy section of the proposed rulemaking stated that the paragraph regarding the disposal of lands acquired in an exchange under the Recreation and Public Purposes Act was not clear and recommended that it be clarified. This section of the proposed rulemaking was designed to reiterate the longstanding policy prohibition against acquiring non-Federal lands through the exchange process for the purpose of immediately disposing of those lands under the Act or any other disposal authority. This paragraph has been rewritten in the final rulemaking to clarify that non-Federal lands will not be acquired for disposal under the authority of the Act.

One comment pointed out what was perceived as an inconsistency between the policy prohibition in the proposed rulemaking against the conveyance of Federally-owned and reserved mineral interests under lands conveyed under the Recreation and Public Purposes Act and the amendment to § 2741.6 made by the proposed rulemaking that clarifies the authority to lease those minerals. The policy prohibition against conveyance of the reserved mineral interest under lands conveyed under the Act is designed to avoid the possibility of split estate situations whereby the mineral estate could be conveyed to the surface owner only to have the surface revert to the United States because of a failure of the owner to comply with the terms and conditions of the conveyance document. The amendment made by the proposed rulemaking to § 2741.6 on mineral leasing would reiterate the policy that reserved Federal mineral interests may be permitted or leased under applicable mineral leasing authorities. These reserved Federal mineral interests have been subject to leasing for years and the amendment was intended to specify the various laws that are involved. Careful review of the two amendments fails to reveal any inconsistency and the final rulemaking retains both of them.

Several of the comments questioned the need for inclusion in the proposed rulemaking of the preapplication consultation provision and questioned its enforceability. The section, which has been retained by the final rulemaking, was included to encourage potential applicants to discuss land acquisition proposals with the Bureau of Land Management well in advance of their filing of an application. Early consultation will enable applicants and

the Bureau to discuss requirements, schedules and processing procedures which will allow both parties to identify problem areas, procedural constraints and methods to expedite action on the proposal. While preapplication consultation is optional and cannot be required of an applicant, it is recommended in order to save time and make the processing of the proposal more efficient. Inclusion of this section simply formalizes preapplication consultation procedures that have been used by the Bureau for the past few years with excellent results, not only in this area but in several other areas of Bureau activity.

Several comments objected to the imposition of a filing fee by the proposed rulemaking and expressed the view that if a filing fee is to be imposed, a fee of $100 is excessive. The Bureau of Land Management has imposed filing fees for a myriad of applications over the years with the amount of the fees being nominal and not truly reflective of the Bureau's costs of processing the applications. Section 304 of the Federal Land Policy and Management Act (43 U.S.C. 1734) authorizes the Secretary of the Interior to establish reasonable filing and service fees with respect to the applications relating to the public lands. The $100 filing fee represents a minimum fee for processing applications under the Recreation and Public Purposes Act and does not recover the Bureau's full costs for the processing of the applications. The fee will be imposed for all applications regardless of the purpose of the application (e.g., recreation, pubic purpose) or the type of applicant (e.g., State and local governments, nonprofit associations, etc.). The final rulemaking adopts the $100 filing fee of the proposed rulemaking with an amendment that fully describes the types of applications that will require the fee. The change was made in response to questions raised in the coments.

Several comments suggested revision of the language of the proposed rulemaking concerning the notice of realty action. One comment pointed out that the Recreation and Public Purposes Act contains provisions that if an application is not filed within 18 months of the lands classification (i.e., issuance of the notice), the lands which were so classified are to be restored to the operation of the applicable public land laws. The proposed rulemaking specified a 12-month period of segregation from the effect of the public land laws. The final rulemaking follows the language of the Act and provides for a period of segregation of 18 months.

Several comments suggested that time could be saved by combining the comment periods on a notice of realty action with that for a land use plan in those instances where a classification decision, in order to be implemented, would require an amendment to the Bureau of Land Management's land use plan. This suggestion has been adopted by the final rulemaking.

The proposed rulemaking contained a new policy directive which would permit immediate patents for using lands for sanitary landfill activities. This policy change was applauded by most of the comments. However, the comments expressed the view that the language of the proposed rulemaking was confusing and lacked clarity. After careful review of the provisions of the proposed rulemaking, this section has been rewritten in the final rulemaking. As a result of the fact that immediate patents may now be issued for lands to be used for sanitray landfill purposes, the lease with option to purchase alternative that appeared in the proposed rulemaking is no longer needed and has been removed by the final rulemaking.

Section 2742.1 of the proposed rulemaking contained a specific section regarding conveyances of omitted lands and unsurveyed islands under the provisions of section 211 of the Federal Land Policy and Management Act (43 U.S.C. 1721). This section has been deleted by the final rulemaking because it repeats language that already appears in §§ 2740.0–3(b), 2740.0–7(c) and 2741.1(c) of the existing regulations.

One comment questioned why §§ 2912.4 through 2912.4–2 of the existing regulations were needed. Those sections contain language explaining the requirements and procedures for leases when the proposed use of the lands under lease is for solid waste disposal. The comment is well taken and the sections are not needed and the final rulemaking deletes them. They are not needed because § 2912.1–1(b) authorizes the authorized officer to include in any lease such terms and conditions as are required by law and public policy. If the proposed use under a lease is for solid waste disposal purposes, the authorized officer would include a reference to applicable law and regulations.

Several comments were received on the provisions of the proposed rulemaking that would permit leasing of lands which included valid mining claims. The major concern raised by the comments was related to the significance of this change in the longstanding policy of the Bureau of Land Management with regard to challenging the validity of mining claims. The comments also expressed concern about the possibility of conflicts arising between a lessee and a mining claimant on lands leased under this provision, as well as concerns about the possibility of damage claims or liability under dual-use situations. The issues raised in these comments have been carefully reviewed. Our review led to the conclusion that some of the concerns were appropriate and that the provisions of the proposed rulemaking, if implemented by the final rulemaking, might result in the types of problems and conflicts noted in the comments. Accordingly, the addition of a new paragraph (h) to § 2912.1–1 proposed by the proposed rulemaking has been deleted by the final rulemaking. The Bureau will continue the existing policy regarding leasing of mining claims that has been in effect for years. This policy requires that public lands included in a mining claim upon which a validity determination has not been made may not be leased or conveyed under the provisions of the Recreation and Public Purposes Act. To further reiterate and clarify this policy, the final rulemaking adds a new paragraph to the general policy section (2740.0–6) describing the policy. The policy statement makes it clear that the Bureau will not spend any of its funds to undertake a validity determination for the sole purpose of conveying property under the provisions of the Recreation and Public Purposes Act. If an applicant for those lands wishes to expend funds to undertake a validity contest of a mining claim, they may make a request for such action of the authorized officer and such contest may proceed if the authorized officer deems it appropriate after considering all of the issues. The applicant will be responsible for the full expense of any contest proceedings.

The principal authors of this final rulemaking are Keith Corrigall and John Mezes, Division of Lands, Bureau of Land Management, assisted by the staff of the Office of Legislation and Regulatory Management.

The Department of the Interior has determined that this document is not a major rule under Executive Order 12291 and will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility act (5 U.S.C. 601 et seq.).

The changes made by the final rulemaking will expedite the processing of applications for disposal of public lands under the Recreation and Public Purposes Act to governmental and nonprofit entities, both large and small. The effect of the changes will be beneficial to all participants in the

program, but will not increase or decrease the overall benefits of the program.

The information collection requirements contained in this final rulemaking have been cleared by the Office of Management and Budget under 44 U.S.C. 3507 and assigned clearance numbers 1004–0009 and 1004–0012.

List of Subjects

43 CFR Part 2740

Intergovernmental relations, Public lands—sales, Recreation.

43 CFR Part 2910

Airports, Alaska, Mines, Public lands, Recreation areas, Waste treatment and disposal.

Under the authority of the Act of June 14, 1926, as amended (43 U.S.C. 869 et seq.) (commonly known as the Recreation and Public Purposes Act), sections 211 and 310 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1721, 1740) and the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701), Part 2740 of Group 2700 and Part 2910 of Group 2900, Subchapter B, Chapter II of Title 43 of the Code of Federal Regulations are amended as set out below.

Dated: November 6, 1985.

J. Steven Griles,

Deputy Assistant Secretary of the Interior.

PART 2740—RECREATION AND PUBLIC PURPOSES ACT—[AMENDED]

1. Part 2740 is amended by adding an authority citation to read:

Authority: The Recreation and Public Purposes Act, as amended (43 U.S.C. 869 et seq.); the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.); the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701).

Subpart 2740—[AMENDED]

2. Subpart 2740 is amended by:

A. Removing the authority citation in its entirety;

B. Amending section 2740.0–5 by adding new paragraphs (d) and (e) to read:

§ 2740.0–5 Definitions.

* * * * *

(d) "Public purpose" means for the purpose of providing facilities or services for the benefit of the public in connection with, but not limited to, public health, safety or welfare. Use of lands or facilities for habitation, cultivation, trade or manufacturing is permissible only when necessary for and integral to, i.e., and essential part of, the public purpose.

(e) "Conveyance" means a transfer of legal title. Leases issued pursuant to subpart 2912 of this title are not conveyances.

C. Section 2740.0–6 is amended by adding new paragraphs (c), (d), (e) and (f) to read:

§ 2740.0–6 Policy.

* * * * *

(c) Where lands are conveyed under the act with a reservation of the mineral estate to the United States, the Bureau of Land Management shall not thereafter convey that mineral estate to the surface owner under the provisions of section 209 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1719).

(d) Lease or conveyance of lands for purposes other than recreational or public purposes is not authorized by the act. Uses which can be more appropriately authorized under other existing authorities shall not be authorized under the act. Approval of leases or conveyances under the act shall not be made unless the public lands shall be used for an established or definitely proposed project. A commitment by lessee(s) or conveyee(s) to a plan of physical development, management and use of the lands shall be required before a lease or conveyance is approved. Use of public lands for nonrecreational or nonpublic purposes, whether by lease or conveyance, may be applied for under sections 203 and 302 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1713, 1732) or other applicable authorities.

(e) The Bureau of Land Management shall not exercise the exchange authority of section 206 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1716) for the purpose of acquiring lands for later conveyance under the act.

(f) The Bureau of Land Management shall not use Federal funds to undertake determinations of the validity of mining claims on public lands for the sole purpose of clearing title so that the lands may be leased or conveyed under the act.

Subpart 2741—[Amended]

3. Subpart 2741 is amended by:

A. Removing the authority citation in its entirety;

B. Redesignating §§ 2741.3 through 2741.8 as §§ 2741.4 through 2741.9, respectively;

C. Adding a new § 2741.3 to read:

§ 2741.3 Preapplication consultation.

(a) Potential applicants should contact the appropriate District Office of the Bureau of Land Management well in advance of the anticipated submission of an application. Early consultation is needed to familiarize a potential applicant with management responsibilities and terms and conditions which may be required in a lease or patent.

(b) Any information furnished by the applicant in connection with preapplication activity or use, which he/she requests not be disclosed, shall be protected to the extent consistent with the Freedom of Information Act (5 U.S.C. 552).

(c) Dependent upon the magnitude and/or public interest associated with the proposed use, various investigations, studies, analyses, public meetings and negotiations may be required of the applicant prior to the submission of the application. Where a determination is made that studies and analyses are required, the authorized officer shall inform the potential applicant of these requirements.

(d) The potential applicant may be permitted to go upon the public lands to perform casual acts related to data collection necessary for development of an acceptable plan of development as required in § 2741.4(b) of this title. These casual acts include, but are not limited to:

(1) vehicle use on existing roads;

(2) sampling;

(3) surveys required for siting of structures or other improvements; and

(4) other activities which do not unduly disturb surface resources. If, however, the authorized officer determines that appreciable impacts to surface resources may occur, he/she may require the potential applicant to obtain a land use authorization permit with appropriate terms and conditions under the provision of Part 2920 of this title.

D. Amending the redesignated § 2741.4 by adding a new paragraph (c) to read:

§ 2741.4 Applications.

* * * * *

(c) Each application shall be accompanied by a nonrefundable filing fee of $100. The filing fee shall be required for new applications as well as for applications for change of use or transfer of title filed under § 2741.6 of this title.

E. Amending the redesignated § 2741.5 by:

1. Amending paragraph (f) by removing all after the first sentence thereof; and

2. Revising paragraphs (h) and (i) to read:

§ 2741.5 Guidelines for conveyances and leases under the act.

* * * * *

(h)(1) A notice of realty action which shall serve as suitable or unsuitable for conveyance or lease under the act shall be issued, published and sent to parties of interest by the authorized officer not less than 60 days prior to the proposed effective date of the classification action. Notices specifying public lands classified as suitable shall include: the use proposed; whether the lands are to be conveyed or leased; and the terms, covenants, conditions and reservations which shall be included in the conveyance or lease document. The notice shall provide at least 45 days from the date of issuance for submission of public comments.

(2) If the notice of realty action states that the lands are classified as suitable for conveyance or lease under the act, it shall segregate the public lands described in the notice from appropriation under any other public land law, including locations under the mining laws, except as provided in the notice or any amendments or revisions to the notice. If, after 18 months following the issuance of the notice, an application has not been filed for the purpose for which the public lands have been classified, the segregative effect of the classification shall automatically expire and the public lands classified in the notice shall return to their former status without further action by the authorized officer.

(3) The notice of realty action shall be published once in the **Federal Register** and once a week for 3 weeks thereafter in a newspaper of general circulation in the vicinity of the public lands covered by the notice.

(4) The notice published under § 1610.5–5 of this title, if designated in the notice, shall serve as the notice of realty action required by this section and shall segregate the public lands as stated in the notice. Any such notice given under § 1610.5–5 of this title shall be published and distributed under the provisions of this section.

(i) The authorized officer may effect a conveyance for a sanitary landfill on public lands if the ultimate use of the public lands after completion of landfill activities shall be for a recreational or public purpose.

* * * * *

F. Amending the redesignated § 2741.6 by amending paragraph (a) thereof by removing the citation "§ 2741.3" and replacing it with the citation "§ 2741.4", by amending paragraph (b) thereof by removing the citation "§ 2741.6(a)" and replacing it with the citation "§ 2741.7(a)" and amending paragraph (c) thereof by removing the citation "§ 2741.7" and replacing it with the citation "§ 2741.8".

G. Amending the redesignated § 2741.7 by adding to paragraph (d) a sentence to read "Where such reserved minerals are subject to disposition under the provisions of the Mineral Leasing Act of 1920, as amended, and supplemented (30 U.S.C. 181 et seq.), the Materials Act of July 31, 1947, as amended (30 U.S.C. 601 et seq.) and the Geothermal Steam Act of 1970 (30 U.S.C. 1001 et seq.), the regulations contained in Subchapter C of this title shall be utilized."

Subpart 2742—[Amended]

4. Subpart 2742 is amended by:

A. Removing the authority citation in its entirety;

B. Redesignating §§ 2742.1 through 2742.4 as §§ 2742.2 through 2742.5, respectively;

C. Adding a new § 2742.1 to read:

§ 2742.1 Lands subject to disposition.

Omitted lands and unsurveyed islands may be conveyed to States and their local political subdivisions under the provisions of section 211 of the Federal Land Policy and Management Act (43 U.S.C. 1721).

PART 2910—LEASES

Subpart 2912—[Amended]

5. Subpart 2912 is amended by:

A. Continuing the authority citation to read:

Authority: Secs. 211 and 310, the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1721 and 1740).

§§ 2912.4, 2912.4–1 and 2912.4–2 [Removed]

B. Removing §§ 2912.4, 2912.4–1 and 2912.4–2 in their entirety.

[FR Doc. 85–29292 Filed 12–9–85; 8:45 am]

BILLING CODE 4310–84–M

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

48 CFR Parts 701, 702, 715, 728, 731, 732, 737, 750, 752, 753, and Appendices

[AIDAR Notice 85–12]

Miscellaneous Changes to the AID Acquisition Regulation

AGENCY: Agency for International Development, IDCA.

ACTION: Final rule.

SUMMARY: The AID Acquisition Regulation is being amended to reflect new office titles required by a reorganization, and to make minor editorial revisions and corrections.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: M/SER/PPE, Mr. James M. Kelly, telephone (703) 235–9855.

SUPPLEMENTARY INFORMATION: We have determined that the changes being made by this Notice are not significant or major changes as defined by FAR 1.301(b), or FAR 1.501, or E.O. 12291.

As required by the Regulatory Flexibility Act, it is hereby certified that this Notice will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 48 CFR Parts 701, 702, 715, 728, 731, 732, 737, 750, 752, 753, and Appendices

Government procurement.

For the reasons set out in the preamble, Chapter 7 of Title 48 of the Code of Federal Regulations is amended as follows:

1. The authority citations in Parts 701, 702, 715, 728, 731, 732, 737, 750, 752, 753, and the Appendices to Chapter 7 are unchanged and continue to read as follows:

Authority: Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended; E.O. 12163, Sept. 29, 1979, 44 FR 56673, 3 CFR 1979 Comp., p. 435.

PART 701—FEDERAL ACQUISITION REGULATIONS SYSTEM

Subpart 701.3—Agency for International Development Acquisition Regulation

701.376–1 [Amended]

2. Section 701.376–1, *Responsibility*, is amended by revising the first sentence to read as follows: "Responsibility for the development and maintenance of the

AIDAR is assigned to the Procurement Executive."

701.376-4 [Amended]

3. Section 701.376-4, *Implementation within AID contracting activities,* is amended by removing the reference to "the Director, Office of Contract Management.", replacing it with a reference to "the Planning, Policy and Evaluation Staff (M/SER/PPE)."

Subpart 701.4—Deviations From the FAR or AIDAR

701.470 [Amended]

4. Section 701.470, *Procedure,* is amended as follows:

a. The initial reference to "the Office of Contract Management, Support Division." appearing in paragraph (a)(2) is removed and replaced by a reference to "the Planning, Policy and Evaluation Staff of the Associate Assistant to the Administrator for Management, M/SER/PPE, hereinafter referred to as 'PPE'."

b. The remaining references to "Support Division", and to "Office of Contract Management, Support Division" appearing in paragraphs (a)(2), (b)(2), (b)(3)(i), (e), and (f)(1), are removed and replaced by references to "PPE".

PART 702—DEFINITIONS OF WORDS AND TERMS

Subpart 702.170—Definitions

702.170-3 [Amended]

5. In section 702.170-3, *Contracting activities,* paragraph (a) is amended by removing (and not replacing) the reference to "Office of Commodity Management", and by removing the references to the "Office of Contract Management". The references to the "Office of Contract Management" are replaced by references to the "Office of Acquisition and Assistance Management".

6. Section 702.170-10, *Head of the contracting activity,* is amended by revising paragraph (a) as follows:

702.170-10 Head of the contracting activity.

(a) AID/Washington.

Position	Limitation
Director, Office of Acquisition and Assistance Management.	None.
Director, Office of Management Operations.	Use of small purchase procedures ($25,000) for services and supplies. Unlimited authority when ordering against GSA or other established U.S. Government ordering agreements.
Director, Office of Foreign Disaster Assistance.	Contracts for disaster relief purposes during the first 72 hours of a disaster in a total amount not to exceed $500,000 (AID Handbook 8, Chapter 5). Routine small purchase authority ($25,000).
Director, Office of International Training.	Use of small purchase procedures up to $10,000. Unlimited for procuring participant training based on published catalog prices, using M/SER/AAM approved forms.

Each of these Office Directors will issue warrants to qualified individuals to actually exercise the authority.

* * * * *

PART 715—CONTRACTING BY NEGOTIATION

Subpart 715.5—Unsolicited Proposals

715.504 [Amended]

7. In section 715.504, *Advance guidance,* paragraph (a) is amended by removing the reference to "PRE/SDB/SB", replacing it with a reference to "OSDBU/MRC".

715.506 [Amended]

8. Section 715.506, Agency procedures and point of contact, is amended by removing the reference to "PRE/SDB/SB", replacing it with a reference to "OSDBU/MRC".

PART 728—BONDS AND INSURANCE

Subpart 728.1—Bonds

728.105-1 [Amended]

9. In section 728.105-1, *Advance payment bonds,* paragraph (b) is amended by removing the reference "the Insurance Advisor, Office of Contract Management.", replacing it with a reference to "the Planning, Policy and Evaluation Staff (M/SER/PPE)."

Subpart 728.3—Insurance

728.302 [Amended]

10. Section 728.302, *Notice of cancellation or change,* is amended by removing the reference to "the Insurance Advisor, Office of Contract Management.", replacing it with a reference to "the Planning, Policy and Evaluation Staff (M/SER/PPE)."

PART 731—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 731.1—Applicability

731.109 [Amended]

11. Section 731.109, *Advance agreements,* is amended by removing the reference to "Overhead and Special Cost Branch, Office of Contract Management.", replacing it with a reference to "Overhead and Special Cost and Contract Close-Out Branch, Office of Acquisition and Assistance Management."

Subpart 731.2—Contracts With Commercial Organizations

731.205-6 [Amended]

12. Section 731.205-6, *Compensation for personal services,* is amended as follows:

a. Paragraph (a)(3) is amended by adding the following parenthetical phrase immediately after the paragraph title, "*Overseas Recruitment Incentive*":

"(The term 'employee', as used in this paragraph, means an employee who is a U.S. citizen or resident alien.)"

b. Paragraph (b)(2) is amended by removing the reference "Support Division, Office of Contract Management." appearing at the end of the paragraph, replacing it with a reference to "Acquisition Support Division, Office of Acquisition and Assistance Management."

Subpart 731.3—Contracts With Educational Institutions

731.371 [Amended]

13. Section 731.371, *Compensation for personal services,* is amended as follows:

a. Paragraph (a) is amended by removing the reference "Support Division, Office of Contract Managment." appearing at the end of the paragraph, replacing it with a reference to "Acquisition Support Division, Office of Acquisition and Assistance Management."

b. Paragraph (c), *Overseas Recruitment Incentive,* is amended by adding the following parenthetical phrase immediately after the title of paragraph (c):

"(The term 'employee', as used in this paragraph, means an employee who is a U.S. citizen or resident alien.)"

Subpart 731.7—Contracts With Nonprofit Organizations

731.770 [Amended]

14. Section 731.770, *OMB Circular A-122, Cost Principles for Nonprofit Organizations; AID implementation,* is amended by removing the references to "The Director, Office of Contract Management" and "The Overhead and Special Cost Branch, Office of Contract Management (OSC).", appearing in paragraph (a), replacing them respectively with references to "The Director, Office of Acquisition and Assistance Management" and "The

Overhead and Special Cost and Contract Close-Out Branch, Office of Acquisition and Assistance Management (OCC)."

731.772 [Amended]

15. In § 731.772, *Compensation for personal services;* paragraph (c), *Overseas Recruitment Incentive,* is amended by adding the following parenthetical phrase immediately after the title of paragraph (c):

"(The term 'employee', as used in this paragraph, means an employee who is a U.S. citizen or resident alien.)"

PART 732—CONTRACT FINANCING

Subpart 732.4—Advance Payments

732.406-70-2 [Amended]

16. In section 732.406-70-2, *Circumstances for use of an LOC,* paragraph (a)(1) is amended by removing the reference to "Chapter 15C", replacing it with a reference to "Chapter 15E". Paragraph (a)(3) is amended by chaning the first word from "To" to "The".

PART 737—SERVICE CONTRACTING

Subpart 737.2—Services of Experts and Consultants

737.270 [Amended]

17. In section 737.270, *Contracting for consulting services,* paragraph (c)(2) is amended by removing the parenthetical phrase at the end of the second sentence, replacing it with the following: "(located in the Bureau for Program and Policy Coordination, Center for Development Information and Evaluation, Development Information Division—PPC/CDIE/DI)".

PART 750—EXTRAORDINARY CONTRACTUAL ACTIONS

Subpart 750.70—Ratification of Unauthorized Contract Awards

750.7000 [Amended]

18. In section 750.7000, *Ratification of unauthorized contract awards,* paragraph (b) is amended by removing the reference to "the Director, Office of Contract Management", replacing it with a reference to "the Procedure Executive".

Subpart 750.71—Extraordinary Contractual Action To Protect Foreign Policy Interests of the United States

750.7109-1, 750.7110-1, 750.7110-2 and 750.7110-3 [Amended]

19. Sections 750.7109-1, *Filing requests;* 750.7110-1, *Investigation;* 750.7110-2, *Intra-agency coordination;* and 750.7110-3, *Submission of cases to the approving authority,* are amended by removing the reference each contains to "Office of Contract Management,", replacing it with a reference to "Planning; Policy and Evaluation Staff (M/SER/PPE)".

PART 752—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 752.70—Texts of AID Contract Clauses

752.7002 [Amended]

20. In section 752.7002, *Travel and transportation,* paragraph (d), *Alternate 73,* The contract clause titled "*Travel Expenses and Transportation and Storage Expenses*" is amended by:

a. Changing the date of the clause from "(Aug. 1984)" to "(Nov. 1985)";

b. Amending paragraph (n), *Storage of household effects,* of the clause to remove the reference to "paragraph(a), above", replacing it with a reference to "paragraph (1), above"; and

c. Amending paragraph (o)(i) of the clause to remove the reference to "the Transportation Support Division, Office of Commodity Management", replacing it with a reference to "the Transportation Division, Office of Acquisition and Assistance Management".

752.7004 [Amended]

21. In section 752.7004, *Source and nationality requirements,* the contract clause titled "*Source and Nationality Requirements for Procurement of Goods and Services*" is amended by:

a. Changing the date of the clause from "(Nov. 1984)" to "(Nov. 1985)";

b. Amending subparagraph (b)(2) of the clause to remove the reference to "the AID Transportation Support Division, Office of Commodity Management. . ." replacing it with a reference to "the Transportation Division, Office of Acquisition and Assistance Management"; and

c. Amending subparagraph (b)(5) of the clause to remove the reference to "Seventeen Street" as the street address of the Maritime Administration, replacing it with a reference to "Seventh Street".

PART 703—FORMS

Subpart 753.1—General

753.107 [Amended]

22. Section 753.107, *Obtaining forms,* is amended by removing the reference to "SER/MO/PUM", replacing it with a reference to "SER/MO/PM/D".

APPENDICES TO CHAPTER 7

Appendix B—Notice to Cost-Reimbursement Type Contractors of Changes in Applicable Standardized Government Regulations

23. Paragraph 5, *Duties and Responsibilities,* of Appendix B, is amended as follows:

a. Paragraph 5(a)(1) is amended by removing the reference to "the Office of Contract Management, Support Division (Attention: SER/CM/SD/SS, Statistical Section)", replacing it with a reference to "the Office of Acquisition and Assistance Management Acquisition Support Division, Support Services Branch (SER/AAM/A/SUP)";

b. Paragraph 5(b) is amended by changing the paragraph title from "*Statistical section, SER/CM/SD/SS*" to "*SER/AAM/A/SUP*";

c. Paragraphs 5(b)(1) and 5(b)(2) are amended by removing the references to "SER/MO/PUM" and replacing them with references to "SER/MO/PM/D";

d. Paragraph 5(c) is amended by removing the references to "SER/MO/PUM" and "SER/CM/SD/SS", replacing them respectively with references to "SER/MO/PM/D" and "SER/AAM/A/SUP"; and

e. Paragraph 5(c)(2) and 5(c)(3) are amended by removing the reference to "SER/CM/SD/SS", replacing them with references to "SER/AAM/A/SUP".

Appendix C—Logistic Support Overseas to AID-Direct Contractors

24. Paragraph 2(b)(3) of Appendix C is amended by removing the reference to "SER/CM", appearing in the last sentence, replacing it with a reference to "SER/AAM".

Appendix F—Use of Collaborative Assistance Method for AID Direct Contracts for Technical Assistance

25. Paragraph 4(d)(3)(iii) of Appendix F is amended by removing the reference to "CM/SOD/OSC", replacing it with a reference to "AAM/A/OCC".

Appendix G—Approval and Reporting Procedures for Contractor Salaries

26. Appendix G is amended as follows:

a. Paragraph 1(c) is amended by removing the reference to "SER/CM/SD/SS", replacing it with a reference to "SER/AAM/A/SUP";

b. Paragraph 2(a) is amended by removing the parenthetical reference "(See AIDPR Appendix A.)" appearing at the end of paragraph 2(a), replacing it with "(See AIDAR Appendix A.)";

c. Paragraph 3 is amended by removing the references to "SER/CM" appearing in the paragraph title and the

second sentence of the paragraph, replacing them with references to "SER/AAM", and by removing the reference to "SER/CM/SD/SS", replacing it with a reference to "SER/AAM/A/SUP"; and

d. Paragraph 4 is amended by removing the reference to "the Office of Contract Management.", replacing it with a reference to "the Office of Acquisition and Assistance Management."

Appendix H—Response to Audit Recommendations

27. Appendix H is amended as follows:

a. References to "SER/CM", appearing in paragraphs 2, 6 and 7(a), and in subparagraphs 5(b), 5(b)(1)(b), 5(b)(1)(c), 5(b)(2)(a), 5(b)(2)(b), 5(b)(2)(c)(iii), and 5(b)(4)(a), are removed and replaced with references to "SER/AAM";

b. References to "CM/SD/SS", appearing in subparagraphs 5(b)(1)(b), 5(b)(1)(c), 5(b)(1)(d), 5(b)(2)(a), 5(b)(2)(b), 5(b)(2)(c)(iii), and 5(b)(4)(a), and in paragraph 6, are removed and replaced with references to "AAM/A/SUP"; and

c. Paragaraph 5(b)(3) is amended by removing the reference to "FM/PAD.", replacing it with a reference to "FM/PAFD.".

Dated: November 25, 1985.

John F. Owens,

AID Procurement Executive.

[FR Doc. 85-29061 Filed 12-9-85; 8:45 am]

BILLING CODE 6116-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Determination of Threatened Status and Critical Habitat for the Desert Dace

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The Service determines threatened status and critical habitat for the desert dace (*Ermichthys acros*), and issues a special rule to allow take in accordance with state law. Known only from an area of thermal springs and immediate outflow creeks in Humboldt County, Nevada, the species survives in about eight of more than 20 springs in six square miles of the area known as Soldier Meadows. This action is being taken because habitat alterations have eliminated much former habitat and the existing population is potentially threatened by additional habitat alteration. This final rule would implement the protection provided by the Endangered Species Act of 1973, as amended

DATE: The effective date of this rule is January 9, 1986.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Suite 1692, Lloyd 500 Building, 500 NE. Multnomah Street, Portland, Oregon 97232.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne S. White, Chief, Division of Endangered Species, at the above address (503/231-6131 or FTS 429-6131)

SUPPLEMENTARY INFORMATION:

Background

The desert dace (*Eremichthys acros*) is endemic to a series of thermal spring habitats in the Soldier Meadows area of Humboldt County, Nevada, where it was discovered in 1939 and described 11 years later by Carl Hubbs and R.R. Miller (1948). This species is the only member of the genus *Eremicthys*. The species has apparently survived in the Soldier Meadows area for at least tens of thousands of years. The species and genus is characterized by the presence of prominent horny sheaths on the jaws. No other cyprinid possesses such a remarkable feeding adaptation. The species is notable for its high temperature tolerance. Desert dace typically occur in water 67° to 97 °F, but have been observed in water as hot as 100.4°F (Nyquist 1963). Water temperature appears to be a major factor controlling the distribution of desert dace within a spring system. When temperature at a springhead exceeds 100°F, desert dace are restricted to the somewhat cooler outflow downstream from the springs.

Most of the thermal springs and their outflow creeks inhabited by the desert dace occur on private lands. The local landowner has modified much of the species' habitat by diverting water away from natural channels into manmade ditches. The diversion of outflow water away from natural channels is especially detrimental in spring systems were the headpool temperature exceeds 100°F and the species can only occupy the outflow creeks.

Two reservoirs exist in the Soldier Meadows area approximately three miles from springs and outflows inhabited by desert dace. Channel catfish (*Ictalurus punctatus*) and smallmouth bass (*Micropterus dolomieui*) have been introduced into one of the reservoirs. If these exotics are introduced into nearby habitats occupied by the desert dace, they would probably compete with and prey on the desert dace. Exotic species may also introduce disease or parasites to which the native species have not been previously exposed.

The Soldier Meadows area has been designated a Known Geothermal Resource Area. Geothermal exploration occurred in the area several years ago but was later abandoned. If geothermal exploration and development are resumed, these activities could impact the desert dace by interfering with the aquifers that supply water to thermal springs in the area.

The desert dace was included in the Service's Notice of Review of Vertebrate Wildlife published December 30, 1982 (47 FR 58454). In a petition dated April 4, 1983, and received April 12, 1983, the Desert Fishes Council requested that the desert dace be added to the List of Endangered and Threatened Wildlife. An administrative finding that the petition presented substantial information indicating that the requested action may be warranted was made May 9, 1983, and reported in the **Federal Register** on June 14, 1983 (48 FR 27273). Publication of the proposed rule on May 29, 1984 (49 FR 22355), signified that the requested action was warranted, and constituted a required finding in accordance with section 4(b)(3)(B)(ii) of the Act as amended in 1982.

Summary of Comments and Recommendations

In the May 29, 1984, proposed rule (49 FR 22355) and associated notifications, all interested parties were requested to submit factual reports or information that might contribute to development of a final rule. Appropriate State agencies, county governments, Federal agencies, scientific organizations, and other interested parties were contacted and requested to comment. A newspaper notice was published in the following newspapers: *Fallon Eagle-Standard* (June 26, 1984); *Elko Daily Free Press* (June 26, 1984); *Las Vegas Review Journal* (June 27, 1984); and *Nevada State Journal* (June 26, 1984). In addition, a public hearing, requested by Mr. James A. Callahan on behalf of Mr. Ken Earp, owner of the Soldier Meadows Ranch, was held in Winnemucca, Nevada, on October 10, 1984. The hearing announcement was published on September 20, 1984 (49 FR 36886), and the comment period extended until October 22, 1984.

Nine letters of comment were received. Comments were received from both the Nevada State Office and

Winnemucca District Office of the Bureau of Land Management, Nevada State Office of Community Services, Nevada Department of Minerals, Nevada Department of Wildlife, Nevada Division of State Parks, Nevada Department of Agriculture, Nevada Division of Environmental Protection, and Mr. James A. Callahan, attorney. Three letters supported the proposed rule, one opposed the rule, four contained additional information, and one was a non-substantive comment.

The Nevada State Office of the Bureau of Land Management pointed out that although only a small portion of dace habitat occurs on public land, a habitat management plan has been completed, a dace transplant to two springs is planned, and a total of 307.22 acres of public land in Soldier Meadows has been designated both an Area of Critical Environmental Concern and a Research Natural Area. The Winnemucca District Office supported the proposed listing and expressed the view that the listing was consistent with District efforts to protect the dace and its habitat.

The Nevada Division of State Parks also supported the proposal and emphasized this support by stating that the area designated as critical habitat is listed in the Nevada Natural Heritage Program. This program identifies representative areas of the State's natural heritage, including plants, animals, and geological formations, as well as scenic and scientific areas, in an effort toward preserving those areas listed.

The Nevada Division of Environmental Protection had no objections to the proposed actions and stated that the proposal would have no apparent adverse impacts on Division programs.

The State Department of Minerals commented that the Soldier Meadows area has been designated as a Known Geothermal Resource Area and geothermal exploration had occurred in the area. This agency further stated that this geothermal resource appears to be of low temperature character useful for domestic or commercial purposes rather than power generation, but future exploration programs may delineate a greater potential for development. The Department recommended that consideration toward future resource development be evaluated before a final recommendation is made on the proposed rule. The Service replies that the 1982 amendments to the Act require that determinations to list species as threatened or endangered be based solely on the best scientific and commercial information available for the species. Economic impacts are not allowed to be considered in making a listing determination. The Act specifies, however, that the economic impact of designating a particular area as critical habitat must be considered. The Service accordingly has prepared an economic analysis of the areas determined in this rule to be critical habitat. This analysis did not bring forth economic or other impacts to warrant consideration of revising the critical habitat designation.

The Nevada Department of Agriculture opposed the proposed rule on the basis that listing the desert dace as threatened would inhibit agricultural production at Soldier Meadows Ranch. The Service responds that the Endangered Species Act of 1973, as amended, only precludes Federal agencies from authorizing, funding, or carrying out activities that are likely to jeopardize the continued existence of a listed species or adversely modify its critical habitat. Unless a proposed private action requires such Federal approval or funding, it would not be precluded by section 7 of the Act. However, the taking prohibitions in section 9 could apply to private actions that result in the taking of a threatened species.

The Nevada Department of Wildlife supported the proposed rule. It did express concern regarding the critical habitat designation since the species occurs primarily on private lands and the designation will provide very limited protection. The Department further suggested easement purchase or restricted development agreements with private landowners as a means of protecting the species. The Service agrees that designation of critical habitat on private lands affords little protection for the species unless Federal approval or funding is required for the action that occurs on private land. However, critical habitat designations can accompany the listing of species under the Act to serve as official notification to Federal agencies that their responsibilities under section 7 of the Act are applicable in a certain area.

The public hearing held on October 10, 1984, was attended by four individuals with only James A. Callahan, representing the owner of the Soldier Meadows Ranch, presenting a formal statement. No additional written comments were received following the public hearings.

Mr. Callahan was concerned that the proposed rule would adversely impact water rights and livestock grazing on private lands. The Service responds that the Endangered Species Act of 1973, as amended, only precludes Federal agencies from authorizing, funding, or carrying out activities that are likely to jeopardize the continued existence of a listed species or adversely modify its critical habitat. Unless a proposed action requires such Federal approval or funding, it would not be precluded by section 7 of the Act.

Mr. Callahan also questioned whether the Act allows for condemnation of private land. The Service responds that it prefers not to employ these powers while alternative means exist for preserving this fish and its habitat.

Additional concern was expressed by Mr. Callahan that desert dace would be transplanted to other water areas in Soldier Meadows. Service policy is to not transplant a species outside its historic range unless there are no other means of preserving the species. If waters within the historic range are not presently supporting dace populations, but are found to be suitable habitat, the Service would support transplants to these waters.

Mr. Callahan also asked if there are areas other than Soldier Meadows where desert dace are present. The Service has reviewed and concurs with scientific literature accepted by ichthyologists and other scientists, as correctly identifying the desert dace as a unique species endemic to a limited number of habitats within Soldier Meadows, Humboldt County, Nevada. No scientific information has ever been presented to the contrary.

Mr. Callahan further questioned whether the Soldier Meadow Desert Dace Habitat Management Plan developed by the Bureau of Land Management was in concert with present Fish and Wildlife Service plans to recover the species. The Service replies that the draft Habitat Management Plan was reviewed by Fish and Wildlife Service biologists and written comments provided to the Bureau of Land Management on January 25, 1983. Specific plans to implement portions of the Habitat Management Plan were also reviewed and commented on July 10, 1984. In both instances, the Service agreed with these plans.

The possibility that springs and riparian areas inhabited by dace would be fenced to exclude livestock was a concern of Mr. Callahan. The Service position presently is that livestock use in the area is not currently a threat to the continued existence of the species, but if livestock were to adversely impact the habitat of the species, control of livestock should be able to be accomplished in a manner that would allow continued livestock access to water in the immediate area.

Summary of Factors Affecting the Species

After a thorough review and consideration of all information available, the Service has determined that the desert dace should be classified as a threatened species. Procedures found at section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations promulgated to implement the listing provisions of the Act (50 CFR Part 424) were followed. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to the desert dace (*Eremichthys acros*) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* The desert dace is endemic to warm springs and their outflow creeks in the Soldier Meadows area of Humboldt County, Nevada. Approximately eight warn springs with water temperatures as high as 100.4° F are occupied by the species. Many of the springs' outflow creeks have been diverted from their natural channels into manmade ditches. the diversions are for agricultural activities, such as irrigation and providing water for cattle on the Soldier Meadows Ranch. These diversions have reduced habitat available to the desert dace. Diversion of spring outflows is especially serious in those spring systems where the water in the spring headpool is too hot to be tolerated by the desert dace. In these systems the species exists only in the natural outflow. The manmade ditches do not provide suitable habitat for the species.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* Not applicable to this species.

C. *Disease or predation.* There is no evidence that either disease or predation has contributed to the threatened status of this species. Disease and predation could both result from the introduction of species not native to this area (see Factor "E" below).

D. *The inadequacy of existing regulatory mechanisms.* At this time the only regulation applicable to the desert dace is a requirement for a State scientific collecting permit for taking the species. There are no laws or regulations to protect the habitat of the desert dace.

E. *Other natural or manmade factors affecting its continued existence.* Reservoirs have recently been constructed on the north and south end of the Soldier Meadows area. Channel catfish and smallmouth bass have been introduced into the southern reservoir. If these exotics should enter habitat occupied by the desert dace they could further reduce dace numbers. The presence of exotic fishes is usually detrimental to native fishes in the western United States due to competition and predation (Deacon *et al.* 1964), as well as the introduction of exotic parasites and disease (Wilson *et al.* 1966). Much of the critical habitat is included in the Soldier Meadows Known Geothermal Resource Area. Although no exploration or drilling is currently occurring in the Soldier Meadows area, the resumption of such activity could result in interference with the thermal aquifers that supply water to springs in the area.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to make this rule final. Based on this evaluation, the preferred action is to list the desert dace as a threatened species, with critical habitat. This listing is appropriate because of past disturbance to habitats that has resulted in populations remaining at relatively low levels that may be adversely impacted by future ground water depletion, geothermal activities, agricultural development, and introduction of exotics. An explanation of the critical habitat designation is presented in the "Critical Habitat" section of this rule.

Critical Habitat

Critical habitat, as defined by Section 3 of the Act, means: (i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection, and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4(a)(3) of the Act requires that critical habitat be designated to the maximum extent prudent and determinable concurrently with the determination that a species is endangered or threatened. Critical habitat is being designated for the desert dace to include all thermal springs and their outflows located within determinable section and fractional section boundaries in the Soldier Meadows area of Humboldt County, Nevada. The designated aquatic habitat within these boundaries is somewhat evanescent, shifting in response to seasonal and other climatic factors. The area enclosed by the determinable boundary is approximately four miles long and varies from one to two and two-thirds miles wide. Mud Meadow Creek is near its eastern edge. The southern edge is approximately one mile north of Fly Creek.

Listing regulations of the Service, 50 CFR 424.12(b), state that when considering the designation of critical habitat, the Service shall focus on the biological or physical constituent elements within the defined area that are essential to the conservation of the species. Known primary constituent elements are to be listed with the critical habitat description.

With respect to the desert dace, the thermal springs and their outflows proposed as critical habitat satisfy all known criteria for ecological, behavioral, and physiological requirements of the species. The quantity and quality of water in the pools and outflow streams inhabited by this fish are the most important factors in its conservation. A range of favored temperatures between about 70° and 102°F restricts the fish to areas of the streams near the headwater pools, but these areas expand in summer, when pool temperatures are too high to be tolerated, and contract in winter, when temperatures in the lower streams drop below the favored range. These specialized requirements are met only in limited but seasonally variable portions of this one thermal spring area. Breeding and the growth of young desert dace are likewise confined to certain parts of the area. The species is native to these springs and outflows and is found nowhere else.

Section 4(b)(8) requires, for any proposed or final regulation that designates critical habitat, a brief description and evaluation of those activities (public or private) which may adversely modify such habitat or may be affected by such designation. Such activities are identified for the desert dace as follows.

In the past, water diversions from spring outflow creeks have modified or eliminated much suitable habitat for this species. Additional modification of springs or their outflow creeks without regard for the species could further adversely affect the species and its critical habitat. In addition, the manipulation of water flows and surface disturbance associated with ranching, and geothermal energy exploration or development, could adversely modify remaining habitat of the desert dace.

It should be emphasized that critical habitat designations only affect activities of Federal agencies through section 7 of the Act. Federal actions that could possibly be affected by this rule include actions of the Bureau of Land Management associated with aquatic habitat modification, grazing, and leasing of lands for geothermal exploration and/or development. Such activities could result in adverse modification of desert dace habitat. Section 7 consultation is designed, however, to explore alternatives or modifications to proposed activities that could avoid jeopardizing the continued existence of listed species or adversely modifying their critical habitat. The consultation process could possibly provide recommendations for measures which, if adopted, would ensure compliance with section 7(a)(2) of the Act.

Section 4(b)(2) of the Act requires the Service to consider economic and other impacts of designating a particular area as critical habitat. The Service has considered the critical habitat designation in light of relevant information obtained through the comment process and concludes that no adjustment of the critical habitat boundaries is warranted. Based on the Bureau of Land Management's existing Habitat Management Plan, the absence of any active or planned geothermal or oil and gas leases within or adjacent to the proposed critical habitat, the insignificant potential impacts to grazing, and the unquantifiable benefits that may result from the critical habitat designation, it is not expected that significant economic impacts will result from the designation of critical habitat on Federal lands. In addition, there is no known involvement of Federal funds or permits for private lands within the proposed critical habitat area. Therefore, no significant impact is expected as a result of this critical habitat designation.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against taking and harm are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR Part 402 and are now under revision (see proposal at 48 FR 29990; June 29, 1983). Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service. With respect to the desert dace, this provision may affect the Bureau of Land Management in the administration of its portion of the critical habitat area.

The Act and implementing regulations found at 50 CFR 17.21 and 17.31 set forth a series of general prohibitions and exceptions that generally apply to all threatened wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take, import or export, ship in interstate commerce in the course of a commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that had been taken illegally. Certain exceptions would apply to agents of the Service and State conservation agencies. General regulations governing the issuance of permits to carry out otherwise prohibited activities involving threatened wildlife species under certain circumstances are set out at 50 CFR 17.32

The above discussion generally applies to threatened species of fish and wildlife. However, the Secretary has discretion under section 4(d) of the Act to issue special regulations for a threatened species that are necessary and advisable for its conservation. The desert dace is threatened primarily by habitat disturbance or alteration, not by intentional, direct taking of the species or by commercialization.

Given this fact, and the fact that the State currently regulates direct taking of the species through the requirement of State collecting permits, the Service has concluded that the State's collection permit system is more than adequate to protect the species from excessive taking, so long as such take is limited to: educational purposes, scientific purposes, the enhancement of propagation or survival of the species, zoological exhibition, and other conservation purposes consistent with the Endangered Species Act. A separate Federal permit system is not required to address the current threats to the species. Therefore, the special rule allows take to occur for the above-stated purposes without the need for a Federal permit if a State collection permit is obtained and all other State wildlife conservation laws and regulations are satisfied. It should be recognized that any activities involving the taking of this species not otherwise enumerated in the special rule are prohibited.

Without this special rule, all of the prohibitions of 50 CFR 17.31 would apply. This special rule would allow for more efficient management of the species, and thus would enhance the conservation of the species. For these reasons, the Service concludes that this regulatory action is necessary and advisable for the conservation of the desert dace.

The final rule brings sections 5 and 6 of the Endangered Species Act into effect with respect to the desert dace. Section 5 authorizes the acquisition of lands or interests therein for the purpose of conserving endangered and threatened species. Pursuant to section 6, the Fish and Wildlife Service would be able to grant available funds to the State of Nevada for management actions aiding the protection and recovery of this species.

Listing the desert dace as threatened would provide for development of a recovery plan for this fish. Such a plan would draw together the State and Federal agencies having responsibility for conservation of the dace. The plan would establish an administrative framework, sanctioned by the Act, for agencies to coordinate activities and cooperate with each other in conservation efforts. The plan would set recovery priorities and estimate the cost of the various tasks necessary to accomplish them. It would assign appropriate functions to each agency and a time frame within which to accomplish them.

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under authority of the National Environmental Policy Act of 1969, need not be prepared in

connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

Regulatory Flexibility Act and Executive Order 12291

The Department of the Interior has determined that designation of critical habitat for this species will not constitute a major action under Executive Order 12291 and certifies that this designation will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule contains no information collection or recordkeeping requirements as defined by the Paperwork Reduction Act of 1980.

Based on BLM's management of its portion of critical habitat, no significant economic impacts are expected to result from the designation of critical habitat on Federal land. In addition, there is no known involvement of Federal funds or permits for the private land included as critical habitat. Any conservation efforts by private landowners would be voluntary. Therefore, no significant economic or other impacts are expected to result from the critical habitat designation on private land. These determinations are based on a Determination of Effects that is available from the Regional Director, U.S. Fish and Wildlife Service, Suite 1692, Lloyd 500 Building, 500 NE. Multnomah Street, Portland, Oregon 97232.

Literature Cited

Deacon, J.E., C. Hubbs, and B.J. Zahuranec. 1964. Some effects of introduced fishes on the native fish fauna of southern Nevada. Copeia 1964:384–388.

Hubbs, C.L. and R.R. Miller. 1948. Two new, relict genera of cyprinid fishes from Nevada. Occ. Pap. Mus. Zool., Univ. Mich., No. 507, 30 pp.

Nyquist, D. 1963. The ecology of *Eremichthys acros*, an endemic thermal species of cyprinid fish from northwestern Nevada. M.S. Thesis, Univ. Nevada, Reno, 247 pp.

Wilson, B.L., J.E. Deacon, and W.G. Bradley. 1966. Parasitism in the fishes of the Moapa River, Clark County, Nevada. Trans. California-Nevada Wildlife Soc. 1966:12–23.

Author

The primary author of this final rule is Donald W. Sada, U.S. Fish and Wildlife Service, 4600 Kietzke Lane, Building C, Reno, Nevada 89502 [702–784–5227 or FTS 470–5227].

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, Fish, Marine mammals, Plants (agriculture).

Regulations Promulgation

PART 17—[AMENDED]

Accordingly, Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, is amended as set forth below:

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

Authority: Pub. L. 93–205, 87 Stat. 884; Pub. L. 94–359, 90 Stat. 911; Pub. L. 95–632, 92 Stat. 3751; Pub. L. 96–159, 93 Stat. 1225; Pub. L. 97–304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*).

2. Amend § 17.11(h) by adding the following, in alphabetical order under "Fishes," to the List of Endangered and Threatened Wildlife:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
Fishes							
*	*	*	*	*	*	*	*
Dace, desert	*Eremichthys acros*	U.S.A. (NV)	Entire	T	210	17.95(e)	17.44(m)
*	*	*	*	*	*	*	*

3. Add the following as special rules to 50 CFR 17.44:

§17.44 Special rules—fishes.

* * * * *

(m) Desert Dace (*Eremichthys acros*).

(1) No person shall take the species, except in accordance with applicable State fish and wildlife conservation laws and regulations in the following instances: For educational purposes, scientific purposes, the enhancement of propagation or survival of the species, zoological exhibition, and other conservation purposes consistent with the Act.

(2) Any violation of applicable State fish and wildlife conservation laws or regulations with respect to the taking of this species will also be a violation of the Endangered Species Act.

(3) No person shall possess, sell, deliver, carry, transport, ship, import, or export, by any means whatsoever, any such species taken in violation of applicable State fish and wildlife conservation laws or regulations.

(4) It is unlawful for any person to attempt to commit, solicit another to commit, or cause to be committed, any offense defined in paragraphs (1) through (3) above.

* * * * *

4. Amend 50 CFR 17.95(e) by adding critical habitat of the desert dace as follows: (The position of this entry under § 17.95(e) will follow the same sequence as the species occurs in § 17.11).

§17.95 Critical habitat—fish and wildlife.

(e) * * *

* * * * *

Desert Dace "(Eremichthys acros)"

Nevada. Humboldt County. Thermal springs and their outflows plus surrounding riparian areas for a distance of 50 feet from these springs and outflows in T40N, R25E, SW¼ Section 5, NW¼NW¼ Section 8, W½ Section 18, W½SW¼ Section 19; T40N, R24E, Section 23, N½SE¼ and S½NE¼ Section 24, SE¼ Section 25, N½ Section 25, and N½ Section 26.

Primary constituent elements of the habitat are considered to be quantity, and thermal and chemical quality of water in headpools and spring outflow streams; presence of a

stable, natural substrate supporting food plants for the fish; and length of outflow streams; adequate for seasonal movements in response to changes of water temperature.

* * * * *

Dated: October 8, 1985.

P. Daniel Smith,

Acting Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 85-29237 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-55-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 663

[Docket No. 41155-5175]

Pacific Coast Groundfish Fishery; Closure and Request for Comments

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of closure and request for comments.

SUMMARY: NMFS issues this notice closing the sablefish fishery off the coasts of Washington, Oregon, and California, and seeks public comment on this action. The Director, Northwest Region, NMFS, has determined in consultation with the State fishery management agencies of Washington, Oregon, and California that the 1985 fishery quota of 13,600 metric tons for sablefish was reached on November 22, 1985. This action will promote conservation and orderly management of the sablefish resource.

EFFECTIVE DATE: This notice is effective from 0001 hours Pacific Standard Time (p.s.t.), December 6, 1985, until 2400 hours p.s.t., December 31, 1985. Comments will be accepted until December 21, 1985.

ADDRESSES: Rolland A. Schmitten, Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NE, BIN C15700, Seattle, WA 98115, or E.C. Fullerton, Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, CA 90731. The aggregate data upon which this determination is based are available for public inspection at the office of the Director, Northwest Region, during business hours until the end of the comment period.

FOR FURTHER INFORMATION CONTACT: R.A. Schmitten, 206-526-6150, or E.C. Fullerton, 213-548-2575.

SUPPLEMENTARY INFORMATION: The regulations implementing the Pacific Coast Groundfish Fishery Management Plan (FMP) at § 663.21(b) require the Secretary of Commerce (Secretary) to prohibit retention or landing of a species when the numerical optimum yield (OY) for that species is reached. The 1985 OY for sablefish is 13,600 metric tons (mt). Based on the best available information, and after consultation with the Washington Department of Fisheries, the Oregon Department of Fish and Wildlife, and the California Department of Fish and Game, the Regional Director determined that this quota was reached on November 22, 1985.

Until November, landings of sablefish seemed to be at rates that would almost reach but not exceed the 13,600-mt OY by the end of the year. The only regulation in effect was a 5,000-pound trip limit on sablefish smaller than 22 inches (total length). However, in mid-November unreported catches were discovered which pushed landings above 90 percent of OY. The regulations state at § 663.27(b)(3) that when 90 percent of OY is reached, the remaining 10 percent will be split equally, 5 percent for trawl gear and 5 percent for fixed gear, and a trip limit will be imposed on trawl landings equal to the average percentage of sablefish in trawl landings that contained that species in 1985. As a result, a trip limit of 13 percent sablefish was placed on trawl landings on November 25, 1985 (50 FR 49048, November 29, 1985).

Data available the last week in November indicate that the 13,600-mt OY for sablefish was reached on November 22, requiring prohibition of further landings of sablefish until January 1, 1986. This prohibition applies to all gear types, whether or not the 5 percent quota has been reached for fixed or trawl gear. This action supersedes the current trip limits for trawl-caught sablefish and for sablefish smaller than 22 inches, and is automatic and non-discretionary under the regulations at § 663.21(b). Accordingly, the Secretary has determined that the OY quota has been reached, and retaining or landing sablefish caught off Washington, Oregon, or California must be prohibited on December 6, 1985, the earliest possible date of implementation. The three states also will prohibit landings of sablefish at this time.

Secretarial Action

No sablefish caught seaward of Washington, Oregon, or California may be taken and retained or landed from 0001 hours p.s.t., December 6, 1985, until 2400 hours p.s.t., December 31, 1985.

Classification

The determination to prohibit further retention or landings of sablefish is based on the most recent data available. This action is taken under the authority of Part 663 and is in compliance with Executive Order 12291. This section is covered by the regulatory flexibility analysis prepared for the authorizing regulations.

Because of the immediate need to prohibit further retention of sablefish and thereby prevent the overharvest that could otherwise result, the Agency finds that advance notice and public comment on this closure are impracticable and not in the public interest, and that no delay should occur in its effective date. The public was notified at the November meeting of the Pacific Fishery Management Council, and again when fishing restrictions were imposed November 25, 1985, that landings of sablefish would reach the OY if not further curtailed. Public comments will be accepted for 15 days after this notice is published in the **Federal Register.** The Secretary, therefore, finds good cause to waive the 30-day delayed effectiveness provision of § 663.23(c).

(16 U.S.C. 1801 *et seq.*)

Dated: December 5, 1985.

Carmen J. Blondin,

Deputy Assistant Administrator for Fisheries Resource Management, National Marine Fisheries Service.

[FR Doc. 85-29263 Filed 12-5-85; 4:57 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 50, No. 237
Tuesday, December 10, 1985

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 70

Voluntary Standards and Grades for Poultry

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rules; extension of comment period.

SUMMARY: On October 24, 1985, the Agricultural Marketing Service (AMS) published a proposed rule with request for comments in the **Federal Register** (50 FR 43204–43209). The proposal would revise the regulations (7 CFR Part 70) for the voluntary grading of poultry products and rabbit products and the voluntary U.S. standards and grades for poultry products, and establish a new grade standard for raw poultry meat. The AMS is extending the comment period to February 28, 1986, because two industry organizations requested additional time to evaluate the proposed rule.

DATE: Written comments must be received on or before February 28, 1986.

ADDRESS: Written comments may be mailed to D.M. Holbrook, Chief, Standardization Branch, Poultry Division, Agricultural Marketing Service, U.S. Department of Agriculture, Room 3944, South Agriculture Building, Washington, DC 20250. Comments submitted on this proposed rule will be made available for public inspection in the Washington, DC, Standardization Branch during regular business hours.

FOR FURTHER INFORMATION CONTACT: M.L. Nichols, Jr., Assistant Chief, (202)447–3506.

SUPPLEMENTARY INFORMATION: On October 24, 1985, AMS published a proposed rule in the **Federal Register** (50 FR 43204–43209) to amend the regulations for the voluntary grading of poultry products and rabbit products and the voluntary U.S. standards and grades for poultry products. These amendments would permit the grading of other boneless poultry, clarify the standards for ready-to-cook poultry carcasses and parts, provide flexibility in color requirement of the official identification symbol and grademark, remove the U.S. Grade A—For Further Processing for ready-to-cook turkey carcasses, establish a new grade standard for raw poultry meat (boneless-skinless poultry products), and make other miscellaneous changes. The comment period was originally scheduled to end on December 23, 1985. Since the publication of the proposed rule, two industry trade organizations have requested additional time in order to more carefully evaluate the proposed rule and make comments. The AMS has determined that there is sufficient justification for extending the comment period until February 28, 1986.

Done at Washington, DC, on: December 5, 1985.

William T. Manley,

Deputy Administrator, Marketing Programs.

[FR Doc. 85-29255 Filed 12-9-85; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 85-AGL-25]

Proposed Alteration of Transition Area; Shelbyville, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to alter the Shelbyville, Illinois, transition area to accommodate a proposed NDB–A Standard Instrument Approach Procedure (SIAP) to Shelby County Airport.

The intended effect of this action is to ensure segregation of the aircraft using approach procedures in instrument conditions from other aircraft operating under visual weather conditions in controlled airspace.

DATES: Comments must be received on or before January 10, 1986.

ADDRESS: Send comments on the proposal in triplicate to: Federal Aviation Administration, Regional Counsel, AGL-7, Attn: Rules Docket No. 85–AGL–25, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Regional Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

An informal docket may also be examined during normal business hours at the Airspace, Procedures, and Automation Branch, Air Traffic Division, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Edward R. Heaps, Airspace, Procedures, and Automation Branch, Air Traffic Division, AGL–530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694–7360.

SUPPLEMENTARY INFORMATION: The present transition area is being expanded to accommodate arrival aircraft utilizing the NDB–A approach procedure. The expansion is needed to ensure that the procedure will be contained within controlled airspace. The additional airspace designated will be approximately a .5 mile expansion to the south of the airport and an additional .5 mile expansion to the east of the 186° bearing from the Shelbyville (SYZ) NDB.

The minimum descent altitudes for this procedure may be established below the floor of the 700-foot controlled airspace.

Aeronautical maps and charts will reflect the defined area which will enable other aircraft to circumnavigate the area in order to comply with applicable visual flight rule requirements.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped

postcard on which the following statement is made: "Comments to Airspace Docket No. 85-AGL-25." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of Regional Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-430, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 426-8058. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list of future NPRM's should also request a copy of Advisory Circular No. 11-2, which describes the application procedure.

The Proposal

The FAA is considering an amendment to § 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to alter the designated transition area airspace near Shelbyville, Illinois.

Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6 dated January 2, 1985.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, transition areas.

The proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration (FAA) proposes to amend Part 71 of the FAR (14 CFR Part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. By amending § 71.181 as follows:

Shelbyville, IL [Revised]

That airspace extending upward from 700 feet above the surface within a 5 mile radius of the Shelby Co. Airport, (lat. 39°24'44"No., long. 88°50'38"W.); and within 3 miles west to 3.5 miles east of the 186° bearing from the Shelbyville (SYZ) NDB facility extending from the 5 mile radius area to 8.5 miles south.

Issued in Des Plaines, Illinois, on November 26, 1985.

Monte R. Belger,

Acting Director, Great Lakes Region.

[FR Doc. 85-29173 Filed 12-9-85; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

Labor Certification Process for the Temporary Employment of Aliens in Agriculture; Adverse Effect Wage Rate for Montana

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule.

SUMMARY: The Employment and Training Administration of the Department of Labor proposes to amend the regulations for the certification of temporary employment of nonimmigrant aliens in agriculture in the United States, to add the State of Montana to the list of States for which adverse effect wage rates (AEWRs) are computed and published annually. The AEWR for Montana will be established and set to prevent the employment of these aliens from having an adverse effect on the wages of similarly employed United States workers.

DATE: The public is invited to submit written comments on the proposed rule on or before January 9, 1986.

ADDRESS: Send written comments to: Assistant Secretary of Labor, Employment and Training Administration, Room 8100, Patrick Henry Building, 601 D Street NW., Washington, DC 20213, Attention: Mr. Richard C. Gilliland, Director, U.S. Employment Service.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Burening. Telephone: 202-376-6228.

SUPPLEMENTARY INFORMATION:

Introduction

The Employment and Training Administration (ETA) of the Department of Labor (DOL) is proposing to amend its regulation at 20 CFR 655.207(b)(2), to add the State of Montana to the list of States for which the Director, U.S. Employment Service, must compute and publish annually an adverse effect wage rate for the temporary employment of aliens in agricultural occupations. An AEWR is a minimum wage rate which DOL has determined must be offered and paid by the employers proposing to employ nonimmigrant alien agricultural workers in the United States. The AEWR for Montana will be established and set to prevent the employment of these aliens from having an adverse effect on the wages of similarly employed United States workers.

Temporary Alien Employment Certification Process

Whether to grant or deny an employer's petition to import a nonimmigrant alien to the United States for the purpose of temporary employment is solely the decision of the Attorney General and his designee, the Immigration and Naturalization Service (INS). 8 U.S.C. 1101(a)(15)(H)(ii) and 1184(a) and (c). Pursuant to the requirement that the Attorney General counsult with appropriate agencies of the government concerning the importation of nonimmigrant (so-called "H-2") workers, INS has determined that prior to granting or denying such petitions it first will request the Department of Labor (DOL) to advise IND on the availability of qualified U.S. workers for the jobs offered to the H-2 aliens, and whether the wages and working conditions attached to such job offers will adversely affect similarly employed United States workers. 8 U.S.C. 1184(c); 8 VFR 214.2(h)(3)(i); *see* 49 FR 15182 (April 18, 1984).

Pursuant to the INS regulations, DOL has published regulations at 20 CFR Part 655, Subpart C, for the certification of nonimmigrant aliens for temporary employment in agriculture and logging in the United States. DOL has determined that similarly employed United States workers had been adversely affected by the importation and employment of nonimmigrant aliens in agricultural employment. It has been determined further that employment of those aliens in a number of States at wage below specifically computed adverse effect wage rates (AEWRs) would adversely affect the wages of similarly employed United States workers. 20 CFR 655.202(b)(9) and 655.207.

Adverse Effect Wage Rates

For many years, DOL has computed and published adverse effect wage rates (AEWRs) for the temporary employment of nonimmigrant alien workers to be admitted by INS under "H–2" visa petitions. *See* H.N. DELLON, "Foreign Agricultural Workers and the Prevention of Adverse Effect", *17 Labor Law Journal* 739 (1966). The AEWR is the minimum wage rate that agricultural employers seeking nonimmigrant alien workers are required to offer to and pay their U.S. and alien workers.

The purpose of an AEWR, as described by the United States Court of Appeals for the Fifth Circuit, is "to neutralize any 'adverse effect' resultant from the influx of temporary foreign workers." It is a "method of avoiding wage deflation." *Williams* v. *Usery*, 531 F. 2d 305, 306 (5th Cir. 1976), *cert. denied*, 429 U.S. 1000; *see Florida Sugar Cane League* v. *Usery*, 531 F. 2d 305 (5th Cir. 1976); *see also Limoneira Co.* v. *Wirtz*, 225 F. Supp. 961 (S.D. Cal. 1963), *aff'd* 327 F. 2d 499 (9th Cir. 1964); *and* 20 CFR 655.0.

Employers applying for temporary labor certifications also must agree to comply with all employment-related laws. 20 CFR § 655.203(b); *see also* 8 CFR 214.2(h)(3)(i). If the employment is covered by a higher wage standard applicable under any Federal, State, or local minimum wage law, the employer must comply with that law. *See, e.g.*, 29 U.S.C. 206(a). If the prevailing wage for the occupation in the labor market is higher, the employer must offer and pay that wage. Thus, a worker in employment under the temporary alien labor certification program must be compensated at the highest of the applicable wage rates, whether that highest rate is the AEWR, the prevailing wage, or the Federal, State, or local statutory minimum wage.

The Secretary of Labor has the authority to set AEWRs to prevent the temporary employment of nonimmigrant aliens from having an adverse effect on the wage rates of similarly employed United States workers. *Shoreham Cooperative Apple Producers Association, Inc.* v. *Donovan*, Docket Nos. 85–6009 and 85–6029 (Decision, 2d Cir. June 13, 1985); *Rowland* v. *Marshall*, 650 F. 2d 28, 30 (4th Cir. 1981); and *Florida Sugarcane League* v. *Usery, supra.*

The AEWR is not set slow the usage of temporary foreign labor in the United States. Its purpose is to ensure that the wage rates of similarly employed United States workers will not be adversely affected by the importation of low-paid nonimmigrant alien workers.

Adversely Affected Employment in the State of Montana

DOL proposes to determine that the employment of nonimmigrant aliens in agricultural employment in the State of Montana has had and will continue to have an adverse effect on the wages of similarly employed United States workers, unless the employers of these aliens are required to offer and to pay to their United States and alien workers and AEWR.

The use of undocumented alien workers in agriculture in Montana is substantiated by the records of INS. In 1984, INS apprehended almost 200 undocumented alien agricultural workers is southwestern Montana. Subsequent to these apprehensions, Montana agricultural employers began filing requests for temporay alien labor certifications, and in 1985 ETA's regional certifying officer granted certifications to employ aliens as irrigators. It is anticipated that applications will be filed again for 1986 and future years.

Continued réliance on the use of undocumented aliens had had a depressing effect on the wages of similary employed United States workers in Montana. A State employment service agency survey conducted in 1985 showed that the prevailing wage rate was near the Fair Labor Standards Act (FLSA) minimum wage. Without a formally established AEWR, it is anticipated that many of these nonimmigrant aliens will be employed at wage rates close to the FLSA minimum wage.

The methodology for computing the AEWR for Montana will be the same as that used for computing past years' AEWRs for the States now listed at 20 CFR 655.207(b)(2). DOL has determined that the methodology can be used to construct AEWRs in a way that is reasonable, cost effective, and geared as much as possible to the reality of agricultural crops, areas, and existing wage factors.

For the above reasons, DOL proposes to amend 20 CFR 655.207(b)(2) to add Montana to the list of States for which AEWRs for agricultural employment are computed and published annually. However, pursuant to 20 CFR 655.207(B)(1), the wage rate for sheepherding employment will be established separately.

Regulatory Impact

The proposed rule would affect only those few agricultural employers in the State of Montana who request certification of temporary employment of nonimmigrant alien workers. Its financial and other impact is not so major as to require the preparation of a regulatory impact analysis. *See* Executive Order No. 12291 (February 17, 1981).

The Department of Labor has notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification pursuant to 5 U.S.C. 605(b), that the proposed rule will not have a significant economic impact on a significant number of small entities. It applies only to the small number of employers in the State of Montana who apply for certification for temporary employment of nonimmigrant alien agricultural workers, and is expected to increase labor costs only moderately for those Montana employer-applicants whose wages are below the computed AEWR.

Catalogue of Federal Domestic Assistance Number

This program is listed in the *Catalogue of Federal Domestic Assistance* at Number 17.202, "Certification of Foreign Workers for Agricultural and Logging Employment."

List of Subjects in 20 CFR Part 655

Administrative practice and procedure, Agriculture, Aliens, Employment, Employment and Training Administration, Forests and forest products, Guam, Labor, Migrant labor, Wages.

Proposed Rule

Accordingly, it is proposed that 20 CFR Part 655 be amended as follows:

PART 655—LABOR CERTIFICATION PROCESS FOR THE TEMPORARY EMPLOYMENT OF ALIENS IN THE UNITED STATES

1. The authority citation for Part 655 is revised to read as follows and the authority citations following all the sections in Part 655 are removed:

Authority: 8 U.S.C. 1101(a)(15)(H)(ii) and 1184(c); 29 U.S.C. 49 *et seq.*; 8 CFR § 214.2(h)(3)(i).

2. It is proposed to amend § 655.207 by revising paragraph (b)(2) to read as follows:

§ 655.207 Adverse effect rates.

* * * * *

(b) * * *

(2) *List of States.* Arizona, Colorado, Connecticut, Florida (other than sugarcane), Maine, Maryland, Massachusetts, Montana, New Hampshire, New York, Rhode Island, Texas, Vermont, Virginia, and West Virginia. Other States may be added as appropriate.

* * * * *

Signed at Washington, DC, this 21st day of November 1985.

William E. Brock,

Secretary of Labor.

[FR Doc. 85-29279 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-30-M

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20 CFR Part 655

Labor Certification Process for the Temporary Employment of Aliens in Agriculture and Logging; Charges for Meals

AGENCY: Employment and Training Administration, Labor.

ACTION: Proposed rule.

SUMMARY: The Employment and Training Administration (ETA) of the Department of Labor (DOL) proposes to amend the temporary alien agricultural labor certification regulations to increase the amount covered agricultural and logging employers may charge their U.S. and alien workers each day for meals. The proposed rule also would provide for annual adjustments of the allowable charges based upon Consumer Price Index (CPI) data.

DATE: Written comments on the proposed rule must be received on or before January 9, 1986.

ADDRESS: Send written comments to: Assistant Secretary of Labor, Employment and Training Administration, Room 8100—Patrick Henry Building, 601 D Street NW., Washington, DC 20213. Attention: Mr. Richard C. Gilliland, Director, U.S. Employment Service.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Bruening, Telephone: 202-376-6228.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Employment and Training Administration (ETA) of the Department of Labor (DOL) is proposing to amend its regulations for the certification of temporary employment of nonimmigrant aliens in agriculture and logging in the United States (20 CFR Part 655, Subpart C), to increase the amount covered employers may charge their workers for providing three daily meals. The increase reflects increases in the cost of food and food preparation in the five years since the regulation was last amended. See 45 FR 11798 (February 22, 1980); see also 46 FR 57031 (November 20, 1981). The proposed rule also would establish a process by which the "meal charge" would be adjusted annually to reflect changes in food and food preparation costs. Notice of these adjusments would be published in the the **Federal Register.**

II. Temporary Alien Labor Certification Process

Whether to grant or deny an employer's petition to import a nonimmigrant alien to the United States for the purpose of temporary employment is solely the decision of the Attorney General and his designee, the Commissioner of the Immigration and Naturalization Service (INS). 8 U.S.C. 1101(a)(15)(h)(ii) and 1184(a) and (c); 8 CFR Part 2. Pursuant to the requirement that the Attorney General consult with appropriate agencies of the Government concerning the importation of nonimmigrant alien (so-called "H-2") workers, INS has determined that prior to granting or denying such petitions it first will request DOL to advise INS on the availability of qualified U.S. workers for the jobs offered to the H-2 aliens, and whether the wages and working conditions attached to such job offers will adversely affect similarly employed workers. 8 U.S.C. 1184(c); 8 CFR 214.2(h)(3)(i).

Pursuant to the INS regulations, DOL has published regulations at 20 CFR Part 655, Subpart C, for the certification of nonimmigrant aliens for temporary employment in agriculture and logging in the United States.

III. Provision of Meals

The temporary alien agricultural labor certification regulations require the employer to provide the worker with three meals a day, except that where under prevailing practice or longstanding arrangement at the establishment workeres prepare their own meals, employers need furnish only free and convenient cooking facilities. 20 CFR 655.202(b)(4).

The regulations require that the job offer to the alien and U.S. workers state the charge to the worker for daily employer-provided meals. The current maximum charge is $4.00 per day, unless the Regional Administrator for Employment and Training (RA) has approved a higher cost. 20 CFR 655.211. The proposed rule would increase the charge permitted without RA approval to $4.94 per day. Employers may petition the RA to allow a higher daily meal charge, currently up to $5.00 per day. 20 CFR 655.202(b)(4) and 655.211. The proposed rule would increase that amount to $6.17 per day, for providing 3 meals per day. The proposed rule's increase in the maximum daily meal charge does not mean that all or most employers covered by this program could increase their meal charges to $6.17 per day. For any charge over $4.94 per day, the petition and documentation requirements of 20 CFR 655.211(b) remain in force.

In developing the proposed rule, ETA examined several statistical series related to food. These were (1) the Consumer Price Index for All Urban Consumers for Food (CPI-U for Food); (2) the U.S. Department of Agriculture's (USDA) Market Basket of Farm Foods Index; (3) the Farm to Retail Price Spread Series; and (4) the Thrifty Food Plan Series. The CPI, published monthly by the Bureau of Labor Statistics (BLS) in DOL, is one of the best known economic indicators of prices. The CPI-U for Food includes the measurement of the retail cost of food purchased in stores as well as food consumed away from home, such as meals in restaurants. The USDA Market Basket of Farm Foods Index includes food prepared at home but excludes food prepared and consumed away from home. The Farm to Retail Price Spread Series measures the difference between the retail cost and the equivalent farm value of foods. It indicates the total charge made by firms for assembling, processing, transporting and distributing the foods that make up the market basket. The Thrifty Food plan uses a base which comes from what households eligible for food stamps pay for food. The data assumes that food for all meals is purchased at the store and prepared and consumed at home. It excludes food prepared and consumed away from home.

Based upon its review of these statistical series, which included consultation with BLS and USDA, ETA concludes that the CPI-U for Food Series, since it does include food consumed away from home, is the most appropriate series to use in computing adjustments in meals charges for the type of operation where food is prepared and served to groups at centralized feeding facilities, as is the

case with most employers who provide daily meals to their agricultural workers.

The Consumer Price Index for All Urban Consumers for Food shows an increase of 23.4 percent from March 1980 through December 1984. Consequently, ETA proposes to use these CPI data and authorize employers who provide their covered U.S. and alien workers with three meals a day to charge the workers each day, without RA approval, no more than $4.94, an increase of 23.4 percent from the current $4.00. ETA also proposes to increase the current maximum daily charge (with RA approval) of $5.00 by 23.4 percent to $6.17. A change higher than $4.94 per day may be authorized with the approval of the RA based on documentary evidence submitted by the employer to justify a higher charge. ETA also proposes to use the 12-month percent change for the Consumer Price Index for All Urban Consumers for Food between December of the year just concluded and December of the year prior to that to compute annual adjustments in the allowable charges, and to provide for annual publication of such adjustments by notice in the **Federal Register**. The first such adjustments will be made and published in 1986.

IV. Anticipated Effect of Proposed Rule on Covered Workers

The majority of employers who provide meals to their covered workers were granted approval in 1980/1981 to charge their workers the current maximum rate of $5.00 per day. A sampling of information supplied by such growers, primarily those in the sugarcane industry in Florida, where virtually all of the workers are served daily meals in centralized facilities, shows that the actual costs to the employers for providing three daily meals to a worker range from $5.50 to $6.61 per day. Not all employers are expected to be able to justify actual costs substantially higher than the proposed new maximum of $6.17 per day for the next season. Hence, employers may be authorized to charge their workers up to the maximum, but not always the maximum allowed. In most cases, based upon information available at present to ETA, the increased daily charge to a worker is expected to be no more than $1.00. The modest increase in the daily meal charge is not expected to have any impact on the recruitment of workers. Moreover, when workers are provided meals in centralized facilities, they get the benefit of more substantial and nutritious food than they might purchase for themselves, as well as having food prepared for them, thus saving them time and energy which would be needed to prepare their own meals.

As the result of increases in adverse effect wage rates (AEWRs) since 1980, ranging from 12.6 percent to 48 percent, depending upon the State involved, the increases in the minimum daily wages of the workers, calculated on the basis of an 8-hour day, range from $3.75 to $15.76. The highest AEWR applies to Florida sugarcane harvesting, where the AEWR increased from $4.90 per hour in 1980 to $6.06 per hour in 1985. Even the lowest estimated increase in the minimum daily wage of a worker exceeds the maximum possible increase in the daily meal charge. Moreover, workers employed on a piece-rate basis, such as apple and citrus fruit pickers, or on a task-rate basis, such as sugarcane harvesters, usually earn considerably more than the guaranteed minimum. Piece rates and task rates have also increased since 1980, since they must be designed to produce at least the applicable AEWR. Hence, disposable income of the workers has increased to the point where an increase in the daily meal charge of about $1.00, in most cases, should impose no undue hardship upon the workers.

Employers have indicated they will be hard pressed to maintain the current quality and quantity of food provided to their workers unless they can help defray a greater portion of the total expense of providing such food by means of an increase in the daily meal charge.

Regulatory Impact

The proposed rule would affect only those relatively few employers in the agricultural and logging sectors using nonimmigrant alien workers ("H–2 visaholders") in temporary agricultural and logging jobs. It would not have the financial or other impact to make it a major rule, and, therefore, the preparation of a regulatory impact analysis is not necessary. See Executive Order No. 12291 (February 17, 1981).

The Department of Labor has notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification pursuant to 5 U.S.C. 605(b), that the proposed rule will not have a significant economic impact on a substantial number of small entities. It applies only to the small number of employers (and their workers) who employ nonimmigrant aliens in agriculture and logging in the United States.

Catalogue of Federal Domestic Assistance Number

This program is listed in the *Catalogue of Federal Domestic Assistance* as Number 17.202, "Certification of Foreign Workers for Agricultural and Logging Employment."

List of Subjects In 20 CFR Part 655

Administrative practice and procedure, Agriculture, Aliens, Employment, Employment and Training Administration, Forests and forest products, Guam, Labor, Migrant labor, Wages.

Proposed Rule

Accordingly, it is proposed that 20 CFR Part 655 be amended as follows:

PART 655—LABOR CERTIFICATION PROCESS FOR THE TEMPORARY EMPLOYMENT OF ALIENS IN THE UNITED STATES

1. The authority citation for Part 655 is revised to read as follows and the authority citations following all the sections in Part 655 are removed:

Authority: 8 U.S.C. 1101(a) (15) (H) (ii) and 1184(c); 29 U.S.C. 49 *et seq.*; 8 CFR 214.2(h)(2)(i).

2. It is proposed to amend § 655.202 by revising pararaph (b)(4) to read as follow:

§ 655.202 Contents of job offers

* * * * *

(b) * * *

(4) The employer will provide the worker with three meals a day, except that where under prevailing practice or longstanding arrangement at the establishment workers prepare their meals, employers need furnish only free and convenient cooking and kitchen facilities. Where the employer provides the meals, the job offer shall state the cost to the worker for such meals. Until a new amount is set pursuant to this paragraph (b)(4), the cost shall not be more than $4.94 per day unless the RA has approved a higher cost pursuant to § 655.211 of this Part. Each year the charge allowed by this paragraph (b)(4) will be changed by the 12-month percent change for the Consumer Price Index for All Urban Consumers for Food between December of the year just concluded and December of the year prior to that. The annual adjustments shall be effective on their publication by the Administrator in the **Federal Register**.

* * * * *

3. It is proposed to amend § 655.211 by revising paragraph (a) to read as follows:

§ 655.211 Petition for higher meal charges.

(a) Until a new amount is set pursuant to this paragraph (a), the RA may permit an employer to charge workers up to $6.17 for providing them with three meals per day, if the employer justifies the charge and submits to the RA the documentary evidence required by paragraph (b) of this section. A denial in whole or in part shall be reviewable as provided in §655.212 of this Part. Each year the maximum charge allowed by this paragraph (a) will be changed by the 12-month percent change for the Consumer Price Index for All Urban Consumers for Food between December of the year just concluded and December of the year prior to that. The annual adjustments shall be effective on their publication by the Administrator in the **Federal Register.**

* * * * *

Signed at Washington, DC, this 25th day of November 1985.

William E. Brock,

Secretary of Labor.

[FR Doc. 85-29280 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 553

US Army Military Personnel Center; Donations of Tributes at Arlington National Cemetery

AGENCY: Department of the Army, DOD.

ACTION: Proposed rule.

SUMMARY: This change clarifies the current rule that only certain individuals and organizations are allowed to donate items to be placed in Arlington National Cemetery. The Department of the Army proposes to revise the rules concerning tributes in Arlington National Cemetery to commemorate events, units, groups and/or organizations.

DATE: Comment must be received on the proposed rule on or before January 21, 1986.

FOR FURTHER INFORMATION CONTACT: Thomas Ellis, Casualty and Memorial Affairs Operations Center, US Army Military Personnel Center, 2641 Eisenhower Avenue, Alexandria, VA 22331-0400 (703) 325-7960.

SUPPLEMENTARY INFORMATION: The presentation and specifications of Tributes placed in Arlington National Cemetery to commemorate individuals, events, units, groups and/or organizations are being clarified by this proposed rule.

List of Subjects in 32 CFR 553

Veterans Cemeteries Government property.

Executive Order 12291

This rule does not constitute a "major" rule as defined by Executive Order 12291.

Regulatory Flexibility Act

This rule does not have "significant" economic impact on a substantial number of small "entities" as defined by the Regulatory Flexibility Act, 5 U.S.C. 601 et. seq.

Paperwork Reduction Act

There are no collection of information requirements contained in this rule that require approval by the Office of Management and Budget under 44 U.S.C. 3501 et. seq.

Accordingly, 32 CFR Part 553 is amended as follows.

PART 553—[AMENDED]

1. The authority citation for Part 553 continues to read as follows:

Authority: 24 U.S.C. Chapter 7.

2. Section 553.22 is amended by adding new paragraphs (j), (k), (l) and Appendix A to read as follows:

§ 553.22 Visitor's Rules for the Arlington National Cemetery.

* * * * *

(j) *Tributes in Arlington National Cemetery to commemorate individuals, events, units, groups and/or organizations.* (1) *General.* Tributes, which include plaques, medals and statues, will be accepted only from those veterans organizations listed in the Directory of Veterans Organizations and State Department of Veterans Organizations published annually by the Veterans Administration or those substantially similar in nature.

(2) *Plaques at trees and other donated items.* Plaques may be accepted and placed at trees or other donated items to honor the memory of a person or persons interred in Arlington National Cemetery or those dying in the military service of the United States or its allies. Plaques placed at trees or other donated items must conform to specifications described in Appendix A, Specification of Tributes in Arilington National Cemetery. A rendering of the proposed plaque shsll be sent to the Director, Casualty and Memorial Affairs Operations Center, HQDA (DAPC-PED-C), Alexandria, Virginia 22331-0400 for approval.

(k) *Tributes to the Unknowns (Unknown Soldier).*—(1) *General.* Tributes, normally plaques, to the Unknowns by those organizations described in § 553.22 (j) above must conform to specifications and guidelines contained in Appendix A, Specifications of Tributes or Plaques in Arlington National Cemetery. Descriptions of the character, dimensions, inscription, material and workmanship of the tribute must be submitted in writing to Director, Casualty and Memorial Affairs Operations Center, HQDA, (DAPC-PED-C) Alexandria, Virginia 22331-0400, for approval.

(2) *Tributes to the Unknowns (Unknown Soldier) Presented by Foreign Dignitaries.* Presentation of tributes by Foreign Dignitaries is allowed only as part of an official ceremony as defined herein.

(l) *Monuments.* Monuments (other than private monuments or markers) to commemorate an individual, group or event may be erected following joint or concurrent resolution of the Congress.

Appendix A.—Specifications for Tributes in Arlington National Cemetery

1. *Purpose:* The Appendix provides specifications and guidelines for obtaining approval for the donation of tributes at Arlington National Cemetery.

2. *Approval.* The Director of Casualty and Memorial Affairs Operations Center, (DAPC-PED-C), Alexandria, VA 22331-0400 exercises general supervision over Arlington National Cemetery; and his approval of proposed tributes to be placed in Arlington National Cemetery is required.

3. *Who May Offer Tributes.*

a. Tributes wil be accepted only from those veterans' organizations listed in the Directory of Veterans Organizations and State Department of Veterans Organizations published annually by the Veterans Administration or those substantially similar in nature. Tributes will not be accepted from individuals or from subdivisions of parent organizations.

b. Only one tribute will be accepted from an organization. However, with prior approval, the inscription of a tribute already presented in Memory of the Unknown Soldier (World War I) may be reworded by the donating organization to commemorate one additional or all the Unknowns, or a new tribute may be substituted for the old one.

4. *Design.*

a. *Character.* The design of the tribute shall be artistically proportioned and shall be consistent with the sacred purpose of the shrine, which is to honor heroic military service as distinguished from civilian service however notable or patriotic.

b. *Dimensions.* The surface area of the tribute, including the mounting, shall not exceed 36 square inches; and the thickness or height shall not exceed 2 inches when mounted.

c. *Inscriptions.*

(1) *Tributes to the Unknowns.* Tributes are accepted only for the purpose of commemorating and paying homage and respect to one or more of the Unknowns.

Thus all tributes must include, either in the basic design or on a small plate affixed thereto, a clear indication of such commemoration. Suggestions follow:

In Memory of

—The American Heroes Known But to God
—The American Unknowns
—The Unknown American Heroes
—The Unknown Soldier
—The Unknown of World War II
—The Unknown of the Korean War
—The Unknown American of World War II
—The Unknown American of the Korean War

The identity of the donor/Date of Presentation.

(2) *Other Tributes Including Plaques at Trees and Other Donated Items.* Inscriptions on tributes will be in keeping with the dignity of Arlington National Cemetery.

d. *Material and Workmanship.* The material and workmanship of the tribute, including the mounting, shall be of the highest quality, free of flaws and imperfections.

5. *Applications.* Requests for authority to present tributes shall be submitted in writing to the Director, Casualty and Memorial Affairs Operations Center, (DAPC–PED–C), Alexandria, Virginia 22331–0400, accompanied by the following:

a. A scale drawing or model, showing the exact inscription and other details of the proposed tribute.

b. A copy of the constitution and bylaws of the organization desiring to make the presentation.

6. *Final approval.* Upon fabrication, the completed tribute will be forwarded to the Director, Casualty and Memorial Affairs Operations Center, (DAPC–PED–C), Alexandria, Virginia 22331–0400 for visual inspection prior to its presentation. After approval, the donor will then be advised and the tribute forwarded to the Superintendent of Arlington National Cemetery until the donor wishes to make the presentation.

7. *Presentation of Tributes.* After authorized acceptance of the tribute the sponsoring organization may arrange appropriate presentation ceremonies with the Director, Ceremonies and Special Events, US Army Military District of Washington, Washington, DC 20319. If presentation ceremonies are not desired, the Superintendent will acknowledge receipt of the tribute and inform the sponsoring organization of the number of the case in which it reposes in the Memorial Display Room at the Amphitheater at Arlington National Cemetery.

Dated: October 16, 1985.

Robert K. Dawson,

Acting Assistant Secretary of The Army (Civil Works).

[FR Doc. 85–29188 Filed 12–9–85; 8:45 am]

BILLING CODE 3710–08–M

Corps of Engineers, Department of the Army

33 CFR Part 209

Review of National Pollutant Discharge Elimination System; Review of Permits

AGENCY: Army Corps of Engineers, DOD.

ACTION: Withdrawal of proposed rule.

SUMMARY: On October 1, 1974, the Corps of Engineers published proposed rules which would establish policy, practice and procedures to be followed by Corps division and district engineers in the review of National Pollution Discharge Elimination System (NPDES) permit applications (39 FR 35369–35373). A sufficient need to finalize these rules never developed. The Corps will continue to review NPDES permit applications for impacts on navigation pursuant to section 402(b)(6) of the Clean Water Act but does not need rules on how to conduct that review.

FOR FURTHER INFORMATION CONTACT: Mr. Sam Collinson or Mr. Ralph Eppard at (202) 272–0199.

Dated: December 2, 1985.

John O. Roach II,

Army Liaison Officer with the Federal Register.

[FR Doc. 85–29187 Filed 12–9–85; 8:45 am]

BILLING CODE 3710–08–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Ch. I

[CC Docket No. 85–348; FCC 85–604]

OCC Joint Petition for Expedited Rulemaking; Equal Access Obligations

AGENCY: Federal Communications Commission.

ACTION: Proposed rules.

SUMMARY: The FCC proposes two new obligations that are now not part of the Bell Operating Companies' (BOCs') equal access obligations. Specifically, the FCC proposes that the BOCs waive any non-recurring charges for trunk rearrangements associated with the deployment of access tandems that were requested, but not available, upon conversion to equal access. The FCC also proposes that the BOCs be required to provide certain marketing data to the interexchange carriers. These proposals are the result of a Commission review of a petition filed by four interexchange carriers requesting the initiation of a rulemaking. The Commission concluded that its policies are fundamentally sound and should not be modified in any substantial manner. The Commission also concluded, however, that these two proposals may help promote competition in the interstate long distance marketplace.

DATES: Comments must be submitted on or before January 6, 1986, and reply comments on or before January 21, 1986.

ADDRESS: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: William Kirsch, Common Carrier Bureau, (202) 632–6363.

Notice of Proposed Rulemaking

In the Matter of GTE Sprint Communications Corporation, US Telecom, Inc., Allnet Communications Services, Inc., and United States Transmission Systems, Inc CC Docket No. 85–348, Joint Petition for Expedited Rulemaking.

"Adopted: November 14, 1985.

Released: December 5, 1985.

By the Commission: Chairman Fowler issuing a statement.

I. Introduction

A. Background

1. Over the last several decades, some of the most important issues raised before this Commission have concerned the introduction of competition in the provision of telecommunications equipment and services. In the customer premises equipment (CPE) market, competition was fostered by a series of regulatory and judicial actions, beginning with the *Hush-a-Phone* and *Carterfone* decisions, continuing with the equipment registration program, and culminating in the *Second Computer Inquiry decision.*[1] As a result of these

[1] In 1956 the U.S. Court of Appeals struck down restrictions in the tariffs of the American Telephone and Telegraph Company (AT&T) prohibiting interconnection of customer-supplied terminal equipment as applied to the Hust-A-Phone device, which attached physically to a telephone handset. *Hush-A-Phone v. U.S.*, 238 F.2d 266 (D.C. Cir. 1956). More than a decade later, the Commission invalidated AT&T's broad tariff prohibition of devices that could be electrically connected (not just physically connected, like the Hush-A-Phone device) to the network. *Carterfone*, 13 FCC 2d 420 (1968), *reconsideration denied*, 14 FCC 2d 571 (1969). A Commission inquiry into subsequent AT&T tariff revisions that permitted such interconnection only through protective coupling devices provided by the telephone company resulted in the Part 68 registration program, *see* 47 CFR 68.1–68.506 (1984), which allows users to connect any terminal equipment to the telephone network if such equipment is connected through protective circuitry registered with the Commission or if the terminal equipment is itself registered. *See* Proposal for New or Revised Classes of Interstate and Foreign Message Toll Telephone Service (MTS) and Wide Area Telephone Service (WATS), First Report and Order, 56 FCC 2d 593, *modified on reconsideration*, 58 FCC 2d 716 1976); Second Report and Order, 58

Continued

decisions and the responses of businesses and customers to the new opportunities for the provision of CPE, competition in the CPE marketplace is now well established.[2]

2. During the same period, we have provided for the introduction of competition into interstate transmission services in a series of decisions beginning with the *Above 890* decision in 1959[3] (which authorized the establishment of private microwave networks) and the *Specialized Common Carrier* decision in 1971 (which permitted new carriers to enter the marketplace and provide alternatives to the interstate transmission services traditionally offered only by the telephone companies).[4] In 1978, as a result of court decisions in the "Execunet" series of cases[5] and the rapid evolution of communications and related technologies, we began a proceeding to determine whether interstate message toll telephone service (MTS) and wide area toll telephone service (WATS), or their functional equivalents, should be provided on a sole-source or competitive basis.[6] In the same year, the new interexchange carriers (other common carriers or "OCCs") entered into the ENFIA agreements establishing the rates they would pay to the local exchange companies for their use of exchange facilities in originating and terminating their calls.[7]

3. In 1980 this Commission concluded that an open entry policy and free competition were in the public interest and would further the goals of the Communications Act.[8] Subsequently, in the *Third Report and Order* in CC Docket No. 78–72 (*Access Charge Order*),[9] we established comprehensive rules governing the process by which local telephone companies would recover the costs of their facilities and services used in the provision of interstate or foreign communications.[10] These rules have now become effective, and the resulting "access charges" are assessed through tariffs filed by the exchange carriers with this Commission. In adopting this access charge plan, we sought to achieve a balance among the following four policy objectives: (1) Preservation of universal service; (2) elimination of unreasonable discrimination or preferences among rates for interstate services; (3) efficient use of the network; and (4) prevention of uneconomic bypass.[11]

4. In the access charge plan, we also sought to maximize the opportunities for full and fair competition among interexchange carriers. In furtherance of this goal, we adopted rules to address the inequalities between the interconnection options offered to AT&T and the OCCs during the transition to equal access provided for in the *Modification of Final Judgment* (*MFJ*) in the AT&T antitrust case.[12] The *MFJ* requires that the divested Bell Operating Companies (BOCs) provide all interexchange carriers with local exchange access "on an unbundled tariffed basis that is equal in type, quality and price to that provided to AT&T and its affiliates."[13] The *MFJ* also established a schedule for the implementation of equal access, providing that it must be available at end offices serving one-third of the Bell Operating Company (BOC) exchange access lines by September 1, 1985, and, subject to certain exceptions and possible waivers, at all end offices upon bona fide request by an OCC by September 1, 1986.[14] To reflect the superior access that would continue to be available to AT&T until equal access was implemented, we determined that AT&T should pay a lump-sum premium charge during the equal access transition period and that the premium charge should be phased out at approximately the same rate as equal access was phased in.[15]

FCC 2d 736 (1976), *aff'd sub. nom. North Carolina Utilities Comm'n* v. *FCC*, 522 F.2d 1036 (4th Cir.), *cert. denied*, 434 U.S. 874 (1977).

In the *Second Computer Inquiry*, we conducted an extensive examination into what would be the most appropriate regulatory framework for the provision of CPE by common carriers and others, in light of technological and competitive developments that had occurred in the industry. We concluded that existing regulation of CPE should be eliminated. *See* Second Computer Inquiry, Final Decision, 77 FCC 2d 384, *modified on reconsideration*, 84 FCC 2d 50 (1980), *further modified on reconsideration*, 88 FCC 2d 512 (1981), *aff'd sub nom. Computer and Communications Indus. Ass'n* v. *FCC*, 693 F.2d 198 (D.C. Cir. 1982), *cert. denied*, 461 U.S. 938 (1983), *aff'd on second further reconsideration*, FCC 84–190 (released May 4, 1984). We proceeded to require detariffing of CPE on a bifurcated basis with all new CPE being removed from tariff regulation on January 1, 1983, and embedded CPE being detariffed subsequently. *See* Procedures for Implementing the Detariffing of Customer Premises Equipment (Second Computer Inquiry), Report and Order, 95 FCC 2d 1276 (1983) and subsequent orders in CC Docket No. 81–893. We recently relieved AT&T of structural separation requirements for its CPE operations. *See* Furnishing of Customer Premises Equipment and Enhanced Services by American Telephone and Telegraph Company, Order, 50 FR 40379 (1985) (hereinafter *Separate Subsidiary Order*).

[2] As we recently found in the order relieving AT&T of structural separation for its CPE operations, the market shares of AT&T, which used to dominate the CPE marketplace, have undergone a rapid and steady decline, and competition in the CPE marketplace is now vigorous and strong. *See Separate Subsidiary Order* at para. 36.

[3] *Allocation of Frequencies in the Bands above 890 Mc.*, 27 FCC 359 (1959), *modified on reconsideration*, 29 FCC 825 (1960).

[4] *See, e.g.*, Specialized Common Carrier Services, First Report and Order, 29 FCC 2d 870 (1971), *aff'd on reconsideration*, 31 FCC 2d 1106 (1971), *aff'd sub. nom., Washington Utilities and Transportation Commission* v. *FCC*, 513 F.2d 1142 (9th Cir.), *cert. denied*, 423 U.S. 836 (1975); Resale and Shared Use of Common Carrier Services, Report and Order, 60 FCC 2d 261 (1976) *modified on reconsideration*, 62 FCC 2d 588 (1977), *aff'd sub. nom., AT&T* v. *FCC*, 572 F. 2d 17 (2d Cir.), *cert denied*, 439 U.S. 875 (1978).

[5] *MCI Telecommunications Corp.* v. *FCC*, 561 F.2d 365 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 1040 (1978), *motion for an order directing compliance with the mandate granted*, 580 F.2d 590 (D.C. Cir. 1978), *cert. denied*, 439 U.S. 980 (1978).

[6] *See* MTS/WATS Market Structure, Notice of Inquiry and Proposed Rulemaking, 67 FCC 2d 157 (1978).

[7] These agreements were an interim measure to bridge the gap between the court decisions in the Execunet cases, which permitted the OCCs to offer services in direct competition with MTS and WATS unless and until we found that such competition was not in the public interest, and our later determination of an appropriate rate structure for all interexchange carriers. The access to the local exchange provided these OCCs was inferior to that provided AT&T for its interstate services. We concluded that the ENFIA agreements, which included rates substantially below those paid by AT&T for local exchange access services, would serve the public interest. *See* Exchange Network Facilities for Interstate Access (ENFIA), Memorandum Opinion and Order, 71 FCC 2d 440 (1979) (hereinafter *ENFIA Order*).

[8] MTS and WATS Market Structure, Report and Third Supplemental Notice of Inquiry and Proposed Rulemaking, 81 FCC 2d 177, para. 24 (1980).

[9] MTS and WATS Market Structure, Third Report and Order, 93 FCC 2d 241 (1983) (hereinafter *Access Charge Order*), *modified on reconsideration*, 97 FCC 2d 682 (1983) (hereinafter *First Reconsideration Order*), *modified on further reconsideration*, 97 FCC 2d 834 (1984) (hereinafter *Second Reconsideration Order*), *aff'd in principal part and remanded in part, Nat'l Ass'n of Regulatory Utility Comm'rs v. FCC*, 737 F.2d 1095 (D.C. Cir. 1984), *cert. denied*, 105 S. Ct. 1224, 105 S. Ct. 1225 (1985), *modified on further reconsideration*, 49 FR 46383 (1984), 50 FR 18,249 (1985) (hereinafter *Third Reconsideration Order*), *aff'd on further reconsideration*, 50 FR 43,707 (1985) *appeal docketed, U.S. Telephone Inc.* v. *FCC*, Nos. 84–1115 (D.C. Cir. March 23, 1984).

[10] The separations rules, which govern the apportionment of local telephone company investment and expense between the interstate and the intrastate jurisdictions, are contained in Part 67 of the Commission's Rules. *See* 47 CFR 67.1–67.701 (1984).

[11] *Access Charge Order* at para. 122.

[12] *United States v. American Tel. and Tel. Co.*, 552 F. Supp. 131 (D.D.C. 1982) ("*Modification of Final Judgment*" or "*MFJ*"), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983). GTE is required to implement equal access pursuant to a consent decree entered into with the Department of Justice to settle an antitrust challenge to GTE's acquisition of Southern Pacific Communications Company (now GTE Sprint). *United States v. GTE Corporation*, 603 F. Supp. 730 (D.D.C. 1984). The remaining independent telephone companies are required to implement equal access in certain end offices pursuant to an order of this Commission. *See* MTS and WATS Market Structure, CC Docket No. 78–72, Phase III, Report and Order, 50 Fed. Reg. 15,547 (1985) (hereinafter *Independent Access Order*).

[13] *Id.* at 227.

[14] *Id.*

[15] *See supra* note 9.

5. Following the adoption of the *Access Charge Order*, we submitted our access charge rules to careful review in four orders on reconsideration. In each instance, we reaffirmed our commitment to the objectives set out in the *Access Charge Order* and to competition in this market, while modifying in certain respects the means we had selected to achieve those objectives. In the *First Reconsideration Order*, we provided that the lump-sum premium charge on AT&T would be replaced with a 35% differential in the per minute charges for the carrier common line element assessed for premium and non-premium access. In the *Second Reconsideration Order*, we provided that the differential between premium and non-premium access charges would be increased to 55% and applied to all access elements and that charges for non-premium access would be assessed on a flat-rate, per line basis for OCCs.[16] We also provided that the non-premium rate would be phased out on an end-office-by-end-office basis as equal access became available.

6. In the *Third Reconsideration Order*, we concluded that to avoid any unreasonable discrimination against smaller, newer OCCs and to promote competition in the interexchange marketplace, the flat-rate charges for non-premium access for the OCCs should be replaced with usage-sensitive charges, effective January 1, 1986.[17] Finally in the *Fourth Reconsideration Order*, we reaffirmed our decision in the *Third Reconsideration Order* to implement usage-based charges for OCC non-premium access.[18]

B. The Joint Petition for an Expedited Rulemaking

7. On June 17, 1985, GTE Sprint Communications Corporation, US Telecom, Inc., Allnet Communication Services, Inc., and United States Transmission Systems, Inc. (hereinafter "petitioners") filed a joint petition requesting the initiation of a rulemaking concerning the transition to competition in the long distance telephone market (hereinafter "Joint Petition"). On June 20, 1985, we issued a Public Notice establishing a pleading cycle on the Joint Petition.[19] Twenty-five parties filed comments, and fourteen parties filed reply comments.[20]

8. In the Joint Petition, the petitioners contend that the evolution to effective competition in the long distance telephone market is threatened by several aspects of this Commission's current transition plan. The petitioners assert that we have focused on the deregulation of AT&T rather than on measures to ensure the development of effective competition. Moreover, the petitioners assert that our equal access policies provide AT&T with substantial additional unfair advantages. In particular, the petitioners assert that Feature Group D (FGD),[21] which is supposed to provide OCCs with equal access, is not equivalent in value to the access provided to AT&T. The petitioners also contend that AT&T possesses substantial monopoly endowments developed during decades of competition-free activity and that AT&T will continue to dominate the long distance telephone market for years to come. The petitioners cite a study prepared by the firm of Booz, Allen and Hamilton[22] on the prospects for the OCCs over the next several years as evidence that the development of competition in the long distance telephone market is threatened. The petitioners assert that we should modify our equal access transition plan and reinstate effective regulatory oversight of AT&T.

9. Specifically, the petitioners ask us to declare a moratorium on further actions granting AT&T "unreasonable pricing flexibility" and to institute an expedited rulemaking to establish new policies for the transition to equal access that would: (1) Require the BOCs to convert OCC access arrangements to FGD only on a LATA-wide basis[23] with tandem switches in place or, alternatively, require that the OCCs pay FGD rates only when such facilities are in place; (2) order AT&T to make customer marketing data available to the OCCs; (3) require AT&T to permit access by the OCCs to AT&T's "advanced operating systems" that provide 800 service, 900 service, and automated credit card and coin-sent paid calling; and (4) reevaluate the validity of the premise that FGD provides OCCs with marketing opportunities equal to those inherent in AT&T's interconnection arrangements.

C. Summary of Comments

10. All the OCCs and associations of OCCs that filed comments support the petitioner's requests.[24] They generally assert that the entire telecommunications industry is undergoing unprecedented change and argue that a number of unforseen and serious deficiencies in the implementation of equal access are jeopardizing the ultimate achievement of a viable, competitive industry structure for long distance service. Lexitel, while generally optimistic about long-term opportunities in the interexchange service marketplace, premises much of its optimism on the fact that high-quality, low-cost intercity transmission facilities are just now becoming available to many OCCs and argues that if the Commission's transitional policies discourage growth of a competitive marketplace, much of this anticipated transmission capacity will not be built. MCI states that the presence of a number of "competitors" in the marketplace does not necessarily mean that there is effective competition in that marketplace. MCI contends that the long distance telephone market will not be truly competitive for years to come. Teltec argues that the Commission should disavow the concept that if the OCCs are unable to survive the rapid demonopolization that characterizes the present transition, they would prove to be inefficient and uncompetitive in the long run.

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[16] In making this determination, we used the rate structure and levels established in the ENFIA tariffs as a benchmark for the transition to equal access. *See Second Reconsideration Order* at paras. 51–55; *see also ENFIA Order, supra* note 7. We determined that 9,000 minutes of use per line was a reasonable estimate of average usage and should be used to compute the monthly per line charge. *See Second Reconsideration Order* at para. 67.

[17] *See* 50 FR 18249 (1985).

[18] *See* MTS/WATS Market Structure, CC Docket No. 78-72, Phase I, Memorandum Opinion and Order, 50 FR 43707 (1985).

[19] GTE Sprint Communications Corporation, United States Transmission Systems, Inc., Allnet Communications, Inc. and US Telecom Inc., Joint Petition for Expedited Rulemaking, RM-5057, Public Notice, Mimeo No. 5287 (June 20, 1985). Comments were filed on July 22, 1985 and reply comments were filed on August 6, 1985.

[20] A list of parties submitting pleadings in this proceeding is attached as Appendix A.

[21] The access tariffs describe four different types of access through a local exchange switch that are known as Feature Groups A, B, C and D. Feature Group D describes the features of the access arrangements that the BOCs have designed to meet their equal access obligations under the *MFJ*.

[22] Booz, Allen & Hamilton, Inc., *Prospects for Major Facilities-Based Other Common Carriers* (March 18, 1985).

[23] "LATA" stands for Local Access Transport Area, a term used to describe the areas created by the AT&T Plan of Reorganization, in which the BOCs provide services. *See* AT&T Plan of Reorganization, *United States v. Western Electric Co., AT&T Co.*, 569 F. Supp. 990, 993 n.9 (D.D.C.), *aff'd sub nom. California v. United States*, 104 S. Ct. 83 Ct. 542 (1983).

[24] These parties include American Satellite Company (ASC), Argo Communications (Argo), Lexitel Corporation (Lexitel), MCI Telecommunications Corporation (MCI), RCA Communications Corp. (RCA), Satellite Business Systems (SBS), TDX Systems, Inc. (TDX), Teltec Saving Communications (Teltec), and the Alternative Carrier Telecommunications Association (ACTA).

11. Those opposing the Joint Petition include AT&T, the BOCs,[25] Continental Telecom (Contel), Southern New England Telephone Company (SNET), the Communications Workers of America (CWA), the National Telephone Cooperative Association (NTCA), the Organization for the Protection and Advancement of Small Telephone Companies (OPASTCO), and the United States Telephone Association (USTA). The International Communications Association (ICA) has on objection to the commencement of a reevaluation of the Commission's transition policies, but does oppose several of the petitioners' specific requests. The Michigan Public Service Commission staff (Michigan) opposes the Joint Petition to the extent that the requested actions would result in intrastate rate increases.

12. AT&T argues that the matters raised by the OCCs are not new or unforseen, but have all been debated and analyzed extensively and are taken into account in present Commission policies. AT&T asserts that the Commission's policies have already achieved effective competition in the long distance market. AT&T states that the OCCs' market performance by any measures—revenues, customers, annual construction programs, or capacity—shows that they have grown and continue to grow at an extraordinary rate. AT&T argues that the petitioners' proposal would only deprive consumers of the benefits they have been led to expect from Commission policies and impose unnecessary costs, higher prices, and less service innovation on the industry.

13. Ameritech asserts that the Commission should make a threshold determination of the validity of the petitioners' sole justification for their request—that some sort of regulatory relief is needed if competition is to survive—and if their assertions are found wanting, the Joint Petition should be summarily dismissed. US West argues that the petitioners' factual claims are groundless and that their requests for regulatory protection from marketplace forces are repugnant to the American view of competition. BellSouth supports the Commission's current access charge plan and argues that no useful purpose that would be served by the commencement of a rulemaking proceeding. NYNEX states that it is clear that neither the Joint Petition nor the supporting comments demonstrate a need for a rulemaking proceeding. Pacific asserts that competition in the interexchange market is still developing and should be allowed to continue to do so without unnecessary Commission intervention at this stage. Southwestern Bell states that a number of these issues have been repeatedly and exhaustively addressed in other proceedings and the remaining issues would be more appropriately addressed in other contexts. Bell Atlantic contends that only two items of the petitioners' requested relief deserve attention: Access to AT&T customer usage information and access to AT&T data base for 800 service.

D. Summary of Commission Response to the Joint Petition

14. In resolving the issues before us in this proceeding, we must first address our current policies concerning competition in the interexchange marketplace and the transition to equal access. We conclude that the record demonstrates that our policies are fundamentally sound and should not be modified in any substantial manner. In particular, we conclude that the requested tariff moratorium is already reflected in our present policies and further action in response to the present petition is therefore unnecessary. For its interstate transmission service offerings, AT&T remains subject to rate regulations under the Communications Act and the full requirements of our tariff review process. We also conclude that granting the petitioner's requests to continue the OCC non-premium discount after equal access is available at an end office or to extend some type of discount to the FGD traffic of the OCCs would not serve the public interest. We do conclude, however, that several issues raised by the petitioners do warrant further study. Therefore, we grant in part petitioners' request for a rulemaking proceeding. Specifically, we propose two new requirements that are not now part of the BOCs' equal access obligations, but that may help promote competition in the interstate long distance marketplace. First, we propose that the BOCs waive any non-recurring charges for trunk rearrangements associated with the deployment of access tandems that were requested, but not available, upon conversion of an end office to equal access. Second, we propose that the BOCs provide certain marketing data to the interexchange carriers. We also find that the petitioners' request for access to AT&T's advanced operating systems for 800 service raises important issues, but we conclude that they should be addressed in the context of a rulemaking petition on the obligations of exchange carriers with respect to 800 service access that was recently filed by Bell Atlantic.

II. Analysis of Issues

A. Tariff Moratorium on Unreasonable AT&T Pricing Flexibility

1. The Petitioners' Position

15. The petitioners assert that the OCCs have been forced to compete solely on the basis of offering lower quality service at discount rates, which has brough them a combined market share of only 10% of the interLATA public switched voice market. The petitioners state that while the OCCs experienced substantial growth in market share and revenue between 1978 and 1983, AT&T's revenue growth in absolute terms was far greater. The petitioners also contend that the recovery of non-traffic sensitive (NTS) costs on a traffic-sensitive basis allows AT&T to enjoy a marginal cost advantage in adding traffic to its network. The petitioners assert that this competitive advantage does not result greater efficiency in AT&T's operations or network, but that is does permit AT&T considerable flexibility in designing new targeted rate schemes that cannot be answered by its competitors.

16. The petitioners state that AT&T has proposed a series of below-cost marketing schemes that put extreme financial pressure on the prospects for competition at the time of the OCCs' greatest vulnerability. The petitioners allege that the Commission has allowed AT&T, in essence, almost unfettered rate flexibility and exacerbated the difficulties that have developed in the transition to a competitive marketplace. They contend that the OCCs have no choice but to maintain prices below AT&T's rates, and any AT&T below-cost price actions exacerbate the OCCs' financial difficulties. The petitioners further agrue that an OCC will have to realize large increases in efficiency to maintain the price differential necessary to retain and attract customers during the transition period and that such efficiencies must be achieved despite the enormous increase in expenses resulting from the implementation of equal access. The petitioners conclude with a request that no tariff changes or pricing schemes be permitted to take effect unless they are clearly and convincingly cost justified.

[25] Ameritech, Bell Atlantic, BellSouth, NYNEX, Pacific Bell and Nevada Bell (Pacific), Southwestern Bell, and Mountain States Telephone and Telegraph Company, Northwestern Bell and Pacific Northwest Bell Telephone Companies (US West).

2. The Comments

17. MCI asserts that AT&T's unrivaled market power and the asymmetric transition to FGD provide AT&T with the incentive both to engage in predatory pricing for competitive services and to overcharge for monopoly services during the transition to equal access. MCI states that no carrier other than AT&T can price a particular offering below cost and survive. RCA argues that the Commission appears to have embarked on the piecemeal deregulation of AT&T and begun favoring such deregulation as an end in itself. ASC argues that the long distance market has yet to reach the level of facilities-based competition that would support the removal of active Commission regulation of AT&T. Argo asserts the AT&T's size permits it to shift costs and establish prices that do not affect AT&T in the short run, but do prevent other market entrants from establishing a competive foothold.

18. AT&T argues that the OCCs ignore the Commission's rules on resale of AT&T's long distance service, which allow competitors to enter the market with little capital investment. AT&T states that, in addition, Commission forebearance policy provides the OCCs with complete flexibility to charge prices and introduce new services. AT&T contends that the OCCs' attempt to prevent AT&T pricing flexibility is an unsupportable effort to deprive customers of the benefits of reduced prices resulting from competition. AT&T argues that the OCCs disregard the proceeding to develop standards for the pricing of AT&T's alternative service offerings and that the pricing guidelines proposed there do not represent the deregulation of AT&T, but simply the application of a more rational cost standard. AT&T asserts that the OCCs also ignore the fact that specific AT&T tariffs are subject to extensive analysis in the tariff review process, citing the investigation of the Pro America tariff as an example. Finally, AT&T asserts that to the extent the OCCs' proposed moratorium contemplates a prohibition on AT&T filing new tariff rates, it is plainly unlawful.

19. A number of BOCs also oppose the OCC request for a tariff moratorium on AT&T. Ameritech states that many of the OCCs' complaints about their lack of pricing flexibility simply result from their desire to maintain existing price differentials for all their customers, even though some customers no longer experience the lower quality access that those price differentials supposedly reflect. Ameritech asserts that the OCCs ignore the obvious solution, which is to charge the higher costs of equal access to customers who benefit from it. Bell Atlantic contends that the impact on the OCCs of recovering NTS costs on a usage basis is a pricing issue that should be considered separately from the technical issues of access service raised here. NYNEX argues that the appropriate answer lies in the provision of access service that is based more on the economic cost of providing the service. NYNEX observes that this Commission has established the mechanisms required to achieve more cost-based access services and argues that the mechanisms should be allowed to operate. US West agrees that the Commission is already aware that the traffic-sensitive recovery of NYS costs impedes competition at all levels.

20. Contel argues that consumers would be denied the benefits of free competition if AT&T's rates are frozen. It also states that it would not be in the public interest to force AT&T to charge noncompetitively high rates simply to provide the OCCs with market shares they would not otherwise be able to capture. Contel further contends that the existing tariff process is adequate to ensure that AT&T's rates are justified and to protect the OCCs' rights.

3. Discussion

21. Under the Communications Act of 1934, it is unlawful for a common carrier to charge rates that are unjust or unreasonable, or that result in unreasonable discrimination, preference, or prejudice with respect to any particular subscriber or class of subscribers.[26] In a monopoly environment, the regulatory implementation of these prohibitions tended to focus on the protection of consumers from rates that were either too high or unreasonably discriminatory. The introduction of, and increase in, competition in the interstate telecommunications market has increasingly made it necessary to address the additional question whether the rates proposed by dominant carriers are to low. In particular, there is a concern that a dominant carrier might attempt to price its competitive offerings below cost, either by shifting costs properly associated with such offerings to its monopoly services or simply by selling at a loss and deliberately sacrificing current revenues, in order to serve an anticompetitive purpose—that is, to drive competitors out of the market and then recoup the initial losses through higher prices and profits in the absence of competition.

22. The petitioners' request is directed at these latter concerns and specifically to any unjustified or below-cost rate schemes proposed by AT&T. Their request and the supporting comments appear to reflect a belief that this Commission has decided to deregulate the service offerings of AT&T. A review of recent Commission action on AT&T's tariff filings demonstrates, however, that this belief has no basis in fact. In our order requiring AT&T to withdraw certain proposed tariff revisions incorporating an optional calling plan called PRO America, we made it clear that AT&T bears the burden of demonstrating that new service offerings are cost justified and will not result in an undue preference to a select customer group.[27] And, in fact, the PRO America offering targeted a segment of the market in which the OCCs have established competitive offerings. Therefore, to the extent that the petitioners are seeking a moratorium on the introduction of tariffed rates that are below cost or are not cost justified, their request has already been addressed by this Commission—there is indeed such a "moratorium" in effect.

23. This Commission must be careful to distinguish, however, tariff reductions that are anticompetitive from those that enhance consumer welfare. We have sought diligently to strike a reasonable balance between, on the one hand, AT&T's need to respond in an increasingly competitive environment and the benefits consumers realize from price reductions spurred by competition, and on the other hand, the need to protect competitors from predatory or other anticompetitive behavior and consumers' long-term interests in the prevention of such behavior. Thus, while we have reduced the public notice period applicable to dominant carrier tariff filings from 90 to 45 days to enable these carriers to respond to competitive challenges, we have also made it clear that in the event we are presented with a tariff filed by a dominant carrier that is of such complexity so as to require a longer period than 45 days, we will extend the notice period to the full 90 days permitted by the Act.[28] And in the case

[26] *See* sections 201(b) and 202(a) of the Act, 47 U.S.C. 201(b) and 202(a)(1982).

[27] *See* AT&T Communications, Memorandum Opinion and Order in CC Docket No. 85-128, FCC 85-510 (released September 30, 1985).

[28] *See* Amendment of Parts 1 and 61 of the Commission's Rules, Report and Order, 98 FCC 2d 855, para. 54 (1984). We streamlined regulations for non-dominant carriers through our Competitive Carrier Rulemaking Proceeding. *See* Policy and Rules Concerning Rates for Competitive Common Carrier Services and Facilities Authorization Therefor, Notice of Inquiry and Proposed

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of PRO America, we not only extended the notice period, but also suspended the effectiveness of the proposed tariff revisions for the full statutory period, instituted an investigation, and subsequently found the proposed tariff to be unlawful.

24. Furthermore, we have recently established guidelines for the review of optional calling plans and other supplemental MTS tariffs offered by dominant carriers.[29] These guidelines are designed to prevent anticompetitive behavior while providing such carriers with increased flexibility to price competitively. And they are consistent with our approach to limit regulatory burdens on all suppliers of interstate MTS offerings, while ensuring just, reasonable, and nondiscriminatory rates for all consumers.

25. This Commission will continue to prevent AT&T from implementing any price reductions that are not cost based and cost justified. At the same time, we must permit price reductions to become effective that AT&T is able to demonstrate do reflect their costs. To prohibit such price reductions would simply amount to imposing a "tax" on many American consumers to provide OCCs with protection from legitimate price competition. Such a result would not be consistent with the public interest. Furthermore, we remain convinced that the tariff process is the appropriate forum for making such determinations on individual tariff proposals.[30] Accordingly, we decline to establish a so-called "tariff moratorium" in this proceeding.[31]

B. The Petitioners' Four Requests for Rulemaking

1. LATA-wide Conversion to Equal Access With Tandem Switches in Place

(a) The Petitioners' Position.

26. The petitioners first request is that we require that end offices be converted to FGD on a LATA-wide basis with access tandems in place or that non-premium rates be eliminated only when such facilities are in place. The petitioners maintain that, for a number of reasons, the scattering of end-office conversions within a LATA imposes burdens on the OCCs that have placed them at a much more serious competitive disadvantage vis-a-vis AT&T than could reasonably have been anticipated at the time the Commission established its rules for the transition to equal access.

27. First, the petitioners claim that the piecemeal introduction of FGD hampers their ability to market equal access services effectively, causes inconvenience and confusion for OCC subscribers, and introduces complications into the utilization of existing OCC dial-up services. Second, the petitioners assert that equal access conversion without tandem switches causes inefficient utilization of local telephone transport plant and unnecessary expenses for the OCCs, including those associated with inefficient network design; increased OCC installation, testing, and maintenance costs; increased costs for private lines used to provide service to distant LATAs; and the costs associated with the rearrangement of trunks once access tandems do become available. Third, the petitioners assert that they are required to maintain dual networks since, for end offices not yet converted to equal access, customers must use non-premium access for originating calls. Furthermore, they assert that OCC customers who reside in areas served by equal access must continue to use non-premium access when they travel, since they cannot determine whether a particular location is served by a FGD office, and that a significant number of presubscribed OCC customers continue to use the non-premium method of access even when premium access is available. The petitioners state that this situation increases their switching, maintenance, testing, ordering, and associated customer service and network administration costs as a result of their need to purchase both premium and non-premium access. Fourth, the petitioners claim that a lack of two-way trunks for FGD service between a carrier's point of presence and FGD tandems at the time of conversion requires the purchase of additional trunks, consumes additional switch capacity, and generates additional testing, maintenance, and administrative costs.

(b) The Comments.

28. A number of OCC commenters, including MCI and SBS, argue that a major problem with the end-office-based implementation of equal access has been the lack of geographic coordination of end-office conversions. Lexitel applauds the voluntary actions of several exchange carriers to cluster such conversions, but argue that voluntary action by certain companies does not reduce the need for Commission action.

29. Most of the OCCs that filed also support the petitioners' arguments on access tandems. For example, TDX states that the implementation of equal access could have been accomplished with far greater efficiency and lower costs if the BOCs had installed access tandems before or at the same time as conversion of end offices. SBS argues that the absence of access tandems for the purpose of concentrating traffic, and the resulting need to install direct trunks from the OCC point of presence to each converted end office, significantly increases access costs per unit of traffic. SBS also supports the petitioners' arguments that OCCs incur significant costs as a result of having to maintain dual networks to operate with both FGD and FGB access services. Like the petitioners, SBS states that it will have to maintain some non-premium facilities indefinitely, even in areas that are fully converted, in order to provide service to customers traveling in unconverted areas and to presubscribed customers who continue to use non-premium access. SBS also states that it has been notified by several BOCs that two-way trunks will be unavailable in a number of end offices at cut-over. SBS adds that, on occasion, attempts to transmit traffic on two-way trunks have been unsuccessful.

30. AT&T states that the Commission has recently denied requests that are identicial to those asserted in the petition and argues that when an end

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Rulemaking, 77 FCC 2d 308 (1979); First Report and Order, 85 FCC 2d 1 (1980); Further Notice of Proposed Rulemaking, 84 FCC 2d 445 (1981); Second Report and Order, 91 FCC 2d 59 (1982), *reconsideration denied*, 93 FCC 2d 54 (1983); Further Notice of Proposed Rulemaking, 47 FR 17308 (1982); Third Further Notice of Proposed Rulemaking, 48 FR 28292 (1983); Third Report and Order, 48 FR 46791 (1983); Fourth Report and Order, 95 FCC 2d 554 (1983); Fourth Further Notice of Proposed Rulemaking, 96 FCC 2d 922 (1984); Fifth Report and Order, 98 FCC 2d 1191 (1984); Sixth Report and Order, 50 FR 1215 (1985), *vacated and remanded, MCI Telecommunications Corp. v. FCC*, 765 F.2d 1186 (D.C. Cir. 1985).

[29] *See* Guidelines for Dominant Carriers' MTS Rates and Rate Structure Plans, Memorandum Opinion and Order, 50 FR 42945 (1985).

[30] We also agree with AT&T that such a moratorium would raise substantial legal questions. *See AT&T v. FCC*, 487 F. 2d 865, 876–81 (2d Cir. 1973); *see also Nader v. FCC*, 520 F.2d 182, 196 (D.C. Cir. 1975). However, in light of our rejection of the proposed moratorium on policy grounds, we need not address these questions here.

[31] The petitioners also complain about the competitive implications of the recovery of non-traffic sensitive costs through usage-sensitive access charges. To the extent that this complaint is intended to demonstrate the need for a tariff moratorium on AT&T, we reject it for the reasons discussed in the text. To the extent it is suggesting that such costs be removed from access charges and recovered in some other fashion, we decline to address it at this time. The Federal-State Joint Board in CC Docket No. 80-286 is scheduled to review in 1986 the effects of recovering such costs through subscriber line charges rather than carrier access charges, on universal service, bypass, economic efficiency, and interexchange competition. The pricing issues raised by the petitioners here are more appropriately addressed in that proceeding. *See* MTS/WATS Market Structure and Amendment of Part 67, Recommended Decision and Order, 49 FR 48325 (1984); Decision and Order, 50 FR 939 (1985).

office is converted to FGD, the OCCs obtain the benefits of equal access in that end office. AT&T states that the OCCs' complaints about the unavailability of access tandems and two-way trunks have been considered and rejected by the Commission and the Court. AT&T asserts that OCCs' concerns about the need to maintain "dual access networks" are misplaced since the disparities between premium and non-premium access are precisely what the discount addresses. AT&T believes that any of the so-called "disadvantages" cited by the OCCs are, at most, transitory and will cease to be of significance in the near future. Indeed, in AT&T's view, all of these alleged disadvantages are more than offset by the discount for non-premium access, which, it asserts, is excessive.

31. The BOCs generally argue that neither the OCC request for discounted access rates until end offices are converted LATA-wide or nationwide, nor the request for alterations to the conversion plan, are new. In particular, they assert that in the *Third Reconsideration Order* the Commission considered and rejected the OCCs' arguments on the issue of the phase-in of equal access and the phase-out of the OCC discount. The BOCs maintain that their equal access plans are reasonable and that the OCCs' request for clustering is merely an attempt to perpetuate their discount for FGA and FGB traffic or even extend it to FGD traffic. The BOCs argue that since the petitioners are obviously aware that LATA-wide conversions are not possible now, nor in the near term, it can be assumed that their purpose is really to obtain discounts for the foreseeable future. The BOCs further assert that the OCCs' request would unreasonably increase the cost of equal access, and that the "solution" of imposing these added costs on AT&T would give AT&T a greater incentive to bypass the BOCs. With respect to the effect of the OCCs' request on independent telephone companies, Contel asserts that mandatory LATA-wide equal access conversion would require reversal of the decision in Phase III of CC Docket No. 78–72 upon which the independents have established long-range plans and would require premature retirement of various non-conforming offices.

32. On the access tandem issue, the BOCs state that, to the extent possible, their conversion plans have been structured to provide for the activation of equal access tandems before subtended end offices are converted. NYNEX argues that the costs and inefficiencies cited by the OCCs are misleading, since the traffic of many carriers is routed directly even when an access tandem is available. Bell Atlantic states that the increased costs to OCCs for direct connection are minimal, with the only additional OCC capital expenditure involving the additional ports on OCC switches. Ameritech and Bell Atlantic state that they waive rearrangement charges for OCCs that modify trunking arrangements to use an access tandem that was not available when originally requested. Ameritech also states that the OCCs' asserted need for a dual network following end office conversions appears to call for better OCC customer education efforts. In Bell Atlantic's view, the OCCs are not maintaining "dual networks"; rather each OCC has a single network with different types of interconnection in different locations. US West states that it is not aware of any shortage of two-way trunks for FGD service in its territory and suggests that one recent incident involving GTE Sprint demonstrates that most problems can best be resolved by the carriers themselves, without regulatory intervention.

(c) Discussion.

33. This Commission has considered at great length the access charge rules that govern interstate competition. In particular, we have reviewed on a number of occasions the premium and non-premium rate categories for access services provided by the exchange carriers to the interexchange carriers during the transition to equal access. Most significantly, we have considered OCC proposals to abandon the end-office approach to phasing out the non-premium discount by extending the discount until access tandems are in place or all, or a substantial majority of, end offices in a LATA are converted. In two orders adopted this past year, we have declined to adopt such proposals and made it clear that the end-office approach to phasing out the discount and the 55% level of the discount are complementary parts of the equal access transition plan.[32]

34. The petitioners' first rulemaking request has two components. First, they ask that we require that end offices be converted to FGD on a LATA-wide basis with access tandems in place. Alternatively, they ask that non-premium rates be eliminated only when such facilities are in place. Under the first component, we would, in effect, have to order or prohibit the BOCs from converting individual end offices to FGD access until access tandems are in place and all end offices in a LATA were able to be converted. The *MFJ*, however, provides a schedule for the implementation of equal access, which, as indicated, requires that by September 1986 it be made available in all BOC end offices for which a bona fide request for equal access has been made. For the purposes of that schedule, equal access services are deemed available in all end offices that are actually converted to equal access and not only in those converted end offices accessible through access tandems or in LATAs in which virtually all end offices are converted. The approach adopted in the *MFJ* is, of course, consistent with pre-divestiture OCC assertions that they should be afforded equal interconnection as soon as possible. Moreover, the OCCs had an opportunity to comment on the present equal access implementation schedules when they were first proposed to the court.[33] The actual implementation of equal access is now at an advanced stage. By the end of this year, approximately 51% of all BOC access lines will be converted to FGD, and these lines represent approximately 70% of all lines that are to be converted by September 1986. Therefore, to the extent the OCCs are requesting that we direct that end offices only be converted on a LATA-wide or SMSA-wide basis, it is our view that this might only serve to delay the provision of equal interconnection pursuant to the court-approved schedule.[34]

35. The second component of the petitioners' request is merely an attempt to revisit the question of the non-premium phase-out despite the fact that we have addressed this question in two recent orders and have made it clear that we tied the phase-out of the non-premium discount to the phase-in of equal access established pursuant to the *MFJ*.[35] Furthermore, in adopting the

[32] *See Third Reconsideration Order and Fourth Reconsideration Order, supra* note 9.

[33] *See e.g.* 552 F. Supp. at 147, 569 F. Supp. at 903, and 569 F. Supp. at 1061–2.

[34] We note with approval, however, the voluntary actions taken by several BOCs, including Pacific Bell, Bell Atlantic and Northwestern Bell, to cluster the conversion of end offices in major metropolitan areas. We encourage other carriers to take similar actions to the extent that this is feasible at this advanced stage of the conversion process.

[35] *See Third Reconsideration Order* at para. 28. In the *Fourth Reconsideration Order* we dismissed the petition for reconsideration of the issue of the phase-out of the non-premium discount on an end-office basis as untimely. We also stated that, to the extent it would be appropriate to address this issue again in the light of new facts or changed circumstances, the Joint Petition provided the proper vehicle for that reexamination. *See Fourth Reconsideration Order* at paras. 28–9. In our view

Continued

current non-premium access differential, we stated that the rate at which the differential would be phased down was a relevant factor in selecting the appropriate differential.[36] As we indicated in the *Third Reconsideration Order*, were we to change the end-office approach to phasing out the discount or alter the present approach in any major respect, we would also find it necessary to consider reducing the level of the discount below 55%.[37] We concluded in that Order, however, that making either type of change would not be in the public interest.[38] Here, the petitioners do not ask for a lower discount coupled with a slower phase-out. Instead, they seek to retain the current non-premium discount for an extended period of time. We conclude that such an extension of the non-premium discount would be both inappropriate and contrary to the public interest.[39] Therefore, we decline to revisit the non-premium phase-out in this proceeding.[40]

36. While the petitioners have not established a basis for revisiting earlier decisions or for Commission intervention modifying the equal access implementation schedule, there is one facet of the access tandem issue we wish to examine further. We are concerned with the possibility that the OCCs may be asked to bear certain costs related to the rearrangement by the BOCs of trunks associated with the deployment of access tandems that were requested, but not available, upon conversion to equal access. Moreover, we are aware that at least two of the BOCs have also demonstrated a concern in this area and are waiving the non-recurring charges for the rearrangement of trunks associated with these access tandems. Therefore, we request that parties comments on whether the waiver of these non-recurring charges should be required by this Commission. We also ask that parties provide estimates on the magnitude of costs associated with rearrangement of trunks occasioned by the deployment of access tandems and address the question of alternative methods of recovery of these costs.

(2) Customer Marketing Date

(a) The Petitioners' Position.

37. The petitioners' second request is that the Commission order AT&T to make customer marketing data available to the OCCs. The petitioners state that AT&T's prior monopoly role provides it with unique customer usage information that permits it to design special rate plans and to advertise more effectively than the OCCs.

38. The petitioners further argue that AT&T's traffic information also can be used to plan and engineer systems with greater precision because such information permits accurate facility forecasting. The petitioners observe that substantial network efficiency penalties are caused by over-forecasting the amount of BOC facilites needed to provide a given level of service and severe service quality penalties are caused by under-forecasting. The petitioners state that without AT&T traffic data or any prior experience in providing service via trunk-side interconnections to individual end offices, the OCCS are left to their best guesses as to facility requirements that can never be as accurate as the data-based forecasts of AT&T.

(b) The Comments.

39. The commenting OCCs support the petitioners' request for access to AT&T customer data on basically the same grounds as those cited in the Joint Petition. AT&T opposes the petitioners' request, arguing that OCC appropriation of AT&T customer usage data would be unlawful and unwise. AT&T states that current interexchange usage data on AT&T customers are AT&T's property and are in the nature of trade secrets and proprietary information that should be protected from disclosure. AT&T argues that release of such data to the OCCs is not necessary to ensure competition, and indeed would be antithetical to competition. AT&T asserts that the OCCs have a sufficiently broad base of customers to develop their own marketing analysis.

40. The other commenting parties generally oppose the petitioners' request. NYNEX argues that a BOC's ability to market its billing and collection services to interexchange carriers would be severely hampered if it were required to disseminate customer toll usage data to the carriers' competitors. Bell Atlantic and US West state that they have offered to make nonlisted customers' names and addresses available to the OCCs. ICA opposes making AT&T's customer marketing data broadly available to any OCC, and argues that release of these data would be unduly intrusive on customers' privacy interests. NTCA and OPASTCO also oppose the petitioners' request on the ground that it would be an improper appropriation of exchange carrier property, but they agree that traffic information is important for the efficient operation of the network. Michigan argues that the BOCs should be required to furnish the OCCs with traffic data on a generic, but not a customer-specific, basis for each exchange group in order to assist the OCCs in traffic forecasting.

(c) Discussion.

41. Historic customer usage data can be a useful tool in the planning, engineering, and installation of carrier networks and the marketing of telecommunications services. It is important to recognize, however, that customer-specific data is subject to legal and policy concerns that protect individual, corporate, and societal interests. In this instance, as ICA—a major user group—observes, the release of customer-specific usage data raises immediate concerns about individual privacy. Indeed, on its face, the request seems to be unduly intrusive. Moreover, these data are clearly proprietary in nature. The petitioners do not address these serious interests with regard to the release of customer/specific data.

42. There may be a middle ground, however, that would provide OCCs with information that would be useful for their planning and marketing purposes, but that would not involve the mandatory release of customer-specific data. In particular, we ask for comment on whether a requirement that the BOCs provide certain disaggregated information to the interexchange carriers might be appropriate. For example, it appears that one BOC, Northwestern Bell, already provides interexchange carriers with certain

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the Joint Petition does not establish new facts or changed circumstances that warrant such a reexamination.

[36] *See Second Reconsideration Order* at para. 76.

[37] *See Third Reconsideration Order* at para. 28.

[38] *Id.*

[39] It appears that, as a practical matter, were we now to adopt a rule that, for example, continued the discount until access tandems were in place, most lines would be subject to premium charges in any event since as of September 30, 1985, approximately 91% of converted lines were accessible through a tandem switch, and in 1986 more than 99% of the lines to be converted will be in end offices with access tandem availability. (The percentages listed here are based on letters filed by the regional Bell holding companies pursuant to our equal access reporting requirements. Copies of these letters will be included in this rulemaking docket.)

[40] None of the other issues raised by the petitioners warrant reconsideration of the non-premium discount or the complementary end-office-based phase-out. Moreover, there is no evidence before us to suggest that any of the issues raised by the petitioners constitutes a serious problem. For example, although there may have been some instances in which two-way trunks were unavailable at the time of an end-office conversion, there is no evidence to suggest that there are widespread shortages of such trunks. Furthermore, to the extent the OCCs maintain so-called "dual networks" because some end offices in an area are not yet converted to equal access, they are compensated since the full 55% discount continues to apply to traffic in and out of these end offices. To the extent the problem arises because OCC customers in converted end offices continue to use non-premium access, it appears to be a matter that warrants more extensive marketing and customer education efforts on the part of the OCCs rather than a continuation of the non-premium discount.

disaggregated data on the demographics and telephone subscribership characteristics of the local telephone exchanges in the major cities it serves.[41] These data include: (1) Historical and projected numbers of business and residence telephone lines; (2) average usage per line; (3) number of firms by industry classification and the number of their employees in the area; (4) breakdowns of the population by occupation, age, and sex, as well as unemployment and labor force participation rates; and (5) number of dwelling units, breakdowns on whether the unit is owner occupied or rented, and housing values or rents paid. Northwestern Bell also apparently compiles, and provides to interexchange carriers, information on the general business climate of the metropolitan areas and states in which it operates. Northwestern Bell provides this information free of charge.

43. Our initial impression is that information like that provided by Northwestern Bell would be valuable to interexchange carriers in their planning and marketing efforts. It also appears that the BOCs may be the most efficient providers of this type of information. Indeed, for certain types of information, they may be the only possible source of data. Therefore, we propose the establishment of an information collection and reporting requirement on the BOCs, and we request comment on the specific nature and extent of any such requirement. In particular, we request that parties comment on whether the Northwestern Bell program would provide a sound, cost-effective model on which to base such a requirement. Finally, we ask that parties address the costs and benefits of such a requirement with respect to each of the categories cited by Northwestern Bell.

3. Access to AT&T's Advanced Operating Systems

(a) The Petitioners' Position.

44. The petitioners' third request is that AT&T be required to permit access by the OCCs to its advanced operating systems that the petitioners state serve as the basis of AT&T's monopoly over 800 service, 900 service, and automated credit card and coin-sent paid calling. The petitioners contend that the Common Channel Interoffice Signalling (CCIS) system database effectively provides AT&T with a monopoly on 800 service and, in conjunction with the DBAS system,[42] allows AT&T to be the only carrier with universal automated credit card calling. They characterize these systems as "unearned advantages" over the OCCs. The petitioners argue that if AT&T retains exclusive rights to this technology, AT&T will remain the only full-service long distance carrier long after equal access is phased in. In their view, the duplication of these operating systems would require the OCCs to expend years of development effort and tens of millions of dollars.

(b) The Comments.

45. Lexitel states that FGD does not now enable the OCCs to offer 800 service at all, and that the access necessary to allow OCCs to offer an 800 service comparable to AT&T's will not be available until at least 1987. Lexitel states that AT&T has aggressively marketed its unique 800 service capability and argues that the data bases necessary to offer 800 service should be made available to the OCCs. MCI argues that AT&T's 800 data base is both a barrier to entry and a source of market power for AT&T. MCI contends that a large business that has a need for both 800 and Out-WATS services may have a preference for dealing with only supplier and therefore may be less likely to order Out-WATS service from an OCC. MCI argues that the Commission should explore, as an interim measure, whether AT&T's 800 facilities should be made available to the BOCs for resale.

46. AT&T argues that the OCCs are not entitled to access to AT&T's proprietary systems. AT&T asserts that the OCCs' claim to AT&T's property ignores the court's decision that the CCIS database is an interexchange asset and the property of AT&T's shareholders. AT&T states that the requested action would not only be unlawful, but poor public policy as well. AT&T contends that if its competitors could simply use AT&T's technology, they would have little incentive to innovate, and, in fact, AT&T itself would have less incentive to commit the resources necessary to produce future innovations. AT&T states that it does not provide 900 service or interLATA coin sent-paid service using the CCIS database and contends that its competitors have the capability of developing their own systems to handle these functions. AT&T states that many OCC 800-like and credit card services are provided without the use of AT&T's CCIS database and that this demonstrates that the access requested by the petitioners is unnecessary.

47. Bell Atlantic agrees with the OCCs that AT&T's monopoly on 800 service is a problem in a competitive environment, but states that it has outlined a plan to solve this problem in a separate petition for rulemaking. Southwestern Bell states that the Bell Atlantic petition accurately outlines the history of the 800 service dilemma, including whether AT&T should permit access to its data base, and that it would be more appropriate to address the 800 service issue in that proceeding. NYNEX states that it has requested that the Department of Justice (DOJ) take the steps necessary to ensure AT&T's full assistance in providing the hardware and software required to implement NYNEX's 800-service data base plan, which would permit customers to change interexchange carriers without changing their 800 numbers. US West argues that any problem that has been created for the OCCs in this area is a result of their tactical decision to litigate most of their complaints with the DOJ in the first instance. US West also states that the OCCs are not required to duplicate AT&T's operating systems in order to provide 800 and calling-type services and asserts that it is eager to deploy the necessary hardware, software, and related data bases.

48. ICA argues that the OCCs should not be given access to 800 service numbers and the underlying data bases and technology if the result would be to disrupt the availability and timeliness of service to its members. NTCA and OPASTCO contend that the property concerned—the AT&T database system—is owned by AT&T and not the ratepayer and that, at the very least, AT&T would be entitled to just compensation under the fifth amendment of the Constitution if the requested relief is granted.

(c) Discussion.

49. 800 service or "In-WATS" is a telecommunications offering that permits the called party to be billed for incoming calls. In particular, it affords businesses and other organizations a means of providing potential customers, or other persons with whom they wish to communicate, an easy-to-use, free method of contacting them. From the introduction of 800 service by AT&T in 1967 until 1981, 800 calls were handled by certain designated originating and terminating offices that utilized a special 800–NXX routing and screening methodology that would identify the service area from which the call originated, verify that this area was

[41] *See* Janice D. Stoney, Northwestern Bell Telephone Company, Testimony before the Senate Committee on Commerce, Science and Transportation (September 11, 1985). A copy of this testimony was provided to the Commission and will be included in this rulemaking docket.

[42] The petitioners state that DBAS is a database system that permits verification of credit card calling records and other calling parameters. Joint Petition at 17, n. 24.

included in the subscribed service area, and route the call to the local network for completion. Under this approach, all of the digits in the 800 service number had significance for the screening and routing functions. The result was that subscribers had no choice of 800 service numbers, and a change in the receiving location or geographic coverage required a change in the 800 service number.

50. In 1981 AT&T implemented a more sophisticated system to screen and route 800 service traffic. This system utilizes AT&T's CCIS database to read and translate the 800 service number into a standard ten digit telephone number, which allows the provision of certain new service options, including 800 service numbers that have verbal significance.

51. The Plan of Reorganization in the *MFJ* assigned the CCIS database for 800 service to AT&T.[43] The plan also provides that AT&T must lease access to the CCIS system to the BOCs for their provision of intraLATA 800 service, provided, however, that AT&T has no obligation to allow BOCs use of the CCIS facilities under any arrangement that would allow access directly or indirectly to AT&T's CCIS network by other interexchange carriers.[44] In addition, the plan provides that the BOCs and the OCCs are entitled to use the 800 prefix for In-WATS service and that the BOCs' Central Staff Organization (now Bell Communications Research) is to administer the North American numbering plan, including the assignment of 800 numbers.[45] Finally, the plan provides that 800 directory assistance is considered an interexchange, inter-LATA service.[46]

52. Prior to divestiture, DOJ filed a motion to amend the Plan of Reorganization and to obtain a temporary waiver of the decree's prohibition on the provision of interexchange services by the BOCs with respect to 800 service.[47] In effect the motion would have granted BOC access to portions of AT&T's CCIS database for an interim period, permitted the BOCs to provide the interexchange services necessary for access to the CCIS system, and required that AT&T provide development assistance and access to the CCIS 800 database in order to facilitate the development by the BOCs of their own database systems. The DOJ motion was supported by the BOCs and several OCCs, including GTE Sprint, MCI, Western Union, and SBS.

53. On January 9, 1985, the court denied the DOJ motion and held that AT&T's database system would not be made available to the BOCs.[48] At the same time, however, the court found that the BOCs were entitled to the software, hardware, and know-how necessary for development of their own database systems.[49] Moreover, the court stated that if the BOCs experience problems in this regard, they, or other parties, could return to the court for appropriate relief.

54. While questions concerning the provision of access for 800 services have been litigated extensively before the court, the Joint Petition has raised these issues, including whether other carriers should have access to AT&T's CCIS system, for the first time before this Commission. However, on July 12, 1985, Bell Atlantic also filed a petition on 800 service, which asks the Commission to initiate a rulemaking to consider the obligations of exchange carriers under the Communications Act to provide 800 service access to the interexchange carriers.[50] In particular, Bell Atlantic requests that the Commission initiate a rulemaking to determine whether access for 800 service is to be provided by all exchange carriers through a standardization BOC database plan. Moreover, Bell Atlantic asks us to address the exchange carriers' obligations concerning interim 800 access during the period necessary for the development of a database plan and asserts that if we require interim 800 access, we should also order AT&T to make its 800 database available to the BOCs. Finally, Bell Atlantic states that if the Commission determines that interim 800 access is required, the BOCs should be allowed to recover the cost of providing the service from all interexchange carriers.

55. In our view, the issues raised by petitioners' request for access to AT&T's CCIS database are included within the broader set of issues on 800-service access that has been raised in the Bell Atlantic petition. We have invited comments on the Bell Atlantic petition, and the pleading cycle is now closed.[51] We anticipate acting on the petition in the near future, and we conclude that petitioners' complaints about their inability to provide 800 services because of the lack of appropriate access arrangements are more appropriately addressed in conjunction with that Bell Atlantic petition.[52]

4. A reevaluation of FDG and FGD Marketing Opportunities

(a) The Petitioners' Position.

56. The petitioners' fourth rulemaking request is for the initiation of an expedited investigation into the proper value of FGD, including a reevaluation of whether FGD provides the OCCs with marketing opportunities equal to those inherent in AT&T's interconnection arrangements. To support this contention, the petitioners appear to rely on many of the same complaints about the equal access process they have raised to support their other requests for specific forms of relief. The petitioners contend that with the equal access conversion process now well underway, it has become obvious that the value of FGD to the OCCs is far from equal to the value AT&T derives from its interconnection arrangements. For example, the petitioners assert that marketing problems associated with the end-office-end-office conversion to

[43] *See United States v. Western Electric, AT&T Co., supra* note 23.

[44] *Id.* at 26 n. 36 and Amendment 1.

[45] *Id.* at App. A, Amendment 33.

[46] *U.S. v. Western Electric*, 569 F. Supp. 1057, 1102 (D.D.C. 1983).

[47] *See United States v. AT&T*, 604 F. Supp. 316, 318 (D.D.C. 1985).

[48] *Id.* at 325.

[49] *Id.* at 326.

[50] THe Bell Atlantic Telephone Companies. Petition for Rulemaking, RM–5101, Public Notice, Mimeo No. 5085 (July 24, 1985.).

[51] Comments were filed August 23, 1985 and reply comments were filed on September 9, 1985.

[52] While petitioners raise issues concerning to 900 service, interLATA coin-sent paid service, and automated credit card service, they and the supporting commenters focus principally on access for 800 service, which appears to be the most important of these services. We conclude that petitioners have not adequately supported their request for a rulemaking on access to the AT&T facilities and databases used to provide these other services. For example, they do not attempt to refute AT&T's assertion that 900 service and interLATA coin-sent paid service are not provided through the CCIS system and that OCCs have the capability of developing their own systems to provide these services. Furthermore, the petitioners' argument that OCCs are entitled to access to these operating systems and databases because they are "monopoly endowments" that have taken on a quasi-public character, in and of itself, proves too much. Unqualified, this argument would allow the OCCs access to virtually all of AT&T's corporate property. Moreover, under this theory it is not at all clear at what point in time AT&T's development efforts ceased being quasi-public in character. Indeed, since AT&T is still subject to rate regulation, the system it is currently developing could be characterized as "ratepayer-financed endowments." *see* Joint Petition at 43, and under the petitioners' theory, subject to OCC access. Thus, we do not accept the petitioners' argument that simply because AT&T developed certain operating systems in a less competitive environment than prevails today, OCCs should be permitted unfettered access to those systems. Also, while petitioners do make a case that 800 service raises certain access-related issues (in that the type of 800 service (OCCs eventually will be able to provide will be directly affected by the 800 service access arrangements implemented by the BOCs), petitioners do not explain how comparable issues are raised by these other services.

equal access preclude OCC use of broadly distributed advertising and necessitate OCC solicitation of customers through expensive marketing techniques (direct mail, telemarketing, or personal visits). The petitioners state that direct marketing techniques require the identification of specific demographic groups and businesses on which to concentrate advertising efforts, yet the usage data possessed by AT&T are not available to the OCCs. The petitioners further complain that it is costly to inform OCC subscribers of the dialing differences that result from using OCC services in both converted and non-converted offices. Moreover, the petitioners argue that the equal access transition must be completed nationwide before a substantial majority of OCC interLATA calls will have equal access at both ends and thus could be expected to match AT&T in signal quality. Finally, the petitioners assert that certain state regulatory actions are serious barriers to competition, including a smaller or no differential in access charges for instrastate, interLATA OCC services and requirements that OCCs block, or compensate the BOCs for, any intraLATA traffic that the OCCs may carry.

(b) The Comments.

57. MCI states that difficulties experienced with presubscription order processing are seriously affecting the equal access transition. MCI contends that these difficulties fall into three major categories: (1) Idenification of customers; (2) solicitation of customers; and (3) processing of customer orders. In particular, MCI argues that not one of the BOCs has instituted an adequate system on reporting and conversion status and states that it remains to be seen whether the allocation of default traffic will curb these processing problems.

58. MCI also contends that clustering end office conversions would complement BOC balloting and OCC marketing efforts, allow media coverage of the event, and neither slow the conversion process nor raise the cost of conversion. Lexitel states that this Commission has never examined what constitutes equal access, nor whether FGD provided at individual unrelated locations provided access equal to that ubiquitously available to AT&T. SBS states that the absence of rational clustering substantially increases its per-prospect advertising costs by requiring the use of expensive and inefficent direct mail advertising. In addition, SBS Notes, customers are not subject to the reinforcement of mass-media advertising at the time they receive their ballots. SBS argues that the equal access conversion difficulties demonstrate that until FGD is widely available throughout each LATA, the OCCs will not receive equal access even in the end offices that have been converted. SBS further asserts that "there is a risk, if not a substantial likelihood," that FGD transmission quality is inferior to AT&T access.

59. MCI also states that there is an underlying disharmony between federal and state policies on the regulation of competition that favors AT&T and requires affirmative FCC intervention. MCI contends that serious problems, including state provisions requiring OCCs to block or pay the BOCs compensation for intraLATA call completion, continue even after certification in many states. MCI states that the equal access market should be defined as interLATA, including intrastate, interLATA communications, and contends that this Commission bears a responsibility to help the states realize that allowing competition for all interLATA services can improve consumer welfare.

60. AT&T states that the OCC allegations concerning "administrative problems" with the presubscription ordering process are before the Commission in CC Docket No. 83-1145 and before the DOJ. Furthermore, AT&T argues that the OCCs have been given precisely what they sought in their demands for technically equal access to local exchange facilities. AT&T states that the OCCs seek to continue receiving the non-premium discount to compensate them for alleged disparities in the transition process even after an end office is converted. AT&T states that the Commission has made it clear from the beginning that the non-premium discount completely offsets the claimed competitive advantage of premium access. AT&T states that the OCCs' complaints about state regulatory requirements are irrelevant since intrastate service is a state matter. AT&T agrees with the OCCs that state commissions have generally not provided discounts for non-premium access as steep as that established by this Commission, (noting that only 9 of the multiple LATA states allow the OCCs discounted access rates comparable to the interstate discount), but argues that this underscores its position that this Commission's discount is too large.

61. The BOCs argue that neither the OCC requests for discounted access rates nor their requests for alterations to the conversion plan are new. The BOCs state that they have made efforts to cluster end office conversions, with areas often corresponding to defined television markets, which should allow more efficient use of mass advertising. The BOCs also insist that the equal access service delivered to the OCCs is the same as that provided to AT&T. The BOCs dispute the OCC's assertion that the equal access process will have to be virtually complete before most OCC calls will use equal access facilities at both ends and with their related argument that a discount should continue until every call is guaranteed to use only equal access facilities. The BOCs state that the probability that a call will be carried over equal access facilities on both ends is far greater than the OCCs admit since they often resell AT&T WATS services. They also argue that the OCCs' calculation is based on the demonstrably false assumption that a call is as likely to go over one access line as another since most traffic is concentrated in metropolitan areas that are generally being converted first. US West asserts that the "value" criteria upon which the petition would rely in calculating the price of exchange access has little to do with the value of access; rather, it is based entirely on the perceived inability of certain OCCs to compete with AT&T even after the technical aspects of access have been fully equalized. With respect to OCC complaints about state regulation, US West adds that the OCCs do not make it clear what they want the Commission to do in this area since they do not request, nor do they make a showing to support, Commission preemption of state regulation of intrastate services.

62. Bell Atlantic states that errors are to be expected in a process as new and complex as equal access implementation and that many of these errors are caused by the OCCs. Bell Atlantic states that it rejects orders only when further processing is impossible and it has established a variety of checks to ensure that it processes orders correctly, including the provision of a list of presubscribed customers ten days after a request. NYNEX asserts that MCI's complaints about specific presubscription order processing problems are largely unsubstantiated and fail to acknowledge the legitimate and highly important operating company concern for accurate implementation of the end user's presubscription selection.

(c) Discussion.

63. The petitioners assert that there are technical and marketing problems associated with FGD, but do not directly request nor demonstrate the need for any specific relief. The petitioners do

not present any evidence that would support a claim that FGD does not satisfy the technical requirements of "equal access." The court declined to impose a stringent definition of "equal access" that would have demanded identical technical quality (*i.e.*, identical values for loss, noise, and echo, and identical possibility of blocking).[53] Instead, the court required only that any technical deviations be so slight as to be imperceptible to customers and that the same general service features be made available to all interexchange carriers upon conversion to equal access. The service features available include, among others, equality in the number of digits to be dialed, access from both rotary-type and tone-dialing telephones, answer supervision to enable the interexchange carriers to know when a call has been completed, and the provision of billing information. We have not sought to impose a different approach because, among other considerations, it places the inerexchange carriers on an equal competitive footing without imposing the unnecessary reconfiguration costs on the local exchange carriers that would be required if a standard requiring absolute technical equality were adopted.

64. The petitioners have not asked us to undertake any technical reevaluation of FGD, and we decline to initiate such a reevaluation here. However, we recently received a petition from TDX Systems, Inc., which alleges that there are serious, systematic operational difficulties with FGD services provided to OCCs that are not experienced by AT&T. We have issued a public notice on this petition and established a pleading cycle.[54] We will carefully review the record compiled in response to the TDX petition and take appropriate steps should its allegations prove to be substantiated.

65. The petitioners here appear to be presenting a different question from that raised in the TDX petition. The petitioners apparently argue that, even assuming access will be equal when all end offices have been converted, the conversion process has subjected the OCCs to handicaps that warrant a reevaluation of the price they pay for such access. If this is the case, the request for an investigation of the value of equal access is merely a repetition of the request that the discount phase-out formula be revised. As previously noted, we have carefully considered and rejected this request in two orders this year. The petitioners have not presented any new information that would provide any basis for changing that decision.

66. Furthermore, to the extent the petitioners are asking use to establish a discount for FGD access, we reject the request. Such a new discount would involve a pure subsidy to benefit the OCCs at the expense of AT&T and its subscribers and is inconsistent with the competitive marketplace. Only true competition can maximize the benefits to consumers in the form of lower prices and a greater variety of goods and services. Moreover, the notion that after equal access has been implemented local exchange carriers should use a value-of-service pricing concept in the provision of access service is a fundamental departure from our determination that access prices should move towards the cost of providing access services. Indeed, value-of-service pricing is inconsistent with a competitive marketplace, which, if freely allowed to operate, tends to drive prices toward costs. Finally, the use of any value-of-service concept to price access services would be impractical since the value of FGD to the recipient is impossible to measure and differs from one OCC to the next. Therefore, we decline to propose any discount for equal access services used by OCCs.

67. We believe it is time, in fact, for all parties to move beyond the question of revising the phase-out of the non-premium discount or establishing a discount for FGD. We believe that industry participants should focus there attention on ensuring that the equal access transition is carried out in an efficient and cost-effective manner. To the extent the carriers encounter serious difficulties, they should bring the specific problems to our attention. We will treat any such filings on a priority basis, and we are prepared, of couse, to adopt appropriate remedies for any legitimate grievances that may be presented. We have already addressed a number of transitional problems that were created by the customer presubscription process in several orders in CC Docket No. 83–1145. In particular, we have found that the routing of all default traffic to AT&T was unreasonable and discriminatory and prescribed instead a uniform allocation plan that because effective May 31, 1985.[55] In sum, we are firmly committed to acting in an expeditious fashion on the TDX petition on FGD access and any other pleadings raising specific issues concerning the equal access conversion process.

68. Finally, with respect to the allegations raised concerning state actions, petitioners have not explicitly asked for any preemptive action on our part, and the current record does not support our proposing any such action. Although the current interstate differential appears to be generally fair to all parties concerned, we recognize that our colleagues at the state level have had to grapple activity with these complex and difficult issues. We are heartened by the fact that a majority of states have permitted intrastate competition for long distance services on an interim or permanent basis. And we will continue to make clear our view that the trend towards fair competition will maximize benefits to all consumers.

III. Ordering Clauses

69. Accordingly, it is hereby ordered That the Joint Petition for Expedited Rulemaking requested by GTE Sprint Communications Corporation, US Telecom, Inc., Allnet Communication Services, Inc., and United States Transmission Systems, Inc. is granted to the extent indicated herein and otherwise denied.

70. Accordingly, it is ordered That parties may file comments on the proposals in this Notice on or before January 6, 1986, and reply comments on or before January 21, 1986.

71. For purposes of this non-restricted notice and comment rulemaking proceeding, members of the public are advised that *ex parte* contacts are permitted from the time the Commission adopts a notice of proposed rulemaking until the time a public notice is issued stating that a substantive disposition of the matter is to be considered at a forthcoming meeting, or until a final order disposing of the matter is adopted by the Commission, whichever comes earlier. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments/pleadings and formal oral arguments) between a person outside the Commission and a Commissioner or a member of the Commission's staff that addresses the mertis of the proceeding. Any person who submits a written *ex parte*

[53] *See U.S. v. Western Electric*, 569 F. Supp. at 1063.

[54] TDX Systems, Inc., Petition for Rulemaking, Public Notice, RM–5196, Mimeo No. 0470 (October 23, 1985). Comments were due November 20, 1985 and reply comments are due by December 5, 1985.

[55] We resolved a number of questions including, among others, the controlling indication of a customer choice, the retroactive allocation of customers converted prior to the default order, and the applicability of charges for customers requesting changes to their initial presubscription. *See* Investigation of Access and Divestiture Related Tariffs, Memorandum Opinion and Order, 50 FR 25982 (1985), *modified on reconsideration*, 50 FR 38200 (1985).

presentation must serve a copy of that presentation on the Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation addressing matters not fully covered in any previously filed written comments for the proceeding must prepare a written summary of that presentation; on the day of oral presentation, that written summary must be served on the Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation described above must state on its face that the Secretary has been served, and must also state by docket number the proceeding to which it relates.[56]

72. It is further ordered That the Secretary of the Federal Communications Commission shall effect publication of this Notice of Proposed Rulemaking in the **Federal Register**.[57]

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix A

The following parties submitted comments on the petition:

Alternative Carrier Telecommunications Association (ACTA)
American Satellite Company (ASC)
American Telephone and Telegraph Company (AT&T)
Ameritech Operating Companies (Ameritech)
Argo Communications Corp. (Argo)
Bell Atlantic Telephone Companies (Bell Atlantic)
BellSouth Corporation (BellSouth)
Communications Workers of America (CWA)
Competitive Telecommunications Association (CompTel)
Continental Telecom Inc. (Contel)
International Communications Association (ICA)
Lexitel Corporation (Lexitel)
MCI Telecommunications Corporation (MCI)
Michigan Public Service Commission (Michigan)
Mountain States Tel. and Tel. Co., Northwestern Bell Tel. Co. and Pacific Northwest Bell Telephone Company (US West)
National Telephone Cooperative Assoc. and Organization for the Protection and Advancement of Small Telephone Companies (NCTA and OPASTCO)
New England Tel. and Tel. Company and New York Tel. Co. (NYNEX)
Pacific Bell and Nevada Bell (Pacific)
RCA Communications Inc. (RCA)
Satellite Business Systems (SBS)
Southern New England Telephone Company (SNET)
Southwestern Bell Telephone Company (Southwestern Bell)
TDX Systems, Inc. (TDX)
Teltec Saving Communications Co. (Teltec)
United States Telephone Association (USTA)

The following parties submitted replies to the comments:

ACTA
AT&T
Bell Atlantic
Bell South
CompTel
Contel
GTE Sprint, US Telecom, Allnet and USTS
Lexitel
MCI
NYNEX
Pacific
SBS
US Telecom Supplemental Comments
US West

Statement of Chairman Mark S. Fowler

This Notice reflects once again this Commission's commitment to full and fair competition in the long distance telephone market. I am convinced that our pro-competitive policies have benefited both consumers, in the form of a wider variety of long distance services at lower prices, and the OCCs, in the form of discounted rates for non-premium access during the transition period and other measures, such as the allocation of customers that do not presubscribe to a long distance carrier.

As we have demonstrated today, we will continue to consider additional measures that are in the public interest and further the competitive process. In this order, we propose the waiver of certain non-recurring charges for trunk arrangements associated with the deployment of access tandems. We also propose a requirement that the BOCs provide certain information to the interexchange carriers that should be useful for marketing and engineering purposes. Furthermore, we will review the Bell Atlantic petition of 800 Service, the TDX petition of Feature Group D access, complaints about implementation of the equal access process, and any other filings that raise substantive or procedural questions concerning competition in the long distance marketplace on an expedited basis. The public interest demands nothing less

It is also clear that our goal of a fully competitive marketplace for the long distance services is not yet complete. As a result, we have retained full rate regulation of AT&T, made clear that any new service offering must be cost-justified, and required that AT&T must continue to provide service and offer any new services throughout the nation, and must geographically average its rates. This approach guarantees that all consumers, including those in rural areas, receive the benefits of competition. And it addresses a major concern raised by the petitioners concerning AT&T's pricing flexibility.

On the other hand, two of the petitioners' requests essentially are attempts to reconsider matters that have been carefully reviewed and decided by this Commission. We are strongly committed to as error-free a process as is humanly possible. But as Commissioner Dawson points out, where service ordering or any other problems arise, the solution is to cure them directly. The rules on access pricing during the transition to full competition were painstakingly crafted in the context of our MTS and WATS Market Structure Inquiry. This proceeding is one of the largest and most comprehensive efforts ever undertaken by a regulatory agency, spanning over 7 years. Throughout this process we have attempted to strike a delicate balance between a number of varied and competing interests. No need is made out here to revisit that balance.

Our policy is to permit competition by all who wish to try to serve the public. All are free to succeed or fail on the basis of their own foresight, skill and industry, and the wishes and desires of consumers. For out part, we recognize that the interexchange carriers other than AT&T need access to local networks equivalent in both price and quality to that afforded AT&T. At the same time, we do not confuse the needs of competitors with our responsibilities to promote competition. A strategy of trying to guarantee the success of all industry participants without regard to their relative efficiency or the economic costs consumers are forced to bear, besides being harmful to consumers, runs the risk of creating the appearance of competition without the reality. Handicapping doesn't benefit consumers—competition does.

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[56] *See generally*, § 1.1231 of the Commission's rules, 47 CFR 1.1231.

[57] The provisions of the Regulatory Flexibility Act (Pub. L. 96.354, 94 Stat. 1164) (September 19, 1980), 5 U.S.C. 601-612 (1984) are not applicable to this proceeding. *See* 5 U.S.C. 601 (1984). The Commission has found that local exchange carriers do not come within the Regulatory Flexibility Act's definition of a small entity. *Amendment of Part 67 of the Commission's Rules and Establishment of a Joint Board*, 96 I CC 2d 781, 810 (1984).

I believe that, as a result of our actions in the past and here today, the future of competition in the long distance telephone market is basically assured. The FCC is committed to taking all action needed to ensure a level playing field. In that context, we expect exchange carriers to make the equal access transition as smooth and fair as is humanly possible. We will expeditiously rule on all complaints about procedural impediments to fair competition. Indeed, all competitors in the long distance market would appear to have nothing to fear but competition itself. And consumers, including rural subscribers, have more and more choices—and nothing to fear at all.

[FR Doc. 85-29176 Filed 12-9-85; 8:45 am]
BILLING CODE 6712-01-M

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47 CFR Part 73

[Docket No. 21474; RM-1968; RM-2810; RM-2978; RM-3397; RM-3684; FCC 85-613]

Amendment of Broadcast Equal Employment Opportunity Rules and FCC Form 395

AGENCY: Federal Communications Commission.

ACTION: Withdrawal of Proposed rule.

SUMMARY: This Memorandum withdraws proposed changes in the Commission's rules and regulations regarding equal employment opportunities in the broadcasting industry. This action is taken in light of concerns raised by the Office of Management and Budget in its review of the Commission's broadcast EEO reporting requirements.

ADDRESS: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Marcia A. Glauberman, Mass Media Bureau, (202) 632-6302.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73

Television, AM radio, FM radio.

Memorandum Opinion and Order; Preceedings Terminated

In the Matter of, Amendment of Broadcast Equal Employment Opportunity Rules and FCC Form 395, Docket No. 21474, RM-1968, RM-2810, RM-2978; Petition for Rulemaking to Amend the Broadcast Network Affiliation Rules and Employment Practice Rules to Extend to Networks and Licensee Headquarters Employment Practice Requirements Now Mandated for Licensees; RM-3397; Petition for Institution of an Inquiry into the Equal Employment Opportunity Policies of the Federal Communications Commission, RM-3684.

Adopted: November 14, 1985.
Released: November 26, 1985.
By the Commission.

1. By this *Memorandum Opinion and Order*, the Commission is terminating the above-captioned proceedings. In a separate action today, the Commission is initiating a new proceeding concerning equal employment opportunity (EEO) policies for broadcast radio and television services. The new proceeding addresses matters raised by the Office of Management and Budget (OMB) in its review of the Commission's broadcast EEO reporting requirement.[1]

2. On November 9, 1977, the Commission initiated a rule making proceeding proposing amendments to its EEO rules and procedures.[2] On June 4, 1980, the Commission adopted a *Second Further Notice of Proposed Rulemaking (Second Notice)* in this proceeding.[3] This *Second Notice* proposed major modifications to the broadcast model EEO program and to the EEO filing requirements for broadcast applicants.[4] In the *Third Report and Order*, the Commission adopted minor modifications to its EEO forms and program as they affect major changes applicants, transferees and assignees, but deferred action on the major revisions it has proposed in the *Second Notice*.[5] These unresolved issues have remained pending before the Commission since the adoption of the *Third Report and Order* on June 16, 1981.

3. On June 13, 1979, the Citizens Communications Center filed a petition on behalf of several civil rights organizations requesting an extension of the Commission's EEO rules, policies and procedures to all broadcasting networks and to all headquarters organizations of multiple licensees.[6] The petition (RM-3397) proposed that these organizations be required to comply with the Commission's EEO rules and policies concerning nondiscriminatory employment practices and affirmative action plans and that they submit Annual Employment Reports (FCC Form 395). In a related action, the Commission transferred a pending proposal to implement a policy to promote minority oriented programming to this proceeding.[7] These matters are still pending before the Commission.

4. On May 30, 1980, the National Radio Broadcasters Association (NRBA) petitioned the Commission to institute an inquiry to review and revise those EEO procedures relating to the use of numerical guidelines for evaluating licensees' employment profiles. In its petition (RM-3684), the NRBA claims that the Commission's numerical guidelines have evolved into a quota system that broadcasters comply with in order to retain their license.[8] The Commission has not acted on this petition yet.

5. On August 26, 1981, OMB disapproved the routine use of the Commission's broadcast EEO program forms.[9] In taking this action, OMB stated that "such [data] collection would only be appropriate when a station appears to be engaged in discriminatory practices as determined from analyses based upon data submitted on the annual [Form] 395 report." OMB has granted a series of extensions to permit continued use of the EEO program reports. We believe that any further

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[1] *See Notice of Proposed Rulemaking* in MM Docket No. 85-350, November 14, 1985, FCC-85-609.

[2] *See Notice of Proposed Rule Making* in Docket No. 21474, 44 FR 60168 (1977).

[3] *See Second Further Notice of Proposed Rule Making*, Docket No. 21474, 45 FR 42729 (1980).

[4] These proposed revisions include changes to several of the elements of the model EEO program, modification of the guidelines for the model EEO program, expanded reporting requirements and some changes to the instructions that accompany the various EEO forms. In an earlier proceeding in this docket, the Commission declined to revise the Annual Employment Report, but did make some modifications to its instructions. *See First Report and Order* in Docket No. 21474, 44 FR 6722 (1979). The Commission also declined to modify its broadcast EEO rules to include handicapped persons. *See Second Report and Order* in Docket No. 21474, 45 FR 15229 (1980).

[5] *See Third Report and Order* in Docket No. 21474, 46 FR 35094 (1981).

[6] The petitioners included the National Association for the Advancement of Colored People, National Organization for Women, Media Reform Committee, Chinese for Affirmative Action, National Latino Media Coalition, National Congress of American Indians, National Association of Negro Business and Professional Women's Clubs, Inc., Black Citizens for a Fair Media, National Council of La Raza and National Black Media Coalation.

[7] This proposal was one of thirty-five proposals designed to enhance the position of Black Americans in all aspects of electronic mass communications contained in a petition for rule making filed by the National Black Media Coalition on October 5, 1979 (RM-3502). Among the actions taken regarding this petition, the Commission transferred this particular proposal to RM-3397 for consideration in conjunction with the related ongoing proceeding. *See Memorandum Opinion and Order* in RM-3502, 47 FR 2d 138 (1980).

[8] We believe that the question of the use of the processing guidelines has been adequately addressed in our *Report and Order* in Docket No. 85-61, 50 FR 40836 (October 7, 1985) concerning implementation of the EEO provisions of the Cable Communications Policy Act of 1984.

[9] Broadcast licensees currently are required to submit a description of their EEO program on FCC Form 396-A, the 5-point Model EEO Program report, as part of their application for a license for a new station or for an assignment of the license of an existing station. As part of their license renewal application, licensees are also required to file FCC Form 396, a 10-point version of the EEO program report that requests additional information concerning EEO activities during the licensee term.

action on broadcast EEO matters should be taken in the context of OMB's decision in its review of the program reporting forms. Therefore, in a separate action today, the Commission is initiating a new proceeding to consider its broadcast EEO policies and procedures in light of the concerns raised by OMB. We believe it is appropriate to address the pending broadcast EEO policy issues in the context of this new proceeding. On this basis we are terminating the pending broadcast EEO proceedings and denying the outstanding petitions for rule making in this area.

6. Accordingly, it is ordered that the above-captioned rule making proceedings are terminated. Furthermore, it is ordered that the petitions for rule making filed by Citizens Communications Center and the National Radio Broadcasters Association are denied.

7. This action is taken pursuant to authority contained in sections 4(i) and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 85-28640 Filed 12-9-85; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 50, No. 237
Tuesday, December 10, 1985

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Interchange of Administrative Jurisdiction of Department of the Air Force Lands and National Forest Lands; Chattahoochee-Oconee National Forest, GA, et al.

Correction

In FR Doc. 85-28295 beginning on page 48816, in the issue of Wednesday, November 27, 1985, on page 48817, second column under "*Louisiana Meridian*, T. 3 N., R. 3 W.," in the second, eleventh and seventeenth lines the word "Northest" should read, "Northeast".

BILLING CODE 1505-01-M

Packers and Stockyards Administration

Depositing of Stockyards; Pierce County Stockyard, Inc., et al.

It has been ascertained, and notice is hereby given, that the livestock markets named herein, originally posted on the respective dates specified below as being subject to the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*), no longer come within the definition of a stockyard under said Act and are, therefore, no longer subject to the provisions of the Act.

	Facility No., name, and location of stockyard	Date of posting
GA-110	Pierce County Stockyard, Inc., Blackshear, Georgia.	May 16, 1959.
MI-117	Northern Michigan Beef Breeders Association, Gaylord, Michigan.	Apr. 28, 1959.
NE-131	Franklin Livestock Market, Franklin, Nebraska.	Dec. 16, 1955.

Notice or other public procedure has not preceded promulgation of the foregoing rule. There is no legal justification for not promptly deposting a stockyard which is no longer within the definition of that term contained in the Act.

The foregoing is in the nature of a change relieving a restriction and may be made effective in less than 30 days after publication in the **Federal Register**. This notice shall become effective upon publication in the **Federal Register**.

(42 Stat. 159, as amended and supplemented; 7 U.S.C. 181 *et seq.*)

Done at Washington, DC, this 4th day of December 1985.

Harold W. Davis,

Director, Livestock Marketing Division.

[FR Doc. 85-29258 Filed 12-9-85; 8:45 am]

BILLING CODE 3210-02-M

Posted Stockyards; Western States Auction Sales, Inc., et al.

Pursuant to the authority delegated under the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*), it was ascertained that the livestock markets named below were stockyards within the definition of that term contained in section 302 of the Act, as amended (7 U.S.C. 202), and notice was given to the owners and to the public by posting notices at the stockyards as required by said section 302, on respective dates specified below.

	Facility No., name, and location of stockyard	Date of posting
AZ-113	Western States Auction Sales, Inc. Vail, Arizona.	Aug. 25, 1985.
GA-193	South Central Livestock, Inc. Fitzgerald, Georgia.	July 15, 1985.
KY-170	Lee City Livestock Co., Inc. Lee City, Kentucky.	July 15, 1985.
MS-161	Meadows Livestock Auction, Inc. Mize, Mississippi.	Sept. 9, 1985.
NC-153	Southeastern Livestock Market, Inc. Chadbourn, North Carolina.	Aug. 12, 1985.
SC-137	Chester Livestock Market, Inc. Chester, South Carolina.	July 15, 1985.
WY-114	Central Wyoming Livestock Exchange, Inc. Glenrock, Wyoming.	July 11, 1985.

Done at Washington, DC, this 4th day of December 1985.

Harold W. Davis,

Director, Livestock Marketing Division.

[FR Doc. 85-29256 Filed 12-9-85; 8:45 am]

BILLING CODE 3410-02-M

Proposed Posting of Stockyards; Martin's Dairy Stockyards, et al.

The Packers and Stockyards Administration, United States Department of Agriculture, has information that the livestock markets named below are stockyards as defined in section 302 of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 202), and should be made subject to the provisions of the Act.

CA-179 Martin's Dairy Stockyards Chino, California
KS-205 Ma Belle's, Inc., Linwood, Kansas
KS-206 Sunflower Horse Auction, Chapman, Kansas
MI-147 Northern Michigan Beef Breeders Association, Gaylord, Michigan
MN-182 Auction Livestock, Inc., Perham, Minnesota
MO-262 Phelps County Livestock Improvement Assn., St. James, Missouri
NY-166 Dairymen's Livestock Market, Inc., Madison, New York
PA-153 Green Acres Enterprises, Inc., d/b/a Green Acres Livestock Auction, Rossiter, Pennsylvania
SC-139 Dudley Auction, Pageland, South Carolina
VI-111 Roberts Livestock & Auctioneering-Sales & Auction Barn, Newport, Vermont

Notice is hereby given that pursuant to authority under the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*), it is proposed to designate the stockyards named above as posted stockyards subject to the provisions of the Act as provided in section 302 thereof.

Any person who wishes to submit written data, views, or arguments concerning the proposed designation, may do so by filing them with the Director, Livestock Marketing Division, Packers and Stockyards Administration, United States Department of Agriculture, Washington, DC 20250, by December 26, 1985.

All written submissions made pursuant to this notice shall be made available for public inspection in the office of the Director of the Livestock Marketing Division during normal business hours.

Done at Washington, DC, this 4th day of December 1985.

Harold W. Davis,

Director, Livestock Marketing Division.

[FR Doc. 85-29257 Filed 12-9-85; 8:45 am]

BILLING CODE 3410-02-KD-M

Soil Conservation Service

Vinton County Road #3 Critical Area Treatment RC&D Measure, OH

AGENCY: Soil Conservation Service, Agriculture.

ACTION: Notice of Finding of No Significant Impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Vinton County Road #3 RC&D Measure in Ohio.

FOR FURTHER INFORMATION CONTACT: Harry W. Oneth, State Conservationist, Soil Conservation Service, Federal Building, 200 North High Street, Room 522, Columbus, Ohio 43215, telephone: (614)-469-6962.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the projects will not cause significant local, regional, or national impact on the environment. As a result of these findings, Harry W. Oneth, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

This measure concerns a plan for critical area treatment along Vinton County Road #3 to stabilize a land slip that is a public safety hazard and erosion problem. Planned works of improvement include the installation of 350 feet of curtain drain, 400 feet of road ditch, and one acre of critical area seeding.

The Notice of Finding of NO Significant Impact (FONSI) has been forwarded to Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Harry W. Oneth.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program. Office of Management and Budget Circular A-95 regarding state and local clearinghouse review of federal and federally assisted programs and projects is applicable.)

Roger A. Hansen,

Deputy State Conservationist.

[FR Doc. 85-29224 Filed 12-9-85; 8:45 am]

BILLING CODE 3410-16-M

CENTRAL INTELLIGENCE AGENCY

Privacy Act of 1974; Elimination of a System of Records

AGENCY: Central Intelligence Agency.

ACTION: Privacy Act of 1974, Notification of Elimination of System of Records.

Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), the Central Intelligence Agency is eliminating a system of records entitled "Library Open Literature Ready Reference File" (CIA 42). The Agency is eliminating this system because it has become obsolete and is no longer being maintained in the Office of Central Reference. With the elimination of the system, the Agency will no longer be able to search for open source material in response to Privacy Act requests. Accordingly, the system, as published in the **Federal Register** on 22 September 1977 (42 FR 48050) and amended on 30 January 1980 (45 FR 6820), is removed from the Agency's compilation of Privacy Act systems.

Dated: November 29, 1985.

Harry E. Fitzwater,

Deputy Director for Administration.

[FR Doc. 85-29229 Filed 12-9-85; 8:45 am]

BILLING CODE 6310-02-M

DEPARTMENT OF COMMERCE

International Trade Administration

Consolidated Decision of Applications for Duty-Free Entry of Mass Spectrometers; Brown University, et al.

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 1523, U.S. Department of Commerce, 14th and Consititution Avenue, NW., Washington, DC.

Docket Number: 84-181R.

Applicant: Brown University, Providence, RI 02912. Original notice of this resubmitted application was published in the **Federal Register** of May 18, 1984.

Docket Number: 84-281.

Applicant: Research Foundation of SUNY, Albany, NY 12201.

Intended use: See notice at 49 FR 37136.

Instrument: Mass Spectrometer, MS-80.

Manufacturer: Kratos Analytical Instruments, United Kingdom.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instruments, for such purposes as the foreign instruments are intended to be used, is being manufactured in the United States.

Reasons: The foreign instruments provide: (1) A mass range of 1 to 2 400 atomic mass units at an accelerating potential of 4,000 electron volts, (2) a capillary/packed GC interface with a scan cycle time of 0.3 seconds per decade and (3) fast atom bombardment. The capabilities of the foreign instruments described above are pertinent to the applicants' intended purposes. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instruments for the applicants' intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc 29268 Filed 12-9-85; 8:45 am]

BILLING CODE 3510-DS-M

Consolidated Decision of Applications for Duty-Free Entry of Mass Spectrometers; NIH NIAAA, et al.

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 a.m. and 5:00 p.m. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 84-56.

Applicant: NIH/NIAAA, Bethesda, MD 20205.

Intended use: See notice at 49 FR 10138.

Docket Number: 84-111R.

Applicant: Medical College of Wisconsin, Milwaukee, WI 53226. Original notice of this resubmitted application was published in the **Federal Register** of April 6, 1984.

Instrument: Mass Spectrometer, MS–80.

Manufacturer: Kratos Analytical Instruments, United Kingdom.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instruments, for such purposes as the foreign instruments are intended to be used, is being manufactured in the United States.

Reasons: The foreign instruments provide: (1) A mass range of 1 to 2,400 atomic mass units at an accelerating potential of 4,000 electron volts, (2) a capillary/packed GC interface with a scan cycle time of 0.3 seconds per decade, (3) fast atom bombardment, and (4) collision-induced decomposition. The capabilities of the foreign instruments described above are pertinent to the applicants' intended purposes. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instruments for the applicants' intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

[FR Doc 29270 Filed 12–9–85; 8:45 am]

BILLING CODE 3510-DS-M

Decision on Application for Duty-Free Entry of Scientific Instrument; Cornell University

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 85–222.

Applicant: Cornell University, Ithaca, NY 14853.

Instrument: Laser, Model PLS 20.

Manufacturer: Opto-Electronics, Incorporated, Canada.

Intended use: See notice at 50 FR 28001.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides a 60 picosecond pulse width at a peak power of 30 mW at a wavelength of 850 nm. The capability of the foreign instrument described above is pertinent to the applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85–29269 Filed 12–9–85; 8:45 am]

BILLING CODE 3510-DS-M

Decision on Application for Duty-Free Entry of Scientific Instrument; University of California, Irvine

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 85–104.

Applicant: University of California, Irvine, Irvine, CA 92717.

Instrument: Electron Spectrometer System, Model ESCALAB MkII.

Manufacturer: VG Scientific, United Kingdom.

Intended use: See notice at 50 FR 11746.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides a monochromatic x-ray source and small spot size (0.2 micron) auger electron spectrometer. The capability of the foreign instrument described above is pertinent to the applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use at the time of order (September 27, 1984).

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85–29264 Filed 12–9–85; 8:45 am]

BILLING CODE 3510-DS-M

Decision on Application for Duty-Free Entry of Scientific Instrument; The University of Chicago

The decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–65, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 84–052R.

Applicant: The University of Chicago, Chicago, IL 60637.

Instrument: GC/Mass Spectrometer/Data System, Model 7250 EHF. Original notice of this resubmitted application was published in the **Federal Register** of January 27, 1984.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides: (1) A mass range of 1 to 2 600 atomic mass units at an accelerating potential of 6000 electron volts (2) a capillary/packed GC interface with a scan speed of 0.2 seconds per decade, (3) alternate CI/EI under computer control with a full cycle time less than one second and (4) fast atom bombardment. The capabilities of the foreign instrument described above are pertinent to the applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85–29266 Filed 12–9–85; 8:45 am]

BILLING CODE 3510-DS-M

Decision on Application for Duty-Free Entry of Scientific Instrument; University of Illinois, Urbana-Champaign Campus

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 196 (Pub. L. 89–651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 85-205.
Applicant: University of Illinois, Urbana-Champaign Campus, Urbana, IL 61801.
Instrument: NMR Superconducting Solenoid, Model 360-89.
Manufacturer: Oxford Instruments Company, United Kingdom.
Intended Use: See notice at 50 FR 26394.
Comments: None received.
Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.
Reasons: The foreign article will be used as an accessory for an existing NMR spectrometer and will provide an operating field of 8.4 tesla in the persistent mode. The capability of the foreign instrument described above is pertinent to the applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85-29267 Filed 12-9-85; 8:45 am]

BILLING CODE 3510-DS-M

Decision on Application for Duty-Free Entry of Scientific Instrument; Western Research Institute

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 84-279R.
Applicant: Western Research Institute, Laramie, WY 82070.
Instrument: Data System, Pyrolysis Probe & Desorption Chemical Ionization Probe. Original notice of this resubmitted application was published in the **Federal Register** of September 7, 1984.
Comments: None received.
Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.
Reasons: The application relates to compatible accessories for an instrument that has been previously imported for the use of the applicant institution. The articles are manufactured by the manufacturer which produced the instrument with which they are intended to be used. The accessories are pertinent to the applicant's intended uses and we know of no comparable domestic instruments or apparatus of equivalent scientific value to the foreign accessories for the applicant's intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85-29271 Filed 12-9-85; 8:45 am]

BILLING CODE 3510-DS-M

Decision on Application for Duty-Free Entry of Scientific Instrument; Yale University

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 85-044R.
Applicant: Yale University, New Haven, CT 06520.
Instrument: CO_2 Laser, Model TEA-601 with Accessories. Original notice of this resubmitted application was published in the **Federal Register** of January 8, 1985.
Comments: None received.
Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.
Reasons: The foreign instrument provides an energy output of 50J with a pulse width of 100 ns. The capability of the foreign instrument described above is pertinent to the applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 85-29265 Filed 12-9-85; 8:45 am]

BILLING CODE 3510-DS-M

[Case No. OEE-1-85]

Ivan Grinon; Order Temporarily Denying Export Privileges

The Office of Export Enforcement, International Trade Administration, United States Department of Commerce (Department), pursuant to the provisions of §388.19 of the Export Administration Regulations, 15 CFR Parts 368-399 (1985), as amended (50 FR 42866, October 21, 1985) (the Regulations), issued pursuant to the Export Administration Act of 1979, 50 U.S.C. app. 2401-2420 (1982), as amended by the Export Administration Amendments Act of 1985, Pub. L. 99-64, 99 Stat. 120 (July 12, 1985) (the Act), has asked the Deputy Assistant Secretary for Export Enforcement to issue an order temporarily denying all export privileges to Ivan Grinon (Grinon), Avda de Chile, 2-0 1-A, Barcelona 28, Spain.

The Department states that, as a result of an ongoing investigation, it has reason to believe that Ivan Grinon (Grinon) was employed by Suin, S.A. (Suin) as an engineer from January 3, 1976 to July 31, 1985. Suin and its owner, Carlos Mira Gallart (Mira), have specifically been the subjects of an order denying them all U.S. export privileges since October 14, 1982 (47 FR 47876, October 21, 1982). By its terms, the denial order also applies to all of Suin's employees. Accordingly, from October 14, 1982 to July 31, 1985, Grinon, as an employee of Suin, was subject to the provisions of the denial order.

The Department additionally states that it has reason to believe that, despite the prohibition in the denial order and contrary to the Regulations, Grinon acted in concert with Mira and others to effect the reexport of U.S.-origin integrated circuit manufacturing and testing equipment and related U.S.-origin technology from Spain to proscribed destinations without the required export licenses or reexport authorization from the Department.

The Department further states that it has reason to believe that, since leaving the employment of Suin on July 31, 1985, Grinon has actively sought work assignments that would involve reexports from Spain in violation of the Regulations. The Department believes that the general circumstances of Grinon's past activities in violation of both the denial order and the Regulations, coupled with his current active solicitation for job offers for substantially similar activities, demonstrate the likelihood of future violations unless action is taken on an expedited basis to preclude such

attempts. The Department submits that a temporary denial order naming Ivan Grinon is necessary in order to give notice to companies in the United States and abroad to cease dealing with Grinon in goods and technical data subject to the Regulations in order to reduce the likelihood that he will continue to engage in activities which are in violation of the Regulations.

Based upon the showing made by the Department, I find that an order temporarily denying all export privileges to Ivan Grinon and to any related party is necessary in the public interest to prevent an imminent violation of the Act and the Regulations. This order is issued on an *ex parte* basis without a hearing based on the Department's showing that expedited action is required.

Accordingly, it is hereby:

Ordered

I. All outstanding validated export licenses in which the respondent or any related party appears or participates, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Licensing for cancellation.

II. The respondent, his successors or assignees, officers, partners, representatives, agents, and employees hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported or to be exported from the United States, in whole or in part, or that are otherwise subject to the Regulations. Without limiting the generality of the foregoing, participating, either in the United States or abroad, shall include participation, directly or indirecly, in any manner or capacity: (a) As a party or as a representative of a party to a validated export license application, (b) in preparing or filing any export license application or reexport authorization, or any document to be submitted therewith, (c) in obtaining or using any validated or general export license or other export control document, (d) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported from the United States, or to be exported, and (e) in financing, forwarding, transporting, or other servicing of such commodities or technical data. Such denial of export privileges shall extend only to those commodities and technical data which are subject to the Act and the Regulations.

III. After notice and opportunity for comment, such denial may be made applicable to any person, firm, corporation, or business organization with which respondent is now or hereafter may be related by affiliation, ownership, control, position of responsibility, or other connection in the conduct of export trade or related services.

IV. No person, firm, corporation, partnership or other business organization, whether in the United States or elsewhere, without prior disclosure to and specific authorization from the Office of Export Licensing shall, with respect to U.S.-origin commodities and technical data, do any of the following acts, directly or indirectly or carry on negotiations with respect thereto, in any manner or capacity, on behalf of or in any association with the respondent or any related party, or whereby the respondent or any related party may obtain any benefit therefrom or have any interest or participation therein, directly or indirectly: (a) apply for, obtain, transfer, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to any export, reexport, transshipment, or diversion of any commodity or technical data exported in whole or in part, or to be exported by, to, or for the respondent or any related party denied export privileges; or (b) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate in any export, reexport, transshipment, or diversion of any commodity or technical data exported or to be exported from the United States.

V. In accordance with the provisions of § 388.19(e) of the Regulations, the respondent may, at any time, appeal this temporary denial order by filing with the Office of the Administrative Law Judges, U.S. Department of Commerce, Room H-6716, 14th Street and Constitution Avenue, NW., Washington, DC 20230, a full written statement in support of the appeal.

VI. This order is effective immediately and shall remain in effect for 60 days.

VII. In accordance with the provisions of § 388.19(d) of the Regulations, the Department may seek renewal of this temporary denial order by filing a written request not later than 20 days before the expiration date. The respondent may oppose any request to renew this temporary denial order by filing a written submission with the Deputy Assistant Secretary for Export Enforcement which must be received not later than seven days before the expiration date of this order.

A copy of this order and of Parts 387 and 388 of the Regulations shall be served upon the respondent.

Dated: December 3, 1985.

Theodore W. Wu,

Deputy Assistant Secretary for Export Enforcement.

[FR Doc. 85-29243 Filed 12-9-85; 8:45 am]

BILLING CODE 3510-25-M

[C-471-502]

Termination of Countervailing Duty Investigation; Carbon Steel Wire Rod from Portugal

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice.

SUMMARY: In a letter dated October 29, 1985, petitioners withdrew their antidumping and countervailing duty petitions, filed on April 8, 1985, on carbon steel wire rod (wire rod) from Portugal. On November 7, 1985, the International Trade Administration (ITC) terminated the antidumping duty investigation. We are now terminating the countervailing duty investigation.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Loc Nguyen or Mary Martin, Office of Investigations, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-0167, (202) 377-2830.

SUPPLEMENTARY INFORMATION:

Case History

On April 8, 1985, we received antidumping and countervailing duty petitions from Atlantic Steel Co., Continental Steel Corp. Georgetown Steel Corp., North Star Steel Texas, Inc., and Raritan River Steel Co., on behalf of the U.S. industry producing wire rod. After reviewing the petitions, we determined that they contained sufficient grounds upon which to initiate antidumping and countervailing duty investigations. We notified the ITC of our actions and initiated the investigations on April 29, 1985, (50 FR 18905 and 19065). On May 30, 1985, the ITC found that there was a reasonable indication that imports of wire rod from Portugal materially injure, or threaten material injury to, a United States industry (50 FR 23084).

On July 11, 1985, we published a negative preliminary determination in the countervailing duty investigation (50 FR 28232). On September 23, 1985, we published an affirmative preliminary

determination in the antidumping duty investigation (50 FR 38566). We stated that, if the investigation proceeded normally, we would make a final determination on the antidumping duty investigation by December 2, 1985. At petitioners' request, we extended the deadline for the final determination in the countervailing duty investigation to correspond with the date of the final determination in the antidumping investigation (50 FR 36129).

Scope of Investigations

The products under investigations is carbon steel wire rod, currently classifiable under item 607.17 of the *Tariff Schedules of the United States* (TSUS).

Withdrawal of Petitions

In a letter dated October 29, 1985, from Atlantic Steel Co., Continental Steel Corp., Georgetown Steel Corp., North Star Steel Texas, Inc., and Raritan River Steel Co., petitioners, notified us that they were withdrawing their April 8, 1985, antidumping and countervailing duty petitions, and requested that the investigations be terminated. A copy of petitioners' letter is appended to this notice. Under sections 734(a) and 704(a) of the Tariff Act of 1930, as amended by section 604 of the Trade and Tariff Act of 1984 (the Act), upon withdrawal of a petition, the administering authorities may terminate an investigation after giving notice to all parties to the investigation. On November 7, 1985, the ITC terminated the antidumping duty investigation. The withdrawal of the countervailing duty petition is based on a bilateral arrangement with the Government of Portugal, signed on November 29, 1985, to limit the volume of imports of this product. We have assessed the public interest factors set out in section 704(a) of the Act and consulted with potentially affected producers, workers, consuming industries, and with the ITC. On the basis of our assessment of the public interest factors and our consultations, we have determined that termination of the countervailing duty investigation would be in the public interest.

We have notified all parties to the investigation and the ITC of petitioners' withdrawal and our intention to terminate. For these reasons, we are terminating our countervailing duty investigation.

December 2, 1985.

Gilbert B. Kaplan,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 85-29244 Filed 12-9-85; 8:45 am]

BILLING CODE 3510-DS-M

Minority Business Development Agency

Financial Assistance Applications; District of Columbia

December 2, 1985

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Notice.

SUMMARY: The Minority Business Development Agency (MBDA) announces that it is soliciting competitive applications under its Minority Business Development Center (MBDC) Program to operate an MBDC for a 3 year period, subject to available funds. The cost of performance for the first 12 months is estimated at $764,706 for the project performance of April 1, 1986 to March 31, 1987. The MBDC will operate in the Washington, D.C. Metropolitan Statistical Area (MSA). The first year cost for the MBDC will consist of $650,000 in Federal funds and a minimum of $114,706 in non-federal funds (which can be a combination of cash, in-kind contribution and fees for services).

The funding instrument for the MBDC will be a cooperative agreement and competition is open to individuals, nonprofit and for-profit organizations, local and state governments, American Indian tribes and educational institutions.

The MBDC will provide management and technical assistance to eligible clients for the establishment and operation of businesses. The MBDC program is designed to assist those minority businesses that have the highest potential for success. In order to accomplish this, MBDA supports MBDC programs that can: coordinate and broker public and private sector resources on behalf of minority individuals and firms; offer them a full range of management and technical assistance; and serve as a conduit of information and assistance regarding minority business.

Applications will be judged on the experience and capability of the firm and its staff in addressing the needs of minority business individuals and organizations; the resources available to the firm in providing management and technical assistance; the firm's proposed approach to performing the work requirements included in the application; and the firm's estimated cost for providing such assistance. It is advisable that applicants have an existing office in the geographic region for which they are applying.

The MBDC will operate for a 3 year period with periodic reviews culminating in annual evaluations to determine if funding for the project should continue. Continued funding will be at the discretion of MBDA based on such factors as an MBDC's satisfactory performance, the availability of funds, and Agency priorities.

CLOSING DATE: The closing date for applications is January 6, 1986 Applications must be postmarked on or before 5 p.m. January 6, 1986.

ADDRESS: Minority Business Development Agency, Washington Regional Office, Room 6711 H.C. Hoover Building, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Willie J. Williams, Regional Director Washington Regional Office; (202) 377-8275.

SUPPLEMENTARY INFORMATION: Questions concerning the preceding information, copies of application kits and applicable regulations can be obtained at the above address.

(11.800 Minority Business Development (Catalog of Federal Domestic Assistance))

Dated: December 2, 1985

Willie J. Williams,

Regional Director, Washington Regional Office.

[FR Doc. 85-29227 Filed 12-9-85; 8:45 am]

BILLING CODE 3510-21-M

National Oceanic and Atmospheric Administration

Marine Mammals; Application for Permit: Deborah A. Glockner-Ferrari and Mark J. Ferrari

Notice is hereby given that an Applicant has applied in due form for a Permit to take marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), the Endangered Species Act of 1973 (16 U.S.C. 1531-1544), and the National Marine Fisheries Service regulations governing endangered fish and wildlife permits (50 CFR Parts 217-222).

1. Applicant:

a. Name: Deborah A. Glockner-Ferrari and Mark J. Ferrari (P171A).

b. Address: 1728 San Luis Road, Walnut Creek, California 94596.

2. Type of Permit: Scientific Research/Scientific Purposes.

3. Name and Number of Marine Mammals: Humpback whale (Megaptera novaengliae) unspecified number of the North Pacific population will be inadvertently harassed during population studies using photographic techniques.

4. Location of Activity: Hawaii, Alaska and California.

5. Period of Activity: 5 years.

Concurrent with the publication of this notice in the Federal Register, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, Washington, DC 20235, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries.

All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the National Marne Fisheries Service.

Documents submitted in connection with the above application are available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, NW., Washington, DC; and

Regional Director, Alaska Region, National Marine Fisheries Service, P.O. Box 1668, Juneau, Alaska 99802;

Regional Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way, NE., CIN C15700, Seattle, Washington 98115; and

Regional Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, California 90731.

Dated: December 2, 1985.

Carmen J. Blondin,

Deputy Assistant Administrator for Fisheries Resource Management, National Marine Fisheries Service.

[FR Doc. 85-29245 Filed 12-9-85; 8:45]

BILLING CODE 3510-22-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Strategic Defense Initiative Advisory Committee; Meetings

ACTION: Notice of advisory committee meetings.

SUMMARY: The Strategic Defense Initiative (SDI) Advisory Committee will meet in closed session, in Patrick AFB, Florida, on January 8–9–10, 1986.

The mission of the SDI Advisory Committee is to advise the Secretary of Defense and the Director, Strategic Defense Initiative Organization on scientific and technical matters as they affect the perceived needs of the Department of Defense. At the meeting on January 8–9–10, 1986 the committee will discuss status of SDI research and management issues.

In accordance with section 10(d) of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C., App II, (1982)), it has been determined that this SDI Advisory Committee meeting concerns matters listed in 5 U.S.C., 552b(c)(1) (1982), and that accordingly this meeting will be closed to the public.

Dated: December 4, 1985.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 85-29262 Filed 12-9-85; 8:45 am]

BILLING CODE 3810-01-M

Department of the Air Force

Privacy Act of 1974; New and Altered Air Force Records Systems

AGENCY: Department of the Air Force (DAF), DoD.

ACTION: Notice of new record system and alteration of another system.

SUMMARY: The Air Force is adding a new record system and altering an existing one.

DATE: The proposed action will be effective without further notice January 9, 1986 unless comments are received which would result in a contrary determination.

ADDRESS: Send comments to Mr. John Updike, HQ USAF/DAQD, The Pentagon, Washington, DC 20330–5024. Telephone: 202/694–3431, Autovon: 224–3431.

SUPPLEMENTARY INFORMATION: The Department of the Air Force systems of records notices subject to the Privacy Act of 1974, as amended, (5 U.S.C. 552a) have been previously published in the Federal Register as follows:

FR Doc. 85–10237 (50 FR 22332) May 29 1985
FR Doc. 85–14122 (50 FR 24672) June 12, 1985
FR Doc. 85–15062 (50 FR 25737) June 21, 1985
FR Doc. 85–26775 (50 FR 46477) November 8, 1985

The record system identified as F050 ATC J is a new record system. The record system identified as F050 AFCC C is an altered system that was previously published on May 29, 1985, at 50 FR 22444. The altered record system is being automated to provide for increased economy of operation with improved accuracy. The Engineering Installation Academy and EI organizations are also being added as locations for the system. A new and altered system report, as required by 5 U.S.C. 552a (o), was submitted on October 22, 1985, pursuant to OMB Circular A–108, Transmittal Memorandum No. 1, dated September 30, 1975 and Transmittal Memorandum No. 3, dated May 17, 1976.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

December 5, 1985

F050 ATC J

SYSTEM NAME:

050 ATC J Branch Level Training Management System (BLTMS).

SYSTEM LOCATION:

All Technical Training Centers of Air Training Command (ATC). Official mailing addresses are in the Air Force Address Director, AFP 12–36, attachment 3.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty military personnel, U.S. government civilian employees, Air Force Reserve and Air National Guard personnel, foreign nationals, and retired or separated Air Force personnel who are attending or have attended a resident training course conducted at one of the Technical Training Centers within the past two years.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records of individual training and education. (1) The ATC Student Records of Training consists of background and test scores. (2) The Graduate Evaluation Master File contains units of assignment or graduates and individual and supervisory responses to training effectiveness questionnaires.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8012, Secretary of the Air Force: Powers and duties; delegation by. (1) Air Training Command Regulation (ATCR) 52–3, Student Measurement; ATCR 52–26, Student Scheduling and Administration; and ATCR 35301, Student Flow Management. (2) Air Force Regulation (AFR) 5038, Field Evaluation of Education and Training Programs.

PURPOSE(S)

(1) To record individual attendance, achievement, and training progress. Provides the data base for producing

summary reports for managing the flow of students through training and the evaluation of training adequacy. Information extracted from these records is provided to the Personnel Data System (PDS) for reporting course completion and changes to assignment availability date, and to the Community College of the Air Force (CCAF) for student's education records. (2) To perform required evaluation of the technical training received by graduates.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Records from this system of records may be disclosed for any of the blanket routine uses published by the Air Force.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored on computer and computer output products.

RETRIEVABILITY:

Retrieved by name or Social Security Number (SSN).

SAFEGUARD:

Records are accessed by authorized personnel who are properly screened and cleared for need-to-know and by those responsible for servicing the record system in the performance of their official duties. Computer records and equipment are kept in lockable offices and access to the computer records is controlled by computer software which includes userids and passwords.

RETENTION AND DISPOSAL:

Records are destroyed two years after information is entered into the Pipeline Management System which is part of PDS.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff for Technical Training, Standards and Policy Directorate, Headquarters Air Training Command, Randolph AFB, TX 78150. (1) The System Manager for a base is the Technical Training Wing, Operations Division, Registrar Branch. (2) The System Manager for a base is the Technical Training Wing, Training Evaluation Division.

NOTIFICATION PROCEDURE:

Requests from individuals should be sent to the System Manager.

RECORD ACCESS PROCEDURES:

Individuals can obtain assistance in gaining access from the local base System Manager.

CONTESTING RECORDS PROCEDURES:

The Air Force's rules for access to records and for contesting and appealing initial determinations by the individual concerned may be obtained from the System Manager and are published in Air Force Regulation 12–35.

RECORD SOURCE CATEGORIES:

Information is obtained from the Personnel Data System for Training (PDST), personnel records, training records, or the individual. (1) Tests and instructor observations. (2) Responses to training effectiveness questionnaires.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

F050 AFCC C

SYSTEM NAME:

050 AFCC C Individual Academic Training Record.

SYSTEM LOCATION:

AFCC System Evaluation School, 1815 Test and Evaluation Squadron (AFCC), Wright-Patterson AFB, OH 45433; AFCC Radar Evaluation School, Hill AFB, UT 84056; AFCC Engineer Installation Academy, Engineering Installation Center, Tinker AFB, OK 73145; Engineering Installation organizations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty of military, Air Force Reserve, Air National Guard, Army National Guard, and Department of Defense civilian personnel, and others who apply for this training.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personnel index; absentee report; class pre-graduation/graduation roster; attendance record; student questionnaires, individual academic standing; record of individual training.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8012, Secretary of the Air Force: Powers and duties; delegation by.

PURPOSE(S):

To record emergency data and course completion information and report student absences to the school commandant.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Records from this system of records may be disclosed for any of the blanket routine uses published by the Air Force.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders and card files, and on computer and computer output products.

RETRIEVABILITY:

Filed by student name.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties. Stored in file cabinet. Automated records are controlled by computer system software.

RETENTION AND DISPOSAL:

Retained for ten years after individual completes or discontinues training course. Records of individual training at EI organizations are retained until individual no longer performs EI duties, then are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Commandant, AFCC Systems Evaluation School, 1815 Test and Evaluation Squadron, Wright-Patterson Air Force Base, OH 45433; Commandant AFCC Radar Evaluation School, Hill Air Force Base, UT 84056; Commandant, AFCC EI Academy, Engineering Installation Center, Tinker AFB OK 73145.

NOTIFICATION PROCEDURE:

Requests from individuals should be addressed to the System Manager.

RECORD ACCESS PROCEDURES:

Individual can obtain assistance in gaining access from the System Manager.

CONTESTING RECORD PROCEDURES:

The Air Force's rules for access to records and for contesting and appealing initial determinations by the individual concerned may be obtained from the System Manager.

RECORD SOURCE CATEGORIES:

Information from individuals and instructor.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 85–29261 Filed 12–9–85; 8:45 am]

BILLING CODE 3810–01–M

Defense Contract Audit Agency

Privacy Act of 1974; Addition of a New DCAA Record System

AGENCY: Defense Contract Audit Agency (DCA), DoD.

ACTION: Notice of a new record system.

SUMMARY: The Defense Contract Audit Agency is giving notice of the addition of a new system of records subject to the Privacy Act of 1974, as amended, (5 U.S.C. 552a).

DATES: The proposed action will be effective without further notice January 9, 1986, unless comments are received which would result in a contrary determination.

ADDRESS: Send any comments to Mr. John van Santen, Assistant Director, Resources, Cameron Station, Alexandria, VA 22304–6178. Telephone: 202/274–7308, Autovon: 284–7308.

SUPPLEMENTARY INFORMATION: The Defense Contract Audit Agency systems of records notices subject to the Privacy Act of 1974, as amended, (5 U.S.C. 552a) have been previously published in the **Federal Register** as follows:

[FR Doc. 85–10237 (50 FR 22884) May 29, 1985

A new system report, as required by 5 U.S.C. 552a(o), was submitted on October 30, 1985, pursuant to OMB Circular A–108, Transmittal Memorandum No. 1, dated September 30, 1975 and Transmittal Memorandum No. 3, dated May 17, 1976.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

December 5, 1985.

RDCAA 152.22

SYSTEM NAME:

152.22 Classified Information Nondisclosure Agreement (NdA).

SYSTEM LOCATION:

Agency Security Officer, Defense Contract Audit Agency, Headquarters, DCAA, Cameron Station, Alexandria, VA 22304–6178.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All employees of DCAA assigned to sensitive postions who are authorized access to classified information.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains original of SF 189, Classified Information Nondisclosure Agreement signed by DCAA employees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order 12356; Sections 641, 793, 794, 798, and 952 of Title 18, U.S. Code; Section 783(b) of Title 50, U.S. Code, and Intelligence Identities Protection Act of 1982.

PURPOSE(S):

To maintain a record of signed Standard Forms 189 which are used as a condition precedent to authorizing individuals access to classified information. The use of the form will enhance the protection of national security information and/or will reduce the costs associated with its protection.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See blanket routine uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

Alphabetically by surname of individual.

SAFEGUARDS:

Records are accessible only by authorized personnel who are properly cleared and trained and who require access in connection with their official duties. Records are stored in locked filing cabinets after normal business hours.

RETENTION AND DISPOSAL:

Records are retained for 50 years from date of signature and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Agency Security Officer, DCAA, Headquarters, DCAA, Cameron Station Alexandria, VA 22304–6178.

NOTIFICATION PROCEDURE:

Information may be obtained from the Records Administrator, Defense Contract Audit Agency, Cameron Station, Alexanderia, VA 22304–6178, telephone (202) 274–7288.

RECORD ACCESS PROCEDURE:

Requests from individuals should be addressed to the Record Administrator, Defense Contract Audit Agency, Cameron Station, Alexandria, VA 22304–6178.

Written requests for information should contain the full name of the individual, current address, and telephone number and current business address. Visits are limited to those offices (Headquarters and six regional offices) listed in the DoD directory in the appendix to DCAA system notices.

For personal visits, the individual should be able to provide some acceptable identification, that is, driver's license or employing office identification card.

CONTESTING RECORD PROCEDURES:

The Agency's rules for contesting contents and appealing initial determinations may be obtained from the Records Administrator, Defense Contract Audit Agency, Cameron Station, Alexandria, VA 22304–6178.

RECORD SOURCE CATEGORIES:

Agency Security Officer, Headquarters, DCAA.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 85–29260 Filed 12–9–85; 8:45 am]

BILLING CODE 3810–01–M

DELAWARE RIVER BASIN COMMISSION

Commission Meeting and Public Hearing

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday, December 18, 1985 beginning at 1:30 p.m. in the Jefferson Room of the Holiday Inn at 4th and Arch Streets, Philadelphia, Pennsylvania. The hearing will be a part of the Commission's regular business meeting which is open to the public.

An informal pre-meeting conference among the Commissioners and staff will be open for public observation at about 11:00 a.m. at the same location.

Applications for Approval of the Following Projects Pursuant to Article 10.3, Article 11 and/or Section 3.8 of the Compact:

1. *Holdover Project—Philadelphia Park (formerly Keystone Racetrack) D–85–72.* A ground water withdrawal project to supply up to 0.35 million gallons per day (mgd) of water to the irrigation system for Philadelphia Park. The total withdrawal from Well Nos. 1, 2, 3, and 4 will be 0.35 mgd. The project is located in Bensalem Township, Bucks County, Pennsylvania. This hearing continues that of November 26, 1985.

2. *Douglas Zee T/A Zee Orchards, Inc. D–80–33 RENEWAL.* An application for the renewal of a ground water withdrawal project to supply a maximum of 26.5 million gallons (mg)/30 days of water for irrigation of the application's farm crops in Harrison Township, Gloucester County, New Jersey. The water will be used to irrigate approximately 440 acres of apples and peaches.

3. *Warrington Township Municipal Authority D–80–50 CP (Revised RENEWAL.* An application to modify the pumping level limit used to control the operation of the applicant's Well No. 5 in Warrington Township, Bucks County, Pennsylvania. The applicant has requested approval to allow more drawdown in the well by increasing the water level limit from 66 feet below the top of the casing to 100 feet. No increase in the approved withdrawal of up to 0.226 mgd is requested. The project well is located in the Southeastern Pennsylvania Ground Water Protected Area.

4. *Media Borough Water Company D–85–29 CP.* An application by the Borough of Media to increase the withdrawal of water from Chester Creek in Delaware County, Pennsylvania. Media currently has permits from Pennsylvania to withdraw 3.0 mgd from Chester Creek and 3.0 mgd from Ridley Creek. The application requested approval to increase the permitted withdrawal from Chester Creek to 6.0 mgd.

5. *The Eastern Foundry Company D–85–80.* A ground water withdrawal project to replace water from Well No. 1 which has become an unreliable source of supply and has been sealed. The proposed withdrawal from the new Well No. 1A will average 0.12 mgd. The project is located in Boyertown Borough, Berks County, Pennsylvania.

Documents relating to these projects may be examined at the Commission's offices. Preliminary dockets are available in single copies upon request. Please contact David B. Everett. Persons wishing to testify at this hearing are requested to register with the Secretary prior to the hearing.

Susan M. Weisman,

Secretary.

December 3, 1985.

[FR Doc. 85–29212 Filed 12–9–85; 8:45 am]

BILLING CODE 6360–01–M

DEPARTMENT OF EDUCATION

Proposed Information Collection Requests by the Office of Management and Budget

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Deputy Under Secretary for Management invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATE: Interested persons are invited to submit comments on or before January 9, 1986.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place, NW., Room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Margaret B. Webster, Department of Education, 400 Maryland Avenue, SW., Room 4074, Switzer Building, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Margaret B. Webster (202) 426–7304.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations.

The Deputy Under Secretary for Management publishes this notice containing proposed information collection requests prior to the submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Agency form number (if any); (4) Frequency of the collection; (5) The affected public; (6) Reporting burden; and/or (7) Recordkeeping burden; and (8) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Margaret Webster at the address specified above.

Dated: December 5, 1985.

Ralph J. Olmo,

Acting Deputy Under Secretary for Management.

Office of Postsecondary Education

Type of Review Requested: Extension.

Title: Loan Transfer Statement for the Federal Student Loan Program.

Agency Form Number: ED 1074.

Frequency: On occasion.

Affected Public: Businesses or other for-profit.

Reporting Burden: Responses: 14,000, Burden Hours: 14,000.

Recordkeeping Burden: Recordkeepers: 14,000, Burden Hours: 7,000.

ABSTRACT: This form is used to report the selling and buying of loans by lenders in the Federal Insured Student Loan Program. Both lenders must complete the document and forward it to the Department. The Department uses the information on this form to determine which lender holds a particular loan and should receive interest and special allowance payments for that loan.

Office for Civil Rights

Type of Review Requested: Reinstatement.

Title: 1986 Elementary and Secondary School Civil Rights Survey.

Agency Form Number: ED 101 and ED 102.

Frequency: Biennially.

Affected Public: State or local governments.

Reporting Burden: Responses: 37,500, Burden Hours: 241,500.

Recordkeeping Burden: Recordkeepers: 37,500, Burden Hours: 6,000.

ABSTRACT: The survey data are used in making preliminary targeting determinations for compliance review sites. The affected public is the school districts and individual schools which provide the data.

[FR Doc. 85–29211 Filed 12–9–85; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Intent To Grant Partially Exclusive Patent License

Notice is hereby given to an intent to grant to Windtech Inc. of Glastonbury, Connecticut, a partially exclusive license to practice in the United States the invention described in U.S. Patent No. 4,083,651, entitled "Wind Turbine with Automatic Pitch and Yaw Control". The patent is owned by the United States of America, as represented by the Department of Energy (DOE).

The proposed license will be exclusive, but limited to the field of use of wind turbines in the generation range greater than 100 kilowatts, and subject to a license and other rights retained by the U.S. Government. DOE intends to grant the license, upon a final determination in accordance with 35 U.S.C. 209(c), unless within 60 days of this notice the Assistant General Counsel for Patents, Department of Energy, Washington, DC 20585, receives in writing any of the following, together with supporting documents:

(i) A statement from any person setting forth reasons why it would not

be in the best interest of the United States to grant the proposed license; or

(ii) An application for a nonexclusive license to the invention in the United States, in which applicant states that he has already brought the invention to practical application or is likely to bring the invention to practical application expeditiously in the field of use of wind turbines in the generation range greater than 100 kilowatts.

The Department will review all written responses to this notice, and will grant the license if, after expiration of the 60-day notice period, and after consideration of written responses to this notice, a determination is made, in accordance with 35 U.S.C. 209(c), that the license grant is in the public interest.

Issued in Washington, DC, on December 2, 1985.

J. Michael Farrell,

General Counsel.

[FR Doc. 85-29289 Filed 12-9-85; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

[ERA Docket No. 85-38-NG]

Yankee International Co.; Application To Export Natural Gas to Canada

AGENCY: Department of Energy, Economic Regulatory Administration.

ACTION: Notice of Application For Authorization to Export Natural Gas to Canada on a Short-Term Basis.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice of receipt on December 5, 1985, of an application filed by Yankee International Company (Yankee) for authorization to export up to 50 MMcf per day for a total of up to 2 Bcf of natural gas to Canada from the date of approval through April 30, 1986. The natural gas will be purchased by Yankee from various suppliers principally located in the states of Oklahoma and Kansas and resold to Union Gas, Ltd. (Union) at the U.S./Canadian border. Union is a local distribution company located in the province of Ontario, Canada, serving the cities of Hamilton and Windsor. Yankee has requested expedited treatment of its application given the immediate, seasonal nature of its proposed project.

The application was filed with the ERA pursuant to Section 3 of the Natural Gas Act and Delegation Order No. 0204-111. Protests, motions to intervene, notices of intervention, and written comments are invited.

DATE: Protests, motions to intervene or notices of intervention, as applicable, and written comments are to be filed no later than 4:30 p.m., on December 26, 1985.

FOR FURTHER INFORMATION CONTACT:

John Glynn, Natural Gas Division, Economic Regulatory Administration, Forrestal Building, Room GA-076, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 252-9482

Diane Stubbs, Office of General Counsel, Natural Gas and Mineral Leasing, U.S. Department of Energy, Forrestal Building, Room 6E-042, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 252-6667

SUPPLEMENTARY INFORMATION: On December 5, 1985, Yankee, a wholly-owned subsidiary of the Yankee Gas Company, which itself is a wholly-owned subsidiary of the Yankee Companies, Inc., filed an application for authorization to export up to 50 MMcf of natural gas per day and a maximum of 2 Bcf for a term ending April 30, 1986. Yankee, a marketer of natural gas supplies acting as agent on behalf of both the U.S. producers and Canadian purchaser, will purchase natural gas from various suppliers located principally in the states of Oklahoma and Kansas. Yankee will then resell these supplies to Union, an Ontario gas distributor, at the international border between the U.S. and Canada in the vicinity of Windsor, Ontario.

Under the proposed export arrangement, Yankee will sell gas to Union on a best-efforts basis, with title passing upon delivery at the border. The sales price, which is fixed for the term of the arrangement, will be $2.45 (U.S.) per MMBtu at the delivery point. The proposed transaction will utilize existing pipeline facilities in both the U.S. and Canada. Yankee states that it will arrange for Panhandle Eastern Pipeline Company to transport the natural gas from its suppliers to the delivery point on a best-efforts basis under established tariffs on file at the Federal Energy Regulatory Commission (FERC).

In support of its application, Yankee states that the proposed export of natural gas is not inconsistent with the public interest. Yankee states that the ERA's principal consideration in determing whether a proposed export is in the public interest is whether there is a domestic need for the gas to be exported, and that a gas supply surplus currently exists in the U.S. Moreover, Yankee maintains that this situation will not change over the term of the proposed export given the short-term nature of the proposed arrangement. Yankee also states that the project will have no potential environmental impacts due to the fact that no new facilities will be constructed for the proposed project.

In making its request for expedited treatment of its export application, Yankee states that prompt ERA action will serve both the national and regional public interest. Yankee cites three reasons why prompt ERA action is necessary in its export request: (1) The arrangement is designed specifically for the 1985-86 winter season; (2) the export would work to alleviate a severe surplus of gas in the states supplying this gas; and (3) the project will reduce the U.S. foreign trade deficit. Because of the need to provide the gas during the winter heating season, the ERA has determined that the public interest will be served by reducing the public comment period to 15 days.

The decision on this application will be made consistent with section 3 of the Natural Gas Act and DOE Delegation Order No. 0204-111, under which domestic need for the gas to be exported is the primary consideration in determining whether it is in the public interest. Parties that may oppose this application should address in their comments whether there is a national or regional domestic need for the gas supply proposed to be exported.

Other Information

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate procedural action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR Part 590. They should be filed with the Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Room GA-076-A, RG-23, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585. They must be filed no later than 4:30 p.m., December 26, 1985.

The Administrator intends to develop a decisional record on the application through responses to this notice by

parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures by provided, such as additional written comments, an oral presentation, a conference, or a trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, the ERA will provide notice to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Yankee's application is available for inspection and copying in the Natural Gas Division Docket Room GA-076-A at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Issued in Washington, DC, December 6, 1985.

Robert L. Davies,

Acting Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 85-29341 Filed 12-9-85; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. CI83-269-000, et al.]

Tenneco Oil Co., et al.; Cancellation of Quarterly Status Conferences

November 20, 1985.

In the September 26, 1984 order in this proceeding,[1] the Commission required special marketing program (SMP) certificate holders to attend quarterly meetings. The Commission also incorporated that requirement in all subsequent SMP orders. These meetings were designed to permit interested persons and staff to discuss the operation of each SMP and to inform the Commission of any difficulties in the programs. These programs terminated on October 31, 1985, in accordance with the September 26, 1984 order and the order in *Maryland People's Counsel* v. *FERC*, 761 F.2d 768 (D.C. Cir. 1985). Accordingly, we consider the final quarterly meetings to be unnecessary. If any such meetings are deemed necessary, the Commission will notice such meetings in the **Federal Register.**

The Commission is cancelling the final quarterly SMP conferences. However, SMP certificate holders remain obligated to file the final monthly report covering October 1985 transactions and to satisfy all reporting requirements set forth in the September 26 order.

By direction of the Commission.

Kenneth F. Plumb,

Secretary.

[FR Doc. 85-29310 Filed 12-9-85; 8:45 am]

BILLING CODE 6717-01-M

[1] Order Amending Certificates of Public Convenience and Necessity, Extending Limited-Term Abandonments, and Establishing Procedures, 28 FERC ¶ 61,383.

ENVIRONMENTAL PROTECTION AGENCY

[A-9-FRL-2936-5; EPA Project No. SAC 84-01]

Approval of Prevention of Significant Air Quality Deterioration (PSD) Permit to Greenleaf Power Corp.

AGENCY: Environmental Protection Agency (EPA), Region 9.

ACTION: Notice.

SUMMARY: Notice is hereby given that on April 18, 1985 the Environmental Protection Agency issued a PSD permit under EPA's federal regulations 40 CFR 52.21 to the applicant named above. The PSD permit grants approval to construct a gas-fired cogeneration power plant in Putnam Parcel, six miles northwest of Yuba City, Sutter County, California. The plant will consist of a natural gas-fired turbine and exhaust heat recovery system, HRSG duct burners, and a wood chip dryer. The permit is subject to certain conditions, including an allowable emission rate as follows: NO_x at 97.4 lbs/hr, CO at 28 lbs/hr, and particulate matter at 8.7 lbs/hr.

FOR FURTHER INFORMATION: Copies of the permit are available for public inspection upon request; address request to: Anita Tenley (A-3-1), U.S. Environmental Protection Agency, Region 9, 215 Fremont Street, San Francisco, CA 94105, (415) 974-8240, FTS 454-8240.

SUPPLEMENTARY INFORMATION: Best Available Control Technology (BACT) requirements include: NO_x controls by water injection, high efficency cyclone collectors and low NO_x design duct burners.

DATE: The PSD permit is reviewable under section 307(b)(1) of the Clean Air Act only in the Ninth Circuit Court of Appeals. A petition for review must be filed by February 10, 1986.

Dated: November 21, 1985.

David P. Howekamp,

Director, Air Management Division, Region 9.

[FR Doc. 85-29234 Filed 12-9-85; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Hearing Designation Order; Southwest Communications, et al.

In re Applications of MM Docket No. 85-360:

	File No.
Susan T. Dowdy, et al., d/b/a Southwest Communications.	BPCT-841221KX.
Southwest Mississippi Television, Company, a limited partnership.	BPCT-850213KH.
Commonwealth Venture Systems, a limited partnership.	BPCT-850215KO.
Robin C. Brandt	BPCT-850215KL.

For Construction Permit for New Television Station McComb, Mississippi.

Adopted: November 22, 1985.
Released: December 5, 1985.

By the Chief, Video Services Division.

1. The Commission, by the Chief, Video Services Division, acting pursuant to delegated authority, has before it the above-captioned mutually exclusive applications for authority to construct a new commercial television station on Channel 28, McComb, Mississippi.

2. On February 15, 1985, the Association of Maximum Service Telecasters (AMST), filed an informal objection to the application of Southwest Communications on the grounds that its transmitter site would be short-spaced 1.13 miles to the reference point for Channel 42, Natchez, Mississippi. On April 16, 1985, Southwest Communications filed an amendment to change the transmitter site, but the amendment increased the short-spacing to 9 miles. AMST also filed an informal objection against

Robin C. Brandt on April 17, 1985, on the grounds that the transmitter site would be short-spaced 2.88 miles to the reference point for Channel 42, Natchez, Mississippi. Sections 73.610, of the Commission's Rules require a minimum separations of 60 miles. Accordingly, issues will be specified to determine whether circumstances exist warranting a waiver of the rule. In assessing the circumstances to determine whether a waiver is warranted, the Administrative Law Judge will consider the fact that the other two applicants have specified fully-spaced sites.

3. Except with respect to Southwest Mississippi Television Company, a Limited Partnership, no determination has been reached that the tower height and location proposed by each of the applicants would not each constitute a hazard to air navigation. Accordingly, an issue regarding this matter will be specified.

4. The effective radiated visual power, antenna height above average terrain and other technical data submitted by each applicant indicate that there would be a significant difference in the size of the area and population which would be served by each. Consequently, the areas and populations which would be within the predicted 64 dBu (Grade B) contour, together with the availability of other television service of Grade B or greater intensity, will be considered under the standard comparative issue, for the purpose of determining whether a comparative preference should accrue to any of the applicants.

5. Carroll Hines is a 33⅓% limited partner in Southwest Communications, an applicant in this proceeding, and is also manager of Sammons Communication Cable System in McComb, Mississippi. This relationship may raise cross-interest questions. However, Mr. Hines has represented to the Commission that he would retire from this position on Decemer 31, 1984. We assume that Mr. Hines has now retired from his position as he indicated he would do by December 1984. If this is not the case, Mr. Hines should so advise the presiding Administrative Law Judge within twenty (20) days from the release of this Order.

6. Carroll Hines and Robert H. Hemeter are each 33⅓% limited partners of Southwest Communications. Each is a 33⅓% shareholder and officer of HWH Corporation, licensee of Stations WAKX and WAKH-FM, McComb, Mississippi. Susan T. Dowdy is a general partner and owner of 33⅓% of Southwest Communications. Her husband, C. Wayne Dowdy, owns 33⅓% of HWH Corporation and is an officer and director of HWH Corporation.[1] Section 73.3555(b)(1) of the Commission's Rules provides that no license for a television station shall be granted to any party if such party directly or indirectly owns, operates, or controls one or more AM or FM broadcast stations and the grant of such license will result in the Grade A contour of the proposed television station encompassing the entire community to which the AM of FM station is licensed. Note 4 of this rule provides, *inter alia*, that applications for UHF television facilities ". . . . will be handled on a case-by-case basis in order to determine whether common ownership, operation or control of the stations in question would be in the public interest."

Additionally, limited partnership interests are nonattributable where the limited partners would not be involved in any material respect in the management or operation of the broadcast station. *Attributation of Ownership Interests*, 97 F.C.C. 2d 997 (1984), *recon. granted in part*, FCC 85-252, released June 24, 1985. The Commission defined the degree of noninvolvement in paragraphs 48–50 of the June 24 decision on reconsideration. Further, the Commission retained the cross-interest policy as to other media interest in the same area. 97 F.C.C. 2d at 1030. Southwest Communications has not certified the "noninvolvement" of Carroll Hines and Robert H. Hemeter in the operation or management of the proposed television station. We conclude, therefore, that the limited partnership interests are attributable. Even if the appropriate "noninvolvement" certification can be made, attributable interests in aural facilities and nonattributable interests in the television facility in the same area, raises a cross-interest question. Accordingly, a multiple ownership/cross-interest issue will be designated.

7. Southwest Mississippi's proposed tower is to be located 1.08 miles from the directional array of AM Station WHNY, McComb, Mississippi. Because of the proximity of the proposed tower to WHNY, grant of a construction permit to Southwest Mississippi will be conditioned to ensure that WHNY's radiation pattern is not adversely affected by the construction of the proposed station.

8. Southwest Mississippi Television Co. (Southwest Mississippi) is a limited partnership whose partners are Louis Alford (general partner), Phillip D. Brady (limited partner) and Albert Mack Smith (limited partner); each owns 33⅓% of the applicant. Southwestern Broadcasting Company of Mississippi, licensee of Stations WAPF and WCCA(FM), McComb, Mississippi, is a limited partnership whose partners are Alford (limited partner), Brady (general partner) and Smith (limited partner). Each owns 33⅓% of the licensee. Southwest Mississippi has not certified the "noninvolvement" of the limited partners in the management or operation of the proposed television station or the aural stations in McComb. The limited partnership interests are, therefore, attributable. Even if sufficiently insulated so as to avoid attribution, the relationship between the radio and television companies raises a cross-interest question. See paragraph 6, *supra*. Accordingly, a multiple ownership/cross-interest issue will be designated.[2]

9. Section 73.3555(c)(3) of the Commission's Rules states that no license for a television station shall be granted to any party if such party directly or indirectly owns, operates or controls a daily newspaper and the grant of such license will result in the Grade A contour of the proposed television station encompassing the entire community in which such newspaper is published. John O. Emmerich, Jr., a limited partner with a 39% equity interest in Commonwealth Venture Systems, a Limited Partnership (CVS), owns a 50% interest in the *Enterprise-Journal*, a daily newspaper published in McComb, Mississippi. The applicant has not certified the "noninvolvement" of John O. Emmerich, Jr. in the management or operation of the proposed television station. We must conclude, therefore, that the limited partnership interest is attributable. Further, even if the appropriate certification can be made, Mr. Emmerich's ownership interest in

[1] Normally, the interests of each spouse are attributable to the other. *Lady Sarah McKinney Smith*, 59 F.C.C. 2nd 388 (1976). While the attribution is rebuttable, the applicant has not submitted a rebuttal. In fact, the applicant has indicated that revenues from the radio station will be used in the television station. Such use of fund suggests a close working relationship between the spouses in the operation of the radio and television station.

[2] Southwest Mississippi has indicated that its principals will divest their respective interests in Southwestern Broadcasting Company of Mississippi if the Commission determines that such interests are attributable. The decision to divest, until the end of the period when amendments can be made as a matter of right, is for the applicant to make, not the Commission. The Commission standard as to "insulation" of limited partners has been clear at least since the release of the *Attribution* decision on April 30, 1984. The applicant did not make an unqualified divestment pledge and it cannot now upgrade its comparative posture.

the *Enterprise-Journal* may be in violation of the Commission's cross-interest policy. See paragraph 6, *supra*. Accordingly, an appropriate multiple ownership/cross-interest issue will be specified.

10. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. Since these applications are mutually exclusive, the Commission is unable to make the statutory finding that their grant would serve the public interest, convenience, and necessity. Therefore, the applications must be designated for hearing in a consolidated proceeding on the issues specified below.

11. Accoringly, it is ordered, That pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, to be held before an Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine with respect to Southwest Communications:

(a) Whether the proposal is consistent with § 73.610 of the Commission's Rules and, if not, whether circumstances exist which would warrant a waiver of the rule.

(b) Whether the interests of Carroll Hines, Robert H. Hemeter and C. Wayne Dowdy in radio station WAKX and WAKH (FM), McComb, Mississippi, and their interests in the applicant, are consistent with § 73.3555 of the Commission's Rules and with the Commission's cross-interest policy and, if not, whether common ownership, operation, or control of WAKX and WAKH(FM), McComb, Mississippi, and the proposed television station would be consistent with the public interest.

2. To determine with respect to Southwest Mississippi Television Co., whether the interests of Louis Alford, Phillip D. Brady and Albert Mack Smith in radio stations WAPF and WCCA(FM), McComb, Mississippi and their interest in the applicant, are consistent with § 73.3555 of the Commission's Rules and with the Commission's cross-interest policy and, if not, whether common ownership, operation, or control of WAPF and WCCA(FM), McComb, Mississippi, and the proposed television station would be consistent with the public interest.

3. To determine with respect to Commonwealth Venture Systems, A Limited Partnership, whether the interests of John O. Emmerich, Jr. in the newspaper, *Enterprise-Journal*, McComb, Mississippi, and in Commonwealth Venture Systems is consistent with § 73.3555(c)(3) and with the Commission's cross-interests policy, and if not, whether common ownership, operation or control of the newspaper, *Enterprise-Journal* and the proposed television station would be in the public interest.

4. To detemine with respect to Robin C. Brandt whether the proposal is consistent with § 73.610 of the Commission's Rules and, if not, whether circumstances exist which would warrant waiver of the rule.

5. To determine with respect to Southwest Communications, Commonwealth Venture Systems, and Robin C. Brandt, whether there is a reasonable possibility that the tower height and location proposed by each would constitute a hazard to air navigation.

6. To determine which of the proposals would, on a comparative basis, best serve the public interest.

7. To determine, in light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

12. It is further ordered, that in the event of a grant of the application of Southwest Mississippi Television Company, A Limited Partnership, it will be conditioned as follows:

Prior to construction of the tower authorized herein, permittee shall notify AM Station WHNY so that, if necessary the AM station may determine operating power by the indirect method and request temporary authority from the Commission in Washington, DC to operate with parameters at variance in order to maintain monitoring point field strengths within authorized limits. Permittee shall be responsible for the installation and continued maintenance of detuning apparatus necessary to prevent adverse effects upon the radiation pattern of the AM station. Both prior to construction of the tower and subsequent to the installation of all appurtenances thereon, a partial proof of performance, as defined by § 73.154(a) of the Commission's Rules, shall be conducted to establish that the AM array has not been adversely affected and, prior to or simultaneous with the filing of the application for license to cover this permit, the results submitted to the Commission.

13. It is further ordered, that, Association of Maximum Service Telecasters, Inc., is made a party respondent to this proceeding with respect to issues 1(a) and 4.

14. It is further ordered, that the Federal Aviation Adminstration is made a party respondent to this proceeding with respect to issue 5.

15. It is further ordered, that to avail themselves of the opportunity to be heard, the applicants and the parties respondent herein shall, pursuant to § 1.221(c) of the Commission's Rules, in person or by attorney, within 20 days of the mailing of this Order, file with the Commission in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this Order.

16. It is further ordered, that the applicants herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3594 of the Commission's Rules, give notice of the hearing within the time and in the manner prescribed in such Rule, and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the Rules.

Federal Communications Commission.

Roy J. Stewart,

Video Services Division, Mass Media Bureau.

[FR Doc. 85-29178 Filed 12-9-85; 8:45 am]

BILLING CODE 6712-01-M

Hearing Designation Order; Westcom Broadcasting Inc., et al.

In re Applications of MM Docket No. 85-354:

	File No.
Westcom Broadcasting Inc. (KESP), Santa Barbara, California. Has: 1290 kHz, .5 kW ND-D, for renewal of license.	BR-830726VX.
Erway Broadcasting Corporation, Santa Barbara, California. Req: 1290 kHz, .5 kW ND-D, for construction permit.	BP-831031AK.

Adopted: November 12, 1985.
Released: December 5, 1985.

By the Chief, Audio Services Division.

1. The Commission, by the Chief, Audio Services Division acting pursuant to delegated authority, has under consideration the license renewal application of Westcom Broadcasting, Inc. licensee of Station KESP, Santa Barbara, California, ("KESP" or "licensee") and the application for a construction permit for the KESP facilities filed by Erway Broadcasting Corporation ("Erway"). Also, before the Commission is Erway's "petition for expedited treatment" of the above-captioned applications which sets forth Erway's objections to a grant of the DESP license renewal. Since this "petition" was not filed as a petition to deny the KESP renewal pursuant to section 309 of the Comunications Act of 1934, as amended, it will be considered an informal objection to a grant of the KESP renewal application pursuant to § 73.3587 of the Commission's Rules.

2. Erway contends that KESP has gone "silent" and will not return to the air

within a reasonable time because of financial difficulties. Claiming that the licensee no longer has a studio, a transmitter site nor equipment, Erway states that the licensee is "in obvious financial distress." Erway alleges that the licensee's default on various promissory notes is evidence of the licensee's financial problems.

3. Regarding KESP's "silent" status, we note that the licensee has requested authority to temporarily discontinue service. In so doing, it has complied with the Commission's Rules. *See* 47 CFR 1740(a)(4). Indeed, by way of background, KESP has continuously apprised the Commission on this matter. We note that KESP has entered into an agreement with the city of Santa Barbara for a site to construct a transmitter and related buildings. Furthermore, the licensee has represented to the Commission that it "has arranged to have all necessary equipment and personnel placed on standby so that construction may begin at the earliest possible time afforded by the city of Santa Barbara . . . and that KESP will resume broadcat operations on or before November 29, 1985." Based on the licensee's representations, the Commission has granted KESP authority to remain silent until November 29, 1985.

4. The issue concerning a contract dispute involving the licensee's alleged failure to make payments on several promissory notes is presently being resolved in the local California courts. It is longstanding Commission policy not to assume jurisdiction over debtor-creditor controversies, recognizing that such issues are beyond our regulatory jurisdiction. *Sonderling Broadcasting Co.*, 46 RR 2d 890, 894 (1979); *John R. Kingsberry*, 71 FCC 2d 1173 (1979). Therefore, no further inquiry into this matter is necessary.

5. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. However, since the proposals are mutually exclusive, the applications must be designated for hearing in a consolidated proceeding on the issues specified below.

6. Accordingly, it is ordered, that, pursuant to section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine which of the applications would, on a comparative basis, better serve the public interest.

2. To determine, in light of the evidence adduced pursuant to the foregoing issue, which of the applications should be granted.

7. It is further ordered, that the petition for expedited treatment filed by Erway Broadcasting Corporation is denied as an informal objection.

8. It is further ordered, that in addition to the copy served on the Chief, Hearing Branch, a copy of each amendment filed in this proceeding subsequent to the date of adoption of this Order shall be served on the Chief, Data Management Staff, Audio Services Division, Mass Media Bureau, Room 350, 1919 M Street NW., Washington, DC 20554.

9. It is further ordered, that to avail themselves of the opportunity to be heard and pursuant to § 1.221(c) of the Commission's Rules, the applicants shall within twenty (20) days of the mailing of this Order, in person or by attorney, file with the Commission in triplicate a written appearance stating an intention to appear on the date fixed for hearing and present evidence on the issues specified in this Order.

10. It is further ordered, that pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3594 of the Commission's Rules, the applicants shall give notice of the hearing within the time and manner prescribed in such rules, and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the Rules.

Federal Communications Commission.

W. Jan Gay,

Assistant Chief, Audio Service, Division, Mass Media Bureau.

[FR Doc. 85-29174 Filed 12-9-85; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

[Docket No. 85-21]

Rinker Materials Corp. v. Port Everglades Authority, Sea-Land Service, Inc. and Trans Freight Lines; Filing of Complaint and Assignment

Notice is given that a complaint filed by Rinker Materials Corporation against Port Everglades Authority; Sea-Land Service, Inc. and Trans Freight Lines was served December 3, 1985. Complainant alleges that respondents have violated sections 10(b)(11), 10(b)(12) and 10(d)(3) of the Shipping Act of 1984 and section 16 of the Shipping Act, 1916 with regard to preferential berthing rights at the Port Everglades marine terminal.

This proceeding has been assigned to Administrative Law Judge Norman D. Kline. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue in such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by December 4, 1986, and the final decision of the Commission shall be issued by April 6, 1987.

Bruce A. Dombrowski,

Acting Secretary.

[FR Doc. 85-29241 Filed 12-9-85; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

American Interstate Bancorporation; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would

not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 1, 1986.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *American Interstate Bancorporation*, Omaha, Nebraska; to acquire First Interstate Insurance Company, ELkhorn, Nebraska, and thereby engage in general insurance agency activities in a place with a population not exceeding 5,000 pursuant to section 4(c)(8)(C)(i) of the Act.

Board of Governors of the Federal Reserve System, December 4, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-29181 Filed 12-9-85; 8:45 am]

BILLING CODE 6210-01-M

Citizens and Southern Acquisition Corp. et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies and Acquisitions of Nonbanking Companies

The companies listed in this notice have applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed companies have also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the Untied States.

The applications are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 30, 1985.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Citizens and Southern Acquisition Corporation*, Atlanta, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of The Citizens and Southern Corporation, Columbia, South Carolina, thereby indirectly acquiring Citizens and Southern National Bank of South Carolina, Columbia, South Carolina.

Citizens and Southern Georgia Corporation, Atlanta, Georgia; has also applied to acqurie 100 percent of the voting shares of The Citizens and Southern Corporation, Columbia, South Carolina.

Citizens and Southern Georgia Corporation, Atlanta, Georgia and *Citizens and Southern Acquisition Corporation*, Atlanta, Georgia; to acquire each of the following bank holding companies and engage in the listed activities: Columbia Credit Life Insurance Company, Columbia, South Carolina, underwriting as reinsurer credit life and disability insurance directly related to extensions of credit by bank subsidiaries, pursuant to § 225.25(b)(8) of Regulation Y and section 4(c)(8) of the Bank Holding Company Act; C&S Financial Services, Inc., Columbia, South Carolina, engaging in equipment leasing, pursuant to § 225.25(b)(5) of Regulation Y and section 4(c)(8) of the Bank Holding Company Act; Citizens and Southern Systems, Inc., Columbia, South Carolina, engaging in data processing, pursuant to § 225.25(b)(7) of Regulation Y and section 4(c)(8) of the Bank Holding Company Act; and Bank Management Advisory Services, Inc., Columbia, South Carolina, engaging in management and operations consulting to nonaffiliated banks, pursuant to § 225.25(c)(11) of Regulation Y and section 4(c)(8) of the Bank Holding Company Act.

Board of Governors of the Federal Reserve System, December 4, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-29182 Filed 12-9-85; 8:45 am]

BILLING CODE 6210-01-M

Kentucky Bancorporation, Inc., et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 27, 1985.

A. **Federal Reserve Bank of Cleveland** (Lee S. Adams, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *Kentucky Bancorporation, Inc.*, Covington, Kentucky; to acquire 100 percent of the voting shares of Kentucky State Bank, Carrollton, Kentucky. Comments on this application must be received not later than January 1, 1986.

B. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Valley Holding Company*, Aurora, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of Valley National Bank of Aurora, Aurora, Illinois.

C. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *American Bancorporation, Inc.*, Sapulpa, Oklahoma; to merge with Beggs Bancshares, Inc., Beggs, Oklahoma, thereby indirectly acquiring The Bank of Beggs, Beggs, Oklahoma. Comments on this application must be received not later than December 30, 1985.

D. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *First White Oak Bancshares, Inc.*, White Oak, Texas; to become a bank holding company by acquiring 80 percent of the voting shares of White Oak State Bank, White Oak, Texas.

Board of Governors of the Federal Reserve System, December 4, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-29183 Filed 12-9-85; 8:45 am]

BILLING CODE 6210-01-M

Smith Associated Banking Corp., et al.; Notice of Applications to Engage de Novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 27, 1985.

A. **Federal Reserve Bank of St. Louis** (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Smith Associated Banking Corporation*, Little Rock, Arkansas; to engage *de novo* directly in acting as agent in the sale of credit life, accident, and health insurance, directly related to extensions of credit by Applicant's subsidiary bank, The Bank of Salem, Salem, Arkansas.

B. **Federal Reserve Bank of Kansas City** (Thomas M. Hoening, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Herington Bancshares, Inc.*, Herington, Kansas; to engage *de novo* through its subsidiary, Herington Financial Services, Inc., Herington, Kansas, in acting as agent in the sale of insurance limited to assuring repayment of the outstanding balance on an extension of credit by a finance company in the event of loss or damage to any property used as collateral for credit does not exceed the limits set for in section 4(c)(8)(B) of the Act. Applicant also proposes to engage in general insurance agency activities in a place with a population not exceeding 5,000, pursuant to section 4(c)(8)(C)(i) of the Act. These activities would be conducted in a circular area, with Herington, Kansas located at its center, and a radius of approximately 20 miles. Comments on this application must be received not later than December 24, 1985.

Board of Governors of the Federal Reserve System, December 4, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-85-29184 Filed 12-9-85; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Information Collection Proposal Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Bureau of Land Management's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone (202) 395-7340.

Title: 43 CFR 1601.5-3, Recreation Visitor Survey.

Abstract: Respondents supply information on their use of recreation opportunities on public lands. This information is used during subsequent land use planning processes to help the Bureau make decisions concerning future management of the surveyed area.

Bureau Form Number: 8310-8.

Frequency: Collected on a one-time basis to solve specific planning and management problems.

Description of Respondents: Recreation visitors to public lands.

Annual Responses: 1800.

Annual Burden Hours: 360.

Bureau clearance officer: Rebecca Daugherty, (202) 653-8853.

Vincent J. Hecker,

Assistant Director, Land Resources.

[FR Doc. 85-29202 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-84-M

[OR 38261]

Exchange of Public Lands; Lane and Linn Counties, OR

The following described public lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

Willamette Meridian

T. 15 S., R. 6 W.,
Sec. 15: NE¼NE¼.
T. 16 S., R. 1 E.,
Sec. 7: Lot 4.

T. 16 S., R. 1 W.,
Sec. 11: SE¼SE¼.
T. 16 S., R. 2 W.,
Sec. 3: SE¼SE¼.
T. 17 S., R. 7 W.,
Sec. 33: SW¼SW¼.
T. 18 S., R. 5 W.,
Sec. 15: NW¼NW¼.
T. 21 S., R. 1 W.,
Sec. 33: SE¼SE¼.
T. 22 S., R. 2 W.,
Sec. 7: SE¼NE¼, NE¼NW¼, NE¼SE¼.

The area described aggregates 399.82 acres in Lane and Linn Counties, Oregon.

In exchange for these lands, the Federal Government will acquire the following described private lands from Coast Range Conifers, an Oregon partnership:

Willamette Meridian

T. 17 S., R. 3 E.,
Sec. 10: Lots 3–5, NW¼NW¼, SE¼NW¼.

The area described above aggregates 154.79 acres in Lane County, Oregon.

The purpose of the exchange is to facilitate resource management opportunities in the South Bank McKenzie River area as identified in the Engene District's Upper Willamette Management Framework Plan. The private lands being offered have very important values for recreation, wildlife habitat, and the preservation of Eagle Rock, an outstanding natural landmark. The public interest will be well served by making this exchange.

The value of the lands to be exchanged is approximately equal, and the acreage will be adjusted to equalize the values upon completion of the final appraisal of the lands.

The exchange will be subject to:

1. The reservation to the United States of a right-of-way for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. Oil and gas rights may be reserved in the final patent. All existing oil and gas leases will remain in effect until expiration.

3. All other valid existing rights, including but not limited to any 43 CFR Part 2812 right-of-way permits or any right-of-way, easement or lease of record.

The publication of this notice in the **Federal Register** will segregate the public lands described above to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. As provided by the regulations of 43 CFR 2201.1(b), any subsequently tendered application, allowance of which is discretionary, shall not be accepted, shall not be considered as filed and shall be returned to the applicant.

Detailed information concerning the exchange, including the environmental analysis and the record of public discussions, is available for review at the Eugene District Office, 1255 Pearl Street, Eugene, Oregon 97401.

For a period of 45 days from the date of publication of this notice in the **Federal Register** interested parties may submit comments to the Eugene District Manager at the above address.

Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

Date of Issue: December 2, 1985.

Melvin D. Clausen,

District Manager.

[FR Doc. 85–29223 Filed 12–9–85; 8:45 am]

BILLING CODE 4310–33–M

Medford District Office, Oregon; Nordic Ski Trails Restriction

Pursuant to Title 43 CFR 8364.1(a) and (b), the following acts are prohibited on designated Nordic (cross-country) ski trails within the Medford District, Bureau of Land Management.

1. Possessing a dog on or within 150 feet of any road or trail designated for Nordic ski use.

This prohibition shall be in effect during those months when the Nordic trails are open for skiing.

This prohibition is made to protect the health and safety of skiers.

Pursuant to Title 43 CFR 8364.1(b), the following persons are exempt from this order:

1. Persons with a permit authorizing the otherwise prohibited act.

2. Any Federal, State, or Local officer in the performance of an official duty.

Pursuant to Title 43 CFR 8360.0–7, violations of this order are punishable by a fine not to exceed $1,000 and/or imprisonment not to exceed 12 months.

Dated this 2nd day of December, 1985.

Hugh R. Shera,

District Manager.

[FR Doc. 85–29219 Filed 12–9–85; 8:45 am]

BILLING CODE 4310–33–M

Information Collection Submitted for Review

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to Bureau Clearance Officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone 202–395–7340.

Title: Monthly Report of Operations, 43 CFR Part 3160.

Abstract: Oil and gas lessees and operators supply detailed information and data on the production and disposition of all production from leases on Federal and Indian Lands. This information allows precise monitoring of production and evaluation of drilling and production technical, safety and environmental factors.

Bureau Form Numbers: 3160–6 and 3160–7.

Frequency: Monthly.

Description of Respondents: Oil and gas lessees and operators.

Annual Responses: 248,876.

Annual Burden Hours: 143,104.

Bureau Clearance Officer: Rebecca Daugherty 202–653–8853.

Dated: November 27, 1985.

George F. Brown,

Assistant Director.

[FR Doc. 85–29218 Filed 12–9–85; 8:45 am]

BILLING CODE 4310–84–M

[W–85415]

Wyoming; Proposed Reinstatement of Terminated Oil and Gas Lease

Pursuant to the provisions of Pub. L. 97–451, 96 Stat. 2462–2466, and Regulation 43 CFR 3108.2–3(a) and (b)(1), a petition for reinstatement of oil and gas lease W–85415 for lands in Goshen County, Wyoming was timely filed and was accompanied by all the required rentals accuring from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5.00 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required $500.00 administrative fee and $106.25 to reimburse the Department for the cost of this **Federal Register** notice.

The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate

lease W-85415 effective September 1, 1985, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Andrew L. Tarshis,

Chief, Leasing Section.

[FR Doc. 85-29213 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-22-M

Minerals Management Service

Development Operations Coordination Document

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the Receipt of a Proposal Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Kerr-McGee Corporation has submitted a DOCD describing the activities it proposes to conduct on Lease OCS 0828, Block 214, Ship Shoal Area, offshore Louisiana. Proposed plans for the above area provides for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Morgan City, Louisiana.

DATE: The subject DOCD was deemed submitted on November 29, 1985.

ADDRESSES: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OSC Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Ms. Angie Gobert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838-0876.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected states, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: December 2, 1985.

John L. Rankin,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 85-29222 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the Receipt of a Proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Tenneco Oil Exploration and Production has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 0902, Block 299, West Cameron Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Sabine Pass, Texas.

DATE: The subject DOCD was deemed submitted on November 29, 1985.

ADDRESSES: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Ms. Angie Gobert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838-0876.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected states, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: December 2, 1985.

John L. Rankin,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 85-29221 Filed 12-9-85; 8:45 a m]

BILLING CODE 4310-MR-M

Bureau of Mines

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone 202-395-7313.

Title: Consolidated Consumer's Report

Abstract: Respondents supply the Bureau of Mines with domestic production and consumption data on nonfuel mineral commodities. This information is published in the Bureau of Mines publications including the Mineral Industry Survey (MIS), *Minerals Yearbook* Volumes I, II, and III, *Mineral Facts and Problems*, *Mineral Commodity Summaries*, *Mineral Commodity Profiles*, and *Minerals and Materials/A Bimonthly Survey* for use by private organizations and other government agencies.

Bureau Form Number: 6-1109-MA.

Frequency: Monthly/Annually.

Description of Respondents: Operations that consume ferrous metals.

Annual Responses: 5,089.

Annual Burden Hours: 1.

Bureau Clearance officer: James T. Hereford 202-634-1125.

Dated: November 7, 1985.

Robert C. Horton,

Director, Bureau of Mines.

[FR Doc. 85-29216 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-53-M

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act.

A request extending the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone 202–395–7313.

Title: Blast Furnace and Steel Furnace Report.

Abstract: Respondents supply the Bureau of Mines with domestic production and consumption data on nonfuel mineral commodities. This information is published in Bureau of Mines publications including the Mineral Industry Surveys (MIS), *Minerals Yearbook* Volumes I, II, and III, *Mineral Facts and Problems*, *Mineral Commodity Summaries*, *Mineral Commodity Profiles*, and *Minerals and Materials/A Bimonthly Survey* for use by private organizations and other government agencies.

Bureau Form Number: 6–1067–A.

Frequency: Annually.

Description of Respondents: Operations that produce pig iron.

Annual Responses: 45

Annual Burden Hours: 180.

Bureau clearance officer: James T. Hereford 202–634–1125.

Dated: November 7, 1985.

Robert C. Horton,

Director, Bureau of Mines.

[FR Doc. 85–29217 Filed 12–9–85; 8:45 am]

BILLING CODE 4310–53–M

National Park Service

National Register of Historic Places; Indiana, et al.; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before November 30, 1985. Pursuant to §60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by December 26, 1985.

Carol D. Shull,

Chief of Registration, National Register.

INDIANA

Elkhart County

Elkhart, *Monteith, Mark L. and Harriet E., House*, 871 E. Beardsley Ave.

Marion County

Indianapolis, *Aston Inn*, 6620 N. Michigan Rd.

Indianapolis, *Haverstick, Hiram A., Farmstead*, 7845 Westfield Blvd.

Parke County

Marshall, *Arch in the Town of Marshall*, Maine and Cuion Sts.

MAINE

Androscoggin County

Lewiston, *Marcotte Nursing Home*, 100 Campus Ave.

Lewiston, *Wedgewood, Dr. Milton, House* 101 Pine St.

Aroostook County

Presque Isle, *Elmbrook Farm Barn*, Parsons Rd.

Cumberland County

Falmouth, *Baxter Summer Home*, Mackworth Island

Hancock County

Bucksport, *Prouty, Jed, Tavern & Inn*, 52–54 Maine St.

Ellsworth, *Ellsworth City Hall*, City Hall Plaza

Lincoln County

Dresden, *Lithgow House*, Blinn Hill Rd.

MARYLAND

Anne Arundel County

Beck Northeast Site (18 AN 65)

MASSACHUSETTS

Berkshire County

Great Barrington, *United States Post Office-Great Barrington Main Post Office*, 222 Main St.

Hampshire County

South Hadley, *United States Post Office-South Hadley Main Post Office*, 1 Hadley St.

OREGON

Lane County

Coburg, *Coburg Historic District*, Roughly area around Van Duyn Rd., Willamette St., Southern Pacific RR tracks, and I–5

Washington County

Beaverton, *Beaverton Downtown Historic District*, Roughly bounded by SW Canyon Blvd., SW East and SW Washington Sts., SW Second, and SW Watson Sts.

PENNSYLVANIA

Allegheny County

Coraopolis, *Coraopolis Bridge (Allegheny County Owned River Bridges TR)*, Ohio River Back Channel at Ferree St. and Grand Ave.

Homestead, *Homestead Pennsylvania Railroad Station*, Amity St.

Pittsburgh *Armstrong Tunnel*, Between Forbes and Second Aves. at S. Tenth St.

Pittsburg, *Homestead High-Level Bridge (Allegheny County Owned River Bridges TR)*, Mononghahela River at West St.

Pittsburg, *Ninth Street Bridge (Allegheny County Owned River Bridges TR)*, Allegheny River at Ninth St.

Pittsburg, *Seventh Street Bridge (Allegheny County Owned River Bridges TR)*, Allegheny River at Seventh St.

Pittsburg, *Sixth Street Bridge (Allegheny County Owned River Bridges TR)*, Allegheny River at Sixth St.

Pittsburg, *South Tenth Street Bridge (Allegheny County Owned River Bridges TR)*, Monongahela River at S. Tenth St.

Blair County

Hollidaysburg, *Hollidaysburg Historic District*, Roughly bounded by Spruce, Bella, Blair, and Juniata Sts.

Bucks County

Bristol, *Grundy Mill Complex*, W. corner of Jefferson Ave. & Canal St.

Langhorne, *Richardson, Joseph, House*, Bellevue and Maple Aves.

Chester County

Marshallton vicinity, *Marshallton Historic District*, Strasburg Rd.

McKean County

Kane, *Anootok*, 230 Clay St.

Philadelphia County

Philadelphia, *Ramcat Historic District*, Market & Twenty-third Sts., U.S. Naval Home on Bainbridge, RR yards and the Schulkill River

Philadelphia, *Scherer, Frank C., Wagon Works*, 801 N. Twenty-seventh St.

Pike County

Milford, *Gordon, Jervis, Grist Mill Historic District*, Water, Mill, and Seventh Sts.

Schuylkill County

Tamaqua, *Reading Railroad Passenger Station—Tamaqua*, Off W. Broad St.

TEXAS

Erath County

Stephenville vicinity, *Wyatt-Hickie Ranch Complex*, Off U.S. 281 NW of TX 913

WEST VIRGINIA

Monongalia County

Morgantown, *Beta Theta Pi House of West Virginia University*, 225 Belmar Ave.

Tyler County
Sistersville, *Wells-Schoff House*, 500 S. Wells

[FR Doc. 85-29254 Filed 12-9-85; 8:45 am]
BILLING CODE 4310-70-M

Upper Delaware National Scenic and Recreational River; Meeting

AGENCY: National Park Service; Interior.

SUMMARY: This notice sets forth the date of the forthcoming meeting of the Upper Delaware Citizens Advisory Council. Notice of this meeting is required under the Federal Advisory Committee Act.

DATE: December 13, 1985, 7:00 p.m.

ADDRESS: Town of Tusten, Narrowsburg, New York.

FOR FURTHER INFORMATION CONTACT: John T. Hutzky, Superintendent, Upper Delaware National Scenic and Recreational River, Drawer C, Narrowsburg, N.Y. 12764-0159. (717) 729-7135.

SUPPLEMENTARY INFORMATION: The Advisory Council was established under section 704(f) of the National Parks and Recreation Act of 1978, Pub. L. 95-615, 16 U.S.C. 1274 note, to encourage maximum public involvement in the development and implementation of the plans and programs authorized by the Act. The Council is to meet and report to the Delaware River Basin Commission, the Secretary of the Interior, and the Governors of New York and Pennsylvania in the preparation of a management plan and on programs which relate to land and water use in the Upper Delaware region. The agenda for the meeting will include items regarding continuance of discussion of requirements for a river management plan. The meeting will be open to the public. Any member of the public may file with the Council a written statement concerning agenda items. The statement should be addressed to the Council c/o Upper Delaware National Scenic and Recreational River, Drawer C, Narrowsburg, N.Y. 12764-0159. Minutes of meeting will be available for inspection four weeks after the meeting at the permanent headquarters of the Upper Delaware National and Recreational River, River Road, 1¾ miles north of Narrowsburg, N.Y., Damascus Township, Pennsylvania.

Dated: December 3, 1985.

James W. Coleman, Jr.,
Regional Director, Mid-Atlantic Region.

[FR Doc. 85-29253 Filed 12-9-85; 8:45 am]
BILLING CODE 4310-70-M

Office of Surface Mining Reclamation and Enforcement

Intent To Prepare a Combined Draft Unsuitability Petition Evaluation Document/Environmental Impact Statement; Tennessee

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of intent to prepare a combined petition evaluation document/environmental impact statement and notice of scoping comment period for the petition to designate certain lands in the Rock Creek watershed in Bledsoe and Hamilton Counties, Tennessee as unsuitable for surface coal mining operations.

SUMMARY: Notice is hereby given that the Office of Surface Mining Reclamation and Enforcement (OSM) intends to prepare a combined petition evaluation document/environmental impact statement (PED/EIS) for the decision on a petition to designate certain lands within the Rock Creek watershed in Bledsoe and Hamilton Counties, Tennessee, as unsuitable for surface coal mining and reclamation operations in accordance with Section 522 of the Surface Mining Control and Reclamation Act of 1977 (SMCRA). OSM has identified four alternatives that the combined PED/EIS would evaluate as described in the supplementary information of this notice. OSM requests that other agencies and the public submit written comments or statements on the need for an EIS on the petition and the scope of the issues which should be analyzed in the combined document.

DATE: Written comments must be received by January 9, 1986, at the address below by 5 p.m. (EST).

ADDRESS: Written comments must be mailed or hand delivered to the Office of Surface Mining, Tennessee Division of Permitting, Attn: Willis Gainer, 530 Gay Street, SW., Suite 500, Knoxville, Tennessee 37902.

Copies of the petition are available upon request from the OSM at the above address. The public record on the petition is available for review during normal working hours at the OSM office listed above.

FOR FURTHER INFORMATION CONTACT: Willis Gainer at OSM office listed above (telephone: 615-673-4348 or FTS 854-4348).

SUPPLEMENTARY INFORMATION: The Legal Environmental Assistance Foundation filed a petition with the OSM on October 10, 1984, to designate lands unsuitable within the Rock Creek watershed Bledsoe and Hamilton Counties, Tennessee. The petition was declared administratively complete on December 7, 1984.

The major allegations for the petition area are:

1. Surface coal mining and reclamation operations cannot be conducted in a technologically and economical manner.

2. Surface coal mining operations would result in significant damage to important historic, cultural, scientific, and esthetic values and natural systems.

3. Surface coal mining would affect renewable resource lands that would result in a substantial loss of long-range productivity of water supplies and food products.

The several alternatives available to OSM for evaluation in the combined document range from not designating any of the lands in the area as unsuitable to designating all lands in the petition areas as unsuitable including designating only parts of the area as unsuitable.

The alternatives are as follows:

Alternative 1—Designate the entire petition area as unsuitable.

Alternative 2—Designate none of the petition area as unsuitable.

Alternative 3—Conditionally designate the petition area as unsuitable.

A. Designate as unsuitable for all surface mining operations those parts of the petition area where it is found that operations would result in significant damage to important natural systems.

B. Designate methods or levels of mining and reclamation that would mitigate the effects of surface coal mining operations on important natural systems of the petition area.

C. Designate as unsuitable for all surface mining operations those parts of the petition area where it is found that reclamation is not technologically and economically feasible.

Alternative 4—Designate the entire petition area as unsuitable for surface coal mining but allow underground mining.

A scoping comment period intended to raise the relvant issues to be addressed by the combined document will close on January 9, 1986. OSM seeks public comments in relation to the scope of issues to be addressed by the impact evaluation, including impacts and alternatives that should be addressed. Written comments submitted should be specific, should be confined to issues pertinent to the petition, and should explain the reasons for the comments. The public comments received during the scoping period will assist OSM in making decisions on the petition

evaluation and environmental impact statement process.

OSM believes that the proposed action is a major Federal action significantly affecting the quality of the human environment which may require the preparation of a EIS. OSM requests public comment on this issue. OSM additionally gives notice here that should information or analyses show that the proposed action does not require an EIS, it will terminate the environmental impact statement process through an appropriate notice in the **Federal Register.**

Dated: December 4, 1985.

Gary Bennethum,

Acting Assistant Director, Program Operations.

[FR Doc. 85-29231 Filed 12-9-85; 8:45 am]

BILLING CODE 4310-05-M

INTERSTATE COMMERCE COMMISSION

[Docket No. W-271 (Sub-4)]

Bridgeport & Port Jefferson Steamboat Co., Extension; Connecticut and New York Points [1]

AGENCY: Interstate Commerce Commission.

ACTION: Notice of intent to prepare an environmental impact statement and scope of study.

SUMMARY: Issuance of licenses to conduct ferry operations on Long Island Sound has been found to require compliance with the environmental impact statement process. A proposed scope of study is developed within. Comment is invited.

DATE: Written comment addressing the contents of this document should be sumbitted by or before January 9, 1986.

ADDRESSES: Written comments should be submitted to: Section of Energy and Environment Office of Transportation Analysis Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Carl Bausch at (202) 275-7316.

SUPPLEMENTARY INFORMATION: In these proceedings, applicants seek licenses from the Interstate Commerce Commission (ICC) to conduct ferry operations on Long Island Sound.[2] We believe that issuance by the ICC of such licenses would constitute major Federal action with the potential to affect significantly the quality of the human environment.[3] Therefore, we will prepare an environmental impact statement.

Consistent with the Commission's statutory mandate (which is to assess whether to grant authority, a first step in the development of new service at a new location) and prior cases involving similar issues, we propose to focus on the environmental impacts of additional ferry operations rather than elements of the proposals that are still not finally resolved and are beyond our jurisidiction, *i.e.*, the construction of docks and highways that will be necessary actually to implement service. See, *e.g., Cross Sound Ferry Services, Inc.* v. *United States*, 573 F.2d 725, 733 (2nd Cir. 1978); *Concord Township* v. *United States*, 625 F.2d 1068, 1074 (3rd Cir. 1980). Moreover, we begin the EIS process cognizant of the fact that in these cases applicants' plans are still too indefinite for all of the environmental effects of the proposed services to be fully and meaningfully evaluated at this time, and that, therefore, this EIS may contain less specific scientific data and analysis than would be the case if all aspects of the proposed service had already been resolved. See Supplemental Environmental Assessment, Finance Docket No. 30300, *CSX Corp—Control American Commercial Lines Inc*, served June 19, 1984.

The ferry operations for with licenses are sought contemplate the movement of vehicles and passengers to and from terminal points in Connecticut and Long Island, New York. We are well aware that the proposed Long Island terminal points (Shoreham, Wading River, Riverhead, and Montauk) are relatively small, undeveloped communities, with existing roadways and public services that may be suited to little more than present-day commerce,[4] and that the inability of these communities to accommodate safely the free flow of vehicles and passengers in transit ultimately may present the greatest potential for significant[5] environmental effects associated with these proposed ferry operations. These, however, are matters of purely local concern and are far removed from this agency's licensing functions. Were we to focus here on docking facilities and construction projects (except to the extent that there is concrete information on them that is made available to us) we would usurp local preogatives. Moreover, our inquiry would ultimately be unproductive because we would have to engage in considerable speculation.

We emphasize, however, that NEPA's requirements will not be thwarted by this approach. Following our preliminary investigation (which has included site inspections, data collection and consultation with officials at all levels of government), it is abundantly clear that all environmental effects associated with these proposals will be thoroughly considered by the responsible Federal, State, and local officials[6] before service actually begins. Because the issuance of a certificate neither directs nor authorizes the erection of physical structures, and because necessary permits will have to be obtained from the state and local authorities before service can begin, we believe we can limit our focus to the environmental effects of the proposed ferry operations insofar as available data permit. See *State of Missouri* v. *Coleman*, 427 F.Supp. 1252 (D.D.C. 1977), approving agency deferral of certain environmental issues where there will be time and opportunity for consideration of such issues in the future.

The approach that we propose in this document is designed to satisfy NEPA to the fullest extent consistent with the policy objectives of the Interstate Commerce Act. We seek assistance

[1] Embraces Docket No. W-1401, Groton-Montauk Ferry Service, Inc. Common Carrier Application, which is consolidated for purposes of our environmental determinations only, because similar environmental issues are involved in each proceeding.

[2] In No. W-271 (Sub-No. 4), applicant seeks to provide service as a common carrier, by water, by self-propelled vessels, in interstate or foreign commerce in the transportation of passengers and their baggage, general commodities and mothoir vehicles between Shoreham, Wading River and the Town of Riverhead, NY on the one hand, and New Haven, CT on the other, and between Montauk, NY on the one hand, and Groton, CT on the other.

In No. W-1401, applicant seeks authority to provide service as a common carrier, by water, by self-propelled vessels, in interstate or foreign commerce in the transportation of passengers and general commodities between Montauk, NY on the one hand, and Groton, CT on the other.

[3] Although water carrier licensing is categorically excluded from the ICC's environmental process [49 CFR 1105.6(c)(4)], a protestant to these proceedings has raised and substantiated environmental issues of sufficient concern to warrant investigation. See 49 CFR 1105.6(d).

[4] Montauk is the only proposed Long Island terminal site with docking facilities, although those facilities have been out of service for years. Potential docking sites in the Shoreham/Wading River area have been studied preliminarily, but no concrete plans have been adopted. Area roadways are generally inferior in terms of design capacity and, in some cases, do not extend to the potential docking sites that have been studied. See, e.g., New York State Department of Transportation, *Long Island Sound Ferry Service Imporvement Study—Summary of Findings* (1981).

[5] Inasmuch as these are site-specific actions, significance is determined by the magnitude of effects in the locale rather than some larger geographic area. 40 CFR 1508.29.

[6] See, e.g., New York State Coastal Management Program, Federal Consistency Process, adopted pursuant to 15 CFR Part 930.

from, and encourage comment by, officials at all levels of government with reviewing authority in this matter.

Dated: December 9, 1985.

James H. Bayne,

Secretary.

[FR Doc. 85-29246 Filed 12-9-85; 8:45 am]

BILLING CODE 7035-01-M

Motor Carrier Application To Consolidate, Merge or Acquire Control Under 49 U.S.C. 11343-11344

The following applications seek approval to consolidate, purchase, merge, lease operating rights and properties, or acquire control of motor carriers pursuant to 49 U.S.C. 11343 or 11344. Also, applications directly related to these motor finance applications (such as conversions, gateway eliminations, and securities issuances) may be involved.

The applications are governed by 49 CFR 1182.1.

Persons wishing to oppose an application must follow the rules under 49 CFR 1182.2. If the protest includes a request for oral hearing, the request shall meet the requirements of 49 CFR 1182.3 and shall include the required certification. Failure seasonable to oppose will be construed as a waiver of opposition and participation in the proceeding.

In the absence of legally sufficient protests as to the finance application *or* to any application directly related thereto filed within 45 days of publication (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (unless the application involves impediments) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice.

Applicant(s) must comply with all conditions set forth in the grant or grants of authority within the time period specified in the notice of effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

Findings

The findings for these applications are set forth in 49 CFR 1182.6.

Volume OP 2-547

MC-F-16812, filed October 18,1985. Colorado Western Stages, Inc. (Stages) (8051 Rosemary Street, Commerce City, CO 80022)—Purchase—Colorado Transportation Group, Inc., D/B/A Alpine Charter Coaches, Inc. (CTG) (5101 Columbine, Denver, CO 80216). Representative: Thomas J. Burke, Jr., Esq., Jones, Meiklejohn, Kehl & Lyons, 1660 Lincoln Street, Suite 1600, Denver, CO 80264. Noncarrier Stages seeks authority to purchase the operating rights of CTG in No. MC-162943 (Lead and Sub-Nos. 1, 2, and 3). The Lead certificate authorizes the transportation of passengers and their baggage, in charter and special operations, (1) between points in Colorado and Wyoming, and (2) between points in Colorado and Wyoming, on the one hand, and, on the other, points in the United States (except Alaska and Hawaii). The certificate in Sub-No. 1 authorizes the transportation of passengers, in charter and special operations, between points in the United States (except Alaska and Hawaii), the certificate in Sub-No. 3 authorizes the regular-route transportation of passengers, in intrastate as well as interstate or foreign commerce, over 19 specified routes in western Colorado, extending into southeastern Wyoming. Major authorized service routes extend between Cheyenne, WY, and Trinidad, CO, over Interstate Hwy 25; between Walsenburg and Durango, CO, over U.S. Hwy 160; and between Denver and Grand Junction, CO, (a) over Interstate Hwy 70, and (b) over U.S. Hwy 6. CTG's Sub-No. 2 is a permit authorizing the transportation of passengers and their baggage and small packages, between points in the United States (except Alaska and Hawaii), under continuing contract(s) with Frontier Services Co., of Denver, CO.

Transferee is wholly owned by Arizona Southern Charter Coaches, Ltd., doing business as Arizona Southern Charter Coaches (Southern) (MC-152600), which is in turn wholly owned by Keith C. Lindsay, Robert E. Fawcett, and Robert McKeehon. In addition to transferee, Southern controls motor common carriers All-Cal Tours, Inc. (MC-145224) and Vermant, Inc. (MC-186240). Robert McKeehon wholly owns motor common carrier Roberts Holiday Lines, Inc. (MC-151061).

James H. Bayne,

Secretary.

[FR Doc. 85-29215 Filed 12-9-85; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-186 (Sub-No. 1)]

The Newburgh & South Shore Railway Co.—Abandonment and Discontinue in Cuyahoga County, OH; Findings

December 3, 1985.

Notice is hereby given pursuant to 49 U.S.C. 10903 that a decision decided December 3, 1985, a finding, which is administratively final, was made by the Administrative Law Judge stating that the present or future public convenience and necessity permit the abandonment by the applicant, The Newburgh & South Shore Railway Company, of its entire line of railroad between milespost 0.48 to the end of the line at milepost 6.00, a distance of 7.33 miles in Cuyahoga County, OH. Pursuant to the Judge's decision, the application for abandonment is granted, effective 30 days from the date of service, except as the Commission may elect to hear a discretionary appeal. However, offers either of financial assistance or to purchase the line must be filed within 20 days of the publication of this notice under the provisions of 49 U.S.C. 10905.

James H. Bayne,

Secretary.

[FR Doc. 85-29214 Filed 12-9-85; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Eradication of Cannabis on Non-Federal and Indian Lands in the Contiguous United States and Hawaii; Intent to Prepare a Supplement to the Draft Environmental Impact Statement

The U.S. Department of Justice, Drug Enforcement Administration (DEA), will prepare a supplement to the Draft Environmental Impact Statement on the Eradication of Cannabis on Non-Federal and Indian Lands in the Contiguous United States and Hawaii.

DEA published a notice in the **Federal Register** on May 23, 1985 that a Draft Environmental Impact Statement (EIS on the Eradication of Cannabis on Non-Federal and Indian Lands in the Contiguous United States and Hawaii had been prepared and was available for public comment. The notice provided for a 45-day public review and comment period which ended on July 8, 1985.

Since the Draft EIS was made available to the public, DEA has received new information concerning material discussed in the Draft EIS. In response to this new information and to provide the public with an opportunity to comment on this new information, DEA will prepare a Supplement to the Draft EIS. The supplement is expected to be filed with the U.S. Environmental Protection Agency on or about January 3, 1986 and released to the public for a

45-day review and comment period. Copies of the Supplement to the Draft EIS will be distributed to all parties on the mailing list for the Draft EIS, all parties who commented on the Draft EIS, and all parties who requested copies of the Draft EIS. Other copies are available on request from Rodolfo Ramirez, Jr., Cannabis Investigations Section, Drug Enforcement Administration, Washington, DC 20537.

John C. Lawn,

Administrator.

December 2, 1985.

[FR Doc. 85-29240 Filed 12-9-85; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Application

Pursuant to § 1301.43(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on October 17, 1985, Hoffmann-La Roche Inc., 340 Kingsland Street, Nutley, New Jersey 07110, made application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370) (for manufacturing diagnostic products for non-human consumption to detect THC in urine)	I
Alphaprodine (9010)	II
Levorphanol (9220)	II

Any other such applicant and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed to the Deputy Assistant Administrator, Drug Enforcement Administration, United States Department of Justice, 1405 I Street, NW., Washington, DC 20537, Attention: DEA Federal Register Representative (Room 1112), and must be filed no later than January 9, 1986.

Dated: December 5, 1985.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 85-29239 Filed 12-9-85; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Employment and Training Administration

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance; International Shoe Co. et al.

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period November 25, 1985–November 29, 1985.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-16,151; International Shoe Co., Windsor, MO

TA-W-16,159; Carilee, Inc., Connellsville, PA

TA-W-16,202; Alatex, Inc., Crestview, FL

TA-W-16,170; Cranston Print Works, Fletcher, NC

TA-W-16,193; Caledonian Manufacturing Co., St. Johnsbury, VT

TA-W-16,199; U.S. Steel Corp., Clairton Works, Clerical Personnel, Clairton, PA

TA-W-16,246; Androme Leather Co., Inc., Gloversville, NY

In the following cases the investigation revealed that criterion (3) has not been met for the reasons specified.

TA-W-16,276; International Carriers, Inc., Flint, MI

The investigation revealed that criterion (3) has not been met. The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-16,262; Glove City Abrading Co., Inc., Gloversville, NY

The investigation revealed that criterion (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

TA-W-16,242; Johnstown Leather Corp., Johnstown, NY

Separations for the subject firm were seasonal in nature.

Affirmative Determinations

TA-W-16,185; Ohio Ferro-Alloys Corp., Powhatan Point, OH

A certification was issued covering all workers of the firm separated on or after July 15, 1984.

TA-W-16,161; Connellsville Sportswear, Connellsville, PA

A certification was issued covering all workers of the firm separated on or after October 1, 1984 and before May 15, 1985.

TA-W-16,163; Eaton Corporation, Residential Circuit Breaker Assembly Dept., Lincoln, IL

A certification was issued covering all workers engaged in employment related to the assembling of molded case circuit breakers separated on or after January 1, 1985 and before June 1, 1985.

TA-W-16,157; Apparel 42, Inc., Rickmann, TN

A certification was issued covering all workers of the firm separated on or after July 1, 1984 and before April 30, 1985.

TA-W-16,153; North Country Leatherworks, Inc., East Rochester, NH

A certification was issued covering all workers of the firm separated on or after October 1, 1984.

TA-W-16,152; Jerold Corporation, Smithfield, NC

A certification was issued covering all workers of the firm separated on or after November 1, 984.

TA-W-16,155; Phar-Shar Manufacturing Co., Leitchfield, KY

A certification was issued covering all workers of the firm separated on or after December 1, 1984.

TA-W-16,172; EG&G Rotron, Orangeburg, SC

A certification was issued covering all workers of the firm separated on or after July 2, 1985.

TA-W-16,183 Middletown Footwear, Inc., Middletown, NY

A certification was issued covering all workers of the firm separated on or after November 1, 1984.

TA-W-16,258; Troytown Shirt Corp., Cohoes, NY

A certification was issued covering all workers of the firm separated on or after July 23, 1984.

TA-W-16,228; Stackpole Corp., St. Marys, PA

A certification was issued covering workers engaged in the production of industrial resistors, molded graphite, and soft ferrites separated on or after July 10, 1984.

I hereby certify that the aforementioned determinations were issued during the period November 25, 1985-November 29, 1985. Copies of these determinations are available for inspection in Room 6434, U.S. Department of Labor, 601 D Street, NW., Washington, DC during normal business hours or will be mailed to persons who write to the above address.

Dated: December 3, 1985.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 85-29283 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-30-M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance; Allied Chemical, et al.

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 20, 1985.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 20, 1985.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street, NW., Washington, DC 20213.

Signed at Washington, DC, this 29th day of November 1985.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Allied Chemical (USWA)	Solvay, NY	11-18-85	11-14-85	16,694	Industrial Chemicals.
Wake Garment Co. Inc. (ILGWU)	Wendell, NC	11-21-85	11-18-85	16,695	Girls's dresses contractor
Clay Adams-Division Becton Dickinson (workers)	Parsippany, NJ	11-13-85	11-24-85	16,696	Medical equipment & machinery.
Sperry Corporation (workers)	Ephraim, Utah	11-12-85	11-1-85	16,697	Assembly & Subassembly of Personal Computers.
Powermatic/Houdaille Inc. (USWA)	McMinnville, TN	11-18-85	11-14-85	16,698	Woodworking machine tools.
Rexnord, Inc. (USWA)	Springfield, MA	11-18-85	11-14-85	16,699	Industrial roller chain.
Signode Corp. (workers)	Florance, KY	11-25-85	11-21-85	16,700	Cutting tensioning, banding & sealing Tools for steel strapping.
Jo Ann Apparel, Inc. (workers)	Ebensburg, PA	11-25-85	11-17-85	16,701	Women outwear and sportwear.
Owens Illinois, Inc. (workers)	Columbus, Ohio	11-25-85	11-19-85	16,702	Glass picture tuber for color T.V.'s.
Reserve Mining Co (USWA)	Silver Bay, Minn.	11-18-85	11-14-85	16,703	Taconite.
Styleleader Frashions (IIGWU)	Waterbury, CT		11-18-85	16,704	Contractor Ladies robes.
Lisanne, Inc. (IIGWU)	Brooklyn, NY	11-21-85	11-18-85	16,705	Mfg. ladies robes.
American Thermostate Corp. (workers)	S. Cairo, NY	11-27-85	11-9-85	16,706	Thermostatic controls,—small appliances.
General Tire, Inc. (URW)	Mayfield, Ky	11-26-85	11-14-85	16,707	Tires, passenger, medium, heavy, light truck.
Zenith Electronics Corp. (IBEW)	Springfield, MO	11-19-85	11-14-85	16,708	19" color TV receivers.
Nike Inc. (workers)	Sanford, ME	11-25-85	11-19-85	16,709	Running shoes.
RTE Powermate, Co. (workers)	Hankensack, NJ	11-13-85	11-4-85	16,710	Electronic powor supplies.
General Motors Corp. (Company)	Rochester, NY	11-21-85	11-18-85	16,711	Fuel systems for GM cars.
Harley-Davidson Motor Co., Inc. (Company)	Milwaukee, WI	11-19-85	11-14-85	16,712	Heavy weight motorcycles & parts and acessories.
Harley Davidson Motor Co., Inc. (Company)	York PA	11-19-85	11-14-85	16,713	Heavy weight motorcyles & parts and accessories.
Crystal Brands, Inc. (Company)	Reading, PA	11-18-85	11-14-85	16,714	Izod spotswear apparel.
Crystal Brands, Inc. (Company)	Reading, PA	11-18-85	11-14-85	16,715	Izod spotswear apparel.
Crystal Brands, Inc. (Company)	Laurildale, PA	11-18-85	11-14-85	16,716	Izod spotswear apparel.
Crystal Brands, Inc. (Company)	Laureldale, PA	11-18-85	11-14-85	16,717	Izod spotswear apparel.
Crystal Brands, Inc. (Company)	Laureldale, PA	11-18-85	11-14-85	16,718	Izod spotswear apparel.
Crystal Brands, Inc. (Company)	Laureldale, PA	11-18-85	11-14-85	16,719	Izod spotswear apparel.
Crystal Brands, Inc. (Company)	Allentown, PA	11-18-85	11-14-85	16,720	Izod spotswear apparel.
Dana Corp. UAW	Richmond, IN	11-22-85	11-19-85	16,721	Heavy duty diesel engine sleeves.
3M Company (Workers)	Freehold, NJ	11-20-85	11-08-85	16,722	Professional audio-viedo tapes.
U-Brand Corp. (Union)	Ashland, Ohio	11-21-85	11-16-85	16,723	Malleable & cast iron pipe fittings.
U-Brand Corp. (Union)	Shelby, Ohio	11-21-85	11-16-85	16,724	Warehouse-malleable & casta iron pipe fittings.
Brookfield Clothes Corp. (workers)	Long Island City, NY	11-22-85	11-19-85	16,725	Men clothes, suits, slack, rain coats, top coats.
Volkswagen of America (UAW)	Charleston, WV	11-21-85	11-14-85	16,726	Sheet metal parts for Volkswagen Golf of America.
Emmaus Manufacturing, Co. (ACTWU)	Emmaus, PA	11-22-85	11-18-85	16,727	Western style shirts for mean and women.
Publishers Paper Co. (IWA)	Molalla, OR	11-19-85	11-11-85	16,728	Sawmill-lumber, studs timbers and etc.
Parker Pen Co. (URW)	Janesville, WI	11-25-85	11-22-85	16,729	Pens, ball point pens, roller ball pens and pencils.
Simpson Timber Co. (IWA)	Shelton, WA	10-30-85	9-9-85	16,730	Boom & Rafters Operations.
Weyerhaeuser Co. (IWA)	Chehalis, WA	10-1-85	9-9-85	16,731	Boom & Rafters Operations.
AT&T Technologies (Communications Workers of America)	Kent, WA	10-1-85	9-30-85	16,732	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America)	Miami, FL	10-1-85	9-30-85	16,733	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America)	Dallas, TX	10-1-85	9-30-85	16,734	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America)	Phoenix, AZ	10-1-85	9-30-85	16,635	Residence & business telephone sets, switching apparatus, part & components etc.

APPENDIX—Continued

Petitioner Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
AT&T Technologies (Communications Workers of America).	Salt Lake City, UT	10-1-85	9-30-85	16,736	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Ballwin, MO	10-1-85	9-30-85	16,737	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Minneapolis, MN	10-1-85	9-30-85	16,738	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Plymouth, MI	10-1-85	9-30-85	16,739	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	E. Syracuse, NY	10-1-85	9-30-85	16,740	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Union, NJ	10-1-85	9-30-85	16,741	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Pittsburgh, PA	10-1-85	9-30-85	16,742	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Cincinnati, OH	10-1-85	9-30-85	16,743	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Milwaukee, WI	10-1-85	9-30-85	16,744	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	New Orleans, LA	10-1-85	9-30-85	16,745	Residence & business telephone sets, switching apparatus, part & components etc.
AT&T Technologies (Communications Workers of America).	Nashville, TN	10-1-85	9-30-85	16,746	Residence & business telephone sets, switching apparatus, part & components etc.

[FR Doc. 85-29282 Filed 12-9-85; 8:45 am]
BILLING CODE 45109-30-M

[TA-W-15,474]

Duolite International, Inc., Redwood City, CA; Revised Determination on Reconsideration

Pursuant to the U.S. Court of International Trade remand of October 25, 1985 in (*George Chapman* v. *Donovan*, USCIT 85-1-00049) citing a lack of substantial evidence that imports did not contribute importantly to worker separations at the Redwood City, California plant of Duolite International, Incorporated, the Department makes the following revised determination on reconsideration.

On reconsideration, more precise information was obtained on the product manufactured by Duolite. The new information shows that company imports of ion exchange resins from the French plant are virtually identical to those produced at Redwood City. This information together with findings already in the investigative case file show company imports in 1983 accounted for a major part of Duolite's sales for that year and a substantial part of its 1983 sales decline.

Domestic sales, plant production and employment declines occurred at the Redwood City plant in 1983 compared to 1982 and ion exchange resins production and related employment ceased in 1984.

Company imports of ion exchange resins increased in the first five months of 1984 compared to the same period in 1983 and ion exchange resins imports by the successor firm inceased in 1984 and 1985. The successor firm supplied the same customers. The rising value of the dollar relative to European currencies influenced company decisions to increase imports.

Conclusion

After careful review of the facts obtained on reconsideration, it is concluded that increased imports of articles like or directly competitive with ion exchange resins produced at the Redwood City, California plant of Duolite International, Incorporated contributed importantly to the decline in sales and production of ion exchange resins and to the total or partial separation of former workers at Duolite International, Incorporated's Redwood City, California plant. In accordance with the provisions of the Traded Act of 1974, I make the following revised determination:

All workers of Doulite International, Incorporated, Redwood City, California who became totally or partially separated from employment on or after September 6, 1983 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 27th day of November 1985.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 85-29281 Filed 12-9-85; 8:45 am]
BILLING CODE 4510-30-M

Bureau of Labor Statistics

Recordkeeping Exception Under the Occupational Safety and Health Act of 1970; American Telephone and Telegraph Co.

AGENCY: Bureau of Labor Statistics, Labor.

ACTION: Notice of recordkeeping exception.

SUMMARY: In accordance with section 6(e) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655) and 29 CFR 1904.13(g), notice is hereby given that the petition of the American Telephone and Telegraph Co. (A.T. & T.), 550 Madison Avenue, New York, New York, to maintain the records for its field installation operations in a manner different from that required by Occupational Safety and Health Administration (OSHA) recordkeeping regulation at 29 CFR Part 1904 has been reviewed by the Associate Commissioner for Occupational Safety and Health Statistics, Bureau of Labor Statistics, and is hereby granted subject to the conditions set forth in the following section B-Order. The exception is being granted because it both effectuates the purposes of OSHA recordkeeping regulations and minimizes costly duplication of records which would otherwise be required of A.T. & T.

EFFECTIVE DATE: December 10, 1985.

FOR FURTHER INFORMATION CONTACT: Mr. William M. Eisenberg, Acting Associate Commissioner for Occupational Safety and Health Statistics, Bureau of Labor Statistics, U.S. Department of Labor, 441 G. Street, NW., Washington, DC 20212. Telephone: (202) 272-3467.

SUPPLEMENTARY INFORMATION:

A. Background

For many years prior to the enactment of the Occupational Safety and Health Act of 1970, A.T. & T. kept records for its operations on the basis of occupational groups subject to comparable hazard exposure. In 1972, A.T. & T. petitioned for permission to continue this procedure contending that it provided

the most useful statistics for the evaluation of accidents incurred by its employees. At that time it was recognized that requiring the widely dispersed A.T. & T. field operations to conform to the establishment-basis recording required by 29 CFR Part 1904 would result in recording problems and would be unduly costly and duplicative. Consequently, the A.T. & T. petition was granted. Since 1972, A.T. & T. has been permitted, under 29 CFR 1904.13, to follow an alternative procedure for keeping the log of occupational injuries and illnesses required by 29 CFR 1904.2 for those corporate entities with field operations.

On January 1, 1984, the Bell System was divested by A.T. & T. This divestiture effectively terminated, insofar as A.T. & T. was concerned, the "Bell System Safety and Results Plan"—the system which served as the basis of the 1972 exception. On July 27, 1984, A.T. & T. filed with BLS, a "Petition of American Telephone and Telegraph Company for Permission to Continue to Follow and Alternative Procedure of Keeping the Log of Occupational Injuries and Illnesses Required by the Occupational Safety and Health Act." The Petition requests that certain corporate entities of the Company with field operations be permitted, consistent with existing practices derived from the 1972 exception to 29 CFR Part 1904, to continue to follow alternative recordkeeping procedures.

B. Order

Pursuant to the authority in Sections 6(e), 8(c)(1), 8(c)(2), and 8(g)(2) of the Occupational Safety and Health Act of 1970, 29 CFR 1904.13, and Secretary of Labor's Order 9–83 (48 FR 35736) and based upon a careful consideration of A.T. & T.'s petition, all procedural and regulatory requirements having been found to be met, the Acting Associate Commissioner for Occupational Safety and Health Statistics hereby order that the following exception to the OSHA recrodkeeping regulations at 29 CFR Part 1904 be granted to A.T. & T.:

1. This experience applies only to A.T. & T. field installation operations. Other organizations of the company, including headquarters locations, manufacturing locations, service centers, and supply centers will keep their records in the manner prescribed by 29 CFR Part 1904.

2. A.T. & T. shall maintain OSHA Form No. 200, the Log and Summary of Occupational Injuries and Illnesses, in its district offices. The log entry for each recordable case shall identify the establishment at which the injury or illness occurred. A separate log shall be maintained at the district office of each of the States or parts of States included in that district. In all other respects the log shall be maintained in accordance with the provisions of 29 CFR 1904.2.

3. A.T. & T. shall maintain OSHA form No. 101, the Supplementary Record of Occupational Injuries and illnesses, or equivalent in the manner provided by 29 CFR 1904.4, except that the supplementary records shall be compiled and maintained at the district installation offices rather than at each establishment.

4. A.T. & T. shall complete and post the Annual Summary, as provided in 29 CFR 1904.5, except that it shall be compiled on a district rather than an establishment basis. The summary shall, however, be posted at each establishment or mailed to each employee in accordance with 29 CFR 1904.5

5. Each district office, pursuant to 29 CFR 1904.6, shall maintain the records for the district for five (5) years following the end of the calendar year to which they relate; and each district office shall have personnel available during normal business hours to provide information from the records maintained there by telephone or by mail.

6. This exception in no way affects the duty of A.T. & T. to post the notices required by 29 CFR 1903.2 at each establishment. Further, A.T. & T. shall post at each establishment the address and phone number of the district office in which the records for that establishment are kept.

7. Nothing in this notice shall be deemed to affect the duties of A.T. & T. to comply with the requirements of any State plan approved pursuant to section 18(b) of the Occupational Safety and Health Act of 1970.

8. Nothing in this notice shall be deemed to affect the duties of A.T. & T. under 29 CFR 1904.7 (access to records) and 29 CFR 1904.8 (reporting of fatalities and multiple hospitalization accidents).

9. A.T. & T. shall continue to report occupational injuries and illnesses as required by 29 CFR 1904.21 and in accordance with the reporting procedures of the Bureau of Labor Statistics.

10. In addition to these conditions, it is understood that this is an exception only from the provisions of 29 CFR Part 1904 in effect on the effective date of this exception. If the regulations in 29 CFR Part 1904 are modified after the effective date of this exception, either by additional provisions or provisions inconsistent with those from which this exception is granted, and if A.T. & T. desires to keep records in a manner different from those modified, then A.T. & T. must petition for exception from the provisions as modified; otherwise, A.T. & T. will be required, by operations of law under the terms of the regulations, to comply with those provisions, as modified.

Effective date. This exception shall become effective on December 10, 1985.

Signed at Washington, DC, on December 3, 1985.

William M. Eisenberg,

Acting Associate Commissioner for Occupational Safety and Health Statistics, Bureau of Labor Statistics.

[FR Doc. 85-29284 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-24-M

Mine Safety and Health Administration

[Docket No. M-85-158-C]

Barnes & Tucker Co.; Petition for Modification of Application of Mandatory Safety Standard

Barnes & Tucker Company, P.O. Box 176, Marion Center, Pennsylvania 15759-0716 has filed a petition to modify the application of 30 CFR 75.1710 (cabs and canopies) to its Tanoma Mine (I.D. No. 36-06967) located in Indiana County, Pennsylvania. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that cabs or canopies be installed on the mine's electric face equipment.

2. Petitioner states that the use of canopies would result in a diminution of safety for the miners affected. Due to the bottom heaving, the canopy has to be lowered to its minimum height which restricts the equipment operator's visibility and dislodges roofbolts.

3. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 9, 1986. Copies of the petition are available for inspection at that address.

Dated: December 4, 1985.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 85-29285 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-85-177-C]

Eastern Associated Coal Corp.; Petition for Modification of Application of Mandatory Safety Standard

Eastern Association Coal Corpoation, One PPG Place, Pittsburgh, Pennsylvania 15222 has filed a petition to modify the application of 30 CFR 75.305 (weekly examinations for hazardous conditions) to its Federal No. 2 Mine (I.D. No. 46-01456) located in Monongalia County, West Virginia. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that weekly examinations for hazardous conditions be made in the return and in at least one entry of each intake and return air course in its entirety.

2. The Federal No. 2 Mine was opened in 1968 in the Pittsburgh coal seam. During the period from 1976 to 1979 a tunnel was driven in the coal seam. The tunnel was constructed with a horizontal partition wall of precast concrete slabs to provide separate intake and return air courses, with the return on top. Due to rib rolls which have caused the large concrete slabs to collapse, approximately 800 feet of the tunnel immediately in by the Shriver Shaft is inaccessible and too dangerous to travel. Rehabilitation of the tunnel in the area of the unstable slabs and ribs would expose workers to hazardous conditions. Although unsafe for travel, the tunnel allows sufficient air to pass to ventilate the affected areas of the mine.

3. As an alternate method, petitioner proposes to establish and maintain two special ventilation check points that would be examined daily by a certified person. Air quantity and methane readings would be recorded and a date board would be located at each check point for the date, time and initials of the person making each examination. All persons assigned the duties of running the check points would be familiar with the ventilation of the area, and any changes would be reported to the mine and ventilation foremen.

4. Petitioner states that the proposed alternate method will provide the same degree of safety for the miners affected as that afforded by the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 9, 1986. Copies of the petition are available for inspection at that address.

Dated: December 4, 1985.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 85-29286 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-85-153-C]

Keystone Coal Mining Corp.; Petition for Modification of Application of Mandatory Safety Standard

Keystone Coal Mining Corporation, 655 Church Street, Indiana, Pennsylvania 15701 has filed a petition to modify the application of 30 CFR 75.1101 (deluge-type water sprays) to its Emilie No. 1 & 2 Mine (I.D. No. 36-00821), its Jane No. 1 & 2 Mine (I.D. No. 36-00823), its Margaret No. 11 Mine (I.D. No. 36-05038) and its Emilie No. 4 Mine (I.D. No. 36-06018) all located in Armstrong County, Pennsylvania, its Urling No. 1 Mine (I.D. No. 36-04852), its Urling No. 2 Mine (I.D. No. 36-04853) and its Urling No. 3 Mine (I.D. No. 36-05658) all located in Indiana County, Pennsylvania. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that deluge-type water sprays, foam generators actuated by rise in temperature, or other no less effective means of controlling fire, be installed at main and secondary belt-conveyor drives.

2. Petitioner states that placing water sprinklers over or near a belt starter box would result in a diminution of safety because the equipment is unattended and could get activated inadvertently, creating a risk of electrical shock or possible electrocution to the miners.

3. As an alternate method petitioner proposes to install either a foam generator system, single line closed head sprinkler system, closed head sprinkler system, or a dry chemical/water deluge system at specific remote head, belt starter and take-up units.

4. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 9, 1986. Copies of the petition are available for inspection at the address.

Dated: December 4, 1985.

Patricia W. Solvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 85-29287 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-85-24-M]

Mississippi Lime Co.; Petition for Modification of Application of Mandatory Safety Standard

Mississippi Lime Company, P.O. Drawer 31, Ste. Genevieve, Missouri 63670-0031 has filed a petition to modify the application of 30 CFR 57.13020 (use of compressed air) to its Peerless Mine (I.D. No. 23-00542) located in Ste. Genevieve County, Missouri. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. The petition concerns the requirement that compressed air not be directed towards a person.

2. Petitioner states that during a regular shift, persons making repairs and operators clearing choke-ups or cleaning up spills get excessive amounts of lime dust on their clothing. If this accumulation of dust on the clothing is not removed, it can work into and through the clothing, causing lime burns to the skin.

3. Several vacuums and blowers have been used and were unsuccessful in removing the dust from the clothing.

4. As an alternate method, petitioner proposes to use the "Guardaire Model No. 80" air gun to remove dust from the employees' clothing. These guns have no center hole through the nozzle, therefore no static pressure build-up. This eliminates the danger of forcing air into the blood stream if the nozzle is pressed against the skin.

5. For these reasons petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments. These comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. All comments must be postmarked or received in that office on or before January 9, 1986. Copies of the petition are available for inspection at that address.

Dated: December 4, 1985.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 85-29288 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-43-M

Office of Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 85-198; Exemption Application No. D-4559 et al.]

Grant of Individual Exemptions; Andron, Cechettini & Asso., Inc., et al.

AGENCY: Pension and Welfare Benefit Programs, Labor.

ACTION: Grant of Individual Exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1954 (the Code).

Notices were published in the Federal Register of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department of Washington, DC. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of pendency were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

Andron, Cechettini & Associates, Inc., Located in Lafayette, California

[Prohibited Transaction Exemption 85-198; Exemption Application No. D-4559]

Exemption

Section I. Exemption for Certain Transactions Involving the Purchase of Interests in AC Investors (the Partnership)

The restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to the purchase of interests in the Partnership by employee benefit plans (Participating Plans), if the general conditions set forth in Section II are met, and if:

1. Each purchase of interests in the Partnership by a Participating Plan is authorized in writing by a fiduciary (the Independent Fiduciary) of each Participating Plan who is independent of the Applicants [1] and their affiliates.[2] If such Independent Fiduciary directs that assets then under management by any of the Applicants be invested in the Partnership, such written authorization by the Independent Fiduciary shall specify such fact and the manner in which such assets shall be transferred to the Partnership.

2. The following persons may not acquire or hold any securities of any company whose securities the Partnership holds (provided, however, that the restrictions contained in this subsection shall not apply to the acquisition of such securities by any venture capital company that is controlled by or managed by Covered Persons as defined below and that is subject to the allocation formula described in section 7 of the Summary of Facts and Representations contained in the Proposed Exemption):

(a) The Applicants and officers, directors and general partners of the Applicants.

(b) Affiliates of AC Investors, AC Associates, Mr. Andron and Mr. Cechettini. ("Covered Persons").

3. The terms and conditions of the partnership agreement (the Partnership Agreement) at the formation of the Partnership and at the time of any purchase of an interest covered by this exemption shall be no less favorable to the Participating Plans than the terms and conditions available in arm's-length transactions between unrelated parties.

4. Prior to accepting any investment of assets in the Partnership by a Participating Plan, the Applicants shall furnish or cause to be furnished to each Independent Fiduciary authorizing such investment a copy of this exemption, the Partnership Agreement, a private placement memorandum which describes the respective rights of the general and limited partners to distributions and capital appreciation, services to be performed by the general partner and the compensation payable therefore, all other material rights and obligations of the partners, and such other information as requested by the Independent Fiduciary.

5. A Participating Plan shall not, after the date of investment of Plan assets in the Partnership, pay to any of the Applicants a separate investment management fee or similar fee with respect to the Participating Plan's assets invested in the Partnership.[3] If a Participating Plan invests in the Partnership during any period for which the Plan has prepaid to any of the Applicants an investment management or similar fee, the amount of such fee will be returned to the Participating Plan. This condition shall not preclude payment by the Partnership to any of the Applicants of expenses and allocations provided in the Partnership Agreement.

[1] The Applicants are AC Associates, Andron, Cechettini & Associates, Inc., Jonathan Andron, and Ralph Cechettini.

[2] All future references to the Applicants will also include affiliates of the Applicants.

[3] This condition shall not preclude the payment by the Participating Plans to the Applicants of investment management or other fees with respect to assets not invested in the Partnership.

6. No sales commissions or similar fees will be charged by the Applicants to any Participating Plan with respect to its investment in the Partnership. No redemption fee or other penalty shall be charged by the Applicants to any Participating Plan which transfers all or a portion of its Plans to the Applicants of investment management or other fees with respect to assets not invested in the Partnership. Partnership interest as permitted by the Partnership Agreement, except that a Participating Plan must compensate the Partnership for reasonable fees and expenses incurred by the Partnership in its efforts to locate a suitable purchaser for the Participating Plan's Partnership interest.

7. The partnership Agreement will require that limited partners receive audited annual financial statements with respect to the Partnership as well as such other information as the limited partner (or a Participating Plan's Independent Fiduciary) may reasonably request concerning the operations and investments of the Partnership.

8. No Participating Plan may invest more than 10% of its assets in the Partnership.

Section II. General Conditions

(a) The Applicants maintain for a period of six years from the date of the transaction the records necessary to enable the persons described in paragraph (b) of this section II to determine whether the conditions of this exemption have been met, except that (1) a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of the Applicants, the records are lost or destroyed prior to the end of the six-year period, and (2) no party in interest shall be subject to the civil penalty that may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975 (a) and (b) of the Code, if the records are not maintained, or are not available for examination as required by paragraph (b) below.

(b)(1) Except as provided in section (2) of this paragraph (b) and notwithstanding any provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to in paragraph (a) of this Section II are unconditionally available at their customary location for examination during normal business hours by:

(A) Any duly authorized employee or representative of the Department or the Internal Revenue Service,

(B) Any fiduciary of a Participating Plan who has authority to acquire or dispose of the interests in the Partnership of the Participating Plan or any duly authorized employee or representative of such fiduciary,

(C) Any contributing employer to any Participating Plan or any duly authorized employee or representative of such employer, and,

(D) Any participant or beneficiary of any Participating Plan or any duly authorized employee or representative of such participant or beneficiary.

(b)(2) None of the persons described in subparagraphs (B) through (D) of this paragraph (b) shall be authorized to examine trade secrets of the Applicants, or commercial or financial information which is privileged or confidential.

Section III. Definitions and General Rules

(a) An "affiliate" means a person with one or more of the following relationships to any of the Covered Persons:

(i) Any person directly or indirectly through one or more intermediaries, controlled by such Covered Persons; and

(ii) Officers, directors, highly compensated employees, relatives of or general partners in any such Covered Persons.

(b) The term "control" means beneficial ownership, by Covered Persons in the aggregate, either directly or through one or more controlled companies, of more than 50% of a company's voting securities.

(c) The term "relative" means spouse and minor children sharing the same household of such Covered Person.

(d) The term "highly compensated employee" means a person whose compensation during the most recent fiscal year exceeds the greater of $30,000 or 10% of the total compensation earned by all employees of the employer.

(e) Each Participating Plan shall be considered to own the same proportionate undivided interest in each asset of the Partnership as its proportionate interest in the total assets of the Partnership as calculated on the most recent preceding valuation date of the Partnership.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on August 19, 1985 at 50 FR 33424.

The Department notes that section 1(2) of the Proposed Exemption incorrectly referred to the allocation formula as being located in paragraph 6 of the Summary of Facts and Representations. The allocation formula is in fact located in paragraph 7 of the Summary of Facts and Representations. In addition, the Department has revised the language contained in section 1(2) of the Proposed Exemption to make it clear that the provision against holding securities held by the Partnership does not apply to the acquisition of such securities by other venture capital companies controlled by or managed by Covered Persons. The Exemption has been amended to reflect the above mentioned changes.

For Further Information Contact: Mr. Alan H. Levitas of the Department, telephone (202) 523-8971. (This is not a toll-free number.)

Southern Fruit Distributors, Inc., Employees Profit Sharing and Benefit Plan (the Plan) Located in Orlando, FL

[Prohibited Transaction Exemption 85-199; Exemption Application No. D-5573]

Exemption

The restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply effective June 29, 1984, to the past cash sale on June 29, 1984 by the Plan of: (1) Its 60% interest in certain real property known as the Southside Shopping Center for $1,629,612 to Southside Shopping Center, Ltd., a Florida limited partnership; and (2) its 10% limited partnership interest in a limited partnership known as Compton Properties, Ltd. (Compton) for $407,988 to the other partners in Compton, provided that the purchase price for these interests was not less than their fair market value as of June 29, 1984.

For a more complete statement of the facts and respresentations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on September 16, 1985 at 50 FR 37603.

For Further Information Contact: David Lurie of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Butte Orthopedic and Fracture Clinic Pension and Profit Sharing Plans (the Plans) Located in Butte, Montana

[Prohibited Transaction Exemption 85-200; Exemption Application Nos. D-5603 and D-5604]

Exemption

The restrictions of section 406(a) 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the lease of certain real property by the Plans to the Butte Orthopedic and Fracture Clinic,

for a 20 year period provided all of the terms of the proposed lease are as favorable to the Plans as those obtainable in a similar transaction with unrelated parties.

Effective Date: This exemption is effective November 21, 1984.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 8, 1985 at 50 FR 41048.

For Further Information Contact: Ms. Linda Hamilton of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Pension and Profit Sharing Plans of Montana Urology, Inc. (the Plans) Located in Butte, Montana

[Prohibited Transaction Exemption 85-201; Exemption Application Nos. D-5605 and 5606]

Exemption

The restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the lease of certain real property by the Plans to Montana Urology, Inc. for a 20-year period provided all of the terms of the lease are as favorable to the Plans as those obtainable in a similar transaction with unrelated parties.

Effective Date: If this proposed exemption is granted, it will be effective on November 21, 1984.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 8, 1985 at 50 FR 41049.

For Further Information Contact: Ms. Linda Hamilton of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Pension Plan for Employees of First National Bank of Akron (the Plan) Located in Akron, Ohio

[Prohibited Transaction Exemption 85-202; Exemption Application No. D-5623]

Exemption

The restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the sale of a parcel of land and the building thereon (together, the Property) by the Plan to the First National Bank of Akron, for $550,000 in cash, provided such amount is not less than the fair market value of the Property on the date of the sale.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 8, 1985 at 50 FR 41051.

For Further Information Contact: Gary H. Lefkowitz of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

The Travelers Separate Account "R" (the Account)

[Prohibited Transaction Exemption 85-203; Exemption Application No. D-5722]

Exemption

The restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply, effective October 9, 1984, to the lease of space in a building by the Account to the Travelers Insurance Company, a party in interest with respect to the Account, provided that the terms of the lease are not less favorable to the Account than those terms obtainable with an unrelated party.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 8, 1985 at 50 FR 41052.

Effective Date: The effective date of this exemption is October 9, 1984.

For Further Information Contact: Mr. E.F. Williams of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

Advance Business Corporation Employees Profit Sharing Plan & Trust (the Plan) Located in Westmont, Illinois

[Prohibited Transaction Exemption 85-204; Exemption Application No. D-5727]

Exemption

The restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply for a period of 5 years, to the proposed loans by the Plan of up to 25% of its assets to Advance Business Corporation (the Employer), and to the guarantee of repayment on the loans by the shareholders of the Employer, provided that the terms of the transactions are not less favorable to the Plan than those obtainable in an arm's-length transaction with an unrelated party at the time of consummation of each transaction.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 8, 1985 at 50 FR 41053.

Temporary Nature of Exemption

This exemption is temporary and will expire 5 years after the date of grant with respect to the making of any loan, subsequent to the expiration of this exemption, the Plan may hold loans originated during this 5 year period until the loans are repaid. Should the applicant wish to continue entering into loan transactions beyond the 5 year period, the applicant may submit another application for exemption.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Robert J. Bray, D.D.S., M.S., P.A., Profit Sharing Plan (the Plan) Located in Rochester, New York

[Prohibited Transaction Exemption 85-205; Exemption Application No. D-5984]

Exemption

The restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the sale of a partnership interest in Red River Associates by the Plan to Dr. Robert Bray, a party in interest with respect to the Plan provided that the terms of the sale are at least as favorable to the Plan as those obtainable in a similar transaction with an unrelated party on the date of its consummation.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on July 26, 1985 at 50 FR 30541.

For Further Information Contact: Ms. Linda Hamilton of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

West Tennessee Motor Express, Inc. Profit Sharing Plan; M&S Company Inc. Profit Sharing Plan (collectively, the Plans) Located in Nashville, Tennessee

[Prohibited Transaction Exemption 85-206; Exemption Application Nos. D-6067 and D-6068]

Exemption

The restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed sale of certain mortgage notes by the Plans to three participants of the Plans, provided that the sales price of such notes is not less than their fair market value on the date of the sale.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 8, 1985 at 50 FR 41057.

For Further Information Contact: Mr. E.F. Williams of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

Smallwood, Reynolds, Stewart, Stewart & Associates, Inc., Profit Sharing Plan and Trust (the Plan) Located in Atlanta, Georgia

[Prohibited Transaction Exemption 85-207; Exemption Application No. D-6136]

Exemption

The restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed sale by the Plan of 18,562 shares of the common stock of JH Restaurants, Inc. (the Shares) to Smallwood, Reynolds, Stewart, Stewart & Associates, Inc., the sponsor of the Plan and a party in interest with respect to the Plan, for cash in the amount of $35,000, provided that such amount is not less than the fair market value of the Shares on the date of sale.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on October 8, 1985, at 50 FR 41059.

Comments and Hearing Requests: The applicant advised the Department that the notice of proposed exemption erroneously stated that the Employer is a law firm, while the Employer is in fact an architectural firm.

For Further Information Contact: Ms. Katherine D. Lewis of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Dixon-Merkle, P.C. Employees Retirement Plan (the Plan) Located in Dearborn, Michigan

[Prohibited Transaction Exemption 85-208; Exemption Application No. D-6242]

Exemption

The restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the sale by the Plan of an improved parcel of real property (the Real Property) for the cash consideration of $130,000, to Drs. Karl Merkle and David W. Peters (Drs. Merkle and Peters), provided the sales price for the Real Property is not less than its fair market value at the time the transaction is consummated.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 8, 1985 at 50 FR 41060.

Written Comments: The Department received one written comment to the proposed exemption and no requests for a public hearing. The written comment, which was submitted by counsel for Drs. Markle and Peters, noted one slight error in the notice of proposed exemption, namely in paragraph number one at page 41060. The second sentence of that paragraph states that the trustees of the Plan, who are also Plan participants, are Dr. Merkle and Dr. Paul Nagy. Counsel wishes to clarify that Paul Nagy is not a doctor or a Plan participant. He is a Plan trustee as well as a certified public accountant who handles the books and records of Dixon-Merkle, P.C.

After consideration of the entire record, the Department has determined to grant the exemption.

For Further Information Contact: Ms. Jan D. Broady of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, D.C., this 5th day of December, 1985.

Elliot I. Daniel,

Assistant Administrator for Regulations and Interpretations, Office of Pension and Welfare Benefit Programs, U.S. Department of Labor.

[FR Doc. 85-29277 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-5297 et al.]

Proposed Exemptions; R.A. Gray & Co., et al.

AGENCY: Pension and Welfare Benefit Programs, Labor.

ACTION: Notice of Proposed Exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1954 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the spending exemptions, unless otherwise stated in the Notice of Pendency, within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state the reasons for the

writer's interest in the pending exemption.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Pension and Welfare Benefit Programs, Office of Regulations and Interpretations, Room N–5669, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. stated in each Notice of Pendency. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N–4677, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register.** Such notice shall include a copy of the notice of pendency of the exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of pendency are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

R.A. Gray & Company Retirement Plan (the Plan) Located in Portland, Oregon

[Application No. D-5297]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the continued leasing beyond June 30, 1984 of certain parcels of real property by the Plan to R.A. Gray & Company (the Employer), provided all of the terms of the proposed leases are at least as favorable to the Plan as those obtainable in an arm's-length transaction with an unrelated party.

Effective Date: If the proposed exemption is granted it will be effective July 1, 1984.

Summary of Facts and Representations

1. The Plan is a defined contribution profit sharing plan. There are approximately 52 participants. The Plan had total assets of $1,617,913 as of February 28, 1984. The trustees of the Plan are Messers. R.A. Gray, John R. Bentley and Hawkin Au (the Trustees). The Trustees are the shareholders and officers of the Employer. The Employer is a general contractor in the construction industry.

2. In 1971 the Employer purchased approximately 7½ acres of unimproved real property located in Tigard, Oregon (the Property). Three parcels of the Property were sold by the Employer to the Plan. The sales prices represented the Employer's cost for the Property. These sales are described as follows:

(a) In May of 1972, the Plan purchased 1.43 acres (Parcel I) for $16,600. There was an immediate lease-back of Parcel I to the Plan Sponsor under a 25-year lease for an annual rental of $1,660.

(b) In August of 1973, the Plan purchased 2.31 acres (Parcel II) for $11,400. There was an immediate lease-back to the Plan Sponsor under a 25-year lease for an annual rental of $1,140.

(c) In July of 1974, the Plan purchased 1.6 acres (Parcel III) for $24,000. There was an immediate lease-back to the Plan Sponsor under a 25-year lease for an annual rental of $2,400.

(d) A fourth parcel of the Property was sold to the Trustees in their individual capacities.

3. The leases of Parcels I, II, and III (collectively, the Parcels) from the Employer (collectively, the Original Leases) were all triple net leases for 25-year terms in which all the expenses incurred with respect to the Parcels were the responsibility of the Employer, as leassee.[1] The Employer immediately constructed improvements on the Parcels. (The Employer retained .9 acres which currently cannot be developed because it is part of a flood plain). The Employer leases the improvements located on the Parcels to unrelated parties.

4. Effective July 1, 1984 the Original Leases were extended (the New Leases). The New Leases were effectuated by addendums to the Original Leases. The New Leases permit the 25-year terms of the Original Leases to expire as now scheduled. The New Lease for Parcel I will expire on May 12, 1997; the New Lease for Parcel II will expire on August 31, 1998; and the New Lease for Parcel III will expire on July 31, 1999. Each of the New Leases provides for a ten-year option to renew. The option will be exercised only upon the approval of the Plan's independent fiduciary.

5. The annual rental for the New Leases is a total of $44,199.[2] This rental amount reflects the fair market rental value of the Property as determined by an appraisal performed by Curtis, Mackenzie & Slocum, Inc., an independent real estate appraisal firm (the Appraiser) located in Portland, Oregon. The Appraiser determined that the fair market value of the Parcels is $441,959 based upon an appraisal of March 24, 1983, and an updated appraisal of December 17, 1984. The value of the Property represents 27 percent of the total assets of the Plan.[3]

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[1] The applicant represents that the Original Leases are covered by section 414 of the Act. The applicant further represents that although the written lease of Parcel III was not signed until July 9, 1974, this lease was made subject to a binding contract in effect on July 1, 1974 and is, therefore, covered by section 414 of the Act. The Department expresses no opinion as to the applicability of section 414 in this instance. However, the applicant represents that it will pay any excise tax which may be due as a result of the Original Leases within 60 days after a final determination of such liability by the appropriate governmental entity.

[2] The annual rental for the New Leases reflects an increase in the annual rental for the Original Leases. The increased rental rate became effective July 1, 1984. The applicant represents that the entire amount of the rent increase was paid to the Plan in cash in February of 1985 which is the close of the Employer's and the Plan's fiscal year. No interest was paid at that time. Although there is an agreement that interest is being charged on the unpaid amount, no payments have been made subsequent to February of 1985. The Plan's independent fiduciary will determine the interest rate in light of current market conditions and its determination of the fair market value for interest rates and collect all monies and interest due the Plan when the proposed exemption is granted.

[3] The applicant represents that the Property will represent not more than 25% of the total assets of the Plan in the 1985–86 Plan year.

The Appraiser also determined that a 10 percent return on land value in the Portland, Oregon area represents a fair market value rate. This annual rental rate will be adjusted every five years to equal 10 percent of the then appraised value of the Property. The annual rental rate for the New Leases will not fall below the initial annual rate of $44,199.

6. The terms of the New Leases provide that the improvements which have been constructed on the Parcels by the Plan Sponsor shall become the property of the Plan at the end of the terms of the New Leases. The New Leases also will contain provisions granting an option to the Plan to purchase the Employer's leasehold interest in the New Leases at any time during the last five years of the New Leases. The purchase price for the leasehold interest will equal the balance of the remaining indebtedness owed by the Employer on the permanent financing it incurred at the time the improvements were completed.

7. The Pacific Western Bank has been appointed to serve as the independent fiduciary for the New Leases (the Independent Fiduciary). The Independent Fiduciary made the following representations by letter of May 23, 1984:

(1) It is unrelated to the Plan and the Employer.

(2) It has examined the Plan's investment portfolio and has determined that the New Leases fit within the Plan's investment scheme.

(3) It has contacted the Appraiser, met with the Trustees, compared the New Leases with other known transactions of leased space in the Portland area and analyzed current market trends and conditions, and as a result, is of the opinion that the New Leases are in the best interest of the Plan.

(4) It has reviewed all of the terms of the New Leases and has determined that all such terms represent fair market value terms.

(5) It has determined that the New Leases provide adequate safeguards for the protection of the Plan and its participants and beneficiaries.

(6) It will monitor all of the provisions of the New Leases.

(7) It will obtain an independent appraisal of the Parcels and make the rental adjustment every five years to reflect the fair market value rental rate.

(8) It will have sole authority to decide whether the Plan should exercise its option to purchase the Employer's leasehold interest and will exercise the option only if it is in the interests of and protective of the Plan.

(9) It will have sole authority to exercise the option to renew the New Leases on behalf of the Plan.

8. In summary, the applicant represents that the proposed transaction meets the statutory criteria of section 408(a) of the Act because:

(a) The initial rental payment for the New Leases equals the fair market rental value of the Parcels as determined by an independent appraisal;

(b) The rental rate will be adjusted every five years to reflect the fair market rental value of the Parcels;

(c) The plan's Independent Fiduciary will monitor all of the terms of the New Leases; and

(d) the Independent Fiduciary has determined that all of the terms of the New Leases are in the interest of and protective of the Plan and its participants and beneficiaries.

For Further Information Contact: Ms. Linda Hamilton of the Department, telephone (202) 523–8881. (This is not a toll-free number.)

Peterson, Thelan & Price, a Professional Corporation Profit Sharing Plan and Trust (the Plan) Located in San Diego, California

[Application No. D–6088]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1985). If the exemption is granted the restrictions of the section 406(a) and 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the proposed cash sale by the Plan of certain shares of common stock in Citizens Western Bank (the Bank), an unrelated party, to Paul A. Peterson, a party in interest with respect to the Plan, provided that the Plan receives at least fair market value at the time of sale.

Summary of Facts and Representations

1. The Plan is a defined contribution profit sharing plan with nine participants and assets in excess of $488,300 as of January 31, 1985. Paul A. Peterson (the applicant) is the principal stockholder of Peterson, Thelan & Price, A Professional Corporation (the Employer) and is also the trustee of the Plan. The principal business of the Employer is providing legal services. Mr. Peterson no longer actively participates in the Plan, but he retains therein an individually directed account (the Account) with current assets of approximately $199,030.

2. Among the assets of the Account are 3,400 shares (the Shares) common stock in Citizens Western Bank (the Bank). Mr. Peterson purchased the Shares on behalf of the Account for $52,700 ($15.50 per share) on July 11, 1980. The applicant represents that the Shares have paid no dividends and have declined in value since their acquisition.

3. The applicant requests an exemption for the cash sale of the Shares by the Account to the applicant for its original purchase price of $52,700. The applicant represents that neither he nor the Employer have any relationship with the Bank other than a personal checking account held by himself and his wife.

4. The applicant submitted a letter from David P. White, Account Executive at the investment firm Bateman Eichler, Hill Richards, stating that, as of April 19, 1985, the Bank's common stock was quoted at $6 per share, at which price the Account's Shares would have an aggregate fair market value of $20,400. The applicant also submitted a letter dated August 2, 1985 from David S. Sackett, Vice President of Sutro & Co., Incorporated, which is registered with the Securities Exchange Commission as the trader or "market maker" of the Bank's common stock, stating that it has not traded above $10 per share in the last eighteen months, and that it currently trades between $6 and $6.50 per share.

5. The applicant represents that the proposed sale is in the best interests of the Plan and its affected account because the Account is not likely to obtain a significant return on the Shares or to receive a better price for the Shares on the open market. Furthermore, the sale will improve the liquidity of the Account.

6. In summary, the applicant represented that the proposed transaction meets the statutory criteria of section 408(a) of the Act because (a) the Account will be relieved of an unprofitable investment; and (b) the sale price of the Shares will be at or above fair market value at the time of sale.

Notice to Interested Person: Since Mr. Peterson is the only participant affected by the transaction, there is no need to distribute notice to interested persons. Comments and hearing requests are due 30 days after the publication of this notice in the Federal Register.

For Further Information Contact: Ms. Linda Shore of the Department, telephone (202) 523–7901. (This is not a toll-free number.)

Construction Industry Laborers Vacation Fund (the Vacation Fund) and the Construction Industry Laborers Welfare Fund (the Welfare Fund; Collectively the Funds) Located in Jefferson City, Missouri

[Application No. L-6186]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) of the Act shall not apply to the transfer of uncommitted reserves by the Vacation Fund to the Welfare Fund. The Welfare Fund is a party in interest with respect to the Vacation Fund as a result of providing administrative services and office space to the Vacation Fund.

Summary of Facts and Representations

1. The Vacation Fund is an employee welfare benefit plan as defined by section 3(1) of the Act and was established in accordance with section 302(c)(5) of the Labor Management Relations Act of 1947, as amended. The Welfare Fund is also an employee welfare benefit plan as defined by section 3(1) of the Act and was also established in accordance with section 302(c) (5) of the Labor Managment Relations Act of 1947, as amended. For the year ending December 31, 1982, employer contributions were made on behalf of approximately 3,048 Vacation Fund participants and approximately 4,320 Welfare Fund participants. The Vacation fund and Welfare Fund have assets of $412,231 and $5,835,550, respectively as of December 31, 1982. There are 12 trustees serving on the Welfare Fund and 2 trustees serving on the Vacation Fund, however, there are no common trustees.

2. The Vacation Fund is an irrevocable trust designed and administered for the purpose of providing vacation and related benefits for participants and beneficiaries. The Vacation Fund was established on June 18, 1970 and the Welfare Fund on April 1, 1952. Participants under the Funds are employees covered by collective bargaining agreements negotiated between various employers and employer associations and the various local unions of the Western Missouri and Kansas Laborers District Council of the Laborers International Union of North American, AFL-CIO (the Union). The Vacation Fund and the Welfare Fund are currently receiving contributions under current collective bargaining agreements.

3. Under the Amended Agreement and Declaration of Trust of the Vacation Fund (the Trust Document), Article IX, Section 1, all funds accumulated by each participant under the Vacation Fund for work performed within the geographic jurisdiction of the Vacation Fund during the calendar period are automatically paid out on an annual basis. Article IX provides as follows:

> The trustees shall have full authority, in their discretion, to determine all questions of nature, amount, manner and time of benefits to be provided . . . Payments and distribution of funds from a participant's account shall be made by check from the commercial bank once each year between December 10 and March 10 of the following year. The vacation account of each participant shall accumulate annually during the period from November 1, to the following October 31.

4. The applicant represents that because of the instability and vulnerable nature of the construction industry many construction workers move from place to place and from employer to employer. As a result, the Vacation Fund has been plagued since its establishment with the return of many of its vacation benefit checks, unclaimed and uncashed. Foreseeing this possibility, the trustees of the Vacation Fund provided for this contingency in the Trust Document, Article IX, section 7. Under section 7, the trustees may adopt rules and regulations concerning situations where the Vacation Fund is unable to locate a participant or beneficiary in order to make a distribution of funds. Under such circumstances, the trustees may cause the funds due a participant which are unclaimed for a period of two years to revert to the general account of the Vacation Fund or to be paid to the Welfare Fund to provide benefits to participants of the Welfare Fund.

5. The applicant states that if for any reason the vacation benefits of a participant are not received, the participant may obtain such benefits by writing to the board of trustees of the Vacation Fund. Each plan participant of the Vacation Fund who has not claimed vacation benefits which become forfeited under the rules of the Vacation Fund and which are subsequently transferred to the Welfare Fund, may still recover the monies due from the Welfare Fund. Therefore, as structured, there will be no ultimate forfeiture of accrued vacation benefits as a result of the transfer if at a later date a participant makes a claim for vacation benefits. The amount of unclaimed vacation benefits for the years 1979, 1980, 1981 and 1982 as December 31, 1982 was $88,335.11 representing unclaimed checks for 1,430 participants. The trustees of the Vacation Fund have declared these unclaimed benefits forfeited and propose to transfer this amount to the Welfare Fund.

6. The applicant states that there is a substantial overlap of participants between the Vacation Fund and the Welfare Fund. As such, the trustees of both funds are of the opinion that the unclaimed and forfeited benefits of the Vacation Fund could best be used to most effectively benefit the participants under the Vacation Fund and Welfare Fund by providing benefits to the participants and beneficiaries of the Welfare Fund. The Welfare Fund provides hospitalization, medical, accidental death and dismemberment, maternity and other related health care benefits to participants and their beneficiaries.

7. The applicant represents that the Vacation Fund makes a diligent search to locate participants whose checks are returned. In attempting to locate a participant for payment of vacation benefits, the Vacation Fund uses the last known address of the participant as provided by the participant to the Vacation Fund, the Union or an employer. For participants for whom the Vacation Fund does not have an address, certain procedures are followed in an attempt to locate a current mailing address. First, periodically, a computer printout listing the name and social security number of participants for whom the Vacation Fund's administrative office does not have an address is prepared. This printout is sent to the Union in the area from which the hours have been reported to the Vacation Fund administrator. The Union is requested to search its records for an address and to provide it to the Vacation Fund office. Second, if the Union is unable to provide an address, a request is sent to the employer who made contributions for the participants to the Vacation Fund. In addition to the periodic inquiries described above, each year, approximately two months before the scheduled annual vacation money payout, a request is sent to the participating Unions and employers for addresses on all participants for which there is none in the Vacation Fund's records. This request is a composite listing of all participants for which the Vacation Fund records show no address available.

8. The applicant represents that the trustees of the Welfare Fund, under the terms of the transfer agreement executed on April 3, 1985 between the Funds (the Transfer Agreement), shall

maintain records which will permit a separate accounting of all forfeited benefits transferred from the Vacation Fund. In addition, the Welfare Fund will accept and process any claims on the forfeited Vacation Fund benefits filed by participants and will pay any benefits due in accordance with the terms of the Vacation Fund.

9. In summary, it is represented that the proposed transaction will satisfy the statutory criteria of section 408(a) of the Act because:

(a) The transfer of assets between the Funds will involve little or no administrative complications;

(b) The rights of Vacation Fund participants will be protected because pursuant to the Transfer Agreement, the Welfare Fund will keep separate records for the transferred funds and will honor future claims by Vacation Fund participants; and

(c) The Funds' trustees have determined that the proposed transfer of uncommitted reserves is in the best interests of the participants and beneficiaries of the Funds.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8971. (This is not a toll-free number.)

Thomas L. Donovan, M.D., Inc., Defined Benefit Pension Trust (the Plan) Located in San Diego, California.

[Application No. D-6193]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 4975(c)(2) of the code and in accordance with the procedures set forth in Rev. Proc. 75-26, 1975-1 C.B. 722. If the exemption is granted the sanctions resulting from the application of section 4975 of the Code, by reason of sections 4975(c)(1(A) through (E) of the code shall not apply to the sale of a 3% interest in International Carbide Co. (Incarb), a limited partnership, by the Plan to Dr. Thomas L. Donovan (Dr. Donovan), a disqualified person with respect to the Plan,[1] for $36,000 in cash, provided that such price is no less than the fair market value of such percentage of Incarb at the time of the sale.

Summary of Facts and Representations

1. The Plan is a defined benefit pension plan covering only Dr. Donovan, who is also the trustee of the Plan. Dr. Donovan is 100% stockholder of Thomas L. Donovan, M.D., Inc., (the Plan Sponsor). The Plan had approximately $59,000 in assets as of July 3, 1985, of which $34,000, or 57% is invested in a 3% limited partnership interest in Incarb.

2. In February, 1985, the Plan purchased a one percent (1%) interest in Incarb for $10,000 from Melvin L. Hubbard (Mr. Hubbard), General Partner of Incarb, and in May, 1985, the Plan purchased a further two percent (2%) interest for $24,000. Incarb, a limited partnership conducting research and development on an unproven new process to make tungsten carbide out of tungsten, currently has twelve limited partners. Approximately 19 partnership percentages have been sold, including 2% sold to Dr. Donovan in his own name.

3. The applicant represents that the Plan's investment in Incarb was highly speculative and, therefore, ill-advised, as such research and development ventures rely on the ability of investors to make use of tax write-offs not available to the Plan in order to show a reasonable profit.

4. Mr. Hubbard stated on August 14, 1985, that the fair market value of a one percent limited partnership interest in Incarb was $12,000, based on the latest sale of a percentage. He further stated that Incarb has shown losses thus far for 1985.

5. The applicant represents that rights to Incarb's patent in Canada were traded to Incarb of Canada (I/C) in exchange for 1.1 million shares of I/C stock. However, I/C stock has no established value as it has not yet been traded. Finally, Norman Goodman, CPA, who is associated with Main Hurdman, CPAs for Incarb, located in Irvine, California, stated that while the last percentage of Incarb sold was on May 31, 1985 for $12,000, because partnership interests such as Incarb's are not readily marketable, any statement as to their fair market value is highly subjective.

6. The applicant seeks an administrative exemption for the Plan to sell its 3% interest in Incarb to Dr. Donovan for the greater of $36,000 in cash or the fair market value of the 3% interest as of the date of sale. The Plan will not be required to pay any commissions or fees in connection with the sale.

7. In summary, the applicant represents that the proposed transaction will satisfy the terms and conditions of section 4975(c)(2) of the Code because: (a) The Plan's interest in Incarb will be sold for no less than its fair market value at the time of the sale; (b) the sale represents a one-time transaction for cash which can be eaily verified; (c) the sale will not reuire the payment of any commissions or fees by the Plan; (d) the Plan will not suffer any loss with respect to its purchase of the partnership interest in Incarb; and (e) the trustee of the Plan has determined that the proposed transaction would be in the best interest and protective of the Plan.

Notice to Interested Persons: Because Dr. Donovan is the sole stockholder of the Plan Sponsor and the only participant in the Plan, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and requests for a public hearing are due 30 days after the publication of this notice in the **Federal Register.**

For Further Information Contact: Joseph L. Roberts III of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Beacon Milling Company, Inc., Employee Stock Ownership Plan (the Plan) Located in Cayuga, NY

[Application No. D-6217]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the extension of credit to the Plan by several parties in interest, including Plan fiduciaries, in connection with the 1976 sale of stock (the Stock) of beacon Milling Company, Inc. (the Employer) to the Plan.

Summary of Facts and Representations

1. The Plan is a leveraged employee stock ownership plan with approximately 277 participants. As of October 27, 1984, it had net assets valued at $2,625,499. The trustees (the Trustees) of the Plan are Wilbur L. Townsend and Alem B. Smith, both officers of the Employer.

2. The Plan was established by the Employer in 1975. In 1976 the Plan entered into an agreement (the Agreement) to purchase 2,458 shares of Employer Stock (out of 4,957 shares then outstanding) from the 31 shareholders of the Employer (the Sellers). The Agreement provided that the Plan would make eighty equal quarterly installment

[1] Since Dr. Donovan is the sole stockholder of Thomas L. Donovan, M.D., Inc. and the only participant in the Plan there is no jurisdiction under Title I of the act pursuant to 29 CFR 2510.3-3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

payments of principal and interest at 7½% annually, for 20 years. Under the Agreement, the Stock was placed into a suspense account and subsequently released and allocated to participants' accounts as the principal payments were made.

3. The applicant represents that the Agreement met the requirements of section 408(b)(3) of the Act, relating to loans to employee stock ownership plans by parties in interest, when it was entered into in 1976.[1] Among its provisions is one dealing with actions to be taken in the event of a Plan default, which provides; "if for any reason, including, inter alia, [the Employer's] inability to contribute sufficient amounts to the plan . . . (and if) . . . any installment of principal and interest is not paid in full within the plan year in which the installment due date falls, and if such default in payment continues until the end of the first quarter after the end of such plan year, the Trustees shall deliver to the Seller[s] forthwith at the end of such first quarter, such number of the Sellers shares as shall have not theretofore been released from the (suspense account) . . ."

Regulations under section 408(b)(3) were issued in 1977 (29 CFR 2550.408b–3) and provide that in the event of a default where the creditor is a party in interest, the agreement must provide for a transfer of plan assets only upon and to the extent of the failure of the plan to meet the payment schedule (section 2550.408b–3(f)). The Agreement, however, was not amended to conform to the Regulations, and when the Plan defaulted on the Agreement on January 31, 1985, the Trustees returned all of the Stock in the suspense account to the Sellers. The applicant represents that 7 of the Sellers are parties in interest (the Parties), and that therefore the return of the Stock to them caused the extension of credit to the Plan to become a prohibited transaction.

4. The applicant represents that the Trustees relied in good faith on prior counsel in drawing up the Plan documents and the Agreement and in keeping the plan documents and Agreement in conformity with the Act and the Code. Prior counsel never indicated any need to amend the Agreement even though the Plan documents were amended several times to conform to amendments to the Code. When the Plan's current counsel discovered the inconsistency of the Agreement with the Regulation on or about May 24, 1985, they consulted with the Internal Revenue Service, and advised the Trustees to immediately retrieve all of the shares which had been transferred to the Parties and recalculate the number of shares to be transferred based on the payment schedule of the Agreement. By June 7, 1985, the Parties returned to the Trustees all of the Stock which had been transferred. The applicant represents that the return of the Stock by the parties to the Plan was a correction within the meaning of Foundation Excise Tax Regulation § 53.4941(e)–1(c), which applies to section 4975 prohibited transactions by reason of Temporary Pension Excise Tax Regulation 141.4975–13. Under § 53.4941(e)–1(c)(1) of the Foundation Excise Tax Regulations, any correction pursuant to Code section 4941 is not an act of self-dealing.[2]

5. The applicant represents that the Trustees relied in good faith on prior counsel's failure to amend the Agreement in deciding that it was permissible to transfer the Stock to the Parties upon the default, and that upon discovering the prohibited nature of the transaction, immediately moved to correct the transaction and to apply for an exemption. The applicant further represents that since the value of the Stock has declined over 30% from the date the Purchase Agreement was entered into the Parties did not gain from the default, but would have been much better off to use their "corporate power" to avoid default and remain under the Purchase Agreement, where the price they were receiving for their Stock was clearly in excess of the current market value. The applicant also represents that since no dividends were paid for the period of the improper satisfaction of the default the Plan suffered no loss due to the transaction and its correction.

6. In summary, the applicant represents that the transaction met the criteria of section 408(a) because: (a) The Plan did not suffer any loss and the Parties enjoyed no gain as a result of the improper satisfaction of the Plan default on an exempt loan; (b) the transaction was entered into on the advice of the Plan's prior counsel that the terms of the Agreement complied with the Act and regulations; and (c) when the Plan's current counsel discovered the prohibited transaction, steps were immediately taken to correct the transaction as quickly as possible.

For Further Information Contact: Mr. David Lurie of the Department, telephone (202) 523–8194. (This is not a toll-free number.)

Pension Plan for the Employees of J.J. Dorbel Corporation (the Plan) Located in Riviera Beach, Florida

[Application No. D–6248]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the proposed sale of an undivided half interest (the Interest), in certain real property (the Property) by the Plan to the William R. Hibel Revocable Trust (the Trust), the trustee and grantor of which is one of the trustees and administrators of the Plan and a major owner of the J.J. Dorbel Corporation (the Employer), the employer of the Plan's participants, provided the sales price is not less than the fair market value of the Interest on the date of the sale.

Summary of Facts and Representations

1. The Plan is a defined benefit pension plan covering two participants, Mr. and Mrs. William R. Hibel, who own 80% of the Employer. Their children, Dr. James Hibel and Dr. Janet Hibel, own the remaining 20% of the Employer. The applicant states that the fair market value of the Plan's total assets is estimated to be $550,000 as of March 14, 1985. Mr. William R. Hibel (Mr. Hibel) makes the investment decisions for the Plan. He is also an officer and director of the Employer and the trustee and grantor of the Trust.

2. The Property is legally described as Units J and L, as set forth on the Condominium Map of Lot 8 of the Second Amended Map of Tahoe Village No. 2, recorded February 2, 1979, as Document No. 29639, Official Records of Douglas County, State of Nevada, together with an undivided 1/12 interest in and to that portion of the designated Common Area as set forth on said Condominium Map. The Plan acquired the Interest for $105,000 from M.L. Lawrence, who is not a party in interest with respect to the Plan, pursuant to an exchange agreement made as of April 26, 1985, in exchange for a half interest

[1] The Department expresses no opinion as to whether the conditions of section 408(b)(3) were met by the Agreement at the time the Agreement was entered into

[2] The Department has no jurisdiction with respect to § 53.4941(e)–1(c) of the Code, and offers no opinion on whether the return of the Stock was a proper correction.

in a vacation residence located at 78A Skyland Court, Zephyr Cove, Nevada (the Zephyr Cove Property) in the Lake Tahoe area. The Plan also received some cash in that exchange. It is represented that the Plan trustee considered such exchange to be the best business alternative available to the Plan at the time, considering that the Zephyr Cove Property had been on the market for a considerable period of time. The Plan has incurred no additional capital expenditures with respect to the Property, has realized minimal income (approximately $1,350) from the Interest, and has incurred normal utility, insurance, and minor maintenance expenses (estimated at between $400 and $500) on the Property. The remaining one-half interest in the Property is owned by J.M. Allovio & Associates Pension Trust, which is not a party in interest with respect to the Plan. The applicant states that the Property is not located proximate to any property owned by the Employer or by Mr. and Mrs. Hibel.

3. Mr. Hibel explains that the Plan wishes to sell the Interest to the Trust for a number of reasons:

(a) As trustee of the Plan, Mr. Hibel notes that the Plan is a co-owner of the Property and there are differing opinions as to the productive use of the Property. For example, one co-owner may want to improve the Property, exchange it for another parcel, or sell it, while the other desires to do something totally different. Mr. Hibel believes that the Plan, therefore, would be in a better position to liquidate, diversify, and invest its assets if its assets were separately owned.

(b) As the rate of inflation in the United States has decreased, the appreciation of real estate has correspondingly decreased, thereby proving the Interest not to be the investment anticipated. Its sale would enable the Plan to invest the sale proceeds in a manner which would yield a much greater return to the Plan. The Plan trustee intends to sell the Interest if, and as soon as, the exemption is granted.

(c) Because the Plan owns an undivided one-half interest in the Property, a readily available market does not exist for the sale of the Interest. The proposed transaction, therefore, would enable the Plan to dispose of an otherwise illiquid asset. In turn, the Plan would acquire proceeds which it could invest and reinvest in liquid and more profitable investments.

4. If the proposed exemption is granted, the applicant represents that the Plan will sell the Interest at the greater of (a) its fair market value as of the date of the sale as determined by Barbara J. McArthur, of McArthur Realty, Incline Village, Nevada, a real estate appraiser who is not related to Mr. or Mrs. Hibel or the Employer, or (b) $105,000 (see 2, above). Barbara J. McArthur has been a real estate broker in Nevada since 1976, has been chosen as the exclusive Sotheby Parke Barnet affiliate in the Lake Tahoe area, has considerable experience valuing real properties in that area, and is considered a real property valuation expert locally, according to the Plan trustee. The sales price, currently estimated by the Plan trustee to be $115,000, will be paid in cash in one lump sum on the date of the sale, and the Plan will not pay any commissions or other expenses incurred in effecting the proposed sale. The applicant states that the Plan has attempted to sell the Interest on the open market, but since it is only a half interest in the Property, the Interest is not readily marketable.

5. In summary, the applicant represents that the proposed transaction satisfies the exemption criteria set forth in section 408(a) of the Act because: (a) The sale will be a one-time transaction for cash, (b) the sales price will equal the greater of (i) the fair market value of the Interest as of the date of the sale, as determined by a qualified independent appraiser, or (ii) the price the Plan paid to acquire the Interest, (c) no commissions or other selling expenses will be charged to the Plan, (d) the sale will enable the Plan to dispose of an asset producing minimal income and will increase the liquidity of the Plan's assets, and (e) the Plan trustee believes that the sale will be in the best interests of the Plan and its participants and beneficiaries.

For Further Information Contact: Mrs. Miriam Freund, of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

Avenue T.V. Cable Service, Inc. Profit Sharing Retirement Plan (the Plan) Located in Oxnard, CA

[Application No. D-6272]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a)(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the proposed cash sale of a parcel of improved real property for $90,000 by the Plan to Avenue T.V. Cable Service, Inc. (the Employer), provided that this amount is not less than the fair market value of the property at the time of sale.

Summary of Facts and Representations

1. The Plan is a profit sharing plan with 17 participants and net assets of $794,895 as of March 31, 1985. On July 14, 1976, the Plan purchased a parcel of improved real property (the Property) from Mr. William C. and Barbara Wilcox, unrelated parties, for $38,000. The Property is located at 1940 East Main Steet, Ventura, California. The applicant represents that the Property was purchased by the Plan because it was thought to be a good investment. The Property has been leased as a donut business since its purchase by the Plan, however, a new donut business has opened up in the area and as a result business has decreased. The applicant states that the rental paid to the Plan is in part based on gross receipts of the lessee and since business has decreased the rentals received by the Plan are expected to correspondingly decrease.

2. The Plan proposes to sell the Property to the Employer for $90,000 in cash. The Employer has agreed to pay all costs related to the sale of the Property. The Property was appraised by Mr. Harold C. White, SRA of Harold C. White Co. as having a fair market value of $85,000 as of January 15, 1985.

3. The applicant represents that the sale of the Property at this time would be in the Plan's best interest because it would convert a non-liquid asset to cash. In addition, the applicant states that a substantial administrative burden would be removed from the Plan's trustees if the Property were sold.

4. In summary, the applicant represents that the proposed transaction satisfies the criteria of section 408(a) of the Act because:

(a) It will be a one time transaction for cash;

(b) The Employer will pay all costs involved in the sale of the Property;

(c) The sale will permit the Plan to dispose of a non-liquid asset; and

(d) The price to be paid for the Property exceeds its appraised value.

Tax Consequences of Transaction

The Department of the Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer results in the plan either paying less than or receiving more than fair market value, such excess may be considered to be a contribution by the sponsoring employer

to the plan and therefore must be examined under applicable provisions of the Code, including sections 401(a)(4), 404 and 415.

For Further Information Contact: Alan H. Levitas of the Department, telephone (202) 523-8971. (This is not a toll-free number.)

John P. Picone, Inc., Employee Retirement Trust (the Plan) Located in Lawrence, New York

[Application No. D-6281]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance witht he procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the proposed continuation of a loan (the Loan) by the Plan to Aussex Realty Company (the Partnership), whose partners are officers and/or shareholders of the employer (the Employer) of Plan participants, provided the terms of the transaction are at least favorable to the Plan as those the Plan could obtain in a similar transaction with an unrelated party, and provided, further, that all excise taxes due on prohibited transactions relating to the Loan prior to the effective date shown below are paid within 60 days of the date the proposed exemption is granted.

Effective Date: If the proposed exemption is granted, it will be effective as of April 30, 1985, the date Mr. Leonard Lustig, the independent trustee with respect to the Loan continuation, determined that the Loan continuation is in the best interests of the Plan participants and beneficiaries.

Summary of Facts and Representations

1. The Plan is a terminated defined benefit plan whose assets have not yet been distributed. As of June 30, 1985, the Plan covered nine participants and had assets totalling $983,334. the trustees of th Plan are Messrs. John Picone, Jr., who is also a partner in the Partnership and the president and a principal shareholder of the Employer, and Richard Tuohey, whose wife, Joanne Tuohey, is also a partner in the Partnership and a principal shareholder of the Employer. The Partnership's two remaining partners are Ms. Albina Picone, who is also an officer of the Employer, and the Estate of John Picone.

2. On April 12, 1985, Mr. Leonard Lustig (Mr. Lustig) was appointed to serve as the independent trustee of the Plan with regard to the Loan continuation. Mr. Lustig is an attorney-at-law duly admitted to practice in New York State. He represents that he is not related in any way to the Employer, the Partnership, Garden Lane Realty Corporation (the Agent), which was the Partnership's agent with respect to the original Loan, or any of the principals of these three companies. He represents further that he has not provided and will not provide legal services to any of the companies or individuals mentioned above during the past 12 months or for the term of the Loan continuation or the 12-month period following final payment of the Loan. Mr. Lustig states that he is experienced in the fields of real estate and real estate financing, has been active throughout his professional career in the area of real estate law, is fully familiar with the value of real estate and leasehold investments in the metropolitan New York City area, has negotiated leases, sales, and purchases of real estate throughout the area, is generally familiar with the investment market as it relates to real estate, and is aware of the obligations and responsibilities of an independent trustee under the Act and of the prudence requirements of the Act.

3. On May 17, 1974, the Plan made the original Loan to the Partnership, acting through the Agent, which was organized and operated solely to act as agent and nominal title holder of the property securing the Loan for the benefit of the Partnership. Said property is 1.167 acres of improved real property located at 31 Garden Lane, Lawrence, New York. The Partnership constructed thereon a two-story building. The land and improvements (the Property) have been leased by the Partnership to the Employer to house the Employer's offices and its heavy equipment shop under a "net lease" for a fixed number of years. The original Loan represented principal indebtedness of $140,000, payable on March 19, 1975. Prior thereto interest only was payable monthly at an annual rate equal to the greater of (i) 9% or (ii) 2% greater than the principal rate charged by Manufacturer's Hanover Trust Company as of the end of the month preceding each payment date. The applicant represents that the original Loan was exempt under section 414(c)(1) of the Act.[4] The applicant represents that the maturity date of the original Loan was extended from March 19, 1975 to March 19, 1976, pursuant to a written agreement that was valid under New York State law at that time.[5]

4. On March 19, 1976, the Plan and the Partnership entered into a modification and extension of the original Loan and mortgage, providing for the same amount of principal indebtedness, the same security, the same interest rate payable monthly until March 19, 1978, and repayments thereafter of both principal and interest in the aggregate amount of $1,419.98 per month until May 19, 1984, when the unpaid balance with accrued interest became payable. The applicant represents that all interest and principal payments on the modified Loan were made timely. The applicant also represents that under New York State law, the modified Loan is not considered a new loan and that the modified Loan was also exempt under section 414(c)(1) of the Act.[6]

5. On April 19, 1984, the Plan and the Partnership extended the time of payment of the principal indebtedness of the modified Loan, then equal to $101,425.59. Such agreement of April 19, 1984 (the 4/19/84 Agreement) provides for interest at the rate of 13% p.a. on such principal, 59 repayments of interest and principal in the aggregate amount of $1,283.28 per month, beginning May 19, 1984, and ending April 19, 1989, and a final payment of $87,230.16 on April 19, 1989, when all other unpaid principal and interest is due and payable. Under the 4/19/84 Agreement, the Loan continues to be secured by the Property. The balance due on the Loan was $86,026.23 as of May 1, 1985, representing less than 10% of the Plan's total assets. The Plan Administrator has advised that within 60 days of the date the Department takes final action on this his exemption application, the disqualified person(s) involved will (i) file IRS Form 5330, Return of Initial Excise Taxes Related to Pension and Profit-Sharing Plans, with the Internal Revenue Service, and (ii) pay the excise taxes that may be due and owing for the period prior to the effective date shown above.[7]

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[4] Section 414(c)(1) of the Act provides that sections 406 and 407(a) do not apply until June 30, 1984, to a loan or other extension of credit between a plan and a party in interest under specified conditions. the Department is expressing no opinion herein as to whether or not the original Loan or the extensions and modifications thereof, described below, were exempt under section 414(c)(1).

[5] See Footnote 1, above.

[6] See Footnote 1, above.

[7] The Department is expressing no opinion herein as to whether or not section 414(c)(1) of the Act exempted the Loan continuation pursuant to the 4/19/84 Agreement until June 20, 1984, or any prior date. However, the Department notes that, whether or not section 414(c)(1) exempted the Loan until June 30, 1984, the Loan clearly constituted a

Continued

6. On December 4, 1984, Mr. Stanley A. Schenck, a licensed real estate broker in the States of New York and New Jersey who has been engaged in the sale and leasing of commercial and industrial buildings and properties for over 20 years, appraised the Property's fair market value as $388,304 (see 3, above, regarding the Property). Mr. Schenck represents that he is not related in any way to the Partnership, the Employer, the Agent, or any of their principals.

7. Mr. Lustig's duties (see 2, above) are (a) to review all proposed renewals, extensions, or modifications of the Loan to confirm in each case that the transaction is in the best interest of the Plan, (b) to assure that the renewal, extension, or modification of the Loan reflects current fair market value as determined by an independent real estate broker or appraiser, and (c) to monitor and implement the Loan agreement and to take any steps necessary to avoid or to mitigate to the extent possible any potential losses to the Plan in connection with the Loan. In his letter dated April 30, 1985, Mr. Lustig states that he has reviewed the documents relating to the 4/19/84 Agreement (see 5, above) and related mortgage, has interviewed the interested parties, and has familiarized himself with the local interest rates, mortgages, and existing loans on similar properties in the area. In addition, he states that he has examined the Plan's overall investment portfolio, has considered the liquidity requirements of the Plan, has examined the diversification of the Plan's assets in light of the Loan, and has determined that the Loan continuation complies with the Plan's investment objectives and policies and that the Plan's liquidity and diversification are adequate. He asserts that the 13% p.a. interest rate under the 4/19/84 Agreement represented 1% over the prime rate on 4/19/84, is comparable to the interest rate the Employer could obtain from a commercial lender on a loan of this type and duration, and represents a fair rate of return. He represents that the terms of the 4/19/84 Agreement are comparable to those in similar transactions between unrelated parties and that the 4/19/84 Agreement will generate high fixed income to the Plan on a very secure basis, enabling the Plan to better achieve its purpose of providing retirement benefits without subjecting Plan assets to unnecessary risk of loss. Therefore, he concludes that the 4/19/84 Agreement is in the best interests of the Plan participants and beneficiaries. The applicant represents that Mr. Lustig made determination on April 30, 1985, the date of the above-mentioned letter from Mr. Lustig.

8. In summary, the applicant represents that the Loan continuation pursuant to the 4/19/84 Agreement satisfies the exemption criteria set forth in section 408(a) of the Act because (a) an independent trustee, Mr. Lustig, believes such Loan continuation is in the best interests of the Plan and its participants and beneficiaries, (b) such independent trustee will monitor the transaction throughout its duration, taking all steps necessary to protect the Plan's interests, (c) the fair market value of the Property, which secures the Loan, as determined by an independent appraiser, is more than three times the amount of the principal balance of the Loan as noted in the 4/19/84 Agreement, and (d) within 60 days of the date the Department takes final action on this proposed exemption, the disqualified persons involved will (i) file Form 5330 with the Internal Revenue Service and (ii) pay the excise taxes due prior to the effective date mentioned above.

For Further Information Contact: Mrs. Miriam Freund, of the Department, telephone (202) 523-8194. (This is not a toll-free numer.)

The Chase Manhattan Bank, N.A. (Chase) Located in New York, NY

[Application No. D-6285]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(b)(2) of the Act shall not apply to the proposed interaccount sale of publicly traded common stocks (the Stocks) from the Chase Bank Inter-Mediate Capitalization Fund (the Capitalization Fund) to the Chase Bank Special Growth Fund (the Growth Fund, collectively, the Funds), which are collective investment funds managed by Chase, provided that the price of the Stocks are their fair market value as of the date of the transaction.

Summary of Facts and Representations

1. Chase is a national banking association incorporated under the laws of the United States which acts as a fiduciary of and provides other services for hundreds of employee benefit plans which are subject to the provisions of Title I of ERISA. Chase currently manages in excess of $5 billion of plan assets and holds as custodial trustee subject to investment direction in excess of $50 billion of plan assets.

Collective investment funds were first established by Chase in 1957 in order to permit the collective investment and reinvestment of monies received and held by it as trustee of trusts established under pension benefit plans (Plans). Participating Plans must be qualified under section 401(a) of the Code and the trusts thereunder exempt from taxation under section 501(a) of said Code. Since October 1984 participation is also permitted by governmental Plans as described in section 805(d)(6) of the Code. Each such trust must specifically authorize the participation of the trust in common, collective or commingled trust funds maintained by Chase. In addition, certain of the Declarations of Trust establishing Chase's collective investment funds provide for the investment of the assets of such funds in other collective investment funds maintained by Chase. Chase currently maintains 15 collective investment funds for its discretionary accounts, including 7 fixed income funds, 4 funds invested in special types of investments (foreign securities and real estate) and 4 equity funds, including the Growth Fund and the Capitalization Fund, emphasizang investments in common stocks of various classifications. Approximately $2.7 billion is invested in all of the collective investment funds maintained for Chase's discretionary accounts.

2. As of June 30, 1985, 54 Plans participated in the Growth Fund and 39 Plans participated in the Capitalization Fund. As of June 30, 1985, the Growth Fund held assets with a fair market value of $491,904,046.27, and the Capitalization Fund held assets with a fair market value of $176,881,135.60. All of the Plans participating in the Capitalization Fund also participate in the Growth Fund. The Chase Bank Equity Fund also participates in each of the Funds.

3. The investment emphasis in each Fund is capital appreciation. The Growth Fund has emphasized companies with market capitalizations of between $25 and $250 million, while the Capitalization Fund has emphasized companies with market capitalization of between $250 and $500 million. Although the foregoing guidelines have established the basic investment emphasis of the Funds, investment is not limited to such securities, and issues have been held in each Fund which fall outside the above-mentioned market capitalization ranges. In addition, there have been instances where the same issue has been held in both Funds. All of

prohibited transaction within the meaning of sections 406(a) and 406 (b)(1) and (b)(2) after June 30, 1984.

the issues now held in the Funds are traded either on a national securities exchange or on the over the counter market.

4. The managers of the respective Funds in reviewing their portfolios have determined to make certan repositionings involving a number of securities issues and have agreed that it would be desirable, on the one hand, for the Growth Fund to acquire certain of the investments currently held in the Capitalization Fund, and, on the other, for the Capitalization Fund to reposition itself in certain respects by the application of the cash to be obtained from such transfer. The primary reason for the investment decisions by the respective Funds was that the issues are deemed to be somewhat more suitable for the Growth Fund based on their market capitalization and their investment characteristics. The managers involved have obtained the approval of Chase's Institutional Investment Committee for the investment restructuring indicated.

5. The applicant represents that the Capitalization Fund has recently experienced a change in managers, which has resulted in a change in investment strategy for that Fund. Upon a review of the Capitalization Fund's holdings, the new manager has chosen to dispose of certain stocks. Twelve of these stocks are ones which the managers of the Growth Fund were familiar with the desire to obtain.

6. Most of the Stocks are of companies with market capitalizations of less than $250 million. The applicant represents that the Growth Fund makes a concerted effort to enhance its investment performance and provide superior returns for its participants by allocating a significant portion of its invested funds for certain special situations within the stock market. These investments provide the managers with the flexibility to take advantage of certain positive events that have not yet been recognized in the value of certain stocks. Examples of a special situation investment include a corporate, asset, or management restructuring; enhancement of shareholder value outside of daily corporate operations; and an unforeseen reversal of a company's fortunes. All the issues proposed for transfer are examples of special situation investments. While a strong investment case can be made for these stocks, these situations do not usually entail a long-term holding period. For this reason, also, it is desirable that they be monitored as closely as possible, capitalizing on the Growth Fund management group's expertise.

7. The applicant further represents that while the sale and purchase of the Stocks could have been effectuated on the open market, transfers effectuated in this manner would entail substantial brokerage commissions, as well as unfavorable market impact on the sale and purchase of the Stocks, many of which have a relatively low trading volume. The applicant initially requested an exemption which would have permitted the sale of 12 particular stocks, with a market value of approximately $26.3 million as of June 30, 1985. Since the initial application, however, the Capitalization Fund has disposed of certain of the Stocks, and the applicant represents that other Stocks may also be disposed of prior to a final grant of this proposed exemption if market and investment considerations so dictate.

8. The price to be paid by the Growth Fund for the Stocks transferred to it will be, for issues listed on a national exchange, the closing market price on the date of transfer and for over-the-counter issues, the mean between the bid and asked prices at the market close on the date of transfer. Chase represents that this pricing procedure will assure that each Fund will receive fair market value in the transfer and neither Fund will obtain an advantage by virtue of the transfer. The transfer will not, in and of itself, have any impact on the respective values of the Funds involved as of the time of transfer. Chase will not receive any commissions, special fees or increases in its regular investment fees for effecting this transfer. The applicant represents that the transfer is being made for the sole purpose of benefiting the interests of plans who participate in the Funds.

9. The need for an exemption arises because the interaccount sales described above might constitute a violation of section 406(b)(2) of the Act, which generally prohibits a plan fiduciary from acting on behalf of or representing, an adverse party in a transaction with a plan.

10. The applicant represents that the proposed sale meets the criteria of section 408(a) of the Act because: (a) The sale will be made for the sole purpose of benefiting the interests of Plans that participate in the Funds; (b) each Fund will receive fair market value in the sale and neither Fund will obtain an advantage by virtue of the sale; (c) the sale will save the Funds from paying brokerage commissions; and (d) Chase will not receive any commissions, special fees or increases in its regular investment management fees for effecting this sale.

For Further Information Contact: David Lurie of the Department, telephone (202) 523-8194. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, D.C., this 5th day of December, 1985.

Elliot I. Daniel,

Assistant Administrator for Regulations and Interpretations, Office of Pension and Welfare Benefit Programs, U.S. Department of Labor.

[FR Doc. 85-29276 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-5641]

Withdrawal of the Notice of Proposed Exemption Involving the United Technologies Corporation Master Trust (the Master Trust), Located in Hartford, CT

In the **Federal Register** dated February 11, 1985 (50 FR 5696), the Department of Labor (the Department) published a notice of a proposed exemption from the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 and from certain taxes imposed by the Internal Revenue Code of 1954. The notice of pendency concerned an application for exemptive relief that was filed on behalf of United Technologies Corporation (UTC) and the Pension Committee of UTC (the Applicants). It involves the purchase by the Master Trust from UTC of all of the outstanding shares of stock of UTC's wholly owned subsidiary, United Properties, Inc., the assets of which consist primarily of certain real property, and other transactions.

By letter dated November 13, 1985, the Applicants' representative has informed the Department that the Applicants wish to withdraw their request for exemptive relief. Accordingly, this application is hereby withdrawn from consideration by the Department.

Signed at Washington, DC, this 5th day of December, 1985.

Elliot I. Daniel,

Assistant Administrator for Regulations and Interpretations, Office of Pensions and Welfare Benefit Programs, U.S. Department of Labor.

[FR Doc. 85-29278 Filed 12-9-85; 8:45 am]

BILLING CODE 4510-29-M

MERIT SYSTEMS PROTECTION BOARD

Initial Appeals and Petitions for Review; Processing Time

AGENCY: Merit Systems Protection Board.

ACTION: Announcement of processing time for initial appeals and policy on processing petitions for review.

SUMMARY: The Merit Systems Protection Board is announcing a clarification of its previously announced policy with respect to the time limits within which it expects to complete processing of initial appeals and petitions for review.

FOR FURTHER INFORMATION CONTACT: Charles J. Stanislav (202) 653-8931.

EFFECTIVE DATE: December 10, 1985.

SUPPLEMENTARY INFORMATION: The Merit Systems Protection Board is required to establish and publicly announce the date by which it intends to complete action on appeals filed with the Board. The Board published notice on February 13, 1979 (44 FR 9446) that all appeals processed by it pursuant to 5 U.S.C. 7701 or 5 U.S.C. 7702 will be decided within 120 days of the filing of the appeal. On July 20, 1984 (49 FR 29492) notice was also published of the Board's general policy to attempt to complete action on petitions for review within 110 days.

After considerable experience with processing appeals and petitions for review, the Board has determined that certain modifications in the previously published announcements are necessary for clarity and technical accuracy. From time to time the Board has cases that cannot be processed because of externally imposed constraints over which the Board has no control, such as Court imposed stays. In all pending and future cases, the Board will advise the parties of the constraint and that the Board cannot further proceed with processing until the constraint is removed. When the constraint is removed, the parties will be informed and advised of the new date for completion in accordance with 5 U.S.C. 7701(i). Therefore, the Congressional purposes of the announcement and reporting requirements are met and the parties are more accurately kept advised of the status of their case.

The previously published notices are cancelled and the following notice is substituted.

Merit Systems Protection Board

Initial Appeals and Petitions for Review; Processing Time Announcement

Pursuant to 5 U.S.C. 7701(i)(1), the Merit Systems Protection Board hereby announces that action on initial appeals processed by it pursuant to 5 U.S.C. 7701(a) or 5 U.S.C. 7702(a)(1) will be completed within 120 days of the filing of the appeal and will attempt to complete action on petitions for review of initial decisions pursuant to 5 U.S.C. 7701(e)(1) within 110 days of the filing of the petition except where:

1. The Board is prevented from processing any case by an external authority or event; for example, a court-ordered stay. On such occasions the parties will be notified promptly of the event and upon lifting of the stay or other event, will be notified of the expected completion date.

2. A notice is issued to the parties setting an initial completion date, greater or less than announced above, which more realistically assures expeditious consideration of the appeal, consistent with the interests of fairness and other priorities of the Board.

In the event that an appeal filed under 5 U.S.C. 7701(a) cannot be decided within the general or specific times announced above and the expected delay will exceed 30 days, a new date for completion of the appeal will be publicly announced by the Board office having jurisdiction over the appeal.

Dated: December 4, 1985.

Herbert E. Ellingwood,

Chairman.

[FR Doc. 85-29230 Filed 12-9-85; 8:45 am]

BILLING CODE 7400-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (85-73)]

National Commission on Space; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting changes.

SUMMARY: The date for the scheduled meeting on December 16-17, 1985, of the National Commission on Space, published in the **Federal Register** November 29, 1985, (50 FR 49143) has been changed to December 16, 1985. Following is the revised agenda.

Agenda

Monday, December 16, 1985

8:45 a.m.—Introduction.
9 a.m.—International Geosphere Biosphere Program.
9:30 a.m.—Nonterrestrial Materials Research.
10:15 a.m.—Inner Solar System Space Infrastructure.
11:15 a.m.—Earth Resources Observations.
1 p.m.—Automation, Robotics, etc.
2 p.m.—Space Commercialization.
2:45 p.m.—International Space Organizations.
3:30 p.m.—Maritime Space Activities.
4 p.m.—Earth Observation Needs of the Third World.
4:30 p.m.—Research and Development in Earth Observations.
5 p.m.—Adjourn.

Dated: December 4, 1985.

Richard L. Daniels,

Deputy Director, Logistics Management and Information Programs Division, Office of Management.

[FR Doc. 85-29180 Filed 12-9-85; 8:45 am]

BILLING CODE 7510-01-M

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

Agency Information Collection Activities Under OMB Review

AGENCY: National Endowment for the Humanities, NFAH.

ACTION: Notice.

SUMMARY: The National Endowment for the Humanities (NEH) has sent to the Office of Management and Budget (OMB) the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comments on this information collection must be submitted on or before January 9, 1986.

ADDRESSES: Send comments to Ms. Ingrid Foreman, Management Assistant, National Endowment for the Humanities, Administrative Services Office, Room 202, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, (202) 786-0322 or Mr. Joseph Lacky, Office of Management and Budget, New Executive Office Building, 726 Jackson Place, NW., Room 3208, Washington, DC 20503 (202) 395-7316.

FOR FURTHER INFORMATION CONTACT: Ms. Ingrid Foreman, National Endowment for the Humanities, Administrative Services Office, Room 202, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, (202) 786-0233 from whom copies of forms and supporting documents are available.

SUPPLEMENTARY INFORMATION: All of the entries are grouped into new forms, revisions, or extensions. Each entry is issued by NEH and contains the following information: (1) The title of the form; (2) the agency form number, if applicable; (3) how often the form must be filled out; (4) who will be required or asked to report; (5) what form will be used for; (6) an estimate of the number of responses; (7) an estimate of the total number of hours needed to fill out the form. None of these entries are subject to 44 U.S.C. 3504(h).

Category: New

Title: Survey of Black Museums
Form Number: Not Applicable
Frequency of Collection: Once
Respondents: Black Museums in the U.S.
Use: Research and program planning
Estimated Number of Respondents: 150
Estimated Hours for Respondents to Provide Information: 3 per respondent

Susan Metts,

Acting Director of Administration.

[FR Doc. 85-29228 Filed 12-9-85; 8:45 am]

BILLING CODE 7536-01-M

NATIONAL TRANSPORTATION SAFETY BOARD

Safety Recommendations Issued; Availability of

SAFETY RECOMMENDATIONS ISSUED

Recommendation Number	Issued to—	Date	Subject
A-85-35 through -49	Federal Aviation Administration (FAA)	7-2-85	Equipment of passenger-carrying aircraft operating under 14 CFR 121, 125, and 135 with approved life preservers.
A-85-53 through -56	FAA	7-22-85	Pratt & Whitney JT8D-15, -17, and -17R series engines; 2nd stage low-pressure turbine disk.
A-85-57 through -58	FAA	9-10-85	Piston connecting rods in Teledyne Continental Model TSIO-360-E, -F and -G engines and turbocharging in Piper Model PA-28R-201T Turbo III Cherokee Arrow, PA-28RT-201T Turbo IV Cherokee Arrow, and PA-28-201T Turbo Dakota airplanes.
A-85-69 through -71	FAA	10-1-85	Helicopter certification standards in 14 CFR Parts 27 and 29; seats, restraint systems, fuel systems, and energy-absorbing structures.
A-85-72	Helicopter Assn. Internat'l and Aerospace Industries Assn. of America.	10-1-85	Helicopter crashworthiness; model-specific occupant protection.
A-85-73 through -76	FAA	11-8-85	Pilatus Britten-Norman BN-2, BN-2A, BN-2B, BN-2T, and BN-2A Mk III model airplanes; protection from fuel contamination.
A-85-77 through -80	FAA	10-16-85	Piper Apache Model PA-23-15-, PA-23-160, and PA-23-235 airplanes; individual fuel line drain valves.
A-85-81 through -85	FAA	10-23-85	Tire explosions in wheel wells.
A-85-87	FAA	10-23-85	Hobbs, Datcon, and similar hourmeter oil pressure switches; appropriate location.
A-85-88 through -90	FAA	11-5-85	Fuel quantity sensors in Piper PA-31T and PA-42 model series airplanes.
A-85-108 through -111	FAA	10-31-85	Cessna Model T303 airplanes; fuel metering unit tee fittings.
A-85-118 and -119	FAA	11-8-85	Bell 214B/214ST model helicopters; collective sleeve assemblies.
A-85-120 and -121	FAA	11-8-85	Pratt & Whitney JT8D-series engines; installation of one-piece, integral sleeve spacer at all six locations in the high-pressure compressor rotor.
HIGHWAY			
H-85-7	Virginia Pupil Transportation Service, Virginia Dept. of Education.	3-22-85	Minimum physical standards for schoolbus drivers.
H-85-17	States of Arkansas, Colorado, Idaho, Kentucky, Louisiana, New Hampshire, New Mexico, North Carolina, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, Washington, Wisconsin, and the District of Columbia.	8-27-85	Operation of nonpublic schoolbuses while deadbolt or similar supplemental locks on emergency doors are engaged.
H-85-18	States of Alabama, Alaska, Arizona, California, Florida, Georgia, Mississippi, Nebraska, South Dakota, West Virginia, and Wyoming.	8-27-85	Operation of public and nonpublic schoolbuses while deadbolt or similar supplemental locks on emergency doors are engaged.
H-85-19	American Bus Assn., American Trucking Assns.	9-10-85	Bus driver fatigue.
H-85-20 and -21	Federal Highway Administration	9-10-85	Commercial vehicle drivers' duty status records; on-duty time.
H-85-27 through -29	Federal Highway Administration	10-16-85	Underwater structural elements of bridges.
H-85-30	National Safety Council	11-5-85	Program to encourage motorists to drive with low-beam headlights on during the day.
INTERMODAL			
I-85-16 through -18	Kentucky Disaster and Emergency Services	7-22-85	Emergency procedures for hazardous materials accidents.
I-85-19 and -20	Research and Special Progams	8-12-85	Classification of hazardous materials.
MARINE			
M-85-51 through -55	U.S. Coast Guard	8-21-85	Safety precautions for air-mover ventilators in potentially combustible atmospheres; electrostatic discharges; injection of steam in non-gas free cargo tanks; inspection of wire rope drum drive chains; safe use of hand held parachute flares.
M-85-56	Mine Safety Appliances Co	8-21-85	Hazards of incentive electrostatic discharge in steam-powered air-mover ventilators.
M-85-57 through -61	U.S. Coast Guard	8-21-85	Fire safety on passenger ships.

SAFETY RECOMMENDATIONS ISSUED—Continued

Recommendation Number	Issued to—	Date	Subject
M-85-62 through -65	Scandinavian World Cruises	8-21-85	Fire safety on passenger ships.
M-85-66	U.S. Naval Weapons Station	9-10-85	Danger zone and speed limit at Anaheim Bay entrance.
M-85-67 through -75	U.S. Coast Guard	8-12-85	Small vessel safety: vessel stability, firefighting, watertight integrity, lifesaving equipment, crew lists, search and rescue forces, radio communications, inclusion of drift of heavily ballasted liferafts on computer search and rescue program.
M-85-76 through -81	Owner/Associates of Fishing Vessel AMAZING GRACE	8-12-85	Stability characteristics and emergency contingency plan for marine accidents.
M-85-82	Nat'l Council on Fishing Vessel Safety and Insurance.	8-12-85	Do.
M-85-83 through -89	U.S. Coast Guard	9-16-85	Small passenger vessel safety; lifesaving equipment; dry exhaust piping installation inspections; life preserver stowage; vessel information accessibility.

Note.—Single copies of these recommendation letters are available on written request to: Public Inquiries Section, National Transportation Safety Board, Washington, DC 20594. Please include addressee's name, date of letter, and recommendation number(s) in your request. The photocopies will be billed at a cost of 14 cents per page ($1 minimum charge).

Dated: December 4, 1985.

Catherine T. Kaputa,

Federal Register Liaison Officer.

[FR Doc. 85-29229 Filed 12-9-85; 8:45 am]

BILLING CODE 7533-01-M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reports or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision.

2. The title of the information collection: 10 CFR Part 20, Standards for Protection Against Radiation.

3. The form number if applicable: Not applicable.

4. How often the collection is required: On occasion.

5. Who will be required or asked to report: NRC Licensees.

6. An estimate of the number of responses: 316,163.

7. An estimate of the total number of hours needed to complete the requirements or request: 374,230.

8. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Not applicable.

9. Abstract:

The NRC is proposing a major revision of 10 CFR Part 20 which provides the requirements for the protection of individuals who are exposed, both within and outside of the workplace, to ionizing radiation from routine activities (normal operations) which are licensed by the NRC. The revisions would affect the recordkeeping and reporting requirements for all categories of NRC licensees.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

Comments and questions should be directed to the OMB reviewer Jefferson B. Hill, (202) 395-7340.

The NRC Clearance Officer is R. Stephen Scott, (301) 492-8585.

Dated at Bethesda, Maryland, this 3rd day of December 1985.

For the Nuclear Regulatory Commission.

Patricia G. Norry,

Director, Office of Administration.

[FR Doc. 85-29250 Filed 12-9-85; 8:45 am]

BILLING CODE 7590-01-M

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the Office of Management and Budget review of information collection.

SUMMARY: The Nuclear Regulatory Commission has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission, new, revision or extension: Revision.

2. The title of the information collection:

These rules, commonly referred to as the "Insider Safeguards Rules," consist of revisions to:

10 CFR Part 50—Domestic Licensing of Production and Utilization Facilities, and

10 CFR Part 73—Physical Protection of Plants and Materials

3. The form number if applicable: Not applicable.

4. How often the collection is required: The requirement for an Access Authorization Plan and revisions to security plans are one-time requirements, with changes to be submitted as occurring. Other information collections are required as occasioned by the occurrence of specified events.

5. Who will be required or asked to report: Power reactor licensees and applicants.

6. An estimate of the number of responses:

10 CFR Part 50—1 per site

10 CFR Part 73—Varies—range 1 to 1,500 per site

7. An estimate of the total number of hours needed to complete the requirement or request:

10 CFR Part 50—2,670

10 CFR Part 73—293,443

8. An indication of whether section 3504 (h), Pub. L. 96-511 applies: Not applicable.

9. Abstract: Power reactor licensees and applicants will be required to prepare and submit for NRC approval an Access Authorization Plan and revisions to security plans, which include the establishment and maintenance of access authorization files for individuals having access to protected areas and vital islands, and other miscellaneous Safeguards amendments to 10 CFR Part 73.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 1717 H Street, NW., Washington, DC 20555.

Comments and questions should be directed to the OMB reviewer, Jefferson B. Hill, (202) 395-7340.

The NRC Clearance Officer is R. Stephen Scott, (301) 492-8585.

Dated at Bethesda, Maryland, this 2nd day of December 1985.

For the Nuclear Regulatory Commission.

Patricia G. Norry,

Director, Office of Administration.

[FR Doc. 85-29252 Filed 12-9-85; 8:45 am]

BILLING CODE 7590-01-M

POSTAL RATE COMMISSION

[Order No. 652; Docket No. A86-4]

Sanitaria Springs, New York 13836 (George C. Williams et al., Petitioners); Order Accepting Appeal and Establishing Procedural Schedule Under 39 U.S.C. 404(b)(5)

Issued: December 3, 1985.

Before Commissioners: Janet D. Steiger, Chairman; Henry R. Folsom, Vice-Chairman; John W. Crutcher; Bonnie Guiton; Patti Birge Tyson.

Docket Number: A86-4.

Name of affected post office: Sanitaria Springs, New York 13836.

Name(s) of Petitioner(s): George C. Williams and others.

Type of determination: Closing.

Date of filing of first appeal papers: November 25, 1985.

Categories of issues apparently raised:

1. Effect on postal services [39 U.S.C. 404(b)(2)(A)].

2. Effect on the community [39 U.S.C. 404(b)(2)(C)].

Other legal issues may be disclosed by the record when it is filed; or conversely, the determination made by the Postal Service may be found to dispose of one or more of these issues.

In the interest of expedition within the 120-day decision schedule [39 U.S.C. 404(b)(5)] the Commission reserves the right to request of the Postal Service memoranda of law on any appropriate issue. If requested, such memoranda will be due 20 days from the issuance of the request; a copy shall be served on the Petitioners. In a brief or motion to dismiss or affirm, the Postal Service may incorporate by reference any such memorandum previously filed.

The Commission orders:

(A) The record in this appeal shall be filed on or before December 10, 1985.

(B) The Secretary shall publish this Notice and Order and Procedural Schedule in the **Federal Register**.

By the Commission.

Charles L. Clapp,

Secretary.

Appendix

November 25, 1985—Filing of Petition

December 3, 1985—Notice and Order of Filing of Appeal

December 20, 1985—Last day for filing petitions to intervene [*see* 39 CFR 3001.111(b)]

December 30, 1985—Petitioners' Participant Statement or Initial Brief [*see* 39 CFR 3001.115(a) and (b)]

January 21, 1986—Postal Service Answering Brief [*see* 39 CFR 3001.115(c)]

February 5, 1986—(1) Petitioners' Reply Brief should Petitioners choose to file one [*see* 39 CFR 3001.115(d)].

February 12, 1986—(2) Deadline for motions by any party requesting oral argument. The Commission will schedule oral argument only when it is a necessary addition to the written filings [*see* 39 CFR 3001.116].

March 25, 1986—Expiration of 120-day decisional schedule [*see* 39 U.S.C. 404(b)(5)].

[FR Doc. 85-29225 Filed 12-9-85; 8:45 am]

BILLING CODE 7715-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC-14826; (File No. 812-6106)]

ASA Limited; Notice of Filing of Application for an Order Pursuant to Section 7(d) of the Act Permitting Amendment of Custodian Agreement

December 4, 1985.

Notice is hereby given that ASA Limited (formerly named American-South African Investment Company Limited and hereinafter referred to as "Applicant"), 54 Marshall Street, Johannesburg, South Africa, registered under the Investment Company Act of 1940 ("Act") as a closed-end, non-diversified management investment company, filed an application on May 2, 1985, and amendments thereto on November 21 and December 2, 1985, for an order of the Commission, pursuant to section 7(d) of the Act, permitting Applicant to amend its Custodian Agreement and other documents. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act for a complete text of the applicable provisions.

Applicant states that it was incorporated in 1958 under the Companies Act of the Republic of South Africa and that it was permitted to register as an investment company, pursuant to section 8 of the Act, and to offer publicly its securities within the United States by an order of the Commission dated August 13, 1958 (Investment Company Act Release No. 2756, hereinafter referred to as "1958 Order"). Applicant further states that it presently has a Custodian Agreement with Citibank, N.A. ("Custodian"), a national banking association, organized and existing under the laws of the United States, with total assets of approximately $155 billion. By a subsequent order of the Commission dated April 7, 1981 (Investment Company Act Release No. 11722), Applicant was permitted to amend its Custodian Agreement in order to allow Applicant to invest available cash in short-term securities.

The application indicates that the Custodian Agreement (which was part of the basis of the 1958 Order) provided that Applicant's purchase or sale of portfolio securities, other than those executed on an "established securities exchange", be settled in the United States; the Custodian Agreement, pursuant to the 1958 Order, defined "established securities exchange" as one encompassed by section 2(a)(26) of the Act, the London Stock Exchange, or the Johannesburg Stock Exchange.

Applicant now proposes to purchase portfolio securities which are issued by non-South African companies (as is permitted by its investment policy), many of which are listed on securities exchanges other than those which are "established securities exchanges" as defined in the Custodian Agreement. Applicant, therefore, proposes to amend the definition of "established securities exchange" as presently contained in the Custodian Agreement to include the Tokyo Stock Exchange, the Toronto Stock Exchange, the Stock Exchange of Melbourne, Ltd. and the Effektenborsenverein Zurich Exchange ("Additional Exchange"), so as to permit the Custodian to settle such transactions in the country where such Exchange is located.

In support of its request to amend its Custodian Agreement, Applicant states that the present requirement that settlement of transactions other than those executed on "established securities exchange" must occur in the United States renders it impracticable for Applicant to purchase portfolio securities on those Additional Exchanges because of various requirements imposed by those Exchanges relating to the delivery and settlement of securities traded on those Exchanges. Moreover, Applicant contends that each of the Additional Exchanges are active Exchanges, with annual trading volumes in the billions of dollars and that those Exchanges are all governed by or operate within an established body of laws or regulations of their respective countries.

In addition, Applicant states it may be or may become either prohibited by law or regulation or financially impracticable (for example, because of shipping costs or the cost of insuring securities during shipping) for Applicant to remove securities purchased by it from the country in which certain

"established securities exchanges" are located. Applicant, therefore, seeks to amend its Custodian Agreement and its Memorandum and Articles of Association to permit the Custodian to appoint an "eligible foreign custodian" as that term is defined in Rule 17f–5 of the Act, or an overseas branch of the Custodian, as its sub-custodian for the purposes of holding securities purchased by Applicant on those Additional Exchanges in Japan, Australia, Switzerland and Canada.

In support of the above request, Applicant represents that, prior to Applicant's purchase of securities on an "established securities exchange" in any of the above countries, if an "eligible foreign custodian" is to be appointed as subcustodian:

(1) A majority of Applicant's board of directors will have determined that maintaining Applicant's assets in that country is consistent with the best interests of Applicant and its shareholders;

(2) A majority of Applicant's board of directors will have determined that maintaining such assets with the particular foreign custodian is consistent with the best interests of Applicant and its shareholders;

(3) A majority of Applicant's board of directors will approved, as consistent with the best interest of Applicant and its shareholders, a written contract which will govern the manner in which such subcustodian will maintain Applicant's assets. That contract will provide that:

(i) Applicant will be adequately indemnified and its assets adequately insured in the event of loss;

(ii) Applicant's assets will not be subject to any right, charge, security interest, lien or claim of any kind in favor of the foreign custodian or its creditors except a claim of payment for their safe custody or administration;

(iii) Beneficial ownership of Applicant's assets will be freely transferable without the payment of money or value other than for safe custody or administration;

(iv) Adequate records will be maintained identifying the assets as belonging to Applicant;

(v) Applicant's independent public accountants will be given access to those records or confirmation of the content of those records; and

(vi) Applicant will receive periodic reports with respect to safekeeping of the company's assets, inlcuding, but not limited to, notification of any transfer to or from Applicant's account.

(4) The board of directors will establish a system to monitor such foreign custody arrangements to ensure compliance with the conditions of Rule 17f-5 of the Act.

(5) A majority of the board of directors, at least annually, will review and approved the continuation of such arrangements as consistent with the best interests of Applicant and its shareholders.

Applicant further represents that, prior to its purchase of securities on an "established securities exchange" in any of those countries, if an overseas branch of the Custodian is to be appointed as subcustodian:

(1) A majority of Applicant's board of directors will have determined that maintaining such assets in such country is consistent with the best interests of Applicant and its shareholders;

(2) Applicant's board of directors will establish a system to monitor such foreign custody arrangements and to ensure that the amount of cash and cash equivalents maintained in the care of such overseas branch is limited to an amount reasonably necessary to effect Applicant's foreign securities transactions; and

(3) A majority of Applicant's board of directors, at least annually, will review and approve the continuation of such arrangement as consistent with the best interests of Applicant and its shareholders.

In addition, Applicant represents that where a majority of the board of directors has determined that a particular subcustodian may no longer be considered eligible under Rule 17f–5 or may no longer be considered an overseas branch of the Custodian, or that continuance of any subcustodian arrangement would not otherwise be consistent with the best interests of Applicant and its shareholders, Applicant will withdraw its assets from the care of that subcustodian as soon as reasonably practicable, and in any event within 180 days of the date when the directors make that determination. In making that determination, Applicant's boad of directors will consider the factors identified by the Commission in the Notes to Rule 17f–5. Applicant further states that should removal of securities purchased by Applicant on those Additional Exchanges become either prohibited by law or regulation or become financially impracticable such that an "eligible foreign custodian" or an overseas branch of the Custodian would be utilized, in that event, Applicant's amended Custodian Agreement and its Memorandum and Articles of Association will not permit it to maintain in excess of five percent of its total assets in each of those countries where an Additional Exchange is located.

In addition, Applicant seeks relief permitting it to maintain in the Republic of South Africa up to three percent of its assets in short-term rand denominated investments issued or guaranteed by the Republic of South Africa rather than in a non-interest bearing account with the Custodian. Applicant states that it would neither incur the currency exchange, shipping and insurance costs nor forego the higher interest yields available on rand denominated investments if available cash is invested in short-term securities rather than in the presently maintained non-interest bearing account with the Custodian. Therefore, Applicant proposes to amend the Custodian Agreement and its Memorandum and Articles of Association to permit the Custodian to appoint Barclays National Bank Limited ("Barclays"), an "eligible foreign custodian" as that term is defined in Rule 17f–5 of the Act.

In support of its request, Applicant represents that, prior to the appointment of Barclays as subcustodian for those short-term investments, Applicant's board of directors will be subject to the same representations applicable to the use of other "eligible foreign custodians" described above. Applicant further represents that as a further condition to this relief, Applicant represents that its Custodian Agreement will be amended so that Applicant will be prohibited from maintaining in excess of three percent of its total assets in South Africa.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than December 27, 1985, at 5:30 p.m., do so by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, DC 20549. A copy of the request should be served personally or by mail upon an Applicant at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date, an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

John Wheeler,

Secretary.

[FR Doc. 85–29272 Filed 12–9–85; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35-23933; 70-7188]

National Fuel Gas Distribution Corp.; Proposed Sale of All Utility Assets in Ohio

December 3, 1985.

National Fuel Gas Distribution Corporation ("Distribution Corporation"), 10 Lafayette Square, Buffalo, New York 14203, a gas utility subsidiary of National Fuel Gas Company, a registered holding company, has filed a declaration with this Commission pursuant to section 12(d) of the Public Utility Holding Company Act of 1935 ("Act") and Rule 44 promulgated thereunder.

Distribution Corporation proposes to sell, pursuant to a sale agreement, all of its utility assets in the State of Ohio to Clearfield Energy, Inc. ("Clearfield"), a non-associated company, for the following cash consideration: the greater of (1) $3,300,000 or (2) the net book value of Distribution Corporation's Ohio rate base as of the last day of the month prior to close of the sale, minus the Ohio portion of Distribution Corporation's accumulated deferred investment tax credit account as of such date. No other consideration is involved.

It is stated that Distribution Corporation desires to sell its Ohio utility assets primarily for administrative convenience. The company has only approximately 5,600 retail customers in Ohio (less than 1% of its total) and received approximately $6.6 million in revenues from Ohio customers in fiscal 1984. These revenues represent less than 1% of the consolidated revenues of Distribution Corporation and its parent company. Yet Distribution Corporation, by having this small presence in Ohio, is obliged to file rate cases and comply with a different set of rate-related regulation, safety-related regulation, and other utility regulation. Distribution Corporation believes that continuation of its operations in Ohio would be unduly burdensome.

The declaration and any amendments thereto are available for public inspection through the Commission's Office of Public Reference. Interested persons wishing to comment or request a hearing should submit their views in writing by December 27, 1985, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the declarant at the address specified above. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for a hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in this matter. After said date, the declaration, as filed or as it may be amended, may be permitted to become effective.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

John Wheeler,

Secretary.

[FR Doc. 85-29273 Filed 12-9-85; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[Designation of Disaster Loan Area 6369]

California; Designation of Disaster Loan Area

Correction

In FR Doc. 85-28436 appearing on page 49147 in the issue of Friday, November 29, 1985, the heading should have appeared as set forth above.

BILLING CODE 1505-01-M

[Designation of Disaster Loan Area 2220]

New Jersey; Designation of Disaster Loan Area

Correction

In FR Doc. 85-28437 appearing on page 49147 in the issue of Friday, November 29, 1985, the heading should have appeared as set forth above.

BILLING CODE 1505-01-M

DEPARTMENT OF STATE

[Public Notice CM-8/912]

Bureau of Oceans and International Environmental and Scientific Affairs; Coca Crop Eradication Programs

AGENCY: Department of State.

ACTION: Finding of No Significant Impact.

SUMMARY: The Department of State has prepared an environmental assessment regarding proposd assistance to coca crop eradication programs overseas using the herbicide Garlon (triclopyr). The assistance would be provided by the Department's Bureau for International Narcotics Matters as part of its mandate to reduce the flow of illicit drugs into the United States from foreign sources.

Based on the findings of the environmental assessment, the Department has concluded that there will be no significant environmental impacts from the proposed program.

Copies of the environmental assessment may be obtained from Paul J. Glasoe, OES/ENR, Department of State, Washington, DC 20520 (Telephone: 202/632-6527).

Dated: December 3, 1985.

Bill L. Long,

Director, Office of Food and Natural Resources.

[FR Doc. 85-29186 Filed 12-9-85; 8:45 am]

BILLING CODE 4710-09-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Order 85-12-4; Docket 42893]

Application of Temsco Helicopters, Inc., for Certificate Authority Under Subpart Q

AGENCY: Department of Transportation.

ACTION: Notice of Order to Show Cause, (Order 85-12-4) Docket 42893.

SUMMARY: The Department is directing all interested persons to show cause why it should not issue an order finding Temsco Helicopters, Inc., fit to engage in interstate and overseas scheduled air transportation.

DATES: Persons wishing to file objections shall do so no later than December 24, 1985; answers to objections shall be filed no later than January 3, 1986.

ADDRESSES: Objections and answers to objections should be filed in Docket 42893 and addressed to the Documentary Services Division, U.S. Department of Transportation, 400 Seventh Street, SW., Room 4107, Washington, DC 20590, and should be served upon the persons listed in Attachment A to the order.

FOR FURTHER INFORMATION CONTACT: Betsy Wolf, (202) 426-7631, Office of Aviation Enforcement and Proceedings, or Patricia T. Szram, (202) 755-3812, Office of Aviation Operations, Special Authorities Division, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590.

Dated: December 3, 1985.

Philip W. Haseltine,

Acting Assistant Secretary for Policy and International Affairs.

[FR Doc. 85-29232 Filed 12-9-85; 8:45 am]

BILLING CODE 4910-62-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

[Notice No. 574]

Commerce in Explosives; List of Explosive Materials

Pursuant to the provisions of section 841(d) of Title 18, United States Code, and 27 CFR 55.23, the Director, Bureau of Alcohol, Tobacco, and Firearms, must publish and revise at least annually in the **Federal Register** a list of explosives determined to be within the coverage of 18 U.S.C. Chapter 40, Importation, Manufacture, Distribution and Storage of Explosive Materials. This Chapter covers not only explosives, but also blasting agents and detonators, all of which are defined as explosive materials in section 841(c) of Title 18, United States Code.

Accordingly, the following is the 1985 List of Explosive Materials subject to regulation under 18 U.S.C. Chapter 40, which includes both the list of explosives (including detonators) required to be published in the **Federal Register** and blasting agents. The list is intended to also include any and all mixtures containing any of the materials in the list. Materials constituting blasting agents are marked by an asterisk. While the list is comprehensive, it is *not* all inclusive. The fact that an explosive material may not be on the list does not mean that it is not within the coverage of the law if it otherwise meets the statutory definitions in Section 841 of Title 18, United States Code. Explosive materials are listed alphabetically by their common names followed by chemical names and synonyms in brackets. This revised list supersedes the List of Explosive Materials dated December 28, 1984 (49 FR 50492) and will be effective as of January 1, 1985).

List of Explosive Materials

A

Acetylides of heavy metals.
Aluminum containing polymeric propellant.
Aluminum ophorite explosive.
Amatex.
Amatol.
Ammonal.
Ammonium nitrate explosive mixtures (cap sensitive).
*Ammonium nitrate explosive mixtures (non cap sensitive).
Aromatic nitro-compound explosive mixtures.
Ammonium perchlorate having particle size less than 15 microns.
Ammonium perchlorate composite propellant.
Ammonium picrate [picrate of ammonia, Explosive D].
Ammonium salt lattice with isomorphously substituted inorganic salts.
*ANFO [ammonium nitrate-fuel oil].

B

Baratol.
Baronol.
BEAF [1,2-bis (2,2-difluoro-2-nitroacetoxyethane)].
Black powder.
Black powder based explosive mixtures.
*Blasting agents, nitro-carbo-nitrates, including non cap sensitive slurry and water-gel explosives.
Blasting caps.
Blasting gelatin.
Blasting powder.
BTNEC [bis (trinitroethyl)carbonate].
BTNEN [bis (trinitroethyl) nitramine].
BTTN [1,2,4 butanetriol trinitrate].
Butyl tetryl.

C

Calcium nitrate explosive mixture.
Cellulose hexanitrate explosive mixture.
Chlorate explosive mixtures.
Composition A and variations.
Composition B and variations.
Composition C and variations.
Copper acetylide.
Cyanuric triazide.
Cyclotrimethylenetrinitramine [RDX].
Cyclotetramethylenetrainitramine [HMX].
Cyclotol.

D

DATB [diaminotrinitrobenzene].
DDNP [diazodinitrophenol].
DEGDN [diethyleneglycol dinitrate].
Detonating cord.
Detonators.
Dimethylol dimethyl methane dinitrate composition.
Dinitroethyleneurea.
Dinitroglycerine [glycerol dinitrate].
Dinitrophenol.
Dinitrophenolates.
Dinitrophenyl hydrazine.
Dinitroresorcinol.
Dinitrotoluene-sodium nitrate explosive mixtures.
DIPAM.
Dipicryl sulfone.
Dipicrylamine.
DNDP [dinitropentano nitrile].
NNPA [2,2-dinitropropyl acrylate].
Dynamite.

E

EDNA.
Ednatorl.
EDNP [ethyl 4, 4-dinitropentanoate].
Erythritorl tetranitrate explosives.
Esters of nitro-substituted alcohols.
EGDN [ethylene glycol dinitrate].
Ethyl-tetryl.
Explosive conitrates.
Explosive gelatins.
Explosive mixtures containing oxygen releasing inorganic salts and hydrocarbons.
Explosive mixtures containing oxygen releasing inorganic salts and nitro bodies.
Explosive mixtures containing oxygen releasing inorganic salts and water insoluble fuels.
Explosive mixtures containing oxygen releasing inorganic salts and water soluble fuels.
Explosive mixtures containing sensitized nitromethane.
Explosive mixtures containing tetranitromethane (nitro form).
Explosive nitro compounds of aromatic hydrocarbons.
Explosive organic nitrate mixtures.
Explosive liquids.
Explosive powders.

F

Fulminate of mercury.
Fulminate of silver.
Fulminating gold.
Fulminating mercury.
Fulminating platinum.
Fulminating silver.

G

Gelatinized nitrocellulose.
Gem-dinitro aliphatic explosive mixtures.
Guanyl nitrosamino guanyl tetrazene.
Guanyl nitrosamino guanylidene hydrazine.
Guncotton.

H

Heavy metal azides.
Hexanite.
Hexanitrodiphenylamine.
Hexanitrostilbene.
Hexogene or octogene and a nitrated N-methylaniline.
Hexolites.
HMX [cyclo-1,3,5,7-tetramethylene-2,4,6,8-tetranitramine; Octogen].
Hydrazinium nitrate/hydrazine/aluminum explosive system.
Hydrazoic acid.

I

Igniter cord.
Igniters.
Initiating tube systems.

K

KDNBF [potassium dinitorbenzo-furoxane].

L

Lead azide.
Lead mannite.
Lead mononitroresorcinate.
Lead picrate.
Lead salts, explosive.
Lead styphnate [styphnate of lead, lead trinitroresorcinate].
Liquid nitrated polyol and trimethylolethane.
Liquid oxygen explosives.

M

Magnesium ophorite explosives.
Mannitol hexanitrates.
MDNP [methly 4,4-dinitropentanoate].
Mercuric fulminate.
Mercury oxalate.
Mercury tartrate.
Minol-2 [40% TNT, 40% ammonium nitrate, 20% aluminum].
Mononitrotoluene-nitroglycerin mixture.
Monopropellants.

N

NIBTN [nitroisobutametriol trinitrate].
Nitrate sensitized with gelled nitroparaffin.
Nitrated carbohydrate explosive.
Nitrated glucoside explosive.
Nitrated polyhydric alcohol explosives.
Nitrates of soda explosive mixtures.
Nitric acid and a nitro aromatic compound explosive.
Nitric acid and carboxylic fuel explosive.
Nitric acid explosive mixtures.
Nitro aromatic explosive mixtures.
Nitro compounds of furane explosive mixtures.
Nitrocellulose explosive.
Nitroderivative of urea explosive mixture.
Nitrogelatin explosive.
Nitrogen trichloride.
Nitrogen tri-iodide.
Nitroglycerine [NG, RNG, nitro, glyceryl trinitrate, trinitroglycerine].
Nitroglycide.
Nitroglycol [ethylene glycol dinitrate, EGDN].
Nitroguanidine explosives.
Nitroparaffins Explosive Grade and ammonium nitrate mixtures.
Nitronium perchlorate propellant mixtures.
Nitrostarch.
Nitro-substituted carboxylic acids.
Nitrourea.

O

Octogen [HMX].
Octol [75 percent HMX, 25 percent TNT].
Organic amine nitrates.
Organic nitramines.

P

PBX [RDX and plasticizer].
Pellet powder.
Penthrinite composition.
Pentolite.
PYX [2,6-bis(picrylamino)-3,5-dinitropyridine
Perchlorate explosive mixtures.
Peroxide based explosive mixtures.
PETN [nitropentaerythrite, pentaerythrite tetranitrate, pentaerythritol tetranitrate].
Picramic acid and its salts.
Picramide.
Picrate of potassium explosive mixtures.
Picratol.
Picric acid (explosive grade).
Picryl chloride.
Picryl fluoride.
PLX [95% nitromethane, 5% ethylenediamine].
Polynitro aliphatic compounds.
Polyolpolynitrate-nitrocellulose explosive gels.
Potassium chlorate and lead sulfocyanate explosive.
Potassium nitrate explosive mixtures.
Potassium nitroaminotetrazole.

R

RDX [cyclonite, hexogen, T4, cyclo-1,3,5-trimethylene-2,4,6,-trinitramine; hexahydro-1,3,5-trinitro-S-triazine]/

S

Safety fuse.
Salts of organic amino sulfonic acid explosive mixture.
Silver acetylide.
Silver azide.
Silver fulminate.
Silver oxalate explosive mixtures.
Silver styphnate.
Silver tartrate explosive mixtures.
Silver tetrazene.
Slurried explosive mixtures of water, inorganic oxidizing salt, gelling agent, fuel and sensitizer (cap sensitive).
Smokeless powder.
Sodatol.
Sodium amatol.
Sodium dinitro-ortho-cresolate.
Sodium nitrate-potassium nitrate explosive mixture.
Sodium picramate.
Squibs.
Styphnic acid.

T

Tacot [tetranitro-2,3,5,6-dibenzo-1,3a,4,6a-tetrazapentalene].
TATB [triaminotrinitrobenzene].
TEGDN [triethylene glycol dinitrate].
Tetrazene [tetracene, tetrazine, 1(5-tetrazolyl)-4-guanyl tetrazene hydrate].
Tetranitrocarbazole.
Tetryl [2,4,6 tetranitro-N-methylaniline].
Tetrytol.
Thichened inorganic oxidizer salt slurried explosive mixture.
TMETN (trimethylolethane trinitrate).
TNEF [trinitroethyl formal].
TNEOC [trinitroethylorthocarbonate].
TNEOF [trinitroethyl orthoformate].
TNT [trinitrotoluene, trotyl, trilite, triton].
Torpex.
Tridite.
Trimethylol ethyl methane trinitrate composition.
Trimethylolthane trinitrate-nitrocellulose.
Trimonite.
Trinitroanisole.
Trinitrobenzene.
Trinitrobenzoic acid.
Trinitrocresol.
Trinitro-meta-cresol.
Trinitronaphthalene.
Trinitrophenetol.
Trinitrophloroglucinol.
Trinitroresorcinol.
Tritonal.

U

Urea nitrate.

W

Water bearing explosives having salts of oxidizing acids and nitrogen bases, sulfates, or sulfamates (cap sensitive).

X

Xanthamonas hydrophilic colloid explosive mixture.

FOR FURTHER INFORMATION CONTACT: Firearms and Explosives Operations Branch, Bureau of Alcohol, Tabacco and Firearms, 1200 Pennsylvania Avenue, NW., Washington, DC 20226 (202-566-7591).

Signed: December 2, 1985.

Stephen E. Higgins,

Director.

[FR Doc. 85-29247 Filed 12-9-85; 8:45 am]

BILLING CODE 4810-31-M

VETERANS ADMINISTRATION

Agency Form Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document contains an extension and lists the following information: (1) The department or staff office issuing the form, (2) the title of the form, (3) the agency form number, if applicable, (4) how often the form must be filled out, (5) who will be required or asked to report, (6) an estimate of the

number of responses, (7) an estimate of the total number of hours needed to fill out the form, and (8) an indication of whether section 3504(h) of Public Law 96–411 applies.

ADDRESSES: Copies of the form and supporting documents may be obtained from Nancy C. McCoy, Agency Clearance Officer (732), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 389–2146. Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Dick Eisinger, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, (202) 395–7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 60 days of this notice.

Dated: December 5, 1985.

Everett Alvarez, Jr.,

Deputy Administrator.

Extension

1. Department of Medicine and Surgery.
2. Residential Care Home Program Sponsor Application.
3. VA Form 10–2407.
4. One time only.
5. Individuals or households; Businesses or other for-profit.
6. 1,000 responses.
7. 80 hours.
8. Not applicable.

[FR Doc. 85–29259 Filed 12–9–85; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 50, No. 237
Tuesday, December 10, 1985

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

FEDERAL RESERVE SYSTEM

Board of Governors

TIME AND DATE: Approximately 11:00 a.m., Friday, December 13, 1985, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed changes to the Plans administered under the Federal Reserve System's employee benefits program.

2. Federal Reserve Bank and Branch director appointments. (This item was originally announced for a closed meeting on December 9, 1985.)

3. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

4. Any item carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 254-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: December 5, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-29334 Filed 12-85; 11:43 am]

BILLING CODE 6210-01-M

2

FEDERAL RESERVE SYSTEM

Board of Governors

TIME AND DATE: 10:00 a.m., Friday, December 13, 1985.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of their routine nature, no substantive discussion of the following items is anticipated. These matters will be voted on without discussion unless a member of the Board requests that an item be moved to the discussion agenda.

1. Proposed amendments to the Board's Rules Regarding Delegation of Authority to expedite the processing of applications and competitive factors reports.

2. Proposed amendment to Regulation D (Reserve Requirements of Depository Institutions) permitting nonmember depository institutions in Hawaii to phase in reserve requirements on money market deposit accounts.

Discussion Agenda

3. Proposed revisions to Regulations D (Reserve Requirements of Depository Institutions) and Q (Interest on Deposits) to reflect the expiration of the Depository Institutions Deregulation Act.

4. Any items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: December 5, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-29335 Filed 12-6-85; 11:43 am]

BILLING CODE 6210-01-M

3

FEDERAL RESERVE SYSTEM

Board of Governors

TIME AND DATE: 11:35 a.m., Friday, December 6, 1985.

The busines of the Board required that this meeting be held with less than one week's advance notice to the public, and no earlier announcement of the meeting was practicable.

PLACE: 20th Street and Constitution Avenue, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Further consideration of Regulation G issues. (This item was originally announced for a closed meeting on November 20, 1985.)

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board, (202) 452-3204.

Dated: December 6, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-29351 Filed 12-6-85; 12:50 pm]

BILLING CODE 6210-01-M

4

LEGAL SERVICES CORPORATION

Committee on Audit and Appropriations

TIME AND DATE: Meeting will commence at 1:00 p.m., Wednesday, December 18, 1985 and continue until all official business is completed.

PLACE: Sheraton Hotel, Navajo Room, 325 N. Kansas, El Paso, Texas 79901.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda
2. Approval of Minutes
   —October 25, 1985
   —November 7, 1985
3. Modification of Budget Guidelines
4. FY 1986 Preliminary Consolidated Operating Budget
5. FY 1987 Budget Mark

CONTACT PERSON FOR MORE INFORMATION: Joel Thimell, Office of Policy Development & Communications (202) 863-1842.

Date issued: December 6, 1985.

Timothy H. Baker,

Secretary.

[FR Doc. 85-29352 Filed 12-6-85; 12:51 pm]

BILLING CODE 6820-35-M

5

LEGAL SERVICES CORPORATION

Board of Directors

TIME AND DATE: Meeting will commerce at 8:30 a.m., Thursday, December 19, 1985, and continue until all official business is completed.

PLACE: Sheraton Hotel, Navajo Room, 325 N. Kansas, El Paso, Texas 79901.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda
2. Approval of Minutes
   —November 8, 1985
3. Election of Chairman and Vice Chairman of the Board
4. Report of the President
5. Discussion and Action on the Recommendations of the Audit and Appropriations Committee
   —Modification of Budget Guidelines
   —FY 1986 Preliminary Consolidated Operating Budget
   —FY 1987 Budget Mark
6. Discussion and Action on the Recommendations of the Operations and Regulations Committee
   —45 CFR Part 1630 (Question Costs)
7. Public comment

CONTACT PERSON FOR MORE INFORMATION: Timothy H. Baker, Executive Office, (202) 863–1839.

Date issued: December 6, 1985.

Timothy H. Baker,

Secretary.

[FR Doc. 85–29353 Filed 12–6–85; 12:52 pm]

BILLING CODE 6820–35–M

6

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of December 9, 16, 23, and 30, 1985.

PLACE: Commissioner's Conference Room, 1717 H Street, NW., Washington, DC.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of December 9

Monday, December 9

10:00 a.m.
Discussion of Threat Level and Physical Security (Closed—Ex. 1)

2:00 p.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)

Tuesday, December 10

9:30 a.m.
Periodic Briefing on NTOLs (Open/Portion may be closed—Ex. 5 & 7)

2:30 p.m.
Review of Enforcement Policy (Public Meeting)

Wednesday, December 11

10:00 a.m.
Briefing on Policy Statement on Nuclear Power Plant Standardization (Public Meeting)

2:00 p.m.
Discussion of Pending Investigations (Closed—Ex. 5 & 7)

Thursday, December 12

9:30 a.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)

2:00 p.m.
EEO Program Plan—Progress Report (Public Meeting)

3:30 p.m.
Affirmation/Discussion and Vote (Public Meeting)
a. Public Service Company of New Mexico's Proposed Sale and Leaseback Transaction for Refinancing Its Interest in Palo Verde 1 (Tentative)
B. Request for Refund of Black Fox License Fee (Tentative)

Week of December 16—Tentative

Tuesday, December 17

10:00 a.m.
Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6)

2:00 p.m.
Briefing on Nuclear Employee Data System (NEDS) (Public Meeting)

Wednesday, December 18

10:00 a.m.
Briefing on Status of Davis-Besse (Public Meeting)

3:30 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of December 23—Tentative

Tuesday, December 24

10:00 a.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of December 30—Tentative

Thursday, January 2

3:30 p.m.
Affirmation Meeting (Public Meeting) (if needed)

ADDITIONAL INFORMATION: Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 and 6) was held December 2.

Affirmation of "Revised Braidwood Order" (Public Meeting) was held December 4.

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING): (202) 634–1498.

CONTACT PERSON FOR MORE INFORMATION: Julia Corrado (202) 634–1410.

Julia Corado,

Office of the Secretary.

December 5, 1985.

[FR Doc. 85–29387 Filed 12–6–85; 3:51 pm]

BILLING CODE 7590–01–M

7

POSTAL SERVICE

Notice of Vote To Close Meeting

At its meeting on December 2, 1985, the Board of Governors of the United States Postal Service unanimously voted to close to public observation its meeting scheduled for January 6, 1986, in Washington, DC. The meeting will involve consideration of the Postal Rate Commission's recommended decision in *Complaint of Tri-Parish Journal, Inc.* (Docket No. C85–2).

The meeting is expected to be attended by the following persons: Governors Camp, Griesemer, McKean, Peters, Ryan and Voss; Postmaster General Carlin; Deputy Postmaster General Strange; Secretary to the Board Harris; General Counsel Cox; and Counsel to the Governors Califano.

The Board of Governors has determined that, pursuant to § 552b(c)(3) of Tile 5, United States Code, and § 7.3(c) of Title 39, Code of Federal Regulations, the meeting is exempt from the open meeting requirement of the Government in the Sunshine Act [5 U.S.C. 552b(b)], because it is likely to disclose information in connection with proceedings under chapter 36 of Title 39 (having to do with postal ratemaking, mail classification and changes in postal services), which is specifically exempted from disclosure by section 410(c)(4) of Title 39, United States Code. The Board also determined that pursuant to section 552b(c)(10) of Title 5, United States Code, and § 7.3(j) of Title 39, Code of Federal Regulations, the discussion is exempt because it is likely to specifically concern the participation of the Postal Service in a civil action or proceeding or the litigation of a particular case involving a determination on the record after opportunity for a hearing. The Board further determined that the public interest does not require that the Board's discussion of this matter be open to the public.

In accordance with Section 552b(f)(1) of Title 5, United States Code, and § 7.6(a) of Title 39, Code of Federal Regulations, the General Counsel of the United States Postal Service has certified that in his opinon the meeting to be closed may properly be closed to public observation, pursuant to section 552b(c)(3) and (10) of Title 5 and section 410(c)(4) of Title 39, United States Code, and § 7.3(c) and (j) of Title 39, Code of Federal Regulations.

David F. Harris,

Secretary.

[FR Doc. 85–29369 Filed 12–6–85; 4:15 pm]

BILLING CODE 7710–12–M

Federal Register

Tuesday
December 10, 1985

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Formaldehyde; Proposed Rule and Notice of Hearing

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-225A]

Occupational Exposure to Formaldehyde

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule and notice of hearing.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposes to amend its existing regulation for occupational exposure to formaldehyde, 29 CFR 1910.1000, Table Z-2. The Assistant Secretary has determined, based on a review and evaluation of studies conducted on the health effects of formaldehyde, that the current permissible exposure limits (PELs) do not adequately protect employee health. OSHA proposes to reduce the existing 8-hour time-weighted average (TWA) exposure limit from 3 parts of formaldehyde per million parts of air (ppm) to either 1 ppm or 1.5 ppm. OSHA proposes to delete both the existing 8-hour ceiling concentration of 5 ppm for formaldehyde and the peak exposure limit of 10 ppm, permitted for up to 30 minutes in an 8-hour day. In addition, OSHA proposes to set an "action level" of either 0.5 ppm or 0.75 ppm, measured as an 8-hour TWA, in order to minimize the compliance burden for employers whose employees have exceeding low exposure to formaldehyde. The proposal also contains provisions for employee exposure monitoring, medical surveillance, recordkeeping, regulated areas, emergency procedures, preferred methods to control exposure, hazard communication, and selection and maintenance of personal protective equipment.

DATES: Written comments on the proposed standard must be postmarked on or before March 10, 1986. Notice of Intention to appear at the informal rulemaking hearings on the proposed standard must be received by March 10, 1986. Parties who request more than 10 minutes for their presentations at the informal public hearing and parties who will submit documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence no later than March 31, 1986. The informal rulemaking hearing is scheduled to begin on April 22, 1986.

ADDRESSES: Written comments, and objections should be submitted to the Docket Officer, Docket No. H-225A, Room N-3670, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Notices of intention to appear at the informal rulemaking hearing, testimony, and documentary evidence are to be sent to Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-225A, Room N-3662, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

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VIII. Summary of the Regulatory Impact Analyses and Regulatory Flexibility Analysis
IX. Environmental Assessment—Finding of no Significant Impact
X. Summary and Explanation of the Proposed Standard
XI. Public Participation—Notice of Hearing
XII. Authority and Signature

I. Introduction

The preamble to the proposed standard on occupational exposure to formaldehyde discusses the events leading to the proposal, the physical and chemical properties of formaldehyde, its manufacture and use, the health effects resulting from exposure to formaldehyde, an assessment of the associated risk, an analysis of the technological and economic feasibility and environmental impact of the proposed revision, and the rationale behind the specific provisions set forth in the regulatory text.

OSHA invites interested persons to submit written comments and evidence relevant to this proposed standard. Comments are requested on the adequacy of the proposed permissible exposure limit (PEL) and action level and whether there is a need for a short term exposure limit (STEL). Comments are also requested on the contents of the various provisions of the proposed standard, on the proposed start-up dates for these provisions, and on any cost effective alternatives that would provide equal or improved employee protection. It is possible that, in the final rule, OSHA could raise or lower the PEL and promulgate a STEL, either alone or in combination with a PEL, should testimony at the public hearing or written comments show convincing evidence of such a need, and the commenter is urged to consider this contingency in responding.

OSHA has already received submissions on the health effects of formaldehyde; on provisions to be included in revising the formaldehyde standard; and on methods, costs, and effectiveness of control strategies that are used to reduce exposure to formaldehyde as a result of questions posed in a January 11, 1985, announcement [50 FR 1547] of a public meeting and an April 17, 1985, publication of an Advance Notice [50 FR 15179]. Although the public is invited to submit any information relevant to the regulation of formaldehyde, material and comments submitted in response to these two announcements have been placed in OSHA's docket on formaldehyde and need not be resubmitted for consideration in the rulemaking.

Specific issues of concern to OSHA are the following:

1. What limits should be set to protect employee health? Should employee exposure limits include or be limited to a STEL?

2. Should OSHA revoke the existing short term exposure limits found at 29 CFR 1910.1000 and at 29 CFR 1926.55 and, if so, what is the justification for the revocation? What exposure levels should be set on the basis of feasibility?

3. What alternative action level could be set? What provisions currently triggered by exposure at the action level should be triggered by exposure at the PEL? If there were no action level, which provisions triggered by an action level should be made applicable to all formaldehyde-exposed employees?

4. What modifications in the exposure monitoring program would be necessary to assure that all employees exposed above the PEL are identified? Would a modification in the proposed action level force exclusion of some methods for monitoring employee exposure because of insufficient accuracy?

5. Can provisions of the proposed standard be modified to assist small businesses in achieving compliance? Should these modifications be limited to only specific sectors of the formaldehyde industry? Which sectors require special attention? Please state the basis for your conclusions.

6. How should a "small business" be defined?

7. How can the provisions of the Hazard Communication standard (29 CFR 1910.1200) be made to apply

effectively in sectors other than manufacturing?

8. What is your experience with qualitative versus quantitative fit testing for respirator use to protect against overexposure to formaldehyde? Can employees who wear negative pressure respirators be adequately protected without quantitative fit testing and specific limits on canister and cartridge lives?

9. When do respirators constitute an acceptable alternative to the use of engineering controls and work practices to limit employee exposure to formaldehyde? Where are respirators unacceptable?

10. Can passive diffusion devices be used to detect short term exposure of employees to formaldehyde? Can they detect levels as low as 0.5 ppm? Please elaborate on any situations where you have found these devices to be unreliable or to give erroneous results.

11. How can requirements for emergency showers and eyewash facilities, personal protective equipment and clothing, cleanup of spills, and other hygiene measures be improved to better reflect good practices in use?

12. Do the limitations placed on coverage of employees under medical surveillance permit a significant hazard to any employees? How should the requirements be modified? If the present limitations are retained, how many of the total formaldehyde-exposed workforce will be eligible to participate?

13. What additional information would be useful in the Material Safety Data Sheet (MSDS)? (Please submit any MSDS's for formaldehyde that may be useful.)

14. Please provide detailed information that would enable OSHA to improve its estimates of risk. Examples of information sought by OSHA include evidence of new health effects, evidence that would better define the risk to workers from known health effects, risk assessments, epidemiological studies (both morbidity and mortality studies), and improved and updated data on the number of workers exposed at different levels for different time periods. OSHA is especially interested in receiving information on how formaldehyde has affected employee sickness absences, productivity, and the concentrations at which such effects occur.

15. Has OSHA accurately estimated all costs associated with achieving compliance with the proposed new rule? Are there any industries where compliance with the proposed rule is economically infeasible? How would these conclusions be modified if a STEL were included in a standard for formaldehyde?

16. Has OSHA adequately represented the results of presently available epidemiological studies? How could this be modified to present the material in the most useful fashion?

17. OSHA has proposed to include all industries within the scope of the standard but proposes to exempt materials containing less than 0.1 percent formaldehyde. What industries will this affect? What exposure concentrations occur in these industries? How can OSHA modify the scope of coverage to better achieve the goal of protecting employee health?

18. Please provide any information available on potentially significant (negative or positive) environmental effects that may occur as a result of the proposal.

19. How does the proposed standard affect industry's economic position, particularly with regard to foreign import competition in the domestic U.S. market, and the price of U.S. goods for export?

20. In addition to monitoring results, industry has the option of relying upon "objective data" to document the fact that employees are not exposed at or above the action level. What data, other than monitoring of employee exposure at the subject plant, are likely to qualify as "objective data," and what mechanisms exist (e.g., trade associations) for supplying such "objective data" to relieve large numbers of firms from monitoring requirements?

21. How should OSHA modify the proposed regulatory text to consider the unique characteristics of the construction industry?

In addition to these specific questions, OSHA is aware that a major epidemiological study of formaldehyde workers is near completion. OSHA has tentatively concluded, based on criteria spelled out in the Cancer Policy that the existing epidemiological evidence is inconclusive with regard to formaldehyde's carcinogenic potential in humans. Consequently, OSHA has relied on animal data both to make the qualitative determination that formaldehyde could be a carcinogen in humans, as well, and to make the quantitative determination of the possible risk associated with occupational exposure to formaldehyde. OSHA is willing to reevaluate and improve upon both of these analyses as better information becomes available. Thus, if the study being conducted at the National Cancer Institute becomes available during the comment period for this proposed rulemaking, the public is encouraged to comment on the study, how it might affect the evaluation of human risk, and how the results might affect OSHA's regulation for formaldehyde.

Interested persons must submit their comments with respect to this proposal on or before February 10, 1986, in quadruplicate, to the Docket Officer, Docket No. H–225A, Room N–3670, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Written submissions must clearly identify the provisions of the proposal which are addressed and the position taken with respect to each issue.

Any comments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be make a part of the record of the proceeding.

II. Pertinent Legal Authority

The primary purpose of the Occupational Safety and Health Act (the Act) (29 U.S.C. 655 et seq.) is to assure, so far as possible safe and healthful working conditions for every American worker over the period of his or her working lifetime. One means prescribed by the Congress to achieve this goal is the mandate given to, and the concomitant authority vested in, the Secretary of Labor to set mandatory safety and health standards. The Congress specifically mandated that:

> The Secretary, in promulgating standards dealing with toxic materials, or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, 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 employee, other considerations shall be the latest available scientific data in the field, the feasibility of standards, and experience gained under this and other health and safety laws. (Section 6(b)(5).)

Where appropriate, the standards are required to include provisions for labels or other appropriate forms of warning to apprise employees of hazards, suitable protective equipment, exposure control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, appropriate medical examinations, and training and education. Moreoever, where a standard prescribes medical examinations or other tests, they must be available at no cost to the employees (section 6(b)(7)). Standards may also prescribe

recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illness (section 8(c)).

Authority for issuance of this proposed standard is found primarily in sections 6(b), 8(c), and 8(g)(2) of the Act. Section 8(c) of the Act. Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. Section 8(c) of the Act empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. In particular, section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." Section 8(g)(2) of the Act empowers the Secretary "to prescribe such rules and regulations as he may deem necessary to carry out (his) responsibilities under the Act."

Section 3(8) of the Act, 29 U.S.C. 652(8), defines an occupational safety and health standard as follows:

> (A) Standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide a safe or healthful employment and places of employment.

The Supreme Court has said that section 3(8) must be applied to the issuance a permanent standard to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment (*Industrial Union Department* v. *American Petroleum Institute*, 448 U.S. 607 (1980)). This "significant risk" determination constitutes a finding that, in the absence of the changes in practices mandated by the standard, the workplaces in question would be "unsafe" in the sense that workers would be threatened with a significant risk of harm (Id. at 642).

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the proposed standard, it must set the standard "which most adequately assures, to the extent feasible on the basis of the best available evidence, that no employees will suffer material impairment of health" (section 6(b)(5) of the Act). The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material impairment of health, subject to the constraints of technological and economic feasibility (*American Textile Manufacturers Institute, Inc.* v. *Donovan*, 452 U.S. 490 (1981)).

In addition, section 4(b)(2) of the Act provides that OSHA's general industry standards would apply to construction and other workplaces where the Assistant Secretary has determined those standards are more effective than the standards which would otherwise apply.

Advisory Committee on Construction Safety and Health

OSHA provided the Advisory Committee on Construction Safety and Health with a copy of the draft regulatory text for formaldehyde to receive the review and comments of its members. On September 26, 1985, OSHA officials met with the Committee to discuss the standard and receive their recommendations with regard to the construction industry. The Committee was in agreement that there should be a separate standard for formaldehyde specifically addressing the needs of the construction industry. However, they also agreed that the standard for general industry should be applied to the construction industry as an interim measure.

State Plans

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of the final standard. These States are: Alaska, Arizona, California, Connecticut [1], Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York [1], North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

III. Events Leading to the Proposed Standard

Background

OSHA's present occupational health standard for formaldehyde (29 CFR 1910.1000, Table Z-2), requires employers to ensure that employee exposure does not exceed three parts of formaldehyde per million parts of air (ppm), determined as an eight-hour time-weighted average (TWA) concentration. Furthermore, an employee's exposure to formaldehyde must not exceed 5 ppm at any time during an eight-hour shift, except for a maximum duration of 30 minutes, when the "acceptable maximum peak" concentration may not exceed 10 ppm. OSHA adopted this standard in 1971 as a national consensus standard under section 6(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655). The Act allowed the Secretary, within two years of the effective date of the Act, to promulgate these national consensus standards without regard to rulemaking. The source of this standard was the American National Standards Institute. (ANSI Z37.16–1967, Acceptable Concentrations of Formaldehyde [Ex. 42–9]. The development of the ANSI standard reflected concern over formaldehyde's irritant effects on the eyes, skin, and respiratory system; offensive odor; and interference with sleep.

In 1946, the American Conference of Governmental Industrial Hygienists (ACGIH) set a 10 ppm threshold limit value (TLV) which was lowered in 1948 to 5 ppm. In 1963, the ACGIH responded to reports documenting formaldehyde's irritant effects by setting a 5 ppm ceiling limit. In 1973, further reports of irritation experienced at levels well below 5 ppm led the ACGIH to lower the recommended exposure limit to 2 ppm.

In December 1976, the National Institute for Occupational Safety and Health (NIOSH) recommended that OSHA reduce the permissible exposure limit (PEL) for formaldehyde to 1 ppm, measured over a 30-minute period [Ex. 42–85]. NIOSH based this recommendation on reports that a few workers experienced eye, skin, and respiratory irritation; objectionable odors; and disturbed sleep when exposed at 0.3 ppm and that complaints became widespread when concentrations exceeded 1 ppm. NIOSH recommended that for exposures which exceed 0.5 ppm there should be increased exposure monitoring, medical surveillance, and associated recordkeeping.

On October 8, 1979, the Chemical Industry Institute of Toxicology (CIIT) sent preliminary findings of an animal bioassay to the Environmental Protection Agency (EPA) under procedures established by section 8(e) of the Toxic Substances Control Act (TSCA). This notification of substantial risk (No. 79–314) indicated that squamous cell carcinomas of the nasal cavities had been observed at interim sacrifice in some rats exposed to formaldehyde at 14.3 ppm. When the study was completed in 1981, final

[1] Plan covers only State and local government employees.

results showed nasal cancers in rats exposed at 5.6 and 14.3 ppm and in mice exposed at 14.3 ppm [Ex. 12].

In a different study, researchers at New York University (NYU) also determined that rats had developed nasal cancer after exposure to 14 ppm of formaldehyde [Ex. 42–86]. Further reports on this study in 1981 and 1982 corroborated CIIT's finding that formaldehyde is an animal carcinogen [Exs. 42–2; 42–3].

In April 1980, the Federal Panel on Formaldehyde was formed and members were scientists from eight federal agencies, including OSHA. The panel reviewed and evaluated the available information on formaldehyde's chronic health effects, with emphasis on the preliminary results of the CIIT study. In November 1980, the panel concluded that it was "prudent to regard formaldehyde as posing a carcinogenic risk to humans" [Ex. 13].

The 1981 publication, Current Intelligence Bulletin 34, "Formaldehyde * * * Evidence of Carcinogenicity", recommended that formaldehyde should be handled as a potential occupational carcinogen [Ex. 42–86]. This document by NIOSH reflected that agency's concern about the potential for adverse effects from chronic exposure to formaldehyde because of the findings in the CIIT and NYU studies, and the conclusions drawn by the Federal Panel.

The Consumer Product Safety Commission (CPSC) relied on the CIIT study and consumer complaint data to ban the use of urea-formaldehyde foam insulation (UFFI) in residences and schools, in April 1982. The ban was based on CPSC's finding that UFFI posed an unreasonable risk of injury from cancer and irritation (47 FR 14366). It was overturned in subsequent litigation (*Gulf South Insulation* v. *CPSC*, 701 F. 2d 1137 (5th Cir 1983)) when the Court held that the CPSC had failed to support its ban with substantial evidence. In particular, the Court found that the Commission had erred in relying on a single study (CIIT) to establish the risk of carcinogenicity for consumers, especially when the figures differed substantially from those in the available NYU study, suggesting that they might be irreproducible. In addition, the Court found that consumer complaint data, which were not correlated to data measuring exposure to formaldehyde, were not an appropriate basis for determining that the "risk of injury from acute irritant effects is unreasonable" (701F. 2nd at 1148).

In 1983, the ACGIH included formaldehyde on its list of industrial substances suspected to be potential human carcinogens and lowered the TLV for formaldehyde to 1 ppm, measured as an 8-hour TWA. The ACGIH also sets a short-term exposure limit (STEL) of 2 ppm for formaldehyde [Ex. 42–8].

In its Third Annual Report on Carcinogens, published in September 1983, the U.S. Department of Health and Human Services listed formaldehyde among the substances or groups of substances that could reasonably be anticipated to act as carcinogens [Ex. 52].

From October 3 through 6, 1983, the National Center for Toxicological Research (NCTR) sponsored a Consensus Workshop on Formaldehyde [Ex. 70–56]. The objective was to move towards resolution of important controversies surrounding formaldehyde's acute and chronic health effects. Over 60 government, industry, and university scientists served on panels which reviewed the major relevant scientific studies. Consensus reports on individual issues were produced and sent to a risk assessment panel, which attempted to apply the supplied information to the development of reasonable risk estimates for humans exposed to formaldehyde. This risk estimation panel concluded that quantitative assessment of formaldehyde's toxic effects was indicated only with respect to carcinogenicity. The panel further concluded that any such quantitative risk modeling should be based on the CIIT study, not on the human epidemiology studies.

On May 23, 1984, the EPA announced that formaldehyde exposures which result from employment in apparel manufacturing facilities and from residence in conventional or manufactured housing potentially present significant risks of widespread harm, and they designated formaldehyde for priority review under section 4(f) of the Toxic Substance Control Act (TSCA). Action under section 4(f) is based on a substance's ability to induce cancer, gene mutations, or birth defects. EPA did not consider formaldehyde's irritant properties in reaching its conclusions [Ex. 42–41].

On February 11, 1985, the Department of Housing and Urban Development (HUD) completed rulemaking covering formaldehyde emissions from pressed wood products used to produce manufactured homes [49 FR 31996; 24 CFR Part 3280]. HUD regulations require that plywood and particleboard cannot emit formaldehyde in excess of 0.2 ppm and 0.3 ppm, respectively.

Petition for an Emergency Temporary Standard

The United States Automobile, Aerospace, and Agricultural Implement Workers of America (UAW), joined by 13 other unions, petitioned OSHA on October 26, 1981, to issue an Emergency Temporary Standard (ETS) which would impose a number of protective requirements for the handling of formaldehyde. On January 29, 1982, OSHA denied the request because it concluded that there was insufficient evidence to find either that employees were in grave danger from formaldehyde exposure or that an ETS was needed to protect workers. The petitioners appealed OSHA's decision to the District Court for the District of Columbia.

On July 2, 1984, the District Court remanded the UAW's formaldehyde petition to the Agency for reconsideration, directing OSHA to treat the petition as a request for an ETS or for the initiation of permanent rulemaking (*UAW* v. *Donovan*, 590 F. Supp. 747 (D.D.C. 1984)). The Court observed that the issues surrounding the regulation of formaldehyde were much more sharply defined and fully documented than they had been when OSHA denied the ETS petition, citing the accomplishments of the Consensus Workshop on Formaldehyde. Therefore, the Court concluded that it would be more productive for OSHA to reconsider the ETS in light of the new data than to reconsider whether its initial denial was appropriate.

OSHA's Office of Risk Assessment prepared a report, entitled "Preliminary Assessment of the Health Effects of Formaldehyde" (the ORA Report) [Ex. 43], which critically reviewed the health issues raised in the Court's reconsideration order. The ORA report, issued on November 5, 1984, also evaluated the quantitative risk assessment models which had been generated to calculate human cancer risk on the basis of the CIIT data. The report and the peer review comments regarding it [Exs. 44–1 to 24] provided OSHA with a basis for determining the significance of the human health risks posed by exposure to formaldehyde.

On January 7, 1985, OSHA again denied the UAW petition, insofar as it requested an ETS, based on the determination that the record still did not support findings that formaldehyde posed a grave danger or that the issuance of an ETS was necessary to protect formaldehyde-exposed workers. OSHA affirmed that it was continuing to

consider the need for permanent rulemaking.

On January 11, 1985, OSHA announced that public meetings would be held in Washington, DC on February 13–15, 1985 [50 FR 1547], to generate information and discussion which would help OSHA to decide whether or not permanent rulemaking should be initiated under section 6(b) of the Act. New information was introduced at the meetings and in post-hearing comments regarding formaldehyde's health effects and the quantitative risk assessment formaldehyde. [Exs. 68–1 to 23; 69–1A to 34; and 70–1 to 58.]

On April 15, 1985, OSHA decided that it would proceed with permanent rulemaking to reduce formaldehyde exposure and published an Advance Notice of Proposed Rulemaking (ANPR) to that effect [50 FR 15179, April 17, 1985]. OSHA based this decision on the determination that the existing standard did not adequately address the adverse health effects associated with occupational exposure to formaldehyde. OSHA solicited information and comments regarding conditions in those industries which produce or use formaldehyde and regarding the availability of formaldehyde control technology. Forty-one comments, many for them containing new information, were received in response to the ANPR [Exs. 77–1 to 41].

IV. Properties, Manufacture, and Uses of Formaldehyde

Formaldehyde, also known as formic aldehyde, methyl aldehyde, and methylene oxide, is a major industrial chemical, ranked 25th in production volume in the United States [Ex. 73–88]. It is used in the production of other industrial chemicals and resins, in the treatment of textiles, in the manufacture of building materials, and in consumer products. Worker exposures may occur in any of these manufacturing processes.

Chemical Properties

Formaldehyde has been assigned a Chemical Abstracts Services (CAS) number of 50–00–0. It is a colorless, pungent gas at room temperature, has a molecular weight of 30, and is the simplest member of the aldehyde class. The term "formaldehyde" is sometimes used to describe liquids composed of various mixtures of formaldehyde, water, and alcohol. However, these mixtures can be referred to as "formalin." The term "formaldehyde" is also used to describe the emissions from products such as UFFI, pressed wood, and permanent press textiles. Selected chemical and physical properties and synonyms for formaldehyde are listed in Appendix A.

In the vapor phase, formaldehyde is a monomer, but its chemistry in aqueous solutions is more complex. Uninhibited solutions not containing any alcohol stabilizer are usually prepared for immediate use and must be stored at elevated temperatures to prevent polymerization. Formaldehyde gas also polymerizes readily, especially in the presence of impurities, and formaldehyde is not sold in this form. The most widely available forms of formaldehyde consist of stabilized aqueous solutions called formalin, alcoholic solutions called Formcels, and solid polymers, eg, paraformaldehyde, capable of releasing formaldehyde gas.

The stability of formaldehyde gas depends on temperature, concentration, and purity. Even traces of water, metals, or other impurities may significantly accelerate reactions leading to formaldehyde's polymerization [Ex. 73–167]. The anhydrous monomeric gas is stable in the vapor phase at temperatures ranging from 80 °C to 100 °C, but it polymerizes upon cooling. At room temperatures, this polymerization occurs slowly and produces a white film of polyoxymethylene on the walls of containers. Cooling formaldehyde gas to temperatures between −20 °C to −80 °C causes condensation and rapid polymerization.

In freshly prepared aqueous solutions, formaldehyde exists in its monohydrate form, methylene glycol. Depending on the age and concentration of the solution, paraformaldehyde and a series of low molecular weight polyoxymethylene glycols having the typical formula, $HO(CH_2O)xH$, may be present. Lower concentrations of formaldehyde favor formation of methylene glycol while higher concentrations and aging of solutions favor formulation of polymers.

Formalin contains 37 to 50 percent formaldehyde and 6 to 15 percent alcohol stabilizer. Alcoholic solutions of formaldehyde, called Formcels, are prepared with methanol, n-propanol, n-butanol, and isobutanol. The relative percentages of alcohol and water in formalin and Formcels affect physical properties such as boiling point and flash point. The flash point (closed cup) changes from 85 °C for a 37 percent formalin solution stabilized with 1 percent methanol to 63.9 °C for a solution with 10 percent stabilizer and to 44.4 °C for a 55 percent formaldehyde-35 percent methanol Formcel solution [Ex. 73–53].

Paraformaldehyde is a solid mixture of polyoxymethylene glycols, which can serve as a source for generation of formaldehyde gas. Amorphous polyoxymethylenes containing 100 residues or more are referred to as alpha-polyoxymethylenes (PO alpha). PO alpha may be formed by addition of sulfuric acid to formaldehyde monomer or lower-residue polyoxymethylenes. Polyoxymethylene alpha subjected to destructive distillation or dissolved in alcohol or water decomposes to yield formaldehyde gas. Other polyoxymethylene derivatives are more resistant to degradation and are not generally regarded as sources of formaldehyde monomer.

Formaldehyde has a high degree of chemical reactivity and good thermal stability. It is capable of undergoing a wide variety of reactions, many of which are useful commercial processes. These reactions can be divided into 3 types: oxidation-reduction, addition or condensation, and self-polymerization.

In oxidation-reduction reactions, formaldehyde is a strong reducing agent. Commercial application of this reaction is used in the production of silvered mirrors.

Addition or condensation reactions are widely applied in industry. Important reactions in this class are aldol condensations, condensations with ammonia, and methylol formation. In aldol condensation, three molecules of formaldehyde react with one molecule of acetaldehyde to form pentaerythritol. The condensation reaction of formaldehyde with ammonia yields hexamethylenetetramine. Methylol formation yields reactive derivatives which are the starting materials used in the manufacture of urea and melamine resins.

The third class of reactions with commercial application is self-polymerization of formaldehyde. As described earlier, formaldehyde tends to form polymers, such as paraformaldehyde, which are used in industry as a source of solid formaldehyde.

Commercial Production

Production estimates for formaldehyde, measured in terms of the commercially available 37 percent aqueous solution, for this year are about 5.5 billion pounds [Ex. 73–174]. In 1983, about 5.4 billion pounds of formaldehyde were manufactured [Ex. 42–127]. Formaldehyde also occurs in the environment because it is formed from incomplete combustion and photochemical oxidation of hydrocarbons, and it is present in cigarette smoke.

About two-thirds of the annual production of formaldehyde is used at the site where it is manufactured or in mills situated nearby. For example, many plants that produce formaldehyde use this formaldehyde captively to manufacture adhesive resins for particleboard and plywood. Such plants are located primarily in the lumber areas of the South and West [Exs. 73–53; 73–174]. The remaining one-third of the formaldehyde produced is available for the domestic and export market [Ex. 73–53], but very little formaldehyde is exported because of the prohibitive costs of the long distance shipping of materials with a high water content.

Formaldehyde is produced commercially by the controlled oxidation of low molecular weight aliphatic petroleum hydrocarbons [Ex. 73–167] and by the oxidation of methanol in the "fuel rich" or "fuel lean" mode in the presence of either silver oxide or various mixed metal oxide catalysts [Exs. 70–1; 73–168 to 170]. Formaldehyde plants are relatively easy to operate and to start up or shut down; therefore, there is little need to stockpile formaldehyde and inventories are usually low.

Formaldehyde solutions can be purchased in methanol free, methanol stabilized (NF), and reagent grades. These solutions consist of 0 to 15 percent alcohol (methanol, propanol, n-butanol, or isobutanol) [Exs. 73–167; 73–171; 73–172] in water containing 30 to 50 percent by weight of dissolved formaldehyde which is introduced into the solution as a gas. In addition to alcohols, commercial preparations may contain formic acid [Ex. 73–171]. Formaldehyde solutions are supplied in glass carboys of 5 to 13-gallon capacity, lined steel drums of 5 to 50-gallon capacity, 55-gallon stainless steel drums, lined wooden barrels, stainless steel or lined tank trucks of 2,000 to 3,000-gallon capacity, and 8,000 to 10,000-gallon tank cars.

Uses of Formaldehyde

Formaldehyde is used primarily as an intermediate in the manufacture of a variety of derivatives including thermosetting resins, polyacetal resins, melamine resins, pentaerythritol, hexamethylenetetramine, butanediol, and ureaform fertilizers. About 53 percent of all formaldehyde produced is consumed in the manufacture of the thermosetting resins which contain phenol-formaldehyde, urea-formaldehyde, and melamine-formaldehyde [Ex. 8]. An additional 7 percent is consumed in the production of thermoplastic acetal resins. About 35 percent is used in synthesis of high volume chemicals including pentaerythritol, hexamethylenetetramine, and butanediol. Two percent is used in textile treating. Small amounts of formaldehyde are present as preservatives or bacteriocides in consumer products such as cosmetics, shampoos, and glues. Some materials prepared from formaldehyde may contain unreacted formaldehyde residues or yield formaldehyde on decomposition.

Urea-formaldehyde resins are produced through methylol formation by controlled reactions of formaldehyde with urea. Urea-formaldehyde resins are useful products because they are resistant to heat, chemicals, and discloration from exposure to heat or light. They are used primarily as adhesives and molding compounds in the manufacture of particleboard, fiberboard, and hardwood plywood and as finishes on textiles to impart crease and wrinkle resistance. Urea-formaldehyde resins are also used in paper treating and coatings.

Phenol-formaldehyde resins are produced by reacting phenol or substituted phenols with formaldehyde to form methylol derivatives which subsequently undergo a condensation reaction to yield resins. These resins are used mainly to bond softwood plywood. They also have some applications in the hardwood plywood industry, for thermosetting molding resins, and for binders for insulation materials such as glass fibers and mineral wools.

Melamine-formaldehyde resins are produced by the reaction of formaldehyde with melamine and the decorative laminates formed from the product are used in the manufacture of furniture and wall panels. Many housewares such as plates, cups, and buttons are produced from these resins. These resins are also used extensively in surface coatings.

Acetal themoplastic resins are used in a wide variety of injection molded parts. About 95 million pounds of these resins were sold in 1980. Present estimates indicate that 7.8 percent of all formaldehyde produced is converted to polyacetal resins [Ex. 73–174]. These "engineering plastics" possess excellent mechanical and electrical properties, and they resist moisture and organic solvents [Ex. 73–173].

Butanediol is formed from the reaction of acetylene and formaldehyde in the presence of a copper catalyst, with subsequent hydrogenation of the resulting butynediol. Butanediol is used to make tetrahydrofuran which is a solvent for PVC, PVDC, and polyurethanes. Butanediol is also used in the manufacture of polybutylene tetraphthalate (PET) thermo-plastic polyester.

Pentaerytritol is used primarily in production of alkyd resins. These resins are used in protective coatings to enhance durability, water resistance, and other qualities. Other uses of pentaerythritol include the manufacture of synthetic lubricants for jet engines and the manufacture of core binders for foundries.

Hexamethylenetetramine, $(CH_2)_6 N_4$, which is formed from formaldehyde and ammonia, reacts like formaldehyde in many instances and is regarded as a special form or source of formaldehyde in industrial use [Ex. 42–85]. Most of this chemical is used to produce curing agents for phenolic thermosetting resins.

Formaldehyde is also used in the manufacture of urea-formaldehyde concentrates for fertilizer, trimethylolpropane; methylene dianiline, chelating agents, durable press textile resins, and other products such as embalming fluids.

The EPA [Exs. 14; 42–41; 70–2] has broken down the uses of formaldehyde into three major categories: Nonconsumptive use, pseudoconsumptive use, and consumptive use. In nonconsumptive use, chemical identity does not change. Examples include formaldehyde's use in disinfectants, preservatives, and embalming fluid. In pseudoconsumptive use, chemical identity changes, but not irreversibly. Formaldehyde can be regenerated and released during downstream use, which leads to the potential exposure of large numbers of workers and consumers. Three pseudoconsumptive uses are production of urea-formaldehyde resins, urea-formaldehyde concentrates, and hexamethylenetetramine. Consumptive use irreversibly changes chemical identity. In consumptive use, formaldehyde is a feedstock in the preparation of other chemicals, and exposure to formaldehyde is limited to manufacturing employees. Little, if any, formaldehyde release occurs from the product under normal conditions of use. Examples include manufacture of phenol-formaldehyde and melamine-formaldehyde resins, acetyl resins, pentaerythritol, trimethylolpropane, and butanediol.

Occupational Exposure to Formaldehyde

In April 1979, the Synthetic Organic Chemical Manufacturers Association (SOCMA) reported that there was substantial occupational exposure to

formaldehyde in a number of industries, which SOCMA divided into three distinct classes, on the basis of the nature of the exposure [Ex. 42–117]. First, there is exposure to formaldehyde that results while manufacturing and handling formaldehyde, paraformaldehyde, and other formaldehyde derivatives. Workers may come into contact with liquids, solids, and gases containing formaldehyde. Their sources of exposure are typical of chemical operations, including leaks from pumps or gaskets, sampling operations, plant upsets, transfer or handling operations, and maintenance. Workers in formaldehyde production, chemical manufacture, and resins production may be exposed to formaldehyde in this manner. Pathologists and embalmers may be considered members of this class because their exposures result from the use of liquids containing formaldehyde solutions.

Second, employee exposure can occur when gaseous formaldehyde is released from resins which are being subjected to heat or pressure processes. Examples include the heat pressing of plywood and particleboard; application of resins to textiles, paper, or insulation and then drying or curing the material; shaping and curing of materials including plastics, abrasives, or foundry molds; and direct handling of formaldehyde as an end use (e.g., film development). Some materials in this group continue to emit formaldehyde gas after direct processing while others such as plastics, do not.

Third, employees can become exposed to formaldehyde when it offgasses from formaldehyde-containing material that is being used to manufacture an end product. Employees affected include those employed in the apparel industry, manufactured housing construction, general construction, and the furniture industry.

The production of formaldehyde and industrial chemicals using formaldehyde involves high volume manufacture (i.e., 10–100 million pounds of formaldehyde per year) and tends to rely on continuous processing. Specialty chemicals produced from formaldehyde, in contrast, generally call for batch processing which requires more material handling and consequently a greater potential for employee exposure [Ex. 42–117]. In the manufacture of plastics, particleboard, and hardwood plywood, employees are potentially exposed to formaldehyde because it can offgas from resins being used. Foundry workers are exposed to formaldehyde gas in mixing, coremaking, mold pouring, and baking because formaldehyde is present in resin binders in sand used for molds. In the funeral service industry, embalmers are exposed to relatively high concentrations of formaldehyde but only for 12 to 16 hours per week.

Formaldehyde-bearing resins, which are used to impart wrinkle and crease resistance to cloth, are capable of offgassing formaldehyde with the resulting effect that employees in both textile finishing and apparel making are exposed to formaldehyde. According to Hayes, the National Cotton Council reports that 62 percent of all apparel fabrics are made of cotton or cotton blends and 80 percent of those apparel fabrics are formaldehyde finished [Tr. 743]. Since it is the sixth largest manufacturing employer in the United States [Ex. 42–117], a very substantial number of workers are potentially exposed to formaldehyde in the garment industry.

OSHA has four estimates of the total number of workers potentially exposed to formaldehyde. Based on a 1972–1974 survey of 5,000 industries, NIOSH estimated that 1.6 million workers are potentially exposed to formaldehyde [Ex. 42–86]. In 1979, a report prepared by Booz, Allen, Hamilton, Inc. Association (the SOCMA study) estimated that 1.4 million workers are exposed to formaldehyde in 57,000 plants.

Two additional estimates of overall occupational exposure have been conducted for OSHA. In 1981, Ashford of the Center for Policy Alternatives (CPA) estimated that 1.34 million workers are exposed to formaldehyde. A 1982 report by Clement Associates estimated that about 1.3 million persons are exposed to formaldehyde based on a review of NIOSH and OSHA inspection data, a 1981 EPA study, and the SOCMA report.

Although the EPA has recently examined many exposure categories for formaldehyde and NIOSH has collected the field data for a new industry survey to update its 1972–1974 study, no additional estimates of the overall number of workers potentially exposed to formaldehyde are presently available. OSHA has collected information for the assessment of the impact of this proposed standard on industries. This indicates that 536,000 employees in about 40,000 establishments are exposed to formaldehyde at concentrations above 0.5 ppm. This is the most recent and thorough information collected on individual industries, and OSHA has determined that it is the best available data on the sectors of the industry that it covers.

Additional sources of information on the degree of employee exposure to formaldehyde exist. For example, the SOCMA study [Ex. 42–117] identified fifty industries as having a potential for "significant" occupational exposure to formaldehyde on the basis of the professional judgments of the contractor, the pertinent trade associations, and other experts. Of these 50 industries, 17 were surveyed, but response rates were poor, *ie.*, 89 (2.6%) of 3,365 companies contacted actually replied [Ex. 70–56].

In 1983, the Consensus Workshop's panel on exposure rejected the SOCMA report as a source to estimate the degree of occupational exposure to formaldehyde. The exposure panel cited the poor rate of survey response, the failure to describe methods used to collect and analyze samples, and the lack of information on circumstances that prompted collection of exposure data as reasons to reject the study [Ex. 70–56]. Since recent surveys in major segments of the industry, including the apparel manufacturers, formaldehyde producers, and wood products and textile finishing, indicate major product changes within the last six years, OSHA agrees with the Consensus Workshop that the SOCMA study should not be relied upon to establish current exposure levels.

OSHA examined its inspection reports on formaldehyde [Ex. 73–158]. While older information supports higher estimates, data from 1984 through the spring of 1985 indicate that employee exposure, on the average, is becoming low. Of the samples taken by OSHA inspectors, 5.9 percent were between 0.5 and 1 ppm and 81 percent were below 0.5 ppm. Information from OSHA inspection reports is from a small and probably nonrepresentative sampling of the formaldehyde industry, which probably accounts for the small percentage of workers found exposed over 1 ppm in the Preliminary Regulatory Impact Analysis as compared with OSHA's inspection data.

The CPA (Ashford) study conducted for OSHA in 1980 estimated exposure levels characteristic of the overall industry. To derive these estimates, CPA relied heavily on NIOSH Health Hazard Evaluations (HHEs) and OSHA inspection reports. Thus, some bias toward overestimation of exposure would be anticipated because all HHEs and many OSHA inspections are based on complaints. CPA estimated that about 850,000 exposures were below 0.25 ppm, 243,000 between 0.25 and 0.49 ppm, 117,000 between 0.5 and 0.99 ppm, 82,000 between 1.0 and 1.9 ppm, and

52,000 at or above 2 ppm. These are midrange estimates, and low and high estimates suggest substantial uncertainty in the figures. Because they are the most consistent figures available for overall exposure when compared with limited, but more recent, data [Ex. 73–158] and reports of individual industries, OSHA has used these figures for overall estimates.

OSHA is interested in obtaining information in the course of rulemaking from industries that believe they will be affected by the standard because they have exposures over the proposed action levels. This is especially important if OSHA has not identified a sector as one that will be impacted. It is equally important that OSHA receive any information that indicates the potential impacts may be less than or different from OSHA's estimates. The public is asked to submit information on the number of employees exposed to formaldehyde at concentrations above the proposed PELs, the number between the proposed actions levels and the proposed PELs, the total number exposed, and the number exposed above the present OSHA PELs of 3 ppm as a TWA concentration and 10 ppm as a peak exposure limit. Any significant problems that would be created by the proposed requirements should also be identified.

At the present time, OSHA has not thoroughly identified sectors of industry and processes where short-term exposure is most likely to occur. Since health data indicates that exposure from a short-term, high concentration of formaldehyde presents a greater risk to workers than a corresponding exposure occurring over the course of the entire workshift, there may be a need to impose a short-term exposure limit as well as a TWA concentration limit. The cost of compliance with a combined standard should not be significantly more than that of achieving a 1 ppm TWA concentration if the STEL were 2 ppm for 15 minutes as recommended by the ACGIH. This is predicated on the assumption that installation of controls necessary to achieve the TWA would automatically result in the substantial control of emissions so that the STEL would be achieved as well. Public comment on any sector of industry or industrial process where this would not be the case, resulting in higher costs or possible infeasibility, is requested.

The ORA Report [Ex. 43] stated that workers employed in the apparel industry, funeral service, foundries, resin manufacture, pathology, and wood furniture manufacture are potentially at high risk from exposure to formaldehyde, either because of high exposure concentrations or widespread exposure potential. More recent material indicating the occupational categories with the highest known exposures to formaldehyde was collected to complete a Preliminary Regulatory Impact Analysis for this proposal. These results are presented as the best available data on current conditions in a later section on the economic impacts of the proposal.

V. Health Effects

Exposure to formaldehyde in humans has been associated with sensory irritation, contact dermatitis, sensitization, and acute changes in pulmonary functions. Inhalation of formaldehyde, a typical mucous membrane irritant, can result in an itchy, runny, or stuffy nose; a dry or sore throat; eye irritation; and headache. Formaldehyde solutions can also damage the skin and burn the eyes if direct contact occurs through splashes or spills.

Formaldehyde has been shown to induce nasal cancer in rats. The finding of carcinogenicity has been confirmed in separate studies. In addition, *in vitro* studies have shown formaldehyde to possess mutagenic activity. This supports OSHA's preliminary finding that formaldehyde is a potential occupational carcinogen.

Epidemiological studies of professional groups exposed to formaldehyde along with other substances have consistently demonstrated excesses of brain cancer and leukemia. It is not possible, however, to determine the contribution of formaldehyde to the induction of these cancers without a complete industrial hygiene assessment of their exposure. Studies of industrial cohorts exposed to formaldehyde have also demonstrated excesses of some site-specific cancers including the lung, buccal cavity and pharynx and of non-malignant respiratory disease. These excesses of site-specific cancers have not been consistent across all industrial groups and may reflect difference in formaldehyde exposure levels and/or methodology.

An analysis of the evidence relating to adverse health effects associated with exposure to formaldehyde is presented below.

Biochemistry and Metabolism

Formaldehyde is a normal metabolite and a vital ingredient in the synthesis of essential biochemical substances in man. It is also an extremely reactive molecule readily forming reversible adducts with nucleophiles present in the biological system and stable cross-links with primary and secondary amines. Heck and Casanova-Schmitz have concluded that "there is little doubt that the reactivity of formaldehyde as an electrophile is the fundamental cause of its toxicity" [Ex. 70–25].

"Active" formaldehyde, not the simple chemical entity CH_2O, is the form used in biosynthesis. The major sources of active formaldehyde are glycine and serine, both of which undergo enzymatically mediated oxidative demethylation in the presence of tetrahydrofolic acid to yield N^5, N^{10}-methylene tetrahydrofolate. Oxidation of this "active" form of formaldehyde results in formation of N^5, N^{10}-methenyl tetrahydrofolate and renders feasible the incorporation of "active" formaldehyde into purines. Reduction of "active" formaldehyde to 5-methyl tetrahydrofolate permits the carbon atom to be incorporated into methionine which can be transmethylated to phosphatidyl choline, methylated RNA, methylated polysaccharides, creatine, and carnitine. From serine, the "active" formaldehyde can be incorported into pyruvate which can be transaminated to alanine, carboxylated to oxaloacetate, or decarboxylated to acetyl coenzyme A. Further reaction can occur leading to entrance of residues of formaldehyde into pyrimidine synthesis and the citric acid cycle. The introduction of labeled formaldehyde molecules into the one carbon pool can result in their incorporation into all major classes of macromolecules [Ex. 70–25].

The thiol group is an extremely effective nucleophile in reacting with the carbonyl group. Thus, glutathione (GSH) and other sulfhydryl compounds should function as effective scavengers in controlling the amount of intracellular formaldehyde present. Although the reaction is reversible, the hemithioacetyl adduct formed is relatively stable and the concentrations of GSH are so high that a substantial fraction of the total formaldehyde exists as a GSH adduct. The GSH adduct is the substrate used in the physiologically important reaction with the enzyme, formaldehyde dehydrogenase (FDH), which oxidizes the hemithioacetyl to formic acid in the bound form, S-formylglutathione. The FDH-catalyzed oxidation of S-hydroxymethylglutathione is possibly the most important pathway for elimination of endogenous formaldehyde [Exs. 42–87; 70–25].

The Chemical Industry Institute of Toxicology (CIIT) has recently studied the hypothesis that metabolism competes with DNA adduct formation, a probable step in the process leading to

carcinogenesis. Glutathione-depleted rats and normal rats were exposed to formaldehyde and the amount of DNA-adduct formed was measured. When the animals were glutathione-depleted by use of phorone, about a 3-fold increase in DNA adducts was found. [Exs. 69–19A; 73–81G; Tr. 263–265].

Oxidative demethylation of N-, O-, and S-methyl compounds by cytochrome P-450-dependent monoxygenases *via* oxygen insertion in a carbon-hydrogen bond to yield formaldehyde is a well known metabolic pathway [Ex. 70–25]. According to Heck and Casanova-Schmitz [Ex. 70–25], "evidence is beginning to be accumulated that the CH_2O formed by metabolism of xenobiotics can be a cause of toxicity." Example where induction of release of formaldehyde by cytochrome P–450 monoxygenases are thought to be accomplished include: hexamethylphosphoramide (a potent nasal carcinogen), dimethylamine, and, to a lesser extent, methyl chloride, where microsomal oxidation is a minor pathway.

Methanol and formaldehyde share common metabolic pathways, which may be particularly important when a worker's exposure is to formalin stabilized with methanol. The ocular damage seen in primates from over exposure to methanol does not occur in rodents, probably because metabolic differences in species lead to marked accumulation of formic acid in the blood of primates but not in that of rodents. Differences in susceptibility of different species to the acutely toxic effects of methanol have been shown to be related to the folate status of the animals. The amount of tetrahydrofolic acid available in a cell is the primary determinant of the rate at which formic acid can be oxidized by the cell to carbon dioxide. This suggests that primates and rodents may exhibit differences regarding formaldehyde metabolism. Although the same pathways for metabolic conversion of formaldehyde to carbon dioxide are present in all mammalian species studied so far, the rates of reaction differ among various species and cell types.

The amount of radioactivity retained in the tissues of rats inhaling formaldehyde labeled with radioactive carbon has been measured [Exs. 73–12; 73–164]. The animals' nasal mucous membranes contained the most radioactivity, which was deposited primarily in the anterior regions of the nose. [The anterior region of the nose also contained the largest number of nasal cancers in rats exposed to formaldehyde for up to 2 years [Ex. 73–81G].] The nasal passages contained 1 to 2 orders of magnitude more radioactivity than the trachea, lung, liver, kidney, jejunum, spleen, heart, brain, and testes [Ex. 73.12], although the well perfused tissues, including the bone marrow, also possessed significant radioactivity [Ex. 73–164].

To determine if the radioactive formaldehyde was metabolically incorporated or covalently bound to macromolecules, Casanova-Schmitz and colleagues at CIIT exposed rats to formaldehyde 6 hr/day for 2 days at 0.3, 2, 6, 10, or 15 ppm. The major route of nucleic acid labeling in the olfactory mucosa, respiratory mucosa, and bone marrow was metabolic incorporation. Covalent binding to respiratory mucosal DNA was also found. The dose-response curve was sigmoidal with a steep increase between 2 and 6 ppm. Metabolic incorporation into respiratory mucosa, in contrast followed a bell-shaped curve similar to that for cell turnover. Covalent adducts with macromolecules were not found in the olfactory mucosa or the bone marrow.

The half life of formaldehyde in the blood of rats, guinea pigs, rabbits, dogs, and cats following intraperitoneal (ip) administration was estimated as about 1 minute [Exs. 42–27; 42–60; 70–25]. In rats exposed at 14.4 ppm for 2 hours, there was no increase in the amount of free or reversibly bound formaldehyde in the blood [Ex. 73–21].

In contrast, when radioactivity was measured in the blood of rats administered labeled formaldehyde by intravenous (iv) injection or inhalation, an extremely slow decrease in radioactivity occurred suggesting retention of substantial quantities of radioactivity for several weeks after administration.

When rats were exposed to ^{14}C-formaldehyde by inhalation or by gavage, approximately 40 percent of the radioactivity was recovered in the expired air [Exs. 42–60; 70–25]. Seventy hours after inhalation, 22 percent of the radioactivity was found in the urine and feces, and between 35 and 38 percent was retained throughout the tissue and carcass. This does not imply that material found at sites remote from the initial point of tissue contact represents DNA adducts, other formaldehyde adducts, or free formaldehyde. The substantial deposition of radiocarbon at sites distant from the primary site of impaction was most probably due to metabolic products.

Heck and collegues [Ex. 73–21] measured the amount of free and reversibly bound formaldehyde in the blood of six human volunteers exposed at 4 ppm for 40 minutes. Results in humans, unlike those in rats, showed great variability, possibly because humans are more heterogeneous. Heck found that on the average, formaldehyde concentrations were the same before and after exposure.

Gottschling and coworkers [Ex. 42–53] examined the concentration of formic acid in urine of veterinary students as a potential biologic indicator of formaldehyde exposure. They found extreme variability in both repeat tests of individuals and the entire group examined. Thus, it appears that formic acid excretion in the urine was not a good indicator of formaldehyde exposure for 2 hours to concentrations of 0.4 ppm or lower.

While it is always possible that some biological indicator of formaldehyde exposure may be discovered, there is presently no evidence to support biological monitoring. For biological monitoring to serve as a surrogate for the concentration of airborne formaldehyde, formaldehyde or a closely related derivative should be measured, and development of such a monitoring method in the future is highly unlikely.

The role of metabolism could be critical to defining whether formaldehyde is a human carcinogen and the expected site(s) of cancer in humans. While formaldehyde appears to be a locally acting carcinogen in rodents, there are no comparative studies of metabolic products or reaction rates to determine the extent to which humans and rodents react differently to formaldehyde. The elevated incidence of some site-specific cancers observed in cohorts of workers exposed to formaldehyde compels OSHA to consider the possibility that species differences in site-specific cancer risks may exist. OSHA has determined, under the terms of the Cancer Policy, that formaldehyde is a potential occupational carcinogen.

Sensory Irritation, Sensitization, and Dermal Effects

Evidence of irritation of the eyes and upper respiratory system when humans are exposed to formaldehyde gas is extensive. Studies in human volunteers, experimental animals, and worker populations address this topic. Although occupational health professionals have infrequently reported cases of ashtma in workers known to have been exposed to formaldehyde, the actual ability of formaldehyde to produce this effect is not certain. Dermatitis resulting from contact with liquid formaldehyde is also well known, having been reported in

several cross-sectional studies of workers and in case studies described in the literature by allergy specialists. In general, studies on the noncarcinogenic effects of formaldehyde do not address the important issues of morbidity rates, lost workdays, and decreased productivity from the various diseases that may be related to or exacerbated by exposure to formaldehyde.

Clinical studies of sensory irritation: In a recent study of formaldehyde-induced eye irritation, Beneral *et al.* [Ex. 42–15] exposed groups of 5 to 28 persons to formaldehyde gas for 6 minutes at 0.35, 0.56, 0.7, 0.9, or 1.0 ppm with clean air as a control. Irritant effects were measured in terms of severity, on a scale of 0 to 3, and response time, defined as the length of time from initial exposure until the subject noticed eye irritation. At the lowest concentration tested, 42 percent of the subjects experienced very slight eye irritation. A statistically significant response occurred at 1 ppm. The authors claimed to have shown dose-response relationships between concentration of formaldehyde, response time, and severity of effect.

Anderson and Molhave [Ex. 42–10] exposed 16 healthy students to formaldehyde. They were studied in groups of four, with each group undergoing four different exposures on four consecutive days. Exposures were to 0.3, 0.5, 1.0, and 2.0 mg/m³ (0.24, 0.4, 0.8, and 1.6 ppm) of formaldehyde in air. Nasal mucociliary flow was measured by the rate of movement of resin particles labeled with technicium. Irritation was graded by the subject's adjustment of a pointer scaled from 1 for complete comfort to 100 for severe discomfort. Mucous flow rate slowed down at higher concentrations of formaldehyde, but no further deceleration was observed with concentrations above 0.5 mg/m³. At the highest concentration tested, there was also a significant rise in the odor threshold for ethyl valerate, a chemical used to test impairment of the ability to smell. At all concentrations of formaldehyde, a time lag occurred before the subjects reported discomfort. At 0.3 and 0.5 mg/m³, no one reported discomfort for the first 2 hours. At higher doses, subjects reported discomfort within the first hour, which increased through the second hour, and diminished after 2.5 hours. Overall 13, 14, 9, and 6 of the 16 subjects reported no discomfort at 0.3, 0.5, 1.0, and 2.0 mg/m³, respectively. The highest individual scores on the irritation pointer were 30, 20, 40, and 50 units, respectively. At the highest concentration, the average discomfort never exceeded 18, which is in the middle of the range describing slight discomfort. At the conclusion of the exposures to 0.3, 0.5, 1.0, and 2.0 mg/m³, 3, 5, 15, and 15 subjects, respectively, complained of conjunctival irritation and dryness of the nose and throat which disappeared by the following morning. The authors concluded that:

> The experience from our 5-hour exposure study at 2 mg/m³ . . . as well as the experiences from other studies at controlled conditions . . . make us believe that the TLV value for this substance should be lower than 3.6 mg/m³.

Weber-Tschopp, Fischer, and Grandjean [Ex. 73–44] investigated the acute irritant effects of formaldehyde in 33 healthy subjects exposed for 37 minutes to concentrations that increased progressively to a maximum of 3.2 ppm. Another 48 subjects received exposure to formaldehyde for 1.5 minutes at normal concentrations of 0, 1, 2, 3, and 4 ppm. Between the serial exposures, there were 8-minute recovery periods. Irritation was measured by obvious annoyance, by the rate of eye blinking, and by a questionnare on irritation of the eyes, nose and throat.

The authors [Ex. 73–44] found that at the same formaldehyde concentration, the degree of annoyance was greater in the discontinuously exposed group. Eye irritation was significantly greater during the continuous exposure, but irritation of the nose and throat was greater during the discontinuous exposure. On the average, significant changes were reported by the authors at the following concentrations: eye irritation—1.2 ppm, nose irritation—1.2 ppm, throat irritation—2.1 ppm, annoyance (desire to leave the room)—1.2 ppm, and increased rate of eye blinking—1.7 ppm. At 0.5 ppm, 2 percent had moderate eye irritation, 11 percent had a doubled eye blinking rate, and 3 percent had a desire to leave the room. At 2.1 ppm, 10 percent had moderate eye irritation, 7 percent had strong to very strong eye irritation, 33 percent had a doubled blinking rate, and 20 percent had a desire to leave the room. The authors concluded from this study that "the irritation threshold for pure HCHO lies in the range from 1 to 2 ppm."

Rader [Ex. 73–88W] exposed two groups of five medical students and employees to formaldehyde for an hour at concentrations of 0, 0.1, 0.2, and 0.5 ppm or 1, 3, and 5 ppm. At least one day elapsed between exposures. Another experiment consisted of exposing ten persons to formaldehyde at 0.5 ppm, with five of them in an atmosphere of normal humidity. The other five were exposed at a relative humidity of 88 percent. Subjects ranked six factors: the perception of odor, conjunctival sensations, feelings in the nose and throat, lacrimation, and nasal secretion. All complaints were directly related to the concentration of formaldehyde. Complaints, on the average, differed significantly over background rates for exposure to air at all concentrations above 0.1 ppm; a marked increase occurred at 3 and 5 ppm. For the 30 minute, 0.5 ppm exposure, total complaints were significantly more frequent in air with relative humidity of 40 percent than in air with relative humidity of 88 percent.

Day and coworkers [Ex. 69–23C2] exposed 18 subjects, nine of whom had previously complained of various nonrespiratory effects from UFFI to 1 ppm of formaldehyde for 90 minutes. On a separate occasion, they exposed the same subjects to off-gas from UFFI which contained 1.2 ppm of formaldehyde for 30 minutes. Neither group showed a clinically or statistically significant response in pulmonary function, leading the authors to conclude that they had found no evidence that either formaldehyde or UFFI off-gas operated as a lower airways allergen or important bronchospastic irritant. However, 15 subjects exposed to formaldehyde at 1 ppm reported eye irritation, seven reported nasal congestion, six had tearing of the eyes, five had throat irritation, three had nasal discharge, two had cough, and one had chest tightness. Although this study did not demonstrate evidence that formaldehyde is an allergen, it describes transient irritation at levels being proposed for regulation of formaldehyde.

Schacter [Exs. 70–26; 70–48] exposed 15 healthy subjects to airborne formaldehyde. The subjects had no history of asthma and a normal response to inhalation of methacholine, a standard test for asthmatic response. Exposures were at 2 ppm with the subject either at rest of exercising. Pulmonary function tests were performed on each subject 5, 15, 25, and 40 minutes after exposure began and 10 and 30 minutes after leaving the exposure chamber. Questionnaires about symptoms were filled out upon each person's entering the exposure chamber, 30 minutes later, and at 4, 8, and 24 hours after the exposure. There was no evidence of bronchoconstriction. Symptoms, such as sore throat, nasal discharge or stuffiness, and eye irritation were reported. Subjects usually described symptoms as mild or moderate, but they reported severe symptoms in a few cases.

Frigas and coworkers [Ex. 73-16] at the Mayo Clinic studied patients with asthma and a history of exposure to formaldehyde gas. Eleven were women and two were men. Their age ranged from 15 to 70 years. Their exposures to formaldehyde, which ranged from 0.1 to 1.2 ppm, were measured in seven cases. Five of the patients were occupationally exposed to formaldehyde. The others were exposed in their residences. All reported symptoms that they attributed to formaldehyde exposure. These symptoms included sensations of chest tightness, coughing or wheezing, nasal congestion, irritation of the eyes, and headache. All but two patients had been healthy before their exposure to formaldehyde, and most noted that their symptoms abated when they were away from the site of exposure to formaldehyde. Five patients were being treated with bronchodilators and a few were using antihistamines at the time of the Frigas study. Use of medications was discontinued during the testing.

Each patient underwent a general physical examination, a chest x-ray, pulmonary function tests, and "standard laboratory tests." Five examined by skin testing showed negative results in a battery of tests of 40 common allergens. All chest x-rays were normal, but one patient had nasal polyps and hyperplastic pansinusitis and another had nasal polyps. Three patients had substantial pulmonary obstruction.

Each patient, while asymptomatic, underwent bronchial challenge for 20 minutes with room air and at least one of three concentrations of formaldehyde: 0.1, 1, and 3 ppm. Spirometry was performed before the challenge; at 0, 15, and 30 minutes; and at 1, 3, 6, and 24 hours. A bronchial challenge was considered positive if it induced a 20 percent or greater decrease in baseline forced expiratory volume in one second (FEV_1) in a dose-related fashion and the placebo did not produce the same effect. By these criteria, not test results were positive, leading the authors to conclude that they were unable to demonstrate that inhaled formaldehyde caused or aggravated asthmatic symptoms.

In a separate editorial, Hyatt [Ex. 45-3] commented that evaluation of possible environmental respiratory irritants in not a simple matter. Concentrations that fail to evoke bronchospasm at rest can produce changes during mild exercise. He also observed that a 20-minute exposure may not adequately reproduce the exposure encountered during an 8-hour workshift.

Sheppard and colleagues [Ex. 70-46] found no evidence that inhalation of formaldehyde in commonly encountered concentrations would cause bronchoconstriction in asthmatics. All seven of their subjects had a history of recurring episodes of wheezing, chest tightness, reversible airways obstruction, and associated allergic rhinitis. All seven were hyperresponsive to histamine and the six tested also responded to sulfuric acid.

Formaldehyde was administered for 10 minutes by mouthpiece under the following conditions: 1 ppm, subject at rest; 1 ppm, subject exercising at a work rate of 100 watts; and 3 ppm, subject exercising at a rate of 100 watts. No evidence of bronchoconstriction, as determined by calculation of specific airways resistance, was found. The authors emphasized the limited nature of their study. None of the subjects had a reported history of formaldehyde sensitivity and the tests were not relevant to the question of whether or not these was specific hypersensitivity to formaldehyde. The authors could not rule out the possibility that exposures of longer duration might cause impairment of pulmonary function. The possibility of a delayed response, which would suggest involvement of an immune function rather than a primary irritation, was not studied, although the authors noted that none of the subjects exhibited noticeable delayed symptoms.

In summary, clinical studies of individuals exposed to formaldehyde indicate that this chemical can irritate the mucous membranes of the eyes and upper respiratory tract within minutes of initial exposure. Volunteers are a self-selected population, and they may differ substantially in age, smoking history, or education from the typical chemical worker. Furthermore, studies involving exposures of limited duration cannot rule out the possibility that problems may become manifest only after repeated exposures occurring over many years. Nevertheless, these studies are useful in identifying formaldehyde-associated changes since they have accurately described the conditions of exposure to that single substance. They are also not prone to recall bias since volunteers generally have had no history of prior exposure to the substance being tested.

Sensory Irritation-Animal Studies: Alarie, Kane, and Barrow [Ex. 70-29] developed an animal model, based on sensory irritation in mice, to establish acceptable exposure limits for chemical irritants. An airborne concentration that inhibited to respiratory rate by 50 percent (RD_{50}) in mice was expected to cause intolerable irritation of the eyes, nose, and throat in a matter of minutes in humans. At one-tenth of the RD_{50}, humans were expected to show some irritation and disconfort but it was also predicted that they would probably accept this concentration at work. At one hundredth the RD_{50}, humans were expected to show minimal irritation. The Swiss-Webster mouse, the strain tested, was of intermediate sensitivity. A factor of ten separated the least from the most sensitive mouse strain. The authors predicted that there would be a similar range of sensitivities in humans.

Alarie *et al.* [Ex. 70-29] examined eleven chemicals, and nine of these had PELs which fit the model's predictions well. Formaldehyde provided the worst fit. The model predicted that, as a maximum, the exposure limit for formaldehyde should be 0.3 ppm, but the OSHA PEL was 10 times higher. The explanation given for how persons have tolerated this PEL was that the initial response to formaldehyde is extremely rapid, gradually fading, and returning again after rest periods. Not all strains of mice show a fading of the response to formaldehyde, and the authors equated these mice with persons who leave their job because of irritation. The result is that the worker population exposed to formaldehyde becomes "self-selected." The authors cautioned against reliance upon a worker's ability to adapt for setting exposure limits because it denies a "wholesome working environment" to nonadapters and lets others feel that the situation is under control when, in fact, a potentially hazardous concentration for some workers may exist. According to the authors, this situation is especially dangerous if the formaldehyde concentration in air increases gradually. There is the potential that extremely hazardous levels can go unrecognized through sequential adaptations to slowly rising environmental concentrations formaldehyde.

Sensory irritation—surveys of workers: Horvath and coworkers at the Marshfield Clinic [Ex. 66-5] assessed the acute and chronic effects of formaldehyde on the mucous membranes and the lungs of 109 employees exposed to formaldehyde resins in particleboard and molded products operations. Formaldehyde concentrations in the workplace were measured at 0.17 to 2.93 ppm. The control subjects were 254 workers in nearby industries with no formaldehyde exposure. Tests administered were the American Thoracic Society respiratory disease questionnaire modified to include questions on mucous membrane irritation and, a second questionnaire designed to examine irritant effects or respiratory symptoms experienced during the workshift, and pre- and post-shift spirometry. There were more men

in the exposed group, and they were slightly older and taller than those in the control group. However, these differences were taken into account in the spirometry results.

The authors examined the possibility that formaldehyde workers are a "survivor population." During the previous 4 years, 54 persons at the plants had quit their jobs. Two had developed formaldehyde dermatitis, and one had experienced exacerbation of preexisting asthma. Thirty two had terminated their employment without further explanation. This information was judged inadequate to determine whether there is a "healthy worker effect."

Pulmonary function test results did not provide evidence of chronic lung effects. Dose-dependent acute changes, thought to depend upon temporary constriction of the airways, were observed in workers exposed to formaldehyde. These changes consisted of statistically significant post-shift declines in forced expiratory flow (FEF) 25–75%, FEF 50%, and FEF 75% which could not be attributed to smoking. Post-shift lung function changes did not correlate with individual airborne formaldehyde levels. A subgroup of "reactors" existed, however, and "reactors" with shifts in FEF 25–75% and the ratio of FEV_1 to forced vital capacity (FVC) were more likely to be formaldehyde workers. Among "reactors", exposure to formaldehyde in the workplace was also a predictor of the degree of post-shift changes.

The answers to the respiratory disease questionnaires suggested no association between exposure to formaldehyde and chronic cough, dyspnea, wheezing, or phlegm production. Complaints of eye, nose, and throat irritation, described as mild to moderate, could be explained as being due to exposure to formaldehyde. The workers exposed to formaldehyde differed significantly from the control group in the number of complaints of itchy and burning eyes, itchy and burning nose, stuffy nose, and sore or burning throat. When the test results were segregated into four categories depending on the degree of formaldehyde exposure (0–0.04, 0.04–0.4, 0.4–1.0, and 1.0–3 ppm), a clear dose-response relationship for acute effects was seen. Exposure category was a predictor of cough, chest discomfort, burning nose, burning eyes, and sore throat. For burning nose, positive responses were given by 2, 16, 27, and 42 percent in the control, low, medium, and high exposure groups, respectively. Corresponding figures for sore throat were 4, 8, 21, and 32 percent. These results led the authors to conclude that formaldehyde is a dose-dependent mucous membrane irritant in a substantial portion of the population working at levels well below the present OSHA PEL of 3 ppm.

Main and Herman [Ex. 73–32] compared the respiratory status of 38 men employed in the coreroom of a foundry with that of a matched group of men employed in the assembly plant. Formaldehyde concentrations ranged from 0.18 to 3.9 ppm. Based on these measurements, the coreroom workers were split into low (<1 ppm) and high (>1 ppm) exposure groups.

All groups were administered an American Thoracic Society respiratory disease questionnaire, pre- and post-shift spirometry, and a chest x-ray. The high exposure group had a statistically significant higher frequency of cough than the assembly workers. All coreroom workers has a significantly higher incidence of eye, nose, and throat irritation, which was more likely to begin after work started and to disappear at the end of the workshift. Dose-dependent decreases in FEV_1, FVC, and FEF 50% observed during the workshift among workers in the coreroom were diametrically opposed by increases in the same measurements among assembly plant workers. The authors concluded that exposure to formaldehyde at concentrations exceeding 1 ppm during a normal workshift caused short term loss of pulmonary function, increased cough, and irritation of eyes, nose, and throat.

At the Celanese facility in Bishop, Texas, Stenzel and Harris [Ex. 72–3] evaluated potential long-term adverse health effects associated with formaldehyde. The purpose of their study was to determine whether or not effects already well documented as occurring during the workday or workweek would be encountered over a period of 6 months or 3 years. To test this hypothesis, Stenzel and Harris obtained the following information: exposure data, physical examinations, spirometry tests, and medical history questionnaires that focused on nasal irritation and pulmonary function.

A total of 971 individuals qualified for the study by having been employed sometime between September 1980, and February 1984, and having completed a company-sponsored physical exam that included spirometry. Their average age was 40.3 years, they were employed an average of 12.7 years, and they had exposure to formaldehyde for an average of 46.0 days/year. Estimated exposure concentrations were 1 to 2 ppm for maintenance work, 0.1 to 0.5 ppm for maintenance and operations supervision, 0.5 to 1.5 ppm for operations workers, 0.1 to 1 ppm for support, and 0 to 0.1 ppm for administrative employees. Twenty-seven percent of the workforce smoked. For each possible effect, data were examined in three ways. First, the authors determined whether a correlation existed between the adverse effect and level of exposure. Then the mean value for each medical test for each group of employees was determined and compared with the mean for the administrative group. Finally, the mean exposure of the individuals with medical test results in the bottom 20 percent of the group was calculated and compared with that of the other 80 percent.

There was no association between duration of exposure (6 months or 3 years) and lowering of FVC, FVC%, FEV_1, FEV_1%, and the ratio of FEV_1/FVC. There were also no trends associated with increasing exposure. The only cluster of effects was for operations and maintenance supervisors, who as a group were also older. Below normal pulmonary function seemed most likely to be related to smoking habits. Nasal irritation was the same in all groups and only maintenance personnel responded differently to questions related to the pulmonary system. The authors felt that this last association was related to recent exposure, and not to long term consequences. The authors concluded that control of exposure to a 1 ppm TWA with a short term PEL of 2 ppm, the internal limits used at Celanese, was responsible for the lack of effects. These conclusions are weakened because of the failure to find effects at any level of exposure.

A 1984 report by Levine *et al.* [Ex. 42–72] examined the respiratory status of white male morticians attending a postgraduate course in West Virginia. Of 112 morticians attending the school, 105 supplied self-completed respiratory disease questionnaires and detailed occupational histories. Ninety nine of the morticians also underwent pulmonary function testing, but 9 pipe or cigar smokers were excluded from the subsequent analysis. The pulmonary function of the morticians compared favorably with that of residents of Oregon and Michigan. The investigators found no evidence of chronic bronchitis and concluded that "long-term intermittent exposure to low levels of formaldehyde gas exerts no meaningful chronic effect on respiratory health."

Levine's group subsequently conducted an independent survey of six funeral homes in the area. They found that mean TWA concentrations of

formaldehyde were 0.3 ppm (range 0.2–0.4 ppm) when intact bodies were being embalmed and 0.9 ppm (range 0.5–1.2 ppm) when autopsied bodies were being embalmed. The short-term exposures, measured for 30 minutes, were 0.4 and 2.1 ppm, respectively [Ex. 42–128].

The Federal Panel on Formaldehyde [Ex. 13] commented on strengths and weaknesses of the study by Levine and his coworkers:

> Although there is a good rationale for studying this occupational group [morticians], an inability to detect a significant response in this study could be due to low cumulative exposure (probably less than 8 hours/day). If we assume 50 persons each in a higher and low exposure group . . . there is an 85% chance of correctly rejecting the null hypothesis of no difference in FEV between exposure groups, if the true difference is 5% . . . This is, however, one of the few studies to attempt to assess long term effects of formaldehyde on lung function . . . A comparison group (e.g., funeral directors) would have provided more confidence in the results and more power in the analysis.

It should be noted that the Federal Panel's criticisms of the study by Levine *et al.* are true of many cross-sectional studies since ideal comparison groups are often not available.

In a study reported in 1977, Plunkett and Barbela [Ex. 42–101] mailed respiratory disease questionnaires to 80 embalmers in 20 funeral homes in the Los Angeles area. Of the 57 who replied, 81 percent had experienced eye irritation, 75 percent had nose or throat irritation, 37 percent skin irritation, 33 percent cough, and 13 percent chest tightness. Nine of the respondents (average age of 35 years, with an average of 11 years of exposure) had symptoms of acute bronchitis and 17 (37 years, 11 years of exposure) had chronic bronchitis. Respiratory irritation, cough, and the sensation of tightness in the chest correlated with smoking history, but about 25 percent of those with bronchitis had never smoked.

Kerfoot and Mooney [Ex. 73–88D] conducted a survey of six Detroit funeral homes and reported the results in 1975. A total of 186 air samples showed average concentrations of formaldehyde of 1.21 (0.17–5.26), 0.35 (0.09–0.89), 0.64 (0.35–1.22), 0.25 (0.13–0.45), 0.61 (0.26–1.23), and 1.39 (0.48–2.10) ppm in the six worksites. The use of ventilation fans appeared effective in reducing employee exposure. Paraformaldehyde powders used in the funeral homes had a mean particle size of 1.6 um, suggesting to the authors that these particles could penetrate into the alveolar sacs of the lung.

The embalmers completed a detailed toxicity survey form, their answers indicating that they had experienced burning eyes and irritation of the upper respiratory tract, including burning noses, sneezing, coughing, and resultant headaches. Three of the seven men had asthma or sinus problems and two had experienced dermatitis in the past. The authors concluded that formaldehyde is an irritant at levels below 2 ppm.

NIOSH, in its Health Hazard Evaluation program, has examined employee who handled formaldehyde solutions at a number of hospitals or laboratories. Histopathology technicians at 13 worksites showed a high prevalence of respiratory and neurobehavioral symptoms and dermatitis. Exposure estimates ranged from 0.2 to 1.9 ppm. Of the technicians, 79 percent reported at least one employment-related physical symptom as compared with 39 percent in a control group. Also, 58 percent of the technicians versus 39 percent of the unexposed controls reported headaches. When they were examined by NIOSH, many technicians had itchy, dry, burning, cracked and bleeding, tight, peeling and scaling, and reddened skin with nail changes [Ex. 78–53].

In other studies, NIOSH reported that 12 of 23 students at a medical school who participated in post-exposure pulmonary function tests showed signs indicative of formaldehyde's effects. Eight had eye irritation and a dry or irritated throat, six had headache, nasal irritation, dizziness, and cough, and one had a response indicating respiratory allergy to formaldhyde [Ex. 78–34]. Three of four veterinary technicians, who worked in a histopathology laboratory where they were exposed to 13 ppm of formaldehyde for 30 minutes each day, had eye, nose, and throat irritation with occasional headache and fatigue [Ex. 78–91]. At a hemodialysis unit in a hospital, 22 nurses, exposed to formaldehyde at concentrations of 0.04 to 1.3 ppm were interviewed. Seven expressed no problems, 12 had upper respiratory and eye irritation, and three showed possible respiratory hypersensitivity. Five had skin problems [Ex. 78–76]. At a college of mortuary sciences, NIOSH found that three of four instructors, who had worked with formaldehyde for 3 weeks to 13 years for 8 to 50 hours a week, had histories of allergy, burning of the eyes and nose, dry mouth and throat, cough, headache, and tearing of the eyes. Another person had retired recently, and he showed signs of possible occupationally-induced asthma [Ex. 78–20].

Alexanderson *et al.* [Ex. 42–5] conducted a cross sectional study of pulmonary function in 47 subjects employed at a carpentry shop where they had been exposed to formaldehyde for at least one year. Their average age was 35.0 years and the average duration of employment was 5.9 years. The mean concentration of dust in the workplace air was 0.5 (0.3–0.7) mg/m^3 and mean formaldehyde concentrations were 0.36 (0.04–1.25) ppm. Twenty subjects employed elsewhere in the carpentry shop served as controls. Although spirometry and single breath nitrogen washout were normal on Monday morning, statistically significant reductions in maximum midexpiratory flow and significant increases in the closing volume as a percent of the vital capacity were found at the end of the workshift. Seventy four percent had symptoms involving the eyes, 36 percent had evidence of nose or throat irritation, and 10 percent complained of "chest oppression." The authors described the deterioration of lung function, probably of an obstructive nature, as moderate, and they predicted that such changes would not cause measurable restriction of physical activities.

In 1981, the Department of Health in New Zealand published a study of formaldehyde's usage, the resulting exposure, and the observed health effects [Ex. 42–91]. A total of 110 persons and 16 firms participated. A control group of comparable age consisted of 56 government employees. Twenty persons who had formerly worked with formaldehyde were also interviewed. Industries examined were particleboard manufacturing, furniture manufacturing, pathology laboratories, mortuaries, manufacturing chemistry, and the production of fiberglass. Mean exposure duration was 7.5 years. Of the workers, 58 percent were exposed for 1 to 4 hours in a day with 42 percent being exposed 4 to 8 hours per day. Average weekly exposure was for 1 to 3 days (34%) or 4 to 6 days (66%). Of the 20 former workers, 15 percent had been exposed 6 or more hours a day, and all were exposed 5 days a week. Their mean age was 66 years (all but one had retired). Total aldehydes concentrations were measured by Draeger tube [Ex. 45–1]. The concentrations fell beween 0.1 to 6.9 ppm [Ex. 42–91]. Formaldehyde concentrations measured in particleboard factories were 0.1 to 1.1 ppm and 1.3 to 2.4 ppm in university and hospital laboratories.

Of the current worker group, 16 (14.5%) reported a skin reaction described as dry and flaking or red and inflamed accompanied by itching and irritation. In three workers, this skin reaction was evident at the time of the interview. There were significant differences in the prevalence of irritant

effects in workers as opposed to controls. Of the 110 workers, 55 had burning or tingling sensations of the eyes, 47 of the nose, 44 of the throat, and 65 had watering of the eyes. Corresponding incidences in the control group of 56 were 3, 8, 13, and 8, respectively. The only significant difference in lower respiratory tract symptomatology between the test subjects and the controls was breathlessness. Sleep disturbance, sinusitis, early morning thirst, and discharge from the eyes were studied but no relation to formaldehyde exposure was found. Sixty percent of the former formaldehyde workers experienced cough with phlegm during cold weather, 45 percent experienced breathlessness, and 40 percent had wheezing. It is possible that these lower respiratory tract symptoms were not related to formaldhyde, however, since the mean age of the retirees was 66 years in contrast to a mean age of 37 years for the control group. Thirty percent of the former workers had experienced a skin reaction to formaldehyde. Their mean duration of exposure, 15 years, was twice that of the current workers examined. This difference, along with the greater intensity of exposure reported by the former workers, might account for the slightly more than doubled incidence of irritated skin among the former workers in comparison with the group of current workers.

Main and Hogan [Ex. 42–76] examined the health effects resulting from exposure to formaldehyde in 21 police department workers housed in temporary offices in mobile trailers. A comparison group consisted of 18 other employees who had not worked in the trailers. Duration of exposure was 34 months. Significantly greater percentages of formaldehyde exposed employees reported eye irritation (81 vs. 17); itchy, runny, or stuffy noses not related to colds (57 vs. 28); throat irritation (57 vs. 22); fatigue (81 vs. 22); and headaches (76 vs. 11). Among those who reported eye, nose, or throat irritation 14 of the 18 reported a disappearance of these symptoms after leaving the trailer each day; the remaining 4 reported their disappearance within several days. Fifteen of the 18 reported onset of symptoms within 1 to 2 hours of reentering the trailer. Thirteen stated that symptoms increased in hot weather. Effects of side stream cigarette smoke and a history of atopy were examined but they could not account for the results. Spirometry tests failed to show any significant differences in pulmonary function and there was no evidence of airways obstruction. Environmental samples were collected by area monitoring. Three one-hour collections were done on four occasions, each time on a Monday morning after the trailer had been closed for the weekend. Formaldehyde concentrations ranged from 0.12 to 1.6 ppm. The authors stated that:

> Since we did not demonstrate an effect on ventilatory function, the physiologic significance of the symptoms is not entirely clear. On the other hand, the widespread finding of symptoms among healthy, employed individuals at levels well below the . . . permissible exposure limit of 3 ppm suggests that the exposure limit may not be sufficiently protective. [Ex. 42–76]

Yefremov [Ex. 42–130] described the results of medical examinations given to 278 employees in a Russian wood-processing plant. Signs of upper respiratory tract irritation, including rhinitis, were found in 129 of the workers. Formaldehyde concentrations in the air of the plant of 2.6 to 11 mg/m^3 (2.1–8.9 ppm), with a maximum of 36.3 mg/m^3 (30 ppm), produced illness in 39 to 66 percent of those exposed. Concentrations of 0.6 to 4.1 mg/m^3 (0.5–3.3 ppm), with a maximum of 8.8 mg/m^3 (7.1 ppm), produced an illness rate of 14.6 to 37.5 percent. The corresponding incidence in unexposed controls was 8.9 percent. Signs of chronic respiratory tract irritation were most pronounced in workers aged 30 to 59 who had worked at the facility less than 5 years. Some workers had what was described as inflammatory pneumonia. Initial signs were a decrease in mucous flow and a diminished ability to smell common odorants. The lower concentrations reported by Yefremov, which resulted in an approximate tripling of illness rate, were close to the ranges that would be permitted by OSHA's present PELs for formaldehyde.

Pisati *et al.* [Ex. 42–100] examined the health status of 20 of 40 workers employed in a small Italian factory producing urea-formaldehyde and melamine-formaldehyde resins. Airborne concentrations of formaldehyde ranged from 1.22 to 4.96 mg/m^3 (1 to 4 ppm). The 20 workers studied had various symptoms including pharyngitis (17 cases), conjunctivitis (12 cases), pruritis (11 cases), eczema (1 case), urticaria (rash) (1 case), and bronchospasm (5 cases). In four cases, epicutaneous and intradermal test results revealed allergy to formaldehyde to be the cause of the disorders. Of these four workers, two had asthmatic bronchitis, one of whom also had pharyngitis, the third had bronchial asthma and urticaria, and the fourth had cutaneous pruritis only. The worker with bronchial asthma and the worker with both asthmatic bronchitis and pharyngitis also complained of pruritis.

Shipkovitz [cited in Ex. 69–8B] conducted a study of 8 textile plants where formaldehyde resins were used to treat fabrics. Airborne formaldehyde concentrations were 0 to 2.7 ppm, with an average of 0.68 ppm. Employees reported annoying odor, constant prickling irritation of mucous membranes, tearing, wheezing, and disturbed sleep. In 4 plants, over 15 percent of the employees complained of respiratory discomfort and illness; 5 to 15 percent of the employees in the other four plants had similar complaints.

NIOSH has conducted several Health Hazard Evaluations in workforces exposed to formaldehyde through resins used in cloth. Workers who made potato bags were exposed to 0.14 to 0.9 ppm of formaldehyde. When NIOSH interviewed these workers for medical complaints, 75 percent described signs of mucous membrane irritation, and many also had chest discomfort or dermatitis [Ex. 78–27]. NIOSH interviewed 26 workers who placed finishing chemicals on cloth, and 15 had eye irritation, six had sinus congestion, 10 suffered from headaches, and two had skin irritation. Exposure to formaldehyde was measured and found to be between 0.16 and 1.12 ppm [Ex. 78–24]. NIOSH also collected health histories on 81 textile workers exposed to 0.7 ppm (range 0.54–0.91) of formaldehyde as a TWA. Limited physical examinations were also performed. On the medical histories, 95 percent of the workers complained of eye irritation, 72 percent of nasal irritation, 35 percent of sore throats, and 25 percent of skin effects. At the time of the physical examination, 10 percent showed eye irritation, 26 percent showed nasal irritation, 2 percent had a sore throat, and 22 percent had skin lesions [Ex. 78–84].

In 1966, the California Department of Public Health conducted a study of a textile garment factory where permanent press clothing was manufactured [Ex. 73–97]. Measurements of airborne formaldehyde concentrations range from 0.9 to 2.7 ppm. The greatest discomfort, tearing of the eyes and irritation of the nose and throat occurred among employees who worked in areas where the largest quantities of incomplete garments accumulated. Sensations of irritation were greatest for 15 to 20 minutes after entering the work area at the beginning of the work day and after a break for lunch.

Employees who had worked more than 5 years at a plant manufacturing filters from phenol-formaldehyde impregnated fibers had reductions in the ratio of FEV_1 to FVC and in maximal expiratory flow at 50 percent of vital capacity when measurements taken on Friday at the end of the work week were compared with those made on the succeeding Monday morning at the beginning of the following work week [Ex. 42-106]. No measurements of formaldehyde were taken specifically for the study, but two previous surveys had measured airborne concentrations of 0.4 to 0.8 ppm, with occasional excursions of 8.8 to 13.5 ppm when ventilating fans were turned off. Workers also had a higher incidence of chronic cough and phlegm than in-plant controls and previously exposed workers who had transferred. The control group had a high prevalence of symptoms usually associated with formaldehyde exposure. Other confounding factors included concurrent exposure to the resins used at the plant and the small number of subjects.

Summary: The effects of formaldehyde observed in clinical studies and cross-sectional surveys of workers have been related to the upper respiratory system. In numerous studies, formaldehyde has caused at least one of the following signs or symptoms: burning and itching of the eyes or nose, stuffy nose, and sore or burning throat. For example, complaints were made by employees manufacturing particleboard and molded plastics (27% with nose and 21% with throat irritation at 0.4 to 1.0 ppm), by foundry coreroom workers exposed to more than 1 ppm of formaldehyde, by police working in an office with formaldehyde concentrations of 0.12 to 1.6 ppm, by embalmers exposed at 0.25 to 1.39 ppm, by carpenters exposed at 0.36 ppm, and by garment workers with exposures of 0.9 to 2.7 ppm. Several groups reported headaches, most likely related to "stuffy noses" or sinusitis. Two groups [Exs. 42-100 and 42-130], exposed at concentrations probably exceeding OSHA's 3 ppm PEL on occasions, showed evidence of chronic resporatory irritation.

Clinical studies of human volunteers indicate that they become aware of sensory irritation from formaldehyde at concentrations around 1 ppm after exposures of a few minutes. Eye irritation is usually the first effect noticed, followed by irritation of the nose and throat. A 5-hour exposure resulted in similar sensory irritation, except that effects were evident at concentrations as low as 0.24 ppm. At 0.8 ppm, 15 of the 16 volunteers experienced mild discomfort and complained of eye and throat irritation at the end of the exposure. These volunteers had impaired mucociliary clearance at concentrations of 0.8 ppm and above.

Symptoms are difficult to quantify because the researcher's ability to chronicle them is determined by the ability of the person who experiences them to describe the sensations. Some scientists have expressed the opinion that they do not feel a quantitative assessment of the risk of irritant effects is possible [Ex. 70-56]. In addition, a no-effect level (NOEL) that would protect all individuals appears to occur at a concentration of formaldehyde so low that it cannot be defined. Even exceptionally sensitive individuals, however, exhibit a decrease in severity and number of symptoms as concentrations of formaldehyde decrease.

Celanese, whose employees did not exhibit loss of pulmonary function, has reported to OSHA that medical examinations have not shown sensory irritation in their workers and that examination of the nasal cavities showed no formaldehyde-related effects in operations or maintenance workers. Celanese attributes these findings to its use of a 30 minute STEL of 2 ppm [Ex. 69-33B].

Acute changes in pulmonary function have been seen in certain groups with exposure to particulate forms of formaldehyde. The Consensus Workshop [Ex. 70-56] concluded that the reduction in pulmonary function observed in the studies reviewed were clinically insignificant, but that selection bias (in the form of workers who had compromised pulmonary function not volunteering to participate in the study) may have underestimated the adverse effects of formaldehyde exposure. According to the Consensus Workshop:

> Workshift (acute) changes in pulmonary function tests (PFT) have been assessed only when other dust was present and/or the formaldehyde itself was a particulate or incorporated in particles. Acute PFT reductions were not consistently present, were small, and showed no regular association with exposure. Although some symptoms were present, the changes in PFT were clinically insignificant, and there is no convincing evidence formaldehyde exposure results in restriction or obstruction at the doses studied. There is some suggestion that the symptoms are reversible and of minor import. However, because of the demonstrated irritant potential of formaldehyde, selection bias may be occurring in the exposed populations so that these studies are likely to underestimate adverse effects of formaldehyde exposure. [Ex. 70-56]

Immunological effects: While irritation of the upper airways is a well known effect of formaldehyde exposure, there is less certainty as to whether inhalation of formaldehyde causes an allergic sensitization affecting the respiratory system. The Consensus Workshop concluded that:

> There are numerous reports that formaldehyde vapor exposure causes direct irritation of both the skin and respiratory tract. By comparison, the evidence for allergic airway responses to formaldehyde is less extensive . . . it is not known whether there are susceptible groups in the population [Ex. 70-56].

Precise thresholds even for the irritant effects of airborne formaldehyde have not been established, because one person may react at much lower concentrations than another [Exs. 42-87; 70-56]. At highly irritating concentrations, well above the 2 ppm level examined by Schacter [Ex. 70-48], formaldehyde produces bronchoconstriction even in normal persons and so it is unnecessary to invoke an immunologic mechanism to explain the effects of formaldehyde on the airways [Ex. 42-51]. Nevertheless, exposure to formaldehyde has been associated with the development of bronchial asthma in humans. In the cases described below the asthmatic attacks have been attributed to formaldehyde sensitization or allergy, but formaldehyde might act also as an airways irritant in persons who already have bronchial asthma. According to the National Research Council (NRC) Committee on Aldehydes:

> Persons with bronchial asthma respond to numerous agents, such as exogenous irritants and allergens, respiratory infections, cold air, smoke, dust, and stress. The asthmatic person seems to represent an extreme on the scale of respiratory sensitivity to inhaled irritants. The data suggest a dose-response relationship, with increasing numbers of asthmatics having attacks as air pollution worsens. Thus, the airways of asthmatics respond to many nonspecific inhaled irritants, including formaldehyde [Ex. 42-87].

According to the same committee, more than 10 percent but less than 20 percent of the general population may be susceptible to formaldehyde. Reactions were judged particularly likely at concentrations of formaldehyde in ambient air greater than 1.5 ppm. The committee also noted that people report mild eye, nose, and throat discomfort and other symptoms at less than 0.5 ppm, with some responses at levels of only 0.25 ppm. An "allergic" reaction with bronchoconstriction and asthmatic

symptoms was thought to occur, but only uncommonly, at very low concentrations.

There are only a few documented cases of occupational asthma attributed to formaldehyde and demonstrated by bronchial inhalation challenge tests [Ex. 42–51]. These include immediate reactions involving specific antibodies and beginning within minutes after exposure to the allergen. Symptoms can include asthma and allergic rhinitis (hayfever). Delayed hypersensitivity occurs 1 to 2 days after exposure. These symptoms may extend throughout weekends and holidays, with sleep disturbed by coughing at night. Some individuals may have both immediate and delayed reactions to formaldehyde.

In one report by Hendrick, et al. [Ex. 42–62], eight of 28 nurses working in a renal dialysis unit developed asthma or bronchitis. Five had recurring episodes for at least 3 years, but only one had experienced any symptoms prior to joining the unit. Two of the five experienced wheezing, a sensation of tightness in the chest, and cough with symptoms worsening at night. They also had hematologic changes including eosinophilia; provocative inhalation tests induced the asthmatic symptoms.

In a second case [Ex. 42–2], a 30-year-old painter developed allergic rhinitis and asthma, relieved by corticosteroids, when he sprayed paint containing formaldehyde. Challenge by provocation tests at 2 ppm led to an asthmatic attack and a decrease in pulmonary function of 47 percent. A 47-year-old female chemical factory worker showed a similar response upon bronchial provocation even though skin tests were negative. Cockcroft [Ex. 73–88X] reported on two carpenters who appeared to develop asthma and rhinitis from some components of a urea-formaldehyde resin system present in particleboard sawdust.

Hendrick and associates [Ex. 42–63] retested two of the nurses, described above, who had developed attacks of asthma after using formaldehyde to sterilize renal dialysis equipment. In 1973 and 1975, they had developed bronchoconstriction at 2 to 10 hours after receiving 3 to 5 ppm of formaldehyde in inhalation provocation tests. When retested with approximately the same challenge concentration, in 1981, the nurse whose original challenge had been in 1973 and who had ceased working in the renal dialysis unit in 1976 did not respond to challenge with 6 ppm of formaldehyde. The other nurse had continued to work in the dialysis unit and to experience 5 to 10 mild attacks of asthma annually, usually related to formaldehyde spills. She gave a bronchoconstrictive response about one-half that recorded in 1975 when exposed to the same challenge concentrations (3 ppm).

Several additional case reports were described in a review article by Bardana and Andrach [Ex. 73–88L]. The initial report of occupational asthma attributed to formaldehyde was said to be a 1939 description by Vaughan regarding a match factory worker. Another study by Popa and colleagues found one of 48 subjects who had a positive bronchoconstriction response to urea-formaldehyde resin fumes. Sakula had also described a case of formalin-mediated asthma in a laboratory technician.

A recent study reporting immune system alterations in F–344 rats exposed to formaldehyde at 61 to 99 ppm for up to 30 days has led to the speculation that exposure to formaldehyde might alter host resistance to infectious agents. Dean *et al.* [Ex. 73–14] exposed B_6F_1 mice to 15 ppm of formaldehyde for 6 hr/day, 5 days a week, for 21 days. This corresponded to the maximum tolerated dose and the maximum period of cell damage before regeneration occurs. In contrast to the rats, mice challenged with bacteria after exposure to formaldehyde showed increased resistance to infection. Other aspects of cell-mediated immunity were unaffected by formaldehyde. The authors believed that the discrepancy seen between the two studies was caused by severe chemical stress of the rats.

Skin Absorption, Dermatitis, and Sensitization of the Skin

Although formaldehyde solutions can present a cutaneous hazard because of irritation and allergic contact dermatitis, this chemical does not appear to present a systemic hazard through the penetration of unabraded skin.

Absorption through the skin: Jeffcoat [Ex. 69–22A] of RTI examined the percutaneous penetration of formaldehyde to determine if offgassed formaldehyde from permanent press clothing would penetrate the skin. The rhesus monkey was selected for testing because its skin permeability resembles that of humans.

In 5 male monkeys examined 24 hours after dermal application of 0.4 to 0.9 $\mu g/cm^2$ of radiocarbon-labeled formaldehyde, 33 percent was bound to the surface layers of the skin at the site of application and 55 percent had evaporated. For monkeys who received an iv injection of radioactive formaldehyde, the primary route of excretion was the breath. The average for four animals was 47 percent in 4 hours, 51 percent in 1 day, and 55 percent in 5 days. Urinary excretion was 2.4 percent of the dose in 1 day and 4.2 percent in 10 days. Based on the amount of radioactivity exhaled in the breath during the 24 hours after dermal or iv administration of formaldehyde, the author calculated that percutaneous penetration was 0.27 percent of the dose. Based on urinary excretion, this figure was 0.46 percent of the dose. These amounts were so low that the author could not distinguish whether penetration was from formaldehyde or an impurity. Tissues and organs of one monkey necropsied 24 hours after dermal application contained less than 0.2 percent of the administered dose.

Formaldehyde was used as a control in a study by Robbins and Norred [Exs. 69–13; 73–63] who investigated the dermal penetration and resultant distribution of radioactivity released from fabric patches treated with ^{14}C-labeled dimethyloldihydroxyethyleneurea (DMDHEU). Materials were applied to the clipped backs of New Zealand white rabbits, chosen because the authors felt there would be little likelihood of underestimating human risk because rabbit skin should be more permeable. As a positive control for the distribution studies, another group of rabbits received injections of formaldehyde through the ear vein. To test dermal penetration of formaldehyde, a third group received occluded patches containing aqueous ^{14}C-formaldehyde applied to a clipped area on the back.

Topically applied formaldehyde was retained in or on the skin in a percentage of the applied dose that decreased from 72 percent to 58 percent when the applied dose increased from 0.37 mg to 37 mg and when the samples were collected 4 hours after the application. Excretion of radioactive carbon dioxide in the expired air during the 4 hours after application of the radioactive formaldehyde to the back increased from 1.18 ug after the 0.37 mg topical dose to 96.2 ug after the 37 mg dose; only small percentages of the applied radioactivity were recovered from the vital organs, the liver and the kidneys having relatively large values (0.117 and 0.43%, respectively, of the 0.37 mg dose and 0.205 and 0.049%, respectively, of the 37 mg dose). The other organs contained less than 0.010 percent of any dose of the applied isotope. Fat and muscle, because of their comparatively large size and diffuse nature, were graded by the percent of applied isotope found in one gram of tissue; fat held 0.003 to 0.006 percent per gram and muscle held 0.001 to 0.006 percent per gram. Formaldehyde or

some other breakdown product of DMDHEU was found in the skin in measurable quantities, but this radioactive material was bound at the site of the patch test and penetrated the dermis poorly.

The uptake of DMDHEU-related products was enhanced by occulusion of the patch and by perspiration, and it was influenced by the manufacturing process used for DMDHEU. Under the most severe conditions, occlusion of the cloth with rubber, 2.5 percent of the radioactivity was transferred from the cloth in 48 hours, but tests with semiocclusion (covering the patch with ordinary cloth), which is more typical of conditions under which clothing is worn, resulted in about a 10-fold decrease in transfer of the radioactivity to the animal. The results of iv administration indicated that for any small portion of formaldehyde absorbed through the dermis, major portions would be excreted in the breath (29% in 4 hrs, 34% in 24 hrs, and 37% in 48 hrs) and urine (3% in 24 hrs and 5% in 48 hrs), although some may be incorporated into macromolecules. This information implies that there is very little systemic exposure to formaldehyde when formaldehyde solutions come into contact with unabraded skin.

The Consumer Product Safety Commission laboratory [Exs. 73–51; 73–61] conducted an investigation to determine whether the radioactivity that penetrated the skin was formaldehyde, an adduct, or some metabolic product. Freshly prepared rabbit skin was placed in a diffusion cell with labeled solutions of formaldehyde in the donor compartment. The radioactivity that passed through to the receptor side (generally below 1%) was analyzed by an enzymatic procedure. No detectable free formaldehyde was found, indicating that any exposure that does occur from the absorption of formaldehyde solutions through the skin is to some large molecule that has incorporated formaldehyde and not to free formaldehyde.

Irritation and sensitization of the skin: Formaldehyde can cause both irritation of the skin and allergic contact dermatitis. Skin irritation is non-immunologic, requiring multiple applications to a site to provoke a response, while allergic contact dermatitis is an immunological response mediated by sensitized T-lymphocytes. Common delayed reactions include erythema, edema, and vesiculation (redness, swelling, and blistering). Formaldehyde probably also causes an immunologic contact urticaria (rash), defined by the Consensus Workshop Group [Ex. 70–56] as an immediate and anaphylactic reaction mediated mainly by IgE antibodies in atopics, but also by IgG antibodies.

Humans can come into contact with low concentrations of formaldehyde from many sources. According to Ulsamer *et al.* [Ex. 42–122]:

> Positive dermal sensitization reactions to formaldehyde have been caused by many products including textiles, paper, cleaning agents, coolants, nail hardeners, photographic chemicals, and embalming fluid. Delayed contact dermatitis reactions have also been produced by resins containing formaldehyde. These include melamine-formaldehyde, urea-formaldehyde, and phenol-formaldehyde resins. Immediate dermal reactions to formaldehyde or products containing formaldehyde have also been reported to occur.

According to the National Research Council (NRC) Panel on Aldehydes [Ex. 42–87], low concentrations of formaldehyde are sufficient to provoke reaction in people with allergic contact sensitization. Formaldehyde and household products containing 1 percent or more of formaldehyde are considered strong sensitizers under the Federal Hazardous Substances Act, and such products must bear a cautionary label.

Threshold levels have been reported for cutaneous irritation and allergic contact dermatitis. The NRC's Committee on Aldehydes [Ex. 42–87] estimated that for human skin a single application of 1 percent formalin, with occlusion, would produce an irritant response in approximately 5 percent of the population. However, the committee noted, the threshold for open application (a test more relevant to occupational exposure) could not be determined from studies available at the time. The threshold level necessary for induction of allergic contact dermatitis has not been estimated precisely, but it appears to be below 5 percent for formalin (about 2% formaldehyde). The approximate threshold for eliciting allergic contact dermatitis in sensitized persons subjected to formaldehyde ranged from 30 ppm for patch test results to 60 ppm for actual use of formalin solutions [Ex. 42–87]. Both the Aldehydes Committee and the Consensus Workshop [Ex. 70–56] caution that these figures are based on very limited data and must be regarded with caution.

To obtain information on whether or not a substance is likely to cause allergic reactions in humans, some investigators have employed guinea pig sensitization tests. Several of these studies have been conducted for formaldehyde. The results have varied according to the formaldehyde concentration and the methodology. The Cosmetic Ingredient Review (CIR) Expert Panel on the Safety of Formaldehyde in Cosmetics, formed by the Cosmetic, Toiletry and Fragrance Association (CTFA), summarized some of these studies as follows:

> Formalin (37% formaldehyde in aqueous solution) elicited skin sensitization when tested by the Draize, Buehler, and Magnusson-Kligman maximization procedures. In two separate studies in which the Buehler technique was employed, 2% formaldehyde in aqueous solution elicited no allergic reaction. Skin sensitization was observed in guinea pigs following repeated intradermal dosing (optimization test); in this study, a 0.04% aqueous formaldehyde solution was used for induction. In four separate guinea pig sensitization studies, the Magnusson-Kligman maximization test was used to evaluate formaldehyde in aqueous solution at various concentrations. Formaldehyde was sensitizing in two of these studies following induction and challenge applications of 2% and 0.8%, respectively. Formaldehyde was nonsensitizing to guinea pigs in a third study where the induction and challenge concentrations were 0.703% and 0.222%, respectively; as well as in a fourth study where the induction, booster, and challenge concentrations were 1.85%, 3.7%, and 0.925% (or 0.463%), respectively [Ex. 42–27].

The results of the studies in guinea pigs are consistent with findings that formaldehyde is a skin sensitizer in humans, but they should not be used as a quantifier of human risk since potential species differences are unknown.

The Committee on Aldehydes describes qualitatively the effects of increasing concentration of formaldehyde on skin reactions:

> With increasing concentration, one sees a higher frequency of responders, probably because skin penetration by formaldehyde varies from one person to another and even from one site to another on the same person. These different amounts of formaldehyde may reach different target sites. The dose needed to elicit a response depends on these factors and others such as occlusion, temperature, contact time, and vehicle [Ex. 42–87].

OSHA has determined that the human thresholds for sensitization are well below levels encountered by many formaldehyde workers. Consequently, workers who are unprotected against the cutaneous hazards of formaldehyde would be placed at an increased risk of developing skin irritation and sensitization from workplace exposure to formaldehyde solutions and products containing formaldehyde.

Studies of allergic contact dermatitis generally consist of case reports and results of test conducted on patients at

an allergy clinic [Exs. 70–45; 73–34; 73–35]. They alert the occupational physician to potential problems but they do not assist in determining the prevalence of formaldehyde-induced dermatitis in the workplace. In the five worker studies cited earlier where dermatitis was mentioned, incidence rates were 1.8, 10, 14.5, 29, and 37 percent [Exs. 42–91; 42–100; 42–101; 66–5; 73–88D].

The following case reports give examples of persons who developed contact dermatitis due to sensitivity to formaldehyde: a 26-year-old workman who had been exposed through the use of fabric softener [Ex. 73–29]; a 20-year-old woman who developed urticaria within 15 minutes from spray starch and formaldehyde [Ex. 73–33]; an offset printing machine clerk who handled a solution containing formaldehyde preservative [Ex. 70–45]; two persons working with newsprint containing formaldehyde resins [Ex. 70–45]; a foundry worker making molds from a sand/paper waste mixture [Ex. 70–45]; renal dialysis workers [Ex. 70–45]; technicians and others working in pathology and histology laboratories [Ex. 70–45]; a mushroom farmer using formaldehyde as a disinfectant [Ex. 70–45]; a lithoprinter using adhesive preserved with formaldehyde [Ex. 70–45]; contact urticaria from formalin-treated leather [Ex. 73–23]; five nurses handling thermometers immersed in a 10% solution of formaldehyde developed eczema [Ex. 69–8B]; workers at a plant processing crease-resistant materials developed tightness in the skin, pruritis (itching), redness of the skin and face, and swelling of the eyelids [Ex. 69–8B]; and itching and red spots in 26 of 120 foundry employees [Ex. 73–103].

Rappaport and Hoffman [Ex. 73–37] described the case of a 27-year-old man, employed as a histology technician, who had hives and epigastric distress of 15 months duration. He was found to be sensitive to aliphatic unconjugated aldehydes ranging from formaldehyde to an 18-carbon aldehyde. Formaldehyde solutions induced urticaria by contact with unbroken skin, lip, stomach (gelatin capsules), intestine (enteric coated capsules), and intramuscular injection.

Wallenstein and Rebhole [Ex. 42–123] examined 180 patients, aged 16 to 67, (99 men, 81 women) who worked in various industries where they received exposures to formaldehyde. Many of the patients had symptoms of bronchial obstruction and rhinitis which the authors regarded as suggestive of nonspecific symptomatology produced by irritation. Twelve (6.2%) reacted to formalin (0.07 to 0.3% formaldehyde). Up to 12 percent reacted at higher concentrations.

In one human experiment [Ex. 42–75], using a modified Draize repeat insult patch test method, 8 percent of 154 subjects were sensitized by an induction concentration of 5 or 10 percent formalin with challenge at 1 percent. In another human maximization test, 18 of 25 subjects exposed to 5 percent formalin and challenged at 1 percent were sensitized. As Maibach noted:

> The above data are minimal; additional experience is needed in animals and in humans to determine the threshold for the induction of sensitization. This information should help in setting exposure limits in occupational and nonoccupational usage. Equally important to the determination of induction concentration required for sensitization is the elicitation data; once one is sensitized, what is the lowest level that will produce dermatitis [Ex. 42–75].

Horsfall [Ex. 42–66] determined this concentration to be less than 1 ppm by intradermal injection. According to Maibach [Ex. 42–75], one investigative group found positive patch tests in 4 of 9 sensitized individuals exposed at the 30 ppm level. Once sensitized to formaldehyde solutions, the worker would be prone to develop dermatitis at an even lower exposure level.

According to NIOSH [Ex. 69–8B], exposure to gaseous formaldehyde has been implicated as a cause of allergic skin reactions in sensitized people. Lesions observed include drying and reddening of the skin of the face, neck, or arms and itching eruptions of the face, neck, arms, or hands. A classical study [Ex. 42–66] often cited to demonstrate this phenomenon is the 1934 report by Horsfall who described a case in which provocative inhalation tests with formaldehyde at 10 ppm produced vesicles on the skin of a sensitized subject.

The Formaldehyde Institute's comments on the ANPR [Ex. 77–19a] contained a report describing a similar case of urticaria of the face, neck, forearms, and hands in a female pathology worker who had no direct contact with formaldehyde but who was exposed only to airborne formaldehyde at concentrations of approximately 1 ppm.

Lee and coworkers [Ex. 70–57] used the guinea pig as an animal model to study sensitization to formaldehyde. The purpose of the study was to identify the route of exposure most likely to cause sensitization and the potency of formaldehyde as a sensitizing chemical. The three routes of exposure employed were inhalation, topical application, and injection. As in the human case reports, the authors were able to induce sensitization in guinea pigs that inhaled formaldehyde.

For inhalation, groups of guinea pigs were exposed to formaldehyde at 6 ppm or 10 ppm for 6 hr/day for 5 days or 10 ppm for 8 hr/day for 5 days. Animals were evaluated for skin sensitivity, production of antiformaldehyde antibody, and respiratory sensitivity (immediate and delayed) to formaldehyde. Two of four animals in the highest exposure group developed dermal sensitivity, although no antibodies or pulmonary sensitization was observed in any animal.

Animals exposed to formaldehyde by injection displayed extensive dermal reactions for skin tests, and two of four animals developed antibodies to formaldehyde. None developed pulmonary sensitivity.

Animals exposed to formaldehyde by dermal contact developed neither pulmonary sensitivity nor formaldehyde antibodies, but they developed skin sensitivity. Both the severity of the dermatitis and the percentage of animals sensitized increased as the dose increased.

According to NIOSH [Ex. 69–8b], individuals sensitized to formaldehyde have developed allergic contact dermatitis from textiles treated with formaldehyde-containing resins. In most cases, patients reacted positively to patch tests performed with the resin-treated textiles which were the apparent cause of their dermatitis.

Adverse reactions to phenol-formaldehyde resins include depigmentation, irritant dermatitis, chemical burns, and allergic contact dermatitis [Ex. 73–88S]. Allergic contact dermatitis from phenol-formaldehyde resins has been associated primarily with those based on paratertiary-butyl phenol and formaldehyde (PTBP–F–R). When 780 patients at a department of occupational dermatology were patch tested with PTBP–F–R and another phenol-formaldehyde resin, 10 were allergic to at least one of the resins although none responded to formaldehyde. Thirteen of another 440 patients patch tested with three phenol-formaldehyde resins responded. One of the 440 patients responded to formaldehyde. Overall, 0.8, 1.0, and 3.3 percent of the patients reacted to the three resins. It is apparent from the different percentages of responses to the three resins that a dermal reaction to a product containing formaldehyde does not necessarily implicate formaldehyde as the precipitating agent.

Andersen and colleagues [Ex. 73–160] conducted guinea pig maximization tests on formaldehyde and three

formaldehyde releasers that contained a hexahydrotriazine structure. The authors noted that clinical experience with one of these chemicals, Grotan BK, is extensive. The frequency of positive patch tests to Grotan BK in different occupational contact dermatitis studies was reported to be 0 to 8 percent. The authors concluded:

> The relationship between formaldehyde contact allergy and reactions from formaldehyde condensates is still unclear. Formaldehyde seems to be the common hapten in some cases: in others sensitization is directed towards the formaldehyde releaser with concomitant negative patch tests to formaldehyde. [Ex. 73–160]

In part, variability of results was related to how the material was prepared because this affected the amount of formaldehyde released.

Andersen and Hamann [Ex. 73–74] found that 15 of 428 patients tested had eczema due to contact with textile finishing resins. Urea-formaldehyde resin was the main contributor, other formaldehyde resins giving only occasional positive patch test results. All 15 patients also responded to a 2 percent formaldehyde solution. The 15 patients with allergic contact dermatitis from textiles constituted 8.6 percent of the patients who were allergic to formaldehyde who, in turn, constituted 3.7 percent of all patients examined from 1970 to 1980.

In summary, formaldehyde solutions present a cutaneous hazard to workers. The reports reviewed by OSHA described incidences of dermal effects of 1.8 to 37 percent. Formaldehyde solutions exert two effects, direct irritation and immunologically-mediated sensitization. Concentrations of about 5 percent or more of formalin are capable of causing irritation to the skin because of direct chemical reaction [Ex. 68–19]. Splashes or spills of such solutions of formaldehyde also can severely damage the eyes [Exs. 43: 69–8B]. The true threshold for immunologically-mediated contact sensitization is unknown but appears to be greater than 0.1 percent formaldehyde (0.3% formalin). In contrast, penetration of the unabraded skin to cause systemic toxicity does not appear to represent a hazard based on the results of animal studies.

A formaldehyde worker who develops skin lesions is not necessarily sensitive to formaldehyde. Dermal sensitivity to formaldehyde-based resins has occurred without sensitization to formaldehyde solutions. In rare cases, the skin response has been related to airborne concentrations of formaldehyde gas and not to direct physical cor tact with formaldehyde solutions.

A person with immunologically-mediated sensitization to formaldehyde would be unlikely to hold a job in an area where there is substantial opportunity for contact with or exposure to formaldehyde. Even so, OSHA does not recommend patch testing for routine or preplacement surveillance to identify these persons because of the possibility that the patch test could sensitize otherwise unaffected employees. In addition, patch tests, alone, would be inadequate to identify all types of sensitization [Ex. 77–19A].

Reproductive Effects

A report of effects on the female reproductive system appears in the Russian literature. Shumilina [Ex. 42–108] found menstrual disorders in 47.5 percent of 446 women employed as fabric trim shop finishers and warehouse inspectors and in 10.6 percent of 200 industrial goods saleswomen. The Federal Panel on Formaldehyde [Ex. 13] concluded from the Shumilina study:

> Though these data have many limitations they raise the possibility that formaldehyde may affect human reproductive processes. Additional research is needed to confirm these effects.

Olsen and Dossing [Ex. 42–98] investigated possible reproductive effects in daycare workers in Denmark. In 1978, seven newly built mobile daycare centers that used particleboard for indoor paneling were opened in Copenhagen. The employees complained of symptoms characteristic of mucous membrane irritation and began to take a disproportionately large number of sick days. To examine this problem, the investigators distributed a questionnaire designed to quantify subjective symptoms and feelings of the 70 mobile center workers and 34 other daycare workers employed in buildings which did not contain formaldehyde-releasing products. Sixty-six (94%) of the mobile center workers and 26 (76%) of the control subjects responded. Although there were no significant differences in the responses to three control questions, menstrual irregularities and unnatural thirst were almost exclusively present in the mobile center staff. Irritation of the eyes, nose, and throat were three times as frequent as in staffs at control institutions. Unnatural drowsiness, headache, and use of analgesics were twice as frequent as in controls. There was a general tendency of the symptoms to disappear after working hours and on weekends. Measurements in the seven mobile centers taken after the survey was performed found formaldehyde concentrations of 0.43 mg/m^3 (0.24–0.55). In control buildings, formaldehyde concentrations were 0.06 (0.05–0.11) mg/m^3. (Corresponding concentrations in ppm are 0.35 and 0.05, respectively).

The Consensus Workshop Panel on Reproduction and Teratology also examined this issue. They noted that there has been only one adequate study of possible teratogenic effects in mammals [Ex. 70–56], a study of Marks and coworkers [Ex. 42–78] in which no adverse reproductive outcomes were found when pregnant mice were intubated with 74 to 185 mg/kg of formaldehyde each day on days 6 to 15 of gestation. This Panel also reviewed the reports of Shumilina, Olsen and Dossing, and Hemminki *et al.* [Ex. 46–61]. This last report showed no evidence of any increase in spontaneous abortions in nurses exposed to formaldehyde even though nurses exposed to ethylene oxide were at increased risk. The Workshop group concluded:

> The panel could find no evidence clearly demonstrating that formaldehyde caused adverse reproductive outcomes. What it found was a paucity of information . . . The panel feels that formaldehyde poses little if any risk as a potential human teratogen [Ex. 70–56].

OSHA agrees that there appears to be little, if any, risk of reproductive or teratogenic effects from the levels of exposure permitted in the occupational environment. As Hayes has pointed out, the failure to detect menstrual disorders in controls in the Olsen and Dossing study was much more unusual than the 30 percent incidence in formaldehyde-exposed workers [Tr. 736]. In contrast, reported incidences of vaginal irritation and discharge were similar in both groups [Ex. 42–98]. A more complete description of reproductive effects and teratogenicity can be found in the ORA report [Ex. 43].

Genotoxicity

The genotoxic effects of formaldehyde have been studied extensively. In general, *in vitro* test systems have shown formaldehyde to be a weak mutagen [Ex. 70–56]. According to Auerbach *et al.* [Ex. 42–11], the suggestion that formaldehyde could induce genetic alterations first appeared in the 1940s with publications describing formaldehyde's mutagenic activity in *Drosophila* larvae, fungi, and bacteria. More recent studies have shown that formaldehyde induces single-strand DNA breaks in normal human fibroblasts [Ex. 73–76]. DNA-protein crosslinks in mouse leukemia L1210 cells [Ex. 73–165], sister chromatid exchanges

in hamster ovary cells and cultured human lymphocytes [Ex. 42–94], sister chromatid exchanges in the mouse lymphoma forward mutagen assay [Ex. 42–23], chromosome aberrations in human fibroblast cultures [Ex. 73–31], and mutations in a variety of cultured mammalian cells [Exs. 42–23; 42–52; 73–92C]. Genotoxicity in *Drosophila melanogaster* larvae was recently confirmed by the genetic mosaic and sex-linked recessive lethal tests [Ex. 73–80] and a mechanism for formaldehyde's action on *Drosophila* has been suggested [Ex. 73–163].

Formaldehyde has been examined in *Salmonella typhimurium* test systems by several investigators with inconsistent results. Golke [Ex. 73–77] found no effect at concentrations of up to 2 moles/plate in tester strains TA 1535, 100, 1538, 98, and 1537 indicating that neither base pair nor frameshift mutations had occurred. Brusick also found negative results in standard Ames *Salmonella* tests [Ex. 42–23], but Temcharoen and Thilly reported a positive mutagenic response in tester strain TM 677 [Ex. 42–119]. Formaldehyde failed to demonstrate activity in a plate assay with TA 100 or in a forward plate assay with TM 677. Both strains were mutated when the procedure was altered to include a liquid preincubation step [Ex. 42–32].

Additional *in vitro* evidence of formaldehyde's mutagenic potential is its ability to cause cell transformation in Balb/c3T3 cells [Ex. 42–23] and C3H/10T1/2 mouse embryo cells [Exs. 42–17; 42–102; 73–1], an indicator that formaldehyde may act as an initiator or at an early stage in the process leading to carcinogenesis. Formaldehyde has also been shown to be a weak promoter in C3H/10T1/2 cells when it is given following administration of a known initiating substance [Exs. 42–46; 73–1].

Studies of *in vivo* genotoxic effects of formaldehyde include the mouse spot test, dominant lethal induction, the micronucleus test, and induction of chromosome aberrations or sister chromatid exchanges [Exs. 42–23; 42–43; 42–47; 73–28; 73–77]. These tests generally have produced negative results [Ex. 70–23]. A small increase in sister chromatid exchanges was noted in the bone marrow of mice exposed to formaldehyde at airborne concentrations in excess of 25 ppm [Ex. 42–23]. However, formaldehyde did not increase either sister chromatid exchange frequency or the number of metaphases displaying chromosomal aberrations in Fischer-344 rats exposed for 6 hrs/day for 5 days at 0.5, 6, and 15 ppm [Ex. 73–28]. Fontignie-Houbrechts [Ex. 40–41] found a dominant-lethal response at weeks 1 and 3 after exposure to formaldehyde, but these findings conflict with a negative study by Epstein *et al.* [Ex. 42–23].

In humans, there is little evidence to suggest that genotoxic effects are occurring. A preliminary description of an ongoing study of medical students reported finding an increase in sister-chromatid exchange in eight persons exposed to formaldehyde at 1.0 ppm intermittently for 10 weeks during an anatomy class [Ex. 42–110]. A second study of six pathology staff workers exposed to formaldehyde at 1.14 to 6.93 mg/m^3 for 4 to 11 years failed to find any detectable differences in either induction of chromosomal aberrations or frequency of sister-chromatid exchanges when these results were compared with those from five unexposed controls [Ex. 70–52].

Ward *et al.* [Ex. 77–19a] provided a battery of monitoring tests for genetic damage to a group of 11 hospital autopsy service workers and 11 matched controls. Workers received intermittent exposures to formaldehyde that ranged from 0.61 to 1.32 ppm calculated as an 8-hour TWA. Subjects were matched for sex, age, and use of alcohol, tobacco, and marijuana. Information was also collected on health, medications, and exposure to other toxins. Tests included sperm count, abnormal sperm morphology, and 2F-body frequency (a measure of chromosome non-disjunction). Evaluation of the impact of confounding variables suggested correlations between reduced sperm count and marijuana use and between increased abnormal morphology and medications. There was no statistically significant difference in any test that could be attributed to formaldehyde, although the authors noted that there may have been a lack of statistical power to detect minor effects.

Fleig *et al.* [Ex. 73–88b] conducted a cytogenetic analysis of the peripheral blood lymphocytes of 15 workers who had been engaged in the manufacture of formaldehyde and its processing into resins for 23 to 35 years. Compared with in-plant controls selected from administration and office staff, a slight but nonsignificant increase in aberrant cells was seen, but only if gaps were excluded. These workers had exposure to formaldehyde not exceeding 5 ppm before 1971 and 1 ppm afterwards.

In general, the results of *in vivo* studies of genotoxic effects do not conform to the results found in *in vitro* test systems. This could be anticipated since at 1 ppm or less, formaldehyde is rapidly assimilated into the metabolic pool or bound to tissue proteins or other macromolecules. These reactions reduce the amount of formaldehyde potentially available to react with genetic material [Ex. 73–15]. Since formaldehyde is rapidly metabolized, OSHA believes that is is unlikely to react at distant sites. However, OSHA has not determined whether or not any formaldehyde metabolites are toxic. Also, the research to date does not preclude the possibility that formaldehyde induces mutations in cells at the site of contact. Likewise, short-term test results indicating that formaldehyde may be capable of acting as a weak promoter and an initiator may have relevance for humans even though the negative or equivocal results in mouse skin studies suggest that any promotional activity in that test system is probably weak. The results from studies on genotoxic effects add further support for the conclusion that formaldehyde should be regarded as a complete carcinogen. However, the results of *in vivo* testing suggest that cytogenetic testing of workers would not be a useful screening device for persons who are exposed to formaldehyde.

Cytotoxicity, the Mucociliary Apparatus, and Cell Proliferation

Two factors which are thought to influence the carcinogenic response elicited by exposure to formaldehyde are the effects on mucociliary clearance and cell turnover. In rats, at low doses, mucociliary flow decreases the amount of formaldehyde available for reaction with the underlying tissues. At high doses, ciliastasis, or stopping of the beating motion of the cilia that move mucous, reverses this effect. The enhanced turnover of cells that occurs to compensate for the chemical damage to the nasal epithelium is thought to serve as a promotor of carcinogenesis in the rat.

Cytotoxicity: In the animal bioassay conducted by CIIT, morphologic changes in the nasal passages had occurred by the time of the initial serial sacrifice [Exs. 12; 42–131]. Subsequent studies to identify the genesis of these changes found acute degeneration of the epithelial cells of the nasal cavity with edema and congestion in rats exposed at 15 ppm for a single 6-hour exposure. By 3 days, ulceration and necrosis of the epithelium were evident. After 5 days, squamous metaplasia was detected in the nasoturbinates, maxilloturbinates, median septum, and lateral wall. In the olfactory epithelium, the principle lesion was mild serous rhinitis. There were mild degenerative changes in the nasopharynx. At 6 ppm, rats had

marked hyperplasia of the respiratory epithelium although degenerative changes were milder. Mice exposed at the same concentrations as the rats developed lesions that were similar to, but less severe than, those in rats. By 9 days, hyperplasia and metaplasia were seen. [Exs. 42–115; 73–50; 73–91E; 73–165].

Pathological results from interim and unscheduled sacrifices of the mice and rats in each exposure group in the CIIT bioassay give substantial information on the subchronic and chronic cytotoxicity of formaldehyde. Gross pathological exams were performed on all animals, and any tissue mass observed was evaluated microscopically. Major tissues from each organ system were evaluated histologically for animals exposed at 0 and 14.3 ppm. Histological sections of the nasal turbinates were evaluated for five anatomical levels in rats and three levels in mice.

Formaldehyde-induced lesions were observed in the epithelial tissue lining the nasal cavity and the proximal trachea. Epithelial dysplasia was detected earlier than squamous metaplasia. Keratin was produced also in areas of the squamous epithelium that were metaplastic. In the 2 ppm rats, squamous cell metaplasia was seen only in the anterior section (level I). Incidences were approximately 10, 33, 60, 100, and 20 percent at 6, 12, 18, 24 (end of exposure), and 27 months, respectively. At 5.6 ppm, epithelial dysplasia and squamous cell metaplasia were observed in level I and in the middle sections (levels II and III). Incidences were about 50 percent in levels I and II at 6 months; 60 percent (level I) and 45 percent (level II) at 12 months; 85 percent (level I), 60 percent (level II) at 18 months; and 100 percent (level I) and 60 percent (level II) and 10 percent (level III) at 24 months. Three months after exposure terminated, there was regression of squamous cell metaplasia at all levels.

At 14.3 ppm, a 30 percent incidence of squamous cell metaplasia was already seen in level III at 6 months, and it increased to 50 percent at 12 months. From 18 months onward, all five levels were examined, and the incidence of squamous cell metaplasia was about 100 percent in the first three levels. At 14.3 ppm, lesions were seen in the posterior sections (levels IV and V) beginning at 18 months, and there was regression of the lesions in these two levels after exposure ceased. Rats exposed at 14.3 ppm experienced early mortality, not only because of cancer, but also because of excess accumulation of keratin and inflammatory exudate which caused severe labored breathing and death.

Significant formaldehyde-induced lesions were also seen in the CIIT mice. Lesions in the nasal cavity were first seen at 12 months in the 14.3 ppm exposure group. By 18 and 24 months, many mice had dysplasia and metaplasia. At 5.6 ppm, a few mice had dysplasia at 18 and 24 months and a few had metaplasia at 24 months. At 2 ppm, mice did not develop degenerative lesions of the nasal mucosa although a few had serous rhinitis. The formaldehyde-induced nasal lesions in mice were less severe than those seen in rats exposed at the same concentration.

A subchronic study in which cynomologus monkeys, Syrian golden hamsters, and Fischer 344 rats inhaled formaldehyde at 0.2, 1, or 3 ppm for 22 hr/day, 7 days/wk, for 26 weeks provides information on additional species, including monkeys, who like humans, are not obligated to breathe through the nose [Exs. 42–16; 42–104]. Several monkeys developed nasal discharge, hoarseness, and cough at 3 ppm; rats were unaffected; and hamsters had a higher frequency of rales, nasal discharge, and lacrimation.

All animals were subjected to gross necropsy, and no exposure-related lesions were found. Electron microscopic examination of the lungs, trachea, and nasal turbinate from 10 rats exposed at 0 or 1 ppm showed no effects. Light microscopic examination performed on the nasal turbinate of all animals, on all gross lesions, and on the lungs and trachea of animals in the 0, 1, and 3 ppm groups showed a possible response in the 3 ppm rats. To clarify this point, the investigators examined additional sections and found squamous cell metaplasia of the nasoturbinate with no effect in the ethmoturbinate. Basal cell hyperplasia was observed in the anterior and midportions of the nasoturbinate. More severe effects were seen in the rats exposed at 3 ppm. Hamsters showed no exposure related effects. One of six monkeys exposed at 1 ppm and all six monkeys exposed at 3 ppm developed squamous cell metaplasia and hyperplasia.

Cell proliferation: Since cell replication can be viewed as a compensatory response to cell damage and necrosis, an increased incidence of cell replication would be expected to occur in direct proportion to the amount of damage and death that occurs when the cell is exposed to formaldehyde. Both dose- and species-dependent responses have been seen in describing formaldehyde's effects on cell replication. Slight increases in cell proliferation were seen in rats exposed at 0.5 and 2 ppm. In rats exposed for 1 to 3 days, an increase from 2 to 6 ppm resulted in an 8-fold increase in cell proliferation during the first day and a 25-fold increase during the third day [Ex. 62].

The increase in cell replication would be expected to greatly enhance the likelihood of a carcinogenic response. Formaldehyde reacts only with single strand DNA. The number of these sites is much greater when more DNA is being replicated. Thus, the likelihood of formaldehyde binding to DNA, forming adducts that lead to mispairing during replication, and resulting in initiated cell populations that expand to neoplasia are all related to cell proliferation. The results seen with regard to cell proliferation are consistent with a nonlinear dose-response curve for cancer seen in the CIIT bioassay and they predict that intermittent, high dose exposures should be more affected than continuous exposure at equivalent cumulative dose.

Mucociliary clearance: Mucociliary clearance can affect formaldehyde's availability to react with the respiratory mucosa in a number of ways. At low doses, proteins, especially albumin, in nasal mucous react with formaldehyde [Exs. 73–81F; 73–91C] and the mucous flow carries any unreacted material toward the nasopharynx, where it can be swallowed. At high doses, however, formaldehyde has an inhibitory effect upon mucociliary function. Formaldehyde can induce a slowing of the mucous flow (mucostasis) and can also stop the beating motion of the cilia which drive the mucous over the surface (ciliastasis). In rats, a no-effect level was reported to be 0.5 ppm [Ex. 73–81F]. Morgan and associates, in observing that Anderson and Molhave had found a slight decrease in nasal mucous flow rate in humans exposed at concentrations as low as 0.8 ppm, noted:

> In the present study, formaldehyde produced inhibition of mucociliary function in the more anterior region of the nose, indicating some similarity between responses in rats and humans [Ex. 73–81F].

Since the slowing of mucociliary flow permits more formaldehyde to penetrate to the surface of the nasal cavity, which would be expected to lead to a higher incidence of cancer, the results could be taken to suggest that humans are more susceptible than rats to the carcincogenic effects of formaldehyde. However, Morgan cautions:

> The progressive inhibition of nasal mucociliary function by formaldehyde in rats is an important feature. This observation

suggests that caution should be exercised when attempting to determine long-term risks to airway clearance mechanisms based upon experiments using only short-term exposures.

Sufficient information exists to conclude that, qualitatively, the influence of mucociliary flow on formaldehyde toxicity would be in the same direction in humans and rats. In the absence of any data on cytotoxicity and cell proliferation caused by formaldehyde in the human, which lead to promotion of cancer, OSHA concludes that formaldehyde's cytotoxic and proliferative effects should be weighed in any determination of human cancer risk.

(1) Carcinogenicity

Results in animals: A 24-month inhalation bioassay of formaldehyde was conducted for the Chemical Industry Institute of Toxicology (CIIT) by Battelle Columbus Laboratories [Exs. 12; 42–116; 42–131]. Exposure groups consisted of 120 male and 120 female animals of each of two species: Fisher 344 rats and B6C3F1 mice. The animals were exposed for 6 hrs/day, 5 days a week at nominal concentrations of 0, 2, 6, and 15 ppm of formaldehyde. Actual concentrations averaged 2.0, 5.6, and 14.3 ppm over the course of the experiment. During the 24-month exposure period, clinical chemistry tests and microscopic examinations were conducted on animals killed at 6, 12, 18, and 24 months. In order to examine lesion recovery, some female mice and male and female rats were retained after termination of exposure. All the mice were killed at 3 months post exposure (27 months on study). Some rats were killed for necropsy at 3 months post exposure, and the rest were killed at 6 months post exposure (30 months on study).

In the rats, there was a significant increase in squamous cell carcinoma of the nasal cavity in both males (51 tumors) and females (52 tumors) exposed to formaldehyde at 14.3 ppm. One male and one female rats exposed at 5.6 ppm also has squamous cell carcinomas in the nasal cavity. All groups of exposed rats had increased incidences of epithelial dysplasia and squamous cell metaplasia of the nasal cavity.

Two male mice exposed at 14.3 ppm had squamous cell carcinomas of the nasal cavity, observed at necropsy at 24 months, which was when exposure ended. The number of nasal cancers found was not satistically significant, but the tumors were accepted as being formaldehyde related and biologically significant because of their histological type and historical rarity in unexposed mice.

Microscopic evaluation of histological sections revealed an increased incidence of epithelial dysplasia and squamous cell metaplasia occurred in male mice exposed at 5.6 and 14.3 ppm and in female mice exposed at 14.3 ppm. During exposure, at least some mice from each exposure group developed rhinitis (inflammation of the mucous membrane of the nose).

Non-neoplastic lesions of the nasal cavity were already evident in rats sacrificed after 6 and 12 months of exposure at 14.3 ppm. These epithelial changes included mild to severe mucopurulent rhinitis, epithelial dysplasia, and squamous metaplasia [Ex. 42–116]. The females of the 14.3 ppm group also had increased incidences of squamous metaplasia of the trachea. The incidence of rhinitis throughout the study period was significant also in the 2.0 and 5.6 ppm groups. In addition, rats exposed at 14.3 ppm had increased incidences of squamous epithelial hyperplasia, squamous atypia, and hyperkeratosis. There was an apparent regression of squamous cell metaplasia of the nasal cavity 3 months after exposure ended for the 2.0 and 5.6 ppm exposure groups [Ex. 42–131].

In describing the lesions found in the nasal cavity of exposed rats the authors stated that:

> Apparent progression from squamous metaplasia to squamous epithelial hyperplasia with increased keratin production and then to areas of squamous papillary hyperplasia with areas of cellular atypia was evident in the high dose group only. More advanced lesions diagnosed as carcinoma "in situ" and, finally, invasive squamous cell carcinomas of the nasal turbinates were present in rats from the intermediate and high exposure groups, but were statistically different from controls in the high exposure group only.

A recent evaluation of histopathologic sections from five levels of the nasal cavities of the CIIT rats found a total of 18 benign polypoid neoplasms with similar morphologic characteristics [Exs. 42–90; 73–50]. The distribution of tumors was a follows: 1 in air-exposed control animals, 8 in the 2 ppm exposure group, 6 in the 5.6 ppm group, and 3 in the 14.3 ppm group. Two animals with polypoid adenomas in the 14.3 ppm group also had squamous cell carcinomas of the nasal passages. A third rat in the high dose group had a malignant neoplasm with morphologic features similar to those of polypoid adenomas, indicating that it might represent a malignant counterpart. The polypoid adenomas were confined to poorly ciliated epithelium in the most anterior part of the nasal cavity and were restricted to the free margins of the naso- and maxilloturbinates and the lateral wall adjacent to these margins.

Additional information on location of the squamous cell carcinomas was obtained for 98 of 103 original animals still having adequate tissue for analysis [Ex. 73–81G]. Single neoplasms were present in 40 male and 40 female rats exposed at 14.3 ppm. Nine additional males and 9 females had multiple neoplasms (21 and 20 tumors, respectively). More than half the squamous cell cancers occurred on the lateral side of the nasoturbinate and adjacent lateral wall at the front of the nose, about 25 percent were located on the midventral nasal septum, and about 10 percent were on the dorsal septum and the roof of the dorsal meatus. A small number (2.5%) were found on the maxilloturbinate. All other regions of the nose did not contain squamous cell carcinomas except as the result of invasion.

The histopathology and clinical chemistry results from the CIIT study were available [Ex. 12] and were reviewed by OSHA to determine if any related effects were present. In the CIIT study, 28 of 115 (24%) rats examined following exposure to formaldehyde at 14.3 ppm showed evidence of bone marrow hyperplasia. Only 7 of 113 or 6 percent of the control rats had bone marrow hyperplasia. While such a finding might occur if an animal also had leukemia, no increase in incidence of leukemia was found and the report states that these lesions appear to be associated with an increased demand for leukocytes and erythrocytes in animals with nasal tumors. Affected animals also had severe purulent rhinitis with an associated increased granulocytopoiesis and erythropoiesis, possibly related to hypoxia. The incidence of leukemia in the 14.3 ppm exposure groups (lower exposures not examined) was 6 percent (7 of 120 animals) with 9 percent (11 of 120 animals) in controls. Information on the incidence of lymphomas in mice was also examined, and there was no association with formaldehyde exposure.

Extensive hematology data for rats and mice were collected in the CIIT study at 6, 12, 18, and 24 months after exposure [Ex. 12]. Measurements included hemoglobin, hematocrit, leukocytes, erythrocytes, mean cell volume, mean cell hemoglobin concentration, reticulocytes, immature neutrophils, mature neutrophils, lymphocytes, eosinophils, and monocytes. In no case was there any

statistically significant trend to increasingly abnormal values as exposure continued. These results are consistent with an absence of excess leukemia, even at the highest dose.

The brains of animals exposed at 14.3 ppm and of control animals were examined histopathologically. There was no evidence in rats or mice of brain lesions related to exposure to formaldehyde [Ex. 12]. Tracheal lesions found in the 14.3 ppm exposed rats, which are obligatory nose breathers, indicate that effects can extend to sites in the respiratory tract beyond the immediate site of impaction. This finding would suggest that the risks of cancer in humans, who are not obligatory nose breathers, are even more likely to involve sites of the respiratory tract other than the nasal epithelium.

Krivanek, in testimony at OSHA's public meeting, also provided an evaluation of the results of the CIIT study to determine if formaldehyde caused brain damage or brain tumors. According to Krivanek:

> At all scheduled sacrifices animals were necropsied and brains were removed and weighed. No differences between exposed and (un)treated animals were found. Brain and spinal cord tissues were examined for both gross and microscopic pathologic changes in high-dose and control animals. Four sections of the brain were evaluated: cerebellum, cerebrum, medulla, and optic nerve.
>
> Simple neurofunctional examinations, such as posture, gait, and pupillary response were performed on all animals prior to scheduled sacrifice at 18, 24, 27, and 30 months in the study. There were no differences found between exposed and control animals. This information coupled with that of the negative histopathologic examinations of nervous system tissue provides strong evidence that formaldehyde does not produce nervous system damage [Tr. 632–633].

The CIIT study, results from other studies of carcinogenicity (discussed later), and considerations based on metabolism led Krivanek to conclude that there is no convining evidence to support a proposition that formaldehyde causes brain cancer or leukemia [Tr. 635–636].

Clearly the presence of malignant nasal tumors in the high dose rats in the CIIT study caused many early deaths. Brown [Exs. 42–22; 44–17] conducted several statistical tests to verify this intuitively obvious effect and to further probe whether or not formaldehyde had any additional influence on mortality. The Kaplan-Meier estimate of the probability of early death, with censoring for sacrifice kills and missing or traumatized animals, was 0.10, 0.15, 0.21, and 0.74 at 0, 2, 5.6, and 14.3 ppm, respectively. The extremely high value at 14.3 ppm demonstrates the effects attributable to nasal cancer. Censoring for these lesions reduces the estimate at 14.3 ppm to 0.22. Brown then applied the Mantel-Haenszel test to the rat data to examine the hypothesis that there is no residual dose-related effect on mortality after censoring for the nasal carcinomas. Instead, a significantly increased incidence of early deaths was found at all exposure levels. This calculation suggested to Brown that there is a mortality effect due to formaldehyde inhalation aside from deaths attributable to nasal cancer and that this effect is induced probably by concentrations of formaldehyde below the 3 ppm PEL. In contrast to the results in rats, no significant compound-related early mortality was seen in mice.

A series of studies conducted at New York University (NYU) [Exs. 42–3; 42–4] corroborates the findings in the CIIT study that inhalation of formaldehyde induces nasal cancer in rats. The initial study was intended to evaluate the effects of inhalation of bischloro(methyl) ether (BCME), a substance known to be carcinogenic in rats. Hydrogen chloride (HCl) and formaldehyde were premixed, and then the concentrated mixture was diluted by exposure chamber air. This approach was intended to maximize the formation of BCME, but only very small amounts of BCME were formed relative to the amount of formaldehyde present. Subsequent to the start of the study at NYU, the CIIIT announced that formaldehyde, one of the reactants, was a carcinogen in another strain of rats. In follow-up, the NYU investigators conducted a separate study containing four groups of animals: one exposed to a premixed HCl-formaldehyde mixture as in the first test, a second exposed to these two gases without premixing, a third group exposed to formaldehyde, and a fourth group exposed to HCl.

All animals were male rats of the Sprague-Dawley strain. They were exposed for 6 hrs/day, 5 days a week for life. They were allowed to die naturally or were killed when moribund. A complete necropsy was performed on each animal, with particular attention being given to the respiratory tract. In the first experiment, histological slides were prepared from each side of the head to display the nasal cavity as viewed laterally from the midline. In the second experiment, the head was cut vertically into four slabs beginning just behind the nostrils and extending to the orbits. Histologic sections were obtained from the face of each slab.

In experiment one, the rats were exposed at nomimal concentrations of 14 ppm of formaldehyde and 10 ppm of HCl (actual concentrations 14.7 and 10.6 ppm, respectively). Of the 99 exposed animals, 28 developed nasal tumors which consisted of 25 squamous carcinomas and 3 papillomas. A high proportion of exposed rats showed squamous metaplasia of the nasal cavity. They also had more epithelial hyperplasia and hyperplasia with atypia than the controls. No primary tumors were observed in the larynx, trachea, or lungs [Ex. 42–2].

Although the final results of the second NYU study have not been published, Albert provided OSHA with a listing of the incidence of nasal tumors in each of the study groups [Ex. 42–3]. In the 100 rats exposed to formaldehyde alone, there were 39 squamous cell carcinomas, 10 squamous cell papillomas, and 1 fibrosarcoma. When the formaldehyde and HCl were premixed, incidences in 100 rats were 45 squamous cell carcinomas, 13 squamous cell papillomas, 1 fibrosarcoma, 1 adenocarcinoma, and 1 esthesioneuroepithelioma. If the two chemicals were not premixed, nasal tumor incidences in 100 rats were: 27 squamous cell carcinomas, 10 squamous cell papillomas, 2 adenocarcinomas, and 1 nasal polyp. There were no nasal tumors in 99 air controls, 98 colony controls, or in 99 animals exposed to HCl alone.

Unlike the CIIT study, the NYU rats developed squamous cell papillomas, a benign counterpart to the squamous cell carcinoma, in the nasal cavity. Adenocarcinomas were found in low incidence in two of the groups of rats. This is consistent with the CIIT findings, but in the NYU study they occurred only in groups also exposed to HCl [Ex. 44–18; Tr. 13]. The much higher incidence of tumors found in the second series of animals is consistent with the results of the CIIT study and appears to be consistent with the more thorough histopathology done on these animals. Only one esthesioneuroepithelioma, a tumor most likely attributable to BCME exposure, was found, indicating that the small concentrations of BCME produced played a minimal role in the results found.

OSHA has determined that this study confirms in a second strain of rats that exposure to formaldehyde can cause cancer in animals, providing further evidence to conclude that formaldehyde should be handled as a potential occupational carcinogen.

In a study reported by Tobe *et al.* [Ex. 73–146], groups of 32 male Fischer 344 rats were exposed to formaldehyde for 6 hr/day, 5 days a week for up to 28 months. Five groups consisted of a

colony control, a room control, and animals exposed to formaldehyde at 0.3, 2.0, and 15 ppm. In the highest dose group, there were 14 cases of squamous cell carcinoma and 5 cases of squamous cell papilloma. No tumors of the nasal cavities were observed at 0.3 or 2 ppm. Rhinitis, squamous metaplasia, and hyperplasia of the nasal respiratory epithelium were observed in all three groups exposed to formaldehyde. The Formaldehyde Institute has questioned the relevance of the hyperplasia and metaplasia at the low doses, noting that rhinitis in controls may have indicated an unclean chamber or poor general health of the animals [Ex. 77–19a]. Since each group contained only 32 animals, as compared with 240 animals per group in the CIIT study, which did not find malignancies of the nasal cavity at 2 ppm, it is not surprising that 2 ppm, and an even lower dose, 0.3 ppm, failed to show a response. The finding of papillomas is consistent with the NYU study and suggests that a combination of related benign (papilloma) and malignant (squamous cell) tumors is a probable response in experimental studies of inhaled formaldehyde. The CIIT study failed to find any papillomas although other benign tumors were observed.

OSHA regards the finding of squamous cell carcinoma in two experimental studies conducted independently of the CIIT study as evidence strongly supporting the conclusion that formaldehyde should be considered to be an occupational carcinogen. In contrast, the failure to find polypoid adenomas in two additional studies indicates to OSHA that the role of the adenomas in assessing the risk of formaldehyde exposure is much less certain.

Dalbey [Ex. 42–33] exposed 88 male Syrian golden hamsters to formaldehyde at 10 ppm for 5 hrs/day, 5 days a week, for their lifetime. A control group contained 132 hamsters. At necropsy, "all major tissues" were preserved in buffered formalin. Two transverse sections of the nasal turbinates of each animal were examined along with longitudinal sections of the larynx, trachea, and lung lobes.

Although no tumors were found in either the formaldehyde exposed or the control group, survival time of formaldehyde-exposed hamsters was significantly reduced ($p < 0.05$) compared with unexposed controls. Areas of hyperplastic and metaplastic nasal epithelium were observed in 5 percent of the exposed animals compared with none in the control hamsters.

The exposure equivalent for comparison of the CIIT study with the Dalbey study would be 8 ppm, a level that might be expected to produce only a few nasal cancers in rats. Furthermore, the histopathology was less complete in the study of hamsters than in the CIIT rats (2 nasal cavity sections vs. 5), further lowering expectations for finding cancer. The chances of finding nasal tumors were decreased even more by the early age at death and the small number of animals in the study group (Exs. 73–87; 76–8b). Thus, Dalbey's results in the hamster are not necessarily indicative of a significant species effect. OSHA agrees with the author's conclusion that "our finding . . . does not necessarily disagree with the reported induction of squamous cell carcinoma in rats."

Dalbey also examined the possibility that exposure to formaldehyde could influence the incidence of respiratory tumors induced by diethylnitrosamine (DEN). Male Syrian golden hamsters were divided into 5 groups. Fifty animals were exposed 5 hrs/day, once per week for life to formaldehyde at 30 ppm. No tumors were observed in the respiratory tract of the group exposed under these conditions. Similarly, no tumors of the respiratory system were observed in 50 colony controls. A third group of 100 animals received 10 injections of DEN, once per week for 10 weeks. Two additional groups of 50 animals received 10 injections of DEN and lifetime exposure to formaldehyde. One group started formaldehyde exposure concurrently and the other started formaldehyde exposure 2 weeks after the last DEN injection. Hamsters receiving concurrent exposures to formaldehyde (administered 2 days prior to each of 10 weekly DEN injections) had a higher number of tracheal tumors/tumor-bearing animals at necropsy than those receiving DEN alone. No enhanced effect was seen when formaldehyde was administered following DEN injection, indicating that formaldehyde did not perform as a promoter. These results indicated to the authors that formaldehyde may act as a cofactor in chemical carcinogenesis in the respiratory tract.

Spangler and Ward reported preliminary results of a skin cancer study in Sencar mice, a species particularly sensitive to two-stage carcinogenesis [Ex. 70–44]. Solutions consisting of 3.7 to 4.0 percent formaldehyde were applied to the backs of female mice, 30 per group. As an initiator, formaldehyde was administered once. As a promoter, it was applied once or twice a week. Positive controls included dimethyl benzanthracene for initiation and 12-o-tetradecanoyl phorbol-13-acetate (TPA) for promotion. Negative controls were administered acetone. Formaldehyde was also tested as a complete carcinogen. The authors felt their preliminary results indicated that formaldehyde, applied to the skin, probably is neither a complete carcinogen nor an initiator. Interim data on promotion were inconclusive.

Krivanek, Chromey, and McAlack [Ex. 70–43] also examined the potential of formaldehyde to initiate or promote tumorigenesis at the site of contact on the skin of female CD–1 mice. Formaldehyde solutions, in a 50:50 acetone to water mixture, were prepared from paraformaldehyde. TPA was used as a known promoter and benz(a)pyrene (BaP) was used for initiation. Formaldehyde, as an initiator, was applied in a single 5 mg dose followed by applications of promoter, beginning two weeks later, three times a week for 180 days. Formaldehyde, as a promoter, was administered under the same protocol at doses of 1.0, 0.5, or 0.1 mg in 0.1 ml of vehicle. As a complete carcinogen, formaldehyde was applied in an initial dose of 5 mg followed by periodic exposures of 1 mg administered for 180 days. All animals were observed for 180 additional days after completion of exposure. Skin nodules were considered positive responses if they persisted at least 30 days.

The results of the experiment were as follows for the following initiator/promoter combinations: acetone/TPA—3/29; BaP/TPA—28/29; HCHO/TPA—5/29; HCHO/acetone—0/30; HCHO/HCHO—0/30; BaP/1.0 mg HCHO—1/30; BaP/0.5 mg CHO—2/30; BaP/0.1 mg HCHO— 7/30; and BaP/acetone—3/29. The 1 mg dose of formaldehyde was mildly irritating to the skin. Large doses (2–5 mg) produced definite skin irritation, so that higher doses of formaldehyde were not considered acceptable. Under conditions of the assay, Krivanek *et al.* concluded that formaldehyde at minimally irritating concentrations did not initiate or promote skin tumors and also failed to act as a complete tumorigen.

The two studies on skin tumorigenesis suggest that formaldehyde does not present a cancer hazard by the dermal route, but they are subject to criticism. Dosage levels had to be restricted because of formaldehyde's ability to damage the skin, and the number of animals tested had to be limited. Thus, critics could contend that these limitations make the skin painting studies too insensitive to detect the cancer risk. Furthermore, formaldehyde is known to react with biochemicals near the surface of intact skin, so that

systemic cancer from the dermal route would be an unexpected finding. That, however, leaves unanswered the question of how a subject would respond if the dose applied were sufficiently concentrated to damage the epidermis, since under such circumstances more formaldehyde would be available systemically.

Over the past years, there have been several other studies of formaldehyde's potential carcinogenicity. These have involved oral or injection site experiments using formaldehyde and hexamethylenetetramine (HMT), which decomposes to formaldehyde within the cell. Watanabe and coworkers examined the effects of subcutaneous (sc) injections of formaldehyde, HMT, and formic acid. While formic acid failed to induce tumors, several rats exposed to the other chemicals developed injection site tumors [Exs. 42–125; 42–126]. HMT has been examined by oral administration in rats and mice either by gavage or in drinking water. In all cases [Exs. 42–18; 42–36], HMT failed to induce observable tumors. It must be noted that all of these studies suffer from severe deficiencies such as small numbers of experimental animals, short duration of exposure, and early death of the animals. These would make the detection of a tumor response much less likely than would be expected according to protocols presently in use for long-term animal bioassays.

Mueller *et al.* [Ex. 73–129] affixed oral cavity tanks containing 3 percent formalin onto the palates of six rabbits. Four were fitted as control animals and 10 additional animals served as colony controls. One animal developed a carcinoma *in situ* at 11 months, one month after cessation of exposure to formaldehyde. This result is consistent with later finding in well-conducted bioassays which demonstrate that formaldehyde affects the site of contact, but it is meaningless in defining potential risk to exposed workers.

Horton *et al.* [Ex. 42–67] conducted a subchronic inhalation study using groups consisting to of from 42 to 60 C3H mice exposed to formaldehyde at 0, 41, 82, or 163 ppm for three 1-hour periods a week. The number of animals dying increased rapidly after 6 hours of exposure at 163 ppm, and this exposure was discontinued. Exposure at 41 and 82 ppm continued for a total of 105 1-hour periods. Thirty-six mice exposed at 41 ppm for 35 weeks were exposed subsequently to formaldehyde at 122 ppm for another 29 weeks. No tumors were found in the lungs or trachea; the nasal turbinates were not examined. However, metaplasia and hyperplasia of the trachea was observed in all exposure groups. The 15 mice that survived exposure at 122 ppm in the extended and intensified study had tracheal metaplasia extending into the major bronchi.

This study design would no longer be considered an acceptable protocol to assess carcinogenic potential. Exposure duration was too short, and survival of the animals exposed an additional 29 weeks was poor. Thus, the number of animals at long-term risk was inadequate to assess formaldehyde's carcinogenic potential. Also, the most likely target site, the nose, was not examined. Other studies [Exs. 70–24; 70–29] suggest that certain strains of mice may reduce their exposure by reducing their respiration rate. Despite these serious limitations, the study provides some qualitative information to suggest that repeated short-term exposure to formaldehyde produces the same types of effects as exposure throughout the course of the day.

In the Texas Indoor Air Quality Study (TIAQS) [Ex. 70–19], Thiess and colleagues conducted a number of experiments designed to examine formaldehyde's potential to cause genotoxic and carcinogenic responses at sites distant to the initial site of contact. In one study, changes in the DNA and RNA contents of selected tissues of the Sprague-Dawley rat as the result of the inhalation of formaldehyde were measured by flow cytometry. In addition, alveolar macrophages in the lung and bone marrow cells were examined microscopically to assess any chromosomal damage possibly related to formaldehyde exposure. The flow cytometry analysis demonstrated small but significant alterations in the RNA content of lung alveolar macrophages as the result of inhaling formaldehyde but no changes in either the DNA or the RNA contents of bone marrow cells. The cytogenetic analysis found no noticeable damage to the bone marrow cells other than an increased number of centric fusions but significant cytogenetic damage (chromatid breaks, chromosome breaks, and centric fusions) to the alveolar macrophages. These findings suggested to the authors that inhaled formaldehyde is capable of producing genotoxic effects in the lower respiratory tract and possibly in bone marrow cells of rats.

To determine whether formaldehyde is capable of inducing cancer in mice exposed by routes other than inhalation, Strain A mice, an especially sensitive species, were given repeated intraperitoneal (ip) or oral doses of one of two types of formaldehyde, *ie.* formalin or paraformaldehyde. These doses were administered 5 times a week for 8 weeks. Sixteen weeks later the animals were killed and the number of adenomas appearing on the lung surfaces were counted. Neither formalin nor paraformaldehyde increased the number of lung adenomas in mice by either route of exposure. As a part of this same experiment, formaldehyde was found to rapidly mobilize from both sites of administration and be expired through the lungs either as itself or as its metabolites.

The TIAQS group also examined the effects of carcinogens and lung irritants on the lung tumor incidence in the Strain-A mouse. Groups of 30 mice were exposed at 0.5, 3, or 15 ppm of formaldehyde for 6 hrs/day, 5 days/wk for 18 weeks. At the end of the exposure period, the mice were killed and the lungs excised. The adenomas appearing on the lung surface were counted under a dissecting microscope. There was a slight elevation in lung tumor response in all experimental groups, although the results were statistically significant only in the group of mice exposed at 15 ppm. In contrast, when urethane was injected also, formaldehyde showed an ability to antagonize the known carcinogenicity of urethane. The authors speculated that this effect might be related to formaldehyde's capacity to inhibit DNA repair resulting in death of the carcinogenically transformed cells.

Additional groups of mice were exposed to butylated hydroxytoluene (BHT), a known lung irritant, or urethane, a lung carcinogen in mice, and formaldehyde (paraformaldehyde or formalin) through the intraperitoneal and oral routes of administration. By the intraperitoneal route, formaldehyde enhanced the carcinogenic effects of urethane, but by the oral route there was neither enhancement nor antagonism, as seen when formaldehyde was inhaled. In the BHT experiments, lung tumors were found, but only when paraformaldehyde was administered.

Specific regions of the rat nasal passage are susceptible to the development of squamous cell carcinomas when exposed to formaldehyde [Ex. 73–81G]. In general, only regions of the nasal epithelium that also experienced inhibition of mucociliary function and acute cytotoxicity during short-term exposures have developed cancer [Ex. 70–22]. No squamous cell carcinomas were found in the ethmoid turbinates, the posterior lateral wall, the maxillary recess, the nasolacrimal duct, or the nasopharynx [Ex. 73–81G]. However, over half of the squamous cell neoplasms occurred on

the nasoturbinates and adjacent lateral wall at the front of the nose while only 2.5 percent were found on the maxilloturbinate. Both these regions show toxic (irritative) effects from short-term exposures, indicating that there are possible regional differences in susceptibility of the rat nasal epithelium to carcinogenic effects of formaldehyde [Ex. 70–22]

OSHA has examined the CIIT study in depth and believes that it provides high quality information. Good laboratory practices were followed and there is a clear dose-response relationship between exposure and nasal cancer in the rat. Information on concurrent controls, specifics of exposure, and age of each rat at death was compiled. The route of administration is directly applicable to worker exposure, and the lower concentrations (2 and 5.6 ppm) bracket OSHA's existing 8-hour PEL for formaldehyde. In addition, biologically significant malignancies were observed in the CIIT mice, and the production of squamous cell cancers of the nasal cavity in rats has been confirmed in two independent studies in the same and a different strain of rat. This information satisfies the criteria described in OSHA's Cancer Policy to support a finding that formaldehyde is a potential occupational carcinogen. There is no evidence in the record that would lead OSHA to conclude that humans and rats react differently to formaldehyde.

Available information is sufficient to conclude that in the rat, formaldehyde is a direct carcinogen acting at the site of application. The three animal inhalation studies indicate that formaldehyde is probably a respiratory system carcinogen in mammals.

The results of the TIAQS suggest that there are interactive effects between formaldehyde and other chemicals. Differences between the effects of paraformaldehyde and formalin were seen in some tests: more rapid excretion of carbon dioxide in expired air from formalin than from paraformaldehyde, antagonism of the carcinogenic action of BHT by formalin, and enhancement of BHT's carcinogenic action by paraformaldehyde. The first of these differences, in particular, may represent interactive effects between formaldehyde and methanol, present in formalin at concentrations up to 15 percent, because methanol is known to be oxidized within the body to formaldehyde.

The Strain-A mouse may not provide a reliable test model to indicate the likelihood of a carcinogenic effect in other strains or species [Ex. 70–35; Tr. 14–15, 78–79]. Certainly, the lung adenomas formed in this highly susceptible strain cannot be considered as demonstrative of a true risk of lung cancer in humans. The results with the Strain A mouse test have had little effect on OSHA's conclusions about actions to be taken.

(2) *Carcinogenicity—Human Data.* A number of epidemiological studies of individuals exposed to formaldehyde have been published in the scientific literature. The groups studied included anatomists, pathologists, morticians, chemical workers, and apparel workers. Many of these studies have also been reviewed by the International Agency for Research on Cancer (IARC) [Ex. 42–70]; the Environmental Protection Agency (EPA) [Ex. 42–40]; and the Epidemiology Panel of the Consensus Workshop on Formaldehyde [Ex. 70–56]. Their conclusions are also summarized below.

The epidemiological studies employ standard epidemiological methods which are briefly explained to assist the general reader who is not familiar with epidemiological terms. A proportionate mortality ratio (PMR) compares the proportion of observed deaths from a specific cause, such as suicide, in the group under study to the proportion of deaths expected from this cause in the standard or comparison population. A standardized mortality ratio (SMR) compares the ratio of the observed number of deaths from a specific cause in the study population to the number of deaths from this cause that would be expected in the general or standard population. The number of expected deaths is usually calculated from the known death rates of the standard population adjusted to the study population for age, sex, race and calendar time period. A case control study compares individuals who have a specific disease (cases) with similar individuals who do not have the disease (controls). The purpose is to determine if the two groups differ in the proportion of persons who have been exposed to a specific factor, in this case, formaldehyde. Statististical power (or power) is related to the number of individuals in the study population and is the ability of the study to detect a statistically significant increase in an effect, such as lung cancer, if one is present in the population.

(a) *Pathologists and Anatomists.* Stroup [Ex. 73–42] conducted a historical prospective mortality study of 2,317 men who were members of the American Association of Anatomists (AAA) for at least one year between 1888 and 1969. Stroup limited the study group to include anatomists, who had lived in the U.S. when they joined the association, and who contributed at least one year of follow-up. Seventy-eight (3.4%) of the anatomists were excluded from analysis because they had died, moved or were lost to follow-up before 1925, leaving 2234. Since reliable cause-specific mortality rates were unavailable for the U.S. population before 1925, person-years experienced between 1888 and 1925 were excluded from analysis. Deaths among the anatomists were compared with U.S. white male standardized mortality rates for 1925–79. Observed deaths due to brain cancer and leukemia were also compared to the expected based on rates from 1900 through 1974 for male members of the American Psychiatric Association (APA).

Stroup noted that formaldehyde has been the major active ingredient in fixatives and preservatives for approximately 100 years. Other potential exposures mentioned were to phenol, benzene, toluene, xylene, osmium tetroxide, picric acid, dioxane, butanol, glutaraldehyde, and acrolein. Stroup estimated from the few quantitative estimates available, that anatomists working with cadavers generally had been exposed to formaldehyde in the 1 to 3 ppm range, with intermittent exposures even higher.

Although exposure data were not available, Stroup determined the anatomists research or teaching interests and gathered information on techniques used in the field to help identify potential exposures. All anatomists were assigned to one of four groups: 45 percent were gross anatomists (most exposure to formaldehyde) and 53 percent were microanatomists (less exposure to formaldehyde). The rest included persons who were both gross and microanatomists (intermediate exposure) and those not in any of the three specialty groups (least exposure to formaldehyde). As of December 31, 1979, 799 (35%) died, 77 (3.6%) had moved out of the U.S., and 39 (2%) had been lost to follow-up.

When the mortality experience of anatomists was compared with that of U.S. white males, there was a significant excess of brain cancer (10 observed, 3.69 expected, SMR = 271, 95% CL = 130 – 498) and an excess to total leukemia (10 observed, 6.7 expected, SMR = 150). The excess of leukemia deaths could be attributed to a significant excess of chronic myeloid leukemia (3 observed, 0.34 expected SMR = 882). There were significant deficits in deaths from all causes (737 observed, 1129 expected, SMR = 65, 95% CL = 61 – 71), from all cancers (120 observed, 188 expected, SMR = 64, 95% CL = 51 – 74), from lung

cancer (12 observed, 43 expected, SMR=28, 95% CL=13–46), and from all non-neoplastic conditions.

Because of concern for ascertainment bias in the diagnosis of brain cancer and leukemia, Stroup compared the mortality experience of anatomists for these sites to that of psychiatrists. The incidence of brain cancer remained significantly elevated (11 observed, 1.9 expected, SMR=579, 95% CL =289–1036); the risk from chronic myeloid leukemia also remained elevated. Stroup also found that the risk of brain cancer was four times greater for gross anatomists who had been characterized as having the most exposure to formaldehyde, than for U.S. white males (7 observed, 1.74 expected, SMR=402, 95% CL=126–750). The death certificates for 11 of the 13 anatomists who died of brain tumors between 1920 and 1980 specified the cell type. All of these were glial cell tumors of neuroectodermal origin. One was a glioma, 6 were glioblastomas, and 4 were astrocytomas. Only 30–50% of primary intracranial neoplasms are of these cell types.

To further examine the possibility of ascertainment bias with regard to socioeconomic status and brain cancer, Stroup compared the observed number of primary intracranial neoplasms among anatomists to the expected based on rates for Rochester, Minnesota (where age and sex-specific incidence rates for brain cancer are available since 1950). The excess of brain cancer remained significantly elevated (10 observed, 4.7 expected, SMR=215, $p<.05$). The greatest excesses in brain cancer occurred in the 35–54 and 55–64 age groups, rather than in the elderly.

Some of Stroup's conclusions follow: (1) Brain cancer and chronic myelogenous leukemia are the only causes of death important among anatomists; (2) all 10 anatomists who died of brain cancer during the 1925 to 79 study period had glial cell tumors; (3) the SMR for brain cancer is greater when psychiatrists, with similar sociodemographic characteristics, were used as a reference group; (4) while the overall incidence of leukemia deaths was not significantly elevated there were significantly greater numbers of chronic myeloid leukemia deaths observed among anatomists; (5) brain cancer incidence remained significantly elevated even after expected deaths were adjusted for socioeconomic effects, but the etiologic agent responsible could not be identified; and (6) since there was a significant deficit in mortality from infectious diseases, it is very unlikely that infectious agents were responsible for the increased risk of gliomas among anatomists.

The Epidemiology Panel of the Consensus Workshop [Ex. 70–56] concuded that ascertainment bias is unlikely to be present in this study because the excesses of brain cancer and leukemia mortality remained significant in comparison to that of psychiatrists. Furthermore, the brain tumor observed among the anatomists were of a specific cell type that was out of line with distribution of cell types observed in autopsy series.

Harrington and Shannon [Ex. 42–59] conducted a historical prospective study of 2,079 male pathologists who were active members of the Royal College of Pathologists or the Pathological Society of Great Britain at some time between January 1, 1955 and December 31, 1973. Deaths within this group were recorded until the end of 1973 and compared with the mortality experience of the population of either England and Wales or Scotland, adjusted for age and 5-year calendar periods. Of the 156 pathologists who had died, death certificates were obtained for all but 5 (3%); 13 pathologists (0.6%) were lost to follow-up by the end of the study period. Among male pathologists in England and Wales, the investigators reported statistically significant increases in mortality from lymphopoietic system cancer (8 observed, 3.3 expected, SMR=242, $p<.01$) and from suicide.

Harrington and Oakes [Ex. 42–58] more recently followed the cohort of members of the Royal College of Pathologists from January 1, 1974 through December 31, 1980, analyzing the mortality experience of 2,720 members (2,307 males and 413 females). During the 6 years, 126 deaths had occurred (110 males and 16 females). Vital status was confirmed for 2,304 (99.9%) of the males and 411 (99.5%) of the females. Death certificates were obtained for all but 5 cases (96%). Most pathologists reportedly had been exposed to formalin during all or part of their professional lives, although levels of exposure were unknown. They were also exposed to a variety of other hazardous materials, such as phenols and TB bacilli.

Noteworthy among the findings of Harrington and Oakes was an excess of deaths from brain cancer (4 observed, 1.2 expected, SMR=331, $p<.01$, 90% CL=113–758). All four brain cancers were of the astrocytoma or glioma cell type.

Social class gradients were described by the authors as being relatively unimportant for this tumor (Social Class I SMR=108). They further stated that there had been no excess in brain cancer mortality among medical practitioners as a group. There were no significant excesses of mortality for other sites.

Levine [Tr. 239–245; Ex. 73–81C] examined the data cited by Harrington and Oakes in reaching their conclusions regarding social class gradients. He concluded that there was a social class trend with respect to brain cancer seen in persons over 65 years of age. However, the small number of deaths, 5 percent of the cohort, suggests that this is a young group and that the mortality experience of persons over age 65 would not be relevant to the interpretation of the study results.

Matanoski [Ex. 42–81] presented unpublished data to OSHA on the mortality experience of male pathologists who were members of the American Association of Pathologists and Bacteriologists (AAPB) and the American Society for Experimental Pathology (ASEP). Matanoski stated that this information had been collected to evaluate the possible effects of exposure to oncogenic viruses, not formaldehyde.

Among 1,336 AAPB members listed through 1969, Matanoski identified 381 deaths between 1915 and 1974. Among 1,439 members of ASEP, Matanoski identified 181 deaths between 1920 and 1974. Matanoski attempted to provide a closer comparison group by using data from the American Psychiatric Association (APA). The psychiatrists and pathologists were expected to have similar education and experience except that psychiatrists would not have had extensive exposure to formaldehyde or oncogenic viruses.

In addition, Matanoski examined the age-adjusted proportional mortality of members of the two pathology societies compared with the combined deaths of psychiatrists (APA), internists (ACP), and otolaryngologists/ophthalmologists (AAOO). Duplicate deaths in AAPB and ASEP (about 30% overlapping membership) were eliminated. Causes of death from each site in the nasal region were examined separately to determine whether excess proportionate mortality occurred at any specific site. Physicians in these societies were not characterized according to their exposure to various chemicals.

In the proportionate mortality analysis, there was a significant deficit of lung cancer for the combined groups of pathologists (12 observed, 21.4 expected, PMR=56, $p<.025$). When AAPB members were compared with the other physician groups, there was a significant excess of kidney cancer (7 observed, 3.2 expected, PMR=2.21,

$p<.05$). When ASEP members were compared with the other physicians, there was a significant excess of primary liver cancer (3 observed, 0.48 expected, PMR=622, $p<.025$). Two cases of hypopharyngeal cancer (PMR=34.9) were identified in members of AAPB as compared to the expected based on the mortality experience of other physicians.

Data were not analyzed by latency or by length of exposure, and it was not possible to determine the percent of each group of pathologists with 20 or more years of exposure and 30 or more years of observation. Matanoski concluded that there was an excess of primary liver, pancreas, and kidney cancers as well as other lymphomas in pathologists and that brain cancer may be more common than expected. She cautioned that these data only associated specific cancer risks with an occupation rather than with a substance.

(b) *Morticians, Embalmers, and Funeral Directors.* Walrath and Fraumeni [Ex. 42–124] studies the proportionate mortality experience of embalmers who were licensed to practice in New York State between 1902 and 1980 and were known to have died between 1925 and 1980. Subjects were identified through the Bureau of Funeral Services and Embalming of the New York State Health Department using registration files of recently deceased embalmers and a ledger containing all registered embalmers at the time of license application. Until 1947, New York State issued separate licenses for embalming and for funeral directing. Deaths among those who held only a funeral director's license were excluded from the cohort. Deaths observed among embalmers were compared with expected deaths by applying age, race, and calendar year-specific proportions of death for each cause among the U.S. male population to the total deaths by 5-year age and calendar periods. Proportionate Cancer Mortality Ratios (PCMRs) were also computed using the total number of cancer deaths as the denominator for calculating the expected deaths at each site.

According to the investigators, formaldehyde has been the main preservative in commercial embalming fluids since the turn of the century. Because actual exposure data were not available, the investigators assumed that individuals licensed as embalmers had greater cumulative exposures to formaldehyde than funeral directors.

Death certificates for 1,678 embalmers were requested but only 1,263 (75%) were received. White males accounted for 1,132 deaths and nonwhite males for 79. Ten women and 42 men of unknown race were excluded from detailed analysis.

Among the 1,132 white male embalmers, there were significant excesses of proportionate mortality from cancer of the colon (29 observed, 20 expected, PMR=143, $p<.05$), skin cancer (8 observed, 3.6 expected, PMR=221, $p<.05$), and arteriosclerotic heart disease (ASHD) (481 observed, 431 expected, PMR=112, $p<.05$). There were significant deficits of deaths from the respiratory system (52 observed, 68 expected, PMR=77, $p<.05$), accidental deaths, and rectal cancer (3 observed, 7.7 expected, PMR=32, $p<.05$).

Among the 79 deaths of nonwhite men, there were significant elevations in proportionate mortality from cancers of the larynx (2 observed, expected not stated) and lymphatic-hematopoietic system (3 observed, expected not stated), and from ASHD (33 observed, 21 expected). There were significant deficits for diseases of the respiratory system and from external causes (1 observed, 4.8 expected for both causes).

Since the year of last licensure was unavailable for decedents listed only in the ledger, it was not possible to measure length of employment or length of licensure. As an alternative, length of time from first licensure to death was used to approximate length of exposure. For white males licensed for 35 or more years, there was an especially significant excess of skin cancer (4 observed, 1.3 expected, PMR=308, $p<.05$). Embalmers who were more than 30 years of age at first licensure had especially significant excess mortality from skin cancer (5 observed, 1.3 expected, PMR=387, $p<.05$) and of the brain and central nervous system cancer (5 observed, 1.7 expected, PMR=294, $p<.05$). Mortality by type of license (embalmer only vs. both embalmer and funeral director) showed that PMRs for skin cancer (5 observed, 1.5 expected, PMR=326, $p<.05$), kidney cancer (6 observed, 2.4 expected, PMR=247, $p<.05$), and cancer of the brain and central nervous system (6 observed, 2.6 expected, PMR=234, $p<.05$) were significantly elevated only among those licensed as embalmers. Analysis by latency among those licensed solely as embalmers showed significant elevations of deaths due to cancer of the brain (5 observed, 1.9 expected, $p<.05$) among those licensed for less than 35 years and of the skin (3 observed, 0.5 expected, $p<.05$) among those licensed for 20 or more years.

As a whole, the group of embalmers experienced nonsignificant elevations in mortality from brain cancer (9 observed, 5.8 expected, PMR=156) and leukemia (12 observed, 8.5 expected, PMR=140). Of the 9 brain cancers, 6 were glioblastomas (67%), 2 were astrocytomas (22%), and 1 was a carcinoma (11%). Walrath and Fraumeni compared their findings with the brain cancer histopathology of the Connecticut Tumor Registry, where during the years 1935–1964 glioblastomas comprised 52 percent of all brain tumors, meningiomas 18 percent, astrocytomas 12 percent, and other cell types 18 percent.

Walrath and Fraumeni concluded that: (1) There was a significant excess of ASHD and a significant deficit of respiratory diseases and accidental deaths among the licensed embalmers; (2) site-specific patterns of cancer mortality were not sufficient to implicate formaldehyde as a carcinogen; (3) there was a significant excess of skin cancer among those licensed 35 or more years of licensure as embalmers and who began to practice embalming when they were older; (4) there were significant increases in proportionate mortality from skin, kidney, and brain cancer among embalmers, and (5) there was no excess of respiratory cancer.

Aside from the limitations of the PMR method in general, namely, the uncertainty whether an excess proportion of deaths from a specific cause reflects a real elevation in mortality or a deficit in the proportion of deaths from other causes, Walrath and Fraumeni stated that this study was limited by: (1) The embalmers and funeral directors being subjected to multiple exposures (tissue moisturizers, antiseptics, dyes, and deodorizers; (2) the unavailability of information of length of employment; (3) incomplete ascertainment of deaths among retirees (thereby understating risk, especially for the development of rare tumors); and (4) the insufficient power to detect rare tumors because of the small size of the cohort.

Commenting on the review of this study in the ORA Report [Ex. 43], Karrh [Ex. 44–14] pointed out that of the 8 observed skin cancers, 4 were malignant melanomas, 3 were squamous cell carcinomas, and one was of unspecified cell type. Since those skin cancers were of different histology, Karrh concluded that they should have separate etiologies. (In experimental animals, however, formaldehyde is known to cause two histologically different types of nasal tumors.)

In addition, Levine [Ex. 44–13] suggested a caveat for PMR studies: If death certificates are not obtained for all who died, more unusual causes, such as brain cancer, are more likely to enter

the files than common causes of death. He further stated that this would create an apparent cause-specific excess attributable to selection bias. Such conjecture seems unlikely, however, since a similar excess brain cancer risk was observed in the study of California embalmers.

Walrath and Fraumeni [Ex. 73–43] also studied the proportionate mortality experience of embalmers first licensed to practice in California between 1916 and 1978 and who were known to have died between 1925 and 1980. Study subjects were identified from licensure records of the California Bureau of Funeral Directing and Embalming. Expected numbers of deaths were based on age, race, and calendar year-specific proportions of deaths among the U.S. male population. PCMR were also calculated using the total number of cancer deaths as a denominator for calculating expected deaths at each site. Exposure included formaldehyde as well as coloring and modifying agents, anti-coaguants, surfactants, and deodorants. Of the 1,109 total deaths, 1,007 occurred among white males. Females and nonwhite males were excluded from subsequent analysis.

There were significant elevations in proportionate mortality from all cancers (205 observed, 170 expected, PMR=121 $p<.05$), brain cancer (9 observed, 4.7 expected, PMR=194, $p<.05$), leukemia (12 observed, 6.9 expected, PMR=175, $p<.05$), colon cancer (30 observed, 16.0 expected, PMR=187, $p<.05$), prostate cancer (23 observed, 13.1 expected, PMR=175, $p<.05$), ischemic heart disease (355 observed, 298 expected, PMR=119, $p<.05$), and suicide. Of the 9 brain tumors, 2 were glioblastomas, 3 were astrocytomas, 1 was an adenocarcinoma, and 3 were of unspecified types. There were significant deficits in proportionate mortality from respiratory system diseases (39 observed, 57 expected, PMR=68, $p<.05$), emphysema (4 observed, 10.5 expected, PMR=38, $p<0.05$), and all other causes.

Since detailed job histories were unavailable, length of licensure was used to approximate length of employment. Of the 1,007 decedents, 506 (50.2%) had 20 or more years of licensure. Mortality by length of licensure showed that among those licensed less than 20 years, there were significant excesses from all cancer (103 observed, PMR=136, $p<.05$) and colon cancer (13 observed, 186=PMR, $p<.05$). Among those licensed more than 20 years, there were significant excesses from colon cancer (17 observed, PMR=188, $p<.05$), prostate cancer (15 observed, PMR=181, $p<.05$), and leukemia (8 observed, PMR=221, $p<.05$).

Similar causes of death affected embalmers in both New York and California. Cirrhosis was a leading cause of death in both. Ischemic heart disease and colon cancer were significantly elevated in both groups, while there was significantly less diseases of the respiratory system, compared to the general population. The excess of brain cancer (statistically significant in the total group of California embalmers and significant only in New York embalmers who began to practice embalming at age 30 or later) is consistent with the findings in Stroup's study of anatomists [Ex. 73–42].

Levine *et al.* [Ex. 42–72] conducted a historical prospective study of 1,477 men first licensed by the Ontario Board of Funeral Services (OBFS) by examination during 1928–57. Since 1914, the names of undertakers qualified for licensure in Ontario were published by the OBFS annual directories. Persons were considered alive at the closing date of the study if records of the OBFS or Registrar of Motor Vehicles indicated that a fee had been paid or communication received on or after January 1, 1978. Expected deaths were computed by applying age and calendar year-specific mortality rates for Ontario males. Because the Ontario rates prior to 1950 were unavailable to the investigators, the mortality rates for U.S. white males were used as a supplement. Since Canadian mortality rates are similar to, but tend to be lower than U.S. mortality rates, the use of U.S. rates to generate expected deaths prior to 1950 would overestimate the expected and thus underestimate the cause-specific risks of dying.

Of the 1,477 men, 337 (23%) had died by January 1, 1978. The vital status of 209 (14%) was unknown. Death certificates were obtained for all but 6 (1.7%), who were known to have been killed during World War II. On average, each member of the cohort was said to have contributed 30 years of observation, but no actual data were given. There were statistically significant excesses of death from all nonmalignant diseases (228 observed, 220 expected, SMR-114, $p<.05$) and diseases of the digestive system (37 observed, 13.7 expected, SMR=197, $p<001$) compared with Ontario males and a significant excesss from cirrhosis of the liver (18 observed, 10.5 expected, SMR-171, $p<05$) compared with U.S. males. A significant excess of deaths from chronic rheumatic heart disease was observed when the investigators accounted for latency bey excluding the first 20 years of licensure.

Levine and his associates [Ex. 70–30] further analyzed the data from the 1,477 Ontario undertakers. The primary change was identification of the vital status of more of the cohort, including an additional 22 deaths. To compensate for the lack of Ontario mortality rates prior to 1950, the investigators determined expected deaths from mortality rates of Ontario men from 1950–77, and based SMRs on data from the 1,413 men living in 1950. Since there are secular increases in cancer mortality, such a procedure results in a bias toward an underestimation of risk.

Of the 1,477 men, 359 (24%) died during the observation period. Sixty-four who died or were lost to follow-up prior to 1950 were excluded from this analysis. On average, each member of the cohort alive in 1950 contributed 25 years of observation, was 33 years old when admitted to the study, and 58 years old at death. As in the previous study [Ex. 42–72], there were significant excesses of death from diseases of the digestive system (28 observed, 14.9 expected, SMR-188, $p<001$), particularly cirrhosis of the liver (18 observed, 7.6 expected, SMR-238, $p<001$), and from chronic rheumatic heart disease (8 observed, 4 expected, SMR-199, $p<05$). Eight of the 18 deaths (44%) from cirrhosis were specifically noted on the death certificates to have been of alcoholic origin. Among Ontario males in general, 34 percent of the deaths from cirrhosis are listed as being of alcoholic origin. The investigators also found three deaths from brain cancer (2.6 expected), including one astrocytoma and two glioblastomas. There were four leukemia deaths (2.5 expected).

The power to detect an increase in cancer incidence of 50 percent above that of Ontario males was 60 percent for lung cancer, 4 percent for nasal cancer, 7 percent for laryngeal cancer, 5 percent for skin cancer, 10 percent for buccal cavity and pharyngeal cancer, 20 percent for brain cancer, and 18 percent for leukemia, reflecting a limited ability to detect excess tumor incidence at these sites.

Levine *et al.* [Ex. 70–34] concluded that: (1) The study group appeared to have consumed more alcohol than the average, which may be related to the small increase in liver cancer, diseases of the circulatory system, and acute respiratory diseases; (2) it was improbable that formaldehyde would cause cirrhosis of the liver; (3) there were no excess deaths from bronchitis, emphysema, or asthma; (4) the small

increase in brain cancer and leukemia is consistent with other studies of embalmers; and (5) epidemilological data to date provide little evidence for the carcinogenicity of formaldehyde in humans at sites of contact.

Chemical Workers. Acheson *et al.* [Ex. 42-1] conducted a historical prospective study of 7,680 men first employed before January 1, 1965 in any of six British chemical or plastics factories where formaldehyde had been manufactured or used. The cohort was assembled using company personnel files. Workers first employed after January 1, 1965, workers for whom essential information was missing (3.9%), and women were excluded from the study. The expected numbers of cause-specific deaths were calculated by person-years using national (England and Wales) rates adjusted for age, sex, and calendar period. When a particular site demonstrated a significant excess of mortality, the national rates were adjusted in a crude manner using local SMRs for the years 1968–78 for lung cancer and 1969–73 for chronic bronchitis deaths. By the end of the follow-up period, December 31, 1981, 21 percent of the cohort had died. Only 2 percent of the study population was lost to follow-up.

Since exposure measurements before 1970 were not available, the investigators subjectively categorized each worker from recorded job skills into one of four exposure categories: high (>2.0 ppm), moderate (0.6–2.0 ppm), low (0.1–0.5 ppm), and background (<0.1 ppm). The year of first formaldehyde manufacture or use varied by factory: Plant 1–1955, Plant 2–1920, Plant 3–1950, Plant 4–1937, Plant 5–1937, Plant 6–1948. At all six factories, some formaldehyde was likely to have been inhaled either as particles of paraformaldehyde or of formaldehyde-based products. For all cohorts combined, 35 percent had been exposed to high (>2.0 ppm) concentrations and 25 percent to background levels, but plant 4 (British Industrial Plastic or BIP) contributed almost all (91%) the workers who were heavily exposed.

Compared with the national rates a significant excess of lung cancer (SMR=124, 95% CI=104–148) existed among workers employed at the BIP factory where the highest exposures to formaldehyde occurred, and there was also a borderline significant linear trend in increased mortality from lung cancer related to increased formaldehyde exposure levels. No relation was found between mortality from lung cancer and length of service for those categorized as having experienced high levels of formaldehyde exposure at BIP. An analysis by further subdivision of those with high exposure was, however, not provided. Mortality from lung cancer related to time period of first exposure to high levels of formaldehyde at BIP was also evaluated.

Men who entered the BIP factory between 1936 and 1946 (when exposure levels were probably the highest) had the highest mortality from lung cancer. In addition, Acheson *et al.* observed a significant excess of mortality from chronic bronchitis among BIP workers observed over the follow-up period 1937–1981 (79 deaths observed, 57 expected SMR=138, 95% CI=109–172). The authors stated that the SMR for chronic bronchitis was 188 for the years 1969–73 in the county where the BIP factory is located.

Acheson *et al.* found statistically significant excess mortality from malignant tumors of the bone (4 observed, 1.0 expected) in the factory with the highest exposure to formaldehyde and other pollutants. At another factory, the investigators found an excess of deaths from rectal cancer (5 observed, 1.3 expected) which was significant when compared with national rates, but not when compared with local rates. With data for the cohorts combined or for the BIP factory alone a significant deficit in all causes of death was observed (SMR=87).

While excess mortalities from brain cancer and leukemia have been noted in studies among professionals who use formaldehyde as a tissue preservative, with the data for all six factories combined Acheson *et al.* report [Ex. 42-1] a statistically significant deficit for cancer of the brain (5 observed, 12.5 expected) and a deficit for leukemia (9 observed, 11.4 expected). The authors did not provide analyses for deaths from these cancers for the BIP cohort alone although analysis for site-specific cancers for each plant were conducted.

Acheson *et al.* [Exs. 66-4; 73-2; 73-3] performed a further analysis of lung cancer mortality for BIP workers by cumulative exposure and duration of exposure to formaldehyde. There was no relation observed between the cumulative dose of formaldehyde and the incidence of cancer among the workers. The authors concluded that the results of this additional analysis oppose the view that formaldehyde is a lung carcinogen in humans, but do not exclude the possibility. Then also stated that the strength of the negative evidence is limited by the small number of men (605) exposed to "high" levels for more than 5 years and followed for more than 20 years after first exposure.

The study by Acheson *et al.* provides one of the relatively more detailed studies of industrial workers exposed to formaldehyde in the manufacturing of a variety of products. The major findings were the observations of a significant excess of mortality from lung cancer and chronic bronchitis among workers exposed to formaldehyde at BIP—the plant where the greatest percentage (73%) of workers experienced "high" formaldehyde exposure levels. As Acheson *et al.* pointed out, "in man, the bronchi are a credible target organ because inhalation of formaldehyde can cause respiratory symptoms and impairment in some cases." At the same time, these workers experienced a significant deficit from mortality from all causes.

Acheson *et al.* also demonstrated a significant exposure response relationship between formaldehyde exposure level and relative risk (expressed as an SMR) of dying from lung cancer. The authors tend to discount the exposure level-(lung cancer) response relationship observed because further analyses showed no relation between cumulative dose of exposure to formaldehyde and lung cancer mortality. They stated that the trend which was apparent with exposure level disappeared when duration of employment was considered because many "high" exposure men worked for only short periods of time (and presumably did not accumulate as much total dose. However, the exposure level-(lung cancer) response is consistent with of the biological response demonstrated in experimental animals. The CIIT study of cellular turnover rates in the rat nasal mucosa demonstrates a higher rate of turnover in the animals exposed for a shorter period of time to the same cumulative dose that resulted in much lower cellular turnover rate when exposed to lower levels over longer periods of time. Furthermore, Acheson *et al.* have demonstrated that the workers who entered the BIP factory during the period when exposure levels were highest, prior to 1945, demonstrated a significant excess of death from lung cancer. Little data were available for cohorts of workers exposed to "high" levels of formaldehyde at the other five facilities studied by Acheson to allow for a further evaluation of high level formaldehyde (lung cancer) response as observed among BIP workers. As the Epidemiology Panel of the Consensus Workshop on Formaldehyde stated after evaluating the data on lung cancer in the Acheson *et al.* study:

If formaldehyde is a human carcinogen, it might only be detectable through study of populations who experience high exposure levels, given the steep dose response exhibited in experimental animals.

Acheson *et al.* also tend to discount their observation of a significant excess of lung cancer among BIP workers exposed to formaldehyde because further analyses based upon a crude adjustment with local lung cancer rates for the period 1968–78 raised the expected number of lung cancer deaths from 103 to 124 as compared to 128 deaths observed from lung cancer over the period 1937–1981.

Such a re-analysis, however, may not be appropriate for the following reasons. Since there is a secular increase in lung cancer rates, the use of rates for 1968–78 to estimate expected deaths in the cohort followed over the period 1937–81 would result in an overestimation of the expected deaths and bias the results toward an underestimation of risk. Second, the application of a crude SMR for the 1968–78 period to the expected number of lung cancer deaths does not take into consideration age distribution differences between the cohort and the local population. This procedure results in a bias toward an underestimate of risk if the occupational cohort has an age distribution that is younger than the general population, which one presumes is usually the case. Third, in the absence of information related to risk factors in the local area such as air pollution, smoking habits and occupational factors within other local industries as pointed out by Acheson *et al.* it is not possible to determine whether the uses of local rates are appropriate for purposes of determining the expected number of lung cancer deaths in the occupational cohort.

Shindell has also expressed concern that the use of local comparison groups with higher than usual lung cancer rates may have obscured an independent effect of formaldehyde [Ex. 44–24].

The observation of a significantly increased risk of death from chronic bronchitis (79 deaths, 57 expected, SMR=138) among the same cohort of BIP workers that experienced a significant excess of lung cancer is also noteworthy in view of previous reports of asthma and pneumonitis associated with occupational exposure to high levels of formaldehyde. The authors stated that the SMR for chronic bronchitis was 188 in the local area for the years 1969–73, but gave no explanation for the selection of these years (other local rates were based on the years 1968–78), nor did they provide information on the stability of rates based on four years of death in the local community. Again, the same criticisms for use of local rates that applied to lung cancer apply to the use of local rates for chronic bronchitis deaths.

In view of the consistent excesses of mortality from brain cancer and leukemia observed among the professional groups exposed to formaldehyde, an additional noteworthy observation by Acheson *et al.* was the deficit of deaths from brain cancer and leukemia with the data for all cohorts combined. The statistical power to detect a 50 percent increase for these cancers was 44 percent. The authors did not present analyses for these cancers for the BIP cohort alone.

Marsh [Ex. 42–79] conducted a matched case-control analysis nested within a retrospective cohort study at a plastics production facility in Massachusetts. The cohort consisted of 2,490 male wage earners who worked for at least one year between January 1, 1950 and December 31, 1966. Expected number of deaths were based on U.S. average annual cause-specific white male death rates adjusted for age and calendar time. To adjust for geographic variations in mortality, expected deaths were also computed based on rates for both Massachusetts and the county from which the workforce was largely drawn. The county rates were limited to 1962–76 for noncancer deaths. In addition to formaldehyde, workers had potential exposure to cellulose acetate, polyvinyl butyral, amino plastics, polystyrene, vinyl chloride polymers, and numerous other products, and the authors made no attempt to characterize exposures of the workers.

Vital status for the period between January 1, 1950 and December 31, 1976, was determined for all but 7 terminated employees (0.03%). For those seven, person-years of observation were calculated until the date of termination. Death certificates were obtained for all but 12 (2%) of the 603 workers known to have died.

Marsh found a significant excess of genitourinary tract cancers (26 observed, 15.4 expected, SMR=169, $p<.05$) when compared with national rates. The excess remained significant ($p<.05$) when compared with both state and local rates. There were no reported deaths from nasal cancer. When the data were analyzed by interval from onset of employment, there was a significant excess of rectal cancer (6 observed, SMR=279, $p<.01$) among those with 30 or more years of latency, and significant excesses of cancer of the prostate (7 observed, SMR=281, $p<.01$) and genitourinary system (11 observed, SMR=211, $p<.01$) among those with 20 to 29 years of latency. When the data were analyzed by duration of employment, there was a statistically significant excess of genitourinary cancer (10 observed, SMR=255, $p<.01$) among those having 10 to 19 years of exposure.

The power to detect an increase in cancer incidence of 50 percent above that in U.S. white males was: 23 percent for buccal cavity/pharyngeal cancer; 84 percent for cancer of the respiratory system; 14 percent for cancer of the larynx; and 82 percent for cancer of the trachea, bronchi, and lung. Since the expected number of deaths from nasal cancer was not given, the power for detecting nasal cancer could not be calculated. It was not possible to determine the fractions of the cohort with 20 or more years of exposure and 30 or more years of observation following initial exposure to formaldehyde.

Marsh considered the major findings to be the significant excesses of cancers of the digestive and genitourinary systems. Without detailed information on work histories and occupational exposures, however, it was not possible to associate these excesses with particular jobs within the plant.

In the matched case-control analysis, two series of individually matched controls who died of causes other than cancer were selected from within the cohort for each of the 44 digestive system and 26 genitourinary cancer cases identified from the cohort portion of the study discussed above. For series 1 controls, each case was matched with four controls by race and age. For series 2 controls, each case was matched with 4 controls by race, age, and date of hire. For digestive system cancer, series 2 controls were also matched by place of birth.

Company industrial hygienists classified jobs into 21 occupational exposure categories (OECs), two of which had a potential for employee exposure to formaldehyde. Cases and controls were classified into those who did and those who did not work in each respective OEC. One individual could contribute exposure time to several OECs because of job changes. Evidence of risk was shown if a relatively higher percentage of workers representing cancer cases had been employed in an OEC than controls.

Marsh found a significantly elevated odds ratio of 8.90 ($p<.05$) based on 4 cases of rectal cancer among workers employed in cellulose nitrate production for periods greater than 5 years. There were no significant findings related to work in resins production or resins

processing, where formaldehyde would have been used or produced.

Marsh stated that matching of 4 controls to one case increased statistical efficiency and decreased confounding variables. The high follow-up (99.7%) in the cohort study eliminated the potential for incomplete case ascertainment. However, the reliability of the study was limited by uncertainty regarding actual exposures, the problem of multiple concurrent exposures, the small number of deaths in many subcategories, the problem of multiple comparisons and significance testing, and the lack of consistency between the two series of control groups.

Marsh [Ex. 42–80] subsequently conducted a proportionate mortality analysis on the deaths which occurred between 1950 and 1976 among male workers in the plant described above. There were 136 deaths among workers who had 1 or more months of potential exposure to formaldehyde. The number of observed deaths was compared with expected numbers calculated by applying cause-specific proportionate mortality of U.S. white and nonwhite males to the total number of deaths in whites and nonwhites after adjusting for age and time period. Expected deaths were also computed based on the rate between 1960 and 1976 for the county where the plant was located. The mortality experience of the workers exposed to liquid formaldehyde was compared also with that of workers exposed only to reaction products of formaldehyde with other chemicals. Complete work histories were obtained for all but one decedent. Death certificates were obtained for 132 out of 136 (97.1%) of the decedents in the formaldehyde-exposed group and for 448 of 456 (98.2%) of those who died in the group exposed to reaction products only.

Overall, no statistically significant excesses or deficits in proportionate mortality were observed. In addition, no significant differences in mortality were observed when the 136 male decedents were compared with their coworker controls.

To investigate the possibility that there is a does-response relationship between cancer mortality and formaldehyde exposure, Marsh also evaluated latency and calculated PMRs for the formaldehyde-exposed group relative to their length of employment in the formaldehyde area. The median length of exposure to formaldehyde was short, *i.e.*, 2.5 years and constituted only one quarter of their overall employment history at the plant.

Marsh found no evidence of a dose-response relationship between formaldehyde exposure and overall cancer mortality. For digestive system cancer, PMRs were higher for workers with greater than 5 years of exposure for latencies of less than 20 years, but the opposite trend was found for latencies over 20 years. For lung cancer, persons with greater than 5 years of exposure showed higher PMRs regardless of the number of years elapsed since initial exposure.

Liebling *et al.* [Ex. 42–74] conducted a proportionate mortality ratio study of formaldehyde exposed workers who died between January 1, 1976 and December 31, 1980. From seniority records, reports of former coworkers, and local newspaper obituaries, the investigators identified 24 male workers (18 white and 6 black) exposed to formaldehyde who had died. This analysis included one overlapping year from Marsh's study [Ex. 42–80], and added four subsequent years of observation (1977–80). Work histories were estimated from time clock numbers on seniority lists.

Proportionate mortality ratios were calculated to examine cause-specific mortality using the age, sex, race, and cause-specific mortality proportions of the U.S. and the county in which the plant was located. Age, sex, and race-standarized PCMRs based on county comparisons were also calculated. The investigators found significant elevations by both techniques for cancer of the colon (4 cases) and buccal and pharyngeal cancer (2 cases). A salaried employee who died from cancer of the nasal sinus and had exposure to formaldehyde was excluded from the cohort because only wage roll workers were studied. Both Karrh [Ex. 44–14] and Gaffey [Ex. 45–7] felt that too much emphasis was placed upon so few deaths and suggested that Liebling *et al.* combine his data with those from Marsh's study.

Wong [Ex. 42–129] reported the preliminary results of a historical prospective study of 2,026 white male workers employed at any time between start-up in the early 1940's of a chemical plant in Bishop, Texas, and December 31, 1977.

The plant at Bishop produced formaldehyde, but Wong did not provide a detailed analysis by work history or exposure because coding was still underway. The U.S. national age, sex, and cause-specific mortality rates for 5-year time periods from 1945–75 were applied to person-years to obtain the expected number of deaths. Of the 2,026 cohort members, 1,829 (90.3%) were alive on December 31, 1977; 791 (43.2%) were actively employed; 146 (7.2%) had died; and 51 (2.5%) were lost to follow-up. Of the 146 deaths, death certificates were obtained for all but 10 (6.8%).

Overall, there was a statistically significant deficit of deaths (146 observed, 197 expected, SMR=74, $p<.01$, 95% CI=63–87). There were significant deficits of diseases of the circulatory system (53 observed, 88 expected, SMR=60, $p<.01$, 95% CI=45–79), particularly arteriosclerotic heart disease (ASHD). There were also significant deficits of nonmalignant respiratory disease (3 observed, 9.4 expected, SMR=32, $p<.05$, 95% CI=6–94), and digestive system diseases (3 observed, 11.5 expected, SMR=26, $p<.05$, 95^{5} CI=5–76).

To eliminate the diluting effect of short-term employees, Wong analyzed the data by length of employment and found no trends with increasing duration. Wong stated that the value of his study was limited by the unlikely possibility that rare causes of death were missed with the members of the cohort lost to follow-up, by the cohort's being too small to detect any risk of nasal cancer of reasonable magnitude, by the lack of smoking histories, by the fact that the cohort was exposed to several materials in addition to formaldehyde, and by the unavailability of work histories at publication time.

While the power to detect deaths from all causes of cancer was 84 percent, the power to detect a 50 percent increase in cancer risk of the cohort compared with U.S. males was 43 percent for lung cancer, 10 percent for brain cancer (3 observed, 1.6 expected) and 1 percent for leukemia (2 observed, 1.7 expected). The power to detect laryngeal or nasal cancer could not be calculated from Wong's report. Forty-four percent (886/2026) of the cohort had 20 or more years of latency. The percent of workers with 20 or more years of exposure or 30 or more years of latency could not be determined.

Tabershaw Associates, Inc. (TAI) [Ex. 42–118] provided the final analysis of the study reported previously by Wong [Ex. 42–129]. There were 2,084 white and Hispanic males employed for any period of time between start-up (1945) and December 31, 1977. As in Wong's analysis, blacks and orientals were excluded from the cohort. No deaths were observed among the nonwhites. In addition to formaldehyde, TAI reported potential exposures to aliphatic alcohols, polyols, paraformaldehyde, trioxane, carbon monoxide, inorganic and organic pigments, benzene, asbestos, and ethylene oxide. Work histories consisted of chronological listing of all jobs ever held by each individual. Three criteria were used to

classify the study subjects as to the presence or absence of formaldehyde exposure: (1) Employment at the Bishop plant for at least one year; (2) assignment to units containing formaldehyde for at least 10 percent of the total time at the plant; and (3) exposure prior to 1977. Employees who did not meet all three criteria were classified as unexposed. The U.S. national age, sex, and cause-specific mortality rates for 5 year periods from 1940–75 were used to generate expected numbers of deaths. Of the 2,084 cohort members, 1,882 (90.3%) were alive as of December 31, 1977; 151 (7.2%) had died; and 51 (2.4%) were lost to follow-up. Death certificates were obtained for all but 14 decedents (9.3%), but all 151 decedents were incuded in the analysis.

Overall, there was a statistically significant deficit of deaths (151 observed, 216 expected, SMR=70, $P<.001$). There was a statistically significant deficit of nonmalignant diseases of the circulatory system (53 observed, 98 expected, SMR=54, $p<.001$). TAI stated that the total exposed cohort had too few deaths for meaningful analysis.

TAI also performed a case-control analysis of all cancer-related deaths in the cohort for five categories of cancer. Controls were cohort members, dead or alive, who had not died from cancer and who had less than 5 years of exposure to formaldehyde. Three white or Hispanic controls per case were matched on the basis of age. Exposure categories were graded by years of employment as <5, 5–15, and >15, the relative risk for the earliest period being assigned an arbitrary value of 1. Relative risk decreased with increasing years of both exposure to formaldehyde and employment.

TAI concluded that: (1) The overall mortality was low with no increased mortality in any worker category, (2) this study did not demonstrate an increased risk of death related to formaldehyde exposure, and (3) the case-control analysis did not demonstrate an association of death due to cancer with either duration of exposure to formaldehyde or length of employment. TAI stated that the utility of this study was limited by: (1) The excess deaths from unknown causes that could have been missed; (2) the need for additional follow-up of the young and small cohort for more meaningful analysis; (3) the lack of statistical power to detect rare cancers like nasal cancer; (4) the potential confounding effect of multiple exposures; and (5) the unavailability of quantitative exposure measurements prior to 1970.

While the power to detect deaths from all causes of cancer was 89 percent, the power to detect a 50 percent increase in cancer risk compared with U.S. males was 44 percent for lung cancer (11 observed, 12.6 expected), 18 percent for lymphopoietic cancer (6 observed, 4.8 expected) 8 percent for prostate cancer (4 observed, 1.6 percent expected), and 12 percent for brain cancer (3 observed, 1.7 expected). The power to detect laryngeal or nasal cancer could not be calculated since the expected number of deaths from these sites were not reported. However, cancer of the entire respiratory system, presumably including the nose, occurred in 12 cases whereas 13.1 cases were expected. The percent of the cohort with 20 or more years of exposure and 30 or more years of latency could not be determined. There were three deaths from brain cancer. Two were categorized as unexposed; one as exposed. The few deaths (151) and low power precluded drawing any conclusions on the cancer mortality experience of this group.

Fayerweather *et al.* [Ex. 42–44] conducted a matched pairs case-control analysis of cancer deaths among chemical plant employees. Cases were identified from active and pensioned male employees at eight DuPont plants. Exposure to formaldehyde for 481 cancer deaths and an equal number of controls was estimated from work histories. About 20 percent of each group was exposed to formaldehyde. The authors adjusted for age, sex, pay class, plant site, and smoking history but presented crude odds ratios having found that adjustment made little difference. Odds ratios for prostate and bladder cancer increased with an increase in the cumulative exposure index. Odds ratios were not substantially elevated for cancers of the brain, kidney, lung or hematopoietic system. The numbers of many cancers were insufficient for meaningful analysis.

(d) *Other Employment.* Stayner *et al.* [Exs. 73–40; 73–166] conducted a proportionate mortality study of garment workers exposed to formaldehyde that offgassed from permanent press cloth used to manufacture shirts. All three plants included for study had used fabric pretreated with formaldehyde resins since 1958. Workers whose survivors were eligible for death benefits were included in the cohort if they met one of the following criteria: (1) Employed at least 6 months and died within 6 months of the date last worked; (2) employed at least 6 months and disabled on the job; or (3) retired between age 62 and 65 after working at least 20 years if retirement occurred prior to 1975, or after working for 10 years if retirement occurred after 1976. About half (49.6%) of the deaths had 21 or more years of employment and 75 percent were white women. Expected proportionate mortality rates were calculated from the U.S. general population adjusted for sex, age, race, and calendar time. Data were analyzed according to duration of exposure, latency, and plant site.

Recent monitoring of formaldehyde in the air at two of the plants conducted in support of the epidemiology study indicated that employees working with cloth pretreated with formaldehyde resins were exposed to formaldehyde at concentrations ranging from 0.1 to 1.0 ppm. Past exposures, while undocumented, were believed to have been higher since recent changes have reduced the amount of free formaldehyde in cloth. Stayner *et al* assumed that an individual's exposure began on the date of initiation into the garment workers union or on January 1, 1958, whichever was later. Exposure was assumed to have ended on the last date of membership in the union.

The proportion of deaths from lung cancer was not elevated. There were significant elevations in mortality from buccal cavity cancer (parotid gland tumors, 3 observed, 0.40 expected, PMR=750, $p<.01$), cancer of the biliary passages and liver (3 cancers of the gall bladder, 1 cancer of the bile duct; 4 observed, 1.28 expected, PMR=313, $p<.05$) and cancer from other lymphatic/hematopoietic sites (3 multiple myelomas, 1 poorly differentiated lymphoma; 4 observed, 1.00 expected, PMR=400, $p<.05$).

The workers in all 3 plants with 10 or more years of latency and 10 or more years of exposure exhibited significantly elevated proportionate mortality from all cancers (51 observed, PMR=137, $p<.05$), parotid tumors (2 observed, PMR=952, $p<.05$), biliary passages/liver cancer (3 observed, PMR=467, $p<.05$), all lymphatic/hematopoietic cancer (8 observed, PMR=283, $p<.01$) and lymphatic/hematopoietic cancer other than of bone marrow (4 observed, PMR=761 $p<.01$). Among those with less than 10 years of latency and exposure, there was a significant increase in cancer of the digestive organs/peritoneum (10 observed, PMR=194, $p<.05$).

Brinton *et al.* [Ex. 73–7] conducted a case control study of 160 patients with primary malignancies of the nasal cavities and sinuses who entered four

hospitals in North Carolina and Virginia between 1970 and 1980. They reported an excess risk of nasal cavity and sinus cancer among female textile workers (RR=1.72) but not among male textile workers. The authors felt that sex difference in nasal cancer risk might reflect sex differences in jobs involving different types of exposures. Brinton *et al.* provided no information on the possibility of formaldehyde exposure to these workers.

Olsen *et al.* [Ex. 73-36] conducted a case-control study of 839 men and women, with cancer of the nasal sinuses, nasal cavities, and nasopharynx diagnosed in Denmark during 1970–82, selected from the files of the Danish Cancer Registry. Nine percent of the cancers were sarcomas and were excluded from the analysis, leaving 488 cases of carcinoma of the nasal cavity and 266 cases of nasopharyngeal carcinoma. Approximately three times the number of cases (2,465) were selected as controls from patients with cancer of the colon, rectum, prostate, and breast diagnosed during the same period. Controls were matched with the cases by sex, age, and year of diagnosis.

Each case and control was sought in the linked Pension Fund Cancer Registry and in the Danish Central Person Registry, which contains job titles for most Danes. Occupational histories were thus available from the Supplementary Pension Fund. Exposure histories were assessed by three industrial hygienists for specific predetermined exposures. The industrial hygienists were unaware of the case-control status of an individual. These histories revealed whether cases and controls had been certainly or probably exposed to formaldehyde or whether information regarding such exposure was unavailable. Among the controls, 4.2 percent of the men and 0.1 percent of the women had been exposed to formaldehyde.

Men exposed to formaldehyde had a statistically significant excess risk of carcinoma of the nasal cavities and sinuses (RR=2.8, 95% CI=1.8–4.3); those exposed to wood dust (RR=2.5, 95% CI=1.7–3.7); and paint, lacquer, and glue (RR=2.1 95% CI=1.4–3.0) had the same sort of risks. After adjustments were made for the confounding effect of wood dust and age, the relative risk of formaldehyde exposure was reduced below the level of significance, whereas the increased risk from exposure to wood dust remained significantly elevated. When there was a latency period of 10 or more years between first exposure and tumor diagnosis, the risk of nasal sinus cancer to males increased very slightly for formaldehyde (RR=3.1, 95% CI=1.8–5.3) and wood dust (RR=2.9, 95% CI=1.8–4.7), but remained the same for paint, lacquer, and glue (RR=2.2, 95% CI=1.4–3.5). There was no significant excess of carcinoma of the nasophary nx among any occupational exposure group.

The investigators concluded that: (1) Persons with exposure to both formaldehyde and wood dust were at higher risk of nasal cancer than were those with exposure to either one of these materials alone; (2) there was 80 percent power to detect a relative risk of nasal cancer of 2.0 among males; (3) formaldehyde exposure may lead to a slight increase in human nasal cancer; (4) when adjustment is made for exposure to wood dust, the increased relative risk of nasal cancer and exposure to formaldehyde is reduced below significance; (5) the joint effect of wood dust and formaldehyde appears to be additive; (6) there is a weak relationship between formaldehyde and nasal cancer in humans.

The investigators stated that their study was limited by: (1) The lack of further histological identification of tumors in the Cancer Registry data; (2) the inability to evaluate the degree of exposure; (3) a potential for misclassification of exposure information in the Register; and (4) a lack of information on occupations prior to 1964. There was, however, no recall bias of exposure histories because this study relied on occupational histories from national registries.

The Formaldehyde Institute [Ex. 45–1] criticized the Olsen study, contending that because there were no actual exposure data, the results of this study were speculative. In addition, because the relative risk of nasal cancer due to exposure to formaldehyde was not significantly elevated after adjusting for wood dust exposure, Levine [Ex. 44–13] stated that this study provides no evidence for the claim by Olsen *et al.* that there is an additive effect between wood dust and formaldehyde exposure.

OSHA has concluded that the study suggests an interaction between wood dust and formaldehyde exposure in the development of nasal cancer. This is the only study which has had sufficient power to detect a two-fold increase in the relative risk of nasal cancer.

Jensen and Anderson [Ex. 73–25] used the Danish Cancer Registry for the period 1943 to 1976 to examine the association between exposure to formaldehyde and the development of lung cancer by 84 Danish physicians (79 males; 5 females). From the Cancer Registery these 84 physicians were matched with 252 physician controls by age, sex, and survival to at least the time of development of lung cancer. The two groups were compared by medical specialities and on employment in pathology, forensic medicine, or anatomy. No male physicians with lung cancer has specialized in pathology (including forensic medicine and anatomy), but 8 of the group (9.5%) had spent some time in that occupation: 23 of the control group (9.1%) had done likewise. The risk in other medical specialities did not differ significantly from that among general practitioners. The authors concluded that the risk of developing lung cancer associated with employment at some time during a medical career in pathology, forensic medicine, or anatomy was not greater than that among general practitioners and that investigations of formaldehyde carcinogenicity should focus on detecting cancers of more proximal parts of the respiratory tract, such as the nasal cavities. However, that this study examined such a small population that any conclusions regarding site specificity of possible formaldehyde-related cancer would be premature.

At the Third International Conference on Epidemiology and Occupational Health, Hayes *et al.* [Ex. 73–45] reported unpublished results of a case control study containing 144 patients diagnosed between 1978 and 1981 as having primary malignancies of the nose and nasal sinuses. This study intended to identify factors associated with development of these tumors. Living controls were selected from municipal registries and deceased controls came from the Netherlands Central Bureau of Geneology. Of the 23 men interviewed who had adenocarcinoma, 14 (61%) were furniture makers. Suspect associations for histologic types other than adenocarcinoma were found among those exposed to paints, nickel, benzene, and formaldehyde, and among those employed in the floriculture industry. Without the actual data, OSHA is unable to draw any conclusions regarding an association between formaldehyde and nasal cancer.

Based on data from Finnish and Swedish national cancer registries and from Danish hospitals, Hernberg *et al.* [Ex. 42–64] conducted a collaborative matched pair case-control analysis of nasal and sinonasal cancer and its possible occupational etiology. Between 1970 and 1980 the authors identified 167 persons who has nasal cancer but were still alive. They were matched by country, sex, and age at diagnosis with living patients who had cancers of the

colon and rectum. There were significant associations between nasal and sinonasal cancer and exposure to softwood dust and combined exposure to hardwood and softwood dusts. Welding, flame-cutting, and soldering were significantly associated with nasal cancer, as was chromium exposure. Occupations where formaldehyde exposure may have occurred showed no association with nasal cancer. Since actual exposure to formaldehyde were not available, and because of the confounding effects of exposure to wood dust, OSHA had determined that no conclusions can be drawn from this study so far as formaldehyde is concerned.

Coggon *et al.* [Ex. 73–13] conducted a case-control study of lung and bladder cancers using a job exposure matrix. Cases were all men under 40 years of age who died in England or Wales between 1975 and 1979. The underlying cause of death for each was recorded as cancer of the trachea, bronchus, or lung. Patients with tumors of nonepithelial origin were excluded. For each case of cancer of the bronchus, two controls who died from other causes were selected by matching for sex, year of death, residence, and date of birth. A similar method was used for bladder cancer cases, who were males under 50 who died during 1975 to 1979. Controls had died from any cause other than bladder cancer and were selected according to the same matching criteria as used for cancer of the bronchus.

Exposures to nine substances, including formaldehyde, were estimated from job titles recorded on the death certificates. An industrial hygienist constructed a job exposure matrix in which 223 occupational units were grouped according to their likely exposure to each of the nine substances. Relative risks were calculated for the group of occupations in which exposures were thought to occur. Within the matrix, exposures were categorized as high, low, or none. Estimated risks for occupational with high exposure relative to no exposure were examined for a dose-response effect.

Of the 223 occupational units listed, cooks, military forces, and construction workers showed significant excess cancer of the bronchus. Asbestos-related occupations showed a significant association with lung cancer as well as a dose-response relationship. No association was found between lung cancer and exposure to arsenic or chromates. Formaldehyde was associated with a significant excess of lung cancer (296 cases, 472 controls, RR=1.5, 95% CI=1.2–1.8, P<.001), but there was no dose-response relationship. The investigators stated that the association between lung cancer and occupations involving formaldehyde exposure was "impressive", but the absence of an increased risk in jobs with high exposure undercuts any assertion of a direct causal relationship. The authors concluded that the results regarding formaldehyde should be viewed with caution due to confounding exposures and the indirect method of estimating exposures.

Two other reports, a case-control study of 14,000 hospital patients [Ex. 42–21] and a historical prospective study of male textile workers who died between 1959 and 1963 [Ex. 42–83] have been cited in various reviews as possibly having some relevance to formaldehyde. Among patients, significant excesses of nasal cancer were found in brickmasons, textile workers, and shoemakers. Male textile workers, particularly fiber preparers have a significant excess of oropharyngeal cancer. Levine [Ex. 44–13] has noted that fiber preparers are not exposed to formaldehyde and that permanent press fabrics were not introduced until after these workers were exposed. Neither of these studies is capable of addressing formaldehyde's potential effects.

(3) *Summary of Evidence Regarding Cancer.* In summary, formaldehyde has been shown to be a carcinogen in two strains of male and female rats in long-term bioassays. This finding is supported by suggestive evidence of carcinogenicity in hamsters and mice and by the positive findings in short-term tests. Based on evidence in the record, OSHA concludes, consistent with its Cancer Policy, that formaldehyde should be treated as a potential occupational carcinogen. This conclusion is also consistent with the IARC evaluation that based, on experimental study results, formaldehyde is a probable human carcinogen.

Among the most noteworthy findings from epidemiologic studies are those of the professional groups who preserve human tissues with solutions containing formaldehyde and other chemicals. These groups consistently demonstrate increased risks of death from brain cancer and leukemia that do not appear to be the result of ascertainment bias. Such findings argue in favor of these occupations being causally related to an increased risk of death from these cancers. A brief review of potential chemical exposure for these groups indicates that formaldehyde is the only substance besides gluteraldehyde to which these groups are exposed and formaldehyde appears to be the only carcinogen to which all three groups are routinely exposed. Whether or not formaldehyde is the causative agent, however, cannot be determined as exposure assessments for these groups have not been reported in detail.

The lack of consistency between the professional groups as compared to the industrial cohorts, in terms of excess brain cancers and leukemias observed might argue against a causal association with formaldehyde. However, the inability to detect similar cancers in excess in the industrial populations studied may be the result of the limited statistical power of each study; differences in exposure classification, mode of exposure, interactions with additional substances to which workers are exposed in the occupational setting and the length of the follow-up period. With regard to the relative risk of death from brain cancer in relation to induction period among the professional groups, each time latency or induction period was considered in the analysis, the relative risk increased.

Among the other important epidemiologic observations is the significant excess of lung cancer observed among industrial workers categorized as having experienced high level exposure to formaldehyde. This cohort also demonstrated a significant correlation between formaldehyde exposures characterized as low, medium and high and increased relative risk of death from lung cancer. Since the lung is considered a target organ in humans because of past reports of respiratory symptoms associated with formaldehyde exposures, it is also noteworthy that this same cohort demonstrated a significant excess of mortality from chronic bronchitis.

On the other hand, the significant reduction in mortality from lung cancer among the professional groups might argue against formaldehyde being a causative agent in the industrial cohort. However, as stated by the Epidemiology Panel of the Consensus Workshop on Formaldehyde:

> * * * the most likely explanation for the deficiencies in lung cancer is that exposed professional workers have been compared with a reference population that has smoked more; data on smoking habit are not available in any of these studies [Ex. 70–56].

If OSHA assumes that the cancer risk assessment based on the findings in rats in the CIIT study is a reasonable measure of the carcinogenic response in humans, it may be difficult to detect significantly increased risks through epidemiologic evaluation unless the

cohorts studies are extremely large and are exposed to relatively high levels of formaldehyde. The OSHA risk assessment predicts that workers exposed to 3 ppm formaldehyde have an excess cancer risk of approximately 7 per 1,000 (0.7%) workers exposed to formaldehyde for an occupational lifetime. If formaldehyde was determined to be a human lung carcinogen, a cancer for which there is a 7 percent probability of death among adult white males, the relative risk or SMR from a study of workers exposed to 3 ppm should be approximately 1.10 (7.7% / 7.0%). Such a relative risk most likely would not achieve a level of statistical significance, even in a large study. In this context, it is again noteworthy that the study of Acheson, et al. demonstrated a significant excess of lung cancer (SMR = 124) among the cohort of workers where the largest majority experienced "high" levels of formaldehyde (greater than 2 ppm), but that an excess of lung cancer was not observed at 5 additional facilities where the majority were exposed to "low" or "nil" levels (less than 0.1 to 0.5 ppm).

In 1982, IARC reviewed published epidemiological studies of populations exposed to formaldehyde and concluded that the studies provided inadequate evidence to assess the carcinogenicity of formaldehyde in humans [Ex. 42–70]. According to IARC, the results of epidemiological studies available at that time were limited because of inadequate sample sizes, methodologies, and power to detect site-specific excesses of cancers.

In October 1983, the Epidemiology Panel of the Consensus Workshop on Formaldehyde [Ex. 70–56] reviewed epidemiologic studies in addition to those reviewed by IARC and drew particular attention to the excesses of malignant brain tumors and leukemia consistently reported in several groups of professionals exposed to formaldehyde, i.e., anatomists, pathologists, and embalmers. The Panel concluded that detection bias would not seem to account for the increased risk of death from these cancers. The Panel also stated these findings did not necessarily implicate formaldehyde, though it was unclear what other important occupational explosures these groups shared. The Panel also indicated that there was some evidence of a dose-response relationship between exposures to formaldehyde and lung cancer and that if formaldehyde is a human carcinogen, it might only be detectable through study of populations who experience high exposure levels given the steep dose response in experimental animals.

The EPA reviewed epidemiological evidence available in 1984 for its decision, pursuant to section 4(f) of the Toxic Substances Control Act, (TSCA) to list formaldehyde as a substance for priority review. The EPA concluded that the available epidemiologic studies suggested formaldehyde might be associated with brain cancer and leukemia [Ex. 42–40].

At this time, it is OSHA's opinion that the epidemiologic evidence suggests that formaldehyde may be associated with lung cancer, brain cancer and leukemia, but that the data are not conclusive. Furthermore, given the estimated quantitative cancer risks in industrial workers exposed to formaldehyde, it may not be possible to detect significantly increased risks through epidemiologic study.

VI. Risk Assessment

A. Introduction

The United States Supreme Court, in the "benzene decision", (Industrial Union Department, AFL–CIO v. American Petroleum Institute, 448 U.S. 607 (1980)) has ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made that there is a significant risk of health impairment at existing permissible exposure levels and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that "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 is practices" [488 U.S. 642]. The Court also stated "that the Act does limit the Secretary's power to requiring the elimination of significant risks" [488 U.S. 644].

Although the Court in the *Cotton Dust* case [American Textile Manufacturers Institute v. Donovan, 452 U.S. 490 (1981)] rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its previous position in "benzene" that a risk assessment is not only appropriate, but also required to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

OSHA has presented its views on risk assessment in detail in several proceedings [48 FR 1867, 48 FR 17292, 48 FR 45956, 48 FR 51124]. A summary of OSHA's approach to quantitative risk assessment is offered below as introduction.

Several approaches have been used to estimate cancer risk from exposure to toxic agents. A standard approach uses mathematical models to describe the relationship between dose (such as airborne concentration) and response (e.g., cancer). Generally, curves are fit to the data points observed at different exposure levels and these curves are used to predict the risk that would occur at exposure levels which were not observed. The shape of these curves is varied, ranging from linear extrapolations from the observed points through the origin (zero exposure and zero risk) to curves which may deviate far from linearity at the very highest and very lowest doses. The use of a particular model or curve can be justified in part by a statistical measure of "fit" to available data points, that is, a statistical test which measures how closely a predicted dose-response curve is to the actual observed data.

In all cases it is assumed that the mathematical curves are reflective of biological processes that control the biological fate and action of the toxic compound. To date, many of these factors have not been quantitatively linked to the mathematical models. Biological factors which may play important roles in the risk assessment are: (1) Dose of the material at the sensitive tissue; (2) the sensitive tissue(s) itself; (3) the nature of the response(s); (4) rates and sites of biotransformation; (5) toxicity of metabolites; (6) chronicity of the compound (cumulative nature of the material or its actions; (7) pharmacokinetic distribution of the material (especially effects of dose on the distribution); (8) the effect of biological variables such as age, sex, species and strain of test animal; (9) and the manner and method of administering the toxic materials to the test animals [48 FR 45969].

It is clear that all of these factors cannot be easily incorporated into a single mathematical mode. Therefore, careful selection of the data for evaluation in the model is important to the risk assessment in order to make use of as much information as possible. In cases where several data sets are available, the results of different approaches applied to different data sets should provide a guide as to the optimal approach to risk assessment.

and they should compare logically with each other.

Several different mathematical models are discussed in this preamble. Most of the models are based on theories of cancer development, such as the onehit, the multistage, and the gamma multihit models. Other models commonly used for risk assessment (such as the probit, logit, and Weibull models) have developed from tolerance curves of responses to toxic substances. These are often applied in the prediction of cancer but have also been used to predict risk for other actions of toxins. A linear model is generally used for epidemiologic data due to its biological plausibility and simplicity of use.

B. Selection of Data for the Dose-Response Curve

1. *Selecting a Suitable Data Set.* The first step required in performing a quantitative risk assessment is the choice of information used to define the dose-response curve. In the case of formaldehyde, one set of data clearly stands out as superior—the CIIT study in rats. The CIIT study examined three dosage levels, in addition to a concurrent control group. It was also conducted under conditions presently believed acceptable for chronic animal bioassays for cancer. Histopathology at the tumor site was more extensive than usually performed in a standard bioassay protocol. This study has also withstood considerable public scrutiny so that any design flaws or experimental errors have been identified and reconciled.

There was considerable support for the use of the CIIT rat study for quantitative risk assessment. The Risk Estimation Panel of the Consensus Workshop found that:

> Data from the CIIT inhalation chronic bioassay are suitable for modeling the dose-response relationship. The data from the formaldehyde studies in Syrian hamsters and the CIIT mouse inhalation study provide information on risk, but do not provide sufficient dose-response information for quantitative model fitting [p. 335, Ex. 70–56].

In addition, the CIIT rat data was employed in every risk assessment submitted to the record (Exs. 42–29, 42–31, 43, 45–5, 69–23B3, 69–15, 73–115, and 73–149). Thus, OSHA has concluded that the CIIT inhalation bioassay in rats forms a strong foundation on which to base a quantitative assessment of risk from formaldehyde exposure.

As in many risk assessments, there are some drawbacks in using the data on rats for assessing human risk. An interspecies correction must be made to apply the dose-response curve to humans. No experimental data clearly establishes how this conversion should be done. The CIIT rat results are highly nonlinear and only attain statistical significance at the highest dose, and there may be large uncertainties associated with extrapolation to low doses. Additional uncertainties may exist regarding lifetime risk because there was serial sacrifice of the animals. Consequently, OSHA has examined the other information available to determine if it would assist in defining a dose-response relationship to represent formaldehyde carcinogenesis.

Reviewers [Exs. 44–11; 45–1] have recommended that OSHA give consideration to the epidemiological data available by using this information to set upper confidence limits on human risk from exposure to formaldehyde. Even a nonpositive epidemiologic study could be used to establish upper confidence limits on human risk. As a minimum, however, an estimate of exposure of the worker cohort to the toxic substance in question must be available. This requirement rules out the use of nearly all the human data on formaldehyde. Of the studies remaining, Fayerweather [Ex. 42–44], for example, estimates exposure but the results are complicated because the cohort has mixed exposures to other unidentified chemicals.

In a second example, NIOSH conducted exposure assessments for garment manufacturing [Ex. 77–38] in support of the Stayner study [Ex. 73–40]. Exposure estimates were at or below the 1 ppm limit being considered by OSHA for the revised formaldehyde standard, with an average of only 0.17 ppm. Durations of exposure of workers to formaldehyde were as short as 6 months. Given such short exposures to such low levels, the failure to find excesses of lung and nasal cancer is not surprising.

A third epidemiologic study, the Acheson study [Ex. 42–1], is sufficiently sensitive to detect lung cancer, but the cohort is young, only 21 percent of the cohort having died. As will be discussed later, results from time-to-response analyses of the experimental animal data [Ex. 45–5] indicate that the risk of cancer from exposure to formaldehyde should be disproportionately associated with later life. Thus, epidemiological studies conducted while most of the cohort is still alive (such as the Acheson study) will almost certainly underestimate the true lifetime risk of cancer from exposure to formaldehyde.

OSHA has examined the human studies that possibly implicate formaldehyde as a carcinogen and concludes that epidemiologic studies presently available provide information insufficient for defining dose-response relationships. OSHA anticipates that such an analysis can be conducted when the NCI study, presently underway, is completed. At this time, OSHA has not relied on the epidemiologic results to assess risk of lifetime exposure of workers to formaldehyde.

It has also been suggested that OSHA should place greater weight on the results of other studies of carcinogenicity in animals [Exs. 44–1; 45–1; Tr. 412-414]. Although some of these, in particular the studies conducted at NYU and by Tobe and associates, provide strong corroboration of the CIIT study, they should not be used in place of the CIIT study to define the dose-response curve. The NYU study involves only one dose, and the study by Tobe *et al.* contains a much smaller number of animals. While it has been suggested that the variant results may be indicative of differences in the strains tested, discrepancies between the first NYU study, the second study, and the CIIT study are clearly much more dependent on the extent of histopathology conducted on the nose than on possible strain differences. (The histopathology of the nose conducted in the CIIT study was much more extensive than in the NYU study). This suggests that there may be an underdetection of risk based on any of the experimental animal studies—particularly where tumors were smaller at lower doses—because histopathology can never provide a total analysis of all the nasal tissue.

Sielken [Tr. 385] has examined the risk predicted by use of the dose-response curve derived from the CIIT data on the mouse. As noted earlier, where tumors were observed in the rats at both 5.6 and 14.3 ppm, cancer was found at only one dosage level in the mouse (14.3 ppm) and the incidence was not statistically significant. Hence, predictions of risk from the mouse data may contain a much greater degree of uncertainty than assessments based on rat data. OSHA believes there is a specific biological phenomenon which accounts for the observed differences in the incidence of cancer in the two species, and this is discussed below.

Much of the initial research conducted at CIIT in followup to the chronic bioassay focused on this marked difference in nasal cancer incidence observed in the rats and the mice. When investigators at CIIT examined respiratory depression due to sensory irritation in rats and mice, they discovered an important difference in their responses [Ex. 69–23E]. At 15 ppm,

mice reduced their minute volume (the volume of gas inspired or expired per minute) by about 80 percent in response to formaldehyde. Rats did not reduce their respiratory exchange as much as the mice, but they still showed a 45 percent reduction [Exs 70–23; 70–24]. The CIIT investigators also defined the surface area of the nasal cavity for each species, which permits calculation of the area on which formaldehyde acts [Ex. 73–164]. Using both the minute volume and the surface area data, Golberg calculated that, at the same level of exposure to formaldehyde (15 μg/1) the rat receives a dose of 0.154 μg/min/cm² while the mouse receives only 0.07 μg/min/cm² [Ex. 70–24]. In other words, the mouse exposed at 14.3 ppm in the CIIT study received only about 50 percent of the effective dose that the rat received at the same level of exposure. Noting this species difference, CPSC and others chose not to include these data in calculating risk estimates because, after adjusting for these differences, any assessment of human lifetime risk based on mouse data would yield results identical to those already calculated based on cancer incidences in the rat. Hence, on the basis of this finding, OSHA has chosen not to conduct a separate analysis of the mouse data.

At this time, OSHA does not believe that species differences regarding reflex apnea (involuntary breath-holding) in the presence of irritating substances are particularly relevant to the worker. An employee performing a job would generally be unable to lower his or her breathing rate. Thus, when dose-response curves are derived from data on cancer incidence correlated with airborne exposure, the rat data are preferred over the results for mice since less breath-holding took place and therefore, this data may represent a situation more typical of human exposure.

2. *Corrections for Early Death.* Several methods have been employed for modification of data on tumor incidence to correct for the serial sacrifice in the CIIT study. For example, one assessment assumed all animals were considered to be at risk [Ex. 45–5]. In another assessment, only animals killed at 24 months were used [Ex. 69–15]. Other corrections include: Exclusion of all animals dying or killed before the first tumor was found at 11 months, prorating lifetime so that the animals contribute to the risk estimate only the portion of their expected average lifetime that they actually lived, and exclusion of all animals dying or killed before 24 months even though some had developed nasal cancer. These methods are discussed in more detail below. All of these methods are artificial and a life-table type of analysis would be preferable. Time-to-tumor models discussed below try to incorporate some life-table characteristics, but in the absence of these data, several of the corrections discussed below represent appropriate handling of the data. While the method used to calculate the number of animals at risk introduces uncertainties which may overstate or underestimate the expected risk, most commenters agreed that some method should be employed to adjust for early deaths.

First, Seigel *et al.* [Ex. 42–109] adjusted for early death by defining the number of rats at risk to include those killed or dying after the appearance of the first squamous cell carcinoma at 11 months provided that the nasal cavity had been examined histologically. Because there was no difference in the tumor response between male and female rats, the results for each exposure group were combined. This gave tumor incidences of 0/216, 0/218, 2/214, and 103/200 at exposure concentrations of 0, 2.0, 5.6, and 14.3 ppm, respectively.

To account for the different periods of time that animals were at risk, CPSC [Ex. 42–31] eliminated from consideration all rats sacrificed at 6, 12, and 18 months and any animals whose nasal cavities were not histopathologically examined. This led to corrected tumor incidence data of 0/157, 0/159, 2/155, and 95/145 at exposures of 0, 2.0, 5.6, and 14.3 ppm, respectively. All animals were assumed to be exposed for about 13 percent of their lifetime, even though some died before the end of the 24 month exposure period.

In a similar fashion, the ORA assessment [Ex. 43] calculated the number of rats at risk by eliminating animals killed before 24 months, those animals whose nasal cavities were not histopathologically examined, and all animals dying before the first tumor was observed at 11 months. This leads to corrected carcinoma incidence data of 0/156, 0/159, 2/155, and 95/145 for exposures of 0, 0.2, 5.6, and 14.3 ppm, respectively.

In calculating the effective number of rats-at-risk, EPA in a draft risk assessment [Ex. 73–149] concluded that all rats dying before the first squamous cell carcinoma was identified at 11 months were not at risk. Rats sacrificed at 12 and 18 months were handled as if they would have responded in the same manner as those that remained alive after the respective sacrifice. This approach yields corrected data of 1/156, 0/159, 2/153, and 94/140 at dosage levels of 0, 2.0, 5.6, and 14.3 ppm, respectively.

Lastly, Kenneth Brown [Ex. 69–15] investigated two methods for adjusting for early death. First, in applying a correction factor for rats that died or were killed early, Brown considered rats sacrificed at 12 months and 18 months to have been at risk for one half and three fourths of their lifetime, respectively. Animals that survived for 24 months or more were considered to have attained their approximate natural lifespan. This approach gave incidences of 0/199, 0/200, 2/200, and 103/199, at 0, 2, 6, and 15 ppm, respectively.

Second, in order to avoid adjustments to the data for interim sacrifices, Brown examined the prevalence of squamous cell carcinoma of the nasal cavity at 24 months. Using this "24-month conditional risk" criteria, (the "conditional" denoting that it applies only to animals that survive 24 months), the incidence of squamous cell carcinoma was 1/101, 0.94, 2/82 and 10/27 at the control and three dose levels. A summary of the adjusted incidences of squamous cell carcinoma for all of these risk assessment is given in Table 1.

As will be discussed later, the low-dose estimate of risk is higher for the 24 month survivors than it is for the population as a whole because the dose-response curve for the 24-month animals is less steep than that for the total group. Because of the lower adjusted incidence at 14.3 ppm (from 52% in the whole population to 37% in the 24-month survivors), coupled with a higher adjusted incidence at 5.6 ppm (from 1% to 2.4%), the dose-response curve approaches zero less rapidly for the 24-month survivors. This leads to a prediction of greater risk at low doses.

TABLE 1.—ADJUSTMENTS FOR EARLY DEATH CIIT INHALATION BIOASSAY *

Dose (ppm)	Adjusted incidence of squamous cell carcinomas							Adjusted incidence of polypoid adenomas
	Kang and Chu *	Clement *	CPSC *	ORA *	EPA *	Brown *	Brown "conditional" *	
0	[2]2/200	0/216	0/157	0/156	0/156	0/199	0/101	[1]1/156
2.1	5/200	0/218	0/159	0/159	0/159	0/200	0/94	7/159
5.6	7/200	2/214	2/155	2/155	2/153	2/200	2/82	5/155
14.3	99/200	103/200	95/145	95/141	95/140	103/199	10/27	2/141

* Ex. 12.

[h] Ex. 73-115. Based on Total Nasal Tumors.
[i] Ex. 42-29, 42-109.
[j] Ex. 42-31.
[k] Ex. 43.
[l] Ex. 73-149.
[m] Ex. 69-15.
[n] Number of rats with tumor/number of rats at risk.
[o] ORA (Ex. 43) and EPA (Ex. 73-149). Only the incidence at 0 and 2.1 ppm were employed in the risk assessment.

C. Brown [Ex. 55-A7] and Gaylor [Ex. 55-A24] have pointed out that prorating risk by fractions of a lifetime survived probably has a bias toward underestimation of risk. This bias would affect the assessments done by EPA and K. Brown. Crump [Ex. 55-A21] provided an explanation for this bias in observing that the probability of one cancer in 40 animals, each with a two percent probability of cancers, is not the same as one cancer in 20 animals each with a four percent probability of cancer. Crump recommended alternative approaches including exclusion of all interim sacrifice animals, inclusion only of those killed after 18 months, and use of time-to-tumor models such as the Weibull-multistage.

Sielken, and Crickett and Crump have developed time-to-tumor models for formaldehyde [Exs. 45-5; 69-23B3]. This type of model can introduce considerable uncertainty, however, where animals have been killed instead of being permitted to die. The uncertainties with regard to formaldehyde are so great that the advantages over quantal response models in predicting lifetime risk are erased. Interestingly, Sielken's approach and the 24-month correction used by the ORA report [Ex. 43] give similar results when a 5-stage model is used. the Crockett and Crump [Ex. 69-23 B3] model, which assumes 3 stages, yields results close to those of the Clement assessment, which uses a 3-stage quantal response model.

The greatest discrepancy in estimating the number of animals at risk among the various alternatives occurs at the highest dosage, 14.3 ppm. A difference of 24 percent is possible at this level (103 tumors/240 animals (43%) with no correction versus 95 tumors/141 animals (67%) if the animals that die before 24 months are excluded). Realistic estimates of risk would require some correction factor to account for early deaths. In this case, differences in methods employed are small. If the data are all fitted to the same mathematical model, the magnitude of error introduced by different corrections is small. If the model is allowed to describe the best possible fit to data, then estimates at low doses can be greatly modified as was described earlier for Brown's 24-month conditional risk model.

Sielken examined three methods for adjusting for early death. Each rat was considered to have a carcinogenic response only if it had a squamous cell carcinoma of the nasal cavity at the time of its death or sacrifice. This restriction was imposed by Sielken to ensure that only life-threatening lesions would be characterized as a "carcinogenic response." Three separate calculations for rats at risk were used: non-sacrificed rats (incidence of 2 tumors/160 rats at 5.6 ppm and 87/160 at 14.3 ppm), rats not sacrificed at 6 or 12 months (2 tumors/200 rats at 5.6 ppm and 93/200 at 14.3 ppm), and all rats (no tumors in 237 control animals, none in 238 exposed at 2 ppm, 2 of 235 at 5.6 ppm, and 103 of 224 at 14.3 ppm). Sielken noted that all three of these methods for calculating rats at risk yielded essentially the same results, so that determination of what constitutes the "best" approach is unnecessary.

3. *Benign and Malignant Tumors.* An issue was raised in the rulemaking regarding the treatment of benign and malignant tumors in the risk assessment. While squamous cell carcinoma of the nasal cavity were observed in the study, papillomas, the benign counterpart of squamous cell carcinoma [Ex. 70-56], were not seen in the CIIT rats. However, other benign tumors of the nasal cavity (polypoid adenomas) were observed at all three dosage levels in the CIIT study. These benign tumors are generally acknowledged to be formaldehyde related [Exs. 12; 42-131; Tr. 42: 107]. Moreover, according to a recent analysis:

> The presence of one malignant neoplasm in the high concentration group, exhibiting similar morphologic features to many of the polypoid adenomas, indicates that it may represent the malignant counterpart of the polypoid adenoma [Ex. 73-50].

There was some discussion as to the relevance of the benign tumors for human risk assessment purposes. The human counterpart of the rat polypoid adenoma is the microcystic papillary adenoma [Ex. 73-50; Tr. 252]. These adenomas in humans apparently constitute about 1.6 percent of all nose and sinus tumors and 2.4 percent of all benign tumors. These human tumors appear to arise from the surface epithelium, and none of the tumors examined were found to be malignant [Tr. 252-253]. (Conclusions which can be drawn from this data are limited, however, since only 17 cases were examined.) According to testimony given by Starr, benign tumors observed in experimental animals (mouse skin and rat liver) usually outnumber carcinomas by a ratio of at least 20-to-1 to 100-to-1 [Tr. 251]. The human data on the incidence of microcystic papillary adenomas and the rat data on the incidence of nasal adenomas versus adenocarcinomas indicate formaldehyde-related benign tumors may display a similar ratio of occurrence.

In general, OSHA holds that the presence of benign tumors should be interpreted as representing a potentially carcinogenic response. For example, the papillomas (the benign counterpart of the squamous cell carcinomas) in the NYU study provide evidence consistent with the finding of squamous cell carcinomas in the NYU, CIIT, and Tobe *et al.* studies. Likewise, the adenocarcinoma in the CIIT study and two similar malignancies found in the NYU study should be considered related to the findings of polypoid adenomas in the CIIT study and they should be attributed to formaldehyde. It should be noted that the degree of transformation of the related polypoid adenomas to their malignant counterparts in both humans and rats is very low. Consequently, it does not seen appropriate to weigh these benign tumors equally with the highly malignant squamous cell carcinomas in a quantitative risk assessment. Moreover, the recently published OSTP guidelines on risk assessment state that tumors with different toxic effects as endpoints should not be combined in assessing risk [Ex. 73-90].

Only two groups, EPA and ORA, have attemped to conduct a quantitative assessment of risk from polypoid adenoma formation. The incidence of these tumors was 1/156, 7/159, 5/155, and 1/241 at 0, 2.1, 5.6, and 14.3 ppm, respectively. Both assessments acknowledge the difficulties in predicting dose-response relationships from these data because the polypoid adenomas did not show a consistently increasing incidence of tumors with increasing dose. Both EPA and ORA eliminated the incidences of cancer at the two highest dose levels and based predictions of induction of cancer at low doses on a linear model, extrapolating directly from effects found at 2 ppm to zero dose. This extrapolation resulted in a risk of 5,625 excess cancer deaths per 100,000 at 3 ppm and 1911 excess deaths per 100,000 at 1 ppm. (Upper confidence limits on these risks were 10,472 per

100,000 and 3,260 per 100,000 at 3 ppm and 1 ppm, respectively).

Several reasons have been postulated to account for the partially inverted does-response curve. In excluding the tumor incidence at 5.6 and 14.3 ppm, ORA assessment noted that the changes occurring in the nasal passages, leading up to squamous cell carcinomas, could have masked the appearance of adenomas at the higher doses. This then, may account for the low incidence of adenomas at high doses (where the squamous cell carcinoma were seen) and it would provide a reason to reject the high dose data in the assessment of benign tumors as underestimating the risk. On the other hand, the EPA observed that at higher doses, cell type needed for these tumors to occur is lost sooner and to a greater extent with increasing dose. That is, there is replacement of the normal epithelial tissue by squamous cell [Exs. 43, 73–87]. Since less respiratory epithelium is available (which will support the benign type of tumors). EPA contends there is a smaller chance for adenomas to develop. Other factors thought to contribute to these discrepancies may be early deaths at the highest dose and differences in time to tumor, however, at this time, it is not possible to predict exactly how the effects at any dose are modified by confounding factors related to formaldehyde's other toxic effects.

OSHA received considerable public comment on the ORA assessment of benign tumors during the peer review process and the public meeting. The omission of the data points at the two highest doses was criticized by CIIT and others [Tr. 246–253, 409–412]. The CIIT agreed that while the large size of the carcinomas and early deaths in animals in the 14.3 ppm group could have affected the ability to detect the much smaller adenomas [Tr. 246–253], the two small carcinomas found in the 5.6 ppm animals were not likely to have masked any occurrence of adenomas. In addition, according to CIIT, the adenomas do not occur at the same site within the nasal cavity as the squamous cell carcinomas. [Ex. 73–81G].

Several commenters have noted that combining weak benign tumor data with data on cancers would greatly weaken the confidence that can be expressed in the overall assessment of risk from formaldehyde exposure [Ex. 73–90; Tr. 248–249]. This is especially true for formaldehyde since its role in producing adenomas, in contrast to squamous cell carcinomas, has not been confirmed in separate studies. Futhermore, the dose-response relationship seen in the adenomas is inconsistent. However, if it is assumed that adenomas contribute to the total human risk of cancer, then the estimates of risk from the adenoma data would dominate estimates of risk in the low dose region.

Because of the lack of a dose-response relationship, questions regarding degree of malignancy, and the small number of tumors involved, there are uncertainties in any QRA that attempts to define a dose-response curve for cancer in humans based on the CIIT data on adenomas. Since the results at 2 ppm are within the range of OSHA's interest without any further extrapolation or speculation, OSHA has decided to use this information to express the risk associated with development of polypoid adenomas without further correction. Using the incidence of tumors at 2 ppm. OSHA predicts an excess risk of benign tumors of approximately 4% (7/159–(1/156)). At this time, OSHA does not believe that it is possible to determine the extent to which lowering exposure will diminish this risk.

C. Risk Estimation Models

Because of the complexity of the carcinogenic process and the fact that so little is understood abut the pathogenesis of cancer. There is uncertaintly in describing the shape of the dose-response curve for carcinogens when data from high doses are used to predict risk at low dose. In general, there are usually no data points in the low dose region to aid in defining the curve. Hence, investigators often turn to mathematical models in an attempt to describe the relationship between dose and response at low doses.

There are several families of models which are generally employed. These include models that rely on a tolerance distribution, Those that are based on mechanism of cancer development, models based on time-to-response and pharamacokinetic models. Examples of mechanistic models include models which assume that cancer develops at the final stage in a series of cell alterations (the multistage model), and those that assume multiple hits are needed before cancer will develop (the multihit model). Several mathematical models available for risk assessment can adequately predict the shape of the dose-response relationship for formaldehyde in the region of the observed experimental data. At low doses, the behavior of different families of models may vary. Since present circumstances do not provide adequate information to identify any one model as the correct expression of formaledhyde's carcinogenic effects, OSHA has examined a number of models in order to understand the range of estimates which may be realized from this data.

While there are uncertainties in extrapolation of the risk of developing cancer from exposure to formaldehyde, confidence in the estimates of risk made from the data is raised by the fact that the experimental data are close to the range of interest. The 3 ppm PEL being revised falls within the range of the experimental data (2 ppm was the lowest concentration tested). The range of risks predicted by the various models does not show great variability at 3 ppm. At lower cencentrations applicable to worker exposure, for example 0.1 to 2 ppm, variability may increase but not nearly as much as is observed at even lower concentrations.

1. *Mechanistic and Tolerance Distribution Models.* In previous quantitative risk assessments of experimental animal data, including several risk assessment for formaldehyde, OSHA has consistently shown a preference for the multistage model of carcinogenesis. This model assumes that the toxic response is the result of an ordered series of biological events and that the occurrence of each event is linearly related to dose. The multistage model can take different forms (in order to conform with different data sets) by assuming a different number of dose-related stages. The linearized multistage model is based on the assumption that when a small dose of a given carcinogen reaches the target tissue, its effect adds to those of other causes of cancer. Since the dose is relatively small, the effects of the carcinogen being explored are augmented by background components in inducing a carcinogenic event. The shape of the overall dose-response relationship at low doses becomes virtually linear, whatever its shape at the tested doses.

The Consensus Workshop Risk Estimation Panel examined the concept of low-dose linear extrapolation. They observed that this extrapolation is not equivalent to fitting a straight line to the experimental data. Linear extrapolation is intended to be used only at doses where adequate experimental information could not be attained because of the large numbers of animals required to measure small risks. The Risk Estimation Panel was able to reach agreement that a linear, low-dose, nonthreshold extrapolation provides an upper limit in the sense that true risk to rats is not likely to exceed this limit. Many members of the panel suggested that linear, low dose, nonthreshold extrapolation should be used in risk assessment. The Risk Estimation Panel,

however, failed to reach a consensus as to either the practical application of these upper limits for human exposures or the exact range of the low dose region over which a linear extrapolation might reasonably be performed [Ex. 70–56].

OSHA was also unable to determine the range that might suggest use of the linearized multistage model although the limited epidemiological evidence now available suggests that any additive effects, if they occur, are well below the region of OSHA's interest. However, no human data is available at this time for comparison with estimates from a linearized multistage model in the 2 to 5.6 ppm range.

In addition, Crump has discussed these properties in relation to the formaldehyde data noting that:

> I hold to the view that the true response is probably linear at low doses . . . It is quite possible that the curve is linear through . . . 5.6 ppm and at 14.3 ppm the mechanisms become saturated and the response . . . nonlinear. If this is the case, the low dose risk would be about that predicted by the linearized multistage model . . . If mechanisms become saturated at lower doses the response could still be linear at the lowest doses, but with the slope far smaller than that . . . for the linearized multistage model. Since we don't know [which of these situations holds], we can't rule out the possibility that the risks are about as large as those predicted by the linearized multistage model [Ex. 55–A50].

Siegel *et al.* [Ex. 42–109] gave several reasons for why they preferred the multistage model to define the dose-response curve: (a) It is based on multistage theories of carcinogenic development for which there is extensive empirical evidence; (b) it is generally compatible with a wide variety of plausible biological mechanisms; (c) it has provided a good fit to many empirical sets of data; and (d) it tends toward conservatism by predicting linearity at low doses, at least for an estimated upper limit on risk.

In performing their quantitative risk assessment, Seigel *et al.* used the multistage model with three dose-related stages. The model has only one positive term (in the cubic term). That is, the carcinogenic response is a function of the cube of the exposure level resulting in a concave upward curve with a steep slope.

Other assessments in the record have employed multistage models with more than three dose-related stages. Mathematically, higher order terms can be used since the model is restricted to require a dose-response curve that is nonnegative at all points of the curve [Tr. 387–388]. For example, both the ORA assessment and the EPA assessment examined multistage models unrestricted by the number of exposure levels. Under these circumstances, the squamous cell carcinoma dose-response curve best fit a 5-stage model with positive coefficients in only the fourth and fifth terms. The 5-stage model gave a better fit to the experimental data than one restricted to three stages.

K. Brown of NIEHS adopted a third approach to fitting multistage models to this data. Brown examined five risk assessment models. Three (probit, logit, and Weibull) were threshold models and two (multistage and gamma-multihit) were mechanistic models. For the multistage model, no attempt was made to restrict the number of terms in the polynomial used to describe the dose response curve. The best fit to the data was obtained with a fifth degree polynomial having positive coefficients in only the two highest terms. When Brown used his "24-month conditional risk" data set, however, multistage model fits a polynomial of degree four having coefficients that are positive in the two highest terms.

Several reviewers have commented that the three-stage multistage model should not be considered because it does not possess sufficient flexibility to fit the data within a reasonable degree of assurance [Exs. 45–1; 55; Tr. 387]. Schultz, however, observed that the original formulation of the multistage model did not anticipate curves in which there would be more dose-related stages in the model than there are dose groups. He commented:

> The use of higher order terms in the model simply to achieve a better fit with the observed experimental data takes advantage of an inherent [mathematical] property of the model for which there is no biological basis. Goodness-of-fit is only one (and, perhaps, the least important) of several reasons for selecting a model for low-dose carcinogenic risk [Ex. 44–11].

There are also several other families of models which have been suggested for the prediction of cancer risk. The Weibull model has received considerable attention and possesses certain advantages as a representative tolerance distribution model. Crump [Ex. 55–A22], noted that the Weibull model is simpler and has a stronger theoretical basis than the gamma multihit model. He further explained the derivation of the Weibull model:

> If the gamma multihit is used to represent probability of cancer arising in a single cell line and different cell lines all compete to become the first to become cancerous, then the Weibull model results.

There is no reason to believe that formaldehyde carcinogenesis is a single event in a group with different tolerance levels leading to a response. Rather, the data shows that the events at 14.3 ppm represent a complex series of events all of which influence cancer response. Thus, a tolerance distribution model is not considered by OSHA to be an accurate representation of the action of formaldehyde and therefore, may not describe the risk appropriately. Other models offered to describe the dose-response relationship are the probit and logit models. These models tend to be less conservative at low doses than the Weibull model. Since they offer no theoretical advantages over the multistage or the multihit models, OSHA has not developed an assessment relating to the probit and logit models at this time.

There is still some controversy over which model should be used in predicting risks from formaldehyde exposure. While EPA examined several models in its draft risk assessment, it based its Section 4(f) determination of unreasonable risk on a three-stage multistage model. Hence, to incorporate some of the uncertainty inherent in selection of a model, OSHA has based its best estimates of risk on a range of models

2. *Time-to-Response Models.* Sielken also applied low dose risk modeling and extrapolation procedures to the CIIT rat data to determine the risk of cancer due to formaldehyde inhalation [Ex. 45–5; Tr. 399–409]. He examined three families of models to determine their impact on the calculation of risk. These included the multistage model, the Hartley-Sielken time-to-response model, and the Weibull model.

Both the Weibull model and the multistage model apply to only one end point, cancer, in a single specified time interval. The third model, developed by Hartley and Sielken also takes into account the impact of the dose level on the length of time until a carcinogenic response occurs. For both the multistage model and the time-to-response model, Seilken set the maximum number of dose-related stages at five. Since the first nasal cancer was detected just prior to 12 months, only latency periods below 12 months were employed. Seilken also examined the results from the multistage model restricted to have fewer terms than the number of dosage levels, but he rejected this model, however, because he felt it was insufficiently curved to provide a good fit to the experimental data.

As can be seen in Table 2, the three models employed by Sielken yield maximum likelihood estimates (MLEs) of the risk that are very similar. This estimated probability was relatively

insensitive to selection of a latency period (eg. 0, 6, or 11 months). In contrast, the probability of a carcinogenic response was highly dependent on the age of the rat with nearly all of the risk occurring only after the large majority of the lifetime had passed. For example, for a given concentration of 1 ppm, Sielken calculated that the risk resulting from a length of exposure equal to 1/2 of a rat's lifetime are only 1/6 the risk associated with exposure for a full lifetime.

If humans respond in the same manner as the CIIT rats, Sielken's results may go far to explain why the epidemiologic studies has been inconclusive so far. Epidemiologic studies of formaldehyde workers have generally involved relatively young cohorts with only a small percentage of deaths. Sielken's time-to-response model indicates that this early experience may not be a good indicator of ultimate lifetime risk.

TABLE 2.—PROBABILITY THAT A RAT WILL DEVELOP A CARCINOGENIC RESPONSE BY THE END OF AN AVERAGE RAT LIFETIME [a], BY DOSE (SIELKEN)

Dose level (ppm)	Time to response [b]	Weibull [c]	5-stage multistage [c]
0.1	8×10^{-3}	2×10^{-10}	8×10^{-10}
0.5	5×10^{-2}	3×10^{-3}	6×10^{-3}
1.0	3×10^{-1}	6×10^{-4}	9×10^{-4}
2.0	4×10^{-1}	1×10^{-1}	2×10^{-1}
3.0	2×10^{-1}	8×10^{-1}	9×10^{-1}

[a] Assumed to be 25.5 months.
[b] Assumed latency period of 11 months.
[c] Based on exclusion of rats sacrificed at 6, 12, and 18 months.

A drawback to Sielken's assessment is that he does not provide any suggestions on how to perform a species-to-species conversion. Thus, he has not made an attempt to make the findings from extrapolation of the CIIT rat data relevant to workers exposed to formaldehyde. The paper addresses only continuous exposures at a roughly constant concentration where exposures occur for 6 hr/day, 5 days a week. Seilken, himself, acknowledges:

> In many practical situations, there are intermittent exposures or exposures where the dose level changes over time. These situations should be recognized as different . . . and call for special risk assessment techniques . . . the development of such techniques is in its infancy . . . [Ex. 45–5].

The situation, which is recognized by Sielken, causes large uncertainties in other risk assessments, as well.

Crockett and Crump [Ex. 69–23B3] applied a time-to-death-from-tumor model, to data on squamous cell carcinomas of the nasal cavity in the CIIT rats. For a fixed time, this model collapses to the multistage model. For a fixed dose, the model reduces to a Weibull distribution in time. Exposures were based on lifetime average daily doses (LADDs) reported previously by EPA [Ex. 42–41]. No attempt to adjust exposure rates to account for anatomical differences between rats and humans was made.

Since the CIIT report did not list causes of death for the animals, it was assumed that all nonscheduled deaths of animals with tumors were due to the tumors. Parameters for estimation of risk were determined as follows. The number of animals on study was 240, 240, 240, and 231 at 0, 2, 5.6 and 14.3, ppm, respectively. Mean daily exposure concentrations were estimated by averaging concentrations for periods of actual exposure over all days during all periods, including weekends and holidays and all hours of the day. The results of these adjustments were 0, 0.35, 0.96, and 2.42 ppm average concentrations related to the nominal concentrations of 0, 2, 6, and 15 ppm, respectively. Average lifetimes were assumed to be 70 years for humans and 945 days for rats. Working lifetimes for humans were assumed to be 40 years. The basic assumption used to estimate human risk was that extra risk would be the same whenever both species are exposed to the same LADD.

The time-to-death-from-tumor model fit a cubic model. MLEs of extra risk were 740/100,000 at a 0.35 LADD (2 ppm occupational exposure equivalent), 71/100,000 at a 0.16 ppm LADD (1 ppm), and 7/100,000 at 0.085 ppm LADD (0.5 ppm). At 0.5 ppm, Crockett and Crump's estimate exceeds Sielken's estimate by a factor of 700, and at 2 ppm the estimates are larger by a factor of 60.

While EPA's draft assessment rejected time-to-tumor models, because of difficulties in dealing with sacrificed animals, there are also advantages to such an approach. For example, such models automatically account for consequences of tumor-induced early death, and they appear to involve less uncertainly than some approaches used to correct for early deaths. Thus, OSHA has not ruled out the time-to-response models of Sielken and Crockett and Crump as devices that can augment information about risk from formaldehyde exposure.

3. *Pharmacokinetic Models.* A customary procedure in quantitative risk assessment is to use the administered dose as the independent variable in describing a dose-response relationship. This implicitly presumes a linear relationship between administered dose and biological activity of the chemical in the target tissue. However, the metabolism and pharmacokinetics of some chemicals are known to be nonlinear [Ex. 56]. To overcome these difficulties some investigators have recommended the use of plausible pharmacokinetic models for assessing risk [Ex. 69–23B4]. According to Paxton *et al.*, however, these pharmacokinetic models have not been accepted as valid for general use because:

> They tend to be considerably less conservative than the currently accepted low-dose extrapolation models without having been demonstrated to be biologically accurate [Ex. 56].

In 1983, Hoel *et al.* [Ex. 69–23B4] proposed a model for assessing cancer risk based on the conclusion that the carcinogenic response should be proportional to the concentration of specific types of DNA adducts. It was further suggested that empirical data on the relationship between cancer incidence and effective dose could then be fitted to a one-hit model [Exs. 56, 63].

For formaldehyde, estimates exist of the total number of DNA adducts formed at several concentrations of formaldehyde, derived from a study conducted by Casanova-Schmitz and coworkers [Ex. 62]. Casanova-Schmitz *et al.* examined the mechanisms by which radioactively labeled carbon (^{14}C) in ^{14}C-formaldehyde was transferred to macromolecules in the respiratory and olfactory mucosa and in the bone marrow of Fischer-344 rats exposed for two 6-hour periods to formaldehyde at concentrations of 0.3, 2, 6, 10, and 15 ppm. The major route of nucleic acid labeling at all concentrations and in all tissues was metabolic incorporation. Protein labeling in the respiratory mucosa was due mainly to covalent binding; evidence for covalent binding of formaldehyde to respiratory mucosal DNA was obtained at concentrations of 2 ppm or greater. While the binding to proteins increased in an essentially linear manner with the airborne concentration, the binding to DNA was significantly nonlinear with respect to airborne formaldehyde concentrations. For example, the formaldehyde covalently bound to DNA at 6 ppm was 10.5-fold higher than at 2 ppm. Casanova-Schmitz *et al.* noted that:

> The nonlinear increase in covalent binding to respiratory mucosal DNA with increasing CH_2O concentrations may be explained either by a decrease in the efficiency of defense mechanisms or by an increase in the availability of reaction sites on the DNA resulting from increased cell turnover [Ex. 62].

To directly compare risk estimates based on delivered versus administered dose, Starr and Buck [Ex. 63] used the data collected by Casanova-Schmitz

and coworkers at CIIT [Ex. 62] to develop a quantitative assessment of the risk of cancer from formaldehyde exposure. Starr and Buck assumed that any type of DNA-formaldehyde adduct formation could be used as a measure of the effective dose at the target site. The dose-response curve was derived from data on the incidence of squamous cell carcinoma of the naval cavity in rats in the CIIT chronic bioassay. To be consistent with a CPSC risk assessment used to support its decision to ban urea-formaldehyde foam, Starr and Buck employed tumor incidence rates through the first 25 months of the study, and they excluded animals sacrificed at 6, 12, and 18 months. Four quantal-response models were employed; the probit, logit, Weibull, and multistage models. The authors estimated a functional relationship between administered dose and delivered dose. The curve was approximated by two linear relations, one from 0 to 2 ppm and the other for concentrations above 2 ppm. For example, at an administered dose of 0.3 ppm, the relative concentration of covalently bound formaldehyde was 0.007 nmol/mg DNA/ppm. At 2.0 ppm, this relation changed to 0.011 nmol/mg DNA/ppm. From 5.6 to 15 ppm, the relative concentration of covalently bound formaldehyde remained fairly uniform, between 0.039 and 0.042 nmol/mg DNA/ppm. The ultimate effect of using this functional model for "delivered dose" to estimate low dose risk is to predict a smaller risk at doses below 2 ppm (airborne) than is predicted by models using administered dose. Since the relationship between administered dose and delivered dose at levels above 2 ppm was assumed to be approximately one-to-one, above 2 ppm, risk estimates for delivered or administered dose are approximately equal. The results are shown in Table 3.

It was hypothesized that the use of delivered dose might lead to linearization of the model in low-dose regions. In fact, Starr and Buck found only marginal improvements in fitting the models when delivered dose were substituted for administered ones.

TABLE 3.—ESTIMATES OF RISK BASED ON ADMINISTERED DOSE (A) AND DELIVERED DOSE (D) AT SELECTED AIR FORMALDEHYDE CONCENTRATIONS *

Concentration (ppm)	Dose measure	MLE *	95 percent upper confidence bound
0.1	A	2.51×10^{-7}	1.56×10^{-4}
	D	4.70×10^{-9}	6.19×10^{-5}
0.5	A	3.14×10^{-5}	6.09×10^{-4}
	D	5.86×10^{-7}	3.10×10^{-4}
1.0	A	2.51×10^{-4}	1.80×10^{-3}

TABLE 3.—ESTIMATES OF RISK BASED ON ADMINISTERED DOSE (A) AND DELIVERED DOSE (D) AT SELECTED AIR FORMALDEHYDE CONCENTRATIONS *—Continued

Concentration (ppm)	Dose measure	MLE *	95 percent upper confidence bound
	D	4.70×10^{-6}	6.24×10^{-4}

* Starr and Buck (1984), Ex. 63.
* Maximum Likelihood Estimated from Multistage Model.

Several factors could account for this failure to find linearity. First, cell turnover may play a concentration-dependent role in promotion of formaldehyde carcinogenesis. A second reason may be that DNA-adduct formation has not been proven to represent the sole mechanism of formaldehyde's carcinogenicity [Ex. 70–49]. While the studies of delivered dose versus administered dose may offer some insight into the relationship between dose and the number of tumors in rats, at this time, there is no evidence to support a similar relationship in humans.

Ashford and coworkers at the Center for Policy Alternatives (CPA) developed a mathematical model to assess human risk from exposure to formaldehyde [Ex. 70–1]. The model uses the information on squamous cell carcinomas in rats from the CIIT animal bioassay and converts the results to humans by use of a body surface area correction. The basis for the model was CPA's hypothesis that the most significant factor contributing to the nonlinear dose-response relationship seen in the CIIT study is caused by dose-dependent changes in the efficiency of the DNA repair process due to cell death and stimulation of cell division.

The CPA model is derived from the presumption that there is an equilibrium point where the generation of lesions by formaldehyde is equal to the loss of lesions through DNA repair and cell death. When a cell dies, it sends a signal to replicate to a proximate cell, and after a time lag, the cell replicates. CPA assumes this reduction in live DNA and the number of lesions to be proportional to formaldehyde concentration.

A carcinogenic transformation occurs when a signal to replicate is received by a cell with an appropriate lesion. (Not all lesions would necessarily result in neoplasia). The rate of tumor production is thus related to the division rate among live cells, which, in turn, is a function of the loss of cells from necrosis. The rate of cellular necrosis in the presence of formaldehyde, or other injurious chemicals, is a combination of the background rate of cell death and necrosis induced by exposure to formaldehyde.

Ashford *et al.* also applied a correction term that allowed for the possibility of multiple primary tumors in the same animal. Then, by assuming that the amount of formaldehyde at the active site is linearly related to the airborne concentration and that there is no situation where a progressive loss of cells occurs, CPA could quantitively estimate tumor production in rats at any dosage level.

CPA examined the number of life-years lost due to cancer induced by formaldehyde and how these would be altered through more stringent standards. Ashford *et al.* examined the 3- and 5-year survival rates for white males and females with nasopharyngeal cancer diagnosed between 1955 and 1964. From these data, the authors computed a log normal distribution for cancer survival after diagnosis. By assuming that the worker population developing nasopharyngeal cancer from exposure to formaldehyde would have a similar age distribution and survival experience, they estimated about 14–18 years of life lost per case of cancer of the upper respiratory tract due to formaldehyde exposure.

4. *Maximum Likelihood Estimates and Upper Confidence Limits.* It has been suggested that the greatest degree of uncertainty in assessment of risk from exposure for formaldehyde at low doses is the decision of whether to consider background carcinogenic effects as additive or independent [Ex. 42–31]. Since nasal cancer is a rare disease in man, it could be argued that the background cancer incidence contributes little, if any, additive risk. However, it is not clear, or even predictable, that there is a one-to-one site specific concurrence in target sites between humans and rats. Humans are exposed to many more carcinogens and tumor promoters (e.g. cigarette smoke, saccharin, aflatoxins) than a laboratory rat.

Since available data have suggested that formaldehyde can interact with several carcinogenic agents or processes, Crump, the EPA, and the CPSC all recommended use of the linearized multistage model at low doses which they felt represented an upper bound on the risk. For example, the CPSC assessment holds that even though the MLE gives the best fit to the experimental data, it does not necessarily give the best description of risk at low doses. The CPSC assessment recognizes that if formaldehyde cannot interact with background processes or other environmental carcinogens, then

the MLE estimate is appropriate. However, if interaction does occur, then the upper confidence limit (UCL) is a better estimate of risk at low doses.

OSHA has chosen the maximum likelihood estimates of risk to describe the best estimates of risk from formaldehyde exposure. To the extent that formaldehyde is acting as one of a group of common carcinogens, this maximum likelihood estimate would lead to an underprediction of risk. OSHA has particular confidence in the use of MLE's because, first, OSHA's estimates do not extend far beyond the region covered by the experimental data. Hence, extrapolation from the maximum likelihood curve seems highly appropriate.

As Sielken pointed out in his testimony:

> The value of a fitted model [the maximum likelihood estimate] at a particular dose is the estimate of the risk at that dose which is most consistent with the presumed family of models; that is to say, that the best estimate of risk under the presumed family of models is the value of the fitted model itself.
>
> In addition, to the model family's best estimate of risk at a dose level, a 95 percent upper confidence limit on that risk can also be constructed. . . . The purpose of a 95 percent upper confidence limits is not to estimate the risk but rather to be sufficiently large so that 95 percent of the time they exceed the true risk. 95 percent confidence limits are upper bounds on risk. They are not estimates of risk [TR 389].

Second, the additional evidence on the pharmacokinetic actions of formaldehyde indicate that the shape of the dose-response curve is highly nonlinear. Even at lower doses, the maximum likelihood curve displays this nonlinearity, whereas the upper confidence limit curve becomes approximately linear. Thus, the use of upper confidence limits as estimates of risk would not be reflective of the known biologics of formaldehyde action.

The ORA report indicated a preference for the use of the 95% upper confidence limits as a measure of risk. The report noted that the MLE, or the point estimate from the best-fitting dose-respone curve, would tend to underestimate risk due to anatomical differences between man and rat and apparently greater cytotoxicity in primates exposed to formaldehyde than in rats. In addition, in presenting an estimate of "total" risk, the ORA added the UCL of the risks based on the squamous cell carcinoma data and the UCL of the risks based on the polypoid adenomas.

The ORA report's conclusion that the UCL was a more meaningful measure of risk than the MLE was criticized at OSHA's public meeting. First, As Dr. Sielken noted, "different 95% upper confidence procedures can yield very different upper bounds on risk. In other words, there's not just one statistical way of computing upper bounds. There are many different procedures" [TR 395]. Thus, depending on the procedure chosen, one could get very different "estimates" of risk. Second, it was noted that if the point estimates, represented by the MLE, are incorrect by some factor related to improper species-to-species conversion, then the UCL is also incorrect. Rather than use the UCL, it would be more appropriate to resolve the discrepancy in the conversion factor.

Thus, as in previous quantitative risk assessments, OSHA has based its best estimates of risk on the maximum likelihood estimates. OSHA has tried to describe its uncertainties in the true estimates of risk by using a range of risks over a number of models. The additional biological evidence on pharmacokinetics gives OSHA confidence that the use of maximum likelihood estimates offers the best representation of the risk from exposure to formaldehyde.

D. Other Considerations

1. *Relative Susceptibilities.* Since OSHA is concerned with protection of workers and data used to define the dose-response curve is from rats, uncertainties enter into the analysis because of the lack of knowledge of the relative susceptibilities of rats versus humans. There are several difficulties in converting the incidence of rat nasal tumors to predictions of human risk since humans breathe more air than rodents, are larger, live longer, are not obligatory nose breathers, and may metabolize formaldehyde differently. Assumptions must allow for differences in body size, nasal surface area, target site, and metabolic rate. For example, differences in target tissue might be expected since humans, unlike rats, are not obligatory nose breathers. Also, the respiratory systems of the two species differ substantially.

Furthermore, workers are a more heterogeneous group than a specific rat strain; they are exposed to other substances that could be cofactors, initiators, or promoters of a carcinogenic response; some are exposed to formaldehyde in a particulate form, unlike the rat which was exposed to a pure gas generated from paraformaldehyde. Thus greater species variability in humans as compared to inbred laboratory animals can be anticipated. A distribution curve for the tolerance to formaldehyde exposure for humans would show a much broader distribution of responses than a similar curve for a single strain of rats. Hence, the range of carcinogenic response will be wide and proportionately more humans should develop cancer at lower doses. Without epidemiological data, no estimate of the magnitude of this effect can be made. Thus, it was suggested that an assessment of risk based on experimental animal data could cause a bias toward underprediction of human risk at low doses.

In assessing the human risk from exposure to formaldelhyde on the basis of the rat data Siegel et al. [Ex. 42–109] assumed that, in the absence of specific evidence, the intrinsic susceptibilities of humans and rats are identical. Seigel and colleagues suggested that this assumption introduces substantial uncertainties in the analysis. This approach is consistent, however, with the more recent recommendations of the Risk Assessment Panel of the Consensus Workshop [Ex. 70–53]. The Panel recommended that airborne concentration could be used as a surrogate for dose in the absence of better information at the present time.

Ashford *et al.* [Ex. 70–1] examined three types of conversion factors to account for differences in susceptibilities: the weight of carcinogen/body surface area times the fraction of lifetime exposed, the weight of carcinogen/body weight times the fraction of lifetime exposed, and intake/nasal sinus area. Ashford and colleagues used the CIIT data to determine that corrections based on relative body surface were more predictive than those based on relative body weight. The correction based on body weight predicted much too high an incidence and, for that reason, it was rejected. The conversion factor based on weight per body surface area—dose in humans equals 3.292 times dose in rats—was used by the authors as the most plausible correction. However, they did not take into account the much greater reflex apnea found at high exposure concentrations in the mouse than in the rat. Without such corrections, this approach is invalidated.

Factors are also needed to correct for a number of additional interspecies differences. These include duration of lifetime exposure, air intake by different species, and relative size of different species. CPA applied a linear correction for duration of exposure as a fraction of normal lifespan. In reaching this conclusion, Ashford *et al.* noted that because the increase in cellular necrosis from a single exposure is greater than linear, exposure at 10 ppm may be more than twice as dangerous as a similar exposure at 5 ppm. However,

experimental data give no reason to predict that the risk from two 3-month exposures for 6 to 8 hr/day at 1 ppm is anything other than the sum of the risks. The minute volume of respiration for male workers inhaling formaldehyde was estimated to be 20 liters as compared with 0.144 liters in the rat, which is only 60 percent of the normal ventilation rate for rats. Surface areas of mammalian bodies have been found to be functions of (body weight) ⅔, which means that the surface area of the human body is about 42 times that of the rat. Based on these presumptions, Ashford *et al.* estimated worker risk per year of exposure to be 2.35×10^{-5} (2.35 per 100,000) at 0.19 ppm. 9.8×10^{-5} (9.8 per 100,000) at 0.75 ppm, 3.2×10^{-4} (32 per 100,000) at 1.5 ppm, and 4.2×10^{-3} (420 per 100,000) at 3 ppm. From these figures, the authors estimated that 1,288 cancers per year (range 4 to 5,700) would occur without additional regulation. If compliance with a 30-minute ceiling of 2 ppm occurred, Ashford *et al.* estimated a residual cancer risk of 42 cases per year (range 2–370). For a STEL of 0.5 ppm, the predicted risk was 18 cancers per year (range 1–132).

Corrections such as calculation of an absorbed dose based on relative surface areas of the nasal cavity were also controversial. Based on CIIT data that estimated the absorbed dose rates to be 0.154 $\mu g/min/cm^2$ for rats exposed at 15 ppm and an estimate of the surface area of the human nose, Siegel *et al.* [Ex. 42–109] calculated a maximum dose to the nasal cavity for the male human of 1.47 $\mu g/min/cm^2$, which is about ten times that found in the rat. Siegel and coworkers also observe, however, that humans do not have to breathe through the nose, and the actual dose to the nasal mucosa could be much less.

In contrast, Squire and Cameron pointed out that structural differences existing between man and animals influence the flow of air currents through the nasal cavity which affects deposition on the epithelial surfaces. According to Squire and Cameron:

> Comparisons between the B6C3F1 mouse, the F344 rat, and man, based on normal minute ventilation and the surface area of the nasal epithelium, indicate that both rodents have approximately twice the relative surface area than man for filtering inspired air. This difference may be interpreted to indicate that man would receive a smaller target dose than rodents if both were exposed to a similar concentration [Ex. 70–31].

These two estimates may represent up to a 20-fold difference in estimated dose. Given these differences, the lack of high quality data on the human nasal surface area, the questionable interspecies comparability of noses, and the probability that target tissues differ for humans versus rodents, OSHA rejected nasal surface area corrections as inadequate for the performance of interspecies comparisons.

Ashford *et al.* also rejected a correction based on nasal surface area because of a lack of information on conversion factors and the implausibility that the nasal sinus area is the sole target site in humans, who can also breathe through the mouth.

Starr and Buck [Ex. 63] relied upon measurements of formaldehyde covalently bound to respiratory mucosal DNA during two 6-hr exposures to provide a measure of amount of formaldehyde actually reaching the target site. There are several difficulties with Starr and Buck's approach. First, the amount of formaldehyde reaching the target tissue in short-term relatively heavy exposures may not be representative of long-term "light" exposures. During short-term heavy exposures, substantial destruction of the nasal epithelium occurs; tissues eventually regenerate, but may contain types of cells not present originally (thus giving rise to the growth of different tumor types). Second, little improvement in the fit of the curve to the experimental data beyond that provided in a plot of the incidence of nasal cancer against the airborne concentration was found. Finally, it is not possible to fit the existing data to humans since no information exists on covalent binding of formaldehyde to human respiratory mucosal DNA.

Models developed by Ashford [Ex 70–1] and by Starr and Buck [Ex. 63] are considered to be too speculative at this time to apply their estimates of risk to worker populations. Ashford's model was derived from the premise that there is a saturable mechanism involved in the carcinogenic process. Starr and Buck assume that the concentration of formaldehyde actually transported to the target site is not linearly related to airborne exposure concentration. Both of these premises are possible, but neither one presents a complete carcinodynamic model. Moreover, Ashford's assumption regarding species-to-species extrapolation does not appear to hold in the light of calculations of the actual inhaled doses for rats and mice. In addition, the Ashford assessment for multiple tumors may need reexamination in light of information now available. Starr and Buck have stated that data do not apply to humans and are based on short-term test results. Thus, OSHA has not used either of these models to quantitatively assess human risk, although the implications of each for the relative risk at high versus low doses is explored.

Given the uncertainties involved regarding species-to-species extrapolation, OSHA has adopted the conclusions of the Consensus Workshop which stated that:

> Although there are differences in formaldehyde carcinogenicity among different species, at present there is no reason to assume that humans would be more or less susceptible than the rat. The panel can only assume that rats and humans exposed for the same proportion of lifetime will exhibit a similar carcinogenic response, all other influences being equal. The panel recognizes that this assumption is based on the lack of information and may change as further data become available [Ex. 70–56].

Thus, in modeling a dose-response relationship for humans from the CIIT rat data, the most appropriate expression appears to be the airborne formaldehyde concentration, as measured in the rats' exposure chambers. At this time, neither the target dose in humans nor the corresponding concentration of formaldehyde in workers' breathing zones can be calculated. It is understood that use of a unit correction factor for species-to-species extrapolation between rats and humans is a gross simplification of a very complex, but otherwise presently unresolved, issue. This step adds to the uncertainty present in the quantitative risk assessment, but the magnitude of the uncertainty and the direction of bias introduced cannot be estimated.

2. *Dose-rate Effects.* Since cell replication can be viewed as a compensatory response to cell damage and necrosis, the differences observed in cytotoxicity from acute and chronic exposures have implications regarding high intermittent exposures. Increased cell replication enhances the chances of formation of DNA adducts because more of the DNA necessary for reaction with formaldehyde (single strand DNA) is present. Thus, increases in cytotoxic effects would be expected to increase the probability of a subsequent carcinogenic response. According to Swenberg [Ex. 42–115]:

> A separate but related consideration is the relative importance of concentration versus cumulative dose. Cytotoxicity and increased cell proliferation appear to be related to the former. If one compares the cumulative dose to rats exposed to 15 ppm formaldehyde 6 hr/day, 5 days/wk (450 ppm-hr/wk) with that of rats exposed to 3 ppm for 22 h/day, 7 days/wk (462 ppm-h/wk) it is readily apparent that similar cumulative doses of formaldehyde resulted, yet the lesions and, presumably, the amount of cell proliferation are vastly different. It would appear then that

formaldehyde concentration is the most important consideration in determining response and that the response changes drastically when toxic concentrations are achieved.

The concept that concentration is a more important factor than cumulative dose was also explored by Clary who noted that:

A total dose can be considered by multiplying concentration by time. At 3 ppm in the Formaldehyde Institute Study, this would be equivalent on a total dose basis to 15 ppm at 6 months in the CIIT study. In the Formaldehyde Institute study, however, metaplasia was not observed in rats exposed at 1 ppm. Again, using the same logic, 1 ppm for 22 h/day, 7 days/week for 6 months would give an equivalent total dose equal to 5 ppm if exposure was only 6 h/day, 5 days/week for 6 months. Metaplasia was seen at 2 ppm in the CIIT study. This suggests that what we are looking at is not a total dose (concentration × time) but is strictly one of concentration [Ex. 42–28].

Since the information presented above indicates that the concentration may be more important than cumulative dose, the data on animal carcinogenicity will be applicable to humans only where exposures occur under approximately the same dosing regimen. At concentrations sufficiently high to cause promotion of cancer through cell proliferation (2 ppm and above), the actual concentration of formaldehyde played a more important role than the cumulative dose. In addition, exposure characteristics of the workplace permit recovery time during periods of non-work, for example, evenings and weekends. At low doses, this could be a factor in reducing risk; however, there are indications that this recovery time does not appear adequate to compensate for the great increase in cell damage at high doses [Ex. 42–115, 70–23].

Swenberg et al. reviewed data on cell proliferation in groups of rats exposed to the same daily dose (ppm × hr) but to different concentrations and durations of exposure [Exs. 42–115; 70–23]. As seen in Table 4 below, increases in cell proliferation occurred under all three test conditions. These increases depended on formaldehyde concentration and on location in the nose. In the most anterior portion of the nose, where mucociliary clearance is minimal, the increase in cell replication (5-fold) was approximately the same in all three exposure groups (ie, the cumulative dose model is the controlling factor). This was in marked contrast to the main portion of the respiratory epithelium, the primary site of squamous cell carcinomas and the area in which mucociliary clearance is prominent. In the midregion, cell proliferation was strictly concentration dependent and not dependent on cumulative dose.

TABLE 4.—Effects of Concentration and Time on Cell Turnover in Rats

Exposure	Percent labeled cells		
	Anterior epithelium 3 days	Central epithelium	
		3 days	10 days
Control	3.0	0.5	0.26
3 ppm × 12 hr	17.0	1.73	0.49
6 ppm × 6 hr	16.4	3.07	0.53
12 ppm × 3 hr	16.4	9.00	1.73

These results suggest that in the concentration range encompassed by OSHA's present standard, concentration may be of much greater importance than cumulative dose. This implies that the 10 ppm peak exposure permitted for up to 30 minutes under the current standard may carry a much higher cancer risk than an equivalent 6-hour exposure (0.83 ppm) as used in the CIIT experiment. Results from the CIIT bioassay itself supports this conclusion. There was a disproportionately large number of animals with tumors observed at the high concentration (67%) in relation to those responding at the lower dose (approximately 1% at 5.6 ppm). Thus while the data may be too scant for a quantitative assessment of risk from short-term exposures at this time, the available evidence indicates that short-term exposure to formaldehyde may present a serious carcinogenic threat, over and above the risk from long-term low-level exposure.

3. *Effects of Promoters on Cancer Risk.* The extremely nonlinear dose-response curve for formaldehyde leads to a very high degree of uncertainty in projecting risk from high to low doses. This curve appears to be representative of two separate processes. At high doses, factors other than genotoxicity play major roles in the carcinogenic response. The slowing down of mucociliary flow permits a greater amount of formaldehyde to penetrate to the nasal epithelium without undergoing reaction (and detoxification) or mechanical removal. Enhanced cell proliferation leaves much more single strand DNA available at any given times for reaction with formaldehyde. Thus, replication before repair occurs is much more likely, and this would directly affect the cancer incidence. Other possible, as yet unidentified, mechanisms leading to cancer promotion may also be involved.

The expression of a carcinogenic effect at lower concentrations is so small relative to the response at the highest concentration tested, 14.3 ppm, that an accurate projection to very low doses is not possible. The effects of promotion caused by tissue damage overwhelm the underlying information on formaldehyde as a complete carcinogen at the dosage levels acceptable for animal testing. Even at the lowest concentration tested, 2 ppm, no malignancies were identified, but slight cytotoxicity was seen. Thus, even at a concentration were cancer incidence rates are not measurable by a standard animal bioassy, an enhanced response due to the influence of promotion would be expected. This in no way constitutes evidence of a true threshold below which no cancer would occur since the results of short-term, *in vitro* tests clearly demonstrate that formaldehyde is capable of initiating a genotoxic reponse without regard to the use of a tumor promoter. However, these same data suggest that the risk associated with the low dose portion of the dose-response curve is very much lower than that seen at high doses even though these risks are difficult to quantify. Clearly, there is a need to assure that workers are never exposed at concentrations where effects of promotion begin to dominate the cancer incidence. At 3 ppm as an 8-hour TWA, a concentration which lies between the 2 and 5.6 ppm concentrations tested in the CIIT study, cytotoxicity would be expected. At the higher level of 5.6 ppm, less than a factor of two above the 8-hour OSHA PEL, frank carcinomas were seen. Thus, a PEL of 3 ppm is clearly within the the region of the dose-response curve where slight incremental changes lead to large increases in risk.

E. Estimates of Cancer Risk for Formaldehyde

1. *Summary of Risk Assessments.* A number of quantitative assessments of risk of exposure to formaldehyde have been conducted. While these studies generally rely on data from the CIIT rat inhalation study, the selection of the mathematical model used to define the dose-response curve varies, showing differences of opinion among authors as to how best to represent the risk of exposure to formaldehyde. The mathematical models most frequently employed were the 3 or 5 stage multistage models, but the Weibull tolerance model, time-to-tumor models, and pharmacokinetic models derived specifically for formaldehyde have also been used. Many different models can be fit to the CIIT data, but estimates of risk from the individual models diverge substantially at low doses. Examples of other methodological differences which result in variant estimates of risk are differences in the correction for serial

sacrifices, the correction factors used to extrapolate to different durations of exposure, and different opinions as to whether background effects and the carcinogenic response due to formaldehyde are independent or additive at low doses.

Kang and Chu [Ex. 73–115] prepared a risk assessment based on preliminary results from the CIIT rat study. Kang and Chu assumed that all 200 animals alive after the 6 and 10 month sacrifice were at risk. Based on incomplete results of the CIIT study, the numbers of animals bearing any type of nasal tumor were 2, 5, 7, and 99 at exposure concentrations of 0, 2.1, 5.6, and 14.1 ppm, respectively. (These figures differ somewhat from the final report of the CIIT study.) In assessing the lifetime risk of cancer in humans, the authors assumed that a direct conversion of dose (in ppm) in animals to dose in humans could be applied. By applying upper confidence limits (UCLs) of the multistage model, Kang and Chu estimated that at 0.1 ppm, 56 workers out of 100,000 would develop tumors. Corresponding risk estimates at exposure concentrations of 0.5, 1.0, 3.0, and 5.0 ppm were 280, 580, 2,300, and 5,500 tumors per 100,000 workers, respectively. In addition, a second method of estimating the risk at low doses was applied to the data. Using a model developed by Gaylor, Kang and Chu estimated 140, 720, and 1,400 tumors per 100,000 workers at doses of 0.1, 0.5, and 1.0 ppm, respectively.

A second quantitative risk assessment for exposure to formaldehyde was performed in 1982 by Clement Associates, Inc. under contract to OSHA [Ex. 42–29]. This work was published later by Siegel *et al.* in a peer reviewed journal, Regulatory Toxicology and Pharmacology [Ex. 42–109]. Siegel *et al.* concluded that the animal data must be used for the risk assessment because there were no adequate epidemiological data for estimating carcinogenic dose-response for human exposure. The CIIT rat inhalation study was selected to predict human risk since it was the only multidose oncogenicity study in animals available. Adjusting for the number of rats at risk in a manner different from Kang and Chu, the tumor incidence rates were 0/216, 0/218, 2/214, and 103/200 at exposure concentrations of 0, 2.0, 5.6, and 14.3 ppm, respectively. Based on a multistage model with three dose-related stages, Siegel predicted the excess number of cancer deaths from exposure to formaldehyde over an entire working lifetime at various concentrations [Exs. 42–29; 42–109]. These are given in Table 5.

TABLE 5.—LIFETIME RISK OF CANCER PER 100,000 WORKERS, CLEMENT ASSOCIATES (1982) [1]

Exposure level (ppm)	Maximum likelihood estimate [2]	95% upper confidence limit
3	620	930
1	23	130
0.5	2.8	58
0.1	<0.1	11

[1] Ex. 42-29. Based on incidence data given in Table 1.
[2] Multistage model with one parameter: q_1 000230.

In comments to HUD on a manufactured housing product standard [Ex. 42–31], CPSC described the methodology it used to estimate risk of cancer associated with residence in mobile homes. To define the dose-response curve, CPSC also used data from the CIIT rat study. CPSC examined other data, including the NYU study and the CIIT mouse study: the CIIT mouse data were not used because of the smaller number of animals at risk (due to unrelated early deaths) and the decrease in respiration rate that occurs when the mice are exposed to formaldehyde. The NYU study was not used because a single dose, 14 ppm, was employed which is inadequate to define the shape of the exposure response curve. CPSC chose the multistage model to calculate individual risk at low doses. CPSC gave estimates for two different ranges of the dose-response curve. If L is level of exposure administered for a lifetime (0.13×ppm for the CIIT rats), the lowest lifetime estimated excess risk was predicted from the maximum likelihood equation with five dose-related stages ($0.000037L^4+0.000011L^5$). At levels below 1 ppm, CPSC calculated the maximum lifetime estimated excess risk from the linear relation, 0.028 L. This UCL presumes interactions with background processes. At 1 ppm, CPSC calculated an MLE of risk of 4.8×10^{-2} (4.8 per 100,000) and a UCL of 2.8×10^{-2} (2800 per 100,000) as lower and upper bounds of individual risks, respectively.

The ORA assessment [Ex. 43] relied on the CPSC analysis to calculate estimates of risk with certain notable methodological changes. The number of rats-at-risk was calculated by eliminating animals killed before 24 months, those whose nasal cavities were not histopathologically examined, and all animals dying before the first tumor was observed at 11 months. In addition to predicting risks from the squamous cell carcinoma data, the ORA report also included a prediction of risk from the benign tumor (polypoid adenoma) data. Adjustments to the number of rats at risk of polypoid adenomas yield 7 tumors in 159 rats-at-risk at 2 ppm and 1 in 156 control animals.

The mathematical models chosen in the ORA report were the multistage model not restricted by the number of experimental doses and the one-hit model. Under these circumstances, the squamous cell dose-response curve best fit a 5-stage model with positive coefficients in only the fourth and fifth terms. The multistage model chosen gave a better fit to the experimental data than one restricted to three stages. A one-hit model was selected for the polypoid adenoma data. Predictions for lifetime risk using the above set of assumptions are presented in Table 6.

TABLE 6.—LIFETIME RISK OF CANCER PER 100,000 WORKERS, THE ORA REPORT (1984) [1]

Exposure level (ppm)	Squamous cell carcinomas [2]		Polypoid adenomas [3]		Total upper 95%
	MLE	Upper 95%	MLE	Upper 95%	
3	71	834	5,625	10,472	11,306
1	0.6	264	1,911	3,260	3,524
0.5	0.03	132	960	1,827	1,959
0.1	0.001	26	193	368	394

[1] Ex. 43. Based on incidence data given in Table 1.
[2] Multistage model with two positive parameters: $q_4=3.954\times10^{-4}$ and $q_5=1.597\times10^{-4}$
[3] Multistage model with one dose-related stage: $q_0=.00643$ and $q_1=.01929$

The EPA has prepared a draft assessment of the risk of cancer to garment workers and residents of manufactured housing in support of their TSCA section 4(f) designation for these two sources of exposure to formaldehyde [Ex. 73–149]. This EPA assessment is a preliminary draft subject to changes recommended by the Science Advisory Board (SAB) of the Environmental Health Committee which reviewed the document on June 26, 1985 [Ex. 73–87]. The EPA based their dose-response modeling on the incidence of squamous cell carcinomas in the CIIT rat study. The CIIT mouse data were considered to be suggestive evidence of carcinogenicity from formaldehyde inhalation, but the results were not used in dose-response modeling because of the limited response. The NYU study in rats was considered corroborating evidence inappropriate for modeling dose-response curves because only one exposure concentration was tested.

Although EPA examined the concept of calculating "delivered dose" from information on DNA-formaldehyde adducts, they chose ambient air concentration as the measure of dose. Risk estimates were calculated by use of the multistage model without restriction. Estimates shown in Table 7, were based on model-derived point estimates for a 5-stage model and their associated upper 95 percent UCLs. The UCLs

correspond to those derived from the linearized multistage model. EPA also examined time-to-tumor models but rejected them because of questions raised regarding lack of information on cause of death in experimental animals and problems regarding how to handle sacrificed animals.

The CIIT study exposed rats for 6 hrs/day, 5 days/wk for 24 months. EPA estimated that apparel workers are exposed for 36 hrs/wk for 40 years and mobile home residents are exposed on an average for 112 hrs/wk for 10 years. To adjust for exposure duration, each estimate of lifetime risk was multiplied by the proportion of a human lifetime actually exposed. This results in a smaller estimated risk than application of a scaling factor to dose before substitution into the model for factors greater than one and a greater correction if the scaling factor is less than one. EPA acknowledges that the correction factors applied are based on simplified assumptions since little scientific knowledge exists to address the problem.

The EPA also calculated risk estimates based on polypoid adenomas although they cautioned that there appears to be little credible evidence that polypoid adenomas progress to the malignant tumors seen in the CIIT study. The EPA employed the same data as was used in the ORA report, 7 adenomas in 159 animals exposed at 2 ppm and 1 in 156 controls. Since the true slope of the dose response curve is unknown, EPA fit a straight line through zero and the exposure data results at 2 ppm. Risk estimates calculated by EPA based on polypoid adenomas and on squamous cell carcinomas are shown in Table 7.

TABLE 7.—ESTIMATES OF RISK PREDICTED FROM TWO TUMOR TYPES, FROM EXPOSURE TO FORMALDEHYDE EPA (1985) [1]

Category	Exposure (ppm)	Squamous cell carcinomas		Polypoid adenomas, individual risk MLE (UCL) [2]
		Individual risk MLE (UCL) [2]	Population risk MLE (UCL)	
Mobile home residents	0.19	3×10^{-4} (3×10^{-3})	< (1933)	2×10^{-3} (4×10^{-3})
Apparel workers area samples	0.23	9×10^{-4} (4×10^{-3})	< (313)	3×10^{-3} (5×10^{-3})
Apparel workers personal samples	0.64	6×10^{-3} (1×10^{-2})	< 1 (777)	8×10^{-3} (2×10^{-2})
Apparel workers NIOSH survey	0.17	4×10^{-4} (3×10^{-3})	< (233)	2×10^{-3} (5×10^{-3})
OSHA standard	3.0	6×10^{-2} (6×10^{-2})		

[1] Ex. 73-149.
[2] Based on incidence data given in Table 1.

EPA noted that the major contributor to the uncertainty seen in the risk estimates is the steep dose-response seen in the rat study. This would not affect the analysis of the polypoid adenoma data. However, EPA also recommended that risk estimates derived from the polypoid adenoma data not be added to estimates derived from the squamous cell carcinoma data because of uncertainties associated with the polypoid adenoma data set, its statistical significance, the uncertain nature of the risk estimation, and the question regarding progression to malignant tumors. In addition, EPA recommended that greater weight be given to risk estimates derived from squamous cell carcinomas because of their frank carcinogenic expression, their statistical significance, and their positive dose-response relationship. This position is in concordance with OSHA's approach.

Brown [Ex. 69-15] evaluated the carcinogenic risk of handling formaldehyde over a range of ambient air concentrations likely to be encountered in the workplace and at home. The data used to construct a dose-response curve were from the CIIT study of rats. Brown reported risk estimates applicable to this species only, and he did not extrapolate these results to humans. As seen in Table 8, the range of risk predicted for lifetime exposures at the present OSHA PEL of 3 ppm is 9 to 82 additional occurrences per 100,000 with UCLs of 212 to 633 additional cancers/100,000. Reduction of exposure to 1.0 ppm reduces risk to 0 to 6.5 additional cases/100,000, with UCLs of 0.2 to 204 cases/100,000.

TABLE 8.—LIFETIME RISK OF SQUAMOUS CELL CARCINOMAS TO RATS PREDICTED FOR VARIOUS MODELS (BROWN)

Exposure (ppm)	Additional cases per 100,000				
	Multi-stage	Probit	Logit	Weibull	Multi-hit
0.5	[1] 0(102)	0.1(3)	0.8(15)	2.2(23)	0(0)
1.0	0.4(204)	0.4(12)	2.9(40)	6.5(56)	0(0.2)
2.0	7.4(411)	3.8(73)	16.2(138)	27.2(161)	0.4(23)
3.0	43.4(633)	23.9(264)	59.9(315)	81.5(329)	0.8(212)

[1] Value in parenthesis is 95 percent upper confidence limit.

2. *Conclusions Regarding Human Risk of Cancer from Workshift Exposures.* OSHA has made preliminary risk estimates using the information discussed in the previous sections. The degree of risk has been calculated for a number of alternative PELs. OSHA believes that these estimates of risk are most applicable to workers whose exposures remain relatively constant throughout the day. Based on the 3- and 5-stage multistage models, the range of estimates for lifetime occupational exposure to formaldehyde is 0–3 cases/100,000 workers at uniform concentration of 0.5 ppm; 0.6–23 cases/100,000 at 1 ppm, 3.2–78 cases/100,000 at 1.5 ppm, 6–184 cases/100,000 at 2 ppm, and 71–620 cases/100,000 at 3 ppm. Actual risk is probably near the midpoint of the range as long as short-term excursions above the 8-hour average do not occur, since some of the variability at the high and low ends is known to be caused by biases introduced into the assessments. If excursions occur, the risk would be higher than the MLE estimates. A reduction in the 8-hr TWA from 3 to 1 ppm represents a 27-fold to 118-fold reduction in risk; reducing the PEL to 1.5 ppm would result in an 8- to 22-fold reduction in risk. A reduction in the PEL from 3 ppm to 0.5 ppm would correspond to a greater than 207-fold reduction in risk.

As in all risk assessments, some uncertainty has entered into the analysis as assumptions were made to fill gaps where data is missing. For formaldehyde, these include the lack of information on human risk, the need to correct cancer incidence rates for sacrificed animals, the limits on ability to detect cancer imposed by the size of the animal study, the enhanced response caused by promotion of cancer at high doses, and the unknown influence of other carcinogens present in the human environment.

Corrections for serial sacrifice do not contribute a major source of error unless the correction factor also affects the model selected, and OSHA has made no attempt to alter the estimates of the original authors. Where bias can be identified, it appears to lower risk estimates slightly. Limitations of sample size tend to cause underestimation of risk at low doses since experimental data can indicate no risk where true risk is about 0.5 cases/100 or less. At high doses, promotional effects can occur because regeneration of cells rendered necrotic by chemical action makes single stranded DNA available for direct chemical reaction. Proliferation of cells, and possible incorporation of altered DNA into them, occurred at all concentrations of formaldehyde tested in the CIIT rat study and this appears to be a major factor contributing to the results seen at the highest dose. Whether the bias introduced because of promoters leads to overestimation of underestimation of risk may depend on the mathematical model chosen. In the case of formaldehyde, these effects are so substantial that they make a precise estimate of risk at low doses difficult. In addition, an unknown degree of uncertainty in the risk estimates occurs because of reliance on animal data as a predictor of human risk; without additional data, the bias introduced into the assessment of risk by this uncertainty cannot be determined.

Based on an assessment of the various mathematical models available for determining risk, OSHA has concluded that the multistage family of models are the most appropriate descriptors of risk. None of the models account for the possibility that the carcinogenic response could be enhanced because of tumor promotion caused by chemically induced toxicity. However, this is known to be the case for formaldehyde, even at the lowest dose tested in the CIIT study. Thus, the observed dose-response curve represents at least two processes, the underlying risk of direct carcinogenesis by low doses of formaldehyde and the risk due to promotion of carcinogenesis by initiators and direct carcinogens. Only the multistage model is capable of adjustment for this second effect. Given the available data, there is no way to distinguish as to whether the 3- or 5-stage model better represents the risk. Consequently, results from both models have been used by OSHA in predicting its best estimate of risk.

Biological evidence indicates that the effects of formaldehyde are strongly related to the concentration of exposure. The CIIT study demonstrates this effect in that exposures at higher concentrations (15 ppm) cause a much greater response that lower concentration (6 ppm). In the CIIT bioassay, however, OSHA notes that animals were exposed at relatively uniform concentrations throughout the study, whereas many workers probably will be exposed to varying concentrations including high ecursions, throughout the day. OSHA's best extimates of risk, therefore, apply to situations where employee exposure is constant. OSHA believes that excursions above the TWA level will result in substantially greater risk than predicted, but due to the lack of adequate data, OSHA has not quantified the extent of the increased risk at this time.

F. Estimation of Risk of Sensory Irritation

In addition to the risk of cancer associated with the short term exposures, there is also a risk from the acute irritant effects of formaldehyde. Sensory irritation is not easily measured by a quantitative clinical test. Rather, it depends on perceptions of the individual, which can be quite variable. Additional factors which some effect are (1) the inherent genetic variability in susceptibility in a heterogeneous species such as humans, (2) the acquisition of tolerance to exposure, and (3) the fact that as concentration increases, both the number of different biological effects and their severity increase. In recognition of these complicating factors, the Consensus Workshop decided not to conduct a quantitative assessment of the risk of irritant effects from formaldehyde [Ex. 70–56]. OSHA, however, believes there is some data which can provide a reasonable basis for quantified approximations, although not the type needed for a rigorous mathematical analysis.

As discussed earlier, in a short term study of irritant effects, Andersen and Molhave [Ex. 42–10] developed a scale of discomfort ratings. They assigned a score of 100 to intolerable discomfort, an average score of 83 to strong discomfort, 50 (average) to discomfort, 17 (average) to slight discomfort, and 0 to no effects. Following 5-hour exposures, healthy volunteers developed conjunctival irritation and dryness of the nose and throat at the following rates; in 19 percent for exposure at 0.25 ppm, in 31 percent at 0.42 ppm, and 94 percent following exposures of 0.83 or 1.6 ppm.

Average subjective discomfort ratings were 7 at 0.33 ppm (0.25 and 0.42 ppm scores averaged), 11 at 0.83 ppm and 18 at 1.6 ppm.

In a study of formaldehyde exposure in 17 industries, SOCMA collected information on nose and eye irritation and calculated average exposure levels. Companies participating in the study indicated no odor 80.0 percent of the time (average exposure 0.3 ppm), barely detectable odor during 12.4 of the work time (average exposure 0.8 ppm), clearly detectable odor 5.8 percent of the time (1.8 ppm average exposure), almost intolerable odor 0.7 percent of the time (2.5 ppm average), and intolerable odor 0.3 percent of the time (3.7 ppm average exposure). These figures are quite consistent with Andersen and Molhave's report where 81 percent of the volunteers exposed at 0.25 ppm and 69 percent exposed to 0.42 ppm experience no discomfort. Likewise, at higher levels of exposure, the clearly detectable odor in SOCMA's report approximately corresponds to an average subjective irritant score of 50, almost intolerable odor to 83, and intolerable to 100. [Ex. 43]

Based on the study by Andersen and Molhave coupled with the SOCMA data on employee estimates of the percentage of time that the odor of formaldehyde was detectable, the ORA report [Ex. 43] provided a rough evaluation of irritant effects that should be experienced at various levels of exposure. It was estimated that exposures over 3 ppm would be nearly intolerable to all workers, and between 1 and 3 ppm all workers would experience some discomfort to strong discomfort. For exposures between 0.5 and 1.0 ppm, 31 to 94 percent were expected to experience slight discomfort. At levels of 0 to 0.5 ppm, up to 20 percent would still experience slight discomfort.

These estimates were based solely on the responses of volunteer subjects and workers. Hence, as a measure of irritation, these estimates are limited by the qualitative descriptors assigned to each level by the interviewees. In addition, these estimates are not able to account for the length of time before adaptation occurs and irritation diminishes. They are, however, strikingly similar to the estimates of irritation effects derived by the National Academy of Sciences, in 1981 [Ex. 42-67]. These are given in Table 9.

TABLE 9.—PREDICTED IRRITATION RESPONSES OF HUMANS EXPOSED TO AIRBORNE FORMALDEHYDE

Concentration (ppm)	Percent of population giving indicated response	Degree of irritation[1]
1.5-3.0	20	7-10
0.5-1.5	p<30	5-7
0.25-0.5	10-20	5-7
<0.25	<20	1-3

[1] Irritation index: 10 = Strong irritation, great discomfort; 7 = Moderate irritation, discomfort; 5 = Mild irritation, mild discomfort; 3 = Slight irritation, slight discomfort; 1 = minimal irritation, minimal discomfort; 0 = No effects.

The cumulative experience of workers and volunteer subjects suggests that at concentrations below 0.5 ppm, the 20 percent response is primarily one of simple odor detection with about half of these individuals showing more severe, but transient, effects of slight eye irritation and dry throat. At 1 ppm, nearly all persons who have not become acclimated to formaldehyde would be aware of its odor when first entering the worksite. Mild irritation of the eyes, nose, and throat would probably occur in about half these persons; only a half of these would complain of slight discomfort. At concentrations of 1.5 to 3 ppm, an increasing percentage of workers would develop eye, nose, and throat irritation even among those who have long-term exposure. In a few, these effects would be mild to moderate at lower levels, increasing to moderate to severe by 3 ppm. Concentrations of 3 ppm become uncomfortable to many workers, about 80 percent, and nearly intolerable to some, about 20 percent. Over 3 ppm, formaldehyde is intolerable to most persons.

VII. Significance of Risk

OSHA's approach to the determination of significant risk of material impairment of health has been documented in a number of recent proposed and final occupational health standards (arsenic 43 FR 19584; asbestos 49 FR 14119; ethylene oxide 49 FR 25763). The process begins with a thorough analysis of the best available evidence of the toxic effects of the chemical in both humans and experimental animals. This is followed by a quantative risk assessment, where possible, to determine the risk at the current permissible exposure limit. This quantitative assessment may be augmented by qualitative assessments of other toxic effects that may not be readily quantifiable. The Agency must then determine whether or not the current permissible exposure limits present a significant risk and whether its actions will reduce that risk.

As a first step in its significant risk determination, OSHA has reviewed the data on the adverse health effects that result from exposure to formaldehyde. This review took into account evidence presented at a public hearing held in February 1985. At this hearing, both the health data and a number of quantitative risk assessments were discussed in great detail. IARC, EPA, and the Consensus Workshop on Formaldehyde have reviewed the available data, and OSHA has benefited from their work. The health data is described in detail in this preamble in Section V—Health Effects, and is summarized briefly below.

At high concentrations, exposure to formaldehyde can be fatal. At slightly lower concentrations, exposure may result in pulmonary edema, inflammation and pneumonia. At much lower concentrations, formaldehyde exposure also produces effects typical of irritant gases and vapors as it reacts with the cellular and noncellular components of the mucous membranes. This reaction results in a number of cytotoxic and genotoxic effects and in such symptoms as eye irritation, with increased blinking and lacrimation, changes in ability to smell, and a dry or sore throat. As the formaldehyde concentration increase, these symptoms impair the ability to work and become so severe that the individual finds continued exposure intolerable.

Although the evidence of acute toxicity in humans is clear, the epidemiological evidence taken alone is inadequate to make any determination of formaldehyde's carcinogenicity. Several studies presently available, although suggestive of an effect, do not provide conclusive evidence of a casual relationship between formaldehyde exposure and human cancer.

Although the human evidence of carcinogenicity is only suggestive, the evidence of carcinogenicity in animals provides a body of evidence upon which to make a qualitative assessment of risk using the criteria established by OSHA's Cancer Policy, 29 CFR 1990. The CIIT study of formaldehyde exposure in Fischer 344 rats is the primary study cited as providing evidence of formaldehyde's carcinogenicity (Ex. 12, 42-116, 42-131). This lifetime inhalation study consisted of a control group and 3 dose groups (2 ppm, 5.6 ppm, 14.3 ppm) that bracket the current PEL (3 ppm). Extensive histopathological examinations revealed squamous cell carcinomas of the nasal cavity in rats in 2 of the 3 dose groups. At 14.3 ppm, there was a statistically significant increase in squamous cell carcinomas of the nasal cavity in rats of both sexes. At 5.6 ppm, one male and one female rat developed a squamous cell carcinoma.

Although the finding in the 5.6 ppm group did not constitute a statistically significant increase, the tumors were considered to be formaldehyde-related because of their histological type and historical rarity.

OSHA concludes that the CIIT study is the most appropriate source of data for the quantitative risk assessment. There was general agreement that the CIIT study was conducted in accordance with good laboratory practices, and it has withstood considerable public scrutiny. The findings of the study were confirmed in two independent investigations (Ex. 42–2, 42–3, 42–4, 73–146). The Risk Estimation Panel of the Consensus Workshop recommended the use of this study for the quantitative risk assessment (Ex. 70–56) and the study was employed in every quantitative risk assessment submitted to the record (Ex. 42–29, 42–31, 43, 45–5, 69–23B3, 69–15, 73–115, 73.149).

Based on an assessment of a number of mathematical models available for the quantitative risk assessment, OSHA has concluded that the multistage family of models are in the most appropriate descriptors of the risk. While the best estinates of risk presented in this document cover a range of risk estimated by a number of multistage models (in particular, the three and five stage models), they also are representative of risks predicted by a number of other models, lncluding time-to-tumor models. This fact raises OSHA's confidence in its determination of the best estimates of risk from formaldehyde and hence, the significance of that risk.

OSHA has determined that the best estimate of lifetime excess risk of cancer at the current permissible exposure limit (3 ppm as an 8 hour TWA) is between 71 and 620 cases per 100,000 exposed individuals. This is, of course, OSHA's preliminary analysis. The questions of the relationship between the animal data and human effects and of estimates of human carcinogenic risk are still open and subject to reevaluation based on the evidence and anaylsis submitted into the rulemaking record.

The Supreme Court concluded that the Agency has broad leeway to determine what constitutes a significant risk. It stated that "we recognize that its [OSHA's] determination that a particular risk is 'significant' will be based on policy considerations." (*IUD* v. *API*, 44 US 656) This range 80.7 to 6 per 1000) encompassed the 1 per 1000 risk that the Supreme Court concluded that a "reasonable person might well consider . . . significant and take appropriate steps to decrease or eliminate it." (*IUD* v. *API*, 448 U.S. 655)

In previous rulemaking such as ethylene oxide (49 FR 25764) and arsenic (43 FR 19584), the Agency has looked for guidance to existing risk rates as to what constitutes significant risk in various occupations. The estimated lifetime excess cancer mortality risk from exposure to formaldehyde is, for the most part, greater than that posed by therisk of fatalities caused by accidents in industries with average risk such as 2.7/1,000 for all manufacturing and 1.6/1,000 for servic industries. It is substantially greater than the risks found in low risk industries such as 0.48/1,000 for electrical equipment and 0.07/1,000 for retail clothing (48 FR 1902) but lower than the risk in higher risk industries such as firefighting which is 27.45/1,000.

OSHA has already concluded in earlier post-Benzene rulemakings which have been upheld by the courts that it was certainly the intent of Congress to reduce risks of average magnitude and of course the Supreme Court indicated that a reasonable person "might well consider" a risk of 1./1,000 (a below average risk rate) signficant "and take appropriate steps to decrease or eliminate it," (IUD v. API 448 US 655). In addition, the risk which formaldehyde would present is additive to risks of accidental injury and death which would exist in the industries where workers are exposed to formaldehyde [See the Agency's earlier discussion in its final arsenic preamble 48 FR 1869, January 14, 1983 upheld in ASARCO, Inc. v. OSHA, 646 F 2nd 483 (9th Cir., 1984)]

If OSHA's final conclusion, after a review of the complete rulemaking record, is that there is sufficient evidence that the risks to humans is significant then OSHA would regulate accordingly. Of course, in th rulemaking OSHA will consider evidence and analysis of the appropriate approach to significant risk analysis.

In light of the discussion of significant risk at 3 ppm, the exposure potentially permitted by the 5 ppm 8-hour ceiling would also constitute a significant risk. The inadequacy of the 10 ppm peak exposure permitted for 30 minutes is based on the quantitative risk assessment of DNA-adduct formation. Results of this analysis lead to the conclusion that 30-minute exposure at 10 ppm is approximately equally as risky as exposure at 3 ppm over the course of the workday.

If after considering the evidence presented in the rulemaking, the Agency follows the analysis of significant risk discussed above, then the analysis indicates that the reduction of the PEL from 3 ppm is reasonably necessary to reduce the risk for formaldehyde exposed workers. The risk at 1 ppm ranges from 0.6 to 23 excess cases per 100,000 workers. A reduction of the PEL to 1 ppm represents a twenty seven- to one hundred eighteen-fold reduction of risk. The risk at 1.5 ppm ranges from 3.2 to 78 excess cases per 100,000 workers. Therefore, a reduction of the PEL to 1.5 ppm represents an eight- to twenty two-fold reduction in risk.

OSHA believes that other evidence in the record, in addition to direct evidence of animal carcinogenicity, independently supports the preliminary finding that of significant risk to humans. For example, Acheson's study of chemical workers exposed to formaldehyde showed an increased mortality due to chronic bronchitis in workers at the facility where the greatest majority (73%) experienced "high" formaldehyde levels (above 2 ppm) [Ex. 42–1].

At the levels permitted by the ceiling and the peak exposure limits, sensory irritation in humans is severe, causing burning and tearing of the eyes, severe irritation of the nose and throat, and even some effects lower in the respiratory system. At 3 ppm, nearly 100 percent of the formaldehyde-exposed workforce would experience some irritation of the eyes, nose, and throat. Twenty percent would experience moderate to strong irritation with great discomfort. Over 30 percent would experience mild to moderate irritation and discomfort. The rest would experience slight to mild effects. These responses would impair the worker's ability to function on the job and they clearly represent material impairment of health even though recovery from the effects may result after leaving the exposure area.

If full compliance with the proposed standard were achieved, there would be a substantial reduction in workers with strong, moderate, and mild irritation with many having no irritation at all. If all companies were able to achieve a 0.5 ppm exposure concentration, then no workers would receive more than mild, transitory irritation. This evidence supports a preliminary conclusion that a lower level would create a substantial reduction in significant risk from noncarcinogenic effects as well. At this time, OSHA does not have information adequate to characterize the number of workers who might be affected by short term exposures to high concentrations of formaldehyde.

Formaldehyde also causes irritation and sensitization of the skin. Direct

chemically-induced irritation can occur from formaldehyde solutions greater than 5 percent. The number of cases of formaldehyde-induced dermatitis appears to vary widely depending on work practices, availability of suitable protective clothing, and the type of exposure. Above 1 percent, and possibly at lower concentrations [Ex. 42-27], sensitization can be induced from contact with solutions of liquid formaldehyde.

While irritation of the skin usually is transient and often may be prevented by improved work practices and protective clothing, sensitization is a much more serious problem. While the methods to prevent sensitization are the same as those to prevent irritation, sensitization is not transient. Once sensitized, the employee will most likely continue to react to even small concentrations of formaldehyde for years after the initiating event. This is especially handicapping because of the presence of formaldehyde in so many consumer products. The sensitized worker may react to permanent press clothing, to draperies, to rugs, to cosmetics, to furniture, and to many of the other items encountered in everyday life. Since it can both prevent a worker from pursuing his employment and disrupt the worker's personal life, sensitization must be considered material impairment.

The finding of benign tumors, polypoid adenomas, in the experimental animal studies further contribute to the preliminary finding of significant risk. These tumors were observed in rats at all three dose levels and were generally acknowledged to the formaldehyde related. Although the Agency chose not to include them in the quantitative risk assessment, they clearly represent an adverse effect caused by formaldehyde.

Information on cytotoxicity provides further support for the Agency's significant risk conclusion. The cytotoxic effects were directly linked to the expression of carcinogenic effects in the rats in the CIIT study. The extremely high incidence of malignant tumors seen in the rats exposed at 14.3 ppm was attributed to several secondary responses in the animals. There were the disruption of normal clearance mechanisms (mucostasis and ciliastasis were seen only at very high doses) and the tumor promotion caused by cytotoxicity. Moreover, cytotoxic effects were seen at the lowest dose tested by CIIT (2 ppm). Additional evidence from a multispecies study indicates that the no observed effect level (NOEL) for cytotoxicity is 1 ppm, a level well below OSHA's present TWA concentration limit of 3 ppm. In addition, *in vitro* studies have shown that formaldehyde induces a number of genotoxic effects such as the induction of single strand DNA breaks, sister chromatid exchange, chromosomal aberrations and mutations in cultured mammalian cells.

OSHA's numerical estimates of the reduction of risk are based on a reduction of exposure levels alone and do not take into account the additional protective effects of other provisions of the proposed standard such as the requirement for certain mandatory work practices. The use of protective work practices and protective clothing that reduce or eliminate skin contact with liquid formaldehyde will reduce the incidence of both irritation and sensitization. This provides one example of how these provisions will provide additional protection and further reduce the risk from exposure to formaldehyde.

Evidence in the record clearly links adverse effects in human and experimental animals with exposure to formaldehyde at or near the current PEL. The quantitative risk assessment for excess cancer mortality if OSHA concludes after considering the evidence presented in the rulemaking that it is supported and the assessment of additional acute risks both independently and together lead OSHA to preliminarily conclude that occupational exposure to formaldehyde presents a significant risk at the current PEL. Further, the proposed standard for formaldehyde is reasonably necessary and appropriate to substantially reduce this risk.

VIII. Summary of the Preliminary Regulatory Impact Analysis and Regulatory Flexibility Analysis

Introduction

Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. In addition, the Regulatory Flexibility Act of 1980 (Pub. L. 96-353, 94 Stat. 1164 [5 U.S.C. 601 et seq.]) requires the Occupational Safety and Health Administration (OSHA) to determine whether a proposed regulation will have a significant economic impact on a substantial number of small entities.

Consistent with these requirements, OSHA has prepared a Preliminary Regulatory Impact and Regulatory Flexibility Analysis (PRIA) for the proposed formaldehyde standard. This analysis includes a profile of the industries that would be covered by the standard, an estimate of the number of exposed workers, nonregulatory alternatives, technological feasibility, costs, benefits, and an overall economic impact of the proposed standard. The PRIA will be available in the Docket Office on December 24, 1985.

Industries and Employees Affected

OSHA's information indicates that the proposed formaldehyde standard could potentially affect approximately 536,000 employees exposed above 0.5 ppm in about 46,300 establishments. Formaldehyde is used extensively in a wide variety of products and processes. The following paragraphs provide an overview of the firms and workers that are most affected by the proposal.

Producers of formaldehyde are categorized in Standard Industrial Classification (SIC) 2869. There are 15 companies at 56 locations in the U.S. that produce formaldehyde. These are widely diversified chemical companies and formaldehyde production comprises only a small segment of their business. Of the formaldehyde they produce, 65 percent is used by the producers to make resins and other formaldehyde-based products.

In the PRIA, OSHA has focused on those industries where employee exposures to formaldehyde are greater than 1 ppm. In these industries cost increases would result from the need to install engineering controls in order to meet the requirements of the proposal. Currently available studies indicate six industries with potential exposures above the proposed permissible exposure limit (PEL) of 1 ppm. These affected industries are SIC 2435, Hardwood Veneer and Plywood; SIC 2492, Particleboard; SIC 2499, Medium Density Fiberboard; SIC 25, Furniture and Fixtures; SIC 2821, Plastics Materials, Synthetic Resins, and Nonvulcanizable Elastomers; and SICs 332 and 336, Ferrous and Nonferrous Foundries. The number of establishments and the number of workers with exposures above 1 ppm in these industries was estimated to be 2,850 and 22,610 respectively.

A second group of potentially affected employees have exposures at or below 1 ppm but above 0.5 ppm. Table 10 shows that approximately 513,400 workers in about 43,500 establishments are potentially exposed within this range.

TABLE 10.—NUMBER OF ESTABLISHMENTS AND EMPLOYEES EXPOSED TO FORMALDEHYDE

SIC	Industry	Establishments			Exposed employees		
		Above 1 ppm	Between 0.5–1 ppm	Total	Above 1 ppm	Between 0.5–1 ppm	Total
With exposures above 1 ppm							
2435	Hardwood plywood	218	88	306	2,700	3,710	6,410
2492	Particleboard	24	21	45	120	2,080	2,200
2499	Fiberboard	10	2	12	341	812	1,153
25	Furniture	742	1,667	2,409	6,500	42,200	48,700
2821	Resins	16	81	97	112	3,294	3,406
332, 336	Foundries	1,840	0	1,840	12,837	32,043	44,880
	Subtotal	2,850	1,859	4,709	22,610	84,139	106,749
With exposures from 0.5–1.0 ppm							
226	Textile finishing	0	750	750	0	14,300	14,300
23	Apparel	0	7,500	7,500	0	250,000	250,000
245, 3792	Mobile home mfg	0	930	930	0	17,900	17,900
2851	Paints, pigments	0	1,440	1,440	0	20,000	20,000
3079	Plastic molding	0	980	980	0	20,100	20,100
7261	Funeral services	0	15,000	15,000	0	52,000	52,000
806, 807	Laboratories	0	15,000	15,000	0	45,000	45,000
	Other	0	NA	NA	0	10,000	10,000
	Subtotal	0	41,600	41,600	0	429,300	429,300
	Grand total	2,850	43,459	46,309	22,610	513,439	536,049

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

Nonregulatory Environment

Systems designed to compensate workers for occupationally related illnesses have not had a significant impact on the extent of worker exposure to formaldehyde for several reasons. It is often extremely difficult to determine the cause of illness at the time the disease is diagnosed. This is a result of the long latency period between the exposure and the onset of disease, and worker mobility. In addition, many workers are not aware of the potential health hazards associated with formaldehyde exposures.

Tort litigation has also been viewed as one mechanism to reduce workplace risks. Although workers who suffer health effects from exposure to formaldehyde may have the option to file suit against a third party, such as a manufacturer or distributor, this does not appear to have happened to date. A review of a number of closed litigation cases on formaldehyde showed only in which a worker was awarded damages against a formaldehyde producer.

Technological Feasibility

Area wide and local exhaust ventilation systems are in widespread use across all industries and their effectiveness has conclusively proven the technological feasibility of reducing ambient levels of formaldehyde to below 1 ppm TWA. Material substitution, process modification, work practice modification and the use of personal protective equipment are currently employed to supplement engineering controls, and they have also been effective in reducing exposure levels in many industries. In estimating the cost of capital equipment to achieve a reduction in the ambient level of formaldehyde in those industry sectors where that level is believed to exceed 1 ppm TWA, area-wide and local exhaust ventilation systems provided the principal bases for unit-cost calculations.

Summary of Costs

OSHA has examined two sets of compliance costs. The first set of costs includes only those associated with the engineering controls required to reduce exposures to the alternative PELs. It is assumed that firms would rapidly install engineering controls to avoid the added costs of purchasing respirators. For the 1.0 ppm PEL, the estimated costs for engineering controls amount to $57.8 million, and the annual operating expenses associated with these engineering controls amount to $14.4 million. Columns 1 and 5 of Table 11 display these estimates by industry sector. For the 1.5 ppm PEL, OSHA estimates the cost of the engineering controls at $38.9 million, and the cost of the associated annual operating expenses at $9.7 million. Columns 1 and 5 of Table 12 present these estimates. In general, the figures are preliminary as over one-half of the outlays are attributed to the foundry industry where compliance cost information is extremely sparse.

The second set of costs are the added burdens that would be incurred for the requirements of the comprehensive carcinogen alternatives, including monitoring employee exposures, training employees, establishing written compliance and emergency plans, and implementing recordkeeping procedures. As shown in Tables 11 and 12, accounting for these additional requirements brings the annual operating costs associated with the 1.0 ppm and the 1.5 ppm PEL alternatives to $28.3 million and $17.0 million, respectively.

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COMPLIANCE COSTS OF 1.0 PPM PEL FORMALDEHYDE STANDARD
(1985 $)

SIC	INDUSTRY	CAPITAL COSTS				ANNUAL OPERATING COSTS				
		ENGINEERING	COMPLIANCE PROGRAM	EMERGENCY PLAN	TOTAL	ENGINEERING RELATED	MONITORING	TRAINING	RECORD-KEEPING	TOTAL
WITH EXPOSURES ABOVE 1 PPM										
2435	HARDWOOD PLYWOOD	8,720,000	21,800	18,360	8,760,160	2,180,000	75,638	64,597	16,749	2,336,985
2492	PARTICLEBOARD	4,188,000	2,400	2,700	4,193,100	1,047,000	25,960	28,383	5,749	1,107,091
2499	FIBERBOARD	1,237,000	1,000	720	1,238,720	309,000	13,605	14,875	3,013	340,493
25	FURNITURE	8,817,000	74,200	144,540	9,035,740	2,205,000	574,660	534,843	127,253	3,441,756
2821	RESINS	300,000	1,600	5,820	307,420	75,000	40,191	65,673	8,900	189,764
332, 336	FOUNDRIES	34,500,000	184,000	110,400	34,794,400	8,625,000	529,584	758,239	117,271	10,030,094
	SUBTOTAL	57,762,000	285,000	282,540	58,329,540	14,441,000	1,259,638	1,466,610	278,935	17,446,183
WITH EXPOSURES FROM 0.5-1.0 PPM										
226	TEXTILE FINISHING	0	0	0	0	0	168,740	154,148	37,366	360,254
23	APPAREL	0	0	0	0	0	2,950,000	2,223,000	653,250	5,826,250
245, 3792	MOBILE HOME MFG.	0	0	0	0	0	211,220	221,717	46,773	479,709
2851	PAINTS, PIGMENTS	0	0	0	0	0	236,000	313,872	52,260	602,132
3079	PLASTIC MOLDING	0	0	0	0	0	237,180	244,577	52,521	534,278
7261	FUNERAL SERVICES	0	0	0	0	0	613,600	637,603	135,876	1,387,079
806, 807	LABORATORIES	0	0	0	0	0	531,000	702,000	117,585	1,350,585
	OTHER	0	0	0	0	0	118,000	146,952	26,130	291,082
	SUBTOTAL	0	0	0	0	0	5,065,740	4,643,869	1,121,761	10,831,370
	GRAND TOTAL	57,762,000	285,000	282,540	58,329,540	14,441,000	6,325,378	6,110,479	1,400,696	28,277,553

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

TABLE-12

COMPLIANCE COSTS OF 1.5 PPM PEL FORMALDEHYDE STANDARD
(1985 $)

SIC	INDUSTRY	CAPITAL COSTS				ANNUAL OPERATING COSTS				
		ENGINEERING	COMPLIANCE PROGRAM	EMERGENCY PLAN	TOTAL	ENGINEERING RELATED	MONITORING	TRAINING	RECORD-KEEPING	TOTAL
WITH EXPOSURES ABOVE 1 PPM										
2435	HARDWOOD PLYWOOD	4,360,000	10,900	18,360	4,389,260	1,090,000	53,749	45,903	11,902	1,201,555
2492	PARTICLEBOARD	2,094,000	1,200	2,700	2,097,900	523,500	13,688	14,965	3,031	555,184
2499	FIBERBOARD	618,500	500	720	619,720	154,625	8,815	9,637	1,952	175,029
25	FURNITURE	4,408,500	37,100	144,540	4,590,140	1,102,125	325,680	303,114	72,119	1,803,038
2821	RESINS	150,000	800	5,820	156,620	37,500	20,756	33,916	4,596	96,769
332, 336	FOUNDRIES	27,255,000	145,360	110,400	27,510,760	6,813,750	340,530	487,559	75,407	7,717,246
	SUBTOTAL	38,886,000	195,860	282,540	39,364,400	9,721,500	763,218	895,095	169,008	11,548,821
WITH EXPOSURES FROM 0.75-1.0 PPM										
226	TEXTILE FINISHING	0	0	0	0	0	84,370	77,074	18,683	180,127
23	APPAREL	0	0	0	0	0	1,475,000	1,111,500	326,625	2,913,125
245, 3792	MOBILE HOME MFG.	0	0	0	0	0	105,610	110,858	23,386	239,855
2851	PAINTS, PIGMENTS	0	0	0	0	0	118,008	156,936	26,130	301,066
3079	PLASTIC MOLDING	0	0	0	0	0	118,590	122,288	26,261	267,139
7261	FUNERAL SERVICES	0	0	0	0	0	306,800	318,802	67,938	693,540
806, 807	LABORATORIES	0	0	0	0	0	265,500	351,000	58,793	675,293
	OTHER	0	0	0	0	0	59,000	73,476	13,065	145,541
	SUBTOTAL	0	0	0	0	0	2,532,870	2,321,934	560,880	5,415,685
	GRAND TOTAL	38,886,000	195,860	282,540	39,364,400	9,721,500	3,296,088	3,217,030	729,888	16,964,506

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

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Health Effects

The potential worker benefits resulting from a reduction in the PEL depend upon current occupational exposure levels, the number of workers exposed, and the risk associated with each exposure level. The lifetime risk of formaldehyde-induced cancer from exposure at 3 ppm (the current PEL) is estimated to range from 71 to 620 per 100,000 employees, depending on the risk assessment model chosen. The lifetime risk of exposure at 1.5 ppm is estimated to range from 3.2 to 77.6 per 100,000 employees, and the lifetime risk of exposure at 1.0 ppm is estimated to range from 0.6 to 23. Based on these risk assessment models, current worker exposures above 1 ppm are expected to cause from 6 to 57 cancers. Calculating benefits only for employees exposed above the proposed PELs indicates that implementation of the 1 ppm PEL would eliminate 6 to 52 of these cancers, whereas implementation of the 1.5 ppm PEL would eliminate 5 to 42 cancers.

Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980, the Assistant Secretary has assessed the expected impacts of the proposed standard on small entities in each of the affected industries.

The proposed requirement for engineering controls has an extended effective date of 1 additional year for those employers with fewer than 20 employees. This small business distinction notwithstanding, the preliminary data indicate that there may be economies of scale to be realized for certain industries in complying with the engineering control requirements of the proposal. Consequently, there may be a significant adverse impact on small entities in the furniture manufacturing and foundry industries. In addition, small entities in the apparel and textile industries may experience adverse impacts as a result of training, monitoring, and recordkeeping requirements.

IX. Environmental Assessment—Finding of No Significant Impact

OSHA has reviewed the proposed standard to reduce occupational exposures to formaldehyde and has concluded that no significant environmental impacts are likely to occur as a result of promulgation of this action. OSHA, of course, reserves the right to perform any additional environmental analyses that may be required as a result of information and comments received in response to this Notice.

In OSHA's April 17, 1985 Advanced Notice of Proposed Rulemaking (ANPR) for occupational exposure to Formaldehyde, information was solicited from the public on a variety of issues including possible environmental impacts of a proposed revised standard. The information and comments submitted in response to the ANPR have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 [42 U.S.C. 4321, et seq.], the Council on Environmental Quality (CEQ) [40 CFR Part 1500], and OSHA's DOL NEPA Procedures [29 CFR Part 11]. As a result of this review, the Assistant Secretary has determined that the proposed rule will not have a significant impact on the external environment.

The preceding description of the proposed standard and its supporting rationale, together with the following discussion, constitute a summary of OSHA's environmental assessment and finding of no significant impact.

In any OSHA regulatory action, two environments may be affected (1) the workplace environment and (2) the general human environment external to the workplace, including impacts on air and water pollution, solid waste, and energy, and land use. Usually regulations have their most significant impacts on the workplace environment, because this environment is under the Agency's jurisdiction. These impacts are beneficial to the workplace environment because they reduce market exposure to toxic and carcinogenic substances. An in-depth discussion and analysis of the workplace environment and the worker benefits of this proposal are presented in earlier sections of this Notice.

In most cases, the effects of previous OSHA regulations on the external environment have been negligible because of their limited scope and application. The following sections summarize what are believed to be the limited potential environmental impacts that could result from provisions established by the proposed formaldehyde regulation.

Impact of the Regulation on the External Environment

As already discussed, the applications and end uses of formaldehyde are numerous and varied. Formaldehyde is used primarily in the manufacture of a variety of derivatives, including phenolic, urea-formaldehyde, and polyacetal resins; melamine, pentaerythritol, hexamethylinetetramine, fertilizers, acetylene derivatives, and a variety of special industrial chemicals. Formaldehyde is used in the production of hardwood plywood, particleboard, wood furniture, paper and paperboard, plastic molders, abrasive products, resins and plastics, industrial chemicals, paints, dyes, embalming agents, pigments, adhesives, sealants, pesticides, mineral wool insulation, cosmetics, mobile homes, in polymer binding systems used by foundries, and in finishing textiles and apparel.

Air Pollution

It has already been shown that occupational exposures to formaldehyde occur by inhalation and by dermal and eye contact. Under the proposed OSHA standard, the current permissible exposure limit (PEL) of 3 ppm would be reduced to 1 ppm or 1.5 ppm as an 8-hour time-weighted average (TWA). Although a reduction in the airborne contaminants in the workplace would reduce worker exposure and risk, this reduction is not anticipated to have a significant effect on the external ambient atmosphere. Although more emissions will theoretically be removed from the workplace to the outside environment, because of the nature of formaldehyde and its ability to dissipate rapidly, no increase in the amount of ambient air emissions is anticipated. Any increased use of local exhaust or dilution ventilation controls in the workplace to control occupational exposures is not likely to significantly increase ambient air emissions. Consequently, in cases where worker exposure is reduced by the use of improved engineering control methods, atmospheric emissions of formaldehyde would have an inconsequential impact on the external environment. Furthermore, it is not expected that the proposal will contribute to the airborne emissions of formaldehyde that already exist in the environment as a result of automobile exhaust, cigarette smoking, from clothing on racks in stores, from pressed wood products in the home, smog, etc. Similarly, it is believed that the amount of ozone in the ambient atmosphere, which is created as formaldehyde degenerates, will not increase significantly as a result of this action.

Under the Clean Air Act [42 U.S.C. 1857 et seq.], and the National Ambient Air Quality Standards for Total Suspended Particulates (Section 109), and the National Emissions Standards for Hazardous Air Pollutants (Section 112), the Environmental Protection Agency (EPA) is responsible for maintaining ambient air quality by preventing or controlling air pollution. To date, there is no air quality limit for formaldehyde, although it is scheduled

to be reviewed as a potential hazardous air pollutant by EPA in the near future. At present, it is not anticipated that the OSHA proposed rule will significantly affect the amount of formaldehyde emissions present in the ambient atmosphere.

Water Pollution

As mentioned earlier, formaldehyde is an important ingredient of permanent press fabric finishing resins. Water treatments are often used in textile and fabric fininshing processes, and to the extent that these or additional water processes may be used in reducing airborne levels of formaldehyde, there may be some slight increase in wastewater effluents as a result of the proposal. However, this is not anticipated to be significant. Wastewater effluents occurring as a result of manufacturing or production processes or from leaks and spills would be covered generally by EPA's Federal Water Pollution Control Act Amendments of 1972. Under these amendments, wastewater effluents are required to be treated by the best practicable control technology (BPT) and the best available technology (BAT) economically achievable by 1983. This would provide for a "no discharge" of process wastewater pollutants to navigable waters and a no discharge of incompatible pollutants. Wastewater treatment systems in existence would be covered by these regulations. In cases where such systems exist, it is reasonable to assume that conventional biological wastewater treatment would effectively remove formaldehyde from water effluents. To date, no BPT or BAT requirement have been developed specifically for formaldehyde. Formaldehyde, by nature, is volatile and does not remain soluble in water for any considerable time. Consequently, formaldehyde has not been considered to be a potentially hazardous wastewater effluent. Therefore, there are no specific limitations on surface water discharges or sewage discharges for formaldehyde. Similarly, there are no current water quality standards for formaldehyde as a primary pollutant under the Safe Drinking Water Act (42 U.S.C. 300f et seq.)

In cases where aqueous formaldehyde is transported or stored, there may be a potential for spills or leaks. Spills containing more than 1,000 pounds of wastewater effluents must be reported as required by the Clean Water Act of 1977 (Pub. L. 95–217, 91 Stat. 1566 [33 U.S.C. 1251 et seq.]). Again, such occurrences are not anticipated to have a significant effect on the environment, as formaldehyde vaporizes and dissipates rapidly.

Water Disposal

Although instances of waste disposal have not been presented to the record, such disposal would be covered by the Resources Conservation and Recovery Act of 1975 (RCRA) (Pub. L 94–580, 90 Stat. 2795 et seq.). This Act provides guidelines for the " . . . collection, source separation, storage, transportation, processing, treatment, recovery, and disposal of hazardous wastes" [42 U.S.C. 6903, Sec. 1004 [7]). The Act also covers the transportation of hazardous wastes to licensed hazardous waste treatment, storage, and disposal facilities. Under RCRA, those products listed as hazardous are covered, but there is no general listing requirement for formaldehyde per se. However, waste streams that contain formaldehyde as commercial chemical products or as effluents of listed pesticides would be covered. In general, under RCRA, waste products that exceed 220 pounds per month would have to comply with recordkeeping requirements. Consequently, to the extent that waste products containing formaldehyde are listed as hazardous substances under RCRA, they would have to comply with these requirements as well. Even so, it should be noted that formaldehyde in waste products such as washwater, sludge, etc., would vaporize rapidly, thereby having the potential to affect air quality more than waste disposal. In any event, OSHA does not expect that the proposed action would significantly increase the amount of waste containing formaldehyde.

Energy and Land Use

The implementation of required engineering controls or the use of certian kinds of respiratory protection to comply with the proposed PEL could result in an increase in total energy requirements or costs for some industries. This may be particularly true where controls are not currently in place and where the proposed PEL is not met.

In terms of land use, OSHA does not anticipate that there will be any significant effect on land use plans, policies, or controls as a result of this action. Similarly, no significant impact is expected on the short-term uses of man's environment or upon the maintenance and enhancement of long-term productivity beyond those already discussed in this Notice.

In conclusion, based on this discussion and other information presented in this Notice, OSHA concludes that as a result of this proposed action, there will be no significant impact on the general quality of the human environment external to the workplace, particularly in terms of ambient air quality, water quality, or solid waste disposal. OSHA, of course, reserves the right to perform additional environmental analyses based on the information and comments received in response to this Notice.

X. Summary and Explanation of the Proposed Standard

The regulatory options before the Agency are quite broad. They range from simply changing the permissible exposure limits in 29 CFR 1910.1000, Table Z–2 through adopting a full health standard including all the provisions found in standards for carcinogens. Based on the Agency's ultimate conclusions with respect to this evidence, after completion of the rulemaking, OSHA might regulate formaldehyde as a carcinogen, as an irritant, or as both. The public is invited to comment on the entire spectrum of regulatory possibilities.

Regulatory Alternative A

The evidence suggests that formaldehyde could be regulated as an irritant even if it is not regulated as a carcinogen. If OSHA ultimately determines that this is the proper course based on all the evidence in the proceeding, the regulatory provisions would be different from those developed for carcinogens. If formaldehyde is viewed solely as an irritant it might be sufficient to lower the permissible exposure limits for formaldehyde contained in Table Z–2 of § 1910.1000 and to rely on existing sections of the general industry standards, such as §§ 1910.132, 1910.133, 1910.134 and 1910.1200, to provide the supplementary coverage needed for employee protection. Comments are specifically requested on the following questions related to the possible regulation of formaldehyde as an irritant.

1. Is an 8-hour time weighted average of 1 ppm (or 1.5 ppm) appropriate for protection against the irritant properties of formaldehyde?

2. Should there be a short term exposure limit (STEL) for formaldehyde and if so at what level and over what duration of time? Should the STEL be in addition to or in place of the time weighted average? It may be suggested that a STEL is especially necessary if formaldehyde is treated as an irritant.

3. Is it appropriate to have a separate ceiling and peak concentration as in the current standard, or is a single STEL more appropriate?

4. Is it sufficient to rely on the existing generic standards for the additional protections required by section 6(b)(7) of the Act or should some or all of the regulatory provisions typically proposed for carcinogens be applied to formaldehyde as an irritant? How should these provisions be modified if formaldehyde is regulated as an irritant?

Regulatory Alternative B

Under the Cancer Policy [29 CFR Part 1990] the evidence available supports the conclusion that formaldehyde is an animal carcinogen and should be treated for regulatory purposes as a potential occupational carcinogen. OSHA has therefore also developed a proposed standard which would be appropriate if formaldehyde is regulated as a carcinogen. A summary and explanation of this proposal is provided below.

The proposed standard for formaldehyde is based on the conclusion that formaldehyde is a skin sensitizer and irritant, an eye and respiratory system irritant, and a potential occupational carcinogen. It contains a permissible exposure limit (PEL) of [1 ppm or 1.5 ppm] as a time weighted average (TWA) concentation. Exposure above the PEL would trigger provisions for periodic medical surveillance and exposure above the action level (half the PEL) would trigger provisions for employee exposure monitoring. Written emergency procedures, and exclusion of inadequately equipped personnel from areas where protective equipment is needed are intended to assure that persons will not be exposed to formaldehyde unnecessarily. Requirements for protective clothing are based, in part, on the conclusion that formaldehyde solutions can be "strong sensitizers" when they come into contact with the human skin. When employees handle concentrations of formaldehyde (in solution) and there is the possibility of spills or splashes getting on the skin or in the eyes, a requirement for the employer to provide emergency shower and eyewash facilities is proposed. Provisions proposed for respiratory protection are in keeping with formaldehyde's role as an irritating and sensitizing agent that is also a potential occupational carcinogen. Labels, signs, and employee training are intended to be generally consistent with requirements in the Hazard Communication standard but they would apply to industries not necessarily covered by Hazard Communication.

Based upon the evidence available, OSHA has determined that there are situations in which construction workers may be exposed to formaldehyde. The transient, substantially out-of-doors exposure, and the short tenure associated with construction employment set this industry apart from those covered by 29 CFR Part 1910. In some cases these features combine to pose special difficulties in designing worker protection programs. The Advisory Committee on Construction Safety and Health has made recommendations concerning health standards for the construction industry [Ex. 74] and this group has requested that OSHA prepare a separate standard for formaldehyde for the construction industry. As an interim measure, they have requested that the most protective standard available be applied. Therefore, OSHA is proposing to apply a single standard to all industries at this time.

There are several approaches to make a proposal for general industry more applicable to construction. If a complete standard is promulgated, certain provisions of the general standard could be modified. Another alternative is to limit the scope of the formaldehyde standard for the construction industry to setting permissible exposure limits, with additional protection provided by recourse to relevant OSHA standards of general applicability such as 29 CFR 1926.103, governing respiratory protection; 29 CFR 1926.55, 29 CFR 1926.100, and 29 CFR 1926.102 relating to protective clothing and equipment; 29 CFR 1926.21 relating to employee training; 29 CFR 1910.141(g)(2) relating to restriction of locations for eating and drinking; and 29 CFR 1926.51(f) relating to washing facilities; and to develop a separate standard for formaldehyde exposure in the construction industry.

OSHA invites comments concerning these approaches and any additional options which would provide full protection to affected construction employees and at the same time would minimize the administrative and economic burden on affected construction employers.

1. *Paragraph (a). Scope and Application.* The proposed standard applies generally to all occupational exposures to formaldehyde. This definition of "formaldehyde" encompasses formaldehyde gas (CAS. No. 50-00-0), liquid solutions containing dissolved formaldehyde such as formalin, and formaldehyde gas released from solid materials such as urea-formaldehyde resins and paraformaldehyde. The proposed standard explicitly applies to the construction industry and to the health care field as well as to general industry. As discussed more fully below, OSHA recognizes that certain problems relevant to occupational health are unique to the construction industry and continues to examine alternative approaches to the regulation of exposure to formaldehyde in the construction industry. OSHA seeks comments on the type of standard that could be most effectively applied to construction operations.

The proposed standard applies to any workplace where exposures to formaldehyde may be found except in workplaces where the only exposure is from liquids in which the concentration of formaldehyde is below 0.1 percent. This exemption is made for several reasons. It is generally consistent with the Hazard Communication standard already promulgated by OSHA. By setting an exemption based on percentage composition, OSHA exempts trivial uses where minor amounts of formaldehyde solutions are present in products such as cosmetics, shampoos, or cleaning agents to act as a preservative. Without such an exemption, groups with truly insignificant exposures might fall under some of the standard's provisions. Finally, at 0.1 percent, formaldehyde solutions would not present a significant hazard of sensitization through dermal contact and their evaporation would not lead to exposures approaching the action level.

It should be noted that while the Hazard Communication standard generally exempts materials containing less than 0.1 percent of a potential carcinogen (as defined in that standard), any material containing formaldehyde that is capable of causing exposure over the PEL or the ACGIH TLV is covered even if the 0.1 percent exemption applies. Similarly, the Hazard Communication Standard would apply if the exposures could cause a health hazard even if the exposure is less than the PEL or TLV. While these uses of formaldehyde would not be covered under the formaldehyde proposal, they would still require labeling and other provisions under Hazard Communication. [29 CFR 1910.1200(d)(5)(iv)].

As stated above, the scope of the standard includes health care workers. There are several uses of formaldehyde in this field which may lead to employee exposure to formaldehyde including tissue preservation, sterilization, and recycling of renal dialysis filters. Under circumstances where formaldehyde is used as a fumigant or a disinfectant, provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

will apply to the person applying the formaldehyde; persons exposed as a result of the pesticidal application would be covered by this proposed standard. This is in accordance with section 4(b)(1) of the Occupational Safety and Health Act of 1970 which, in order to avoid duplicative regulatory efforts, states that it will not apply "to working conditions of employers with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." The proposed standard also applies to a number of other groups not usually covered in OSHA standards. These groups include laboratory workers as well as workers in the funeral industry who are exposed to formaldehyde in the workplace.

2. *Paragraph (b). Definitions.* The proposal is framed in broad terms so it, naturally, encompasses many employers whose employees are exposed to formaldehyde at concentrations well below the PEL. To handle such situations, OSHA generally applies an "action level" to exempt employers whose employees are at minimal risk from exposure to a toxic material from certain provisions of the applicable standard. The proposal would set an action level for formaldehyde of either 0.5 ppm or 0.75 ppm (half the proposed PELs of 1 ppm and 1.5 ppm, respectively) so that employers could focus their attention on employees whose exposure may be significant rather than on every single employee who may be exposed no matter how minuscule the exposure. Initially, all employers whose employees may receive exposure to formaldehyde must determine the extent to which their employees are exposed. Once an employer has demonstrated that an employee is exposed to formaldehyde below the action level, the employer need only take minimal action regarding these employees, such as providing employee training and any protective equipment needed to prevent skin contact with liquid formaldehyde, since neither of these provisions are triggered by an exposure concentration.

Several commenters to the ANPR opposed an action level for formaldehyde [Exs. 77-10; 77-17; 77-19a; 77-23; 77-25; 77-28; 77-34]. Reasons given were that it would not be useful because the OSHA Hazard Communication standard will require training programs and labels on products [Ex. 77-28], because there are no long-term health risks [Ex. 77-10], and because of opposition to requirements for medical surveillance and environmental monitoring [Exs. 77-18; 77-19a; 77-34]. Other commenters to the ANPR recognized that the use of an action level can increase the cost-effectiveness of a standard by relieving firms of regulatory burdens when employee exposure to formaldehyde is minimal [Exs. 77-12; 77-22; 77-27; 77-32; 77-34; 77-37].

There are two theories behind the inclusion of an action level for formaldehyde. One is based on statistical considerations, and the other is of a toxicological nature.

The statistical basis for establishing an action level is that measurements of employee exposure can vary considerably for a number of reasons, including process variations, sampling and analytical methods limitations, and seasonal changes. Even when all measurements on a given day may fall below the PEL, there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed the PEL. It has been shown that when measured levels are greater than one-half the PEL, the employer cannot have a high degree of confidence that employees are not being exposed to formaldehyde concentrations in excess of the PEL during at least some part of the work week when exposures are not measured. Conversely, when the employer has collected sufficient samples to take into account the various process and sampling related variabilities, and the concentrations are below the action level, the employer can have a reasonable degree of confidence that the PEL is not being exceeded on days when measurements are not taken.

The toxicological basis for an action level takes into account the variability of individuals in reacting to a toxic substance when it is inhaled or otherwise taken into the body. Experiments conducted on laboratory rodents minimize these inherent differences in genetic composition by selecting inbred animals from the same strain and same colony for testing. Their environments are further controlled in terms of exposures to other substances, to diet, to diurnal variations, and to temperature and humidity. Because all of these factors are variables in humans, there is a much wider range of responses to formaldehyde in workers than in test animals. In particular, these differences are seen in employee complaints and signs and symptoms of irritation from formaldehyde. Even though a few persons can handle exposure to formaldehyde at the present PEL of 3 ppm without undue complaint, at least 20 percent of the general population would have irritation at the proposed PELs of 1 ppm and 1.5 ppm. To better identify and protect persons who might be most prone to develop cancer and who are the most sensitive to the inhalation of formaldehyde an action level is established.

The proposed standard provides a definition for the term "emergency". Emergencies are occurrences such as equipment failure, failure of engineering controls, or ruptures of containers, that could result in an unexpected release of formaldehyde, potentially forcing workers to don protective equipment or evacuate the workplace. Because of the variety of uses of formaldehyde, the most severe emergency that could be credibly predicted will differ substantially on a case-by-case basis. Thus, the definition as well as what is expected of the employer is necessarily flexible.

In the proposed standard, the term "formaldehyde" applies in the following cases: (1) To the specific chemical entity with molecular formula CH_2O, CAS No. 50-00-0, and molecular weight 30, (2) to all liquids containing more than 0.1 percent by weight of this specific chemical; and (3) to the offgassing of material from all solids which are capable of releasing the chemical, CH_2O, into the atmosphere. Examples of "formaldehyde" regulated under this standard consist of formalin and of formaldehyde released from paraformaldehyde, urea-formaldehyde resins, and similar formaldehyde-containing resins.

3. *Paragraph (c). Permissible Exposure Limit.* The proposal provides for permanent reduction in the permissible exposure limit to one of two alternative limits: either an eight-hour time-weighted average of 1 part of formaldehyde per million parts of air (1 ppm) or an eight-hour time-weighted average of 1.5 parts of formaldehyde per million parts of air (1.5 ppm). OSHA proposes to revoke the existing permissible exposure limits of 3 ppm as an eight-hour time-weighted average, 5 ppm as a ceiling concentration, and 10 ppm as a peak concentration which are contained in 29 CFR 1910.1000,Table Z-2. The proposed alternative PELs are based on preliminary findings by OSHA that occupational exposure to formaldehyde presents a significant risk of material impairment of health.

OSHA has determined that occupational exposure to formaldehyde at the current PELs clearly poses significant risks of material impairment of health and functional capacity. Material impairment means employees contracting cancer; skin, eye, and respiratory irritation; and skin sensitization due to formaldehyde

exposure. In this case, OSHA is proposing alternative PELs of 1 ppm or 1.5 ppm because there is some question as to which PEL is most appropriate to respond to the health hazards posed by formaldehyde in the workplace.

First, with regard to cancer, OSHA has developed and analyzed quantitative risk assessment models using dose-response data for induction of squamous cell carcinoma in rats, producing results which show significant risk consistent with the Court's opinion in the Benzene case. From these models, OSHA's best estimate of risk of developing cancer for workers exposed to formaldehyde at the 3 ppm concentration permitted by the present standard for a working lifetime is 71–620 cases per 100,000 persons. This is not the full extent of risk from cancer at the present PELs. Based on testimony by CIIT [Tr. 246–253] and evidence of the tumors from the CIIT rat study [Exs. 12; 42–90; 42–131; 73–50]. OSHA estimates that at 2 ppm, there is roughly a 4 percent risk of developing other tumors, and that 1 to 5 percent of these might be life-threatening malignant forms.

OSHA has calculated, from the squamous cell carcinoma data in rats, that reducing the PEL to 1 ppm, as an 8-hour TWA concentration limit would decrease the risk estimated from these malignant tumors to 0.6 to 23 cases per 100,000 working life exposures. Reducing the PEL to 1.5 ppm would decrease the estimated risk to between 3.2 to 78 per 100,000.

Information showing alterations of the cellular structure in the nasal passages of animals exposed for 6 months at 2 and 3 ppm, but not at 1 ppm [Exs. 12, 42–104], further supports the conclusion that lowering the PEL to 1 ppm or 1.5 ppm would substantially reduce the risk that any workers would suffer neoplastic changes. Such alterations, particularly those that show a disruption of the structure of the cell, may be indicators of an early stage in a process that can lead to cancer if exposure is continued. Thus, consideration should be given in setting a PEL to choosing a level at which altered cell structure in the nasal passage has not been seen.

Second, OSHA has determined, based on research involving human and animal subjects and cross-sectional surveys of workers, that formaldehyde exposure at the current PEL has resulted in serious eye, skin, and respiratory irritation and occasionally resulted in respiratory sensitization. Presently existing conditions also have resulted in dermal sensitization.

Irritants, by nature, are corrosive in action. They inflame the moist mucous surfaces of the body. At sufficiently high concentrations, the acute response is so severe that the worker cannot tolerate the exposure. At lower concentrations, exposure to irritants results result in a loss of functional capacity, but such a loss is transient, fading once the employee has left the workplace where the formaldehyde exposure was occurring. Workers may become less susceptible to formaldehyde's irritant effect at low concentrations as acclimatization occurs. However, damage to the cells of the respiratory passages will continue, even without the warning provided by the irritation. OSHA is also concerned that employees exposed at the present TWA of 3 ppm will be repeatedly irritated as they enter, leave, and then return to the formaldehyde exposure area, effectively disabling many of them from continuing their work. Employees exposed at the 30-minute peak of 10 ppm would experience tearing of the eyes and other major discomforts. OSHA notes that NIOSH recommended a standard for formaldehyde in 1976 to protect workers solely from these irritant effects [Ex. 69–8B]. NIOSH's recommendations included a 1 ppm limit measured for 30 minutes and other industrial hygiene and medical provisions. OSHA agrees with NIOSH that the proposed standard can be justified by irritation effects alone.

OSHA has determined that exposure to formaldehyde at the present standard of 3 ppm clearly presents a significant risk of material impairment of employees. The significance of this risk has already been informally acknowledged by industry, which had reacted to the developing information regarding the potential health effects of formaldehyde by voluntarily reducing exposure among its employees.

Commenters in the furniture and pressed wood products industries [Exs. 77–4; 77–21; 77–28; 77–34] contend that a 2 ppm PEL, as an 8-hour TWA, would be sufficiently protective, while commenters from the apparel, decorative laminate, manufactured housing, textile, and particleboard industries [Exs. 77–23; 77–9, 77–14, 77–27, and 77–34] state that they would accept a 1.5 ppm PEL, as an 8-hour TWA. Several industry commenters [Exs. 77–23; 77–32] generally subscribe to the Formaldehyde Institute recommendation that the PEL should be reduced to between 1 and 2 ppm measured as an 8-hour TWA [Ex. 77–19a].

The Manufactured Housing Institute supported a 1.5 ppm TWA on the basis that it is "the most stringent level . . . which can be justified, based on existing scientific data" [Ex. 77–14]. This level was also recommended by a number of other commenters from the textile and wood products industries [Ex. 77–2, 77–24, 77–27, and 77–39]. A 1.5 ppm PEL would reduce occupational formaldehyde exposure to below the range where severe irritant effects would be expected.

Hess and Clark [Ex. 77–8], the Hardwood Plywood Manufacturers Association [Ex. 77–18], the Occidental Chemical Corporation [Ex. 77–37], and the College of American Pathologists [Ex. 77–37] recommended a 1 ppm TWA for formaldehyde on the basis that employers who are dealing with irritant, hazardous, or toxic effects should provide a safe and healthful work environment. Many producers of formaldehyde and formaldehyde products have already reduced workplace exposures to or below 1 ppm in order to protect their employees from irritant effects. This would provide an adequate level of protection against the various adverse effects associated with formaldehyde exposure.

Since some persons would experience symptoms of mild irritation at concentrations above 0.5 ppm, OSHA also considered lowering the PEL to 0.5 ppm as an 8 hour TWA. This would further reduce the cancer risk to between 0.3 and 2.8 cases per 100,000 employees exposed for a working lifetime. OSHA's determination of an appropriate PEL, however, is not limited to estimation of risks of acute and chronic effects. Compliance with the regulatory requirement must be shown to be feasible. The record contains relatively little information on the feasibility of a 0.5 ppm PEL, although OSHA continues to request information on this option. Two recent studies, funded by the Formaldehyde Institute, examine feasibility of regulatory options, including a 0.5 ppm PEL, in nine industries [Ex. 50; 77–19]. The authors of one of these reports, the Heiden study [Ex. 77–19] indicate that a 0.5 ppm PEL may be economically infeasible. For five of the eight industries reporting capital investment data, the capital compliance costs for a complete standard with a 0.5 ppm PEL estimated by Heiden were more than 100 percent of their annual capital expenditures. In addition, the National Electrical Manufacturers Association [Ex. 77–9] commented that a PEL set at 0.5 ppm or lower would impose serious hardship on their industry. Thus, OSHA has tentatively determined that a 0.5 ppm PEL may be economically infeasible in several segments of the formaldehyde industry.

The industry commenters raise feasibility, small business impact, and

foreign competition issues in a general manner in support of their comments, but they do not present specific enough technological, financial, or exposure data necessary for OSHA to determine whether any of the permissible exposure levels under consideration would be infeasible. OSHA encourages industry and all other parties interested in this proceeding to provide OSHA with data on current exposure levels and the feasibility and need for achieving lower levels which will aid the Agency in evaluating the alternatives. OSHA believes that either the 1 ppm PEL or the 1.5 ppm PEL would be reasonable standards and that either limit would reduce occupational risks associated with formaldehyde exposure.

Short Term Exposure Limit (STEL): The present standard allows a maximum peak exposure of 10 ppm and a STEL of 5 ppm as long as the 8-hour TWA is no greater than 3 ppm. OSHA believes that there is great cause for concern about the degree of irritation permitted by the present ceiling and peak concentration limits. As the National Particleboard Association (NPA) commented in response to the ANPR [Ex. 77–39]:

> The 10 ppm peak currently permitted . . . would cause severe short-term discomfort to workers and the NPA urges its abolition. The current 5 ppm ceiling should also be lowered. NPA recommends that OSHA set a STEL of 2 ppm to avoid serious irritation and discomfort [Ex. 77–39].

Even if the PEL is lowered to 1 ppm or to 1.5 ppm as an 8-hour TWA, there is still the possibility that a short-term exposure limit (STEL) will be needed to ensure that employees are not exposed to bursts of formaldehyde which, while not necessarily in violation of the PEL, would potentially expose employees to excess risk of acute and chronic health effects. Evidence in the record indicates that formaldehyde causes acute effects at levels which would be permissible under the proposed PEL of 1 ppm or 1.5 ppm when measured as an 8-hour TWA [Ex. 73–72, 77–11, 73–97]. The acute effects associated with formaldehyde exposure include eye and upper respiratory tract irritation, as well as skin sensitization, which makes the worker extremely susceptible to or intolerant of very low levels of formaldehyde that may be encountered as part of every day life. While some people may suffer from these acute effects at extremely low levels of exposure, the number of people likely to suffer from some or all of these acute effects and the severity of the effects will increase as the short-term exposures increase, with a substantial percentage of the exposed population suffering moderate to severe effects above 2 ppm.

In addition, evidence in the record indicates that high exposures of formaldehyde over a short period of time are more harmful than low doses over a long period of time, even where the total dose is the same. As discussed more fully above, Swenberg et al. [Ex. 70–23] found that animals with higher concentration exposures incurred more lesions and more cell turnover than animals with almost identical cumulative doses administered at a lower rate over a longer period of time. This increased cell turnover is in response to cell damage caused by formaldehyde exposure and is thought to be associated with increased risk of cancer.

If the health effects of formaldehyde are related to total dose alone, without regard to temporal distribution of that dose, an 8-hour TWA limit on exposures will reduce the risk of those health effects by limiting the total dose received. However, if the effects from exposure can be shown to be greater when the total dose is received in a short period than when it is spread over a longer period, an 8-hour TWA limit alone might not be adequate to reduce the risks. In the event of such a "dose-rate" relationship being established, a STEL might be warranted as a supplement to the TWA in order to provide protection against additional risk attributable to concentration of the dose over short periods.

The ACGIH as well as the ILO have recommended that short-term exposure limits or ceilings be adopted as part of the permissible exposure limit for formaldehyde. The National Particleboard Association recommended a STEL for formaldehyde because:

> . . . the relevant health consideration—irritation—is noncumulative and totally reversible. Therefore, the most important regulatory aspect is a more stringent limitation on short term exposures. The current ceiling[s] . . . are too high. Such levels will produce discomfort for workers. The peak should be eliminated. A new short term exposure limit ("STEL") should be set at a lower level—perhaps two ppm—which would provide a margin of safety from strong irritation [Ex. 77–39, p. 3].

Many industry commenters also generally favor the implementation of a 2 ppm STEL [Exs. 77–4, 77–5a, 77–16 to 77–20, 77–23, 77–27, 77–37, 77–39]. In fact, some have already adopted STELs as internal exposure guidelines [Ex. 77–16, 77–5a, 77–17, 77–24, 77–37]. The ACGIH suggests that a STEL of 2 ppm may prevent the development of "serious or persistent adverse effects" [Ex. 73–159]. In addition, the Formaldehyde Institute believes that a revision in the current 10 ppm short-term limit is appropriate and supports a 2 ppm STEL based on research by Yale University, the Mayo Clinic, and Frigas [Ex. 77–19a]. Temple-Eastex [Ex. 77–28] suggested a 3 ppm STEL. On the other hand, NIOSH and the American Nurses' Association [Exs. 77–11; 77–40] have proposed a 30-minute ceiling of 1 ppm. A number of other countries, including Australia, Belgium, Japan, the Netherlands, and the United Kingdom, have adopted maximum acceptable concentrations of 2 ppm for formaldehyde.

Some of those advocating a STEL of 2 ppm felt that it should be measured over a 30 minute period [Ex. 77–19a, 77–4, 77–5a, 77–19a] while others, such as the ACGIH, DuPont, and Occidental Chemical recommended that the STEL be for a 15 minute period [Ex. 73–159, 77–16, 77–37]. OSHA requests comments on whether the STEL, if promulgated, should be based on a 15 minute or a 30 minute period.

Based on the present record, OSHA recognizes that there is substantial and widespread support for the use of a STEL to supplement the 8-hour TWA. There are also compelling reasons of health risk to consider the need for a STEL.

If a STEL is enacted, a 2 ppm STEL during a 15- or 30-minute period seems to be the most likely choice although other figures, including 1 ppm, have also been suggested. OSHA will continue to examine the adequacy and need for the proposed TWA concentration limit and will consider values both higher and lower than 1 ppm.

4. *Paragraph (d). Exposure Monitoring.* Section 6(b)(7) of the Act mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." OSHA has determined that the proposed monitoring program for formaldehyde meets this objective because it assures that employees will be aware of any employee exposures exceeding the PEL.

This proposal would require the employer to conduct initial monitoring to identify all employees who are exposed to formaldehyde at concentrations at or above the action level. When an employee's exposure is at or above the action level, the employer would be required to monitor the employee's exposure to formaldehyde on a periodic basis.

OSHA has proposed that periodic monitoring must be conducted with sufficient frequency to assure that a true measure of existing conditions is made. Once the employer becomes aware of employee exposure above the PEL, the employer is obligated by other provisions of the proposed standard to take actions to lower that exposure. More frequent monitoring is warranted to determine the effectiveness of these measures in protecting workers.

As the result of newly installed control technology or improved work practices, the employee's exposure to formaldehyde may decrease. When the employee's exposure is definitely below the action level, the employer would be able to discontinue monitoring of the employee. If an employee's exposure had been over the PEL, the employer could decrease the frequency of monitoring when there is conclusive evidence that the employee's exposure has decreased to below the PEL or below the action level, as appropriate.

Although several industries expressed opposition to being compelled to conduct employee exposure monitoring, they did not suggest alternative methods for assuring that the employer keeps informed of the concentrations of formaldehyde to which the employees are being exposed. It could be argued that action, and not simply awareness of employee exposures, is needed on the part of the employer to comply with the proposed standard, but a lack of knowledge of employee exposure levels assures that compliance with the formaldehyde standard as proposed would be purely coincidental. Thus, OSHA has determined that the employer's need to know the exposures existing among the workers is fundamental to the provision of a healthful workplace. Exposure monitoring is considred a critical item in the proposed standard.

There are circumstances where very small amounts of formaldehyde are present in the workplace, but at concentrations such that the employer would be covered under the formaldehyde standard. To minimize the costs of initial monitoring for these employers, OSHA has proposed that they may substitute a determination that employees are exposed below the action level based on objective data. Where objective data are used in lieu of monitoring data to make a determination that monitoring will be unnecessary, the employer must document the available information that supports an exemption and must maintain a record of this information.

The proposed standard does not require downstream employers to generate their own objective data on formaldehyde concentrations likely to be released from a product. Some industries have developed information about formaldehyde emissions from various products because of other regulations or the need to limit consumer exposure. For example, the wood products industries have standardized product emissions tests [Exs. 70–3; 70–15] designed to show that they are achieving the HUD product standard [Ex. 70–27].

Objective data can be useful to the employer to determine the concentrations of formaldehyde in the workplace. In combination with information on room dimensions, air exchange rates, and other pertinent data, some employers may be able to show that the action level could not be exceeded. For example, by knowing the ventilation rate in a workplace and the quantity of material generated, the employer may be able to calculate the maximum exposure that could be anticipated. To perform this calculation, the employer must include a safety factor to take into account poor mixing of the material into the entire room, locations of fans, and proximity of the workers. A safety factor of 10 has been recommended generally except that a safety factor of 100 was suggested when the employee stays relatively close to the source [Ex. 73–176].

The purpose of the monitoring program is to enable the employer to calculate the actual exposure of each employee who is exposed to formaldehyde at concentrations over the action level. To do this, the employer must first establish where exposure to formaldehyde occurs and then detect changes or trends that occur over time. The employer must then devise a sampling strategy that will assure identification of all employees exposed above the action level.

To comply with the proposed standard, the employer need not use statistical procedures to decide who to monitor. Instead, the employer may measure the actual exposure of each potentially exposed employee. In most circumstances, however, it is more cost-effective to establish a monitoring program based on the variabilities of employee exposure.

The primary sources of variation that affect estimations of occupational exposure are: random sampling device errors (eg. fluctuations in pump flow rate); random analytical method errors (eg. fluctuations in the chemistry laboratory); random within-day fluctuations in formaldehyde concentration; random between-day fluctuations; systematic errors of measurement (eg. improper calibration of pump); and systematic changes in the contaminant airborne concentration (eg. from opening windows, turning off ventilation). Random day-to-day and shift-to-shift fluctuations are influenced most by the physical process generating formaldehyde, the nature of the formaldehyde to which the workers are being exposed, and the work habits of the employee.

The random fluctuations of a contaminant in a plant generally greatly exceed the random variations found for sampling and analysis. Consequently, OSHA does not permit the employer to discontinue monitoring solely on the basis that employee exposure has decreased to below the action level for a single monitoring period and OSHA also requires the employer to sample for each shift unless the employer has demonstrated that the within-day fluctuations are minimal.

Before the employer can establish who should be monitored, the employer must conduct a material survey to find where in the workplace formaldehyde is being used and if so the conditions of use. This first step requires the determination and tabulation of all work operations where formaldehyde is used or produced. This information is generally available from purchase records or material safety data sheets.

Next, the employer must investigate the process or work operation. Some processes tend to cause greater problems of dust generation or liquid spills. For example, heat processes liberate more formaldehyde gas from urea-formaldehyde resins than most other operations.

Finally the employer or his representative needs to visit the workplace and observe the actual work operations. Attention must be given to employee location in relation to the source of formaldehyde. Adequacy of each employee's work practices needs to be examined. Attention should be given to employee complaints or symptoms of exposure and to the air flow patterns within the work area. The goal of this first phase of the initial determination, to identify whether any employee may be exposed to airborne concentration of formaldehyde in excess of the action level, should now be met.

To determine if the action level is actually exceeded, the employer will have to conduct exposure monitoring. In general, a sampling strategy that employs the most efficient use of resources requires identification and measurement of the employee presumed to have the highest exposure risk. This employee is selected by observation and

is usually the person closest to the source. However, the closest person may spend time at other sites and air movement patterns and differences in observed work habits may also occur, leading to the choice of another employee.

The object of selecting the maximum risk person is to determine if the measured exposure of any employee is above the action level. If the exposure of the most-heavily exposed employee does not exceed the action level, then it is safe to assume that the exposure of the other employees in the work area are also not exposed above the action level and no further action is needed upon the part of the employer until conditions change so that the validity of the measurement can no longer be assured.

If the exposure of the maximum risk employee is over the action level, then the employer must identify and measure other employees whose exposures may be above the action level. Once all such employees are identified, the employer has completed initial monitoring and may use this information to select the employees who will be monitored periodically.

OSHA requires periodic monitoring of employees exposed over the action level every six months and periodic monitoring of employees exposed every six months and periodic monitoring of employees exposed over the PEL every three months. One of the most important reasons for periodic measurements of employee exposure is to detect trends or systematic changes in the long-term exposure average. A secondary benefit is a better estimate of the variation of the exposure over extended periods, but this in not the primary purpose of periodic exposure monitoring. Periodic measurements are one of the most informative ways to detect hazardous shifts in exposure levels or to indicate that hazardous levels are being approached.

In some cases, the employer will be unable to select the maximum risk worker with reasonable certainty. In general random sampling is less desirable than sampling of the maximum risk employee. The distribution of sampling results for any given operation is usually log-normal. This means that exposure averages cover a wide range of values, often over an order of magnitude. The maximum risk employee can easily have exposures 200 to 300 percent over the group average, and there is a good chance that by the use of group averages, the exposure of this employee will be underestimated. Use of average exposure may be acceptable when the standard deviation on the sampling results for the group are very low, eg. a GSD of 1.15 or less (see NIOSH publication 77-173, Occupational Exposure Sampling Strategy, by N.A. Leidel, K.A. Busch, and J.R. Lynch for details).

If random sampling of the group is used, a larger number of samples will probably be required [Ex. 73-176]. For example, to ensure with a 90 percent confidence that at least one of the workers with exposure to formaldehyde in the highest 10 percent is measured by the random sampling method, 9 of 10 employees must be measured. Likewise, 13 of 20, 16 of 30, 17 of 40, and 18 of 50 employees must be measured. Again, the purpose of such sampling is the same as the measurement of the maximum risk employee, to determine if the measured exposure of any employee is above the action level.

Once the random sampling is conducted and employee exposures as calculated from the results, the employer has completed the initial monitoring requirement and must then implement periodic monitoring as required.

OSHA requires that monitoring of employee exposure be conducted by personal sampling in the employee's breathing zone and does not permit the use of respirators to be taken into account in calculating the employee's exposure. However, it is recognized that area sampling, continuous monitors, and leak detection are an integral part of most industrial hygiene programs. Indeed, these measures can help to define the sources of emissions of formaldehyde, which can be invaluable information for the initial determination. Monitoring of emissions is also necessary to evaluate the effectiveness of engineering controls. Area samples are useful in defining the boundaries of regulated areas.

OSHA agrees with commenters [Exs. 77-18; 77-20] who point out that the diverse uses of formaldehyde and the many acceptable monitoring methods are reasons why requirements for exposure monitoring should be performance-oriented. However, OSHA feels that some guidance should be given to assure the adequacy of the information collected and to ensure that the standard can be enforced.

There are several methods available for measuring employee exposure to formaldehyde [Exs. 58, 77-19a]. Most use solid or liquid sorbents and sampling pumps, followed by analysis of the samples by instrumental methods. OSHA's Salt Lake City laboratory, which supports the Agency's compliance effort, employs a polaragraphic method (see Appendix C). Several methods have been developed by NIOSH, although NIOSH no longer recommends method no. P&CAM 318 because it was found to give erroneously low results under most field situations [Ex. 77-11]. Passive dosimeters are used by many companies because they are simple and relatively inexpensive. With passive badges, formaldehyde can be measured as easily by small firms as by large companies. However, different monitors appear to be more applicable than others in dusty or humid conditions and some problems with low or erratic readings have been reported [Ex. 58-12]. In addition, there are several commercially available portable gas analyzers and monitoring units capable of giving continuous readouts which can be useful as instantaneous area monitors [Exs. 58; 77-19a].

The proposal does not specify the use of a particular monitoring method. To some extent this will depend on the resources of each employer and the potential interferences present in each worksite. The proposal does require the employer to chose a method which is sensitive enough to detect formaldehyde in the range encompassed by the PEL and the action level.

The employer must determine that the method chosen can measure airborne concentrations of formaldehyde of [1 ppm or 1.5 ppm] as an 8-hr TWA within ±25% of the "true" value at the 95% confidence level. This means that 95 percent of the measurements must be as accurate as the standard requires. If the method used is unbiased and the errors generated are normally distributed, the coefficient of variation (CV), also known as the relative standard deviation (RSD) can be used to judge if the method has the required accuracy. The CV in percentage units is the standard deviation of the method, times 100, divided by the true value. The required total coefficient of variation of the sampling and analytical methods are: above the PEL, total CV less than 12.8 percent; at or below the PEL but above the action level, total CV less than 25.5 percent [Ex. 73-176]. OSHA has included this accuracy requirement in other toxic substance standards. It was also one of the criteria for acceptability of methods of sampling and analysis developed specifically for the Standards Completion Program. (These methods have an "S" designation in the second edition of the NIOSH Manual of Analytical Methods).

The proposed standard requires the employer to notify the employee of the monitoring results that represent the employee's exposure. This information must be in writing, but to make this requirement less burdensome to some

employers who may not have an adequate system existing for distribution of copies of the results, this written notification obligation may be met by posting the results along with an identifier of all employees represented by the monitoring results in an area regularly used by all of the affected employees (eg. the job site, at the entry to the area). If the PEL is exceeded, the employer must post a description of corrective measures which will be taken. This is mandated by section 8(c)(3) of the Act and OSHA considers this provision necessary to alert the affected employees to the condition.

Based on OSHA's experience with other toxic substance standards, a 15-day period is considered a reasonable maximum time to inform affected employees of monitoring results after they have been received by the employer. It has been suggested by a member of the Construction Advisory Committee that more prompt notification is needed when the PEL is being exceeded, and OSHA is considering this option, but it is believed that the use of a calendar-day as opposed to a working day requirement should satisfy most of these objections.

5. *Paragraph (e). Regulated areas.* The proposal would require employers to establish a regulated area where airborne exposures to formaldehyde exceed the PEL. Access to the regulated area would be restricted to persons whose duties require their presence in the area. This provision applies when the PEL is likely to be exceeded, and it does not apply to inadvertent releases covered under the section on emergencies.

The purpose of a regulated area is to ensure that employers make employees aware of the presence of formaldehyde at levels above the PEL in the workplace. The establishment of a regulated area is an effective means of limiting the risk of exposure to substances known to be or suspected of having potential carcinogenic activity in humans. Because of the serious nature of the possible exposure and the need of persons entering the area to be protected by properly fitted respirators, the number of persons given access to the area should be limited to only those employees needed to do the job. The regulated area must be demarcated with signs clearly indicating that only authorized persons wearing proper protective equipment may enter the area. If OSHA ultimately decides to regulate formaldehyde only as an irritant, the decision to include regulated area provisions in the final rule may have to be reconsidered.

This section also requires that, whenever an employer at a multi-employer worksite establishes a regulated area, that employer must communicate effectively the location and access restrictions to other employers at the worksite. Such communication would lessen the possibility that unauthorized persons would enter the area or that workers not involved in formaldehyde-related operations would be exposed inadvertently. OSHA would require employers whose employees are exposed to formaldehyde at concentrations above the PEL to be responsible for coordination of their work with other employers whose employees could suffer excessive exposure because of their proximity to the source of exposure to formaldehyde.

The regulated area provision reflects OSHA's concern that the employees at nearby sites be aware of the existence of the hazard and respect the need to remain outside of the perimeters delineated as a regulated area. While this could be accomplished by the employees of the second employer simply reading the signs posted by the first employer, this would not assign accountability. If the second employer is aware of the hazards, then it is the responsibility of the second employer to assure that his employees do not enter the regulated area of the first employer without permission and proper protective equipment.

6. *Paragraph (f). Methods of Compliance.* The proposed standard would require the employer to reduce employee exposures to within the permissible limit by use of feasible engineering and work practice controls. Employers would be required to institute engineering and work practice controls to reduce exposures to the lowest feasible level even if these measures, alone, would not reduce the concentration of airborne formaldehyde below the PEL. The employer would be required to supplement these controls with respirators to ensure that employees are not effectively exposed to formaldehyde at levels above the PEL.

OSHA would require that employers use engineering controls to comply with the proposed standard, because these controls would reduce exposure hazards in the workplace environment by removing, at least in part, the contaminant from the air. OSHA has found that employers also generally need to modify their work practices in order to operate engineering controls effectively. OSHA considers the use of respirators to be the least satisfactory approach to exposure control because they provide adequate protection only if employers ensure that respirators are properly fitted and worn. Unlike engineering controls and work practices, respirators are intended only to protect employees who are wearing them from a hazard, rather than reducing the hazard. OSHA has concluded that employers have been unable to ensure that respirators would consistently provide the necessary protection. Accordingly, OSHA would permit reliance on respirators only insofar as employers can demonstrate that the engineering controls and work practices needed to comply with the PEL are infeasible or unavailable. This is appropriate because the employer is in the position to know the amount of capital investment that can be feasibly appropriated for control measures, the types of control devices that are available for controlling emissions in his particular industry, the costs and availability of these devices, the extent to which work practices can be modified to reduce employee exposure, and alternative methods to achieve the same goals.

There are certain activities, often involving maintenance and repair operations as well as those in emergency situations, where the use of engineering and work practice controls is not feasible. Where engineering controls are not feasible, the employer, nevertheless, has the obligation to protect employees. This obligation may require the use of respirators as a primary means of control.

OSHA policy in the past in this matter has been spelled out in the Respiratory Protection Standard, 29 CFR 1910.134(a)(1), which applies to all exposures to airborne toxins, and in the Air Contaminant Standard 29 CFR 1910.1000(e), which applies to exposures to all substances listed in Table Z-1, Z-2, and Z-3. This policy was inherent in the national consensus standards which were adopted by OSHA in 1971, pursuant to section 6(a) of the OSH Act of 1970.

Subsequent additions to Subpart Z, which were developed through section 6(b) rulemaking proceedings also reflect OSHA's determination that employers must control hazards by engineering and work practice controls instead of respirators to the extent feasible.

Several groups, including the apparel industry and pathologists, [Exs. 77-2; 77-9; 77-35] have indicated that their members do not consider respirators a reasonable alternative for exposure control in their work situations. Reasons cited included worker resistance, safety, and the need to be able to communicate

during work. Workers would be required to wear full facepiece respirators in nearly every case to prevent eye irritation. Because full facepiece respirators are heavier, less comfortable, and restrict vision and speech even more than half mask respirators, worker resistance to the use of respirators probably would be even higher than normally encountered in an industrial setting. OSHA is also concerned about the apparent safety hazard that the use of respirators, particularly full-facepiece respirators would seem to pose in industries where formaldehyde is used. OSHA requests comments from the public on the applications where the use of respirators has been an effective method for the control of exposures to formaldehyde. This information should analyze how employees accepted the respirators, safety hazards introduced, possible productivity losses or gains, and any other limitations imposed by the use of respirators. OSHA also seeks information on situations where respirator use for the control of formaldehyde exposure is unacceptable.

While it is not a completely prohibited practice, OSHA discourages the use of worker rotation as a tool for complying with the PEL. Because sensory irritation is a concentration-dependent health effect that can occur within a matter of minutes, employees will be unable to tolerate concentrations much above 1 ppm for any substantial portion of the workday. Workers would be especially unable to tolerate the extremely high exposure levels, as high as 32 ppm in 15 minutes, that are theoretically possible consequences of the proposed PEL. In addition, if OSHA finds formaldehyde to be a potential occupational carcinogen, this would be another reason to discourage employee rotation to achieve the PEL. If the PEL is achieved by rotating workers, then many additional cases of cancer might result. Consequently, worker rotation is a poor industrial hygiene practice for achieving the PEL for formaldehyde.

There are other acceptable ways that some industries have used to lower employee exposure without incurring costs from installation of engineering controls. Employers in the wood products and textile industries, including garment manufacturing, have successfully reduced emissions from consumer products while at the same time reducing employee exposures to formaldehyde by product substitution and reformulation. These changes have been primarily in the area of substitute resins or resins formulated to contain less releasable formaldehyde [Exs. 69–7; 69–9; 69–13; 70–5; 70–8; 70–9; 70–14 to 16; 77–2; 77–14; 77–18; 77–20; 77–39]. There is an additional benefit to control of exposure through product substitution because this also reduces subsequent exposure of employees in downstream industries and consumers who purchase the product. Even though OSHA does not explicitly recognize product substitution as another method for controlling employee exposure to formaldehyde, OSHA encourages this practice where employers find it a cost-effective substitute for engineering controls.

7. *Paragraph (g). Respiratory Protection.* When engineering controls and work practices cannot reduce employee exposure to formaldehyde to within the PEL, the employer must protect employees' health by the use of respirators. The proposal requires employers to provide respirators at no cost to the employee and to ensure that employees use the respirators properly. OSHA views this allocation of costs as necessary to effectuate the purposes of the Act. This requirement would make explicit an agency position which has long been implicit in the promulgation of health standards under section 6(b) of the Act.

Whenever respirator use is permitted under the proposal to control exposures to formaldehyde, the employer must implement a comprehensive respiratory protection program. The protection program must include the elements set forth in the general respiratory protection standard, 29 CFR 1910.134 which contains basic requirements for proper selection, fit, use, cleaning, and maintenance of respirators.

The proposal also contains a table (Table 1) listing the types of respiratory protection to be provided based on airborne concentrations of formaldehyde in the workplace. The respirator selection table is consistent with the American National Standard Institute's Z–88.2–1980 respirator protection factor table. Although half-mask respirators are permitted to maximize employee comfort when concentrations of formaldehyde are only slightly above the proposed PEL, many workers are likely to develop eye irritation at these levels. Such workers will need full facepiece respirators even at these relatively low concentrations because of their eye irritation. The respirator selection table makes clear that full facepiece respirators must be provided if an employee complains of eye irritation, even if the amount of formaldehyde to which the employee is exposed is low enough to otherwise permit selection of a half facepiece respirator.

Employers would select respirators from those certified as being acceptable for protection against formaldehyde by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH), under the provisions of 30 CFR Part 11.

When negative pressure respirators are used, OSHA would require respirator fit testing because proper fit is critical to the performance of negative pressure, air-purifying respirators. With this type of respirator, a negative pressure is created within the facepiece of a properly fitted respirator when the wearer breathes. A poorly fitted respirator would allow workplace air to enter the facepiece through gaps and leaks in the seal between the face and the facepiece instead of passing through the sorbent material. Obtaining a proper fit for each employee may require the employer to provide two or three different sizes and types of masks so that an employee can select the most comfortable respirator having a facepiece with the least leakage around the face seal.

Quantitative fit testing is a procedure whereby the level of penetration of a test agent of a known concentration is measured inside the facepiece of a respirator. Different facial features and contours necessitate experimentation with different facepieces to obtain a good seal for each wearer. Quantitative fit testing is recognized to be a good method for determining how well a respirator fits the wearer and it promotes better fitting in that it allows the employer to determine which facepiece, among a number of available facepieces, is the best fitting. The best fitting facepiece can then be selected for the tested employee to use.

The proposed standard would require the use of quantitative fit testing where negative pressure respirators are used to reduce employee exposures to formaldehyde and a nonmandatory protocol is included as Appendix D. OSHA has determined that quantitative fit testing is necessary in this case because of the peculiar warning properties of formaldehyde. The odor threshold of formaldehyde has been reported to be approximately 1 ppm [Ex. 73–120], but with repeated exposures to small amounts of formaldehyde, the worker's ability to detect 1 ppm of formaldehyde is lost. Because formaldehyde reacts with the nerve endings of the nose, repeated exposure also diminishes the ability to smell common odorants such as those used in

qualitative fit testing [Exs. 42–10; 42–71; 42–136]. Thus, there is a definite risk that some workers who have been exposed to formaldehyde in the past would select an improperly fitting respirator during a qualitative fit test and then be unable to perceive that the respirator is not providing adequate protection under conditions of actual use. For these reasons, OSHA proposes that negative pressure respirator fit testing be conducted by quantitative measures only.

In a number of other standards, OSHA has allowed the employer to use qualitative as opposed to quantitative fit testing of negative pressure air-purifying respirators. (See for example the ethylene dibromide proposal and the final rule in lead, 29 CFR 1910.1025(f)). Qualitative fit testing is a technique whereby a person wearing a respirator is tested to see whether a test agent with a low odor threshold can be detected inside the respirator. Qualitative fit testing is a more subjective test than quantitative testing because it depends on the individual's ability to detect the test agent rather than actually measuring the amount of the test agent entering the facepiece.

Quantitative fit testing is more expensive to perform than qualitative fit testing and it does require the use of moderately sophisticated testing equipment. The lead standard, while originally requiring the use of quantitative fit testing, was subsequently modified to permit the use of quantitative fit testing following a rigid protocol. This modification of the lead standard was based on a finding that under the circumstances of that case, qualitative fit testing could provide the same assurances of employee health protection as qualitative fit testing (47 FR 51110–51119, November 12, 1982).

In the case of formaldehyde, OSHA has determined that in some cases respirators selected by use of a qualitative fit test procedure may provide inadequate protection to employees who must wear them. Moreover, a consideration of the differing properties of the two substances supports this decision. Thus, the record presently existing for formaldehyde favors the use of quantitative fit testing despite the contrary decision in the lead standard. Lead had not been described as a potential occupationsl carcinogen. Biological monitoring provided a backup to air monitoring so that respirator failure would be discovered because of an increase in the employee's blood lead. There was also no indication that exposure to lead would cause a commonly used odorant, amyl acetate, to give erroneous and potentially dangerous results. Also, the lead standard specified precise retesting schedules for quantitative fitting methods, which aggravated any problems due to the unavailability of testing facilities.

In the case of formaldehyde, OSHA does not believe that the imposition of the requirement to perform quantitative fit testing will impose an undue burden on employers. It does not appear that there will be widespread use of negative pressure respirators to meet the proposed PEL (See Preliminary Regulatory Impact Analysis). In the case of lead, other hand, many employers would have had to rely on negative pressure respirators over a long period of time, thereby aggravating occasional difficulties that may be encountered with the testing method.

While OSHA believes that the requirement to do quantitative fit testing for negative pressure respirators is generally feasible as proposed, this does not necessarily mean that every employer in every situation will find the requirement feasible. This does not make the requirement infeasible, however. If an individual employer has trouble meeting this requirement, a positive pressure respirator meeting the specifications in Table 1 may be used. In addition, depending on the particular circumstances involved, an employer might successfully apply for a temporary variance to meet the requirement in the unlikely event that the employer encounters difficulty in obtaining equipment or hiring personnel to comply with this requirement. OSHA intends to consider this issue further if public comment shows that a different approach might be warranted.

Under 29 CFR 1910.134, the employer must ensure that employees' respirators fit properly and leakage is minimized. By choosing from only those respirators specified in Table 1, the employer minimizes the change that the respirator will provide an inadequate fit since selection criteria are based on worst fits, and not on averages. Thus, any half mask showing a fit factor of less than 10 and any full facepiece showing a fit factor less than 50 must be rejected because it will not be adequate to prevent employee exposure above the PEL. Respirator fit testing is conducted in an idealized setting, and fit factors found are generally much better than what could be expected under conditions of actual use. Consequently, if at all possible, the employer should permit selection of a half mask only if a fit factor of at least 100 was measured. Likewise, full facepiece masks having a fit factor of less than 1,000 should not be selected.

Once the proper respirator has been selected, a simple fit test performed at the start of each shift by each employee wearing a negative-pressure respirator can meet the objective of demonstrating that a facepiece seal is being obtained. This test can be either a positive pressure test, in which the exhalation valve is closed and the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure test, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Employees must receive training to perform this test properly.

The existing regulation, 29 CFR 1910.134, requires the employer to properly train the employee to wear the respirator and to establish a respiratory protection program containing basic requirements for proper selection, use, cleaning, and maintenance of respirators. For employers to ensure that employees use respirators properly, OHSA has found that the employees need to understand the respirator's limits and the hazard it is protecting against in order to appreciate why the employer imposes specific requirements to be followed when respirators are used.

Respirator canisters and cartridges have limited useful lives. Because the olfactory nerves are able to adjust to slight incremental increase in formaldehyde [Ex. 70–29], workers are unable to detect slowly developing leaks that would be expected to occur in a developing respirator failure. Because of these inadequate warning properties, especially in long-term employees who are also less sensitive to the smell of formaldehyde, cartridges must be replace after one workshift and canisters must be replaced within 48 hours after first use or in accordance with the manufacturer's specifications if an end-of-service-life indicator to show when breakthrough occurs is attached. The respirator wearer who detects the odor of formaldehyde or feels eye irritation should leave the area immediately and replace the air purifying device before reentry. However, the ability to perceive formaldehyde dulls over time as a worker adapts to it, and the perception of odor should never be relied upon as an indicator of respirator effectiveness.

8. *Paragraph (h). Protective Equipment.* Many studies in the record show that formaldehyde can cause irritation and allergic contact dermatitis. The proposed standard requires that the employer provide and assure that

employees who are subject to skin contact with formaldehyde solutions use appropriate protective clothing and equipment that will prevent the skin and eyes from coming into direct contact with these solutions. Similarly, workers must be provided with and wear appropriate protective clothing and equipment to prevent skin or eye contact with irritating or sensitizing solid materials containing formaldehyde. The equipment to prevent skin and eye contact with sensitizing or irritating materials containing formaldehyde is stated in performance language in view of the widely varying characteristics of different formaldehyde resins and various formaldehyde-treated materials. Moreover, it would be extremely difficutlt to provide an exhaustive list of the various materials containing formaldehyde which might be irritating or sensitizing, especially since new formaldehyde-based resins are being developed on a continuing basis.

The proposal is sufficiently performance-oriented to allow the employer enough flexiblity to provide only the protective clothing and equipment necessary to protect employees in each particular work operation from the formaldehyde exposure encountered. Therefore, compliance can be tailored to fit the hazards posed on a day-to-day basis. A number of operations will not require protective clothing or equipment, especially when the chances of skin contact with formaldehyde solutions are extremely unlikely. On the other hand, where there is a possibility of skin contact with formaldehyde solutions or irritating or sensitizing forms of materials containing formaldehyde the selection and amount of protective clothing and equipment must be adequate to achieve the objective, that is, to prevent skin contact.

Types of appropriate equipment might include full body protective suits, aprons, boots, head covering, and face shields. The "ACGIH Guidelines for the Selection of Chemical Protective Clothing" lists butyl rubber, neoprene, nitrile, PVC, and chlorinated polyethylene as material which can provide adequate protection against a 37 percent formaldehyde solution [Ex. 48]. The proposal does not require that protective clothing be of one of these named materials; the list is included merely as an aid to the employer. The employer must provide any protective clothing or equipment that can demonstrably provide similar protection against the strength (concentration) and form of formaldehyde being used. In this way, the proposed standard will not interfere with any developing technology or innovative techniques that may efficiently protect the skin and eyes of formaldehyde-exposed employees.

Generally, the hazards sought to be protected against in the protective clothing and equipment sections of the various OSHA health standards are the hazards to skin and eyes from liquid and solid forms of the regulated substance. Here, however, the record evidence also indicates that airborne concentrations of formaldehyde at levels within the range of the proposed PEL can cause eye irritation in some individuals. Therefore, the proposal requires the employer to make gas-proof goggles available to any employee suffering eye irritation from airborne concentrations of formaldehyde. (In a similar vein, the proposal provides that employees wearing half mask respirators suffering eye irritation must wear full facepiece respirators instead of half-facepiece respirators.)

There is some information in the record to indicate that individuals may even develop allegeric dermatitis from exposure to airborne concentrations [Exs. 42-66; 69-8B]. This situation is thought to be quite rare, especially at exposure levels likely to be encountered in today's workplace.

The proposal also includes a provision requiring the employer not to allow the employee to take or wear home work clothing or equipment that is wet with liquid formaldehyde or contaminated with formaldehyde solids. This is consistent with good industrial hygiene practice and is designed to eliminate or greatly reduce the possible exposure to formaldehyde, a potential occupational carcinogen, that might result from contact with contaminated work clothes by fellow employees as well as family members of the exposed employee. Similarly, the proposal provides that contaminated work clothing must not be reworn until it is cleaned. Re-wearing work clothing that is contaminated with irritating or sensitizing formaldehyde materials is prohibited to prevent additional exposure and an enhanced chance of irritation or sensitization to formaldehyde from such exposure.

The proposal provides that formaldehyde contaminated clothing and equipment be stored in such a manner as to minimize employee exposure. Thus, the area where formaldehyde-dampened clothing and equipment is stored must be sufficiently apart from areas where employees work or congregate or from facilities which are used by employees so that no additional exposure to employees results from storing the formaldehyde-dampened articles in this manner. When formaldehyde-bearing articles are stored in containers, the containers shall be labeled to warn of the potential hazard. Where the equipment and clothing is stored in a segregated area (as opposed to a container), prior to cleaning, the storage area shall have a warning sign to alert employees to the hazard. The requirements proposed for the storage of contaminated equipment and clothing constitute good industrial hygiene practice and are consistent with practices recommended by the British chemical industry [Ex. 73-64].

9. *Paragraph (i). Hygiene Protection.* The proposal requires that the employer provide quick drenching facilities at convenient locations within the work area for the immediate use of any employee who gets formaldehyde splashed on the face or whose skin or clothing becomes wet with formaldehyde solutions. The quick drenching facilities, also known as emergency showers, should be able to drench the employee with piped-in water applied with force. Such facilities are necessary in workplaces where employees work with formaldehyde solutions.

Skin contact with liquid formaldehyde has been associated with irritation, allergic contact dermatitis, and delayed reactions including swelling, redness, and blistering. Sensitization may also result from skin contact with liquid formaldehyde. Non-impervious clothing which becomes wet with formaldehyde solutions also poses a hazard because the clothing holds the formaldehyde against the skin, thereby aggravating the exposure.

Two factors which affect the severity of the skin reaction to formaldehyde are the concentration of formaldehyde as well as the length of time that the wet material remains in contact with the skin. In addition, any time a portion of the body becomes wet with a concentrated solution such as formalin (37% formaldehyde), the employee's exposure to airborne concentrations of formaldehyde is necessarily increased because of the close proximity of the substance to the employee's breathing zone and its tendency to evaporate. Employees working near such a worker may also suffer increased exposure. Therefore, it is necessary to remove the formaldehyde from the skin and clothes with dispatch to reduce the likelihood and severity of dermatological problems and reduce the chance of overexposure to airborne concentrations of formaldehyde likely to result.

The proposal also requires that eye wash fountains be available within the

immediate work area for emergency use when there is any possibility of the eyes being splashed with liquid formaldehyde. Liquid formaldehyde can cause severe damage if it gets into the eyes. For example, in a standard test for eye irritation, 0.005 ml of a 15 percent formalin solution (6% formaldehyde applied to the eyes of rabbits caused corneal and conjunctival swelling and inflammation of the iris, reactions which were regarded as a severe response [Ex. 42-87]. Where the worker sustains splashes of formaldehyde solutions in the eyes, damage can be greatly reduced by immediately flushing the eye with copious amounts of water. Eye wash fountains located in the immediate work area will greatly reduce the amount of time to implement this procedure and therefore, can be expected to mitigate the effects of accidental splashes of formaldehyde solutions into the eyes.

The proposal also requires the employer to provide regular shower facilities and change rooms for employees required to wear protective clothing to prevent skin contact with formaldehyde. Employees can use these facilities in a non-emergency situation to change into and out of protective clothing and to wash off formaldehyde-bearing materials that are irritating or sensitizing to the skin.

Details of shower placement depend on the characteristics of each plant. Where employees may become drenched with large quantities of formaldehyde solutions, the emergency showers must be placed in areas where there is immediate access to affected employees.

10. *Paragraph (j) Housekeeping.* The proposed standard requires that all employers institute a program to detect leaks and spills of formaldehyde in the workplace. This program would include visual inspections of operations involving formaldehyde on a regular basis. The employer is also obligated to institute a regular maintenance program to help assure that leaks of formaldehyde do not occur.

When formaldehyde is released into the workplace environment because of a leak, spill, or other process upset, the proposal requires the employer to promptly repair the source of the leaks and clean up all spills. These work practices aid in minimzing the number of employees exposed as well as the extent of any potential for excess formaldehyde exposure. The proposal is necessarily performance-oriented, since procedures for clean up in the many different industries differ greatly according to the percent of formaldehyde being used, the nature of the manufacturing process, the type of plant involved, and whether the formaldehyde is present as a gas, a liquid, or a solid. Hence, OSHA does not specify a partticular methods for cleaning up spills of formaldehyde. Measures for clean-up of liquids should provide for the rapid containment of the leak or spill so that additional areas will not be affected because the liquid spreads. Clean-up procedures for dusts must not redisperse the dust into the workplace air during the clean-up operation. Thus, operations such as blowing the dust with compressed air must be prohibited. OSHA is interested in receiving comments from the public as to whether the final rule should specify the appropriate method of cleaning up spills to minimize the exposure of workers preforming the operation.

The proposal also requires that the persons who are assigned to clean-up and repair operations must be adequately protected by respirators and protective equipment, as appropriate, so that they will not be overexposed while fixing leaks or cleaning up spills. These proposed requirements are consistent with good industrial hygiene practice, and OSHA believes that they are also consistent with current practices in a major portion of the formaldehyde industry.

11. *Paragraph (k). Emergencies.* OSHA's health data show that short-term overexposure to large quantities of formaldehyde can cause severe pulmonary damage and death. Therefore, massive releases of formaldehyde should be viewed as an emergency situation requiring evacuation of potentially affected employees. Spills or leaks of smaller quantities may also constitute an emergency in the isolated area affected. The proposal would require the development of a written plan which complies with § 1910.38(a) and implementation of the measures needed to alert employees in the event that an emergency arises. Guidance on the types of situations that may constitute an emergency and the information that should be developed is available in a separate appendix to Subpart E—Means of Egress of the General Industry Standards.

Section 1910.38(a) applies to all emergency action plans required by a particular OSHA standard. The action plan must be in writing and cover the actions the employer and the employees must take to ensure employee safety from fire, toxic chemical releases, and natural disasters. The plan must include at least the following elements: (1) Emergency escape procedures and escape route assignments; (2) procedures to be followed by employees who remain to operate critical plant operations before they evacuate; (3) procedures to account for all employees after the emergency evacuation is complete; (4) rescue and medical duties for those employees who are designated to perform them; (5) the preferred means of reporting fires and other emergencies; and (6) the names or job titles of the persons or departments who can be contacted for further information or explanation of duties. Because of the potentially serious consequences of massive exposure to formaldehyde, OSHA is explicitly requiring the employer to establish prearrangements for transportation and medical assistance, rather than permitting reliance on emergency first aid.

In addition to the emergency plan, § 1910.38(a) requires that the employer establish an employee alarm system and designate and train a sufficient number of persons to assist in the safe and orderly emergency evacuation of the affected employees. The emergency plan must be reviewed with each employee when the plan is developed, whenever the employee's responsibilities or designated actions change, and whenever the plan is changed. Each employee must receive instruction on the emergency plan upon initial assignment and the written plan must be kept in the workplace and accessible for employee review. Because of the importance of training in the response to a real emergency, OSHA is requiring the employer to incorporate the emergency plan as a part of the annual training and education requirements as well.

Employers would provide employees assigned to correct the emergency conditions with appropriate respirators and other protective equipment. In general, the appropriate respirator will involve a self-contained breathing apparatus (SCBA) because the emergency reentry will involve entry into an area of unknown, but potentially high exposure.

Respirators bought specifically for the purposes of escape should be SCBAs, and at the minimum, gas masks equipped with canisters. The SCBA is necessary in situations where a potentially very high concentration of formaldehyde exists. Where a SCBA might not provide ample time to escape, the less protective, but longer lived gas mask equipped with a canister might be preferred, because it will permit a longer time for escape than a SCBA.

To select the proper respirators and other protective gear that may be needed to escape, the employer needs to give considered thought to how long the

employee would remain in the area, whether he could escape without serious injury or health consequences, and whether donning all protective equipment, including respirators, that might be useful would take so long that the employee would actually receive more exposure to formaldehyde while donning the equipment to escape. Additional emergency equipment, such as eye-flushing stations and emergency showers, should be available.

12. *Paragraph (l). Medical surveillance.* Section 6(b)(7) of the Occupational Safety and Health Act, 29 U.S.C. 655(b)(7) authorizes the Secretary to promulgate standards imposing a requirement for medical examinations when this action is necessary and appropriate. The proposal would require each employer to institute a medical surveillance program for employees exposed above the PEL. These persons are at the highest risk of material impairment of health from exposure to formaldehyde, and these individuals would be required to use a respirator at least part of the time.

There are also requirements under § 1910.134(b) that require the employer to maintain a complete respiratory protection program for employees who must wear respirators. In particular, this regulation has provisions for examination by a physician of the employee wearing a respirator. To clarify the language in that section as OSHA intends it to apply to formaldehyde, OSHA is proposing to require specific medical examinations for anyone who is assigned to wear respirators.

The medical examinations proposed for the annual examination include: (1) Medical and work histories that identify persons who have preexisting conditions placing them at high risk from formaldehyde exposure or respirator use; (2) a physical examination that gives the attending physician opportunity to observe whether the patient has signs indicative of a health problem related to occupational exposure to formaldehyde or respirator use; (3) a pulmonary function test including at least a determination of forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1); and (4) any other information the examining physician requires. This information may include the results of clinical tests such as, but not limited to, tests to determine whether respiratory or dermal sensitization by formaldehyde has occurred. Information collected in the medical surveillance should include significant changes in weight, facial contour (e.g. from loss of teeth or growth of facial hair), and any other information that would suggest the employee should be retested for respirator fit.

In the case of pulmonary function tests, specific measurements are required on an annual basis for persons who wear a respirator. Pulmonary function tests may contain other beneficial information for the physician's evaluation when the patient is a worker exposed to both formaldehyde and particulate material. The testing requirements also assure that the physician has the information available in each case to enable preparation of the required written opinion.

The requirement that the employer need make routine medical surveillance available only to employees exposed over the PEL does not remove the employer from the obligation to provide medical surveillance to any employee in an emergency.

Situations resulting in acute toxicity can arise at any time since accidents and emergencies are not scheduled events. The proposal requires that medical exams triggered by emergency exposures include the taking of medical and work histories and any other examination or test considered appropriate by the examining physician. The proposal is designed to give the physician sufficient flexibility to deal with the nature and degree of exposure sustained. This is simply a statement of what constitutes good medical practice.

The proposal would obligate the employer to pay for time spent taking the medical examination regardless of whether or not it is taken on work time and the exam must be given at a reasonable time and place. It is necessary that exams be convenient and without loss of pay to the employee to help ensure that employees do not refuse to take them.

All examinations and procedures would be performed by or under the supervision of a licensed physician and be provided without cost to the employee. Certain parts of the proposed examination do not necessarily require the physician's expertise and could be conducted by another person under the supervision of the physician.

The employer would have to provide the physician with a copy of the final standard and its relevant appendices; a description of the affected employee's duties as they relate to exposure to formaldehyde; and information from the employee's previous medical examinations conducted for purposes of complying with this proposed standard. Making this information available to the physician would assist the physician in evaluating the employee's health in relation to assigned duties and to fitness to wear and use personal protective equipment.

The proposal would require the employer to obtain a written opinion from the examining physician regarding the results of the medical examinations. Whether the employee has any detected medical conditions possibly caused or aggravated by exposure to formaldehyde or use of respirators, any recommended restriction upon the employee's exposure to formaldehyde or upon the use of protective equipment including respirators, and a statement that the physician has informed the employee of the results of the medical examination or treatment. This written opinion should not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde.

Requiring the physician to supply the employer with a written opinion would provide the employer with a medical basis to aid in the determination of initial placement of employees and to assess the employee's ability to work in protective equipment. Providing an employee with a copy of the physician's opinion within 15 calendar days of receipt by the employer would ensure that the employee has been informed of the results of the medical examination in a timely manner. Findings or diagnoses which are unrelated to occupational exposure to formaldehyde would be excluded to reassure employees participating in medical surveillance that they will not be penalized or embarrassed by the employer's obtaining information about them not directly pertinent to formaldehyde exposure.

The results of the representative employee exposure monitoring are part of the information that would be supplied to the physician responsible for medical surveillance. These results contribute valuable information to assist the physician in determining if an employee is likely to be at risk of harmful effects from formaldehyde exposure. A well-documented exposure history would also assist the physician in determining if a disease that is observed (eg. dermatitis) may be related to formaldehyde exposure. It will assist the physician who must recommend restrictions on the employee's occupational exposure options based on medical findings. An indication of how often a patient's exposures exceed the PEL and the degree of exposure involved would alert the physician to the need to reexamine the employee's suitability for

use of a respirator especially when there are changes in the employee's appearance (eg. facial hair, weight change) or work history (eg. a recent increase in the amount of time spent in an area where respirators are needed, an increase in exposure concentration).

The employer is responsible for the retention of all medical records collected as part of the surveillance program for formaldehyde whether or not they show evidence of a health impairment because uncertainties exist as to the medical evidence that may eventually be found relevant to formaldehyde exposure. Because of the employee's right to privacy and because the employer, who probably lacks medically-related training, has no need to scrutinize the unevaluated recordings or results from clinical tests, OSHA does not foresee that the employer needs to take physical possession of the medical records of employees. Requirements for record retention and access can be handled by contractual arrangement, with the physician retaining the actual test results for the required period of time.

Persons who are required to wear negative pressure respirators must have good pulmonary function or they will place an added strain on the heart's function. Likewise, persons who wear positive pressure respirators work in areas where the formaldehyde concentration is exceedingly high and most have their pulmonary function evaluated also. OSHA's recommendations and requirements for medical surveillance are based on consideration of these effects.

OSHA has not found specific screens to detect persons who will be most susceptible to developing formaldehyde-related cancer at some later date. Even if a specific test were available to detect cancer, this test would not be expected to yield positive findings in employees early in their careers. By the time cancer would be observable, persons who need an examination would not necessarily even be continuing to work with formaldehyde and probably would not be receiving the surveillance indicated in this proposal. Certain conditions seen in younger workers can point to a greater risk of developing cancer at some time in the future, however. Evidence that formaldehyde is damaging the tissues in the nasal passages or other parts of the upper respiratory tract would constitute definite evidence that the employee is being placed at high risk of subsequent disease, including possibly cancer. Persons with chronic sinusitis or nasal polyps may be at higher risk of nasal cancer regardless of their formaldehyde exposure (Ex. 42–19). A history of smoking and alcohol consumption would suggest also that a patient is at higher than normal risk of developing certain types of respiratory cancer. Work that causes an employee to be exposed to tissue preservatives suggests a risk of brain cancer, regardless of whether or not this cancer is causally related to exposure to formaldehyde. Evidence of any of these effects or conditions should suggest a high-risk category for future development of cancer.

The best method to detect whether a worker is developing a chronic condition related to exposure to formaldehyde appears to be a combination of the survey of medical and work histories along with a thorough medical examination of the eyes, nose, throat, and skin. It is particularly important that records from previous examinations be available to the attending physician so that any trends indicative of a changing condition can be identified. If questionable or positive results are found, the physician should consider whether additional testing or referral to a specialist is needed.

Asthma, loss of pulmonary function, and dermal effects caused by or exacerbated by formaldehyde exposure are best identified through the conduct of a proper medical examination and history. Specific tests for asthma and for dermal sensitization exist, but they are not recommended as screening tools because they are capable of sensitizing persons who had not been affected previously. These specific tests should be considered by the physician if a medical history indicating probable sensitization exists or if the employee presents with signs or symptoms indicative of sensitization.

Formaldehyde can cause acute changes in pulmonary function, particularly if it is carried on respirable particles. Although these changes appear to be mild and reversible, they indicate that formaldehyde probably is reaching the lung. This suggests that there may be a higher risk of chronic toxicity, including lung cancer, for persons with acute shifts of pulmonary function. OSHA is presently undecided on whether or not to require specific types of pulmonary function testing in industries in which exposures to formaldehyde and to particulate matter occur. Special protocols for testing would probably be required since pulmonary function alterations are acute and there does not appear to be an irreversible loss. Public comment is sought particularly on whether there is a need for routine pulmonary function tests for some workers and, if there is, on the types of tests that should be administered. In addition, comment is requested as to the appropriate exposure level to trigger medical exams as well as pulmonary function tests.

Specific requirements are also imposed with regard to the wearing of respirators. Because negative pressure respirators place an unacceptable burden on a worker who already has poor or marginal lung function, these persons need to be identified and another type of action, such as the assignment of a powered air-purifying respirator, taken. At preassignment and at least annually thereafter, the employee must be provided with a pulmonary function test and the physican must determine if the employee has any medical conditions that would limit or prevent the use of certain types of respirators. These tests and evaluations must be repeated at least annually as long as the employee continues to wear a respirator. In particular, the physician should look for evidence of respiratory effects that might make the use of a negative pressure respirator inadvisable, evidence that the respirator assigned is ineffective in preventing toxic signs and symptoms of formaldehyde exposure, and for evidence of eye irritation in any employee who has been wearing a half-piece respirator. In addition, the physician has the responsibility to alert the employer when evidence such a change in weight in an employee indicates that a new quantitative fit test of the respirator is needed to assure the continued effectiveness of the negative pressure respirator. OSHA views this need for the physician to make determinations regarding respirator use as an especially important obligation since qualitative fit testing is considered unreliable for formaldehyde and no routine fit-test requirement is imposed.

In certain industries, the amount of formaldehyde that could be released in foreseeable accidents (eg. burst pipe, storage tank leak) is sufficient to injure employees seriously. These situations need to be evaluated in advance and written emergency plans need to be developed. Part of such planning includes the provision of medical care to overexposed employees by trained persons familiar with the effects of acute overexposure to formaldehyde. More commonly, employees who experience an acute alteration of normal function upon exposure to formaldehyde or dermal effects from contact with liquid formaldehyde are likely to do so on a nonroutine basis not particularly compatible with the scheduling of

periodic medical surveillance. Proper medical attention must be provided to the affected employee at the time of such acute emergency exposure. Because of the wide range of effects that could be involved, the content of nonroutine emergency examinations and medical surveillance is left to the discretion of the responsible physician.

In response to OSHA's Advance Notice (50 FR 15179), a number of organizations commented that routine medical surveillance to monitor acute irritant effects from formaldehyde would be unnecessary and inappropriate (Exs. 77–17; 77–19a; 77–20; 77–21; 77–39;). These comments, however, appear to be based on an interpretation that statement in the ANPR that OSHA was concerned only with irritant effects. Therefore, these commenters based their statements on the necessity and appropriateness of medical examinations on the prevention or detection of irritant effects.

In formulating its proposed medical surveillance, OSHA carefully examined the recommendations of other groups and of commenters to OSHA's ANPR on formaldehyde. The Michigan Hospital Association Service Corporation stated (Ex. 77–32):

> Certainly medical examination following an accidental exposure as a result of a spill would be appropriate. Medical examination following the development of any dermatitis skin exposure would be appropriate.

NIOSH, in recent comments to OSHA (Ex. 77–11) addressed the types of effects expected to occur both routinely in susceptible workers and after an accidental release as follows:

> Ocular and upper respiratory irritation have been noted between 0.1 ppm and 5.0 ppm; exposures at 10 ppm to 20 ppm have produced cough, tightness in the chest, a sense of pressure in the head, and palpitation of the heart; exposures at 50 ppm to 100 ppm can cause pulmonary edema and pneumonitis. Dermatitis, as a result of contact with formaldehyde-containing additives, is well documented.

NIOSH concluded that medical examinations should be directed at detecting these effects.

In their criteria document on formaldehyde [Ex. 69–8b] NIOSH recommended medical examinations to be administered to workers exposed to formaldehyde at concentrations in excess of 0.5 ppm (30-minute sampling period) or to those who have contact with formaldehyde in solid or liquid form. This recommendation consisted of: (1) A preplacement examination to include comprehensive medical and work histories with special emphasis on any evidence of chronic inflammatory reaction of the respiratory tract, of skin hypersensitivity, of other allergic conditions, and an evaluation of the employee's ability to use positive and negative pressure respirators; (2) counselling of employees or applicants who have medical conditions which would be directly or indirectly aggravated by exposure to formaldehyde; and (3) a physical examination in the event of overexposure to formaldehyde.

The UAW has addressed the issue of what they would consider appropriate medical monitoring for acute irritation, sensitization, and chronic toxicity (Ex. 77–12). The UAW recommends that all employees exposed to formaldehyde receive medical examinations performed by or under the supervision of a licensed physician. Specific attention would be paid to the skin, eyes, nose, and respiratory tract. Examinations would include spirometric testing, but no other specific tests were recommended.

Although all opposed specific clinical tests, the Formaldehyde Institute, the ATMI, the National Cotton Council, and Monsanto recommended use of medical history questionnaires to assure that employees who experienced discomfort receive medical attention.

The Formaldehyde Institute examined and rejected a number of possible tests for medical surveillance. Concentrations of formaldehyde in blood and levels of formic acid in urine did not correlate with occupational exposure, leading the Formaldehyde Institute to conclude that there are no useful biological markers indicative of exposure to formaldehyde (Ex. 77–19a). Cytogenetic analysis was rejected as a possible screening tool because several studies reportedly had shown no significant changes in workers exposed to formaldehyde. The Formaldehyde Institute concluded that skin patch tests have limited value because they demonstrate only one type of allergy; moreover there is no dermal exposure to aqueous or solid formaldehyde in many industries. They considered intradermal injection of formaldehyde solutions useless as a test for sensitivity to formaldehyde and potentially dangerous. Bronchial provocation tests were described as rarely positive, cumbersome, very expensive, and not generally available. The Formaldehyde Institute cited the apparent rarity of asthmatic responses and comments of the Consensus Workshop regarding respiratory tract allergy and pulmonary function losses as reasons to conclude that routine pulmonary function testing of formaldehyde would be unwarranted.

Monsanto (Ex. 77–15) also addressed medical surveillance in four areas: Sensitization, irritation, carcinogenicity, and neurotoxicity. Monsanto estimated that only 1 nasopharyngeal cancer in every 30,000 to 50,000 exams would be found, so that testing for the presence of this type of cancer would be unjustified. Monsanto also concluded that immunological studies are unnecessary because sensitive individuals can be identified in other ways. Surveillance for behavioral or neurotoxic effects was thought to be premature since there is presently no consensus regarding formaldehyde's ability to produce these effects. Finally, Monsanto did not believe that routine examinations would be effective, but they recommended that the complaints of symptomatic individuals should be recorded at an in-house health facility where the exposures of persons with symptoms could also be examined.

It appear to OSHA that recommendations for screening of workers by a disease questionnaire could be an effective means of screening for medical examinations, but only if a preexisting program for referral to a physician trained in recognition of the effects of overexposure to formaldehyde exists. In addition an effective medical disease questionnaire would have to be available and a knowledgeable occupational health nurse would have to review the results to make proper referrals to the physician. Except as otherwise noted with regard to pulmonary function tests, OSHA also agrees with the commenters who examined specific tests and rejected them as not useful for the monitoring of formaldehyde-exposed employees.

The UAW has suggested to OSHA that a standard for formaldehyde should include a provision for the employer to provide medical removal protection benefits for each employee removed from exposure to formaldehyde or otherwise limited as a result of medical findings or recommendations (Ex. 77–12). The employer would be required to maintain the earnings, seniority, and other employment rights and benefits of the employee as though the employee had not been removed.

The Formaldehyde Institute suggested the establishment of a response mechanism for "the rare reported symptoms that do occur." They elaborated:

> Most companies have a complaint mechanism that includes a policy of reassigning employees in response to the sensitization phenomenon observed in a few hypersusceptible individuals who cannot work in an atmosphere containing even trace amounts of formaldehyde without discomfort. Where individual complaints are significant, that is chronic skin reaction of more than

several weeks or significant respiratory effects, the affected employee may be referred to a physician for approriate evaluation at the expense of the company. The Institute believes that such a response is appropriate even though the symptoms may not be related to formaldehyde exposure (Ex. 77–19a).

The National Cotton Council, in noting that most companies reassign employees who cannot work in an atmosphere containing even trace amounts of formaldehyde without discomfort, also concluded that a response mechanism to identify hypersusceptible employees would be of value (Ex. 77–20). The Cotton Council provided an example of what they consider an appropriate mechanism for reporting and responding to observed symptoms. According to the Cotton Council:

> Some textile companies use questionnaires for employees prior to employment in an area of chemical exposure and on a periodic basis to update the employee's health history. These questionnaires may be part of a periodic physical examination administered to all employees or they may be associated with special exposure circumstances . . . Affirmative responses on the questionnaire are reviewed and clinically evaluated by an occupational health nurse; if necessary, further review is carried out by a physician. If clinically indicated, further testing may be ordered (Ex. 77–20).

The ATMI endorsed the use of such questionnaires for surveillance of employees exposed to formaldehyde. The ATMI indicates that surveys have been used on a trial basis in two facilities and that they have proven satisfactory for general chemical surveillance (Ex. 77–27).

The ATMI also noted that the review could include special testing, if clinically indicated, and medical summaries from other physicians who have attended the applicant. Recommendations for repeat testing of personal protective equipment (eg. respirators) and medical monitoring or workplace modification would be made from the review of the employee's survey and entered into the employee record.

The United Paperworkers Union is surveying their membership regarding formaldehyde exposure and controls (Ex. 77–31). Preliminary results showed formaldehyde concentrations in a range between 0.1 and 0.5 ppm, but at those levels, one-half to two-thirds of the union members participating in the survey reported coughing, tearing of the eyes, and an excess incidence of chronic sinusitis and bronchitis. The Paperworkers also found several cases of cancer and allergic asthma among formaldehyde-exposed members. According to the Paperworkers, "we report this at this time not to imply that these are formaldehyde-related, but to indicate that these cases are of concern and will be investigated more fully." On the basis of their experience, the Paperworkers stated:

> When physical examination or testing is appropriate to properly diagnose and treat a formaldehyde-related illness, it should be required. However, we feel very strongly . . . that the need for medical removal protection needs to be addressed, particularly when sensitization occurs.

In response to the initial petition and to ANPR comments recommending medical removal protection (MRP) and to evidence that workers are being transferred as the result of sensitivity to formaldehyde, OSHA has examined whether or not MRP would be appropriate for formaldehyde workers and tentatively concludes that a form of medical removal similar to that provided for lead would not be useful for rehabilitating a worker who has become sensitized to formaldehyde. Unlike lead, where removal of a worker from further exposure gives the worker's body a chance to excrete the toxic chemical before irreversible damage occurs, sensitization to formaldehyde is not a readily reversed process. Once sensitized, the worker is unlikely to ever return to exposure that had been tolerated and the worker's health must be considered permanently impaired, at least insofar as further exposure to formaldehyde is concerned. Thus, temporary removal of several months duration would be ineffectual.

OSHA is interested in receiving public comment on this issue, specifically on the percentages of formaldehyde exposed workers who are removed from exposure and how frequently such transfer has led to a loss of wages or benefits. If it appears that there are significant abuses occurring or that a large number of persons are having to leave the worksite for a brief period such as a few hours to a few days without any compensation in order to recover from acute irritant effects of formaldehyde exposure, then OSHA will reconsider if some short-term MRP to recover from acute irritation is warranted.

13. *Paragraph (m). Hazard Communication.* The proposed standard for formaldehyde extends the employer's obligations to label containers of formaldehyde to all sectors of the industry, and not just to manufacturing. Generally, chemical manufacturers, importers, and distributers would be required to label, tab, or mark each container of formaldehyde being used in or leaving the workplace.

The proposal exempts from the labeling requirements furniture as well as garments, bedclothes and draperies made from fabric treated with formaldehyde. The purpose of the proposed exemption is to avoid the possible defacing of products which are essentially in final form for the consumer. Therefore, the proposal contemplates that formaldehyde treated material such as bolts of cloth, for example, would be labeled since this would not be defacing. Clothing made with such cloth would not need to be labeled. Similarly, containers of lumber would have to be labeled, while furniture would not. Such a scheme would help assure appropriate labeled warnings in those situations where large amounts of formaldehyde-treated materials are likely to be stored or handled, such as lumber yards, fabric stores and warehouses. Such labeling would not impose onerous burdens, would not be defacing and would provide appropriate employee warning and protection. Even in the specific circumstances listed in the proposed exemption where labeling is not required, employees would still have the protection provided by the Material Safety Data Sheets that must accompany the initial shipment of any formaldehyde treated product capable of off-gassing.

In implementing this provision for labels, OSHA encountered several situations that need to be clarified as they relate to formaldehyde and hazard communication. The Hazard Communication standard specifically exempted wood and wood products from coverage. The reasons given were that their identity within the workplace is unmistakable and their characteristic hazards well known. The preamble discussed wood impregnated by pesticides, concluding that the pesticide in the wood would be covered by EPA under FIFRA. Thus, the wood itself would be covered by the wood exclusion from OSHA's Hazard Communication Standard, while the pesticide use would be covered by the labeling exclusion provided for FIFRA-regulated pesticides. The preamble to the Hazard Communication Standard also noted, however, that "non-excluded chemicals which are used in conjunction with . . . wood products, or are known to be present as impurities in these materials, are covered by . . . [the Hazard Communication] Standards" 48 FR 53280, 53289. Wood products which use formaldehyde would not be exempt from the requirements of the Hazard Communication standard since the use of formaldehyde, in this instance, is not

for pesticidal purposes. Therefore, the intention of the Hazard Communication Standard was to cover wood products treated with a non-excluded chemical such as formaldehyde. In order to clarify this matter and provide additional notice to those concerned, by incorporating the hazard communication obligations into the formaldehyde proposal, 29 CFR 1910.1200(b)(95) which contains the wood or wood products exclusion is declared inoperative.

Requirements proposed in this paragraph ensure that employers inform their own employees about the hazards of formaldehyde through the use of signs and labels on containers in the workplace. This requirement as it applies to the manufacturing segment would be consistent with the OSHA's standard 29 CFR 1910.1200 on Hazard Communication (48 FR 53280, November 25, 1983). Other segments of industry would also be required to comply since the record evidence for formaldehyde indicates that several of the nonmanufacturing segments present substantial hazards to workers from exposure to formaldehyde.

The proposal would create obligations for employers that do not presently exist in the Hazard Communication standard. Employers who are outside the manufacturing segment would be covered unless they are exempted from the general industry standard because of the percentage composition of the formaldehyde containing solutions they use. The formaldehyde standard would also create one additional obligation for chemical manufacturers and importers to provide MSDSs to all employers purchasing formaldehyde or formaldehyde-treated products. This change is necessary to assure that the employer in the nonmanufacturing sector can meet the obligations for training imposed by this proposal.

The proposed requirements for signs and labels discussed above are consistent both with section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed, and with the requirements of OSHA's Hazard Communication standard, § 1910.1200(f) although these provisions for signs and labels apply to all industries where there is potential for formaldehyde exposure, and not just to the manufacturing segment.

OSHA proposes that required labels remain affixed to containers leaving the workplaces except for specific exemptions permitted by Hazard Communication or this proposal. This requirement would assure that all affected employees, not just those working for a particular employer, are apprised of the hazardous nature of exposure to formaldehyde. This is particularly warranted in the case of formaldehyde, which has many downstream uses accounting for nearly all the workforce potentially exposed to formaldehyde.

An employer's obligation, under section 6(b)(7) of the Act, to inform employees of hazardous conditions is not limited to the employer's own employees. When an employer manufactures, formulates, or sells a product, it may unavoidably expose not only its own employees but also those of other employers to the hazards inherent in the presence of formaldehyde in the workplace. The proposal would make it clear that the obligation to inform extends beyond the immediate workplace. This is especially important when the manufacturer, formulator, or seller is the only employer able, through his knowledge of the product, to provide the information necessary to protect employees. A narrow reading of the statutory authority would defeat its protective purposes by effectively preventing the downstream employee from obtaining adequate information about workplace hazards. Furthermore, hazard labels would alert other employers who, in the absence of such labels, might not know that formaldehyde is present in their workplaces and that they have incurred an obligation to comply with the standard.

The proposal would also require that manufacturers or importers of formaldehyde make the material safety data sheets that they have obtained to comply with provisions of paragraph (g) of OSHA's Hazard Communication standard (29 CFR 1910.1200) available to all employers purchasing their formaldehyde products. Although the Hazard Communication standard applies to most facilities that will be affected by the formaldehyde standard (SICs 20–39), many workplaces where formaldehyde is used (e.g., hospitals), are not currently included in the scope of the Hazard Communication standard. The proposal would enable those employers to comply with the proposed requirements to communicate the hazards to employers exposed to formaldehyde treated products.

14. *Paragraph (n). Employee Information and Training.* The proposed standard would required that employers provide training programs on formaldehyde for all employees covered by this proposed standard. For employees who are exposed below the action level, the employer would be required to provide this training at the time of their initial assignment to a formaldehyde area and whenever a new hazard that could increase the employee's exposure to formaldehyde is introduced into the work area. For employees exposed at or above the action level, this training would be conducted at least once a year.These requirements are consistent with section 6(b)(7) of the Act and they are also consistent with the requirements for employee training imposed on the manufacturing sector by the Hazard Communication standard.

The employer would be required to make a copy of the standard, its appendices, and other written material used in the training program available to affected employees and their representatives so that the can review the material when they feel it is necessary. This requirement, in combination with the training program, would ensure that employees understand their rights and duties under this proposed standard.

The employer would also be required to provide, upon request, all materials relating to the training program to the Assistant Secretary and Director. This would provide an objective check of compliance with requirements of this paragraph.

OSHA recognizes that formaldehyde might be only one of a number of substances to which an employee could be exposed simultaneously. Therefore, OSHA has proposed education and training requirements for formaldehyde which could easily be adapted to constitute a comprehensive program of employee training and education to deal with workplace hazards. Compliance with the training requirements of the proposed formaldehyde standard automatically constitute compliance with OSHA's Hazard Communication standard's requirements for training as they relate to formaldehyde exposure.

OSHA considers training to be one of three vital components in a comprehensive hazard communication program. No one of these three components alone—labels, material safety data sheets, or training—can be demonstrated to be completely effective in communicating hazards. The purpose for having training provisions is to establish the minimum information required for these programs to function successfully to reduce the potential for workers to suffer illnesses and injury from exposure to formaldehyde.

To assure that employees receive adequate protection from formaldehyde exposure, the employer must train them in the purpose and proper use for any protective equipment and clothing that

they are using. They also must be trained to perform their jobs in a manner that minimizes their exposure to formaldehyde. To achieve the goals outlined by the emergency plan, it must be implemented and employees trained in their responsibilities in the event of an emergency.

The proposed standard would require that training be provided at least annually for employees exposed at or above the action level. OSHA believes that annual training would be both necessary and sufficient to ensure that these employees remain aware of the hazards of formaldehyde and their rights and duties under the proposed standard. Since employees exposed at levels below the action level are unlikely to receive any significant exposure to formaldehyde, it is less important that they are trained yearly. These persons will also not be wearing respirators and will not be and will not be participating in periodic exposure monitoring. Thus, more frequent training of the most effected employees is a proper allocation of resources.

15. *Paragraph (o). Recordkeeping.* Section 8(c)(3) of the Act provides for the promulgation of regulations requiring employers to maintain accurate records of employee exposures to potentially toxic or harmful physical agents which are required to be monitored or measured. The proposed standard would required that employers who rely on objective data in order to gain exemption from the proposed monitoring requirements maintain records that show that basis and reasoning used in reaching the conclusion that the employer should be exempted. In this respect, the objective data substitute for the initial monitoring requirements and the requirement to maintain a record protects the employer at later dates from the contention that a initial monitoring was conducted.

The proposed rule would require that employers keep records to identify the employee monitored and to accurately reflect each employee's exposure. The proposal would also require that the employer keep an accurate medical record for each employee subject to medical surveillance. Section 8(c) of the Act authorizes the promulgation of regulations requiring an employer to keep necesssary and appropriate records regarding activities to permit the enforcement of the Act or to develop information regarding the causes and prevention of occupational illnesses. OSHA has determined that, in this context, requiring employers to maintain both medical and exposure records (including pulmonary function test results related to respirator use and initial determinations or justifications of exemption from monitoring is necessary and appropriate. In addition, medical records are necessary for the proper evaluation of the employee's health. Since the purpose of long term retention of respirator fit test results is not seen, OSHA has proposed to require keeping these test results only until the next fit testing.

The proposed standard would require that all required records be made available upon request to the Assistant Secretary and the Director of NISOH for examination and copying. Access to these records would be necessary for OSHA to monitor compliance. These records also contain information which either of the agencies may need to carry out other statutory responsibilities.

The proposed rule would provide that employees, former employees, and their designated representatives would have access to exposure determinations and records upon request. Section 8(c) of the Act explicitly provides that "employees or their representatives shall be provided with an opportunity to observe . . . monitoring . . . and to have access to the records" of monitoring and exposures to toxic substances". Several other provisions of the Act contemplate that employees and their representatives are entitled to have an active role in the enforcement of the Act. Employees and their representatives need the pertinent information concerning exposures to toxic substances and the consequences for the health and safety of the employees if they are to benefit properly from these statutorily created rights.

In addition, the proposal specifies that access to exposure and medical records by employees, designated representatives, and OSHA shall be provided in accordance with 29 CFR 1910.20. OSHA promulgated 29 CFR 1910.20 as the generic rule for access to employee exposure and medical records on May 23, 1980 (45 FR 35212). It applies to records created pursuant to specific standards and to records which are voluntarily created by employers. OSHA retains unrestricted access to medical and exposure records but its access to personally identifiable records is subject to the Agency's rules of practice and procedure concerning OSHA access to employee medical records, which have been published at 29 CFR 1913.10. An extensive discussion of the provisions and the rationale for § 1910.20 may be found at 45 FR 35312. The discussion of § 1913.10 may be found at 45 FR 35384. It is noted that revisions to the access to records standard are being developed in an ongoing rulemaking proceeding. The formaldehyde standard may be affected by any changes which result from the rulemaking effort.

It is necessary to keep records for extended periods of time because of the long latency periods commonly observed for the induction of cancer caused by exposures to carcinogens. Cancer generally cannot be detected until 20 or more years after onset of exposure. The extended record retention period is therefore needed for two purposes. First, possession of past and present exposure data and medical records furthers the diagnosis of workers' ailments. In addition, retaining records for extended periods makes possible a review at some future date of the effectiveness and adequacy of the proposed standard.

The time periods required for retention of exposure records and medical records would be thirty years and the period of employment plus thirty years, respectively. These retention requirements would be consistent with those in the OSHA records access standard and with pertinent sections of the Toxic Substances Control Act.

The proposed standard would require employers who are going out of business without a successor to notify the Director of NIOSH in writing at least 90 days prior to the disposal or records and to transmit them to NIOSH unless told not to do so by NIOSH. The employer would be required to comply with any other applicable requirements set forth in the records retention standard.

16. *Paragraph (p). Dates.* As proposed, the final rule would become effective sixty (60) days following publication in the Federal Register. This will give the employer some time to familiarize themselves with the standard. The various provisons have phased in effective dates.

Some companies have to hire industrial hygiene and chemistry expertise to conduct exposure monitoring before they could obtain the results, evaluate them as part of the initial survey, and select and order necessary protective equipment. This would require some more time to complete and up to an additional 6 months is permitted for the employer to complete this phase. When exposures are determined and personal protective equipment is available the medical surveillance can be conducted. Up to six months after the effective date are also permitted for these provisions so that employers can conduct necessary contractual arrangements and provide medical surveillance. As other parts of the plan for controlling employee

exposure are implemented, many of the items needed to deal with emergencies would become available. Thus, the written emergency plan is also given an extended compliance date of six months.

The most difficult part of the proposed standard may be the implementation of feasible engineering controls because extensive planning is needed to identify and order any needed equipment. A prolonged installation may also be involved. Thus, the most extended compliance time, one year after the effective date is given to complete this task. Because it is more difficult for small business to obtain necessary capital for engineering controls, businesses having a total workplace of 20 or less employees are given an additional year to achieve compliance with the requirements for engineering controls.

Delayed Effective Date for Small Business. OSHA is aware that there are many small businesses which would be effected by the proposed standard. For example, the Regulatory Impact Analysis indicates that two of the industries with the highest projected compliance costs, foundries and wood furniture, are made up of 53 and 75 percent, respectively, small business.

OSHA is concerned that small firms may experience difficulty in achieving compliance with the proposed PEL because they lack the financial resources needed to meet the projected capital costs. OSHA has already noted in its regulatory flexibility analysis, above, that economies of scale may operate to the disadvantage of small businesses attempting to comply with engineering control requirements. Indeed, a number of the industry comments received in response to the ANPR (50 FR 15179) questioned whether small businesses could afford to comply with a 1 ppm PEL. If a PEL of 1.5 ppm is adopted, on the other hand, there may be little or no regulatory burden on small businesses because evidence in the record indicates that most are already in compliance. (Exs. 77–3, 77–18, 77–19a, 77–21, 77–27 and 77–30).

OSHA is investigating whether any regulatory relief from the proposed standard, such as a delayed effective date for those provisions which would impose engineering and work practice control requirements, would be necessary or appropriate. OSHA will consider requests for regulatory relief or regulatory alternatives for small businesses within the context of its overriding commitment to requiring that employers provide employees with safe and healthful working conditions.

OSHA encourages interested parties to submit information which will assist OSHA in its consideration of what if any regulatory relief is necessary. OSHA is especially interested in any particular compliance problems that a business might face because it is small. OSHA has considered a business to be small when it has fewer than 20 employees. OSHA invites comment on the 20 employee threshold, including any suggested alternatives. OSHA requests that commenters requesting any differential regulatory treatment for small businesses describe their proposals in detail and provide evidence to support their contentions that the relief is necessary and the adoption of their proposals would enable small businesses to attain compliance without compromising the employee health or safety.

OSHA is continuing to collect data on the economic and technological aspects of compliance with the formaldehyde proposal. Public comment on the relevant issue of start-up dates is sought, especially on items that need extended start-up dates, on the definition of what constitutes a small business, and on industries that may require special considerations to enable them to achieve the proposed standard.

Appendices

Appendices have been included in this proposed standard for informational purposes. None of the statements contained within the appendices would establish a mandatory requirement not otherwise imposed by the standard, or detract from an obligation which the standard would impose.

The information contained in Appendices A and C would aid the employer in complying with requirements of the standard. The information in Appendix B provides a physician with the information needed to conduct medical surveillance programs. Appendix D provides a protocol for quantitative fit testing of negative pressure respirators. The paragraph on training contained in the proposed standard would specifically require that employers provide the information contained in Appendix A to employees as part of their information and training programs.

Appendix C gives details of the sampling method used by OSHA to monitor employee exposures to formaldehyde.

References

The studies and other information listed in this proposal by exhibit number are the primary sources upon which the proposal has been based. A complete set of references is available for examination and copying at the OSHA Technical Data Center, Docket Office, Room N3672, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC.

Request for Comments

OSHA invites interested persons to submit written data, comments, and views relevant to this proposed standard. The views of the public are sought on the need for the various provisions of the proposed standard, on cost effective alternatives that provide equal or improved employee protection, and on anticipated difficulties seen in the implementation of any of OSHA's proposed provisions. In particular, attention should be paid to the proposed start-up dates for the various provisions.

OSHA has already received submissions on the health effects of formaldehyde; on provisions to be included in revising the formaldehyde standard; and on methods, costs, and effectiveness of control strategies that are used to reduce exposure to formaldehyde as a result of questions posed in a January 11, 1985, announcement (50 FR 1547) of a public meeting and an April 17, 1985, publication of an Advance Notice (50 FR 15179). Although the public is invited to submit any information relevant to the regulation of formaldehyde, material and comments submitted in response to these two announcements have been placed in OSHA's docket on formaldehyde and need not be resubmitted for consideration in the rulemaking.

Interested persons must submit their comments with respect to this proposal on or before March 10, 1986, in quadruplicate, to the Docket Officer, Docket No. H–225A, Room N–3670, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Written submissions must clearly identify the provisions of the proposal which are addressed and the position taken with respect to each issue.

The comments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

XI. Public Participation—Notice of Hearing

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard including economic and environmental impacts, will be provided at an informal public hearing scheduled to begin at 10:00 A.M. on in

the Auditorium, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Notice of Intention to Appear

All persons desiring to participate at the hearing must file in quadruplicate a notice of intention to appear, postmarked on or before April 22, 1986, addressed to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-225A, Room N-3662, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone 202-523-8024.

The notices of intention to appear, which will be available for inspection and copying at the OSHA Technical Data Center Docket Office (Room N3672), telephone 202-523-7894, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The approximate amount of time requested for the presentation;

(4) The specific issues that will be addressed;

(5) A detailed statement of the position that will be taken with respect to each issue addressed; and

(6) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence.

Filing of Testimony and Evidence Before Hearing

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of his testimony, including any documentary evidence to be presented at the hearing, to the OSHA Division of Consumer Affairs. This material must be received by March 31, 1986, and it will be available for inspection and copying at the Technical Data Center Docket Office. Each such submission will be reviewed in light of the amount of time requested in the notice of intention to appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation, and may be requested to return for questioning at a later time.

Conduct of Hearing

The hearing will commence at 10:00 A.M. on April 22, 1986, with resolution of any procedural matters relating to the proceeding. The hearings will be conducted in accordance with 29 CFR Part 1911. The hearing will be presided over by an Administrative Law Judge who will have all the powers necessary or appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911. Following the close of the hearing or of any posthearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The proposed permanent standard will be reviewed in light of all oral and written submissions received as part of the record.

XII. Authority and Signature

This document was prepared under the direction of Patrick R. Tyson, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210.

Accordingly, pursuant to sections 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657), 29 CFR Part 1911 and Secretary of Labor's Order No. 9-83 (48 FR 35736), 29 CFR Part 1910 is proposed to be amended as set forth below. In addition, pursuant to section 4(b)(2) of the Act, OSHA has determined that this new standard would be more effective than the corresponding standards now in Subpart B of Part 1910, and in Parts 1915, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, these corresponding standards would be susperseded by these changes. This determination, and the application of the new standard to the maritime and construction industries, would be implemented by adding a new paragraph (i) to § 1910.19.

List of Subjects in 29 CFR Part 1910

Formaldehyde, Occupational safety and health, Chemicals, Cancer, Health risk-assessment.

Signed at Washington, DC. this 2nd day of December, 1985.

Patrick R. Tyson,

Acting Assistant Secretary of Labor.

PART 1910—[AMENDED]

Part 1910 of Title 29 of the Code of Federal Regulations is therefore proposed to be amended as follows:

1. The authority citation for Subpart B of Part 1910 would be revised to read as set forth below, and the authority citations following all sections in Subpart B of Part 1910, except for source citations (FR citations) and Effective Date Notes, would be removed:

Authority: Sec. 4, 6, and 8 of the Occupational Safety and Health Act, 29 U.S.C. 653, 655, 657; sec. 107, Contract Work Hours and Safety Standards Act, 40 U.S.C. 333; sec. 41, Longshoremen's and Harbor Workers' Compensation Act, 33 U.S.C. 941; Walsh-Healey Act, 41 U.S.C. 351 et seq.; Pub. L. 91-54, 40 U.S.C. 333; PL 85-742, 33 U.S.C. 941; National Foundation on Arts and Humanities Act, 20 U.S.C. 951 et seq.; Secretary of Labor's Orders 12-71 (36 FR 8754), 8-76 (41 FR 2505), or 9-83 (48 FR 35736) as applicable; and 29 CFR Part 1911.

2. A new paragraph (i) would be added to § 1910.19, to read either as alternative A or alternative B as follows:

§ 1910.19 Special provisions for air contaminants.

(i) *Formaldehyde.* [Alternative A: The entry for formaldehyde in Table Z-2 of § 1910.1000] [Alternative B: § 1910.1048] shall apply to the exposure of every employee to formaldehyde in every employment and place of employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or 1910.16, in lieu of any different standard on exposure to formaldehyde which would otherwise be applicable by virtue of those sections.

3. The authority citation for Subpart Z of Part 1910 would be amended by adding one of the following alternative citations:

Authority: Secs. 6, 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Orders 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736) as applicable; and 29 CFR Part 1911.

* * * * *

[Alternative A] Section 1910.1000, Formaldehyde listing, also issued under 29 U.S.C. 653.

[Alternative B] Section 1910.1048 also issued under 29 U.S.C. 653.

§ 1910.1000 [Amended]

4. Alternative A

In table Z-2 of 1910.1000, the entry for "formaldehyde (Z37.16-1967)" would be amended in the column headed "8-hour time weighted average", by revising "3 p.p.m" to read "1 p.p.m or 1.5 p.p.m". Also, the entry "5 p.p.m" under the column headed "Acceptable ceiling concentration", and the entries "10 p.p.m" and "30 minutes", under the column headed "Acceptable maximum peak above the acceptance ceiling concentration for an 8-hour shift", would be removed.

Alternative B. In Table Z-2 of § 1910.1000, the entry "Formaldehyde (Z37.16-1967) . . . 3ppm . . . 5ppm . . . 10ppm . . . 30 minutes" would be

removed and a new § 1910.1048 would be added, to read as follows:

§ 1910.1048 Formaldehyde

(a) *Scope and application.* (1) This section applies to all occupational exposures to formaldehyde.

(2) This section does not apply to: (i) liquid formaldehyde solutions containing less than 0.1% formaldehyde and (ii) solid materials made from or containing formaldehyde that are incapable of releasing formaldehyde into the workplace air.

(b) *Definitions.* For purposes of this standard, the following definitions shall apply:

"Action Level" means a concentration of [0.5 part formaldehyde per million parts of air (0.5 ppm) or 0.75 part formaldehyde per million parts of air (0.75 ppm)] calculated as an eight (8)-hour time-weighted average (TWA) concentration.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person required by work duties to be present in regulated areas or authorized to do so by the employer, by this section, or by the OSH Act of 1970.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" is any occurrence such as, but not limited to equipment failure, rupture of containers, or failure of control equipment that is likely to, or does result in an unexpected significant release of formaldehyde.

"Employee exposure" means the exposure to airborne formaldehyde which would occur if the employee were not wearing a respirator.

"Formaldehyde" means gaseous CH_2O (Chemical Abstracts Service Registry No. 50-00-0), liquids containing more than 0.1% formaldehyde, and solids capable of relasing CH_2O into the atmosphere.

(c) *Permissible exposure limit (PEL).* The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds [1.0 part formaldehyde per million parts of air (1 ppm) or 1.5 parts of formaldehyde per million parts of air (1.5 ppm)] as an 8-hour TWA.

(d) *Exposure monitoring*—(1) *General.* (i) Each employer who has a workplace covered by this standard shall monitor employees to determine their exposure to formaldehyde.

(ii) *Exception.* Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde products present in the workplace, under foreseeable conditions of use cannot result in the release of airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level, the employer will not be required to measure employee exposure to formaldehyde.

(iii) When an employee's exposure is determined from representative sampling, the measurements used shall be representative of employee's full shift exposure to formaldehyde.

(iv) Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts.

(2) *Initial Monitoring.* The employer shall identify all employees who may be exposed at or above the action level and measure and accurately determine the exposure of employees so identified.

(i) Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy that measures sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

(ii) To determine a representative sampling strategy, the employer shall systematically examine process and workplace variables to identify employees to be monitored. The following variables that affect exposure potential shall be considered:

(A) Investigation of worksites where the nature of the operation or process indicates possible release of formaldehyde into the work environment to identify the sources of these emissions.

(B) Investigation of worksites where there have been employee complaints or symptoms indicative of possible exposure to formaldehyde.

(C) Analysis of exposure patterns within the worksite, including each employee's distance from the source of formaldehyde, employee mobility, air movement patterns, and differences in work habits.

(iii) The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

(4) *Periodic monitoring.* (i) The employer shall periodically measure and accurately determine exposure to formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level.

(ii) If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

(iii) If the last monitoring results reveal employee exposure above the PEL, the employer shall repeat monitoring of the employees at least every 3 months.

(5) *Termination of Monitoring.* The employer may discontinue monitoring for employees if surveillance has revealed, through at least two consecutive sampling periods, that employee exposure is below the action level, provided that the results are statistically representative and consistent with the employer's knowledge of the job and work operation.

(6) *Accuracy of monitoring.* Monitoring shall be accurate, to a 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of formaldehyde at the PEL and to within plus or minus 35 percent for airborne concentrations of formaldehyde at the action level.

(7) *Employee notification of monitoring results.* Within 15 days of receiving the results of exposure monitoring conducted under this standard, the employer shall notify the affected employees of these results, in writing, either by distributing copies of the results to the employees or by posting the results. If the employee exposure is over the PEL, the employer shall develop and implement a written plan to reduce employee exposure to or below the PEL, and the written notice to employees shall contain a description of the corrective action being taken by the employer to decrease the exposure to within the permissible exposure limit.

(8) *Observation of monitoring.* (i) The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to formaldehyde required by this standard.

(ii) When observation of the monitoring of employee exposure to formaldehyde requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide and require the observer to use such clothing and equipment and shall assure that the observer complies with all other applicable safety and health procedures.

(e) *Regulated areas.* (1) The employer shall establish regulated areas where

exposures to formaldehyde may exceed the PEL. These areas shall be posted at all entrances and accessways with signs bearing the following information:

DANGER

FORMALDEHYDE

POTENTIAL CANCER HAZARD

EYE AND RESPIRATORY SYSTEM IRRITANT

RESPIRATORS REQUIRED

ADDITIONAL PROTECTIVE EQUIPMENT MAY BE REQUIRED

(2) The employer shall limit access to regulated areas to authorized persons.

(3) Whenever an employer at a multi-employer worksite establishes a regulated area, that employer shall communicate the location and restrictions of access to the regulated area to other employers with work operations at that worksite.

(f) *Methods of compliance*—(1) *Engineering controls and work practices.* The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to formaldehyde at or below the PEL, except to the extent the employer has established that such controls are not feasible.

(2) *Exception.* Whenever feasible engineering and work practice controls cannot reduce employee exposure to or below the PEL, the employer shall apply them to reduce employee exposures to the lowest levels achievable and shall supplement these controls with respirators which satisfy this standard.

(g) *Respiratory protection*—(1) *General.* Where respiratory protection is required, the employer shall provide, at no cost to the employee and shall assure the proper use of the respirators which comply with the requirements of this paragraph to reduce employee exposures to or below the PEL. Respirators shall be used in the following circumstances:

(i) During the interval necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; and

(iv) In emergencies.

(2) *Respirator selection.* (i) The appropriate respirators as specified in Table 1 shall be selected from those approved by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11.

(ii) The employer shall make available a powered air purifying respirator, meeting the specifications in Table 1, to any employee who experiences difficulty wearing a negative pressure respirator to reduce exposure to formaldehyde.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION AGAINST FORMALDEHYDE

Condition of use or formaldehyde concentration (ppm)	Facepiece pressure	Minimum required respirator
Up to 10 times the PEL	–	Half-mask respirator [1] with cartridges specifically approved for protection against formaldehyde.
Up to 50 times the PEL	–	Full facepiece with cartridges or canisters specifically approved for protection against formaldehyde.
Up to 100 ppm [2].	+	Full facepiece, powered air-purifying respirators equipped with cartridges or canisters specifically approved for protection against formaldehyde.
	+	Supplied air respirator equipped with full facepiece.
Above 100 ppm, or unknown.	+	Full facepiece self contained breathing apparatus (SCBA).
	+	Full facepiece supplied air respirator with positive pressure air supply for escape.
Firefighting	+	Full facepiece self contained breathing apparatus (SCBA).
Escape	+	Any escape self-contained breathing apparatus.
	–	Any gas mask equipped with canisters specifically approved for protection against formaldehyde.

[1] A full facepiece respirator must be provided and used if eye irritation is experienced.
[2] The IDLH is considered to be 100 ppm.

(3) *Respirator usage.* (i) Where respirator use is required by this standard, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f). Meeting the specifications outlined in the medical surveillance section of the standard shall constitute compliance with 29 CFR 1910.134(b)(10).

(ii) The employer shall perform quantitative fit tests and record the results at the time of initial fitting for each employee assigned to wear a negative pressure respirator. The quantitative fit testing shall be repeated for any employee if it is recommended by the examining physician.

(A) Respirators selected shall be from those exhibiting the best facepiece fit.

(B) No respirator shall be chosen that would potentially permit formaldehyde concentrations in excess of the permissible exposure limit in the employee's breathing zone.

(iii) Where air purifying chemical cartridge respirators are used, the air purifying cartridges shall be replaced at the end of each work shift.

(iv) Unless the canister contains an end-of-service-life indicator to show when breakthrough occurs, canisters used on air purifying canister type respirators shall be replaced at the completion of two workshifts within a 48-hour period. A label shall be attached to the canister indicating the date and time when it was first installed on the respirator.

(v) Employers shall permit employees to leave the work area to wash their faces and respirator facepieces as needed to prevent skin irritation from respirator use.

(h) *Protective equipment and clothing*—(1) *Provision and use.* When the employee's skin may come into contact with liquids or irritating or sensitizing solids containing formaldehyde, the employer shall provide appropriate protective equipment and clothing, at no cost to the employee, and assure that the employee uses this protective equipment and clothing. Examples of such protective devices include full body protective clothing, gloves, boots, head and neck covering, and face shields and goggles.

(i) The employer shall select and provide protective equipment and clothing in accordance with 29 CFR 1910.132 and 29 CFR 1910.133.

(ii) When an employee experiences eye irritation from exposure to airborne formaldehyde, the employer shall make gas-proof goggles available at no cost to the employee.

(2) *Removal and Storage.* (i) Clothing and protective equipment that becomes contaminated with formaldehyde shall be stored in such a manner so as to minimize employee exposure and not be worn again until cleaned or laundered.

(ii) Storage areas and containers with formaldehyde-contaminated clothing or equipment shall have a label which contains the following information:

DANGER

CONTAINS FORMALDEHYDE

POTENTIAL CANCER HAZARD

EYE AND RESPIRATORY SYSTEM IRRITANT

(iii) The employer shall assure that no employee takes home equipment or clothing contaminated with irritating or sensitizing materials containing formaldehyde or wet from splashes or spills of formaldehyde.

(3) *Cleaning and Replacement.* (i) The employer shall clean, launder, repair, or replace all required protective clothing and equipment for each affected employee as necessary to assure its effectiveness.

(ii) The employer shall assure that only trained persons remove protective clothing and equipment from storage for the purposes of laundering, cleaning, or disposal.

(iii) The employer shall inform any person who launders or cleans such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

(i) *Hygiene protection.* (1) The employer shall provide change rooms and showers, as described in 29 CFR 1910.141, for employees who are required to change into protective clothing to prevent skin contact with formaldehyde.

(2) If employees may become splashed with formaldehyde solutions, the employer shall provide conveniently located quick drench showers and assure that affected employees use these facilities immediately.

(3) If there is any possibility that an employee's eyes may be splashed with liquid formaldehyde, the employer shall provide eye-wash fountains within the immediate work area for emergency use.

(j) *Housekeeping.* The employer shall conduct a program to detect leaks and spills, including regular visual inspections of operations involving solutions of formaldehyde or formaldehyde gas.

(1) Preventative maintenance of equipment, including surveys for leaks, shall be undertaken at regular intervals.

(2) In work areas where spillage may occur, the employer shall make provisions to contain the spill, to decontaminate the work area, and to dispose of waste.

(3) The employer shall assure that all leaks are repaired and spills are cleaned promptly by employees wearing suitable protective equipment (including respirators) and trained in proper methods for cleanup and decontamination.

(4) Formaldehyde-contaminated waste and debris shall be placed for disposal in sealed containers bearing a warning containing the following information:

CAUTION

CONTAINS FORMALDEHYDE

AVOID INHALATION AND SKIN CONTACT

(k) *Emergencies.* (1) A written plan, including at least the elements prescribed in 29 CFR 1910.38(a), shall be developed for each workplace where there is employee exposure to formaldehyde.

(2) All employees shall be thoroughly trained of their responsibilities in the event of an emergency.

(3) The employer shall assure that appropriate equipment and supplies shall be located in each area where an emergency could occur.

(4) The employer shall make provisions for immediate evacuation, transportation, and medical assistance at a designated medical facility for affected employees.

(5) The employer shall assure that only designated personnel furnished with appropriate personnel protective equipment and trained in reentry procedures shall clean up spills or repair leaks.

(6) All employees, except those designated to correct the situation, shall be evacuated from the area where the emergency occurred until cleanup has been completed.

(l) *Medical surveillance*—(1) *Employees covered.* The employer shall institute medical surveillance programs for all employees required to wear a respirator to reduce their exposure to formaldehyde and for employees exposed to formaldehyde in emergencies.

(2) *Examination by a physician.* The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician and are provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(3) *Periodic examinations.* The employer shall make medical examinations available to each employee who is required to wear a respirator at the time of initial assignment and at least annually thereafter. The medical examination shall include:

(i) A medical and work history with emphasis on evidence of eye, nose, or throat irritation; shortness of breath; sinusitis, skin reaction or hypersensitivity; and allergic conditions, such as asthma or hay fever.

(ii) A physical examination with emphasis on evidence of irritation or sensitization of the respiratory system or skin, shortness of breath, or irritation of the eyes.

(iii) A pulmonary function test, to include at least a determination of forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1).

(iv) Any other test which the examining physician deems necessary to complete the written opinion.

(v) Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde or use of a respirator on the increased risk of impairment of their health.

(4) *Examinations for employees exposed in an emergency.* The employer shall make medical examinations available as soon as possible to all employees who have been exposed to formaldehyde in an emergency.

(i) The examination shall include a medical and work history with emphasis on any evidence of eye, nose, or throat irritation; shortness of breath; sinusitis; skin reaction or hypersensitivity; and allergic conditions, such as asthma or hay fever.

(ii) Other examinations shall consist of those elements considered appropriate by the examining physician.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and Appendices A, B, and D;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The representative exposure level for the employee's job assignment;

(iv) A description of any personal protective equipment and respiratory protection used or to be used by the employee; and

(v) Information from previous medical examinations of the affected employee within the control of the employer.

(6) *Physician's written opinion.* (i) For each examination required under this standard, the employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:

(A) The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde or from use of a respirator.

(B) The physician's opinion as to whether there is a need to reevaluate the effectiveness of the respirator used by the employee.

(C) Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment including respirators.

(D) A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to

formaldehyde, whether these conditions may have resulted from past formaldehyde exposure, and whether there is a need for further explanation or treatment.

(ii) The employer shall obtain the results of the medical examination and tests from the physician.

(iii) The employer shall provide a copy of the physician's written opinion to the effected employee within 15 days of its receipt.

(m) *Hazard Communication*—(1) *General.* Notwithstanding any exemption granted in 29 CFR 1910.1200(b) (1), (3) and (5) each employer who has a workplace covered by this standard shall comply with the requirements of 29 CFR 1910.1200 (e)–(j).

(2) *Labels.* (i) The employer shall assure that precautionary labels complying with the requirements of 29 CFR 1910.1200(f) are affixed to all containers of formaldehyde or formaldehyde-treated products leaving the workplace and all containers of formaldehyde and formaldehyde-treated products in the workplace.

(ii) Labels shall include the following information:

CAUTION

CONTAINS FORMALDEHYDE

EYE AND RESPIRATORY SYSTEM IRRITANT

POTENTIAL CANCER HAZARD

AVOID INHALATION

(iii) The following formaldehyde-treated products or containers of these products do not need to be labeled:

(A) Garments, bedclothes and draperies made from fabric treated with formaldehyde; and

(B) (Furniture.

(iv) *Substitute warning labels.* The employer may use warning labels required by other statutes, regulations, or ordinances which impart the same information as the warning statements required by this paragraph.

(3) *Material Safety Data Sheets.* (i) Any employer who has a place of employment covered by this standard who manufactures or imports formaldehyde or materials capable of releasing formaldehyde shall comply with the requirements of 29 CFR 1910.1200 (g) with regard to the development and updating of Material Safety Data Sheets.

(ii) Formaldehyde manufacturers, importers and those distributing formaldehyde or formaldehyde-treated products capable of releasing formaldehyde shall assure that Material Safety Data Sheets and updated information are provided to all employers purchasing such materials or products at the time of the initial shipment and at the time of the first shipment after a material safety data sheet is updated.

(n) *Employee Information and Training.* (1). *Participation.* The employer shall assure that all employees who are assigned to workplaces covered by this standard participate in a training program.

(2) *Frequency.* (i) Employers shall provide employees with information and training on formaldehyde at the time of their initial assignment and whenever a new hazard from formaldehyde is introduced into their work area.

(ii) Employers shall provide such information and training on at least an annual basis for all employees exposed to formaldehyde concentrations at or above the action level.

(3) *Training Materials.* The training program shall be conducted in a manner which the employee is able to understand and shall include:

(i) A copy of this regulation and discussion of its contents with an explanation of the contents of the material safety data sheet for formaldehyde.

(ii) The purpose for and a description of the medical surveillance program required by this standard; including:

(A) The potential health effects associated with exposure to formaldehyde plus a description of the signs and symptoms of exposure to formaldehyde.

(B) Instructions to immediately report to the employer the development of signs or symptoms of overexposure to formaldehyde;

(iii) Description of any operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

(iv) The purpose for, proper use of, and limitations of personal protective clothing and equipment;

(v) Instructions for the handling of spills, and emergency and cleanup procedures;

(vi) An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

(vii) A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

(4) *Access to training materials.* (i) The employer shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost to the affected employees.

(ii) The employer shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary and the Director.

(o) *Recordkeeping*— (1) *Exposure measurements.* The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

(i) The date of measurement;

(ii) The operation being monitored;

(iii) The methods of sampling and analysis used and evidence of their accuracy and precision;

(iv) The number, durations, and results of samples taken;

(v) The type of protective devices worn; and

(vi) The names, job classifications, social security numbers, and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

(2) Exposure determinations. Where the employer has determined that no monitoring is required under this standard, the employer shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

(3) *Medical surveillance.* The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under this standard. This record shall include:

(i) The name and social security number of the employee;

(ii) The physician's written opinions;

(iii) A list of any employee health complaints that may be related to exposure to formaldehyde.

(iv) A copy of the medical examination results, including the medical history, questionnaire responses, and results of any medical tests required by the standard or mandated by the examining physician.

(4) *Respirator Fit Testing.* (i) The employer shall establish and maintain accurate records for each employee subject to negative pressure respirator fit testing required by this standard.

(ii) This record shall include:

(A) A copy of the protocol selected for respirator fit testing.

(B) A copy of the results of any quantitative fit testing performed.

(C) The size and manufacturer of the types of respirators available for selection.

(D) The date of the most recent fit testing, the name and social security number of the tested employee, and the respirator type and facepiece selected.

(iii) Respirator fit testing records.

(5) *Record Retention.* The employer shall retain records required by this standard for at least the following periods:

(i) Exposure records and determinations shall be kept for 30 years.

(ii) Medical records shall be kept for the duration of employment plus 30 years.

(iii) Respirator fit testing records shall be kept until replaced by a more recent record.

(6) *Availability of Records* (i) Upon request, the employer shall make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary and the Director.

(ii) The employer shall make employee exposure records, including estimates made from representative monitoring and compliance plans, available upon request for examination and copying to the subject employee, or former employee, and employee representatives in accordance with 29 CFR 1910.20(a)–(e) and (g)–(i).

(iii) Employee medical records required by this standard shall be provided upon request for examination and copying, to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee.

(7) *Transfer of records.* (i) The employer shall comply with the requirements on transfer of records set forth in the standard, Access to Medical Records, 29 CFR 1910.20(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least 90 days prior to disposal and transmit them to the Director.

(p) *Dates* (1) *Effective date.* This section shall become effective [60 days after publication of the final rule] unless otherwise noted below.

(2) *Start-up dates*—(i) *Exposure measurements and determinations.* (A) Initial monitoring or objective determinations that no monitoring is required by the standard shall be completed by (6 months after the effective date of the final rule).

(B) Measurements representative of employee exposure to formaldehyde taken in the preceeding six months may be used to fulfill the initial monitoring or exposure determination requirement provided the sampling and analytical methods used meet the accuracy and confidence levels required by this standard.

(ii) *Medical surveillance.* Medical surveillance required by this standard shall be completed by (6 months after the effective date of the final rule).

(iii) *Emergency plan.* The emergency plan required by this standard shall be completed by (6 months after the effective date of the final rule).

(iv) *Engineering and work practice controls.* Engineering and work practice controls required by this standard shall be implemented as soon as possible, but no later than one year after the effective date of this standard except for businesses employing less than 20 employees. These small business entities shall implement engineering and work practice controls as soon as possible, but no later than two years after the effective date.

Appendix A—Substance Technical Guidelines for Formaldehyde

I. Physical and Chemical Data

A. Substance Identification.

Chemical name: Formaldehyde.

Chemical family: Aldehyde.

Formula: HCHO.

Molecular weight: 30.03.

Chemical Abstracts Service (CAS) number: 50–00–0.

Synonyms: BFV—Karsan; Fannoform—Lysoform; Formaldehyde, gas—Methanal; Formaldehyde, solution—Methyl aldehyde; Formalin—Methylene oxide; Formalith—Morbicid; Formic aldehyde—Oxomethane; Formol—Oxymethylene; Fyde—Paraform; HCHO—Superlysoform; Ivalon.

Hazardous Ingredients:

Aqueous formaldehyde solutions contain from 37–50% formaldehyde (CAS No. 50–00–0), and various percentages (1.0–15%) of methanol (CAS No. 67–56–1).

B. Physical Data.

Boiling point (760 mm Hg): 96.1–101.1 °C.

Freezing point: Slowly forms paraformaldehyde below 80 °C.

Specific gravity (H_2O = 1 @ 20 °C): 1.1111–1.525.

Vapor pressure (37 °C): 47–58 mm Hg.

Vapor density (Air = 1 at 20 °C): 1.03.

Solubility in water (% by wt @ 20 °C): Complete.

Percent volatiles by volume: 100.

Appearance and odor: Clear, colorless liquid, pungent odor.

II. Fire, Explosion Hazard, and Reactivity Data

A. Fire:

Flammable limits in air (% by volume): Lower: 7.0; Upper: 73.0.

These flammability limits are for pure formaldehyde gas.

Flash point (test method):

Tag closed cup (ASTM D56): 158–185 °F for aqueous solutions containing 37–52% formaldehyde.

Extinguishing media:

Use dry chemical, "alcohol foam", or CO_2; water may be ineffective, but should be used to keep fire-exposed containers cool.

Special fire fighting procedures: Learn procedures and responsibilities in the event of an emergency such as a fire in your workplace. Become familiar with the appropriate equipment and supplies used in an emergency. For example, wear a self-contained breathing apparatus (SCBA) and complete personal protective equipment for reentry in an emergency. In case of a fire, dilute burning liquid with water spray to reduce intensity of flames.

Unusual fire and explosion hazards: None.

National Fire Protection Association Section 325M & 704M Designation:

Health: 2—Materials hazardous to health, but areas may be entered freely with full-faced mask self-contained breathing apparatus which provides eye protection.

Flammability: 2—Materials which must be moderately heated before ignition will occur. Water spray may be used to extinguish the fire because the material can be cooled below its flash point.

Reactivity: 0—Materials which (in themselves) are normally stable even under fire exposure conditions and which are not reactive with water. Normal fire fighting procedures may be used.

B. Reactivity.

Stability: Stable.

Conditions to avoid:

Strong alkalies, high temperatures and temperatures below 68 °F. Reactions with phenol are usually exothermic.

Incompatibility (Materials to avoid):

Strong oxidizing agents, caustics, strong alkalies, isocyanates, anhydrides, oxides, and inorganic acids.

Hazardous combustion or decomposition products: Carbon dioxide, carbon monoxide, hydrogen and formaldehyde gas.

Hazardous polymerization: Will not occur.

III. Health Hazard Data

A. Permissible Exposure Limits.

OSHA proposal:

[1 ppm or 1.5 ppm] as an 8-hour time-weighted average (TWA) concentration.

B. Acute Effects of Exposure.

Ingestion (swallowing):

Liquids containing 10% to 40% formaldehyde cause severe irritation and inflammation of mouth, throat, and

stomach. Severe stomach pains will follow ingestion with possible loss of consciousness and death. Ingestion of dilute formaldehyde solutions (0.03–0.04%) may cause mild discomfort in the stomach and pharynx.

Inhalation (breathing):

Highly irritating to upper respiratory tract. Effects of irritation in experimental animals are evident even at exposures of 2 ppm. May cause inflammation of lining of nose, throat, and lungs at mildly irritating concentrations, with bronchopneumonia and edema possible from extremely irritating exposure. Exposure above 100 ppm may be fatal.

Skin (dermal):

Contact with the liquid causes irritation, drying, cracking, and scaling. A single application of 1% formalin may produce an irritant response. Prolonged and repeated contact causes a hardening or tanning effect. Contact may cause an allergic dermatitis. Allergic contact dermatitis may be induced by less than 1% formalin.

Eye contact:

Exposure to formaldehyde gas or contact with liquids containing formaldehyde can cause tearing and severe irritation. Contact with liquids can cause severe burns. Application of a 15% formalin solution to the eyes of rabbits resulted in severe reaction (corneal and conjunctival edema).

Note.—The perception of formaldehyde by odor and eye irritation become less sensitive with time as one adapts to formaldehyde. This can lead to overexposure if a worker is relying on these warning properties.

Acute animal toxicity data: Oral, rats: $LD_{50} = 800$ mg/kg; Dermal, rabbits; $LD_{50} = 250$ mg/kg; Inhalation, rats: LCLo = 250 mg/kg.

C. Chronic Effects of Exposure.

Carcinogenicity:

Formaldehyde has the potential for causing cancer and other adverse effects in humans. These effects have been demonstrated in various animal experiments which show formaldehyde to be a cancer causing agent. In one study, rats exposed to formaldehyde at 14.3 ppm for 24 months developed nasal cancer. Rats exposed at 5.6 ppm and mice exposed at 14.3 ppm also developed nasal cancers, but not in statistically significant numbers.

Mutagenicity:

Formaldehyde is a mutagen in several *in vitro* test-systems, but studies of *in vivo* genotoxic effects generally have produced negative results.

Toxicity:

Rats exposed to formaldehyde at 2 ppm and 3 ppm developed benign tumors, changes in the cell structure, and inflamed mucous membranes of the nose.

D. Emergency And First Aid Procedures.

Ingestion (swallowing):

Induce vomiting of conscious patient immediately by giving 2 glasses of water and pressing finger down throat. Contact a physician immediately afterwards.

Inhalation (breathing):

Remove patient from contaminated area. If breathing has stopped, give artificial respiration, then oxygen if needed. Contact a physician as soon as possible.

Skin contact:

Remove contaminated clothing and wash the skin with large amounts of water. If irritation persists, contact a physician.

Eye contact:

Flush eyes with water for at least 15 minutes. Contact a physician immediately.

IV. Spill, Leak and Disposal Procedures

A. Steps to Take if Materials are Released or Spilled.

Place leaking container in well ventilated areas. Eliminate ignition sources. Use foam to control vapors. Flush area with water sparingly or use an absorbent to contain and/or remove spill. Dike the spill to minimize contaminated area and facilitate salvage or disposal. Avoid run-off into storm sewers and ditches which lead to natural waterways. Neutralize with ammonium hydroxide or complex with sodium sulfite. (NOTE: This reaction is reversible.) Call the National Response Center (800–424–8802) if spill is in reportable quantity (1000 lb/day of formaldehyde) under "Superfund". If required, state and local authorities should be notified.

B. Waste Disposal Method.

Incineration, biological oxidation with proper acclimation of system, landfill only if solidified prior to disposal. Use of injection wells may provide an alternative means of disposal for compatible materials.

V. Monitoring and Measurement Procedures

A. Exposure above the Permissible Exposure Limit.

Eight hour exposure evaluation:

Measurements taken for the purpose of determining employee exposure for the workshift are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee.)

Monitoring techniques:

Sampling and analysis may be performed by collection of formaldehyde on liquid or solid sorbents with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct reading instruments, or passive dosimeters as long as measurements taken using these methods accurately evaluate the concentration of formaldehyde in employees breathing zones.

OSHA's method:

Appendix C describes the validated method of sampling and analysis which has been tested by OSHA for use with formaldehyde. The employer is obligated to select a monitoring method which meets or exceeds the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of formaldehyde at [1 ppm or 1.5 ppm] and to plus or minus 35 percent for concentrations of 0.5 ppm.

B. Qualifications.

Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers must assure that the evaluation of employee exposures is performed by a technically qualified person.

VI. Protective Clothing and Equipment

A. Respiratory Protection (specify type).

Use NIOSH-approved formaldehyde cartridge or canister respirator within use limitations of these devices. In all other situations, use self-contained breathing apparatus (SCBA).

B. Protective Gloves: Neoprene or rubber gloves.

C. Eye Protection: Gas goggles, full facepiece respirator.

D. Other protective equipment:

For operations where spills or splashing may occur, use an impervious body covering and boots. A safety shower and eye bath must be available.

VII. Miscellaneous Precautions and Guidelines

A. Precautions in Handling and Storage.

Small containers should be protected from physical damage. Detached storage is preferred. Outdoor storage facilities should be insulated and equipped with heating equipment to maintain a minimum storage temperature of 68 °F. Indoor storage areas should be sloped toward a drain or retention area.

Warehouses should be equipped for maximum ventilation in case of leaks or spills.

B. Other Precautions.

Keep formaldehyde in closed containers and away from heat, sparks, and flames. Keep containers closed to the extent possible. Use formaldehyde only in areas where ventilation is adequate. Avoid breathing air where the odor of formaldehyde persists. Avoid prolonged or repeated contact with formaldehyde solutions and wash with soap and water after handling. Do not enter storage areas not adequately ventilated.

C. Ventilation.

Local exhaust:

Recommended when appropriate to control employee exposure.

General (mechanical):

May be inadequate as the sole means of controlling employee exposure.

VIII. Medical Surveillance

Medical surveillance can play an important role in protecting employees' health. All employees are encouraged strongly to participate in the program.

A. Periodic.

The employer must make a medical surveillance program available at no expense to employees and at a reasonable time and place. The periodic surveillance program must cover all employees required to wear a respirator. The program must be made available to these employees at the time of their initial assignment and at least annually thereafter.

The surveillance program shall consist of:

(a) A detailed work and medical history.

(b) A complete physical examination.

(c) Pertinent laboratory examinations to ascertain abnormalities associated with respirator use or aggravated by formaldehyde exposure.

(d) A pulmonary function test including at least forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1).

Because employees who receive periodic medical surveillance wear respirators, the physician is required to assess pulmonary status, which includes an annual pulmonary function test. At the physician's discretion, the periodic examination relating to the use of respirators may also include a chest x-ray. The physician must collect other information from the medical and work histories and the physical examination needed to make a determination of the person's suitability to use a respirator and the need for a reevaluation of respirator fit.

The employer must provide the following information to the physician:

(1) A description of the employee's duties as they relate to formaldehyde exposure;

(2) The concentration of formaldehyde and duration of exposure to formaldehyde of the employee;

(3) A description of any personal protective equipment the employee is required to wear; and

(4) The results of prior medical examinations and opinions concerning the employee's health as it relates to information collected to comply with the standard for occupational exposure to formaldehyde.

After a medical examination the physician must prepare a written report containing:

(1) The physician's opinion as to whether the employee has any medical condition which places that employee at an increased risk of material impairment to health from exposure to formaldehyde or use of respirators.

(2) Any recommended special protective measures to be provided; and

(3) Any recommended testing or limitation on the use of respirators.

All records from medical examinations, including disease surveys, must be retained.

B. Additional.

Medical consultation must be made available promptly if the employee is experiencing signs or symptoms of overexposure to formaldehyde.

C. Emergency.

In the event that an employee is exposed to formaldehyde in an emergency situation or develops signs or symptoms associated with acute toxicity from formaldehyde exposure, the employer must provide the employee with a medical examination as soon as possible. This examination shall include all the steps necessary to stabilize the health of the employee. The examining physician may recommend a 72-hour medical observation period to ensure that any delayed systemic effects which may result from acute exposure are minimized.

Appendix B—Medical Surveillance Guidelines for Formaldehyde

I. Health Hazards

The occupational health hazards of formaldehyde are mainly related to its toxic effects after inhalation, after direct contact with the skin and eyes, and after ingestion.

II. Toxicology

Inhaled formaldehyde causes irritation of the eyes, nose, and throat. A typical mucous membrane irritant, it can result in an itchy, runny, or stuffy nose; a dry or sore throat; eye irritation; and headache. These effects are similar to a cold or allergy produced by other membrane irritants including viruses or pollens. Both severity and number of effects increase with increasing exposure, but they are rapidly reversible once the worker is removed from the source of exposure.

It has been suggested that formaldehyde can potentiate preexisting asthma, but it is unclear whether formaldehyde, itself, can cause respiratory sensitization. About 10 to 20 percent of the general population tends to exhibit hypersusceptibility, and these persons are the most likely to respond to the effects of formaldehyde. Workers exposed to formaldehyde and respirable dusts may undergo decreases in pulmonary function over the workshift.

Formaldehyde has caused nasal cancer in laboratory rodents exposed at 5.6 to 14.3 ppm for 30 hours a week for up to a lifetime. It possesses mutagenic activity in *in vitro* test systems but has not been found to cause chromosomal abnormalities in exposed workers. Epidemiological evidence is too insensitive to predict whether humans would also develop nasal cancer. Limited evidence in humans suggests that if it is a lung carcinogen, it is only weakly active. Professionals (embalmers, pathologists, anatomists) appear to be at excess risk of brain cancer, but a causal link to formaldehyde has not been proven.

Formaldehyde at 2 ppm has damaged the epithelial cells contained in the lining of the nasal cavities of animals and induced benign tumors, thought to be similar to microcystic papillary adenomas in humans. Some evidence exists that humans may be at greater risk of nasal cancer if they have a history of sinusitis or nasal polyps.

The effects of formaldehyde on the skin consist of primary irritation and allergic sensitization. Repeated contact causes hardening and cracking. Persons who are allergic to formaldehyde may develop allergic contact dermatitis in response to even low concentrations of this substance. Some persons also develop sensitization to formaldehyde-containing resins. Because higher concentrations (5% or more) may produce skin damage, a 2 percent solution of formalin (0.8% formaldehyde) is recommended for any patch testing done to confirm diagnosis of formaldehyde allergy in symptomatic patients. Routine surveillance by patch testing is not recommended.

III. Signs and Symptoms of Acute Overexposure

The concentration of formaldehyde that is immediately dangerous to life and health (IDLH) is 100 ppm. Exposures between 50 and 100 ppm cause severe injury to the respiratory tract, such as pulmonary edema, inflammation, pneumonitis, and pneumonia. Between 10 and 20 ppm, irritation is so severe that it is difficult to take a normal breath. At levels of 1 to 5 ppm, some persons will experience mild to moderate irritation, particularly of the eyes.

Formaldehyde is a moderate skin irritant. At concentrations above 5 percent, it may produce reddening and inflammation. It is a severe irritant to the eyes and can lead to permanent eye damage. Swallowing formaldehyde solutions causes immediate irritation of the mouth, throat, and stomach, resulting in nausea and vomiting. In extreme cases severe abdominal pain is experienced, possibly followed by collapse and even death.

IV. Surveillance and Preventive Considerations

As noted above, formaldehyde can cause both sensory irritation and an inflammatory reaction with cellular and tissue damage. It causes irritation and sensitization of the skin and irritation with possible sensitization of the respiratory system. Animal studies indicate that it is a tumorigen at 2 ppm and a carcinogen at 5.6 ppm and above. Limited evidence in humans is inconclusive with regard to formaldehyde's carcinogenic effects, but this evidence suggests that some workers who are exposed to formaldehyde are also at excess risk of developing brain cancer. The physician should be aware of the findings of these studies in evaluating the health of employees exposed to formaldehyde.

Adequate screening tests to determine an employee's potential for developing serious chronic diseases, such as cancer, frequently do not exist. While there is no specific test for formaldehyde, the animal studies indicate that tumor promotion, leading to a much higher incidence of cancer, occurs when tissue damage and cell death occur. Such effects may be observable by examination of the nose and upper respiratory tract. In addition, a history of smoking and alcohol consumption would predispose an individual to develop certain types of cancer in the respiratory system. A history of nasal polyps and sinusitis may also predispose a person to nasal cancer. A work history of exposure to wood dust and possibly to employment in the textile industry would suggest an additional risk of nasal cancer.

It is important for the physician to become familiar with the conditions in which the employee is potentially exposed to formaldehyde. The physician also must become familiar with the signs and symptoms that indicate a worker might be receiving unacceptable exposure to formaldehyde. Such symptoms might include complaints of eye, nose, and throat irritation possibly with associated complaints of recurrent headaches. Signs might include dermatitis, reddened eyes or skin, dry and cracked skin appearing "leathered", and evidence of damage to the nasal passages. Other evidence that might suggest an effect from formaldehyde in some circumstances would include asthma or acute changes in pulmonary function. These signs and symptoms are especially important in evaluating the medical and work histories and in conducting the physical examination. When the physician detects evidence pointing toward unacceptable formaldehyde exposure in an active employee, the physician should recommend in the written opinion that measures be taken by the employer to decrease the exposure of the employee and lower the risk of serious long-term consequences.

The employer is required to institute a medical surveillance program for all employees who are or will be exposed to formaldehyde at or above the permissible exposure limit (1.0 ppm). The employer must provide annual pulmonary function tests to these employees since they would be required to wear a respirator to reduce formaldehyde exposure. All examinations and procedures must be performed by or under the supervision of a licensed physician at a reasonable time and place for the employee and at no cost to the employee.

Although broad latitude in prescribing specific tests to be included in the medical surveillance program is extended to the examining physician, OSHA requires inclusion of the following elements in the routine examination:

(1) Medical and work histories with special emphasis on eye, nose, or throat irritation; shortness of breath; sinusitis; skin reactions or hypersensitivity; and allergic conditions such as asthma or hayfever.

(2) A physical examination with particular emphasis on any evidence of irritation or sensitization of the respiratory system and skin, evidence of shortness of breath, and evidence of irritation of the eyes.

(3) A pulmonary function test including at least forced vital capacity and forced expiratory volume in one second.

(4) Any laboratory or other test deemed necessary by the examining physician.

In addition, the physician must determine the worker's suitability for respirator use. Workers or job applicants who have medical conditions that would be aggravated by exposure to formaldehyde or use of a respirator need to receive counseling on the increased risk of impairment of their health from working with formaldehyde.

In certain cases, to provide sound medical advice to the employer and the employee, the physician must evaluate situations not directly related to formaldehyde. For example, employees with skin diseases, whether or not they are formaldehyde related, may be unable to tolerate wearing protective clothing. In addition, those with chronic respiratory diseases may not tolerate the wearing of negative pressure (air purifying) respirators. Additional tests and procedures that will help the physician determine which employees are medically unable to wear such respirators must include a pulmonary function test with measurement of the employee's forced vital capacity (FVC), and forced expiratory volume at one second (FEV_1). Ratios of FEV_1 to FVC as well as measured FVC and measured FEV1 to their expected values corrected for variations due to age, sex, race, and height must be calculated. Whether a chest X-ray will provide useful information should be considered.

While little is known about the long term consequences of high short-term exposures, some animal data indicate that this type of exposure may present a higher risk than the same total dose delivered over the entire workday or workweek. Thus, it appears prudent to monitor such affected employees closely.

In the event of emergency exposure, and especially when the employee experiences signs and symptoms possible related to formaldehyde exposure, the employer is required to provide the employee with the opportunity for additional medical surveillance. Because these situations may be quite specific, the judgment of the physician is particularly needed to determine appropriate tests. When acutely toxic effects are seen, there is an obvious need for medical assistance substantially beyond the minimum

requirements specified in OSHA's proposed formaldehyde standard.

The employer is required to provide the physician with the following information: a copy of this standard and appendices A, B, and D; and description of the affected employee's duties as they relate to the employee's exposure concentration; the exposure concentration from representative monitoring along with the employee's duration of exposure (eg. 15 hr/wk, three 8-hr shifts a week, full-time); a description of any personal protective equipment, including respirators, used by the employee; and the results of any previous medical determinations related to formaldehyde exposure for the affected employee that are within the employer's control.

The employer is required to obtain the results of the medical examinations and a written statement from the physician. This statement must contain the physician's opinion as to whether the employee has any medical condition which would place the employee at increased risk of impaired health from exposure to formaldehyde or use of respirators. The physician must also state his opinion regarding any restrictions that should be placed on the employee's exposure to formaldehyde or upon the use of protective clothing or equipment such as respirators. The physician's opinion must also contain a statement regarding the suitability of the employee to wear the type of respirator assigned and a recommendation as to whether or not respirator fit testing should be conducted. Finally, the physician must inform the employer that the employee has been informed by the physician of the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion is not to contain any information on specific findings or diagnoses unrelated to occupational exposure to formaldehyde. After the employer has received the physician's statement, the employer is required to make this information available to the affected employee.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in determining that their health is, or is not, being impaired by formaldehyde, and to assess the employee's ability to use protective clothing and equipment.

Appendix C—Sampling and Analytical Methods for Formaldehyde

A number of methods are available for monitoring employee exposure to formaldehyde. In general, sampling is conducted using solid or liquid sorbents and sampling pumps, and the subsequent analysis of the samples is conducted by colorimetry, gas chromatography, or polarography. Passive dosimeters and detector tubes also have been used for determination of formaldehyde in the environment. There are several commercially available portable gas analyzers and monitoring units as well. The various methods available have different advantages and interferences [Exs. 58; 77–19], so that the best method available will depend to an extent on the type of operation being monitored.

This appendix describes the method presently used at the OSHA Analytical Laboratory in Salt Lake City for measurement of formaldehyde. The method is the most sensitive method presently validated for measurement of employee exposure and it is almost free of interferences. Inclusion of this method in the appendix does not imply that it is the only one which will be satisfactory. Other methods may also be acceptable provided they can determine formaldehyde at the permissible exposure limit within ±25% of the "true" value at the 95% confidence level. Where applicable, the method must also be able to measure formaldehyde at the action level to ±35% of the "true" value with a 95% confidence. This accuracy requirement applies to other toxic substance standards promulgated by OSHA and it was also the basis used for methods of sampling and analysis developed by the Standards Completion Program.

OSHA's Analytical Laboratory Method

1. *Introduction*

1.1 *Scope*

This method describes the collection of airborne formaldehyde in the breathing zone of personnel and the subsequent analysis of those samples by differential pulse polarography.

1.2 *Principle*

A known volume of air is drawn through a midget fritted glass bubbler containing 10% methanol in water to collect the formaldehyde. The analyte is reacted with hydrazine (H_2NNH_2) reagent to form a formaldehyde-hydrazone compound. An aliquot of the resulting sample is determined by differential pulse polarography at a dropping mercury electrode.

2. *Sampling Procedure*

2.1 *Apparatus*

(a) Personal Sampling Pump. A personal sampling pump calibrated within 5% at the recommended flow rate with representative sampler in line to minimize errors associated with uncertainties in the volume sampled.

(b) Filter holder, 3-piece cassette, polystyrene, 37-mm diameter.

(c) Mixed cellulose acetate membrane filters, 0.8 um pore size, 37 mm diameter Millipore Type AA or equivalent, supported by stainless steel wire mesh screen.

(d) Midget fritted glass bubblers, glass 25–mL, silanized.

(e) Shipping vials, silanized, 20 mL, Teflon-lined caps.

Note.—The use of materials fabricated from Polyvinyl Chloride (PVC) or Bakelite products for the collection and/or storage of formaldehyde is not acceptable.

2.2 *Procedure*

(a) A minimum sample size of 30 L is recommended. Sample at a known flow rate of 0.5 to 1 L min (section 2.1a). The maximum volume sampled should not exceed 160 L at 1 L/min.

(b) Connect the bubbler containing 15 mL of 10% methanol to the sampling pump with Tygon or rubber tubing. Don't use PVC tubing preceding the bubbler. Substitution of a midget impinger for a fritted glass bubbler is unacceptable.

(c) If evaporation losses occur during sampling, add additional solution to the bubbler to maintain the required concentration of methanol in the collecting solution.

(d) Terminate sampling at the predetermined time and record the sample flow rate, collection time and ambient temperature and pressure. If pressure reading is unavailable, record the elevation.

(e) Blank. With each batch of ten samples submit at least one bubbler sample from the same lot of sorbent solution which is subjected to the same handling as for the samples except that no air is drawn through it. Label this as a sample blank.

(f) Transfer the bubbler solution to a 20 mL glass vial. Rinse the bubbler with 2 or 3 mL of the sample collecting solution and pour the rinsings into the sample vial. Place the Teflon lined cap tightly on the vial and use vinyl or waterproof tape around the cap to prevent leakage during shipment. Use of plastic storage containers or Bakelite caps are not acceptable.

3. *Analytical Procedure*

3.1 *Apparatus*

(a) Polarographic Analyzer or Controller-Model 374 manufactured by Princeton Applied Research (PAR) or equivalent.

(b) Polarographic Cell Sequencer—PAR M316 or equivalent.

(c) 15 mL glass polarographic cells.

(d) Nitrogen purification apparatus-deoxygenation system.

(e) volumetric and micropipettes, volumetric flasks, beakers and general laboratory glassware.

(f) pH meter.

3.2 *Reagents*

All chemicals should be ACS reagent grade or equivalent.

(a) *Methanol solution, 10% (V/V)*: Dilute 100 mL of reagent grade methanol to one liter with deionized water.

(b) *Acetate buffer, pH 4*: Prepare an equimolar mixture of acetic acid and sodium acetate. 0.1 M. in deionized water.

(c) *Hydrazine reagent, 2% (W/V)*: Dissolve 2 grams of hydrazine sulfate ($H_2NNH_2 \cdot H_2SO_4$) in deionized water and dilute to 100 mL with deionized water. Close tightly and make fresh weekly.

(d) *Supporting electrolyte*: Mix 10% methanol solution, acetate buffer, and 2% hydrazine reagent in the ratio of 5:4:1 respectively. Prepare 100 mL of this solution for each analysis. Make fresh daily.

(e) *Formaldehyde stock solution, 100 ppm:* Dissolve 2.7 grams (about 3 mL) of 37% formaldehyde solution in one liter of deionized water. This solution must be standardized as described in Section 3.4.1. The solution is stable for at least 3 months. (Note: After 3 months, re-standardization is required).

(f) *Formaldehyde solution, 100 ppm, 10 ppm, and 1 ppm:* Make appropriate serial dilutions of the formaldehyde stock solution with 10% methanol.

(g) *Reagents in standardization of formaldehyde stock standard solution:*

(1) *Sodium carbonate*, certified, 99% minimum purity: Dry at 120 °C for 2 hours, then transfer to a dessicator. Dry to a constant weight. Use as a primary standard.

(2) *Sulfuric acid* H_{2SO4}), concentrated (98%):

(3) *Sulfuric acid*, 0.1 N: Add 3 mL of concentrated sulfuric acid slowly to one liter of deionized water.

(4) *Sodium sulfite*, 12.5% (W/V): Dissolve 140 grams of reagent in deionized water and store in a refrigerator.

3.3 *Sample preparation*

(a) Measure and record the total volume of each sample with a graduated cylinder.

(b) Transfer the sample solution to a 25 mL volumetric flask. Rinse the graduated cylinder and the vial in which the sample was received with two small portions of 10% methanol and add to the sample in the flask. Dilute the sample to volume with 10% methanol.

(c) Add exactly 4 mL of the sample solution, 4 mL of acetate buffer and 1 mL of 2% hydrazine reagent to the polarographic cell.

3.4 *Standard preparation*

3.4.1 *Standardization of formaldehyde stock solution*

(a) Use pH meter and adjust the pH of 25 mL (measured by graduated cylinder) of sodium sulfite solution to 9.6 with 0.1 N H_2SO_4.

(b) Weigh 50±0.05 grams of formaldehyde stock solution into a 250 mL beaker.

(c) Add 25 mL of the previously adjusted sodium sulfite solution. Titrate to pH 9.6 with 0.1 N H_2SO_4 which was standardized at the same endpoint with the certified sodium carbonate. Calculate ppm formaldehyde as follows:

Formaldehyde, ppm = (A—B)(C)(D)/E (1)

Where A = milliliters of H_2SO_4 solution required to titrate the sample,

B = milliliters of H_2SO_4 solution required to titrate the blank,

C = normality of the H_2SO_4 solution in milliequivalents per milliliter,

D = (30 milligrams per milliequivalent of HCHO) (1000 micrograms per milligram) or 30 X 10^3 µg/meq of HCHO,

E = grams of sample used.

3.4.2 *Formaldehyde calibration standards*

(a) Prepare series of standards in the analytical range of 0.05 to 10 ppm by appropriate serial dilutions.

(b) Add the aliquots of the appropriate formaldehyde stock solutions, using the calibrated micropipets, to the polarographic cell containing exactly 10 mL of supporting electrolyte.

3.5 *Analysis*

(a) Soak all glassware and polarographic cells in 6M nitric acid, rinse thoroughly with deionized water and air dry prior to using.

(b) Turn on the polarographic analyzer and the automated cell sequencer, in order, and allow to warm up for at least 30 minutes.

(c) Analyze the sample by polarography using the conditions specified in the operating and service manuals for the polarograph being used.

(d) Prepare the samples and the working standard solutions as described in section 3.3 and 3.4.

(e) Purge each standard and sample for 5 minutes with pre-purified nitrogen.

(f) Analyze the reagent blank (supporting electrolyte), run a standard calibration curve and the samples. A standard should be reanalyzed after every five or six samples.

(g) Record the peak current, (nA), for each standard and sample. The differential pulse polarogram of formaldehyde hydrazone at a dropping mercury electrode yields a peak at approximately −0.850 V.

(h) Use any available least square regression program to plot a calibration curve of peak current. (nA) vs concentration (ppm, ppb or total µg) of standards.

4. *Calculations*

(a) Read the weight, in µg, corresponding to each response (nA), from the standard curve (3.5–h). No volume corrections are needed if the standard curve is based upon µg per 10 ml formaldehyde and the volume of the sample determined is identical to the volume of the standards determined.

(b) Corrections for the blank must be made for each sample:

$$\frac{\mu g}{mL}\ \text{HCHO (blank corrected)} = \frac{\mu g\ \text{HCHO}}{\text{sample aliquot (mLs)}} - \frac{\mu g\ \text{blank}}{\text{blank aliquot (mLs)}}$$

(c) The concentration of formaldehyde in the air sampled can be expressed in mg/m^3, which is numerically equal to µg/L.

$$mg/m^3 = \frac{\text{(corrected µg/mL from section 4-b) (sample volume)}}{\text{(air volume sampled, liters)}}$$

(d) Another method of expressing concentration is ppm (corrected to standard conditions of 25 °C and 760 mm Hg).

$$ppm = [mg/m^3]_X \frac{[24.45]}{[M.W.]}$$

Where 24.45 = molar volume (liters/mole) of analyte, at 25 °C and 760 mm Hg
M.W. = molecular weight (g/mole) of analyte
298 = temperature (°K) at 25 °C

Appendix D—Quantitative Fit Test Procedures

1. *General*

a. The method applies to the negative-pressure nonpowered air-purifying respirators only.

b. The employer shall assign one individual who shall assume the full responsibility for implementing the respirator quantitative fit test program.

2. *Definition*

a. "Quantitative Fit Test" means the measurement of the effectiveness of a respirator seal in excluding the ambient atmosphere. The test is performed by dividing the measured concentration of challenge agent in a test chamber by the measured concentration of the challenge agent inside the respirator facepiece when the normal air purifying element has been replaced by an essentially perfect purifying element.

b. "Challenge Agent" means the air contaminant introduced into a test chamber so that its concentration inside and outside the respirator may be compared.

c. "Test Subject" means the person wearing the respirator for quantitative fit testing.

d. "Normal Standing Position" means standing erect and straight with arms down along the sides and looking straight ahead.

e. "Fit Factor" means the ratio of challenge agent concentration outside with respect to the inside of a respirator inlet covering (facepiece or enclosure).

3. *Apparatus*

a. *Instrumentation.* Corn oil, sodium chloride or other appropriate aerosol generation, dilution, and measurement systems shall be used for quantitative fit test.

b. *Test chamber.* The test chamber shall be large enough to permit all test subjects to freely perform all required exercises without distributing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air yet uniform in concentration throughout the chamber.

c. When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particular filter supplied by the same manufacturer.

d. The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000.

e. The combination of substitute air-purifying elements (if any), challenge agent, and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of PEL to the challenge agent at any time during the testing process.

f. The sampling port on the test speciment respirator shall be placed and constructed so that there is no detectable leak around the port, a free air flow is allowed into the sampling line at all times and so there is no interference with the fit or performance of the respirator.

g. The test chamber and test set-up shall permit the person administering the test to observe one test subject inside the chamber during the test.

h. The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent constant within a 10 percent variation for the duration of the test.

i. The time lag (interval between an event and its being recorded on the strip chart) of the instrumentation may not exceed 2 seconds.

j. The tubing for the test chamber atmosphere and for the respirator sampling port shall be the same diameter, length and material. It shall be kept as short as possible. The smallest diameter tubing recommended by the manufacturer shall be used.

k. The exhaust flow from the test chamber shall pass through a high-efficiency filter before release to the room.

l. When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

4. *Procedural Requirements*

a. The fitting of half-mask respirators should be started with those having multiple sizes and a variety of interchangeable cartridges and canisters such as the MSA Comfr II-M, Norton M, Survivair M A-O or Scott-M. Use either of the tests outlined below to assure that the facepiece is properly adjusted.

(1) *Positive pressure test.* With the exhaust port(s) blocked the negative pressure of slight inhalation should remain constant for several seconds.

(2) *Negative pressure test.* With the intake port(s) blocked the negative pressure slight inhalation should remain constant for several seconds.

b. After a facepiece is adjusted, the test subjects shall wear the facepiece for at least 5 minutes before conducting a qualitative test by using one of the methods described below and using the exercise regime described in 5-a, b, c, d, and e.

(1) *Isoamyl acetate test.* (When using organic vapor cartridges).

The test subject who can smell the odor should be unable to detect the odor of isoamyl acetate squirted into the air near the most vulnerable portions of the facepiece seal. In a location which is separated from the test area, the test subject shall be instructed to close her/his eyes during the test period. A combination cartridge or canister with organic vapor and high-efficiency filters shall be used when available for the particular mask being tested. The test subject shall be given an opportunity to smell the odor of isoamyl acetate before the test is conducted.

(2) *Irritant fume test.* (When using high-efficiency filters).

The test subject should be unable to detect the odor of irritant fume (stannic chloride or titanium tetrachloride ventilation smoke tubes) squirted into the air near the most vulnerable portions of the facepiece seal. The test subject shall be instructed to close her/his eyes during the test period.

c. The test subject may enter the quantitative testing chamber only if she or he has obtained a satisfactory fit by as stated in 4-b of this Appendix.

d. Before the subject enters the test chamber, a reasonable stable challenge agent concentration shall be measured in the test chamber.

e. Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half-mask and 1 percent for a full facepiece.

f. A stable challenge agent concentration shall be obtained prior to the actual start of testing.

g. Respirator restraining straps may not be overtightened for testing. The straps shall be adjusted by the wearer to give a reasonable comfortable fit typical of normal use.

5. *Exercise Regime.* Prior to entering the test chamber, the test subject shall be given complete instructions as to her/his part in the test procedures. The test subject shall perform the following

exercises, in the order given, for each independent test.

a. *Normal Breathing (NB).* In the normal standing position, without talking, the subject shall breathe normally for at least one minute.

b. *Deep Breathing (DB).* In the normal standing position the subject shall do deep breathing for at least one minute pausing so as not to hyperventilate.

c. *Turning head side to side (SS)* Standing in place the subject shall slowly turn his head from side between the extreme positions to each side. The head shall be held at each extreme position for at least 5 seconds. Perform for at least three complete cycles.

d. *Moving head up and down (UD)* Standing in place, the subject shall slowly move his head up and down between the extreme position straight up and the extreme position straight down. The head shall be held at each extreme position for at least 5 seconds. Perform for at least three complete cycles.

e. *Reading (R)* The subject shall read out slowly and loud so as to be heard clearly by the test conductor or monitor. The test subject shall read the "rainbow passage" at the end of this section.

f. *Grimace (G)* The test subject shall grimace, smile, frown, and generally contort the face using the facial muscles. Continue for at least 15 seconds.

g. *Bend over and touch toes (B)* The test subject shall bend at the waist and touch toes and return to upright position. Repeat for at least 30 seconds.

h. *Jogging in place (J)* The test subject shall perform jog in place for at least 30 seconds.

i. *Normal Breathing (NB)* Same as Exercise a.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

6. The test shall be terminated whenever any single peak penetration exceeds 5 percent for half-masks and 1 percent for full facepieces. The test subject may be refitted and retested. If two the three required tests are terminated, the fit shall be deemed inadequate. (See paragraph 4-h).

7. *Calculation of Fit Factors*

a. The fit factor determined by the quantitative fit test equals the average concentration inside the respirator.

b. The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

c. The average peak concentration of the challenge agent inside the respirator shall be the arithmetic average peak concentrations for each of the nine exercises of the test which are computed as the arithmetic average of the peak concentrations found for each breath during the exercise.

d. The average peak concentration for an exercise may be determined graphically if there is not a great variation in the peak concentrations during a single exercise.

8. *Interpretation of Test Results*

The fit factor measured by the quantitative fit testing shall be the lowest of the three protection factors resulting from three independent tests.

9. *Other Requirements*

a. The test subject shall not be permitted to wear a half-mask or full facepiece if the minimum fit factor of 100 or 1,000, respectively, cannot be obtained. If hair growth or apparel interfere with a satisfactory fit, then they shall be altered or removed so as to eliminate interference and allow a satisfactory fit. If a satisfactory fit is still not attained, the test subject must use a positive-pressure respirator such as powered air-purifying respirators, supplied air respirator, or self-contained breathing apparatus.

b. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface.

c. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respirator diseases or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

d. The test subject shall be given the opportunity to wear the assigned respirator for one week. If the respirator does not provide a satisfactory fit during actual use, the test subject may request another QNFT which shall be performed immediately.

e. A respirator fit factor card shall be issued to the subject with the following information:

(1) Name

(2) Date of fit test.

(3) Protection factors obtained through each manufacturer, model and approval number of respirator tested.

(4) Name and signature of the person that conducted the test.

f. Filters used for qualitative or quantitative fit testing shall be replaced weekly, whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily or sooner if there is any indication of breakthrough by the test agent.

10. In addition, because the sealing of the respirator may be affected, quantitative fit testing shall be repeated immediately when the test subject has a:

(1) Weight change of 20 pounds or more.

(2) Significant facial scarring in the area of the facepiece seal.

(3) Significant dental changes; i.e.; multiple extractions without prothesis, or acquiring dentures.

(4) Reconstructive or cosmetic surgery, or

(5) Any other condition that may interfere with facepiece sealing.

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Part III

General Services Administration

48 CFR Ch. 5

Multiple Award Schedule Procurement; Proposed Rule and Meeting

GENERAL SERVICES ADMINISTRATION

48 CFR Ch. 5

[GSA Notice V-1]

Multiple Award Schedule Procurement

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Notice of proposed rule and meeting on proposed rule.

SUMMARY: This notice invites written comments on a proposed revision to the General Services Administration (GSA) Multiple Award Schedule (MAS) policy statement of October 1, 1982 (47 FR 50242, Nov. 5, 1982), and announces forthcoming public meetings on the proposal. The proposed revisions are based on the results of an internal GSA review of the policy, as well as public comments received on an earlier proposal. GSA published proposed clarifications and revisions to the current policy statement in the March 26, 1985, **Federal Register** (50 FR 11910). A number of comments were received on the proposed revisions regarding (1) consideration of a firm's pricing arrangements to dealers, distributors and original equipment manufacturers (OEM) in the MAS negotiation process, (2) disclosure of prices on other Federal contracts, (3) revisions to the price reduction clause, and (4) disclosure of sales, discount and marketing data on the Discount Schedule and Marketing Data Sheets (DSMD). As a result, additional changes have been made in the proposed revision regarding these issues, and comments are requested on the proposed policy statement. GSA is particularly interested in receiving comments or suggestions on ways of reducing the administrative burdens without compromising the agency's ability to get the best price for the products or services being acquired.

DATES: Comments should be submitted on or before January 24, 1986; public meetings to be held on January 10, 13, and 14, 1986 (see Supplementary Information for times and locations); parties interested in attending a public meeting are requested to notify GSA on or before January 6, 1986 to indicate which meeting they will attend and whether they desire to make a statement.

ADDRESS: Comments and requests to speak may be mailed to Ms. Marjorie Ashby, Office of GSA Acquisition Policy and Regulations, 18th & F Sts., NW., Room 4026, Washington, DC 20405, telephone (202) 523–3822. Request to speak should identify the individual, firm, and the meeting that the individual will be attending.

FOR FURTHER INFORMATION CONTACT: Mr. Edward J. McAndrew, Office of GSA Acquisition Policy and Regulations, (202) 566–1128.

SUPPLEMENTARY INFORMATION:

Public Meetings

Public meetings on this proposal will be held on the dates and at the locations listed below:

Friday, January 10, 1986, Washington, DC, Location: General Services Building, First Floor Auditorium, 18th & F Sts., NW., Time: 10 a.m. (EST);

Monday, January 13, 1986, San Francisco, CA, Location: Holiday Inn, Golden Gateway, 1500 Van Ness Avenue, Time: 9 a.m. (PST);

Tuesday, January 14, 1986, Independence, MO, Location: Harry S. Truman Library, Library Auditorium, Highway 24 and Delaware (enter thru Main Museum entrance), Time: 9 a.m. (CST).

Impact

The Director, Office of Management and Budget (OMB), by memorandum dated December 14, 1984, exempted certain agency procurement regulations from Executive Order 12291. The exemption applies to this rule. The General Services Administration (GSA) certifies that this document would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The revisions in the MAS policy statement represent clarifications of existing policy and attempts to reduce the administrative burden on contractors and prospective contractors. Therefore, no regulatory flexibility analysis has been prepared. After consideration of comments received, the information collection requirements in this rule will be submitted to OMB for approval under 44 U.S.C. 3501 et seq.

Authority: 40 U.S.C. 486(c).

The complete text of the revised MAS policy statement follows:

Dated: December 3, 1985.

Patricia A. Szervo,

Associate Administrator for Acquisition Policy.

Policy Statement on Multiple Award Schedule

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Contract Pricing Arrangements

I. Introduction.

This policy statement addresses certain significant issues concerning the establishment and maintenance of pricing arrangements under multiple award schedule (MAS) contracts for supplies and services. Except for Information Resource Management Service ((IRMS) schedule contracts awarded under the Teleprocessing Service Program (TSP) and where otherwise stated, this policy statement applies to the Information Resources Management Service (IRMS) and the Federal Supply Service (FSS) MAS contracts.

In providing supply support to customer agencies, the General Services Administration (GSA) is responsible for determining the best method of such support. GSA will continue to review its MAS contracts to ensure that the appropriate method of procurement is used to obtain maximum competition, beneficial pricing, and satisfactory support to customer agencies.

When GSA provides supply support through the MAS program, it acts as the contracting agent for all Government organizations authorized to use MAS contracts. Customer agencies should be able to buy schedule items at prices that are equal to or better than those obtainable from any other source under similar circumstances. In its role as the Government's contracting agent, it is GSA's goal to obtain beneficial pricing arrangements with vendors, consistent with the Government's large volume of purchases.

II. Discount Schedule and Marketing Data

The Government will require offerors to submit data with their initial proposals on sales, discount and marketing practices as specified in the Discount Schedule and Marketing Data (DSMD) sheets. Subsequent to the initial submission of data, offerors are required to update the discount and marketing data in the event that changes occur prior to the conclusion of negotiations, and provide such additional information as may be requested by the contracting

officer during MAS negotiations. The required discount and marketing data includes business activity and transactions over the MAS maximum order limitation (MOL). Sales data submitted with initial proposals need not be updated during MAS negotiations unless inadvertent errors are discovered in the data initially submitted, changes in sales data occur affecting the commerciality of the products or services being offered to the Government, or an update is specifically requested by the contracting officer. The data provided by offerors will be used by the contracting officer to analyze proposals, determine commerciality of products or services offered to the Government, establish negotiation objectives, and determine price reasonableness.

The DSMD sheets do not require the submission of sales, discount or marketing data relating to the Congress of the United States, including any of its offices or instrumentalities. Further, except in IRMS MAS solicitations, the DSMD sheets require the submission of discount or marketing data relating to contracts with Federal agencies. However, discount and marketing data relating to other Federal agencies may be required by IRMS contracting officers on a case-by-case basis. While such data relating to contracts with Federal agencies may be required and used in MAS negotiations, Federal agencies will not be used as the basis of a MAS award.

The sales data in the DSMD will be submitted for the 12-month period specified by the offeror in Paragraph 9 of the DSMD sheets. Paragraph 9(b) of the DSMD sheets only requires sales data for a representative sample of the offeror's largest dollar sales volume items sold to the Government under the MAS contract(s) or, for an offeror with no current or recent MAS contract, estimated to be sold to the Government under a MAS contract that are claimed to be commercial by the offeror in accordance with FAR 15.804–3(c) and 15.804–3(f). Paragraph 9(c) of the DSMD requires the submission of sales data by the offeror for each item that does not meet the tests of commerciality in the Federal Acquisition Regulation (FAR).

Offerors will certify, at the time their initial proposals are submitted, that sales, discount and marketing data included with those proposals is accurate, complete and current as of the date the proposal is submitted. At the conclusion of negotiations, offerors will be asked to certify any additional data provided or requested during negotiations. Failure to submit sales, discount and marketing data specified in the DSMD sheets, furnish data requested by the Contracting Officer during negotiations or certify the accuracy, completeness or currency of any data submitted may result in no award. If, subsequent to award, the data submitted is found not to be accurate, complete and current, the defective pricing clause will be activated and consideration will be given to cancelling the MAS contract, if still in effect.

III. MAS Contract Pricing Arrangements

The Government's goal in negotiating MAS contract pricing arrangements is to obtain a discount from a firm's established catalog or commercial price list which is equal to or greater than the discount given to that firm's most favored customer. The most favored customer (MFC) discount is equal to the best discount given by a firm to any entity with which that firm conducts business. The Government will negotiate a contract price relative to a vendor's commercial pricing/sales practices. In establishing its negotiation objectives, the contracting officer will consider all sales, discount, pricing, and marketing data submitted on the Discount Schedule and Marketing Data (DSMD) sheets.

Negotiation objectives will be determined on a case-by-case basis based on the following considerations:

(a) The overall volume of Government purchasing anticipated under a resulting contract.

(b) A comparison of the prices/discounts offered the Government with those granted to other customers of the offeror.

(c) A comparison of the terms and conditions under which the Government and the other customers contract.

The determination of the negotiation objective and any modification thereto is the responsibility of the contracting officer. The contracting officer must exercise judgment in establishing the negotiation objective and in determining whether the objective has been met. In establishing the negotiation objective, the contracting officer may consider factors cited by the offeror which make the Government different from other customers. For example, the offeror may grant special pricing to an original equipment manufacturer (OEM) because the OEM buys the product in a slightly different configuration, or with a different warranty, or in large quantities at one time. Similarly, dealers and distributors may receive special pricing because they buy in large quantities and/or provide marketing, warehousing, distribution or other services, thus relieving the offeror of these costs. State and local governments may receive special pricing because they establish, through the sealed bid, single award process, a contract in which the offeror will receive all of the state or local government's business for a year for that type of product/service. In such situations, it is the offeror who must provide information identifying such factors, the evaluation of the factors identified and the method used for developing the valuation. Contracting officers shall obtain information necessary to judge whether these factors and their valuation are reasonable. The contracting officer must weight the similarities against the differences and arrive at a negotiation objective which is fair and reasonable to both the offeror and the Government, once again taking into consideration the conditions under which the Government buys.

There is no obligation on the Government to establish a contract with every vendor who submits an offer and there is no guarantee that every vendor who submits an offer will receive a contract. Contracts will only be considered when a sufficient requirement exists for the type of product/service being offered, the terms and conditions stated in the solicitation are met, the prices/discounts are equal to or better than those offered to any other customer (taking into consideration any differences in terms and conditions), and the offeror meets all other solicitation requirements as to responsiveness and is determined responsible by the contracting officer.

However, under certain circumstance, the contracting officer may consider an award where the discount offered to the Government is not equal to or greater than a firm's MFC discount. If the contracting officer decides that the negotiation objective has not been met, the contracting officer must exercise further judgment in deciding whether to reject an offer. In exercising this judgment, the contracting officer must weigh the effect that the rejection of the offer will have on meeting the Government's needs. In any event, after negotiations and before recommending award, the contracting officer must be able to make the determination that the prices/discounts being offered by the supplier are fair and reasonable.

IV. Discounts to Educational Institutions

For purposes of this paragraph "Educational Institution" is defined as: A school maintaining a regular faculty and established curriculum, and having an organized body of students in attendance. It includes public and

private primary and secondary schools, colleges, universities, normal schools, and technical schools. Prices to "Educational Institutions" will not be the government's negotiation objective. The Government's negotiation objective will be the offeror's best pricing arrangement other than that given to an educational institution. However, to be considered for an MAS contract, the offeror must also offer the same pricing arrangement that it grants to other educational institutions to the Government for its similar educational institutions, such as: the Department of Defense (DOD) dependent schools; Bureau of Indian Affairs schools; Military Academies; Judge Advocate General Schools; Government formal training centers.

V. Quantity and Aggregate Discounts.

In establishing negotiation objectives and in the negotiation process, emphasis will be placed on obtaining discounts based on the aggregate volume of sales for a MAS contract. Negotiation objectives will be established to obtain volume discounts in line with the discounts available to the offeror's other customers. In developing negotiation objectives based on the aggregate volume of sales, consideration may be given to taking discounts on aggregate volumes of sales at the conclusion of the contract period, although it is preferred that the discounts be obtained when orders are placed.

VI. Maximum Order Limitation (MOL)

All MAS contracts must contain an MOL. The solicitation will include proposed MOL level(s). Negotiation of MAS contracts must include consideration and establishment of MOLs. The level at which the MOL is established will depend upon the Government's discount arrangement under the schedule and the estimate of sales volume above which suppliers are likely to quote lower prices in other types of contracts. The MOL established in the negotiation process shall be included as a term in the MAS contract.

VII. Price Reductions

All MAS contracts will contain the Price Reductions clause contained in this document. The Price Reductions clause is intended to maintain the relationship that is established at the time of award between the Government and the offeror's customer(s) upon which the MAS contract is predicated. The contracting officer will identify at the conclusion of negotiations and include in the MAS contract, the customer or category of customers upon which the MAS contract is predicated. Neither Federal agencies nor the Congress of the United States, including its offices or instrumentalities, shall be identified as the basis of the MAS contract.

Note.—This does not affect the provisions in the clause concerning price reductions to Federal agencies.

After the conclusion of negotiations, any changes in pricing (including prices, discounts or terms and conditions) by the contractor that result in a less advantageous relationship between the Government and the customer, category of customers, or customer(s) within the identified category will result in a price reduction to the Government to the extent necessary to restore or retain the original relationship.

The following Price Reductions clause will be used in all MAS contracts.

Price Reductions

(a) *General.* This clause is intended to ensure that throughout the term of the contract the Government maintains its relative position with respect to price, discount, and terms and conditions in relation to that of the identified customer, category of customer, or customer(s) within the identified category. For the purposes of this clause, a price reduction means:

(1) A general reduction in the prices contained in the commercial catalog, price list, schedule, or other documents, or granting of more favorable terms and conditions than were offered by the contractor and used by the Government to establish the prices in this contract; or

(2) A reduction in price, increase in discount, or granting of more favorable terms and conditions to the identified customer, category of customer, or customer(s) within the identified category of customer (hereinafter "customer").

(b) *Reductions to customers other than Federal agencies.* (1) At the conclusion of negotiations, the Contracting Officer and the offeror shall identify and include in the MAS contract the customer upon whom the contract award is predicated and the relationship between that customer and the Government which is to be maintained throughout the contract period.

(2) If, after the date of the conclusion of negotiations, the Contractor effects a price reduction, as defined in paragraph (a) above, with respect to any items covered by this contract, the Contractor shall (i) promptly report such price reduction to the Contracting Officer with an explanation of the circumstances under which it was made, and (ii) to the extent that such price reduction is determined by the Contracting Officer to have disturbed the relationship between the identified customer and the Government, provide an equivalent price reduction to the Government for the remainder of the contract period, or until a further price reduction occurs; or, in the case of a temporary price reduction for the duration of the period in which such temporary price reduction is in effect as agreed to by the Contracting Officer and the Contractor.

(3) A price reduction resulting from any of the following is exempt from the application of (2)(ii) above: (i) a firm fixed price definite quantity contract in excess of the maximum order limitation specified in this contract and with a specified date(s); (ii) a sealed bid, single award contract with a state or local government or with the District of Columbia; (iii) an error in quotation or billing, provided that the error is promptly reported and documented to the Contracting Officer.

(c) *Reductions to Federal agencies.* [This paragraph does not apply to non-schedule ADP/Telecommunications/Teleprocessing Service contracts entered into with Federal agencies or to Federal Supply Service optional use schedule contracts for maintenance and repair of equipment.]

Except for temporary "Government-only" price reductions described below, if, after the date of conclusion of negotiations, the Contractor gives a price reduction to any Federal agency and the quantity purchased falls within the contract maximum order limitation, such price reduction will apply to all subsequent orders of the contract item by Federal agencies under this contract for the duration of the contract period or until a further price reduction is given. The Contractor may offer to the Contracting Officer a temporary "Government-only" price reduction which has a duration of 30 calendar days or more, except during the last month of the contract period when any such offer must be for the remainder of the contract period.

(d) *Effective dates and notifications.* [This paragraph does not apply to non-schedule ADP/Telecommunications/Teleprocessing Service contracts entered into with Federal agencies or to Federal Supply Service optional use schedule contracts for maintenance and repair of equipment.]

(1) Any price reduction pursuant to (b) above, shall be effective for orders placed by Government agencies under this contract as of the effective date of a general price reduction, or as of the date of acceptance of the contractual agreement between the Contractor and the customer.

(2) Any price reduction pursuant to (c) above, shall be effective as of the date of acceptance of the initial order from the Federal agency under the price reduction, except that a temporary "government-only" price reduction will be effective at the beginning of any temporary price reduction period as agreed to be the Contracting Officer and the Contractor. The effective date of any temporary price reduction due the Government under this clause will allow sufficient time for the notification of Federal agencies of the applicable price reduction prior to the beginning of the Government's temporary price reduction period.

(3) The amount of time allowed for notification of Federal agencies and the duration of the temporary price reduction period for the Government, pursuant to paragraph (b)(2) will be commensurate with that provided by the Contractor to the customer or category of customer who received the temporary price reduction due the Government under the clause.

(4) Except for temporary "Government-only" price reduction notification in (c) above, the Contractor shall notify the Contracting office and the Federal agencies, in writing, of any price reduction pursuant to (b) and (c) above at the same time as notice is given to the Contractor's customer of the price reduction. Price reductions of this type must be reported under the circumstances described in paragraph (b)(2) above.

(5) Failure to give timely notice of any price reduction pursuant to (b) and (c) above, will require that such price reduction (including temporary price reductions) apply to the contract for the duration of the contract period, or until a further price reduction is granted, and may constitute a basis for termination of the contract as provided in the Default clause of the contract.

(6) The Contractor shall invoice at such reduced price and indicate thereon that the price reduction is pursuant to this Price Reductions clause until such time as the contract is modified.

(e) *Contractor's statement of price reduction.* [This paragraph does not apply to non-schedule ADP/Telecommunications/Teleprocessing Service contracts entered into with Federal agencies or to Federal Supply Service optional use schedule contracts for maintenance and repair of equipment.]

The Contractor shall furnish within 30 calendar days after the end of the contract period a statement certifying either (1) that there were no applicable price reductions; or (2) that all applicable price reductions were reported to the Contracting Officer and that such price reductions were passed on to the Federal agencies.

(End of Clause)

VIII. Economic Price Adjustments

The contracting officer will determine on a schedule-by-schedule or class-by-class basis whether items on an MAS schedule, or within an MAS class, are subject to unstable prices, thus warranting the use of an EPA clause.

Attachment 1—Multiple Award Schedule Pricing Guide

Multiple Award Schedule (MAS) Pricing Guide

I. Discount Schedule and Marketing Data

A. *Requirement for Offeror to Submit Pricing Data.* Proposals must be supported by statements and analyses or other evidence of reasonable prices and by such information concerning other vital matters as is deemed necessary by the contracting officer. Each MAS solicitation will include Discount Schedule and Marketing Data sheets to be completed for each Special Item Number (SIN) and submitted as a part of the offeror's proposal. When this form is completed in its entirety, along with pricing data from current or prior contracts and preaward audits, it should provide the necessary data, in most cases, to enable the contracting officer to complete the price analysis and develop the negotiation objective.

B. *Initial Review of Offeror's Proposal.* As soon as possible after receipt of proposals, the contracting officer should review in detail the offeror's submission in response to the Discount Schedule and Marketing Data sheets. If the offer has failed to respond to specific data elements or if the response is not adequate, the contracting officer should immediately request that the offeror correct any deficiencies in the data submission. In this regard, a specific date for the receipt of the required data should be established with the offeror. Also, it is important that the data be received well in advance of schedule negotiations to permit adequate time for a price analysis by the contracting officer.

C. *Timeliness of the Procurement Action.* The process, to the extent practical, should begin early enough to allow for award of MAS contracts by the beginning of the proposed schedule period.

II. Prenegotiations

A. *Establishing the Negotiation Objective.* In preparing for negotiations, the contracting officer will establish specific negotiaton objectives based upon a properly prepared price analysis. This price analysis will serve as the basis for the negotiation objectives including the rationale for the objectives established. The elements of the price analysis are listed in Section IV of this pricing guide.

B. *Negotiation Objective.* In establishing the negotiation objectives, contracting officers must remain cognizant of the Government's goal in negotiating MAS contracts, namely, to obtain discounts equal to or better than an offeror's discounts to its most favored customer. The most favored customer discount is defined as the largest discount given to any entity with which the offeror does business. These are factors that may make the Government different from a firm's other customer(s). Such factors may include, but are not limited to, items such as (1) terms and conditions, (2) warranties, (3) FOB point, (4) outside marketing, distribution and/or service networks, (5) the existence of a considerable difference between products sold to an offeror's customer(s) and those sold to the Government.

Although the contracting officer may recognize these differences through proper analysis and documentation, the volume purchased by the Government under the MAS contract must also be considered. In addition, the contracting officer must take into consideration whether the most favored customer discount is the discount to educational institutions. (See paragraph IV under Contracting Pricing Arrangements of the MAS policy statement.)

C. *Documentation of the Price Analysis and Negotiation Objective.* The contact file will contain the written price analysis report in support of the Government's negotiation position.

The supporting documentation will necessarily vary depending upon the complexity and estimated dollar volume of the contract. The price analysis and negotiation objective will be a part of the price negotiation memorandum (see Section V of this pricing guide.) The supporting documentation required at this point in the procurement process will normally include:

(1) General description of the procurement.

(2) Adequacy of data submitted by the offeror.

(3) The elements of pricing analyzed prepatory to establishing the negotiation objective. (See Section IV of this pricing guide.)

(4) The negotiation objective and the supporting rationale.

(5) Major differences between the offeror's proposal and the negotiation objective.

(6) The offeror's documentation and rationale if less than the MFC discount is provided. This will also include the contracting officer's evaluation of that data.

D. *Approval of Negotiaton Objectives.* The negotiation objectives shall be approved by the contracting director, or designee, prior to negotiations.

III. Catalog Item Verification

A. *Definition of Established Catalog Price.* FAR 15.804–3(c) states that for an item to be exempt from the cost or pricing data requirement based on catalog price, the price must be, or be based on, (1) an established catalog price, (2) of commercial items, (3) sold in substantial quantities, (4) to the general public. The criteria contained in the following paragraphs should be applied in determining whether an item falls within the scope of this definition.

B. *Established Catalog Price (FAR 15.804–3(c)(1)).* This is a price that is included in a catalog, price list, schedule or other form that is regularly maintained by the manufacturer or vendor, is either published or otherwise available for inspection by customers and states prices at which sales are currently or were last made to a significant number of buyers who constitute the general public. The

following questions will help the contracting officer determine if there is an established catalog price.

(1) Is there a printed catalog, price list, published price or other formal document showing prices and applicable discounts, if any?

(2) Can an audit validate from the seller's records that the price offered is a regular catalog price with appropriate discounts?

If the answer to either (1) or (2) above is "no", the proposal does not meet the test of a catalog priced item.

C. *Commercial Item (FAR 15.804–3(c)(3)).* This is an item (the term includes both supplies and services) of a class or kind that is regularly used for other than Government purposes and is sold or traded in the course of normal business operations. The following questions will help the contracting officer determine if the item is a commercial item.

(1) Is the item or service identical to that described in the catalog?

(2) Is the item or service so similar it can be priced by reference to calatog prices?

(3) Is the item or service so similar that differences can be identified and priced as add-ons or deducts from catalog prices by price analysis or other known prices?

If the answer to either (1), (2) or (3) above is "no", the proposal does not meet the test of a catalog item.

D. *General Public (FAR 15.804–3(c)(5)).* An item is sold "to the general public" if it is sold to other than affiliates of the seller and to non-Government entities. Items sold to affiliates of the seller and sales for end use by the Government are not sales to the general public. The following questions will help the contracting officer determine if an item is sold to the general public.

(1) Does the seller's data show sales over the appropriate past period as between Government and non-Government entities?

(2) Is there general knowledge of large public sales of products regularly stocked by dealers or regularly traded in the marketplace?

(3) Can an audit validate from the seller's records that sales have been made to non-Government entities?

If the answer to either (1), (2), or (3) above is "no", the proposal does not meet the tests of a catalog item.

E. *Substantial Quantities (FAR 15.804–3(c)(4) and 15.804–3(f)).* Supplies are sold in substantial quantities when the facts or circumstances are sufficient to support a reasonable conclusion that the quantities regularly sold are sufficient to constitute a real commercial market for the item. This test is usually in terms of total quantities sold, but it also should include the number of times the item has been sold and how many times a given price or price structure has been accepted by buyers free to choose. Nominal quantities, like models, specimens, samples and prototype or experimental units do not meet this requirement. Services sold in substantial quantities are those that are customarily provided by the company, with personnel regularly employed and with equipment regularly maintained solely or principally to provide such services. FAR 15.804–3(f) contains the guidelines for determining whether the "substantial quantities" criterion are met. Also, the sales data requested in Paragraph 9 of the Discount Schedule and Marketing Data is set forth in a format to facilitate the contracting officer's analysis of this requirement. The following questions will help the contracting officer determine if the items have been sold in substantial quantities:

(1) Are reported sales to non-Government entities at least 55 percent of total sales and those at catalog price less applicable discounts at least 75 percent of this amount? When the answer to this question is "yes" the item meets the "substantial quantity" test.

(2) Are reported sales to non-Government entities at least 35 percent of total sales and those at catalog price less applicable discounts at least 55 percent of this amount? When the answer to this question is "yes" the test of substantial may be deemed to have been met when (i) the criteria in B, C, and D above are met, (ii) the nature of the item or total quantities sold clearly supports such a conclusion even though the Government is the major user, and (iii) approval of the contracting director or designee is obtained.

(3) Can an audit verify from the seller's records that commercial sales meet the test of (1) and (2) above?

(4) Are reported sales to non-Government entities less than 35 percent of total sales to all customers (Government and non-Government)? If the answer is "yes", the item does not meet the test of substantial quantities. Therefore, if the item is to be included in the MAS, cost or pricing data must be obtained and evaluated in accordance with FAR 15.804.

F. *Catalog Price Exemption.* A catalog price exemption to the need for submission of cost or pricing data can be granted for products or services offered on MAS solicitations when the requirements set forth in paragraphs A through E above have been met. The Discount Schedule and Marketing Data (DSMD) sheets in the MAS solicitation are used in lieu of the Standard Form 1412, Claim for Exemption from Submission of Certified Cost or Pricing Data, for claiming an exemption from the requirement to submit cost or pricing data based on catalog price. (FAR 15.804–3(e)). Paragraph 9 of the DSMD sheets requires the submission of sales information by the offeror for use by the contracting officer, among other matters, for determining commerciality of products or services offered under the solicitation. In this regard, offerors are permitted to certify that sales information on items offered to the Government under the solicitation meet the tests of commerciality prescribed in FAR 15.804–3(c) and the criterion in FAR 15.804–3(f). Offerors are required to provide sales information on a sample of items, so certified, with the largest actual dollar sales volume under the offeror's MAS contracts for the most recent 12-month period designated by the offeror in the DSMD. The contracting officer will determine the number of items in the sample for which sales information must be furnished. If an offeror does not have or has not recently had an MAS contract, actual sales information for the designated 12-month period will be provided on items estimated to have the largest dollar sales volume under the contract that may be awarded to the offeror under the MAS solicitation. Where items cannot be so certified and the sales are $100,000 or more, the required sales information in Paragraph 9 must be submitted by the offeror. The $100,000 threshold is designed to reduce the administrative burden on offerors and contracting officers in deciding whether to grant an exemption from the cost or pricing data requirement. However, contracting officers are not precluded from requiring sales information on items whose annual sales are between $25,000 and $100,000 if the circumstances of a particular procurement action warrant. The information provided will be used in determining whether an item should be exempt from the cost and pricing data requirement.

IV. Price Analysis

A. *Requirement for Price Analysis.* FAR 15.805–2 and 15.805–3 state that some form of price or cost analysis should be made in connection with every negotiated procurement action. FAR 15.804–3(h) states that even though an item qualifies for exemption from the requirements for submission of certified cost or pricing data, price analysis must be performed to determine the reasonableness of the price and the need for further negotiation.

B. *Preparation for Negotiations.* Preparation for negotiations after receipt of the offer begins with a properly prepared price analysis report. The price analysis should provide the basis for establishing the specific negotiation objectives and the reasons why these objectives were established.

C. *Price Analysis Techniques.* Most of the data needed to perform the price analysis will be submitted by the offerors as required by the Discount Schedule and Marketing Data sheets. Another source of data is the historical files on existing or prior contracts. Questions on the proposal that arise during the price analysis effort will be addressed to the offeror. The price analysis may include the following elements, as appropriate:

(1) *Discount arrangements on the existing or prior year contract.* Data from these sources can be accumulated prior to receipt of proposals. Information should include: estimated and actual sales volume; categories of customers and discount arrangements; the MAS discounts negotiated; and, any problems or significant events that were experienced during the negotiations affecting the Government's negotiation position. Price reduction information submitted in accordance with the Price Reductions clause should also be included. This information is the data base from which to start the price analysis after proposals are received.

(2) *Offeror's commercial sales data.* The sales data submitted in Paragraph 9 of the Discount Schedule and Marketing Data sheets will be used to determine price reasonableness, the commerciality of products or services offered and the discount the Government should receive. As a general rule, the larger the percent of commercial sales to total sales, the more reliance the Government can place on prices being set in the marketplace. Because products or services available under schedules should be for the most part commercial items, it is essential that the commerciality of the products or services be established preparatory to negotiations. Where products or services do not clearly meet the tests of commerciality, contract negotiators are required to analyze whether these products or services are comparable to others which meet the tests of commerciality or there are other circumstances that can be used in judging why such items should be considered commercial. Additional information may be required from the offeror in assessing commerciality. Where products or services are not commercial, cost or pricing data is required.

(3) *The prices and discounts proposed by the offeror.* The offeror's proposal should be reviewed to develop an understanding of the prices or discounts offered to the Government as compared with offeror's discounts to other entities and to determine if the sales data required is included in the proposal. The analysis of the proposal should determine the reasons for differences between the offered discounts, and other discount arrangements; whether there are special discount arrangements; or other concessions that the offeror makes which should be included in determining the Government's negotiation position.

(4) *Net price evaluation.* Comparison of net prices may be utilized in the evaluation of offers under MAS contracts. Consideration should be given to including products with the lowest net price on the schedule even though there may be instances where the offeror submitting the lowest net price may not offer the most favored customer pricing. In addition, you may compare the net prices offered by one offeror with net prices of similar items offered by the other offerors to assist in the price reasonableness determination. This may be done on a sampling basis using the high dollar volume items listed on the Discount Schedule and Marketing Data sheets.

(5) *Other sources of information.* Consideration may be given to the following:

(a) Recommendations contained in preaward audits, from other pricing specialists, or from other appropriate sources.

(b) Trend analysis of price changes using appropriate indices such as the Producer Price Index, other similar market indicators, and price changes in similar products offered by other companies.

(c) The comparison of offered prices/discounts to local retail and discount house catalog prices.

(6) *The overall discount policy of the offeror.* The Discount Schedule and Marketing Data sheets require that complete disclosure regarding discount policy and price reductions in any other form be made. This would include, but is not limited to, such things as quantity discounts, end-of-year discounts, discounts for multiple quantities, free service or installation, training, bonus goods of any kind, trade-in allowances, rebates of any kind, F.O.B. point, payment terms, incentives, or guaranteed prices. The price analysis should determine whether any such items are included in the offeror's proposal to the Government and the consideration that they should be given in establishing the Government's negotiation position.

(7) *Volume of Government sales.* The offeror's price to the Government takes into account the volume of Government business anticipated for a fixed period.

V. Negotiations

A. Negotiations can begin upon completion of a properly prepared price analysis and establishment of the Government's negotiation objectives.

B. During the negotiations, Government negotiators will address aggregate discounts based on the estimated volume of sales under the schedule contract giving consideration to the Government's manner of ordering.

C. In the event that the Government's negotiation objective cannot be met, the contracting officer must exercise judgment in deciding whether to reject the offer. In exercising this judgment, the contracting officer must weigh the effect that the rejection of the offer will have on meeting the Government's needs. Whenever a decision is made to award an MAS contract where the Government's discount is not equal to or better than the MFC discount, the contracting officer will:

(1) Ensure the analysis and reasons for this decision are fully documented and justified in the contract file.

(2) Obtain approval for such a decision at a supervisory level higher than the contracting officer, regardless of the dollar value.

D. The Government will not award an MAS contract to a firm that does not give the Government a price equal to the best price given or available to its volume end user customers under similar circumstances.

E. Negotiation of MAS contracts must include consideration and establishment of maximum order limitations (MOLs). The level of the MOL depends on the Government's negotiated discount arrangement and the estimate of sales volume above which suppliers are likely to quote lower prices in other types of contracts. The MOL established in the negotiation process must be documented at the conclusion of negotiations and included in the MAS contract.

F. In All MAS contract negotiations, the contracting officer is required to make an affirmative determination that the prices negotiated are fair and reasonable (FAR 15.803(c)).

G. A price negotiation memorandum (PNM) must be prepared at the conclusion of each negotiation (See FAR 15.808). The PNM is the document that

brings together all the principal elements of the negotiation leading to the decision that the price/discount is fair and reasonable. In support of that decision, the PNM should contain the significant considerations shaping the pricing/discount arrangement. These include:

(1) A summary of the offer received (prices, terms, etc.), the Government's negotiation position (objectives) and the negotiation results. Any revised or adjusted offers and any revised or adjusted Government negotiation objectives will be explained.

(2) Names and titles (position) of the Government and contractor representatives who participated in the negotiations.

(3) Reference to the price analysis report should be made or, where appropriate, actual incorporation of the price analysis. (Elements of the price analysis report are in Section II, paragraph C of this pricing guide).

(4) Where cost or pricing data is required, the narrative should cover the products or services that require submission of cost or pricing data, the source of the data, the analysis of the data and its use in negotiations. Where the requirement for cost or pricing data is waived, the determination and findings in support of such waiver will be appended to the PNM.

(5) Where preaward audit or other pricing assistance is available, the PNM should identify the recommendations. Where the recommendations are not used, appropriate rationale will be included on why they were not used. Any alternate position will be documented and supported with factual data.

(6) Any exceptions to the Government's terms and conditions will be documented as will any special or non-standard contract provision.

(7) The PNM will document the initial negotiation objectives and actual negotiations including the offers and counteroffers made by the parties with supporting rationale for all Government positions.

(8) The document will include the MOL level established with supporting rationale.

(9) The document must clearly demonstrate and support the determination that the price/discount negotiated is reasonable. It must document any decision to accept less than the best pricing arrangement granted to the most favored customer. The PNM should also identify the offeror's data used in the negotiation process.

(10) The PNM must be signed and dated by the contracting officer as evidence that it is the official record of negotiations and that it complies with GSA policies and procedures.

PRICE ANALYSIS—CHECK SHEET

	Yes	No
1. Did the offeror submit adequate data in response to the solicitation?		
2. If data submitted by offeror was not adequate, did the contracting officer request that deficiencies be corrected?		
3. Did offeror then submit adequate data?		
4. Did the contracting officer verify that the items meet the test of (see FAR 15.804-3(f)):		
a. Established catalog price		
b. Commercial item		
c. General public		
d. Substantial quantities		
5. Did the contracting officer prepare a price analysis on the offerors proposal?		
6. Did the contracting officer compare the offerors prices/discounts to existing or prior contracts and reconcile differences?		
7. Did the contracting officer compare proposed price lists to prior lists and evaluate changes?		
8. Did the offerors propose the MFC discount to the Government?		
9. If MFC discount was not offered, did the offeror's proposal provide the required documentation in support thereof?		
10. If MFC discount was not offered, did the contracting officer evaluate why and use it in developing the Government's negotiation position?		
11. On a sample basis, did you compare "net prices" on high dollar volume items to similar items offered or available from other sources?		
12. Did the contracting officer determine whether the offeror is a manufacturer selling direct to the Government without a dealer network; or a manufacturer selling direct to the Government even though he has dealers; or a manufacturer selling to the Government through dealers; or a dealer selling direct to the Government (dealer must submit manufacturer's price list); or sells to the Government through some other means?		
13. Did the offeror offer their standard commercial warranty and specify where it is located in their offer?		
14. In FSS procurements, did the offeror state whether the warranty offered to GSA is more favorable, less favorable, or equal to the commercial warranty? If the warranty offered to GSA is more favorable or less favorable than the commercial warranty, did the offeror submit information describing the differences between the warranty offered and the commercial warranty and provide the value (expressed as a percentage of the catalog price)?		
15. In FSS procurements, are installation and instructions offered (if "yes" did the offeror provide details or indicate where the information may be found in the offer)?		
16. In FSS procurements, are installation and instructions offered to the Government more favorable than those offered to other customers (if "yes", did the offeror describe how it is more favorable and provide the value expressed as percentage of the catalog price)?		
17. In FSS solicitations, was information obtained on the following?		
a. Is stock on hand of the items offered maintained?		
b. Is the Special Item Number(s) offered displayed in showrooms?		
c. Are design and layout assistance related to this Special Item Number provided free of charge?		
d. If the offeror is a dealer, has the offeror arranged for other dealers to participate under the schedule contract?		

PRICE ANALYSIS—CHECK SHEET—Continued

	Yes	No
e. Will the offeror administer all incoming orders, including requests for expediting and follow-up?		
18. Are the prices negotiated at least equal to the best price that the offeror grants to its end user most favored customer?		
19. Does the PNM contain an affirmative determination that the prices negotiated are fair and reasonable and set forth the basis for such determination?		
20 Did the contractor certify data initially submitted with the proposal and again, at the conclusion of negotiations, on information provided during negotiations and any changes to the data originally submitted with the proposal?		

Attachment II—Discount Schedule and Marketing Data Sheets

Solicitation No. ————

Discount Schedule and Marketing Data

Name of Offeror ————

GSA Special Item No. ————

Instructions to Offerors:

Discount and sales information must be completed for each GSA Special Item Number (SIN) for which an offer is submitted. If discount information is the same for all products under each SIN, SINs may be combined. However, separate sales information required under paragraph 9 must be provided for each SIN.

Information required by each space *must* be furnished. If not applicable, indicate by "N/A". Information furnished relating to discounts, allowances and sales information will be treated as "CONFIDENTIAL" by the Government except for final price and discounts awarded by the Government. Submission of data fulfills the requirement of FAR 15.804-3(e) and eliminates the need for offerors to submit a Standard Form 1412, Claim for Exemption from Submission of Certified Cost or Pricing Data. *Failure to provide accurate, complete and current data as required may result in no award being made or may subject the contractor to liability for refunds pursuant to the defective pricing provisions of this contract.*

1. *Identification of a Price List as the Basis for This Offer:*

(Check and attach ——— copies of the dated price list.)

(a) ——— Manufacturer's catalog/pricelist ———— (indicate type).

(b) ——— Dealer's catalog/pricelist.

(c) ——— Retailer's catalog/pricelist.

(d) ——— Other (specify) ————.

2. *Identification of Items Offered.* How many model/type of catalog items do you offer under this GSA Special Item Number ——— (enter number).

Discount and Sales Information

3. *Discounts.* The following concessions are offered to the Government for delivery FOB destination. In OIRM solicitations, list also concessions to the Government for delivery FOB origin.

(a) *Regular Discounts.*

Discount offered on the above GSA Special Item Number is ———% from pricelist dated ———, *plus* prompt payment discount, as stated on the first page of this solicitation

(additional details may be entered below or attached). If discounts vary, show discounts on pricelist.

(b) *Quantity Discounts.*

(1) List any quantity discounts included in this offer.

(2) Can models/products be combined to obtain quantity discounts?

Yes——— No———. If yes, provide details.

4. *Aggregate or End of Contract Additional Discounts.* An additional discount of ——— percent is is offered to the Government which will be applied to the actual aggregate sales in excess of the following base figure under this contract:

(a) For current MAS contractors, aggregate sales (annualized) to the Government for most recent 12-month period under similar contract(s) is $———, based on sales during the period ——— to ———.

5. *Discount and Concessions.*

(a) List below the best discount and other concessions resulting in the lowest net price (regardless of quantity and terms and conditions) on sales other than sales under the GSA schedule from *pricelist* for the same or similar products or services offered to the Government under this solicitation. NOTE: Where the best (lowest) net price offered was based on other than a discount from a pricelist or was based on a discount from a pricelist other than the pricelist used as the basis of the offer to the Government under this solicitation, the lowest net price granted shall be translated into a discount from the pricelist and used as the basis of the offer to the Government under this solicitation. The discounts shown below should reflect the lowest net prices granted to any customer under any circumstances. (Show percentages and delivery terms).

	Percent (%) of gross sales	Regular discounts (%)	Quantity discounts (%)	Aggregate discounts (%)	Commissions to other than employees (%)	Prompt payment	FOB point	Other discounts concession
(1) To dealers/retailers								
(2) To distributors/wholesalers								
(3) To educational institutions								
(4) To state, county, city, and local governments								
(5) To original equipment manufacturers (OEM)								
(6) To others (specify); e.g., nat'l accts., sales agreements, Federal agencies (except in IRMS solicitations)								
(7) If a dealer, indicate discount received from mfg's pricelist								

Discount and Sales Information

(b) Do you offer, for any customer of any class within the MOL or outside of the MOL, other discounts and/or concessions including but not limited to the following, regardless of price list, which result in lower net prices than those offered the Government in this offer?

Yes——— No——— rebates of any kind, including year-end or end-of-contract discounts?

Yes——— No——— multiple quantity unit pricing plan?

Yes——— No——— cumulative discounts of any type which cover items being offered?

Yes——— No——— products (models)/services that may be combined for maximum discounts?

Yes——— No——— others (specify).

If answer to any of the above is "Yes", provide detailed explanation including the value expressed as a percentage of the list price and the manner in which the value of the discount/concession was calculated.

6. Identical Products Information.

(a) Are any of the models/products offered herein sold by the offeror under a different trade name(s)? Yes———, No———. If "Yes", explain and provide applicable pricelists.

(b) To your knowledge, are there identical products offered herein contained in any other GSA Schedule contract? Yes———, No———. If "Yes", identify the product, schedule and contract.

7. *Allowances:* Do you offer any of the following allowances to any customer?

(a)——— Trade-in allowances?

(b)——— Return/Exchange goods policy?

(c)——— Reduced prices on samples, demonstrator models, reconditioned items or floor models?

(d)——— Do you give any allowances not mentioned above?

If the answer to any of the above is "yes," provide a detailed explanation of the allowance and identify the customer or category of customer to whom the allowance is offered.

8. *Blanket Purchase Agreements* (this section only applies to Federal Supply Service (FSS) solicitations).

Estimate the percentage of your sales made to the U.S. Government under Federal Supply Schedule Blanket Purchase Agreements.

———Percent.

List agencies below:

1.———

2.———

3.———

4.———

9. *Sales Data.*

(a) This section requires (1) that sales information be provided to enable the contracting officer to determine that the items offered under this solicitation meet the tests of commerciality in (FAR 15.804–3(c)); and, (2) that pricing data is furnished in sufficient detail to enable the contracting officer to perform a price analysis in accordance with FAR 15.804–3(h).

(b) The offeror certifies that, except for individual models/types or catalog numbers cited in paragraph (c) below, all other models/types or catalog numbers offered to the Government under this solicitation meet the tests of commerciality in FAR 15.804–3(c) and the criterion prescribed in FAR 15.804–3(f). Of the individual models/types or catalog numbers so certified, sales information for the most recent 12-month period, as designated by the offeror, must be provided in the table below for each of the ——— models/types or catalog numbers with the largest actual dollar sales volume under the offerors's MAS contract(s). Offerors who do not have, or have not recently had, a MAS contract shall provide actual sales information for the most recent 12-month period, as designated by the offeror, on the models/types or catalog numbers estimated to have the largest dollar volume sales against any contract resulting from this solicitation. The sales information provided is for the prior 12 months, from ——— to ——— for this special item number.

(1) Total annual sales to the Government under this special item number $———.

(2) Total annual sales to all entities (excluding sales included in #1 above) under this special item number $———.

1	2	3	4	5	6	7	8
Model/Type or catalog no.	Total annual sales to Fed. Govt. $ | % of col. 5	Total annual sales to non-Government customers at catalog price (Includes such sales at catalog list price less established or published discounts).	Total annual sales to non-Government customers at other than catalog price. $ | % of total of col. 3 plus col. 4, if more than than 25%.	Total annual sales: Columns 2, 3, and 4.	Provide information below for largest discount granted to any customer, except in IRMS solicitations. Qty | Discount (See note 4 below)	List the lowest price at which the item was sold for comparable sales/quantities shown in col. 2 to any customer during the past year, except in IRMS solicitations. Qty | Price (See note 4 below)	Is the discount in column number 6 greate than your current offer under this solicitation? Yes__ No__. If yes, provide complete documentation and rationale of the difference. Merely submitting copies of documents such as terms and conditions of commercial contracts, commercial warranties, etc., will not be adequate to justify the difference.

(c) Sales information in the table below shall be provided for each individual model/type or catalog number in the above special time number that is not certified commercial when experienced annual Government sales are $100,000 or more.

1	2	3	4	5	6	7	8
Model/Type or catalog no.	Total annual sales to Federal Government $ | % of col. 5	Total annual sales to non-Government customers at catalog price. (Includes such sales at catalog list price and at catalog price less established or published discounts.	Total annual sales to non-Government customers at other than catalog price. $ | % of total of col. 3 plus col. 4, if more than 25%.	Total annual sales: Columns 2, 3, and 4.	Provide information below for largest discount granted to any customer, except in IRMS solicitations. Qty | Discount (See note 4 below)	List the lowest price at which the item was sold for comparable sales/quantities shown in col. 2 to any customer during the past year, except in IRMS solicitations. Qty | Price (See note 4 below)	Is the discount in column number 6 greater than your current offer under this solicitation? Yes__ No__. If yes, provide complete documentation and rationale of the difference. Merely submitting copies of documents such as terms and conditions of commercial contracts, commercial warranties, etc., will not be adequate to justify the difference.

Note:

1. Federal Government sales include all sales to U.S. Government and its instrumentalities and for U.S. Government use, sales directly to U.S. Government prime contractors and to their subcontractors or suppliers at any tier, for use as an end item or as part of an end item, by the U.S. Government.

2. Non-Government customer is defined as other than Government or affiliates (include sales to distributors, dealers, OEM, national accounts, educational institutions, state, etc.).

3. Discounts are reductions to catalog or market prices (published or unpublished) applicable to any customer, including OEMs, dealers, distributors, national accounts, states, etc.; and any other form of price reduction such as concessions, rebates, quantity discounts, allowances, services.

4. In Information Resource Management Service solicitations, columns 6 and 7 do not include data relating to other Federal contracts.

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Part IV

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Benzene; Proposed Rule and Notice of Hearing

DEPARTMENT OF LABOR

29 CFR Part 1910

[Docket No. 11-059C]

Occupational Exposure to Benzene

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule and notice of hearing.

SUMMARY: The Occupational Safety and Health Administration proposes to reduce its existing benzene permissible exposure limit (PEL) (29 CFR 1910.1000, Table Z-2) of 10 parts benzene per million parts of air (10 ppm) to an eight (8)-hour time-weighted average of 1 ppm to reduce substantially a significant health risk. The agency also proposes an "action level" of 0.5 ppm to encourage lower exposures for employees while reducing administrative burdens on employers. The proposal provides for certain methods of exposure control, personal protective equipment, measurement of employee exposures, training, medical surveillance, hazard communication, and other provisions. The proposed revision is based on OSHA's preliminary determination that the standard is needed to reduce the risk of leukemia and other adverse health consequences of exposure to benzene.

DATES: Comments concerning the proposed standard and notices of intention to appear at one of the informal rulemaking hearings must be postmarked on or before February 14, 1986. Parties requesting more than 10 minutes for their presentation at the hearings and parties submitting documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence no later than February 26, 1986. Four informal public rulemaking hearings are scheduled as follows.

Washington, D.C.: March 11, 1986.
New Orleans, LA.: March 25, 1986.
Los Angeles, CA.: April 2, 1986.
Chicago, IL.: April 8, 1986

ADDRESSES: Comments are to be submitted to the Docket Officer, Docket No. H-059C, Room N-3670, U.S. Department of Labor, Third and Constitution Avenue, NW., Washington, DC 20210, telephone (202) 523-7894.

Notices of intention to appear at the informal rulemaking hearings, testimony and documentary evidence are to be sent to: Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-059C, Room N-3662, U.S. Department of Labor, Third Street and Constitution Avenue, NW., Washington, DC 20210, telephone 202-523-8024. All informal public hearings will begin at 10:00 A.M.

The locations of the informal public hearings are as follows:

Washington, DC: The Auditorium, Frances Perkins Department of Labor Building, Third and Constitution Avenue, NW.

New Orleans, LA: Peach Tree Room, Regency Conference Center (Use 500 Poydras Plaza entrance), Hyatt Regency New Orleans, At Louisiana Superdome, Poydras at Loyola Avenue, New Orleans, Louisiana 70140 (Telephone: 504-561-1234).

Los Angeles, CA: Redondo Room, Sheraton Plaza—La Reina Hotel, 6101 West Century Boulevard, Los Angeles, California 90045-5380 (Telephone: 213-642-1111).

Chicago, IL: TWA/NWO Room, Hyatt Regency O'Hare, 9300 West Bryn Mawr Avenue, River Road at Kennedy Expressway, Rosemont, Illinois 60018 (Telephone: 312-696-1234).

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, OSHA, U.S. Department of Labor, Office of Public Affairs, Rm. N-3641, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

I. General

The preamble to the proposed standard on occupational exposure to benzene discusses the events leading to the proposal, physical properties, manufacture and use, health effects of exposure, degree and significance of the risk presented, an analysis of the technological and economic feasibility, regulatory impact and regulatory flexibility analysis, and the rationale behind the specific provisions set forth in the proposed standard. The discussion follows this outline:

I. General
II. Pertinent Legal Authority
III. History of Regulation
IV. Chemical Identification, Production and Use
V. Health Effects
  A. Introduction
  B. Hematotoxic and Carcinogenic Effects in Humans
  C. Cytogenetic Effects in Humans
  D. Experimental Evidence: Carcinogenicity
  E. Experimental Evidence: Subchronic Effects
  F. Experimental Evidence: Cytogenetic and Other Effects
  G. Skin Absorption
  H. Metabolism
VI. Preliminary Quantitative Risk Assessment for Benzene
VII. Significance of Risk
VIII. Summary of Regulatory Impact and Flexibility Analysis and Feasibility Analysis
  A. Introduction
  B. Industry and Exposure Profile
  C. Benefits Analysis
  D. Technological Feasibility
  E. Cost of Compliance
  F. Economic Feasibility Analysis
  G. Regulatory Flexibility Analysis
IX. Conclusion and Permissible Exposure Limit
X. Summary and Explanation of the Proposed Standard
  A. Scope and Application
  B. Definitions
  C. Permissible Exposure Limit
  D. Regulated Areas
  E. Exposure Monitoring
  F. Methods of Compliance
  G. Respiratory Protection
  H. Protective Clothing and Equipment
  I. Medical Surveillance
  J. Communication of Benzene Hazards to Employees
  K. Recordkeeping
  L. Observation of Monitoring
  M. Dates
  N. Appendices
XI. Environmental Impact
XII. Clearance of Information Collection Requirements
XIII. Public Participation—Notice of hearings
XIV. Proposed Standard and Appendices

Public comment on all matters discussed in this notice and all other relevant issues is requested for the purpose of assisting OSHA in the development of a new standard for occupational exposure to benzene. Persons need not resubmit information already submitted in response to the Request For Information published at 48 FR 31412 (July 8, 1983).

Comment is requested on all relevant issues, including health effects, technological and economic feasibility, and provisions which should be included in a final benzene standard. The following list of questions is provided to assist persons in formulating comments, but it is not intended to be inclusive or to indicate that participants need to respond to all issues or follow this format.

1. Does OSHA's proposed 1 ppm benzene standard substantially reduce significant risk and is it feasible and appropriate? Should a different exposure limit be set and what are the reasons?

2. Should OSHA adopt a 1 ppm PEL with a 40-hour time weighted average instead of the 8-hour time weighted average proposed herein? If so, on what basis?

3. What is the risk of developing cancer (leukemia) or any other adverse health effects that might arise from exposure to benzene at OSHA's current

limits and from exposure to alternative limits of less than 10 ppm?

4. What are the numbers of workers exposed to benzene, their current exposure levels, the methods of monitoring, duration and frequency of exposure, the jobs being performed, and the Standard Industrial Classification (SIC) Codes for industries and processes using benzene?

5. Which of the following control methods are available to reduce exposures to benzene to alternative 8-hour TWA's of 5, 1, 0.5 and 0.1 ppm?

a. Engineering controls including: ventilation and collection, isolation and containment, substitution of product or process and modification of process or equipment.

b. Work practices, housekeeping and administrative controls.

Please provide a detailed discussion and documentation of the use of these controls, their application in various work settings, their efficiency, their costs, and the time necessary for implementation.

6. What is the lowest feasible level of benzene exposure achievable by engineering controls and work practices? For example, can benzene exposures be reduced by present technologies to 5 ppm, 1 ppm, 0.5 ppm, or 0.1 ppm?

7. What are the capital and operating costs to achieve those lower exposure levels? Are those costs economically feasible for the affected industries? How would the time allowed to install these engineering controls affect these costs?

8. What is the appropriate compliance strategy utilizing engineering controls, work practices, and respirators for reducing exposures to benzene?

9. Are there conditions under which respirator use should be permitted in addition to those proposed? What respirator fit testing requirements should be included in the final standard and when should such testing be performed?

10. Are there any unique conditions in work settings where benzene is produced or used where feasible engineering controls are not available?

11. Have there been technological improvements or changes in the production or use of benzene for the purpose of improving productivity or product quality which have also resulted in reductions in benzene exposures?

12. What are the appropriate scientific and industrial hygiene principles to determine whether a short-term exposure limit (STEL) should be incorporated into a standard? Does the evidence available indicate that a STEL should be included in this benzene standard? If so, what should that short-term exposure limit be?

13. What is the level of benzene contamination in petroleum naptha, toluene, xylene and other solvents currently in use?

14. What processes are available to reduce benzene contamination in solvents? To what levels can benzene contamination be reduced in solvents, and what are the economics of those processes after reaching large scale production?

15. What measurement and analytical methods are available for use in determining compliance with a benzene exposure limit of less than 10 ppm?

16. Is it necessary to establish provisions for medical examinations, respirators, personal protective clothing and equipment, hygiene facilities and practices, regulated areas, maintenance of records, housekeeping, employee information and training, and labels and signs? What form should such provisions take in the final standard? To what extent are these provisions currently being employed by industry and what are their costs?

17. In order to perform an economic feasibility analysis, it is helpful to have a financial and economic profile of the industries producing and using benzene. The following information is requested to aid in the preparation of that profile. Data should be provided for the last five years. Data already submitted to OSHA or JRB need not be resubmitted.

a. What were the total annual volumes and dollar values of production, shipments, and inventories?

b. What were the total annual investments categorized as replacement, expansion, modernization, and environmental health and safety?

c. What were the retained earnings, after tax income, total assets, stockholders' equity, net worth, depreciation charges, and debt-equity ratios?

d. What were the total annual employment levels and labor turnover for the industries with benzene exposures for the last 5 years?

18. OSHA and JRB have performed detailed feasibility analyses for the industry sectors where impacts would be significant and OSHA believes that impacts in other segments would not be substantial. Comments are requested from any other industry segments on additional impacts which should be considered prior to issuing a final standard.

19. The benzene record includes copies of the Regulatory Impact Analysis and the JRB report, and this document presents OSHA's feasibility analysis. Comments are requested on those analyses, the feasibility and the cost-effectiveness of the proposed standard and alternatives.

20. The Agency has prepared a draft Regulatory Flexibility Analysis analyzing the impacts of the proposed standard on the small businesses which OSHA believes may be affected and adapting the proposed standard to take into account the circumstances of small business where appropriate. The following information is requested for small businesses in addition to the information OSHA has gathered.

a. What kinds of small businesses or organizations and how many of them would be affected by regulating exposures to benzene?

b. Which, if any, federal rules may duplicate, overlap, or conflict with an OSHA regulation concerning benzene?

c. Will difficulties be encountered by small entities when attempting to comply with requirements of the proposed standard? Can some of the requirements be deleted or simplified for small entities, while still achieving comparable protection for the health of employees of small entities?

d. What timetable would be appropriate to allow small entities sufficient time to comply?

21. The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.) requires that each Federal agency consider the environmental impact of major actions significantly affecting the quality of the human environment. Any person having information, data, or comments pertaining to possible environmental impacts is invited to submit them and accompanying documentation to OSHA. Such impacts might include:

a. Any positive or negative environmental effects that could result should a standard be adopted;

b. Beneficial or adverse relationships between the human environment and productivity;

c. Any irreversible commitments of natural resources which could be involved should a standard be implemented; and

d. Estimates of the degree of reduction of benzene and other hydrocarbons in the environment by the proposed OSHA standard and alternatives.

In particular, consideration should be given to the potential direct or indirect impacts of any action, or alternative actions, on water and air pollution, energy usage, solid waste disposal, or land use.

II. Pertinent Legal Authority

This proposed standard and issuance of a final standard is authorized by sections 6(b), 8(c), and 8(g)(2) of the

Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655(b), 657(c) and 657(g)(2). Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. It states:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, 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 employee, 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 standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

Section 3(8) defines an occupational safety and health standard as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."

The Supreme Court has held under the Act that the Secretary, before issuing any new standard, must determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment. *Industrial Union Department* v. *American Petroleum Institute*, 448 U.S. 607 (1980). The court stated that ". . . 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" (488 U.S. at 642). The Court also stated "that the Act does limit the Secretary's power to requiring the elimination of significant risks" (448 U.S. at 644, n. 49).

The Court indicated, however, that the significant risk determination is "not a mathematical straitjacket," and that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge (and that) . . . the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656). The Court also stated that "while the Agency must support its finding that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is "'significant' will be based largely on policy considerations." (448 U.S. at 655, 656, n. 62).

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the proposed standard, it must set a standard "which most adequately assures, to the extent feasible on the basis of the best available evidence, that no employees will suffer material impairment of health . . ." Section 6(b)(5) of the Act. The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility. *American Textile Manufacturers Institute, Inc.* v. *Donovan*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is." (452 U.S. at 509). The Court stated that the Agency could use cost-effectiveness analysis and choose the least costly of two equally effective standards. (452 U.S. 531, n. 32).

Section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." Section 8(g)(2) gives the Secretary authority to "prescribe such rules and regulations as he may deem necessary to carry out (his) responsibilities under this Act." Section 4(b)(2) gives the Secretary power to apply this standard through the contract powers of the government and to make it applicable under other statutes.

In addition, the Secretary's responsibilities under the Act are amplified by its enumerated purposes, which include:

> Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651(b)(1));
>
> Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to business affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act; (29 U.S.C. 651(b)(3));
>
> Building upon advances already made through employer and employee initiative for providing safe and healthful working conditions (29 U.S.C. 651(b)(5));
>
> By providing for the development and promulgation of occupational safety and health standards providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem; exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions * * *. (29 U.S.C. 651(b)(6));
>
> Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment (29 U.S.C. 651(b)(13));
>
> And developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems (19 U.S.C. 651(b)(5)).

Because the benzene standard is reasonably related to these statutory goals and the Agency's preliminary judgment is that the evidence satisfies the statutory requirements, and that the proposed standard is feasible and substantially reduces a significant risk of leukemia and other adverse health effects, the Secretary preliminarily finds that the proposed standard is necessary and appropriate to carry out his responsibilities under the Act.

III. History Of Regulation

Benzene has been recognized as a toxic substance capable of causing acute or chronic effects since 1900. An initial exposure limit of 100 ppm was recommended in 1927 by Winslow. In the 1940s, as a result of blood abnormalities and one death among rubber coating workers exposed to benzene concentrations ranging from 40 to 80 ppm, the state of Massachusetts lowered its permissible limit for benzene exposure to 35 ppm.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommended a threshold limit value (TLV) for benzene exposure of 100 ppm in 1946. This TLV was reduced in 1947 to 50 ppm. In 1948, following Massachusetts' lead, ACGIH adopted a TLV of 35 ppm. In 1963, a TLV of 25 ppm was proposed by the ACGIH. At this time, blood changes, aplastic anemia, and other blood dyscrasias served as a basis for this action. No mention was made of any association of leukemia with benzene exposure. In 1974, the ACGIH adopted the TLV of 10 ppm which had sometime earlier been

recommended by the American National Standards Institute.

The present OSHA standard for benzene (29 CFR 1910.1000, Table Z-2) was adopted in 1971 without rulemaking under the authority of section 6(a) of the Act. Neither the ANSI standard nor the resultant OSHA standard was based on the possible leukemogenic effects of exposure of exposure to benzene.

On May 3, 1977, the Assistant Secretary for OSHA issued an Emergency Temporary Standard (ETS) for Occupational Exposure to Benzene (42 FR 22516), pursuant to sections 6(c) and 8(c) of the Act. A temporary stay of that standard before it took effect was issued May 20, 1977 in the case *American Petroleum Institute et. al.* v. *Occupational Safety and Health Administration et. al.* (Fifth Circuit, No. 77-1973). No decision on the merits of the Emergency Temporary Standard was ever issued but the ETS never took effect because of various stays. A decision on jurisdiction was issued December 7, 1977 by the D.C. Circuit in *Industrial Union Dept. AFL-CIO* v. *Bingham*, 570 F. 2d 965 (D.C. Cir. 1977).

On May 27, 1977, OSHA published a proposed permanent standard to control occupational exposure to benzene (42 FR 27452). The public hearings on the benzene proposal were held July 19 through August 10, 1977.

On February 10, 1978 (43 FR 59181), OSHA promulgated a permanent standard for occupational exposure to benzene, 29 CFR 1910.1028. This standard was based on a determination by OSHA that the available scientific evidence qualitatively established that employee exposure to benzene presented the cancer hazard of leukemia. In accordance with OSHA's regulatory approach to the control of employee exposure to carcinogens at that time, OSHA had set the PFL to the lowest feasible level once qualitative evidence of carcinogenicity was demonstrated. The standard, therefore, limited employee exposure to benzene to 1 ppm as an 8-hour time weighted average concentration, with a ceiling level of 5 ppm for any 15 minute period during an 8-hour workday. The standard also prescribed limits on eye and skin contact with benzene and included monitoring, medical, training and other provisions.

The standard was challenged in the case of *American Petroleum Institute et. al.* v. *Occupational Safety and Health Administration et.al.*, 581 F.2d 493 (Fifth Cir. 1978). The Fifth Circuit vacated the standard on the basis that the Act required OSHA to perform a cost benefit analysis which it had not performed to demonstrate substantial benefits. The Court vacated the skin absorption provisions on the basis that the agency should have waited for a further study which the Court believed would be definitive and would only take a few months to complete.

On July 2, 1980, the U.S. Supreme Court upheld the decision of the Fifth Circuit vacating the new benzene standard in *Industrial Union Dept.* v. *American Petroleum Institute*, 448 U.S. 607 (1980). The Supreme Court did not reach the issue of cost-benefit analysis. (It was later decided in *American Textile Manufacturing Institute*, v. *Donovan*, 452 U.S. 490 (1981), that OSHA standards were not to be based on cost benefit analysis.) However, the Supreme Court held that before OSHA issued a new standard under section 6(b), it must determine that a significant risk existed (based on quantitative estimates, if possible) and that a new standard would substantially reduce or eliminate that risk. It held that OSHA's qualitative determination for benzene did not meet that requirement. See the discussion under Legal Authority above. After the vacating of the new standard, the old benzene 10 ppm standard remained in effect.

On April 14, 1983, OSHA received a petition requesting an Emergency Temporary Standard reducing benzene exposures to 1 ppm (Ex. No. 126). In support of their position, the petitioners presented quantitative risk assessments which they argued demonstrated significant risk at 1 ppm. In a letter on July 1, 1983, Assistant Secretary Auchter denied the petition for several reasons (Ex. No. 150). First, the risk assessments presented needed additional review prior to a decision. Second, exposure data indicated that more than 90% of benzene exposed workers were already exposed under 1 ppm and most of the rest were exposed between 1 and 3 ppm. Consequently, the additional risk remaining in the interval before a thorough review could be completed was much less than if exposures were higher. Third, as the Supreme Court has noted, Congress has "narrowly circumscribed the Secretary's power to issue temporary emergency standards." (For example, OSHA issued an ETS for asbestos on November 4, 1983 (48 FR 51086). The Fifth Circuit U.S. Court of Appeals stayed the ETS on November 23, 1983 and ruled on March 7, 1984, that the ETS on asbestos was invalid. *Asbestos Information Ass'n.* v. *OSHA*, 727 F2d 415.) Finally, the Supreme Court's benzene decision indicated that a more thorough analysis was needed on feasibility issues. However, the Assistant Secretary stated that OSHA would review on an expedited basis the quantitative risk assessments performed on benzene and the new scientific evidence, and that the Agency intended to proceed with an expedited rulemaking. A feasibility analysis commenced immediately.

On July 8, 1983, OSHA published in the **Federal Register** a Request for Information and Regulatory Schedule (48 FR 31412). The Agency requested information about benzene generally and answers to twenty-three questions regarding a variety of relevant issues concerning current occupational exposures to benzene. Among the areas covered was information developed since 1977 concerning the health effects of benzene, its toxicologic properties, estimates of the risk presented, current occupational exposure levels, approaches and costs for reducing exposures and their cost-effectiveness. Comments were due by August 22, 1983. On August 26, 1983, OSHA extended the comment period to September 6, 1983 (FR 48 38858) at the request of several interested parties, so that they would have sufficient time to respond.

OSHA received thirty-five comments in response to the Request for Information. References to the content of the comments received from the various submissions will be made in the relevant parts of the preamble discussion. This proposal is based on OSHA's review of all the evidence, new developments since 1977, and the comments to the request for information.

OSHA contracted with the Institute for Environmental Mediation to encourage interested trade unions, trade associations and other interested non-governmental parties to enter into discussions among themselves to see if they could narrow issues on benzene regulation. On February 13, 1984, OSHA was notified that the trade unions, trade associations and other non-governmental parties had not agreed on a joint document, though they agreed that informal discussions by the interested non-governmental parties were useful.

Later information indicated that there might be a possibility of agreement. Meetings commenced in June. However, OSHA was notified on July 16, 1984 that agreement had not been reached.

On December 7, 1984, several trade unions and a public health organization filed a petition for writ of mandamus in the United States Court of Appeals for the District of Columbia Circuit under the name *United Steelworkers of America, AFL-CIO-CLC, et al.* v. *Raymond J. Donovan, Secretary of Labor, et al.* (Ex. No. 163). The petition requested the Court to direct OSHA to

proceed with benzene rulemaking on an expedited basis.

IV. Chemical Identification, Production and Use

Benzene (C_6H_6) is a clear, colorless, non-corrosive, highly flammable liquid with a strong, rather pleasant odor. The low boiling point and high vapor pressure of benzene cause rapid evaporation under ordinary atmospheric conditions, giving off vapors nearly three times heavier than air.

Benzene is produced primarily by the petrochemical and petroleum refining industries by a process called catalytic reformation, which converts certain lower octane hydrocarbons into higher octane aromatics. These two industries are responsible for 98 percent of the total U.S. production of benzene. Recovery through catalytic reformation, including the benzene formed from the hydrodealkylation of toluene, accounts for aproximately 75 percent of the total quantity produced. Recovery of coal-derived benzene, primarily as a by-product of the coking process in steel mills, was once the major source of benzene. Today, however, this process accounts for only 2 percent of the total United States production.

The first major industrial use of benzene was as a solvent in the rubber industry just preceding World War I. During World War I, benzene production was stimulated greatly by the demand for and resulting production of toluene in the manufacture of explosives. The large quantities of benzene which were produced resulted in its more widespread use as a starting point for the manufacturing of various organic compounds. This situation led to greatly increased uses of benzene as a solvent in the artificial leather, rubber goods, and rotogravure industries.

Many products contain benzene exclusively as the result of contamination. Benzene is a naturally occurring compound in crude oil and natural gas (e.g., the benzene content of these streams varies by geographical location and is usually between 0.1 and 3.0 percent by volume), and some degree of benzene contamination occurs in products refined from crude oil and natural gas (e.g., solvents, fuels, and oils) because of the nature of the fractional distillation process by which these substances are produced. Benzene generally does not improve the performance of these materials.

Unreacted benzene may also be present in major benzene derivatives (e.g., ethylbenzene) or in other specialty chemicals that use benzene as a feedstock (e.g., dicyclopentadiene). The presence of unreacted benzene in major derivatives or other specialty chemicals is undesirable from the producer's point of view and is not generally useful to product users.

Industries and processes currently using benzene or liquids containing benzene include the chemical, printing, lithograph, rubber cement, rubber fabricating, paint, varnish, stain remover, adhesive, and petroleum industries. Benzene is also used extensively in chemical laboratories as a solvent and as a reactant in numerous chemical applications. Where benzene is produced, used or stored in large amounts, it is generally contained in enclosed systems, although exposures can occur during liquid transfer operations, from equipment leakage and carryover losses, and in maintenance operations.

V. Health Effects

A. Introduction

Benzene has been known to be a bone marrow poison since the report of aplastic anemia by Santesson (1897) (Ex. No. 159–70) and the report of a blood abnormality that is thought to have been a case of leukemia by LeNoir and Claude (1897) (Ex. No. 159–50). The first clearly established case of leukemia in association with benzene exposure was published by Delore and Borgomano in 1928 (Ex. No. 159–23).

Over the years, reports in the literature have linked hundreds of cases of aplastic anemia, leukemia and other diseases of the blood to benzene exposure. It has been established that benzene exposure is causally linked to leukemia, most predominantly of the myelogenous cell type and its variants, aplastic anemia (an often fatal disease of the bone marrow) and suppression of various cellular elements of the peripheral blood, either singularly or in combination, i.e., depression of white cells or leukocytes (leukopenia), red cells (anemia), platelets or thrombocytes (thrombocytopenia) and all three of these cellular elements (pancytopenia). In the early stages of leukopenia,anemia, thrombocytopenia or pancytopenia, the effects may be reversible.

In the 1970's, formal epidemiologic studies evaluated the relative risk of leukemia among benzene exposed individuals. These studies along with the numerous case reports have shown that benzene alone or in combination with other chemicals is associated with several hematological disorders including myelogenous leukemia and its variants, acute and chronic lymphatic leukemia, multiple myeloma, paroxysmal nocturnal hemoglobinuria, various forms of lymphoma, aplastic anemia and various cytopenias. The basic mechanism by which benzene affects bone marrow precursor cells is still unclear.

Although suspicion of types of cancers other than of the lympho-hematopoietic system has been raised, these have not been adequately evaluated from epidemiologic cohort or case-control studies of workers exposed to benzene. The studies have not had sufficient statistical power to detect low excess relative risks. However, since 1978, experimental studies have demonstrated that benzene administered either by oral gavage or by inhalation induces cancer of multiple sites in experimental animals. A study recently released by the National Toxicology Program (NTP) has demonstrated the induction of at least nine separate types or sites of tumors in mice and rats.

Several consensus groups have confirmed the carcinogenic potential of benzene, including the American Conference of Governmental Industrial Hygienists (ACGIH–TLV, 1983, Ex. No. 159–5), the International Agency for Research on Cancer (IARC) (1982, Ex. No. 128–8), and the National Toxicology Program (NTP) (Ex. No. 148).

Benzene is known to cause chromosomal damage in the circulating lymphocytes of exposed workers. Information also indicates that chromosomal damage in workers may be associated with benzene exposures below 10 ppm. The scientific literature includes many case reports, case series, and epidemiologic studies which qualitatively link benzene exposure with these conditions in humans. This literature has been reviewed and summarized many times (NAS, 1976; Goldstein, 1977; OSHA, 1978; IARC, 1982; and others; Ex. Nos. 128–5, 7, 8, 59).

Recent experimental studies have also demonstrated chromosomal damage in experimental animals exposed by inhalation for short periods of time to 10 ppm benzene in air. One study also demonstrates chromosomal damage from only 4 hours atmospheric exposure to 28 ppm benzene while another shows significant chromosomal damage induced by 6 hours of atmospheric exposure to 10 ppm benzene. The major reports of these findings are presented in more detail below.

B. Hematotoxic and Carcinogenic Effects in Humans

The toxic effects of benzene on the human hematopoietic system are well documented in the literature. A common clinical finding in benzene hematotoxicity is a decrease in various

formed elements of the circulating blood, called cytopenia. This decrease may manifest itself as pancytopenia and aplastic anemia or as unicellular cytopenias (Goldstein, 1977; Ex. No. 59).

Aplastic anemia or hypoplastic anemia is a rare disorder, characterized by cytopenia in the peripheral blood and in the bone marrow. Aplastic anemia is a disease with a very poor prognosis. It has a high case—fatality rate of about 30–50% within one year of diagnosis. Annual mortality from aplastic anemia in the U.S. is estimated to be 4 to 5 deaths per million population. An important feature of aplastic anemia is its association with acute nonlymphocytic leukemia (ANLL). Not only do aplastic anemia and ANLL share etiologic agents such as benzene, but cases of aplastic anemia from various causes are known to progress to leukemia (Szklo, 1980) (Ex. No. 159–80). Modan et al. (1975) (Ex. No. 159–54) reported that 11% of the 93 cases of aplastic anemia detected in Israel between 1961 and 1965 subsequently developed ANLL.

Both aplastic anemia and leukemia can be thought of as hematopoietic disturbances of the bone marrow. They may both occur as a result of similar pathogentic mechanisms. This hypothesis is supported by the findings of Vigliani and co-workers in Italy and by Aksoy and co-workers in Turkey. These investigators have described series of cases of leukemia and aplastic anemia attributed to occupational benzene exposure. Aksoy (1980) (Ex. No. 144–039) reported on 44 cases of pancytopenia among 28,500 benzene exposed workers in Istanbul, Turkey during the years 1967 to 1979. Twenty-three of the 44 cases (52%) experienced remission of the aplastic anemia. Fourteen of the 44 cases (32%) died from complications of aplastic anemia or pancytopenia. Six of the 44 cases (14%) later died from leukemia. Aksoy also reported that in twenty-six percent of 42 leukemia cases, the leukemia was preceded by a period of pancytopenia. The interval between the pancytopenic period and the onset of leukemia varied between 6 months and 6 years.

Vigliani (1976) (Ex. No. 128–15) summarized cases of benzene hemopathy seen at the Institutes of Occupational Health of Pavia and Milano. At the Institute in Milano from 1942 to 1976, 66 cases of chronic benzene poisoning were seen. Of 18 deaths in this group, 7 were from aplastic anemia and 11 were from leukemia. All cases were employed at rotogravure plants, shoe factories, and other industries using benzene as a solvent. At the Institute at Pavia from 1959 to 1974, 135 cases of benzene hemopathy among workers in shoe manufacturing were enumerated. Of 16 deaths, 3 were from aplastic anemia and 13 were from leukemia. With data from both clinics combined, there were 10 deaths from aplastic anemia and 24 from leukemia.

Ott et al. (1978, Ex. No. 128–33) reported three deaths from leukemia and one from aplastic anemia among benzene exposed employees of a chemical manufacturing facility. The NIOSH follow-up study of benzene exposed Pliofilm workers has found 9 leukemia cases and 3 to 4 aplastic anemia cases among persons fitting the cohort definition (Rinsky, 1984) (Ex. No. 159–65). These studies indicate that the ratio of leukemia to aplastic anemia is approximately 2 or 3 to one.

The classification of neoplastic diseases of the hematopoietic system has developed out of their gradual historical recognition. The major disease categories differ with respect to morphologic and clinical manifestations and often in their resonse to therapy. Leukemia may be divided into granulocytic leukemias (which inlcude myelocytic, monocytic and erythroblastic cell types) and lymphocytic leukemias. Both granulocytic and lymphocytic leukemia may in turn be separated into acute and chronic forms. The designations "acute" and "chronic" are related to the rapidity of development of symptoms, signs and complications in these forms of leukemia (Wintrobe, 1974) (Ex. No. 159–103). Lymphoma may be divided into Hodgkin's disease and non-Hodgkin's lymphomas. Another major cancer of the hematopoietic system is multiple myeloma, a neoplasm affecting the bone marrow.

An association between occupational exposure to benzene and the occurrence of leukemia was suggested in 1928 by Delore and Borgomano (Ex. No. 144–178), who described acute lymphoblastic leukemia in a worker who had been exposed to benzene for five years. Since that time, numerous reports of cases and case series have described leukemia in workers exposed to benzene, either alone or in combination with other chemicals (Hunter, 1939, Ex. No. 144–143; DeGowin, 1963, Ex. No. 144–155; Tareef et al., 1963, Ex. No. 2–28; Vigliani, and Saita, 1964, Ex. No. 128–12; Goguel et. al., 1967, Ex. No. 144–146; Aksoy et al. 1972 1974, 1976, Ex. Nos. 128–9, 10, 11; Vigliani, 1976, Ex. No. 128–5; Girard and Revol, 1970, Ex. No. 144–177; Aksoy, 1977, 1980, Ex. Nos. 144–39, 160; and those reviewed by Goldstein, 1977, Ex. No. 128–59). The leukemia cases reported have been myelogenous, monocytic, erythroblastic, and lymphocytic leukemias. Reports of other diseases associated with benzene exposure have included malignant lymphoma, multiple myeloma, myeloid metaplasia and paroxysmal nocturnal hemoglobinuria (Aksoy, 1980, Ex. No. 144–39).

Aksoy and coworkers (1974, 1976, 1977, 1980, Ex. Nos. 22, 128–72, 11, 43) reported the crude incidence of leukemia between 1967–1973 among 28,500 shoe, slipper and handbag workers exposed to benzene in Istanbul to be approximately 13.5 per 100,000, compared to an estimated annual leukemia incidence of 6 per 100,000 for the general population of Turkey, resulting in a relative risk of 2 for all cell types of leukemia combined. This risk estimate was based upon the diagnosis of leukemia in 26 shoeworkers at the Internal Clinic of Instanbul Medical School and did not take into consideration differences in the age structure of the population of shoeworkers and the general population. From the several reports by Aksoy et al., peak benzene exposures for the 28,500 shoeworkers were estimated to have varied between 210 and 640 ppm. Average exposure concentrations were estimated to be between 150–210 ppm when adhesives containing benzene were being used and between 15–30 ppm during other times. Duration of exposure is estimated to be 9.7 years based on the average length of exposure for the leukemia cases.

On the basis of the series of reports by Aksoy et al. the Carcinogen Assessment Group (CAG) of the Environmental Protection Agency (EPA) calculated a relative risk of 20 for non-lymphoblastic leukemia among Istanbul shoeworkers exposed to average benzene levels ranging from 15–250 ppm (CAG, 1979, Ex. No. 128–6). The difference between the relative leukemia risk of 2 as estimated by Aksoy et al. and 20 as estimated by CAG is related to adjustments made by CAG for the background incidence of leukemia in Turkey, attributed differences between the age structure of Turkish shoeworkers and the general population on which the national rate was based and adjustment for cell types of leukemia on which the CAG relative leukemia risk was based. These factors contributed equally to the difference between the Aksoy and the CAG estimates of risk. IARC (1982, Ex. No. 128–8) also evaluated the reports of Aksoy et al. and determined that the relative risk of acute non-lymphocytic

leukemia among Istanbul shoeworkers was 24. This evaluation by IARC resulted in a relative risk 12 times higher than the 2-fold elevated risk reported by Aksoy et al. and is based on the ratio of acute non-lymphocytic leukemia to chronic forms of leukemia for benzene exposed versus non-benzene exposed individuals in the Aksoy studies of shoeworkers.

Vigliani and Saita (1964, Ex. No. 128–12) estimated the incidence of acute leukemia attributed to benzene exposure in the Provinces of Milan and Pavia during 1962 and 1963 to be at least 20 times higher than expected when compared to the general population, based on 11 cases among approximately 5,000 persons exposed to benzene in the rotogravure and shoe industries. Data were not presented in the report to allow for validation of the estimated risk.

Vigliani (1976, Ex. No. 128–14) summarized the cases of benzene hemopathy (leukemia and other blood disorders) treated at two clinics in Italy. Between 1942 and 1975, 66 cases of benzene hemopathy, 11 of which were leukemia, were seen at the Institute of Occupational Health in Milan. The affected individuals worked in rotogravure plants, shoe factories and other industries using benzene as a solvent. Benzene concentrations in air near rotogravure machines were calculated to range between 200 to 400 ppm, with peaks up to 1500 ppm.

At the Institute of Pavia, 135 workers with benzene hemopathy were seen, 13 of which were leukemia, during the period 1959-1974. All of these cases came from shoe manufacturing occupations where benzene concentrations in the workplace were reported to have ranged from 25-600 ppm but mostly in the range of 200–500 ppm.

Because of numerous case reports of leukemia and other blood disorders associated with occupational benzene exposure, NIOSH conducted a cohort mortality study. Infante et al. (1977, Ex. No. 128–17) reported on a cohort of 748 white male workers occupationally exposed to benzene at any time between 1940 and 1949 in two manufacturing facilities producing rubber hydrochloride (Pliofilm). Vital status ascertainment at the time of the initial report was 75% complete. In order not to overestimate the risk, the authors assumed that those with vital status undetermined were alive until the follow-up cut-off date. (The resulting relative risks from cause-specific mortality were subsequently shown to have been underestimated when the follow-up was completed (Rinsky et al., 1981, Ex. No. 128-32).) Causes of death were ascertained from diagnoses given on death certificates. Although there were fewer deaths from all causes reported among the benzene exposed workers (140) than the number expected based on age and calendar period adjusted death rates for U.S. white males (187.6), a significant excess of leukemia deaths was observed (7 observed vs. 1.38 expected). All 7 leukemia deaths were from myelogenous or monocytic leukemia, constituting a 10-fold relative risk for deaths from the two cell types combined, based on estimates of leukemia cell-type distribution derived from incidence data from the Connecticut Tumor Registry. Monitoring data and existing industrial hygiene assessments led to the conclusion that the environment of the workers in Pliofilm production was not contaminated with other materials known to be associated with the induction of blood disorders. Infante et al. further stated that workers' exposures to benzene were generally within the recommended limits in effect at the time of employment, that is, they were between 100 ppm and 10 ppm during the years 1941–1975.

Tabershaw and Lamm (1977, Ex. No. 159–81) raised several questions about the report by Infante et al. (1977, Ex. 128–17) pertaining to the possibility of excluding workers from the study who may have been exposed to benzene, the benzene levels to which they were exposed, the nature of selection of the facilities for study and the relative risk of death from all types of luekemia combined as well as for specific cell types of leukemia among cohort members.

In reply to the questions raised by Tabershaw and Lamm, the NIOSH investigators evaluated past exposures in both plants in further detail, and reported that, although other solvents were used in various areas of both plants, benzene was found to be the only solvent used in the manufacture of rubber hydrochloride, except for chloroform, which was used between 1936 and 1949 in one plant (Ex. No. 128–17; 128–32). The authors agreed with Tabershaw and Lamm that occasional high excursions occurred in airborne benzene levels (up to several hundred ppm). They found, however, that the estimates of airborne concentrations for most of these excursions were based on area samples and not personal samples and occurred in areas entered only infrequently by workers. They estimated that workers' actual eight-hour time-weighted average breathing-zone exposures fell generally within accepted limits of 10 to 100 ppm.

To evaluate the relative risk of death from leukemia at each of the two plants, the NIOSH investigators specifically analysed leukemia mortality in each (Ex. No. 128–17; 128–32). They found excess mortality in both plants: In one, 2 cases were observed versus 0.58 expected for a standardized mortality ratio (SMR) of 345; and in the other, 5 cases were observed versus 0.67 expected (SMR–746). However, the authors noted that the decision to examine mortality separately for the two plants was not made prior to initial analysis and therefore should not be given undue emphasis. In OSHA's opinion, it seems appropriate to combine data for the two facilities because the operations through which workers were exposed to benzene were virtually identical.

NIOSH agreed with Tabershaw and Lamm that the estimated 10-fold relative risk of death from myeloid and monocytic leukemias combined as presented initially (1977) was too high. The re-analysis by NIOSH resulted in a relative risk of 8.5 for these types of leukemia (Ex. No. 128–17). In OSHA's opinion, the slight reduction in the excess relative risk does not influence the interpretation of the study results.

In their reply to Tabershaw and Lamm, the NIOSH investigators (Ex. No. 128–17) also indicated that "pipefitters, mechanics, and maintenance personnel were not included because company records did not show which men had responsibilities in pliofilm production." During the follow-up, it was learned that at least one pipefitter who had responsibilities in pliofilm was known to have died from acute myelogenous leukemia. This leukemia death, however, could not be included in the statistical analyses because it did not fit the initial cohort definition.

Dr. Marvin Sakol, a hematologist who practiced in the community where one of the studied facilities was located, testified during the 1977 OSHA benzene hearing that he treated at least two additional cases of leukemia not identified by the NIOSH investigators during their follow-up of study cohort members. He stated that he did not have permission from the families to release the names. Dr. Sakol further testified that the determination of cause of death by use of death certificates resulted in errors of underascertainment of deaths potentially related to benzene exposure. For example, for one individual with documented evidence of exposure to benzene who had "essential thrombocytopenia" which "can cause

obstruction of the coronary vessels," the coroner indicated on the death certificate that death was from myocardial infarction (a heart attack). Another individual who had "intolerable itching . . . due to his lymphosarcoma, and so he jumped off a high-level bridge" had a death certificate diagnosis of suicide and this certificate, according to Dr. Sakol, did not mention his lymphosarcoma. Another individual who began working in Pliofilm operations in 1950 was treated by Dr. Sakol and died from acute myeloblastic leukemia. In this case, the discharge diagnosis was changed to aplastic anemia so his "widow would receive $10,000 in industrial compensation" (Sakol, OSHA 1977, TR 285–329).

Dr. Sakol presented information indicating that at least five individuals, of whom 3 died from leukemia, one from thrombocytopenia and one from lymphosarcoma were not included as such in the statistical analyses of the NIOSH study. If these individuals were included, the estimated excess risk would increase substantially. OSHA seeks comment on whether these individuals should be included in the analyses for purposes of determining a "maximal estimate" of relative risk for lymphohematopoietic disease in the NIOSH cohort.

Rinsky et al. (1981, Ex. No. 128–32) more recently completed the follow-up of the cohort of Pliofilm workers through June 30, 1975. They reported a statistically significant excess of leukemias. There were seven cases observed, as compared to 1.25 expected resulting in a SMR of 560. The authors indicated that 58% of the cohort members had been employed for less than one year. When the data were analyzed by length of employment, a significant excess in leukemia was observed among workers employed 5 or more years, but not among workers employed for less than 5 years. Among the latter group, 2 workers had died from leukemia compared to 1.02 expected, an excess which was not statistically significant. However, among workers employed for 5 or more years, 5 had died from leukemia compared to 0.23 expected, yielding a SMR of 2100. Five additional cases of leukemia, four of them myelogenous, were reported among workers who had responsibilities in Pliofilm manufacturing. These deaths were not included in the statistical analysis of the original cohort (employed sometime between 1940–49) because they occurred either after the study end date of June 30, 1975 (one case), began employment in pliofilm after 1950 (one case), were salaried rather than hourly employees (one case) or had incorrect underlying cause of death indicated on the death certificate (2 cases). Four of these deaths are in addition to those mentioned by Dr. Sakol as not being included in the analysis. (Case number 12 in Rinsky et al. (1981) was mentioned by Sakol.)

Rinsky et al. (1981, Ex. No. 128–32) provided further detail on atmospheric benzene concentrations to which the cohort was exposed. For one Pliofilm manufacturing facility, information on benzene concentrations between 1946 and 1976 was available from a series of reports by the Industrial Commission of Ohio, the Ohio Department of Health, the company, the University of North Carolina and a NIOSH survey. According to NIOSH investigators, most of the data in these reports appears to have been derived from area samples taken with detector tubes with the exception of the company surveys of 1973–75 and the NIOSH walk-through survey conducted in 1976 when personal breathing zone air samples were measured. While the short-term area samples measured over the years indicated that some benzene levels were above 100 ppm, most were below 100 ppm. Furthermore, short-term area peak exposures may not be indicative of actual breathing zone exposures. The Rinsky et al. (1981, Ex. No. 128–32) report cites several documents indicating that workers were required to wear respirators when exposed "even momentarily" to exposures considered above the recommended level at the time. For example, a report from 1955, when the recommended limit was an 8-hour average of 35 ppm, indicated that workers entered areas where benzene exposures ranged from 19–680 ppm, but that respirator usage was required when workers spent less than one hour in the high exposure areas. However, one evaluation of benzene exposure made in 1973–74 at the same facility, when the exposure limit was 10 ppm as an 8-hour average, indicated that respirators were required but were often not worn when workers entered areas where high benzene levels were found (Rinsky, et al. 1981, Ex. No. 128–32). Thus, available information indicates that respirators were generally used when workers entered areas above the recommended limit.

Limited information on exposure levels was available for the second location. One report from the Ohio Department of Health dated 1948 indicated there were "a few conditions wherein an employee might be subjected to an extremely high concentration of benzol," but that employees were "well aware of the toxicity of benzol and have been instructed to, and do, wear respirators when they are required to enter" these areas. Environmental data from this location believed to have been derived around 1957, when the recommended 8-hour TWA was 25 ppm, indicate atmospheric levels of benzene ranging between zero and 100 ppm based presumably on short-term area samples. Because respirators were used at this facility and management was aware of the toxicity of benzene, OSHA considers as reasonable NIOSH's assessment that personal exposure to benzene at this facility as well as at the earlier mentioned plant was generally within the recommended limits at the time of exposure.

Ott et al. (1978, Ex. No. 128–33) conducted an historical prospective study of mortality among 594 white males occupationally exposed to benzene in a chemical manufacturing facility and employed at any time between 1940 and 1970. Two deaths from leukemia were observed versus one expected. The authors noted that a third death was categorized on the death certificate as bronchopneumonia with myeloblastic leukemia listed under "other significant conditions." (Since individuals with terminal leukemia often die from bronchopneumonia, the underlying cause of this death was listed incorrectly on the death certificate as due to pneumonia.) Ott et al. (1978) included this third case of myelogenous leukemia in their analyses and noted that 3 cases of myelogenous leukemia compared to 0.8 expected cases based on incidence data from the Third National Cancer Survey are statistically significant. With regard to other findings of interest in relation to benzene toxicity, the authors indicated that a fourth cohort member died from aplastic anemia while a fifth died from pernicious anemia. Although one breathing zone sample for benzene reached 937 ppm in an area of the plant where the highest exposures were recorded, the time-weighted-average (TWA) exposures ranged from 0.1–35 ppm for various job categories.

Assessment of atmospheric benzene levels in the three production areas from which workers were selected for study indicated that exposures to the cohort had always been fairly low, reflecting the use of closed continuous systems. In production area one, estimated TWA benzene exposure based on breathing zone samples ranged between 0.1 and 6.2 ppm for the years 1944 to 1973. In production area two, TWAs ranged between 0.3 and 14.7 ppm between 1953 and 1972, while in production area three

the averages ranged between 4 and 35.5 ppm for the years 1952–1974. The authors then calculated cumulative dosage for each employee by multiplying the mean TWA exposure for each job category by the number of months spent exposed to each level.

Using the data from the Ott study in its calculation, OSHA estimated that the cohort was exposed for an average of 9 years to an average concentration of about 5 ppm benzene. OSHA's preliminary evaluation of this study is that it represents direct observation of a leukemogenic risk from low level benzene exposure.

Decoufle et al. (1983, Ex. No. 128–30) reported on an historical cohort mortality study of 259 male employees employed from January 1, 1947 through December 31, 1960 at a chemical plant where benzene had been used in large quantities. Followed to December 31, 1977, four deaths from lymphoreticular cancers had occurred when 1.1 would have been expected based on the national rate for a relative risk of 3.7. Three of the deaths were due to leukemia as compared to 0.4 expected, resulting in a relative risk of 6.8. One of the leukemia deaths had treatment for multiple myeloma initiated 2 years prior to his development of leukemia.

The authors noted that the two year latency period from initiation of chemotherapy to development of leukemia in their case was typical of that seen in other instances of therapy induced leukemia in myeloma patients. The expected number of deaths from multiple myeloma, polycythemia vera, and other neoplasms of lymphoid tissue combined which was not presented in the published study was estimated by the authors to be 0.23 (Decoufle, 1984, Ex. No. 159–22). The two cases of multiple myeloma observed in the study plus previous reports of multiple myeloma associated with benzene exposure suggested to the authors an etiologic role for benzene in the pathologies of tumors of B-cell lineage (multiple myeloma and chronic lymphatic leukemia). The authors did not present any information on benzene exposure levels for these chemical workers.

Several epidemiological studies of refinery workers have been reported since 1977. Thomas et al. (1982, Ex. No. 144–71) studied the proportional mortality for 2,509 active and retired members of the Oil, Chemical and Atomic Workers International Union (OCAW) who worked at three oil refineries in the Beaumont-Port Arthur, Texas area for Texaco, Mobil, and Gulf Oil. With data for the three refineries combined deaths due to leukemia (PMR=1.83), multiple myeloma (PMR=1.96), Hodgkin's disease (PMR=1.34), and non-Hodgkin's lymphoma (PMR=1.32) were elevated, especially among retired workers. Deaths from cancers of the brain (PMR=2.21), prostate (PMR=1.38), stomach (PMR=1.52), pancreas (PMR=1.42) and circulatory disease (PMR=1.04) were significantly elevated whereas deaths from cancer of the bladder (PMR=0.14) and non-malignant respiratory disease (PMR=0.57) were significantly reduced.

Thomas et al. (1984, Ex. No. 159–84) followed the previous cohort mortality studies with a case-control study to examine work histories for evidence of any unusual distributions of cause-specific mortality by work category. Work histories were obtained from company personnel records and summarized by classifying job titles and departments into work categories. A worker was exposed to a work category if he had worked at least 1 day in that category 15 or more years prior to his death. Controls were selected from active and retired union members who had worked at the same refinery, were of the same race and sex, and had died of causes other than those being investigated. Cases and controls were matched on age at death, date of death, and age of first membership in the union. Additional cases identified subsequent to the proportionate mortality study and added to the data from that study included one brain tumor, four stomach cancers and four leukemia deaths. One leukemia death was eliminated because the wrong death certificate was obtained, and work histories were not located for two leukemia cases, leaving 34 leukemia cases in the analysis. Controls used for brain tumor, stomach cancer and leukemia comparisons were pooled and their work histories were used to estimate usual employment patterns within refinery work categories. These patterns were compared with work histories of the 9 cases of multiple myeloma, 9 cases of Hodgkin's disease and 23 cases of non-Hodgkin's lymphoma identified in the previous PMR study, rather than basing comparisons on the work histories of matched controls for the latter cancer deaths.

The relative risk (odds ratio) of leukemia was elevated among persons exposed to two job categories: Treating and boilermaking. The risk of leukemia increased with increasing duration of employment. Stomach cancer risk was elevated among maintenance workers and workers exposed to lubricating oils and paraffin wax processing. No strong associations for brain tumor risk were seen with any work category. In the comparisons with pooled controls, no unusual distributions with work category were noted for the cases of multiple myeloma, Hodgkin's disease, or non-Hodgkin's lymphoma. For this study the number of cases of each cancer type was small; consequently the ability to detect excess risk was low unless the actual risk was very high. The authors stated several limitations about the ability to associate specific cancers with specific chemicals because of changes in job classifications over time, lack of sensitivity and specificity of chemical exposures associated with job categories, and job mobility resulting in study subjects being classified as exposed in multiple work categories.

Wen et al. (1983, Ex. No. 159–100) studied male hourly and salaried workers employed for any length of time on any job at a refinery in Port Arthur, Texas, between January 1937 and January 1978. Although these authors found no statistically significant increases in mortality (except for bone cancer) among these workers compared with the general U.S. population, increases in SMRs were observed for Hodgkin's disease, leukemia, cancer of other lymphatic tissue, kidney and skin cancers. Furthermore, excesses were noted in deaths due to leukemia among white hourly workers, Hodgkin's disease and cancer of other lymphatic tissue among nonwhite hourly workers, and lymphopoietic cancers among salaried workers.

Thirty deaths from leukemia were observed among male hourly workers employed for one year or more where 21.3 would have been expected. Using the Poisson distribution in a one-tailed test of significance, a statistically significant excess of leukemia is indicated.

The study by Wen et al. has been criticized because the cohort was made up of all Gulf employees and thus included many unexposed persons in the population at risk, including clerical and managerial employees. Because Wen et al. did not identify the population at risk of exposure to the refinery process, the SMR's might have been diluted. Moreover, because 9–10% (338 deaths) of the cohort was lost to follow-up, with more complete follow-up the SMR's might increase. Those lost to follow-up may have included terminated employees with possibly shorter durations of exposure (Ex. No. 159–52).

Theriault and Goulet (1979) (Ex. No. 159–81A) reported the results of a mortality study of 1205 men who had worked at an oil refinery in Quebec for

more than 5 years between 1928 and 1975. Survival status was determined as of December 31, 1976 for 1015 of these men. Nine percent (108) were deceased and 75% (907) were alive. Sixteen percent (190) were lost to follow-up. The distributions of live and dead men as compared to the distributions of those lost to follow-up, on the basis of age and date of first employment, were said to be similar by the authors, and therefore, were not expected to generate bias in the study results. On the contrary, the differences in the distributions, when those lost to follow-up are compared to the deceased, appear to be great and could account for the failure of the study to observe statistically significant excesses of deaths due to cancer and other causes. In spite of this potential bias, the authors observed a significant excess of deaths due to brain cancer among persons with fewer than 20 years of exposure to refinery work (SMR=652), and increased numbers of cancers of the digestive system (SMR=117), bone (SMR=238), kidney and genital systems (SMR=118) and leukemia and lymphoma (SMR=127) among these workers when compared with the number expected among the Quebec population.

Hanis et al. (1979) (Ex. No. 159–34A) studied the risk of mortality from cancer among 15,032 men who were active employees or annuitants of Imperial Oil limited during 1964 to 1973. 865 employees with 5 to 15 years of sevice were lost to follow-up. 6,681 short-term employees with less than 5 years of employment were excluded from the study population because it was not considered practical to trace these employees. The company provided the following information on active employees or annuitants: Age, years of service, vital and employment status, date of retirement, date of death, cause of death, job title, job function and location. Information on job title, function, and location was used to classify workers as to exposure, moderate exposure or nonexposure to petroleum or its products or as refinery/non-refinery workers. Five cancer deaths that occurred in employees under the age of 40 were excluded from the mortality analyses. Employees in jobs which exposed them daily to crude petroleum or its products were found to have more than three times the risk of esophageal and stomach cancer and about twice the risk of lung cancer when compared with nonexposed employees. The risk of cancer increased with longer duration of employment among these exposed workers. Refinery workers were found to have twice the risk of cancer of the intestines and other digestive organs when compared with non-refinery workers, but no relationship with duration of employment was evident in this study. Mortality rates for cancers of the lymphatic and hematopoietic system were increased among those moderately exposed employees as compared with nonexposed (RR=1.88) but not among those exposed every day to petroleum or its products. No analysis was done specifically for leukemia deaths in this cohort.

Hanis et al. (1982) (Ex. No. 159–34B) examined the mortality experience of 8,666 employees and retirees of Exxon's Baton Rouge, Louisiana refinery and chemical plant who worked at least one month between 1970 and 1977. Among these employees, there were 1199 known deaths and 835 persons (9.6% of the cohort) were lost to follow-up. Mortality due to all causes was less than expected when compared with age, gender, race, and calendar-year specific U.S. death rates. Although they were not statistically significant, increases were observed in deaths due to diseases of the blood and blood forming organs (ICD8:280–289) (SMR=222), and cancers of the pancreas (SMR=152), testis and other genitalia (SMR=222), kidney (SMR=155), brain and central nervous system (SMR=102), all lymphopoietic cancers (SMR=109) and lymphoreticular sarcoma (SMR=119). For the group of 6,281 operators, mechanics and laborers, elevated SMRs were observed for all cancers of the disgestive tract, cancer of the esophagus, large intestine, pancreas, bladder, testis/other genitalia, kidney, brain/CNS, lymphoreticular sarcoma, cancer of other lymphatic tissues and for other lymphopoietic cancers. These results are suggestive of increased risks among these workers, especially when the large proportion of employees lost to follow-up and the exclusion of 142 workers with missing work histories from the calculation of SMRs by occupational category are considered. Also, the increase in deaths due to diseases of the blood and blood forming organs raises concerns about whether these deaths included cases of aplastic anemia.

In a preliminary report of a prospective study of the morbidity and mortality of petroleum industry employees in the U.S., Schottenfeld et al. (1981) (Ex. No. 128–26) observed statistically significant increases in the incidence of acute and chronic lymphocytic leukemias among refinery workers, of multiple myeloma among petrochemical workers, and of cutaneous melanoma among workers in the Middle Atlantic region of the U.S. Expected values were derived from U.S. age-specific cancer incidence rates from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute for 1977. Seven cases of acute and chronic lymphocytic leukemias were observed among refinery workers compared with 2.6 expected for a standardized incidence ratio (SIR) of 274. Nonlymphocytic leukemias were increased in petrochemical and refinery workers (SIR=113) but not significantly. Multiple myeloma was elevated significantly among the petrochemical workers (SIR=552). The authors stated that these results should be viewed as preliminary because the period of observation was quite short, the number of older workers included in the analysis was limited, and the degree of underreporting of mortality was unknown.

Rushton and Alderson (1981) (Ex. No. 159–69) reported the results of a case-control study of leukemia deaths among men employed at 8 oil refineries in the United Kingdom. Two sets of controls were selected from the total refinery population: one was matched with cases by refinery and year of birth, the other was matched by refinery, year of birth and length of service. Job histories obtained from refinery personnel records were used to categorize each person's benzene exposure as low, medium, or high, and the potential benzene exposure of cases was compared with that of controls. Although no overall excess of deaths from leukemia was found when compared with expected numbers based on national rates, the risk of leukemia for men with medium or high exposure was significantly greater ($p=0.05$) than the risk for men with low benzene exposure.

Devine and Barron (1983) reported the results of a case-control study (Ex. No. 142–32B) within a cohort mortality study (Ex. No. 142–32A) of white male employees. The cohort from which the cases were drawn was made up of all persons employed for a cumulative total of at least 5 years at a Texaco refining, petrochemical or research facility and who worked at least one day between January 1, 1947 and December 31, 1977, and who were employed by the facility on their last day of employment or the December 1977 closing date. Employees who worked one to five years at the Port Arthur facilities were also included so that short employment patterns could be evaluated. Port Arthur employees made up 43% of the cohort. Among 19,077 white males, slightly elevated SMRs

were observed for cancer of the pancreas (SMR=104), brain cancer (SMR=108), Hodgkin's disease (SMR=106), leukemia (SMR=113), cancer of other lymphatic tissue (SMR=111) and benign neoplasms (SMR=144). The SMR for all causes of death was 84.

For the case-control study, case groups consisted of white males who had died from one of several types of cancer and for whom a work history record was available. The control group for the case-control study was randomly selected from the cohort of noncase while males who had a work history record and who had died after age 30. The work histories of this group were compared with those of each case group. Separate analyses were made for exposure if ever worked in a job category and for longest job worked. Rate ratios (RR) compared mortality in the exposed and unexposed persons for each job category.

Significantly elevated rate ratios were demonstrated for leukemia deaths among workers in utilities; asphalt plants; and lube oil refining; and among pipefitters and utilities controlmen. A significantly elevated rate ratio for other lymphatic cancer was found among persons employed in fluid catalytic cracking units (RR=3.1). Significantly elevated rate ratios were found for brain tumors among persons employed in research and quality control laboratories; filter units; paraffin, refrigeration and ammonia process units; general maintenance; and lube oil refining. A significantly elevated RR for pancreatic cancer was found in workers in packaging and shipping and in asphalt plants. A significantly elevated RR for stomach cancer was seen among gas plant; maintenance and yard; and lube oil refining workers; and among structural and metal workers and cleaners. Employees in general maintenance, yard work and in managerial jobs were at significantly increased risk of kidney cancer. Persons in many specific job categories were found to be at increased risk of cancer. Which of these categories has the potential for exposure to benzene is uncertain, but it is highly likely that pipefitters and maintenance workers are among those that have the relatively highest exposure to benzene.

In 1983, Shell Oil Company reported the results of an evaluation of mortality among active employees and retirees from two manufacturing locations (Ex. No. 142–13–A). Deaths occurred between January 1, 1973 and December 31, 1982. At the Wood River, Illinois Refinery, a significant excess of deaths due to leukemia was observed (14 observed; 6.4 expected) resulting in a SMR of 219 for all leukemia. Eight deaths were observed from acute myelogenous leukemia (AML) whereas 2.0 were expected, resulting in a SMR of 400. On the basis of these observations, an epidemiologic consultant to the company concluded:

> There is no reasonable possibility that the data are the result of any error or errors or random variations of consequence; nor is it likely that these findings can be attributed to confounding by a non-occupational cause of AML . . . . The specific cause of the excess of AML at Wood River is unknown. However, benzene is an established cause of AML, and there is anecdotal evidence that in years past benzene was present in the ambient air at Wood River at levels that exceed the current standard. Thus, benzene is the most likely cause of the excesses seen.

At the Deer Park, Texas Refinery facility, 6 deaths from all forms of leukemia were noted among refinery workers as compared to 2.60 expected, SMR-230. Three acute myelogenous leukemia deaths were observed versus about 0.8 expected, SMR-375. These results were of borderline statistical significance. The study of mortality at both of these facilities examined causes of death for "active" employees and retirees and excluded "terminees" who were not followed after termination of employment at Shell. Thus, the actual number of cases of leukemia related to exposure in this occupational setting may have been greater.

Further analysis by job category for the 14 leukemia deaths identified among the 3,976 white males included in the Wood River Refinery was submitted to OSHA in May 1984 (Ex. No. 160–12). Of 14 leukemia deaths identified (versus 6.6 expected) in the study, 3 had worked in laboratory jobs where benzene was used, 5 spent most of their careers as maintenance workers, but it was not known if they were assigned to benzene units, while 6 were categorized as probably having no benzene exposure above refinery background levels.

In December of 1984, the results of a case control study of the 14 leukemia deaths identified between 1973–1982 at the Wood River Refinery were submitted to OSHA (Ex. No. 165). A statistically significant relative risk of 9.5 for acute myelogenous leukemia was observed for engineering field foremen. Relative risks for leukemia for other department/job categories ranged between 1.5 and 4.6, but were not statistically significant. In the authors' opinion, the former observation met all criteria for a positive result. However, they felt its interpretation remained unclear. As a result of the statistical analyses presented, the authors concluded that the study produced no distinctly positive result and that the reason for the excess leukemia among the refinery workers remained unexplained. The authors raised several possible explanations for their failure to statistically associate the leukemia with any specific chemical. Among the limitations listed were small sample size, the jobs and departments described did not specify distinct substance exposures, and the substance of greatest interest to the authors, benzene, is volatile and could have drifted from location to location causing ostensibly unexposed jobs actually to entail exposure.

An historical prospective mortality study was conducted by Wong et al. (1983) for the Chemical Manufacturers Association (CMA) (Ex. No. 151–A). The mortality experience of 4,602 male chemical workers from seven plants who were occupationally exposed to benzene for at least 6 months between 1946 and 1975 was compared with that of 3,074 chemical workers from the same or similar plants who had no known occupational exposure to benzene. Vital status was followed through December 31, 1977. Of the 7,676 men in the total cohort, 6,463 (84.2%) were found to be alive, 1,036 (13.5%) were deceased, and 177 (2.3%) were of unknown vital status. Death certificates were obtained for 1,013 (97.8%) of the deceased employees. Those lost to follow-up were included in the analysis only until the last date of contact and their mortality experience was assumed to be similar to the rest of the cohort.

Exposure to benzene was divided into continuous (with some intermittent) exposure (3,536 men) and intermittent or casual exposure (1,066 men). Continuous exposure was divided into 4 categories of 8-hour TWAs and 3 categories of peak exposures:

	Parts per million
8=hour TWA	
Low	<1
Medium	1–10
High	11–50
Very High	>50
Peak	
Low	<25
Medium	25–100
High	>100

Intermittent exposure was characterized by peaks only, as indicated above. Each job was divided into 34 uniform tasks and the amount of time spent at each

task was determined. Benzene exposure for each task was based on available industrial hygiene measurements and production and process changes. These were summed for each job. Industrial hygiene data for some plants were limited prior to 1970. Two plants (6 and 7) did not use the uniform task approach and exposures were estimated by supervisors or an industrial hygienist.

The standardized mortality ratio (SMR) was used to compare cause-specific mortality for both those exposed and unexposed to benzene with the general U.S. population. Expected values were based on U.S. national age-cause-race-specific mortality rates for 5-year time periods from 1946–1977. For some site-specific cancers that appeared to be in excess among the benzene exposed cohort, further analyses were conducted contrasting observed deaths in the exposed group with observed deaths among workers at the same plants who were not exposed to benzene. The Mantel-Haenszel chi-square and relative risks were used for these comparisons.

Age and race adjusted Mantel-Haenszel chi-squares and relative risks for all lymphatic and hematopoietic cancers combined indicated a significantly increased risk for benzene exposed (continuous and intermittent) white males (RR=4. 66, p=0.03) when compared to the non-exposed workers. This excess was primarily due to seven leukemia deaths observed in the exposed group and none observed in the nonexposed group. When only continuously benzene exposed workers were compared with the nonexposed group, the excess of lymphopoietic cancer was significant for white males and all males, respectively (RR=5.3, p=0.02; RR=3.2, p=0.04). None of the seven leukemia deaths were of the acute myelogenous cell type. Two were chronic myeloid leukemia, two were chronic lymphatic leukemia, and one each was from unspecified lymphatic leukemia, acute lymphatic leukemia, and acute other unspecified leukemia. The remaining lymphatic and hematopoietic cancer deaths in benzene exposed workers were due to multiple myeloma (3), reticulum cell sarcoma (3), Hodgkin's disease (2), lymphosarcoma (1), and other lymphoid tissue neoplasms (3).

Of the 3 deaths from multiple myeloma observed among the benzene exposed workers, 2 were identified among the intermittent exposure group as compared to 0.56 expected (RR=3.8) based on U.S. rates. (Since deaths from multiple myeloma were not observed among the non-benzene exposed workers, an expected value based on the latter group would not have been appropriate.)

Analysis by length of exposure indicated to the author that it was not a particularly sensitive parameter for quantification of either leukemia or lymphopoietic cancer mortality risk. However, when the data were analyzed by cumulative exposure, statistically significant dose-response relationships were detected for leukemia as well as for the broader category of all lymphopoietic cancer. As shown in Table C, for those with less than 180 ppm-months of exposure, a 2-fold risk of all lympho-hematopoietic cancers was observed, whereas for those with more than 720 ppm-months of benzene exposure, a 4-fold relative risk of all lymphatic and hematopoietic cancers combined was observed when compared to the mortality experience of non-benzene exposed employees. The Mantel-Haenszel chi-square was significant for an upward trend analysis for all lymphohematopoietic cancers (p=0.02) and for leukemia (p=0.01) and of borderline significance (p=0.057) for non-Hodgkin's lymphopoietic cancer.

TABLE C.—MANTEL-HAENSZEL RELATIVE RISKS AND EXTENSION CHI-SQUARES FOR LYMPHATIC AND HEMATOPOIETIC CANCER, LEUKEMIA, NON-HODGKIN'S LYMPHOMA AND NON-HODGKIN'S LYMPHOPOIETIC CANCER BY CUMULATIVE OCCUPATIONAL EXPOSURE TO BENZENE, ADJUSTED FOR AGE AND RACE

Cause of death (8th ICD)	Cumulative exposure (ppm-months)	Observed deaths	Relative risk	Chi-Square	p-value
Lymphatic and hematopoietic cancer (200–209)	Non-exposed	3	1.00		
	<180	5	2.10		
	180–719	5	2.95	[1] 5.42	0.020
	[2] 720	5	3.93		
Leukemia and aleukemia (204–207)	Non-exposed	0			
	<180	2			
	180–719	1	([3])	[1] 6.46	0.011
	[2] 720	3			
Non-Hodgkin's lymphoma (200, 202, 203)	Non-exposed	2	1.00		
	<180	3	1.40		
	180–719	3	2.23	0.14	0.713
	[2] 720	1	1.07		
Non-Hodgkin's lymphopoietic cancer (200, 202-207)	Non-exposed	2	1.00		
	<180	5	2.71		
	180–719	4	2.96	3.64	0.057
	[2] 720	4	4.12		

[1] Statistically significant at the 0.05 level.
[2] Lymphatic and hematopoietic cancer includes Non-Hodgkin's lymphoma, Hodgkin's disease and leukemia.
[3] Undefined.
Source: Wong et al. (1983) (Ex. No. 151–A).

Analyses were also performed to determine the relationship between peak exposure to benzene, i.e., maximum peak below 25 ppm, or between 25–100 ppm, or above 100 ppm, and relative risk. No significant peak exposure response relationship was observed. These findings suggest that a cumulative dose concept may be better than a maximum peak exposure concept when trying to determine dose-response relationships. It should be noted, however, that those experiencing peak exposures below 25 ppm had a relative risk of 3.4 while those subjected to peaks exceeding 100 ppm had a relative risk of 3.1. Thus, lack of a peak exposure response relationship in the study may be the reflection of a high relative risk among those experiencing relatively lower peak benzene exposures.

As a result of the analyses, Wong et al. concluded that there was a significant association between occupational exposure to benzene and leukemia, all lymphopoietic cancers, as well as non-Hodgkin's lumphopoietic cancer.

A number of studies have noted exesses of mortality from chronic lymphatic leukemia, myelogenous leukemia and lymphosarcoma among persons exposed to benzene and benzene containing solvents while employed in the rubber industry (McMichael et al, 1975, Ex. No. 128–18; Monson and Nakano, 1976, Ex. No. 128–20; Tyroler et al, 1976, Ex. No. 144–21; Delzell and Monson, 1982, Ex. No. 144–32).

The International Agency for Research on Cancer (IARC) (1982) (Ex. No. 159–38A) has reviewed many of the epidemiologic studies of cancers risk among workers in the rubber industry. Excesses of cancer of the lymphatic and hematopoietic systems were observed among rubber workers in both the U.S. and the U.K. IARC concluded that there was sufficient evidence to indicate an excess occurrence of leukemia in rubber workers and to indicate a causal association with occupational exposures, presumably to solvents.

An increased risk of leukemia has been reported among persons with

atomic bomb exposure and potential occupational exposure to benzene as compared to individuals who experienced atomic bomb exposure only (Ishimaru et al, 1971, Ex. No. 128–16). In all of these studies, potential exposure to benzene was assumed from history or occupation.

Some studies of workers occupationally exposed to benzene have not reported significant excesses of cancer. Thorpe (1974) (Ex. No. 144–202) reviewed data for 38,000 petroleum refining and petrochemical workers in eight European countries and reported no excess of deaths due to leukemia. IARC reviewed this study and stated "the study suffers from problems of ascertainment, specificity and validity of diagnosis and the 'healthy worker effect' in the calculation of SMRs" (IARC, 1982, Ex. No. 128–8). More detailed discussions of the limitations of the methodology used by Thorpe have been published (Brown, 1975; IARC, 1982; Infante and White, 1983) (Ex. Nos. 159–14, 2–35, 128–8).

In a study involving 784 persons employed in footwear and tire processing and fabrication in a Finnish rubber plant for at least 3 months between 1953 and 1976, Kilpikari (1982) (Ex. No. 144–158) reported no significant excess cancer risk. However, the number of workers studied was quite small and the follow-up period was short, resulting in little statistical power to detect any increase in risk, if one were present. Furthermore, the relative risk of death due to cancer among person exposed for more than 10 years was 1.7.

The induction period for benzene and leukemia appears to have a wide range. Deaths from leukemia among workers occupationally exposed to benzene have occurred in as short a time period as 2 years and as long as 50 years after estimated onset of exposure. We have attempted to estimate the induction period from reports that provided the data to allow such an analysis.

Aksoy (1977) [Ex. No. 144–160] reported 34 cases of leukemia among shoeworkers in Turkey between the years 1967 and 1975. Proliferation of benzene as a major solvent in the shoe industry in Turkey began in 1961 and was prohibited from use as a solvent in 1969. Assuming that all the cases were first exposed in 1961, his report indicates that the induction period for the 34 leukemia cases ranged from 6 to 14 years with a median of 11 years. If cases were first exposed after 1961, the induction period obviously would be shorter. If follow-up were extended, the average induction period might either increase or decrease depending upon year of initial exposure and death.

Vigliani (1976) [Ex. No. 128–5] reported the induction period to range from 3 to 23 years with a median period of 9 years based on 11 cases of acute leukemia observed at the Clinica del Lavoro of Milano. The NIOSH report (Rinsky et al. 1981) [Ex. No. 128–32] indicates a median period of 12 years (range 2 to 22 years) between initial benzene exposure and death from leukemia based on the 8 cases that fit the study cohort definition and follow-up period. The induction period may be overestimated in this study for two reasons. First, induction period was defined as the interval between initial exposure and death rather than clinical recognition of leukemia; second, by cohort definition, workers who were initially employed between 1937–1949 had to survive between 1 and 13 years to be included in the study cohort. (Follow-up began in 1950.) Thus, individuals who may have died from leukemia with a short induction period would not have been included in the study.

In the recent CMA study by Wong et al. (1983) [Ex. No. 152], the median induction period for 7 leukemia deaths ranged between 6 and 49 years with a median of 28 years. OSHA believes, however, that estimates of leukemia induction period based on this study would be overestimated. Induction period was again defined as the time interval between initial exposure to benzene and death, rather than clinical manifestation of leukemia. This distinction is of particular importance in the Wong et al. study as the major cell type of the leukemia deaths was lymphocytic—a cell type which has a much longer survival time than myelogenous leukemia (the most common cell type associated with benzene exposure). Because of advances in treatment, individuals with lymphatic leukemia may survive 20 or more years, whereas, those diagnosed with myelogenous leukemia usually do not survive more than a year.

The study of primarily retired Shell Oil company workers employed at the Wood River, Illinois and Deer Park, Texas facilities indicates a period of 17 to 54 years between date of hire and death from leukemia [Ex. No. 142–13]. The median period was 36 years for 14 Wood River leukemia deaths and 33 years for 8 Deer Park leukemia deaths. The induction period for leukemia as a result of benzene exposure from this study would be biased toward an overestimate, because the study consisted mainly of retired workers. These workers had to survive to retirement in order to be included in the study. Vital status of terminated workers was not determined. Date of initial employment (from which induction period was estimated) did not necessarily correspond to date of initial exposure to benzene, which could not be clearly defined.

On the basis of the evaluation of the above mentioned reports that considered induction period for leukemia, OSHA believes that the reports by Aksoy (1977), Vigliani (1976) and NIOSH (1981) (Ex. Nos. 144–160, 128–15, 32) provide the most complete data and largest numbers of cases upon which to make such an estimate. The Aksoy report suggests an induction period of 11 years based on 34 cases of leukemia, the Vigliani reports suggests a period of 9 years based on 11 cases of leukemia and the NIOSH study indicates a median period of 12 years (based on 8 deaths) between initial exposure to benzene and death from leukemia. Thus, OSHA preliminarily believes that 11 years is a reasonable estimate of the average time for the induction of leukemia associated with occupational exposure to benzene. Public comment on this question is solicited.

C. Cytogenetic Effects in Humans

Cytogenetic changes indicate an alteration in the genetic material (DNA) of a cell. An increasing amount of evidence indicates that latent diseases such as cancer, birth defects, and genetic disease may be initiated by alterations in cellular DNA (Bloom et al., 1981) (Ex. No. 159–12). Thus, cytogenetic studies analyze alterations or aberrations in the structure or number of chromosomes and exchanges of segments between the two chromatids or arms of a chromosome, called sister chromatid exchange. These changes in the chromosomes indicate that the DNA or genetic material of the cell has been altered by some genotoxic agent.

Induced cytogenetic changes in lymphocytes have been shown to be a sensitive indicator of low level exposure, brought about by such factors as occupational exposure to radon daughters and exposure to ionizing radiation (Bloom et al. 1981) (Ex. No. 159–12). Although such undesirable changes cannot be used to predict specific health effects in an individual, they do give an estimate of the magnitude of an exposure that could increase the risk of disease (under question) in the exposed population (Bloom et al. 1981) (Ex. No. 159–12). Consequently, as stated by an expert

panel on cytogenetics, "* * * cytogenetic study of both chromosomal aberrations and SCEs (sister chromatid exchanges) has a clear place in the evaluation of human populations exposed to known or suspected mutagens * * *. Furthermore, many, if not most, agents causing aberrations, or clastogens, are also carcinogens, at least in animals" (Bloom et al. 1981) (Ex. No. 159-12). In addition to benzene, several substances known to cause chromosomal aberrations in humans are also known to cause cancer in humans, i.e., vinyl chloride, radon daughters, ionizing radiation, arsenic, myleran, melphalan, and chromium (IARC, Suppl. 4, 1982) (Ex. No. 159-38). Moreover, individuals who have inherited chromosome breakage syndromes like Fanconi's anemia, Bloom's syndrome and ataxia telangiectasia, or persons with chromosomal anomalies like Down's Syndrome are known to have increased risk of developing cancer.

Thus, numerous investigators have studied chromosomal aberrations in bone-marrow cells and peripheral lymphocytes from persons known to have been exposed to benzene, including patients with either a current or a past history of benzene-induced blood dyscrasias. Studies have repeatedly demonstrated significant increases in chromosomal aberrations. This literature has been reviewed by IARC (1982) (Ex. No. 128-8). Therefore only some of the studies indicating benzene induced chromosomal damage will be discussed here.

Forni and collaborators (Forni et al., 1971a,b) (Ex. Nos. 128-48, 144-93) examined two groups of workers with chronic benzene poisoning. One group included 25 subjects who had recovered from benzene hemopathy one to 18 years previously, plus four others showing acute toxicity at the time of first chromosome examination. The other group was comprised of 34 workers in a rotogravure plant who had been exposed in 1952-1953 to concentrations of 125-532 ppm benzene in air, leading to toxic effects. Lymphocytes from both groups showed significantly higher levels of chromosomal aberrations than those from age-matched controls. Follow-up cytogenetic studies indicated a tendency toward a decrease in unstable aberrations and a persistence or increase in stable aberrations (Forni et al., 1971) (Ex. No. 128-48).

The finding of significant increases in chromosomal aberrations in blood and bone marrow (Forni and Moreo, 1967, 1969) (Ex. Nos. 128-46,47) and in lymphocytes from clinically symptomatic subjects exposed to benzene has been confirmed in several other investigations (Hartwich et al., 1969 (Ex. No. 128-51); Sellyei and Kelemen, 1971 (Ex. No. 128-58); Erdogen and Aksoy, 1973 (Ex. No. 128-53); Hudak Gombosi, 1977 (Ex. No. 128-54); Van den Berghe et al., 1979 (Ex. No. 128-55). Forni and Moreo (1967, 1969 (Ex. No. 128-46, 47)) hypothesized that such aberrations are involved in the eventual development of leukemia in benzene-exposed individuals.

Tough and others (Tough and Court Brown, 1965 Ex. No. 144-136; Tough et al., 1970 Ex. No. 128-49) studied workers in three different factories who had been exposed to benzene in the atmosphere for approximately one to 25 years. The workers showed no evidence of acute benzene toxicity. Among the 38 workers who had been exposed to 25-150 ppm benzene until two to four years prior to blood sampling, the incidence of cells with unstable chromosomal aberrations was higher than was expected in the general population. Other workers exposed intermittently to approximately 12 ppm benzene for 2-26 years showed no increase in chromosomal abnormalities in their lymphocytes. The authors hesitated, however, to relate these effects to benzene exposure alone, since there was evidence that age and other environmental factors may also have been contributory.

Other studies report increased levels of chromosomal aberrations in asymptomatic workers who had been exposed to benzene (Hartwich and Schwanitz, 1972 (Ex. No. 128-52); Khan and Khan, 1973 (Ex. No. 128-56), Fredga et al., 1979 (Ex. No. 128-57)). In one study, although the rate in individual workers was at the upper limit of normal (Hartwich and Schwanitz, 1972 (Ex. No. 128-52)), the mean aberration rate of cells from nine refinery workers exposed to relatively low levels of benzene was significantly elevated when compared with that in controls. In a study of lymphocytes from 12 industrial gasworks workers exposed to benzene, a statistically significant increase in chromosomal aberrations was found (Fredga et al., 1979) (Ex. No. 128-57). The increase in the 12 industrial workers studied was regarded as being due to benzene exposure (5-10 ppm).

Watanabe et al. (1980, Ex. No. 144-46) found no evidence of an increased frequency of chromosomal aberrations but reported a low frequency of sister chromatid exchange among nine female workers engaged in painting ceramics who had been exposed to 1-9 ppm for 1-20 years or in seven female workers who had been exposed to 3-50 ppm benzene for 2-12 years. However, urinary excretion of phenol was not elevated in post-shift samples when compared with pre-work samples in the same workers, indicating atmospheric exposures below 10 ppm at the time of the survey (NIOSH, 1974) (Ex. No. 84B-3).

A study of Dow Chemical Company workers indicates a significant increase in chromosomal aberrations in workers whose average benzene exposures were below 10 ppm (Kilian and Daniel, 1978) (Ex. No. 159-45). 52 benzene exposed workers whose average exposure was less than 10 ppm were compared with 44 per-employment controls. Workers who had been exposed to low-level benzene for an average of 56.6 months were found to have twice the percentage of chromosomal breaks and three times more marker chromosomes than the control group. Almost twice as many benzene workers as controls had both breaks and markers (p less than 0.01).

Picciano (1979) (Ex. No. 144-118) further analyzed the data from the Dow study. Thirty-eight exposed workers (73.1 percent) had chromosome breaks as compared to 18 nonexposed individuals (40.9 percent) with chromosome breaks. When individuals with both chromosome breaks and markers were compared, less than 3 percent of the non-exposed individuals showed changes while 27% of the workers exposed to bezene revealed such aberrations (p less than 0.001). These workers were also exposed to other aromatic hydrocarbon solvents. The degree of contact with those solvents was less than with benzene. An elevation of chromosomal aberrations was evident in workers exposed to less than 1 ppm as compared with controls. A linear dose-response relationship between chromosomal damage and benzene levels ranging between less than one and 10 ppm was observed.

D. Experimental Evidence of Carcinogenicity

Since the publication of the 1978 benzene standard, new experimental results demonstrating benzene induced cancer in animals have been reported. These studies were carried out in three independent research centers: the University of Bologna, Italy, under Dr. C. Maltoni, the New York University under Dr. C.A. Snyder and the National Toxicology Program (NTP) with Dr. James Huff as project manager. All three studies found benzene to be carcinogenic in animals.

Maltoni and Scarnato (1979) (Ex. No. 144-76) reported that doses of 50 and 250 mg/kg of body weight of benzene

given orally to Sprague-Dawley rats 4-to-5 days weekly for 52 weeks was carcinogenic, in a dose-response manner. Benzene was found to cause Zymbal gland carcinomas, mammary carcinomas and leukemias. Among the female rats, 0/30, 2/30 and 8/22 of the control, low and high dose groups, respectively, developed Zymbal gland carcinomas. Using the Cochran-Armitage test, the positive trend was statistically significant ($p=0.001$). Using the Fisher exact test, the difference in frequency of Zymbal gland carcinomas between the control and high-dose group was also significant, $p=0.003$. Among the same groups of female rats 3/30, 4/30 and 7/32, respectively developed mammary gland carcinomas, and 1/30, 2/30 and 1/32, respectively, developed leukemias.

Among the male rats of the control, low and high dose groups, 0/30, 0/30 and 4/33 developed leukemias (unspecified). Using the Cochran-Armitage test the positive trend was statistically significant ($p=0.008$) but the difference between the control and high dose groups was not significant using the Fisher exact test ($p=0.069$) (IARC, 1982) (Ex. No. 128–8). No Zymbal gland carcinomas were observed in either the control or benzene treated male rats. In the high dose group, Maltoni and Scarnato (1979) (Ex. No. 144–76) also observed two female rats with skin carcinomas and one male rat each with a hepatoma and a subcutaneous angiosarcoma. These types of tumors were not observed in the control or low dose groups.

In another study by Maltoni et al. (1982) (Ex. No. 144–30), Zymbal gland carcinomas were induced in rats exposed to airborne concentrations of benzene. In these studies benzene was administered by inhalation at a concentration of 200 ppm, 4-hours daily, 5-days a week to pregnant Sprague Dawley rats from the 12th day of pregnancy up to the delivery of the offspring. The offspring were then exposed by inhalation to 200 or 300 ppm of benzene for 4 or 7 hours per day, respectively, for 5-days a week for up to 104 weeks. At 104 weeks, of the 137 male and female rats at risk, eight (5.87%) had developed Zymbal gland carcinomas as compared to 0% for the concurrent controls.

Snyder et al. (1978) (Ex. No. 144–127) published a preliminary report on inhalation studies of benzene in CD–1 mice. Groups of 40 CD–1 mice were exposed for 6 hours/day, 5 days/week, for life to atmospheric concentrations of O (control), 100 ppm or 300 ppm benzene. Two mice in the 300 ppm benzene exposed groups developed myelogenous leukemia. No leukemias were observed in the control or 100 ppm benzene exposed groups.

Snyder et al. (1980) (Ex. No. 128–77) reported 8 cases of lymphoreticular neoplasm (6 thymic lymphocytic lymphomas, 1 plasmocytoma, and 1 hemocytoblastic leukemia) among 40 C–57 black mice exposed to airborne concentrations of 300 ppm benzene for 6 hours a day, 5 days a week for life. Among the control mice, two developed hemolymphoreticular neoplasms (two lymphocytic lymphomas). The increase in these neoplasms among the treated mice was statistically significant ($p=0.005$).

The National Toxicology Program (NTP) has recently completed a 2-year chronic toxicity study of benzene in mice and rats (Ex No. 148). Male rats were administered benzene doses of 50, 100 and 200 mg/kg of body weight by oral gavage for two years. Female rats were administered 25, 50 and 100 mg/kg. Mice of both sexes were administered benzene doses of 25, 50 and 100 mg/kg. There were 50 animals per sex per treated group plus 50 animals per sex for the control group. Benzene was carcinogenic for male and female F344 rats and male and female B6C3F1 mice. Leukopenia also was induced in both sexes of mice and rats.

NTP (Ex. No. 148) concluded the following:

> Under the conditions of these studies, there was clear evidence of carcinogenicity of benzene for male F344/N rats, female F344/N rats, male B6C3F$_1$ mice and female B6C3F$_1$ mice. For male rats, benzene caused increased incidences of Zymbal gland carcinomas, squamous cell papillomas and squamous cell carcinomas of the oral cavity, and squamous cell papillomas and squamous cell carcinomas of the skin. For female rats, benzene caused significantly increased incidences of Zymbal gland carcinomas and squamous cell papillomas and squamous cell carcinomas of the oral cavity. For male mice, benzene caused increased incidences of Zymbal gland squamous cell carcinomas, malignant lymphomas, alveolar/bronchiolar carcinomas and alveolar/bronchiolar adenomas or carcinomas (combined), Harderian gland adenomas, squamous cell carcinomas of the preputial gland. For female mice, benzene caused increased incidences of malignant lymphomas, ovarian granulosa cell tumors, ovarian benign mixed tumors, carcinomas and carcinosarcomas of the mammary gland, alveolar/bronchiolar adenomas, and alveolar/bronchiolar carcinomas.

The following tables summarize the major increases in the incidence of tumors found in the NTP study.

TABLE I.—INCIDENCE OF SELECTED TUMORS IN THE MALE F 344/N RAT[1]

Types of tumor	Dose (in ppm's and percent)			
	Vehicle control (O ppm)	50 mg/kg (57 ppm)[2]	100 mg/kg (117 ppm)	00 mg/kg (234 ppm)
Zymbal gland carcinoma	2/50 (4)	6/50 (12)	10/50 (20)	17/50 (34)
Squamous cell papillomas (oral cavity)	1/50 (2)	6/50 (12)	11/50 (22)	13/50 (26)
Squamous cell carcinomas (oral cavity)	0/50 (0)	3/50 (6)	5/50 (10)	7/50 (14)
Squamous cell Papillomas (skin)	0/50 (0)	2/50 (4)	1/50 (2)	5/50 (10)
Squamous cell carcinomas (skin)	0/50 (0)	5/50 (10)	3/50 (6)	8/50 (16)

[1] NTP Study, 1983.
[2] Equivalent 8-hour atmospheric exposure level for 5 days per week assuming 100 percent absorption.

TABLE II.—INCIDENCE OF SELECTED TUMORS IN THE FEMALE F 344/N RAT[1]

Types of tumor	Dose (in ppm's and percent)			
	Vehicle control (0 ppm)	25 m/kg (24 ppm)[2]	50 mg/kg (48 ppm)	100 mg/kg (97 ppm)
Zymbal Gland Carcinomas	0/50 (0)	5/50 (10)	5/50 (10)	14/50 (28)
Squamous cell papillomas (oral Cavity)	1/50 (2)	4/50 (8)	8/50 (16)	5/50 (10)
Squamous cell carcinomas (oral Cavity)	0/50 (0)	1/50 (2)	4/50 (8)	5/50 (10)

[1] NTP Study, 1983.
[2] Equivalent 6-hour atmospheric exposure level for 5 days per week assuming 100 percent absorption.

TABLE III.—INCIDENCE OF SELECTED TUMORS IN THE MALE B6C3F1 MOUSE [1]

Types of tumor	Dose (in ppm's and percent)			
	Vehicle Control (0 ppm)	25 mg/kg (20 ppm)[1]	50 mg/kg (40 ppm)	100 mg/kg (80 ppm)
Zymbal gland squamous cell carcinomas	0/49 (0)	1/48 (2)	4/50 (8)	21/49 (43)
Malignant lymphomas	4/49 (8)	9/48 (19)	9/50 (18)	15/49 (31)
Alveolar/bronchiolar carcinomas	5/49 (10)	11/48 (23)	12/50 (24)	14/49 (29)
Alveolar/bronchiolar adenomas or carcinomas (combined)	10/49 (20)	16/48 (33)	19/50 (38)	21/49 (43)
Harderian gland adenomas	0/49 (0)	9/48 (19)	13/50 (26)	11/49 (22)
Squamous cell carcinomas (preputial gland)	0/49 (0)	3/48 (6)	18/50 (36)	28/49 (57)

[1] NTP study, 1983.
[2] Equivalent 8-hour atmospheric exposure level for 5 days per week assuming 100 percent absorption.

TABLE IV.—INCIDENCE OF SELECTED TUMORS IN THE FEMALE B6C3F1 MOUSE [1]

Types of tumor	Dose (in ppm's and percent)			
	Vehicle control (0 ppm)	25 mg/kg (19 ppm)[2]	50 mg/kg (38 ppm)	100 mg/kg (76 ppm)
Malignant lymphomas	15/49 (31)	24/25 (53)	24/50 (48)	19/49 (39)
Ovarian granulosa cell tumors	1/47 (2)	1/44 (2)	6/49 (12)	7/48 (15)
Ovarian benign mixed tumors	0/47 (0)	1/44 (2)	12/49 (24)	7/48 (15)
Mammary gland carcinomas	0/49 (0)	2/45 (4)	5/50 (10)	10/49 (20)
Alveolar/bronchiolar adenomas	4/49 (8)	2/42 (5)	5/50 (10)	9/49 (18)
Alveolar/bronchiolar carcinomas	0/49 (0)	3/42 (7)	6/50 (12)	6/49 (12)

[1] NTP Study, 1983.
[2] Equivalent 8-hour atmospheric exposure level for 5 days per week assuming 100 percent absorption.

At the time of the 1978 rulemaking, there was controversy on whether benzene had been clearly demonstrated to cause cancer in experimental animal studies. All these studies have provided considerable evidence that benzene is a carcinogen in animals and that benzene administered orally or by inhalation produces tumors at multiple sites in animals. OSHA preliminarily concludes there is evidence that benzene is a potent carcinogen in animals on the basis of multiple site carcinogenicity in both sexes of 2 species of experimental animals and at the lowest dose tested which is equivalent in humans to 19–24 ppm benzene inhaled over an 8-hour workday. These findings add support to the evidence that benzene is a human carcinogen and suggest that cancers other than of the lympho-hematopoietic system also may be involved in humans.

E. Experimental Evidence: Subchronic Effects

Recently, a subchronic inhalation toxicity study of benzene in Sprague-Dawley rats and CD–1 mice has been reported (Ward et al. 1982) (Ex. No. 159–95). Groups of 150 mice or 50 rats per sex were exposed to concentrations of 1, 10, 30, or 300 ppm of benzene vapor, 6 hours per day, 5 days per week, for 13 weeks. Additional rats and mice of similar sized groups were exposed under similar conditions (filtered air) and served as controls. Thirty mice and 10 rats per sex in each group were killed after 7, 14, 28, 56 and 81 days of treatment. The criteria used to evaluate exposure effects included: Behavior, body weights, organ weights, clinical and gross pathology, and histopathology. Fifty animals per sex of each species were also concurrently exposed for cytogenetic studies. In addition, blood serum was obtained for immunological assays. No consistent exposure-related trends were observed by clinical observations or in body weight. Exposure-related clinical pathologic changes were seen in animals of both species exposed to the highest concentration (300 ppm). In the mice, these changes included decreases in hematocrit, total hemoglobin, erythrocyte count, leukocyte count, platelet, count, myeloid/erthyroid ratios and percentage of lymphocytes. Mean cell volume, mean hemoglobin, glycerol lysis times, percentage of neutrophils, and the incidence and severity, the red cell morphologic changes were decreased in the mice. In the rats, decreased leukocyte counts and decreased lymphocyte percentages were the only exposure-related clinical pathological alterations. Histopathological evaluations revealed changes in the thymus, bone marrow, lymph node, spleen and testes of mice exposed to 300 ppm and in most cases the severity of incidence of the lesions was greater in the males. Exposure-related lesions consisted of a slightly decreased femoral bone marrow and cellularity in animals receiving 300 ppm. This study was not designed to determine carcinogenicity as the animals were only exposed for 13 weeks rather than for lifetime (104 weeks) as required for carcinogenicity testing.

F. Experimental Evidence: Cytogenetic and Other Effects

Numerous studies have demonstrated the induction of chromosomal aberrations in several species of experimental animals. These data have been recently reviewed by IARC (1982) (Ex. No. 128–8). Only the studies completed since the IARC review are discussed below.

At a meeting held by the Permanent Commission and International Association on Occupational Health in August 1983 (Ex. No. 159–62A). Tice and colleagues summarized results from a series of cytogenetic studies in mice exposed to benzene by various routes of administration at Brookhaven National Laboratory. Among their findings were the observations that:

1. One four-hour inhalation exposure to benzene at concentrations ranging from 28 ppm to 3000 ppm induced a linear increase in SCEs in mouse bone marrow cells. A single atmospheric exposure to 28 ppm, the lowest dose tested in this experiment, resulted in a 2-fold elevation in SCEs (Tice et al., 1982) (Ex. No. 159–88). 2. Modification of the magnitude of the SCE response to inhaled benzene by age (3–12 mo.), gender (male vs female), and genetic constitution (DBA/2 vs C57B1/6) emphasized the importance of these factors when attempting to extrapolate animal data to human health risks and suggested that segments of the population sensitive to one or more of the genotoxic/cytotoxic effects of benzene probably exist (Tice et al., 1982) (Ex. No. 159–88). 3. Exposure to benzene at concentrations ranging from 10 to 400 ppm for 9 days (6 hr/day) induced a significant increase in micronuclei (a measure of bone marrow chromosomal damage) in peripheral blood cells of C57B1/6 male mice.

Recent work at New York University Medical Center (Ex. Nos. 146–1, 2,) has

demonstrated that exposure of C57B1 mice to 10 ppm benzene for 6 days reduced the mitogen-induced blastogenesis of femoral B-cells to 30% of control values. Moreover, 6 days exposure to 10 ppm was just as effective at reducing blastogenesis as 6 days exposure to higher benzene concentrations. In addition, splenic T-cell mitogen-induced blastogenesis was reduced to about 40% of control values after 6 days of exposure to concentrations of 31 ppm benzene. These results indicated to the authors that exposures to benzene at or near the current occupational exposure limit may affect certain immune functions.

In a study by Baarson et. al (1983) (Ex. No. 146–2), C57B1 mice were exposed 6-hours a day, 5-days a week to 10 ppm of benzene for 178 days. Benzene was found to cause a progressive depression in the *in vitro* Colony forming ability of one of the erythroid progenitor cells (CFU–E). Colony growth of cells from exposed mice was only 5% of control colony growth after 178 days of exposure. Burst forming cell growth was depressed to 55% of control growth after 66 days but returned to control growth values at 178 days. The benzene exposed mice also exhibited depressions in the number of splenic nucleated red cells and in the number of circulating red cells and lymphocytes. The authors suggest that these results demonstrate that low level exposure to benzene may be hematotoxic.

Until recently, the data available from short-term tests on the mutagenic potential of benzene indicated that benzene induces chromosomal damage but not mutations. These data have been the subject of several reviews (IARC) (Ex. No. 128–8); Von Halle (1983, Ex. No. 159–94). *In vivo* and *in vitro*, benzene has been shown to cause chromosome breaks, aberrations, and sister chromatid exchanges. Benzene has been found to be negative in the Salmonella/microsome assay and in other prokaryotes. No evidence could be found in the published literature reviewed by Von Halle for the induction of point mutations in lower organisms and in mammalian cell culture systems. However, Kale and Baum (1983, Ex. No. 159–44) found that benzene did not induce significant increases in sex-linked recessive lethal mutations or translocations in Drosophila or crossovers in Drosophila spermatocytes when compared with unexposed controls. However, induction of crossing-over in spermatogonia was several times more than that in controls. The authors concluded from these findings that benzene may be a stage-specific chemical and that if mutations can also be induced in spermatogonial cells, then replication may be required for mutation induction by benzene.

Crespi and Penman (1984, Ex. No. 159–19A) reported at the 15th Annual Meeting of the Environmental Mutagen Society that benzene was found to be mutagenic in human cells in a recently developed gene-locus mutation assay utilizing a metabolically competent human lymphoblastoid cell line. This assay measures the induction of mutations at the hypoxanthine guanine phosphoribosyl transferase locus via resistance to the purine analog 6-thioguanine (6TG). The mutant frequency in the benzene treated cultures was statistically greater than both the concurrent negative controls (p less than 0.005) and the historical negative control data base for this cell line and locus (p less than 0.0001). OSHA solicits comments and further information on the mutagenicity of benzene.

G. Absorption of Benzene Through the Skin

Two of the earliest studies on skin absorption of benzene in humans were carried out in Italy in 1946 and 1955. Cesaro (1946) (Ex. No. 2–47) exposed human volunteers for 20–30 minutes in an airtight box saturated with benzene. The subjects' heads were outside the box. No benzene was detected in the breath of these subjects. The ratio of inorganic sulfate to total sulfate excreted in urine is used as an indicator of the breakdown of the metabolites of benzene in the body, and thus indicates absorption of benzene. There was no significant change in this ratio in the urine of the subjects of this study.

Conca and Maltagliati (1955) (Ex. No. 2–46) carried out measurements of benzene in breath and urinary sulfate ratio of three human volunteers. Subjects were fitted with fume masks to prevent inhalation of benzene, and their hands and forearms were immersed in benzene for 25–35 minutes. Skin irritation with burning and painful sensations occurred after 5–10 minutes. No benzene was detected in the breath and no change in urinary sulfate ratio was found.

Both studies used limited analytical methodology. The determination of breath benzene level used a colorimetric method that could not detect trace or very low levels of benzene. The urinary sulfate ratio measurements are not sensitive enough to detect benzene absorption unless considerable amounts of benzene are absorbed.

Hanke et al. (1961) reported that complete saturation of the skin of the human forearm with benzene resulted in absorption at a rate of 0.4 mg/cm^2 of surface area per hour (Ex. No. 144–175).

Maibach reported results of studies of skin absorption in the rhesus monkey using carbon ^{14} labeled benzene (Ex. No. 143–2a,b). The studies addressed single and multiple exposures of intact skin of the forearm to full strength (100%) benzene and a benzene containing (0.35%) rubber solvent used in passenger tire manufacturing. One study protocol addressed single exposures to stripped skin with 100% benzene. Single exposures to the palmar surface of the hand with the tire rubber solvent were also evaluated. A single application of full strength benzene to intact skin of the forearm resulted in 0.172% of the benzene being absorbed while multiple exposures resulted in 0.766% being absorbed. A single exposure of full strength benzene to stripped skin of the forearm resulted in 0.909% absorption. A single exposure to 0.35% benzene in a rubber solvent to the palmar surface of the hand resulted in 0.597% benzene absorption, whereas a single exposure to the same solvent on intact skin of the forearm resulted in 0.080% absorption. Multiple exposure to the solvent on the forearm resulted in 0.597% benzene absorption. These studies suggest that multiple exposures to benzene on the skin result in a greater percentage being absorbed as compared to a single exposure. They also indicate greater skin penetration of benzene for the palm as compared to forearm skin. As would be expected, a single application of benzene to stripped skin resulted in a 5 times greater penetration of benzene as compared to absorption through intact forearm skin.

In September 1983, OSHA requested that NIOSH undertake a study of the amount of benzene absorbed through the skin as a result of skin contact with petroleum naphtha, a solvent commonly used in tire building operations. The results of the study by Susten et al. were submitted to OSHA in April 1984 (Ex. No. 156A).

The NIOSH study was conducted on hairless mice using dermal application of petroleum naphtha containing 0.5 percent benzene radiolabeled with ^{14}C. Under the conditions of the experiment, approximately 1 percent of the applied benzene was absorbed through the skin. On the basis of these results, NIOSH calculated that a worker building 150 tires per day could absorb approximately 6 mg of benzene daily through intact skin; the upper and lower 95 percent confidence limits are 8.4 and 3.7 mg/day. The 6 mg of benzene absorbed through the skin may be

compared to an estimated 14 mg of benzene that would result from inhalation of 1 ppm over an 8-hour day (Ex. No. 143–2b). According to the NIOSH investigators these quantitative findings are consistent with those of Maibach who studied benzene absorption through the intact skin of rhesus monkeys.

Workers building tires are known to have cracked and fissured skin on their hands as a result of daily contact with tire building solvents. Thus, evaluation of benzene absorption through skin that is not intact may have a bearing on the actual benzene skin penetration of workers building tires. In this regard, the study by Maibach (Ex. No. 143–2b) indicates that benzene exposure to stripped skin in the rhesus monkey results in 5.3 times the absorption as compared to exposure to intact skin. If this factor is applied to the study results of NIOSH or Maibach, approximately 32 mg (6 mg × 5.3) of benzene could be absorbed daily through the skin as a result of exposure to petroleum naphtha in tire building operations. OSHA seeks comments on these studies.

H. Metabolism

The metabolism of benzene in humans and animals follows many similar pathways (Rusch et al., 1977, Ex. No. 159–68). Benzene is metabolised in the liver and its primary oxidative products include phenol, catechol and quinol. Further oxidation may produce hydroxyquinol and muconic acid. Subsequently, these oxidative products are transformed to phenylsulfuric and phenylgluconic acids, which are excreted as their alkaline salts.

The primary oxidation of benzene occurs via the cytochrome p-450-dependent monooxygenase system, resulting in biologically reactive intermediates, such as benzene oxide which spontaneously forms phenol (Irons and Pfieffer, 1982 Ex. No. 159–41). Evidence indicates that benzene per se does not represent the principal structural moiety causing the identified toxic effects on the bone marrow or lymphoid system (Irons and Pfeiffer, 1982, Ex. No. 159–41).

The metabolism and elimination of benzene in humans appear to be similar to those in rats and mice; the amounts of various metabolites, the extent of metabolism, and the nature of the phenol conjugates depend on the species, strain, and route of administration (Rusch et al., 1977, Ex. No. 159–68). The similarities in the metabolism of benzene and similar effects on bone marrow toxicity in both animals and humans would tend to support the use of rats and mice for bioassay studies on the carcinogenicity of benzene.

Irons (1983) (Ex. No. 159–41A), has shown that hydroquinone, a benzene metabolite, does cause bone marrow suppression in the mouse and under an appropriate experimental regimen will produce symptomatology that is consistent with aplastic anemia. Irons (1983) (Ex. No. 159–41A) also reported that intermittent exposure appears to be much more potent at producing bone marrow aplasia than continuous exposure to a relatively greater amount of benzene and suggested that protection of workers in an occupational setting requires prevention of peak exposures rather that the progressive lowering of the TWA in the absence of regulating or limiting transient exposure situations.

VI. Preliminary Quantitative Risk Assessment for Benzene

A. Introduction

The scientific literature has documented hundreds of cases of leukemia, aplastic anemia, and other blood abnormalities which have been associated with benzene exposure. Epidemiologic studies of workers exposed to benzene have demonstrated significant excesses of leukemia, multiple myeloma, lymphatic cancers and cancers of other sites as well as chromosomal aberrations. Several of these studies have provided a reasonable basis for quantitative cancer risk assessment. More recently, experimental animal studies have demonstrated the induction of cancer, chromosomal damage and bone marrow toxicity in relation to specific benezene exposure levels. All of this information has been used to the extent feasible in OSHA's preliminary determination of risk associated with benzene exposure levels. OSHA seeks comments on methodologies for intergrating epidemiologic and experimental studies for purposes of determining quantitative estimates of disease associated with benezene exposure.

Although benzene exposure has been associated with leukemia, aplastic anemia, multiple myeloma, various forms of lymphoma, pancytopenia, and depression of singular blood cell lines and to a lesser degree with other types of cancer and paroxysmal nocturnal hemoglobinuria, OSHA has based its risk assessment from human studies on leukemia only. This procedure was based upon a determination that some of the above mentioned conditions were either identified in case reports and relative risks could not be quantified, or achieved statistical significance in studies where occupational benzene exposure could not be specifically quantified, or that study results were released only recently precluding necessary discussion of findings and the development of a quantitative cancer risk assessment. As a result, the total disease risk associated with benzene exposure may be underestimated. OSHA seeks expert opinion on the methodology for inclusion of mortality from disease other than leukemia in its assessment of quantitative disease associated with benzene exposure.

A succinct explanation of the rationale and basis for quantitative risk assessment has been presented in previous OSHA proceedings and is partially reiterated here as an introduction to the subject (See Arsenic 48 FR 1864, 1/14/83; ethylene dibromide, 48 FR 45956, 10/7/83; ethylene oxide, 48 FR 17284, 4/21/83; asbestos, 49 FR 4118, 4/10/84).

Several approaches have been used to estimate cancer risk from exposure to toxic agents. A standard approach uses mathematical models in an attempt to fit curves to risk levels observed at different exposure levels and from these curves to predict the risk at other, usually lower, exposures. These curves range from linear extrapolations to zero exposure and zero risk to curves which may deviate far from linearity at extreme doses. The use of a particular model or curve can be justified in part by statistical measures of "fit" to available data points. These considerations have been reviewed from the statistical standpoint (Krewski and Van Ryzin, 1981) (Ex. No. 159–48).

In all cases, it is assumed that the mathematical curves are reflective of biological processes that control the biological fate and action of the toxic compound. To date, these factors have not been quantitatively linked to the mathematical models. Studies can contribute useful information in the development of a quantitative risk assessment if they provide reasonable estimates of excess risk and dose. Such assessments can be improved by incorporating additional biological factors, though these are not necessary to obtain an estimate of disease risk. Information on several biological factors which, if available, may augment the accuracy of the risk assessment include: (1) The identity of sensitive tissue(s); (2) dose of the material at the sensitive tissue(s); (3) the nature of the response(s); (4) rates and sites of biotransformation; (5) toxicity of metabolites; (6) chronicity of the compound (cumulative nature of the material or its action(s)); (7)

pharmacokinetic distribution of the material (especially effects of dose on the distribution); (8) external effect modifiers resulting from exposure to additional substances or agents; (9) internal effect modifiers such as age, sex, nutritional status, inherited differences in enzyme activities, and species and strain for test animals; (10) and the manner and method of dose administration.

It is clear that not all of these factors can be determined easily or incorporated into a single mathematical model. Even if they could be identified, it would be difficult to determine the weight that should be given to each factor. In the specific case of benzene and leukemia, the basic mechanism whereby benzene affects the bone marrow is still unclear. Nevertheless, selection of data for evaluation in a model is an important factor in the risk assessment.

With regard to benzene specifically, experimental and epidemiological study results serve to elucidate the type of relationship that may exist between benzene exposure and adverse effects on the bone marrow. Several experimental studies (Tice et al. 1983, Ex. No. 159–87; Gad-el Karim et al. 1984, Ex. No 159–32; Kligerman et al. 1983, Ex. 159–47; Baarson et al. 1984, Ex. No. 159–8) and one epidemiologic study (Picciano, 1980, Ex No. 128–60) have demonstrated a linear dose-response between benzene exposure and increased frequencies of sister chromatid exchanges (SCE's), micronuclei in bone marrow erythoblasts, chromosomal breakage in circulating lymphocytes and decreases in colony forming unit erythroid (CFR–E), i.e., ertythroid progenitor cells. These study results demonstrate a linear relationship between benzene exposure and several manifestations of toxicity to the bone marrow and suggest that a linear model may have the most reasonable biological basis.

Quantitative cancer risk estimates based on epidemiologic data require assumptions about the shape of the dose-response relationship and the duration of exposure. Epidemiologists have frequently assumed a linear model for dose-response (IARC, 1982). Although it is recognized to be a rather simplified model which may vary with the biological factors mentioned above, the linear model has scientific plausibility (Crump et al., 1976 (Ex. No. 217–32–H7); Acheson and Gardner, 1980 (Ex. No. 159–1); Committee on the Biological Effects of Ionizing Radiation, 1980) (Ex. No. 159–55).

In developing its criteria for arsenic, the Arsenic working group (WHO, 1981) (Ex. No. 159–104) of the World Health Organization stated:

> The use of the linear non-threshold model is recommended for extrapolation of risks from relatively high dose levels, where cancer responses can be measured, to relatively low dose levels, which are of concern in nvironmental protection where such risks are too small to be measured directly either through animal or human epidemiological studies.
>
> The linear non-threshold model has been generally accepted among regulatory bodies in the USA for chemical carcinogens (IRLG) and for ionizing radiation on an international basis (ICRP). The linear non-threshold philosophy was accepted by a Task Group on Air Pollution and Cancer in Stockholm in 1977 (Task Group on Air Pollution and Cancer, 1978). The scientific justification for the use of a linear non-threshold extrapolation model stems from several sources: the similarity between carcinogenesis and mutagenesis as processes which both have DNA as target molecules, the strong evidence of the linearity of dose-response relationships for mutagenesis, the evidence for the linearity of the DNA binding of chemical carcinogens in the liver and skin, the evidence for the linearity in the dose-response relationship in the initiation stage of the mouse 2-stage tumorigenesis model, and the rough consistency with the linearity of the does-response relationships for several epidemiological studies; for example, aflatoxin and liver cancer, leukaemia and radiation.

While the multistage model also seems plausible, the linear model is a reasonable approximation of the multistage model at the response rates of concern. Furthermore, the linear model seems biologically sensible since it assumes risk is linearly proportional to dose.

The issue of the effects of cessation of exposure and subsequent follow-up on risk is also a problem in modeling dose response relationships from epidemiologic studies. As stated by IARC (1982) (Ex. No. 159–38):

> If on the one hand, the exposure acts as an early-stage initiator, then the risks remain somewhat the same after cessation. If, on the other hand, the chemical is a promoter, then the risk decreases after elimination of the exposure . . . The typical occupational study involves continued follow-up of workers after they have left the workplace. The resulting risk ratios may thereby misrepresent the true risks for a continued exposure.

The "misrepresentation" referred to would be an underestimate of the risk from continuous exposure. Since most of the epidemiologic studies used for risk estimation are based on working populations exposed for relatively short periods of time and the dose calculated for those studies is spread over an entire occupational lifetime, the risk of death from leukemia may be underestimated if benzene is a promotor as well as an initiator.

In order to estimate the potential quantitative risk of cancer for workers exposed to benzene, OSHA has reviewed several quantitative risk assessments and other epidemiological and toxicological studies submitted in response to the request for information (Benzene ANPR, 48 FR 31412, February 10, 1978). Predictions based on both human data and extrapolations from other species were considered.

OSHA has examined several possible exposure scenarios for lifetime occupational exposure to benzene including TWA exposures ranging from 10 to 0.1 ppm. The following discussion gives a brief description of each of the risk assessments, summarizes the results and offers OSHA's preliminary determination of the level of risk posed by occupational exposure to benzene.

B. Terminology and Definitions

Several statistical/technical terms are defined here for reference in reading this section.

(1) *Mathematical model:* A well-defined mathematical equation describing the relationship between dose (e.g. parts per million of benzene) and response (e.g. number of cancer deaths among workers or number of tumor-bearing animals). The biological data are used to define the relationship; that is, a curve is "fit" to the data.

(2) *Mathematical fit:* A term used to describe how close a predicted dose-response curve is to the actual observed points. Fit is often measured by a Chi-squared goodness-of-fit statistic and its corresponding p value. The closer the p value is to one, the better the fit.

(3) Several different mathematical models have been developed for high dose to low dose extrapolation. Most of the models are based on theories of cancer development, such as the one-hit, the linear, the multistage, and the gamma multihit model.

a. Linear model: This model assumes that the expected number of chemical-cell interactions is directly related to dose. It cannot take into account repair, detoxification reactions and metabolic activation.

b. Multistage model: This model assumes that the toxic response is the result of an ordered series of biological events and that the occurrence of each event is linearly related to the dose. (Note: At doses relevant to occupational exposure, the linear or one-hit model is a reasonable approximation of the multistage model.)

c. Probit model: Use of this model results in a typical sigmoid-shaped

curve; strongest in the 5% to 95% response area. Zero responses are approached very rapidly as the dose decreases.

d. Logit model: Use of this model also results in a sigmoid-shaped curve symmetric about the 50% response point. It approaches zero response more slowly than the probit model.

e. Weibull model: This quadratic model is a generalization of the one-hit model which allows for non-linear responses in the low dose region. The response may be concave or convex depending on estimates from the observed data sets.

f. Gamma Multihit model: This also assumes that an expected number of chemical-cell interactions is related to dose, but it further assumes that a number of responses is needed to produce the cellular response. Thus, the model may fit data observed at higher doses better than the one-hit model (Ex. No. 11, p. 100–102).

(4) *Extrapolation/interpolation*: Once a mathematical model is fit to a set of data points, one may wish to predict the risk at other points along the curve. Extrapolation is the prediction of risk outside the range of the observed data; interpolation is the prediction of risk within the range of the observed data. The term interspecies extrapolation refers to the prediction of risk in one species (e.g. humans) based on observations in other species (e.g. rats).

C. Summary of Risk Assessments

1. *Risk assessments based on epidemiologic data.* IARC (1982) (Ex. No. 159–38) conducted a quantitative risk assessment of workers exposed to benzene based on four studies. The first study chosen was that of Rinsky et al. (1981) (Ex. 128–32) who completed the follow-up begun by Infante et al. (1977) (Ex. 128–17). For this analysis, IARC initially selected the relative risk of 21, associated with at least 5 years of exposure to benzene, which it believed to be a lower bound for risk associated with lifetime exposure. Since the cumulative adult white male (ages 20–75 years) expected probability of death from all types of leukemia combined is approximately 7 per 1000 in the general population of the U.S., the excess relative risk of 20 (21–1.0) was multiplied by 7 to yield 140 deaths from leukemia per 1000 workers exposed to benzene. As an alternative approach, IARC assumed that the relative risk of dying from leukemia increases linearly during continuous exposure. Since the overall relative risk of death from leukemia in the study was 5.6 and the leukemia cases had an average of 8.5 years of exposure, IARC calculated the excess relative risk for 45 years of exposure to be 24.4 (5.6–1.0 x 45/8.5). The excess relative risk was then applied to age-specific rates for leukemia which resulted in an estimated 170 excess deaths from leukemia per 1000 workers exposed over an occupational lifetime. IARC noted that exposures to the cohort ranged between 10 ppm and 100 ppm. While acknowledging uncertainties in exposure estimation, IARC stated that "assuming exposure was at the upper end of the range, then it is reasonable to postulate that a working lifetime exposure to 100 ppm of benzene would be likely to result in 140 to 170 cases of leukemia per 1000 exposed workers." With regard to assumptions concerning dose, IARC (1982, Ex. No. 128–8) stated that:

> • • • data on past exposures are almost always incomplete. However, one may sometimes be confident that the historical dose rate is known within an order of magnitude. It is of first importance in dealing with risk calculations to insure that they reflect the degree of uncertainty in the estimates of dose rate. This is often most simply done by citing upper and lower bounds of such estimates.

Although with benzene IARC did not state an assumption that workers were exposed to the lower end of the range, such an assumption would be consistent with the IARC opinion on risk assessment and would result in an estimated excess risk of 140 to 170 leukemia deaths per 1000 workers exposed to average benzene levels ranging between 10 ppm and 100 ppm based on the Rinsky et al. report.

IARC also selected the study of benzene exposed workers by Ott et al. (1978, Ex. No. 128–33) to determine an estimate of leukemia risk. Three cases of myelogenous leukemia were observed as compared to 0.80 expected, yielding a relative risk of 3.75. The average duration of exposure of the cohort was estimated by IARC to be approximately 8 to 9 years. Since the levels of exposure reported by Ott et al. ranged from very low (less than 2 ppm), to low (2–9 ppm), up to a high exposure of 30 ppm, IARC assumed exposure ranged from 1–30 ppm. IARC concluded that the exposure-response relationship observed in the Ott study was compatible with that based on the Rinsky et al. study.

Since the U.S. white male adult lifetime probability of developing myelogenous leukemia is about 5 per 1000, OSHA estimated the working lifetime excess risk from this cohort, using the methodology IARC employed for Rinsky et al. (1981) (Ex. No. 128–32), to be 72 per 1000 workers exposed to benzene (3.75–1.0 x 45/8.5 x 5/1000). (This latter calculation was not carried out by IARC.) Therefore, the relative risk of dying from leukemia in this study was 3.75 as a result of 8–9 years of exposure to average levels of benzene ranging between 1–30 ppm, resulting in an estimated 72 excess leukemia deaths per 1000 workers exposed for an occupational lifetime.

IARC (1982) (Ex. No. 159–38) also stated that the study of Vigliani (1976) (Ex. No. 128–5) suggests a "relative risk of 20:1 for the heavily exposed workers (200–500 ppm), with a median tumour latency of 9 years. This also appears to be quantitatively compatible with the Infante-Rinsky values (4 times higher risk and a 2–5 times higher exposure rate)."

If one assumes that the exposure period for the cases in the Vigliani (1976) (Ex. No. 128–5) report represents average exposure for the group studied (in the Infante-Rinsky cohort it actually overestimates length of exposure by a factor of eight) using methodology IARC employed for Rinsky et al. (1981) (Ex. No. 128–32), OSHA estimated an excess risk of 475 leukemia deaths (20.0–1.0 x 45/9 x 5/1000) per 1000 workers exposed to 200 to 500 ppm benzene. (This latter calculation was not carried out by IARC.)

With regard to the fourth report used by IARC for its quantitative risk assessment on benzene, it stated, "The exposure levels of several hundred ppm observed by Aksoy (1977) (Ex. No. 144–160) and the interpretation of his study give a relative risk of the order of 25, which is also in agreement with the above calculations." (Thus, IARC interpreted the four epidemiologic studies as providing evidence for a linear dose response relationship between benzene exposure and relative risk of death from leukemia).

Aksoy (Aksoy, 1977 OSHA) (Ex. No. 44) testified that the concentrations of benzene to which workers were exposed reached a maximum concentration between 150–210 ppm. Assuming that the exposure period for the cases in the Aksoy study represents average exposure for those exposed to benzene, and using IARC methodology, OSHA estimated an excess risk of 534 acute non-lymphocytic leukemia deaths (24–1.0 x 45/9.7 x 5/1000) per 1000 workers exposed to an average of 150 to 210 ppm benzene.

A summary of the IARC benzene risk assessment data along with a range of OSHA estimated excess risks based on IARC methodology for exposure levels of 10 ppm and 1 ppm using linear extrapolation is shown in Table A. The excess risk per 1000 workers from

lifetime occupational benzene exposure to 10 ppm ranges from 9. 5–720, while the risk from exposure to 1 ppm ranges from 1.0–72. Of the four studies used for risk estimation, estimates of relative risk and exposure level are more exact for the studies by Ott et al. (1978) (Ex. No. 128–33) and Infante-Rinsky (1977, 1981) Ex. Nos. 128–7, 32). For the latter study, IARC assumed that the cohort was exposed for an average of 8.5 years based on average exposure time for those who died from leukemia. However, the median length of exposure for the entire cohort was less than one year (Rinsky, et al. 1981) (Ex. No. 128–32). Therefore, the linear extrapolation for the Infante-Rinsky study as shown in Table A, based on IARC's assumptions, would overestimate the dose in relation to response (relative risk of death from leukemia).

TABLE A.—ANALYSIS OF RELATIVE RISK AND EXCESS LEUKEMIA RISK PER 1,000 WORKERS EXPOSED TO BENZENE FOR AN OCCUPATIONAL LIFETIME BY STUDY BASED ON IARC METHODOLOGY (1982) *Used for Infante-Rinsky Study Results*

Authors	RR	Estimated Exposure	Occup. lifetime excess risk per 1,000	Excess risk per 1,000 exposed to—	
		To Cohort		10 ppm	1 ppm
				10 ppm	1 ppm
Ott et al. (1978)	3.75	1–30 ppm, for 8–9 yrs	[1] 72	24–720	2.4–72
Infante et al (1977)	5.6	10–100 ppm, 8.5 yrs average exposure for cases [2].	170	14–170	1.4–17
Rinsky et al. (1981)	21	5 yrs average	140	14–140	1.4–14
Vigliani (1976)	20	200–500 ppm, 9 yrs average exposure for cases.	475	9.5–23.8	1.0–2.4
Aksoy (1977)	25	150–210 ppm,[3] 9.7 yrs average exposure for cases.	534	25.4–35.6	2.5–3.6

[1] Based on exposure of 8.5 yrs.
[2] IARC extrapolated average exposure of cases (8.5 yrs.) to average exposure for cohort.
[3] Based on testimony of Aksoy at 1977 OSHA Hearing.

Note.—IARC did not perform all calculations in last three columns. There were performed by OSHA using IARC methodology for the Infante-Rinsky study and IARC opinion that "risk calculation * * * reflect the degree of uncertainty in the estimates of dose rate * * * by citing upper and lower bounds of such estimates (IARC, 1982).

White et al. (1982, Ex. No. 128–37) reported a quantitative estimate of leukemia mortality associated with occupational benzene exposure. They selected the NIOSH (Infante et al. 1977; Rinsky et al. 1981) and DOW (Ott *et al.* 1978) (Ex. Nos. 128–7, 32, 33) studies for their risk assessment as they felt these studies more adequately met their requirements of providing both an estimate of relative risk and a reasonable characterization of previous exposure conditions.

For the NIOSH study, White et al. (1982) (Ex. No. 127) based the risk assessment on the experience of workers who had 5 or more years of employment, because the elevated risk was statistically significant only for this group. The standardized mortality ratio (SMR) was 2100 (5 observed leukemia deaths versus 0.23 expected). Workers who had been employed for less than 5 years were not included in the assessment. For these individuals the SMR was 200 (2 leukemia deaths observed versue 1.02 expected). The range of duration of exposure for those workers with more than 5 years of employment was estimated to be 5 to 30 years. The authors calculated that workers could have been exposed for 5 years to an average of 83 ppm benzene or 415 ppm-years, or they could have been exposed for 30 years to an average of 50 ppm, or 1500 ppm-years. The estimates of levels of exposure were based on industrial hygiene information from the report by Rinsky et al. (1981) (Ex. No. 128–32) for the period 1941–1975. Since some workers had been exposed to benzene as early as 1937, White et al. assumed exposures from 1937–1941 to have been 150 ppm benzene, which is 50% above the maximum allowable concentration or peak exposure level recommended in 1941.

For the OTT et al. study (1978) (Ex. No. 128–32), White et al. (1982) (Ex. No. 127) based their risk assessment on the 3 observed cases of leukemia as compared to 0.8 expected (SMR is 375, p less than 0.05). Based on data in the OTT et al. study, the benzene dose for the entire cohort was estimated to have ranged from 500 to 1500 ppm-months, or 42-125 ppm-years. White et al. (1982) (Ex. No. 127) noted that the cumulative dose of benzene for the three leukemia cases ranged between 1.6 ppm-year and 45 ppm-years.

To describe the relationship between benzene dose and the probability of developing leukemia, White et al. selected the linear model as they felt the epidemiologic evidence available for benzene exposure and leukemia did not include the detail needed to test the appropriateness of more complex models. In OSHAs opinion, selection of this model seems appropriate as linear dose response relationships exist for several end points measuring toxic effects on the bone marrow (Tice et al. 1983; Baarson et al. 1983 (Ex. No. 146–2); Gad el Karen 1983; Picciano, 1979 (Ex. No. 144–118; Wong et al. 1983 (Ex. No. 151A).

To determine the excess probability of developing leukemia for a given dose of benzene over a defined period of time, White et al. (1982) (Ex. No. 127) determined the lifetime adult white male (ages 20–84 years) probability of developing leukemia (0.0070 for all cell types and 0.0050 for myelogenous leukemia) and the rate at which the excess probability of leukemia increased with each increment in dose. Separate risk estimates were then calculated for both studies using the above mentioned values.

As shown in Table B, based on the NIOSH study, the excess leukemia risk was estimated to be 44 to 152 per 1,000 workers exposed for an occupational lifetime (45 years) to an average of 10 ppm benzene. The excess risk of death from leukemia associated with exposure to 1 ppm for 45 years ranged from 5 to 16 per 1,000 workers.

Based on the study by Ott et al. (1978) (Ex. No. 128–33), the excess risk of death from leukemia was estimated to be 48 to 136 per 1,000 workers exposed for an occupational lifetime to 10 ppm, while the excess risk was 5 to 15 per 1,000 for those exposed to 1 ppm for 45 years. In discussing their results, White et al. (1982) (Ex. No. 127) noted that the range of excess risk was based on the uncertainty in the benzene exposure levels from the NIOSH and DOW studies, but that the projected risk did not reflect the uncertainty associated with the risk ratios from the studies. For instance, they stated,

> The upper 95% confidence interval for the SMR of 2,100 from the Rinsky et al. report is 5073. The use of this value would have resulted in much higher risk estimates. Thus, even though these risk estimates are expressed as ranges, the upper range of the risk estimates actually would have been greater if the uncertainty of the SMRs had been included in the analysis.

TABLE B.—ESTIMATE OF EXCESS LEUKEMIA DEATHS PER 1000 WORKERS EXPOSED TO BENZENE BY NUMBER OF YEARS EXPOSED AND EXPOSURE LEVEL

Years exposed	Exposure levels			
	10 ppm		1 ppm	
	NIOSH study	DOW study	NIOSH study	DOW study
45	44–152	48–136	5–16	5–15
30	30–104	32–93	3–11	3–10

TABLE B.—ESTIMATE OF EXCESS LEUKEMIA DEATHS PER 1000 WORKERS EXPOSED TO BENZENE BY NUMBER OF YEARS EXPOSED AND EXPOSURE LEVEL—Continued

Years exposed	Exposure levels			
	10 ppm		1 ppm	
	NIOSH study	DOW study	NIOSH study	DOW study
15	15-54	16-48	1.5-5	2-15
5	5-18	5-16	0.5-2	0.5-2
1	1-4	1-3	0.1-0.4	0.1-0.3

Source: White et al. 1982.

OSHA is also aware of two cases of leukemia among pliofilm workers who were not located by the NIOSH investigators during their follow-up (Sakol, 1977 OSHA, TR 285-329). Although the addition of these cases to the White et al. (1982) risk assessment based on the NIOSH study would substantially incease the estimated leukemia risk, the authors chose not to include them.

On the basis of the White et al. assessment (See Table B) a reduction in the 8-hour TWA exposure to benzene from 10 ppm to 1 ppm would result in a reduction in risk of death from leukemia ranging from 43 to 136 per 1000 workers exposed over an occupational lifetime. (This risk assessment does not take into consideration any reduction in risk that may be achieved by early detection of blood abnormalities (through medical surveillance) that may precede any preleukemia phase, or by early detection of conditions that may result in extending survival, particularly for those individuals who have experienced relatively higher benzene exposure levels in the past.)

OSHA solicited opinion on the risk assessment by White et al., 1982 from a number of recognized experts in the field of occupational health, or risk assessment, representing government, academia, or industry (Ex. No. 137). Each reviewer was provided with a copy of the White et al. (1982) (Ex. No. 127) assessment. Opinions of the assessment varied. Dr. Brian MacMahon (Ex. No. 137-5) and Dr. Bruce Karrh (Ex. No. 137-1) felt that the underlying studies upon which the assessment was based were too limited for purposes of conducting a quantitative cancer risk assessment. Dr. Philip Cole, stated "it is only an opinion that epidemiologic evidence regarding the leukemogenicity of benzene is 'conclusive.' " (Ex. No. 137-3) Dr. Cole's statement was based on his view that most of the epidemiologic studies of benzene and leukemia have methodological limitations and that the case reports of leukemia among benzene workers "are of limited scientific value." However, several consensus groups including IARC and the National Toxicology Program have concluded that there is sufficient evidence that benzene is carcinogenic to humans.

Dr. Irving Kessler (Ex. No. 137-2) was of the opinion that the underlying studies represented the best available information. Dr. Kessler and Dr. David Gaylor (Ex. No. 137-9) stated that the results of the assessment seemed plausible and were well documented. Dr. Karrh negated the NIOSH study on the basis of the critique of Tabershaw and Lamm (1977) (Ex. No. 159-81) and Van Raalte and Grasso (1982) (Ex. No. 159-91). Comments on these critiques have been addressed in the section on epidemiologic study results.

Dr. Norman Breslow, Dr. Cole, Dr. Charles Brown and Dr. Gaylor all thought the linear model used by White et al. (1982) was acceptable and that other more complex models were not justified (Ex. Nos. 137-3, 4, 7, 9). However, Dr. Wiliam Rowe felt other models should be evaluated in addition to the linear model while Dr. Karrh (Ex. No. 137-1) felt the linear model was unverifiable. The issue of model selection can best be summarized by Dr. Charles Brown (Ex. No. 137-7) who stated:

> The "correct" model is unknown, and will remain so until we know the mechanistic relationship between benzene exposure and leukemia; however I do not believe that the data warrant more sophistication than the simple linear model (to which the one-hit model is a very close appoximation at low response rates); in addition, since the range over which the dose extrapolation is performed appears to be relatively small (one order of magnitude?), the dose-response model should have a small effect on the risk assessment results.

Dr. Cole and Dr. Brown (Ex. Nos. 137-3, 7) felt that the exclusion from the risk assessment of individuals in the NIOSH study who had less than 5 years of benzene exposure and a relative risk of 2 for death from leukemia resulted in a bias toward an overestimate of the quantitative risk based on the NIOSH study. OSHA is of the opinion that the latter data should have been included in the assessment, but that inclusion of these data would not change the dose response. For example, individuals with less than 5 years of exposure had a median duration of exposure of about 0.5 years (Rinsky, 1983 Ex. No. 159-65A). If one assumes that these individuals were exposed to a TWA of 100 ppm benzene (a maximal estimate), their cumulative dose of benzene would be 50 ppm-years associated with a relative risk of 2, or 7 per 1000 excess leukemia deaths. This estimate would fit comfortably within the estimate of 5 to 16 excess leukemia deaths per thousand workers exposed for an occupational lifetime to 1 ppm, e.g., 45 ppm-years of exposure.

Three reviewers raised the issue of the cumulative dose concept of exposure used by White et al. (1982) (Ex. No. 127). Dr. Bruce Karrh was of the opinion that short-term, high intensity exposure was the mode of exposure to benzene (Ex. No. 137-1). Dr. Brown was of the opinion that the cumulative dose model may not be a valid measure but that the epidemiologic data would not provide the proper measure of exposure (Ex. No. 137-7). He suggested the use of animal studies to resolve the issue of dose rate and duration of exposure. Dr. Norman Breslow stated that dose additivity and low dose linearity should be adopted as biologically reasonable and scientifically prudent assumptions in the absence of specific evidence to the contrary (Ex. No. 137-4).

Under OSHA contract, Crump and Allen (1984) (Ex. No. 152) recently estimated excess leukemia deaths among workers exposed to benzene based on three epidemiologic studies. Two alternative models were used, the linear relative risk model and the linear absolute risk model. The relative risk model is derived by assuming that the age-specific mortality from benzene is proportional to the background mortality. The absolute risk model follows from assuming the added benzene mortality is the same for all ages, given equal doses. Different measures of benzene exposure were considered, namely, cumulative exposure in ppm-years; weighted cumulative exposure in ppm-years, in which exposure in the most recent 2½ years prior to the 5-year age interval under scrutiny made no contribution and exposures more than 7½ years in the past were given progressively less weight; a "window" exposure in ppm-years, in which the only exposure counted was that in a 10-year "Window" between 2½ and 12½ years prior to the 5-year age interval of interest; and peak exposure, defined as cumulative exposure in ppm-years but disregarding all exposures less than 100 ppm.

Using cumulative exposure with the relative risk model, the maximum likelihood estimate of additional deaths from leukemia for workers occupationally exposured for 40 years to 10 ppm was 88 per 1000. (Table C). The 95% confidence interval (CI) for this estimate ranged between 34 and 184 excess leukemia deaths per thousand workers. For those exposed to 1 ppm for

40 years the excess leukemia risk was 9.5 (95% CI = 3.5–21) per 1000. These estimates were derived using data from the Rinsky et al., Ott et al. and Wong et al., studies combined. The corresponding maximum likelihood estimates of excess leukemia mortality using weighted cumulative exposure were 29 per 1000 associated with 10 ppm and 3 per 1000 associated 1 ppm. These latter estimates are based upon the Rinsky et al. and Ott et al. cohorts; the data in the Wong et al. cohort were not available in a form that permitted this type of analysis.

TABLE C.—ESTIMATED EXCESS LEUKEMIA DEATHS PER 1000 WORKERS FOR 40 YEARS OCCUPATIONAL EXPOSURE USING RELATIVE RISK AND CUMULATIVE EXPOSURE MODEL, CRUMP AND ALLEN, 1984

Exposure level	Life excess leukemia risk per 1000 employees[1]		
	NIOSH	CMA	All 3 (including DOW) studies combined
10 ppm	63	121	88
1 ppm	6.3	13	9.5

[1] Maximum likelihood estimate.

Using the relative risk model and cumulative dose, the assessment based on data solely from the CMA study by Wong et al. indicated that the excess leukemia mortality per 1000 workers occupationally exposed for 40 years to 10 ppm was 121; the 95% confidence limits ranged between 1.1 and 243. The assessment for 10 ppm benzene based on the NIOSH study by Rinsky et al. indicated 63 excess leukemia deaths; the 95% confidence limits ranged between 21 and 129 per 1000 as a result of 40 years exposure. For 40 years of exposure to 1 ppm, the excess risk per 1000 was 13 based on the CMA study and 6.6 based on the NIOSH study. Estimates based on the Dow study by Ott et al. were not performed separately because of the small number of leukemia deaths observed in the study.

Crump and Allen (Ex. No. 152) indicated a slight preference for estimates based on the relative risk model over the absolute risk model as it seemed more plausible to them that the effect of benzene exposure should be larger when the background occurrences of leukemia are larger. They also indicated a preference for estimates based on cumulative or weighted cumulative dose over those based on window dose because window dose allowed the risk to disappear completely after 15 years, which they interpreted as being at variance with the Japanese data on atomic bomb survivors. Crump and Allen also tended to prefer the weighted cumulative dose model over the cumulative dose model as it seemed somewhat implausible to them, based on the Japanese A-bomb data, that a brief exposure early in life would entail the same risk 50 years hence as 15 years hence. In regard to this preference, OSHA notes that the mode of industrial benzene exposure is different than A-bomb exposure. Workers are exposed to low levels or intermittent bursts of benzene over many years, whereas, A-bomb survivors experienced a single burst of radiation exposure.

With further regard to relative risk of dying from leukemia in relation to time period of benzene exposure, epidemiologic study results of workers exposed to benzene indicate relative risks for myeloid and monocytic leukemias (the most predominant cell types associated with benzene exposure) to range from 3.75 to 8.7 for cohorts of predominantly active or terminated employees as compared to 4.0 for cohorts of predominately retired employees (Ex. No. 142–13A–Shell study). Thus, the relative risk of death from leukemia seems to remain high following cessation of exposure. OSHA seeks comment on the Crump and Allen risk assessment and preference of models and dose accumulation.

The Carcinogen Assessment Group (CAG) of the Environmental Protection Agency estimated leukemia risk associated with ambient benzene exposure (Albert et al. 1979, Ex. No. 128–6). This assessment was based on the occupational studies by Infante et at. (1977) (Ex. No. 128–17) several studies by Aksoy reported between 1974–77 and the study by Ott et al. (1978) (Ex. Nos. 128–7, 33, 43; 144–5, 160).

For the Infante et al. study (1977) (Ex. No. 128–17) CAG calculated a relative risk of 7.2 (9 observed leukemia deaths versus 1.25 expected). Although Infante et al. (1977) (Ex. No. 128–17) observed 7 leukemia deaths in their study cohort, CAG included the two leukemia deaths mentioned by Dr. Sakol as not having been identified in the follow-up of the NIOSH study.

Benzene exposure for the cohort studied by Infante et al. was estimated by CAG in 1979 to have ranged from 40 ppm for 35 years to 24 ppm for 25 years for the entire cohort. (OSHA is aware that this estimate now represents an overestimate in the number of years of exposure for the cohort as Rinsky et al. (1981) (Ex. No. 128–32) reported that 58 percent of the cohort was exposed to benzene for less than one year.)

For the Aksoy studies, CAG estimated that the relative risk of developing non-lymphoblastic or lymphoid leukemia for Istanbul shoeworkers was 20 (based on a comparison to a general population rate) and that they were exposed to an average (geometric mean) of 64 ppm benzene for an average of 9.7 years based on the average length of exposure for the leukemia cases.

For the study by Ott et al. (1978), CAG used the relative risk of 3.75 for myelogenous leukemia among workers exposed to an estimated average benzene dose of 51 ppm-years. CAG then used a linear non-threshold model to estimate leukemia risk from 1 ppm benzene exposure breathed over a lifetime which it considered 70 years. The geometric mean of the slope estimates for the three studies as calculated by CAG was 0.024. This figure is interpreted as indicating that a lifetime exposure (70 years) to 1 ppm benzene would result in 24 excess myelogenous leukemia deaths per 1,000 individuals. Converting the CAG risk estimate into an estimate for lifetime occupational exposure (45 years, 240 workdays per year, 8 hours per day) would result in 33.8 excess leukemia deaths per 1,000 workers exposed to 10 ppm benzene, or 3.38 per 1,000 exposed to 1 ppm for an occupational lifetime.

The CAG quantitative cancer risk assessment has been reviewed and modified by several groups using various assumptions about benzene exposure and relative risk from the underlying studies. The reports by Hattis et al. (1980) of the Massachusetts Institute of Technology (Ex. No. 133) and Davis and Schneiderman (1983) of the Environmental Law Institute (Ex. No. 135) show a higher leukemia risk than that reported by CAG, while the reports by Bartman (1982) (Ex. No. 161) and by Lamm (1983) prepared for the American Iron and Steel Institute (Ex. No. 142–28B) show a lower risk. Different assumptions on the various aspects of the underlying studies made by the groups mentioned above account for the different results. However, the assumption made by these groups does not appear to be better supported than the CAG assumptions made in 1979.

A number of scientists believe the CAG assumptions on dose and relative risk are reasonable and well supported. The CAG risk assessment establishes an estimate of leukemia risk among benzene exposed individuals that is similar to the estimates made by IARC (1982) (Ex. No. 159–38) and White et al. (1982) (Ex. No. 127).

All four cancer risk assessments mentioned above were consistently based on linear non-threshold model and all selected the same or similar studies to estimate leukemia risk.

Although the assessments were derived from studies of various design involving exposure to benzene in different occupations, the extrapolated excess risks observed in association with the current PEL of 10 ppm are similar. Upon review of the quantitative cancer risk assessments by White et al., IARC and CAG, OSHA is of the preliminary opinion that reasonable assumptions by all groups were made on the basis of the data available. OSHA is preliminarily utilizing the White et al., estimate as a reasonable mid-range estimate, consistent with other assessments when using mid-range assumptions, to be the basis for significant risk analysis. In addition, OSHA views the study by Ott et al. (1978) (Ex. No. 128–33) to constitute direct observational data demonstrating excess leukemia risk associated with low level benzene exposure.

2. Risk Assessments Based on Experimental Bioassays. Experimental bioassays have served as a basis for the majority of quantitative cancer risk assessments. While risk estimates based on single compound exposures to experimental animals can readily determine dose and response, they pose some difficulty in extrapolation to humans for a number of reasons including factors associated with interspecies variability in metabolism, and human insult by a host of other chemicals in the environment which may interact to potentiate the carcinogenic response. For example, the incidence of angiosarcoma of the liver in experimental animals administered vinyl chloride (VC) alone is much lower than the incidence when the animals have ethanol (drinking alcohol) added to their drinking water (Ex. No. 159–63A). Thus, extrapolation of cancer risk to humans based solely on VC administration may result in a much lower estimate of risk.

Likewise, when interaction has been studied in humans with asbestos and cigarette smoking or alcohol and cigarette smoking, a synergistic interaction resulting in a much higher risk of lung cancer and esophageal cancer, respectively, have been demonstrated in contrast to the summation of risk from exposure to these agents independently.

The Carcinogen Assessment Group (CAG) of the EPA has conducted a quantitative cancer risk assessment for benzene based on the results of experimental bioassays (CAG 1983, Ex. No. 159–15). The preliminary results of its analyses are based upon the report of benzene exposure by oral gavage to Sprague-Dawley rats by Maltoni in 1982 (Ex. No. 128–75) and the report of benzene induced hematopoietic neoplasms in male C57BL mice following inhalation exposure by Snyder et al. in 1980 (Ex. No. 128–77).

For the Maltoni study results reported in 1982, CAG based its risk estimates on Zymbal gland carcinomas, hematosarcomas and hematosarcomas and lymphoblastic leukemia combined in male and female rats exposed for 52 weeks at dose levels of 50 or 250 mg/kg of body weight. CAG did not adjust for survival of animals as data were not available to do so. (If exposure to the carcinogen shortens lifespan of the animals, lack of adjustment results in an overestimate of dose and hence an underestimate of cancer risk in relation to dose.) Equivalent lifetime human dose was determined by extrapolating the lifetime experimental dose using a correction factor to account for differences in surface area between humans and rats. This procedure resulted in an equivalent human dose of 3.1 mg/kg/day and 15.5 mg/kg/day from low and high dose benzene administration to male rats, respectively and an equivalent dose of 2.6 and 13.–1 mg/kg/day from low and high dose benzene administration to female rats, respectively. CAG then used the multistage model for all three categories of cancer mentioned above, plus the Probit and Weibull models for Zymbal gland tumors since there were two data points for this cancer. If only one data point is available, the Probit and Weibull models are not applicable because the parameters cannot be uniquely estimated.

For the Synder et al. report of 1980, CAG used the incidence rates for lymphocytic lymphoma and all hematopoietic neoplasms in male mice exposed to 300 ppm benzene by inhalation for 6 hours/day, 5 days/week, for up to 488 days, the time at which the last benzene treated animal died. For this study, CAG made an adjustment for survival of the animals in the exposure groups.

With use of the multistage model CAG estimated the upperbound of the lifetime excess human cancer risk associated with continuous exposure to 1 ppm benzene to range from 10 per 1000 individuals (using data for hematosarcomas from the Maltoni study or data for lymphocytic lymphoma from the Snyder et al. study) to 34 per 1000 (using data for Zymbal gland carcinoma from the Maltoni study). Using the Probit and Weibull models, the upperbound of the lifetime excess cancer risk associated with 1 ppm exposure based on the data for Zymbal gland carcinoma was estimated to be 70 and 80 per 1000 respectively. The Weibull model predicted a greater risk than the other models over the range of exposure considered because the shape parameter was estimated to be less than one and thus have a sublinear (concave downward) dose-response curve at low doses. The Probit model gave the second highest risk, while use of the multistage model resulted in the relatively lowest risk.

CAG also calculated the maximum likelihood estimate (MLE) based on data for Zymbal gland tumors using all four models mentioned above. With the multistage or one-hit models which are linear at low response rates, CAG calculated the maximum likelihood estimate resulting from lifetime exposure to 1 μg/cubic meter of benzene to be 6.52×10^{-6} which is equivalent to 0.0212 for lifetime exposure to 1 ppm. Using the Probit model, the MLE gave virtually the same result as the multistage and one-hit models. The Weibull model gave a higher MLE. This MLE of risk from the multistage is approximately 0.030 or 30 excess leukemia deaths per 1000 workers exposed for an occupational lifetime to 10 ppm benzene. The risk at 1 ppm is one-tenth or 3 per 1000.

The National Toxicology Program (NTP) has recently released a draft of the results from its 2-year carcinogenesis studies of benzene. Although the text may be revised, the tumor data were considered adequate for evaluation by the NTP board of scientific advisors at its October 1983 meeting. Fifty F344/N rats and 50 B6C3F mice of each sex were administered benzene in corn oil by oral gavage (NTP, 1983, Ex. No. 148). Doses of 0, 50, 100, or 200 mg/kg body weight of benzene were administered to male rats and doses of 0, 25, 50, or 100 mg/kg body weight benzene were administered to female rats and to female and male mice for 5 days per week for 103 weeks. Since the body weights of the female and male mice throughout the experiment were approximately 32 and 42 grams respectively and their minute volumes were approximately 27 and 34 ml of air, assuming 100% absorption of benzene, the mice were given doses of benzene equivalent to an 8-hour inhalation of 18.9 ppm (low dose female mice) to 80 ppm (high dose male mice).

Since the body weights of the female and male rats were approximately 250 and 400 grams respectively and they breath either 168 ml (females) or 251 ml (males) of air per minute, their doses of benzene were equivalent to 8-hour exposures ranging from 24.2 ppm (low

dose female rats) to 234 ppm (high dose male rats). This conversion does not take into consideration adjustments for differences in surface area between rodents and humans which would result in lower equivalent doses to humans and therefore higher risks.

Significantly increased incidences of neoplasms were observed at multiple sites for both sexes of mice and rats. Although leukemia was not induced in either species, dose-related bone marrow hematopoietic hyperplasia was observed in mice and dose-related leukopenia was observed in both sexes of mice and rats. Although a formal quantitative cancer risk assessment has not been completed for these new study results, the findings appear to be very significant in the evaluation of risk associated with known dose level of benzene. In addition to the findings of benzene induced cancers of the Zymbal gland, oral cavity and skin in rats, six sites or types of tumors such as malignant lymphoma and lung cancer were induced in male mice while seven sites or types of tumors such as lymphoma, lung cancer, ovarian cancer, mammary (breast) cancer and liver cancer were induced by benzene in female mice. Such multiple site carcinogenic response in both sexes of two species of rodents is unusual and should be considered as further evidence of the carcinogenic potency of benzene. Further concern for the carcinogenic potency of benzene is raised in the NIP study by the observation of effects at multiple sites at the lowest dose tested in mice (equivalent to 8-hour, 19 ppm exposure to humans without correction for surface area).

OSHA requested Dr. Kenny Crump, an expert in the field, to perform a quantitative risk assessment based on the NTP data. OSHA has submitted this report into the docket. Crump and Allen (Ex. No. 152) estimated excess risk of dying from leukemia and other cancers based on experimental data. Estimates of excess risk from 40 years of occupational exposure to 10 ppm benzene derived from application of the linearized multistage model to animal data on leukemia ranged from 0.4 to 1.5 per 1000. (It should be noted, however, that a good animal model for benzene and leukemia has not yet been developed.) When data from the NTP bioassay on all squamous cell carcinomas were used, the corresponding estimates of MLE ranged from 7.65 per 1000 in male rats to 19.9 per 1000 in male mice. (Table D). These estimates are somewhat lower than those based on epidemiologic data.

In discussing the results of their analyses, Crump and Allen stated that estimates made from human data should take precedence over those from animal data in the case of benzene, because the former estimates are derived from reasonably good studies involving both the species (man) and the route of exposure (air) of interest. The National Research Council of the NAS Committee on the Institutional Means for Assessment of Risks to Public Health has stated recently that "well-conducted epidemiologic studies that show a positive association between an agent and a disease are accepted as the most convincing evidence about human risk. (NAS, 1983, Ex. No. 159–57).

TABLE D.—CRUMP AND ALLEN RISK ASSESSMENT, 1984—ESTIMATES OF HUMAN RISK PER 1000 WORKERS BASED ON ANIMAL STUDIES

Exposure level	NTP (1983)		Goldstein et al. (1930)	Maltoni et al. (1983)
	Male mice[2]	Male rat[1]	Male mice[3]	Rat[3]
10 ppm	19.9	7.65	0.74	1.46
1 ppm	2.01	0.77	0.077	0.15

[1] Based on all squamous cell carcinomas.
[2] Base on leukemia.
[3] Based on leukemia.

OSHA requests comments on estimates of risk from benzene exposures based on animal data.

3. Studies showing effects on DNA and bone marrow. a. Studies of human exposure. Numerous studies have demonstrated significant excesses of chromosomal aberrations in both bone marrow cells and peripheral lymphocytes of workers exposed to benzene. This information has been reviewed recently by IARC (1982, Ex. No. 128–8). The earlier studies demonstrated chromosomal aberrations not only in workers who had severe benzene-induced pancytopenia, but also in subjects who had recovered from benzene hemopathy and in subjects exposed to benzene who did not manifest overt signs of blood damage (Forni et al., 1971, Ex. No. 128–48). These individuals had been exposed to benzene levels exceeding 10 ppm as the reports indicate their benzene exposures ranged between 25 and 530 ppm.

More recent studies have demonstrated chromosomal aberrations in workers exposed to benzene levels that averaged below 10 ppm. Fredga et al. (1979, Ex. No. 128–57) have demonstrated a significant increase in chromosomal aberrations among 12 industrial workers exposed for several hours a day to benzene levels ranging between 5 and 10 ppm as compared to expected values from 15 controls.

In 1978, DOW Chemical Company released the results of its cytogenetic studies of workers exposed to benzene (Holder, 1978 Ex. No. 159–45). Dow stated, "since increased rates of chromosomal aberrations are often associated with increased risk of malignancies—including leukemia—we have cytogenetically studied a group of 52 employees exposed to benzene for one month to 26 years." The results demonstrate a significant excess of chromosomal aberrations among the benzene exposed workers as compared to controls. Average benzene exposures of these workers were initially reported as being below 10 ppm with peak exposures exceeding 100 ppm, but that the frequency of peaking was unknown (Holder, 1978, Ex. No. 159–45). In response to a request from OSHA in 1980, Dow supplied more detailed supplemental information on benzene exposures for these individuals (Docket No. H–059, Ex. No. 230X–10). The report states that sufficient data, defined as one data point per person-year experience, were available to characterize exposures for 32 of the 52 individuals in the benzene-exposed group. Personal monitoring data from 1973 to 1976 showed that average 8-hr TWA exposures ranged from less than 0.1 ppm to 7.4 ppm, with the maximum TWA observed for one job classification being 18.3 ppm. Because the job classifications that were selected for the monitoring were those where the estimated potential for benzene exposure was greatest, it is possible that the exposures for job classifications without monitoring data, such as foreman and production superintendent, were less than those measured for other job classifications. In addition, the report states that 9 of the 52 examined workers were employed in job classifications where they may have been exposed to benzene at levels of 35 ppm to 100 ppm for periods of several minutes. It is not stated, however, whether respirators were worn during these operations. There is no evidence to indicate that any of the remaining 43 workers had ever been exposed to similar peak exposures. In addition, 9 of the 52 workers had been previously employed in another ethylbenzene plant, but no exposure data were provided for that plant.

Further analysis of the data for chromosomal aberrations addressed the distribution of individuals with both chromosome breaks and markers by benzene exposure levels as contrasted with data for controls (Picciano, 1979, Ex. 144–118). Less than three percent of non-exposed individuals showed these

aberrations in contrast to more than 20 percent for those exposed to average levels below 1 ppm, to more than 25 percent for those exposed to average benzene levels between 1–2.5 ppm to more than 30 percent for those exposed to levels averaging between 2.5–10 ppm.

This study demonstrates an exposure level-response for chromosomal breakage resulting from average benzene exposures below 10 ppm and perhaps below 1 ppm. Whether this damage to chromsomes is due to average low level exposure or to short-term peak exposures is not known. Dow is of the opinion that the damage may be the result of short-term peak exposures to benzene and stated "considering the peak exposure levels for the group as a whole, the results appear consistent with indications of cytogenetic effects previously reported in the literature" (Holder, 1978 Ex. No. 159–45).

As mentioned earlier, there is expert scientific opinion that the induction of chromosomal aberrations serve to give an estimate of the magnitude of an exposure that could increase the risk of disease (Bloom et al. 1981). Thus, OSHA's preliminary conclusion is that the cytogenetic studies by Fredga et al. (1979, Ex. No. 128–57) and DOW Chemical Company (Holder, 1978; Venable, 1980; Picciano, 1979, Ex. Nos. 159–45, 144–118) add to the growing body of evidence that there is an elevated risk of disease associated with average benzene exposure levels at and below 10 ppm.

b. Studies of experimental animals exposed to benzene. Dose related effects on human DNA and bone marrow resulting from benzene exposure quite often have to be estimated on the basis of the best available industrial hygiene information. Thus, experimental studies in which dose can be controlled may serve to augment epidemiologic observations. In this regard, several recent experimental studies have demonstrated adverse effects on chromosomes and bone marrow in relation to low level benzene exposure. Several of these new significant findings were presented at the International Conference on Benzene held in New York on November 3–4, 1983.

Tice (Tice et al., 1983, Ex. No. 159–87) presented a paper demonstrating that exposure to benzene at a concentration of 10 ppm in air, 6 hours/day, for 9 days induced a significant increase in micronuclei (a measure of bone marrow chromosomal damage) in peripheral blood cells of C57BL/6 male mice. These investigators also demonstrated that mice exposed to 28 ppm benzene for only 4 hours had a 2-fold increase in sister chromatid exchanges (SCEs) in bone marrow cells. The effect on mouse bone marrow cells increased linearly with increasing levels of 4-hour benzene exposure indicating a linear dose response by level of 4-hour exposure.

Gad-El-Karim (Gad-El Karim et al., 1983, Ex. No. 159–32) also reported a dose response and a 2-fold increase in micronuclei in CD–1 mice administered two oral doses of benzene at concentrations as low as 8.8 mg/kg body weight. Assuming that the CD–1 mice weighed 25 grams and their minute volume of air intake is 24 ml, this dosage would be equivalent to two eight-hour atmospheric exposures of approximately 6 ppm.

Dr. Andrew Kligerman reported recent findings at an International Symposium on Sister Chromatid Exchange held at Brookhaven National Laboratory (Kligerman et al. 1983, Ex. No. 159–47). Male DBA/2 mice exposed to 10 ppm benzene by inhalation for only 6 hours demonstrated a significant increase in SCE and in micronuclei.

Collectively, these studies demonstrate chromosomal damage in bone marrow cells as a result of only two daily benzene exposures equivalent to 6 ppm, or one 4-hour exposure to 28 ppm, or one 6-hour exposure to 10 ppm or 9 days (6 hrs/day) of exposure to 10 ppm.

Synder presented the results from two studies recently completed at New York University (Baarson et al. Ex. No. 146–2; Rosen, et al. Ex. No. 146–1). In the Baarson et al. study, C57BL mice were exposed by inhalation to 10 ppm benzene for 6 hours/days, 5 days/week for 32, 66 and 178 days. Since most leukemias and related disorders in man seem to involve stem cell anomalies, the response of hematopoietic stem cells was investigated. Progenitor cells from benzene-exposed mice showed markedly reduced abilities to form colonies compared to cells from control mice. Both marrow and splenic colony forming unit-erythroid (CFU–E) were depressed to 5% and 10% of control values, respectively after 178 days of exposure. Marrow burst forming unit-erythroid (BFU–E) colonies were significantly reduced to 55% of control values after 66 days of exposure, but returned to control values at 178 days. The mice also exhibited significant depressions in the numbers of circulating red cells and lymphocytes.

In a second study, short term exposure (6 hours/day for 6 days) to 10 ppm benzene in air significantly depressed mitogen-induced blastogenesis of both B- and T-lymphocytes in mice. (Rosen et al., 1984)] Ex. No. 159–66). Moreover, 6 days exposure to 10 ppm benzene was just as effective as reducing blastogenesis as 6 days exposure to higher benzene concentrations. The authors concluded that benzene exposure at or near the current occupational limit may affect certain immune functions. OSHA interprets these latter studies in animals as indicating that less than one week of exposure to the current permissible exposure limit for benzene may be associated with consequential damage to human health, i.e., chromosomal damage to bone marrow cells, significant depression of the bone marrow and disturbances of immune system function, all of which represent a potential significant hazard to human health.

In summary, the above studies show chromosomal damage from benzene exposures equivalent to 28 ppm for only 4 hours (Tice, 1983) (Ex. No. 159–87), 10 ppm for 6 hours (kligerman, 1983) (Ex. No. 159–47), 6 ppm for two 8-hour exposures (Gad-el-Karim, 1983) (Ex. No. 159–32), or 10 ppm for 6 hours/day for 9 days (Tice, 1983) (Ex. No. 159–87). The Dow cytogenetic study demonstrates significant chromosomal breakage among workers exposed to TWA benzene concentrations below 10 ppm.

VII. Significance of Risk

OSHA's overall analytic approach for setting worker health standards is a four step process consistent with recent court interpretations of the OSH Act and rational, objective policy formulation. In the first step, quantitative risk assessments are performed where possible and considered with other relevant factors to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the proposed standards being considered for the substance will substantially reduce the risk. In the third step, OHSA looks at the best available data to set the most protective exposure limit that is both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might consider the risk significant and take steps to decrease it. The Court stated:

> It is the Agency's responsibility to determine in the first instance what it considers 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 the appropriate steps to decrease or eliminate it. (*I.U.D.* v. *A.P.I.*, 448 U.S. at 655).

The Court stated that "while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." The Court added that the significant risk determination required by the OSH Act is "not a mathematical straightjacket," and that "OSHA is not required to support its findings with anything approaching scientific certainty." The Court ruled that "a reviewing court (is) to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge (and that) * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

As part of the overall significant risk determination, OSHA considers a number of factors. These include the type of the risk presented, the quality of the underlying data, the reasonableness of the risk assessments, the statistical significance of the findings and the significance of risk (Arsenic, 48 FR 1864, January 14, 1983).

Benzene exposure causes a number of serious health risks. As discussed in section V–A benzene exposure is a cause of leukemia, most specifically acute myelogenous leukemia. Adult leukemia has a low survival rate (unlike childhood leukemia), and a shorter latency period than many types of cancer. It clearly is a very serious disease. Findings also suggest that benzene is associated with multiple myeloma (cancer of the bone marrow) and lymphatic cancers.

Benzene exposure is also known to cause aplastic anemia. This disease of the bone marrow reduces the body's oxygen transportation abilities, resistance to infection and clotting abilities. It can lead to death and often cannot be effectively treated. Even in those instances where the condition is responsive to therapy and the patient survives, the individuals cellular elements of the blood rarely return to normal values.

Benzene exposure is also associated with other blood disorders under the general classification of pancytopenias. These conditions are serious, but often treatable and reversible if caught in their early stages.

As discussed in the health effects section, benzene exposure is also clearly associated with chromosomal damage. While such findings do not provide direct evidence for a genetic or carcinogenic effect, they do constitute indirect evidence for cancer because cellular DNA is being adversely affected.

Clearly both cancer, predominantly leukemia, and aplastic anemia are risks of the most serious and often fatal kind. The other disease risks are also serious, though not usually fatal. Although this significant risk discussion concentrates on the leukemia risk, and concludes that that risk alone is significant, the other risks, through not as readily quantifiable, add to the significance of the risk presented.

The underlying epidemiologic studies which provide a basis for the quantification of risk are in general of reasonable quality, clearly demonstrate a relationship between benzene exposure and leukemia, and provide a basis for risk assessment. There is a reasonable basis for determining the exposed population and excluding other agents. In the Infante, Rinsky, Ott and Wong studies there is reasonable follow up. Follow up is not as extensive in the Aksoy and Vigliani studies, but the methodology would tend to underestimate disease incidence. The Rinsky, and Ott studies provide a reasonable basis for estimating dose, a better basis than the other studies. Though the estimates of dose are not as narrow as would be preferred, they do provide a useable range. The International Agency for Research on Cancer and the Carcinogen Assessment Group of the Environmental Protection Agency have concluded that the data available are sufficient to perform risk assessments on the relationship between benzene exposure and leukemia. This is OSHA's preliminary conclusion as well.

Since 1978, three major studies of high quality in experimental animals have confirmed the carcinogenicity of benzene. As discussed above the National Toxicology Program (NTP) has demonstrated statistically significant, dose-dependent increases in tumors of multiple sites for both sexes of two species according to their standard protocol. A minimum of nine benzene related tumor types or sites have been induced in mice and rats by the NTP. Maltoni also demonstrated the induction of cancer in rats exposed to benzene through an inhalation study as discussed above.

Section VI above discusses at length the risk assessments performed for benzene, the basis for those assessments and criticism of those assessments. OSHA preliminarily concludes that the estimates presented in Table B based on the linear model are its present best estimates of risk. As discussed in the section on risk assessment, it is believed that the simpler linear model is more appropriate than more complex models when there is not sufficient mechanistic information available to justify a more complicated model and when the range of extrapolation is relatively narrow. Therefore, the choice of models will not make a dramatic difference to the estimates of risk. In addition, CAG and IARC believe the linear model most appropriate for benzene induced cancer in humans.

The question of an appropriate model for the benzene risk assessment has generated a variety of views. OSHA's final conclusions will, of course, be dependent on the evidence presented during the course of the rulemaking. OSHA specifically requests evidence and opinion on this question.

The Table B estimates are based on utilizing the central band of exposure estimates. Relatively higher estimates of exposure lead to lower estimates of risk per unit dose but the higher estimates seem less well supported for two reasons. First, the White et al. assessment of Ott utilized the highest level in each range rather than the midpoint level of dose. Secondly, some industrial hygienists frequently measure the highest exposure area where workers may or may not be present. Consequently the measured exposures in these studies tend to overestimate the employee's average exposure. In addition, respiratory protection was sometimes worn in high exposure areas reducing the dose below the area sample taken. Relatively lower estimates of dose lead to higher estimates of risk per unit of dose, but would indicate a greater degree of care in reducing exposures than what is currently thought was common in the earlier days.

OSHA's preliminary preferred estimate of risk of death from leukemia resulting from a working life time exposure to benzene at 10 ppm is 44–152 cases per 1000 exposed employees. OSHA preliminarily concludes that risks in this range are significant. This is consistent with OSHA's determination or preliminary determination at the existing permissible exposure level for three carcinogens recently subject to rulemaking: Inorganic arsenic (Jan. 14,

1983; 48 FR 1864, 1896) ethylene oxide (Apr. 21, 1983; 48 FR 17284, 17295; and ethylene dibromide (Oct. 7, 1983; 48 FR 45975). Those estimates per 1000 employees for a working life time exposure were 148–425 lung cancer deaths from inorganic arsenic, 63–109 cancer deaths from ethylene oxide and 70–110 angiosarcoma cancer deaths from ethylene dibromide, based on the PEL's prior to the completion of new lower standards.

In addition, OSHA concluded or preliminarily concluded that, if it were feasible, OSHA would seek to reduce the predicted remaining risk at the level set or proposed by the new standards. This risk for a working lifetime exposure per 1000 employees was 8 cases for inorganic arsenic, 2 to 6 cases for ethylene dibromide; and 1–2 cases from ethylene oxide.

Further guidance for the Agency in evaluating significant risk is provided by an examination of occupational risk rates and legislative intent. For example, in the high risk occupations of fire fighting, and, mining and quarrying the average risk of death from an occupational injury or an acute occupationally related illness from a lifetime of employment (45 years) is 27.45 and 20.16 per 1,000 employees respectively. Typical occupational risk of death in occupations of average risk are 2.7 per 1,000 for all manufacturing and 1.62 per 1,000 for all service employment. Typical lifetime occupational risks of death in occupations of relatively low risk are 0.48 per 1,000 in electric equipment and 0.07 per 1,000 in retail clothing. These rates are derived from 1979 and 1980 Bureau of Labor Statistics data from employers with 11 or more employees adjusted to 45 years of employment for 46 weeks per year.

There are relatively few data on risk rates for occupational cancer as distinguished from occupational injury and acute illness. The estimated cancer fatality rate from the maximum permissible occupational exposure to ionizing radiation is 17 to 29 per 1,000. (47 years at 5 rems; Committee on the Biological Effects of Ionizing Radiation (BEIR) III predictions.) However most radiation standards require that exposure limits be reduced to the lowest level reasonably achievable below the exposure limit (the ALARA principle). Approximately 95% of radiation workers have exposures less than one-tenth the maximum permitted level. This risk at one-tenth the permitted level is 1.7 to 2.9 per 1,000 exposed employees.

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Based on this it is clear that Congress gave OSHA authority to reduce risks of average or above average magnitude when feasible. Further the Supreme Court stated that "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 take the appropriate steps to decrease or eliminate it."

Within this context, OSHA's preliminary risk estimates from benzene are substantially higher than other risks which OSHA has concluded are significant, are substantially higher than risk of fatality in occupations of high risk as well as occupation of average risk, and are substantially higher than the example presented by the Supreme Court. Consequently OSHA concludes that risk estimates of 44–152 leukemia deaths per 1000 employees is clearly significant and preliminarily concludes that benzene presents a significant risk at 10 ppm.

Other estimates of risk discussed in this document based on assumptions which are not well supported range down to 9 per 1000. Estimates in that range would also be significant based on the above reasoning.

OSHA notes that a large number of employees currently exposed to benzene are exposed at well under one-tenth the current exposure limit. Many employers appear to be keeping exposure low. Therefore most current benzene exposed employees are exposed to risks much below the risk levels presented.

OSHA preliminarily concludes that the proposed 1 ppm benzene standard will substantially reduce a significant risk of leukemia. The new standard will result in a reduction of at least 39 to 136 excess leukemia deaths per 1000 employees exposed at the current 10 ppm level, a 90% reduction. The actual reduction is likely to be greater. As a result of the action level, many employers may be motivated to reduce exposures where feasible below 0.5 ppm to reduce their industrial hygiene costs. In addition, the lowering of exposure is likely to reduce the incidence of chromosomal aberrations and other blood dyscrasias. As discussed in the medical surveillance section, early detection of blood dyscrasias can reduce the incidence of aplastic anemia and leukemia. The medical provisions will therefore further reduce the incidence of disease greater than the reduction in exposure level will predict.

The performance oriented industrial hygiene provisions which will minimize skin contact, will further reduce benzene exposure. Finally, the provision encouraging the development of solvents with less than 0.1% benzene contamination will also further reduce benzene exposures. In consequence OSHA's preliminary conclusion is that the proposed standard will substantially reduce a significant risk both in areas where the reduction is quantifiable and additionally will result in very real but non-quantifiable further substantial reductions in risk.

Finally, OSHA preliminarily concludes that the proposed standard is carrying out Congressional intent within the limits of feasibility and does not attempt to reduce insignificant risks. Under both the Congressional intent and the Supreme Court's guidance, OSHA would, if it were feasible, seek to reduce the level of risk estimated to remain at 1 ppm by the risk assessment. However, as just discussed, OSHA expects the action level, industrial hygiene and medical surveillance provisions to reduce risk substantially below those predicted by the mathematical models, though the additional reduction cannot be quantified. OSHA preliminarily concludes that its proposed benzene standard will protect employees and that employers who fulfill the provisions of the standard will be taking reasonable steps to protect their employees from the hazards of benzene. Indeed many employers have already reduced exposures of employees to below those of the proposed standard.

VIII. Summary of Regulatory Impact and Flexibility

Analysis and Feasibility Analysis

A. Introduction

Executive Order 12291 (46 FR 13197, Feb. 19, 1981) requires that a regulatory analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) similarly requires the Occupational Safety and Health Administration (OSHA) to consider the impact of the proposed regulation on small entities.

Consistent with these requirements, OSHA has prepared a Preliminary Regulatory Impact and Regulatory Flexibility Analysis for the proposed benzene standard. This analysis describes the industries affected by the standard, the non-regulatory and regulatory alternatives considered, some of the potential benefits that will accrue to employees exposed to benzene at their places of work, the costs of compliance with the proposed standard, and the technological and economic feasibility of the proposed provisions.

B. Industry and Exposure Profiles

Benzene is produced primarily by the petrochemical and petroleum refining industries by a process called catalytic reformation, which converts certain lower octane aliphatic hydrocarbons into higher octane aromatic hydrocarbons. These two industries are responsible for 98 percent of the total U.S. production of benzene. Recovery through catalytic reformation, including the benzene formed from the hydrodealkylation of toluene, accounts for approximately 75 percent of the total quantity of benzene produced. Recovery through coal-derived benzene, primarily as a by-product of the coking process in steel mills was once a major source of benzene. Now it accounts for only 2 percent of the total United States production.

Benzene production tends to reflect the state of the economy. Production from petroleum rose from 1.4 billion gallons in 1976 to a pre-recessionary peak of 2.0 billion gallons in 1980, a 43 percent increase. Although information on the amount of benzene produced only from petroleum is not available for 1982, total benzene production declined by 33 percent from 1980 to 1981, and by an additional 20 percent from 1981 to 1982. Associated with this decline in benzene production was a corresponding decline in the sales of many of the major benzene derivatives, such as alkylbenzene, aniline, chlorobenzene, and nitrobenzene. Production of benzene and its derivatives is now increasing, reflecting the improvement in the economy (JRB, Ex. No. 153).

International competition in the production and sale of industrial organic chemicals (i.e., SIC 2865 and SIC 2869) is increasing but represents a small percentage of consumption. Between 1979 and 1982, the quantity of benzene imported rose from 3.9 percent of domestic consumption in 1979 to 12.3 percent in 1982 (DRI, 1983) Ex. No. 154).

OSHA estimates that approximately 270,000 workers are exposed to benzene in seven major industry sectors which fall under the Agency's jurisdiction. These sectors include the benzene producers (i.e., petrochemicals, petroleum refining, and coke and coal chemical manufacturing), the rubber tire manufacturing industry, and firms engaged in the bulk storage and transportation of benzene and petroleum products containing benzene.

In three industry sectors—petrochemicals, petroleum refineries, and coke and coal chemicals—the manufacturing processes likely to contribute to benzene exposures are either highly automated or are performed infrequently. Exposed employees are generally the unit operators, tankcar loaders and unloaders, laboratory technicians, and maintenance personnel.

In the manufacturing of rubber tires, benzene exposures occur as a result of the use of benzene-contaminated solvents. Exposed employees include process operators, workers responsible for the storing, mixing, loading, and unloading of solvents, laboratory technicians, and maintenance personnel. Supervisory personnel may also be exposed to solvents containing benzene.

In three other industry sectors—bulk terminals, bulk plants, and transportation—the exposed employee population consists primarily of those who load and unload benzene and material containing benzene. Employee exposures reach peak levels while these materials are being transferred; however, transfer operations may not occur on a day-to-day basis.

OSHA believes that the exposure profile presented in Table A is representative of the industries analyzed. The data used to estimate the population at risk for each of these industry sectors were gathered from JRB's site visits, JRB's industry surveys, docket responses to OSHA's Request for Information Regarding Occupational Exposures to Benzene, and contacts with trade associations and labor unions. Whenever possible, the data were corroborated by using multiple reference sources. Because of data limitations, the populations at risk include all employees exposed to benzene in the course of their work, without regard to the duration of such exposure.

TABLE A.—NUMBER OF EMPLOYEES EXPOSED TO BENZENE [2] (BY EXPOSURE LEVELS AND BY INDUSTRY DIVISIONS)

Industry sector	8-Hour TWA Benzene Concentrations (ppm)						Total
	.00–.10	.11–.50	.51–1.0	1.1–5.0	5.1–10.0	10.0+	
Petrochemical producers	5,460	4,064	1,224	1,212	159	122	[1]12,242
Petroleum refineries	36,510	14,751	2,600	2,148	283	226	[1]56,517
Coke and coal chemical		3,550	422	436	71	18	[1]4,499
Tire manufacturers	34,645	24,375	4,095	1,820	0	0	[1]65,000
Bulk terminals	14,556	8,260	1,335	932	1,988	25	[1]27,096
Bulk plants	26,845	15,234	1,178	14,787	56	[1]61,093	
Transportion via tank truck	32,558	10,996	2,523	1,380	48	95	[1]47,600
Total all sectors	150,574	81,230	14,660	9,646	17,336	533	[1]274,047

[1] Figures do not total in some cases due to rounding.
[2] This table summarizes the worker groups for which OSHA has good exposure data. However, due to the ubiquitous nature of benzene (e.g., it is a naturally occuring constituent of crude oil, natural gas and coal), OSHA was not able to obtain exposure data for some worker groups such as oil and gas well drillers exposed to benzene.
Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis, 1984.

Table A does not include workers employed by firms that are either covered by the exclusions (see the discussion of the exclusions under the scope section) or that fall under the jurisdiction of other regulatory agencies. Additionally, the profile does not include workers employed in the miscellaneous industries that use products containing small quantities of benzene (i.e., solvent, inks, paints, etc.) and by contract maintenance firms (i.e., oil well servicing, tank cleaning, etc.) because exposure data for these industries were not available. OSHA requests exposure data on these sectors that can be integrated into the analysis.

OSHA believes that the firms that use solvents contaminated with benzene will be able to switch to solvents with very low concentrations of benzene. As such solvents are excluded from the scope of the proposed standard, this approach will provide the most cost-effective means of complying with the proposed standard. Tank maintenance firms have the problems of flammability and asphyxiation to contend with, which are general to most petroleum products in confined spaces. This standard does not specifically address these problems. (See for example, 1910.106.)

C. Benefits Analysis

The reduction in the occurrence of occupational illnesses that would result if the proposed benzene standard is promulgated represents the major benefit of the proposed standard. Some aspects of these benefits can be quantified, such as the reduced risk of leukemia and aplastic anemia due to direct exposure to benzene. OSHA's analysis of the lives that would be saved because of the proposed benzene regulation is based predominantly on the OSHA quantitative risk assessment for leukemia (see Section VII), because the quantitative relationships between benzene exposure and the development of diseases other than leukemia have not been systematically developed. Scientific data are available, however,

that can be used to estimate the ratio of leukemia deaths to aplastic anemia deaths. Based on the assumption that the relationship between observed benzene-induced leukemia deaths and aplastic anemia deaths is constant, OSHA has estimated the number of benzene-induced aplastic anemia deaths under the various proposals by multiplying the number of predicted benzene-induced leukemia deaths by this ratio.

OSHA has estimated only the number of benzene-induced leukemia and aplastic anemia deaths that might be prevented by lowering the proposed standard. Consequently, this analysis will tend to underestimate the total benefits of the proposed regulation, because some of the benefits that are expected to accrue as a result of benzene regulation were not included.

- The substantial decrease in exposures because many employers will choose where cost effective and feasible to reduce exposures below the 0.5 ppm action level.
- The potential decrease in the number of leukemia cases that may not occur as a result of progression from non-malignant blood disorders because of medical removal.
- The potential decrease in the number of benzene-induced non-malignant blood dyscrasias in the exposed populations.
- The potential decrease in the number of chromosomal changes in the exposed populations.
- The potential decrease in the number of benzene-induced cases of leukemia caused by percutaneous absorption of benzene.
- The decrease in the number of cases of dermatitis caused by dermal contact with benzene or benzene-containing liquids.

Furthermore, because of a lack of exposure data, the analysis does not include the benefits of a revised benzene standard for employees who are exposed to benzene in the following circumstances:

- Employees who are exposed to solvents contaminated with benzene (other than tire industry employees).
- Employees who are exposed to benzene-contaminated products that are made from benzene-contaminated solvents (adhesives, caulks, glues, and paints, etc.).
- Employees who may be exposed to hazardous waste containing benzene at hazardous waste management facilities and in the solvent recovery industry.
- Employees who are exposed to benzene when it is used as a solvent in the chemicals and pharmaceuticals industries and when it is used as a denaturing agent for ethyl alcohol.
- Employees who are exposed to benzene in the manufacture of small volume derivatives (various chlorobenzenes, biphenyl, and maleic anhyride, etc.).

Using the quantitative risk assessment, which estimates a reduction in the risk rate from 44–152 per 1000 at 10 ppm to 5–16 per 1000 at 1 ppm, OSHA has estimated the excess cancer deaths that are expected to occur among directly exposed workers in the seven industry sectors cited above during the next 50 years. Based on current benzene exposure levels OSHA estimates that by reducing the PEL to 1.0 ppm, the number of excess leukemia deaths occuring in these seven industries will be reduced by 571 deaths over the 50-year period. (See Office of Regulatory Analysis Report, 1984, for calculations.)

OSHA's estimates of the relationship between benzene exposure and aplastic anemia is based on a case study by Vigliani which examined cases of benzene exposed workers at the Institutes of Occupational Health in Milano and Pavia, Italy, during the period 1942 through 1975 (Ex. No. 128–15). Vigliani reports that a total of 24 workers died from leukemia during this period. In addition, Vigliani also reports 177 cases of chronic benzene poisoning, of which 10 cases resulted in death from aplastic anemia. Based of the assumption that the Vigliani case study is typical, then the ratio of deaths from benzene-induced non-malignant blood dystrasias to deaths from benzene-induced leukemia is 0.42 (e.g., 10/24). (This assumption is supported by evidence in the Ott study (Ex. No. 128–33) where the ratio is 0.33 = ⅓ and the Rinsky study (Ex. No. 128–32) where the ratio is 0.33 to 0.44 ([3 or 4]/9).) Based on this ratio, OSHA estimates that an additional 240 lives will be saved as a result of the proposed benzene standard due to a reduced incidence of death due to aplastic anemia (i.e. 571x0.42).

OSHA believes that proper medical examinations can identify blood abnormalities in workers exposed to benzene prior to the onset of more serious symptoms. The workers' exposures can then be controlled (e.g., possibly by removal from high-risk areas), and in some cases, the abnormalities will be reversed before the workers' condition progresses to diseases, such as aplastic anemia or leukemia (Ex. No. 217–34, H–059). This analysis is supported by evidence from physicians carrying out regular examinations of benzene workers, who found that removal from benzene exposure after the detection of early blood abnormalities may result in a return to normal.

Moreover, Dr. Jandl states that 16 percent of aplastic anemia deaths can be prevented through early diagnosis and proper medical treatment (Ex. No. 217–34, H–059). Thus, OSHA believes that the prevention of 16 percent of the estimated aplastic anemia deaths predicated to occur without medical surveillance can be used as a lower bound estimated of the total benefits accruing from the proposed medical surveilliance program. OSHA has not attempted to quantify any benefits that may occur from the proposed medical surveillance program that may detect workers with types of benzene-induced non-malignant bone marrow toxicity other than aplastic anemia, that could eventually progress to malignant disease if exposure continued.

OSHA estimates that 11 deaths from aplastic anemia are potentially avoidable due to the proposed medical surveillance provision by multiplying the estimated number of aplastic anemia cases predicted to occur as the result of exposures above the 0.5 ppm action level (which triggers medical surveilance) by the estimated portion of aplastic anemia deaths that are preventable through medical surveillance (16%). Thus, OSHA estimates that the benzene proposal will save a total of 822 lives during a 50-year period (i.e., 571+240+11) (See Office of Regulatory Analysis Report, 1984, for calculations).

D. Technological Feasibility

OSHA has preliminarily determined that the proposed standard is technologically feasible. The methods that can be used to reduce employee exposure to benzene include conventional technologies such as air monitoring, double mechanical seals, exhaust ventilation, leak detection, and use of respiratory protection for intermittent exposures. Such technologies are commonly known and currently used to some degree in the affected industries.

OSHA's assessment of technological feasibility is based on information collected by JRB Associates, Inc. (Ex. No. 153), on current exposure levels resulting from existing controls, on the availability of controls needed to reduce exposures from current levels, and on other evidence present in the docket. Of course, OSHA's ultimate determination will be based on all the evidence in the record and OSHA invites comments on this issue.

Engineering Controls

Petrochemical Production, Petroleum Refinery, and Coke and Coal Chemicals

The process units in the petrochemical, petroleum refinery, and coke sectors are similar in that they are large, automated, enclosed systems comprised of process vessels, pipes, valves, pumps, and compressors. The processes are also similar in that they generally operate at temperatures and pressures exceeding ambient conditions.

Although benzene exposures in these industry sectors are generally low because of the closed nature of the process units, exposures above the 1.0 ppm level can result from the following:

- Process sampling,
- Wastewater containing benzene,
- Leaks,
- Loading and unloading operations of benzene and benzene-containing materials,
- Tank gauging, and
- Maintenance operations.

OSHA believes that non-maintenance worker exposures to benzene can be reduced to the 1.0 ppm exposure limit through the use of some combination of the following engineering controls and work practices:

- Installing double seals and containment systems on pumps.
- Installing ventilated enclosures for process sampling.
- Enclosing wastewater collection systems.
- Installing enclosed oil or water separator on wastewater treatment systems.
- Instituting manual leak detection surveys and promptly repairing the leaks that are found.
- Instituting the work practice of requiring employees to stand upwind of open hatches during manual tank gauging or installing automatic tank gauging equipment.

Based on the JRB report, OSHA believes that it may be possible for these sectors to generally reduce employee exposures to the 0.5 ppm TWA through the following controls in addition to those listed above:

- Installing closed hatch or automatic loading systems for the tank truck, railcar, and barge loading operations. (Note: since barges are under the jurisdiction of the U.S. Coast Guard, respirators may be the only "feasible" means of required protection for barge loaders who fall under OSHA's jurisdiction.)
- Increasing the frequency of manual leak detection surveys and promptly repairing the leaks that are found.
- Installing automatic leak detection equipment to monitor problem areas.

JRB was not able to ascertain, however, the degree to which these controls will ensure that all non-maintenance employees are consistently exposed to less than 0.5 ppm TWA especially in the benzene production areas.

In order to attempt to achieve a 0.1 ppm permissible exposure limit (PEL), OSHA believes that these particular industry sectors would be required to make major changes in the way they operate in order to isolate workers in benzene-free control rooms and eliminate routine benzene exposures in activities that are typically performed outside the control room (i.e., collecting quality control samples and loading benzene and liquids containing benzene). OSHA preliminarily concludes that the proposed 1.0 ppm PEL is technologically feasible for these sectors.

Rubber Tire Manufacturers

Volatile solvents are used in tire manufacturing to promote "tack," or stickiness, to enhance elastic properties, and to extend or substitute for part of the rubber material. Rubber solvents such as hexane, toluene, xylene, white gasoline, and petroleum naphtha are used in varying degrees in the manufacturing process. These solvents, which have their own related health hazards, are also contaminated with benzene. The percentage of benzene present in these solvents depends on the type of process and the quality control procedures used by each solvent producer. Benzene exposure may occur at many different locations and at any volatile-solvent-using operation in tire manufacturing operations.

OSHA believes that there are two basic procedures that the tire manufacturers could use to reduce worker exposures to benzene in these areas. First, they could utilize solvents that have lower benzene concentrations (i.e., below 0.1 percent). Second, the tire manufacturers could dilute the benzene in the ambient air by providing increased ventilation in the work environment. This option could be carried out by utilizing a combination of local exhaust ventilation, process enclosure, and dilution ventilation systems. OSHA believes that the industry will generally choose to go to solvents with below 0.1 percent benzene to be excluded from the standard as the more protective and cost-effective option. OSHA preliminarily concludes that both approaches are technologically feasible for meeting the requirements of the proposed standard.

Bulk Terminals, Bulk Plants, and Transportation

These sectors are considered together in this feasibility analysis because they have the same types of exposure sources and employ the same types of engineering controls. Based on available information, OSHA believes that the exposures to benzene above 0.5 ppm in these sectors predominantly occur during the open-hatch loading of trucks and during the manual gauging of storage tanks and tank trucks. In addition, some routine maintenance activities are associated with benzene exposures greater than 0.5 ppm (8-hour TWA).

Exposures during tank gauging can be controlled by instituting simple work practices. When the gauging tape is lowered into the tank from the hatch on top of the tank, the gauger should stand upwind from the hatch.

Exposures that occur during open-hatch top loading of trucks at terminals or plants can be reduced by using closed-hatch loading or bottom loading systems. These systems can be expected to reduce benzene exposures to below 0.5 ppm even where a vapor control system is not used. OSHA, therefore, preliminarily concludes that the standard is technologically feasible for these sectors.

Users of Liquids Containing Benzene

The proposed benzene standard would exclude those work operations that use liquid mixtures containing less than 0.5 percent benzene (by volume). Five years after the promulgation date of the final standard, only those work operations that use liquid mixtures containing less than 0.1 percent benzene would be excluded from the scope of the standard.

Three methods are available for reducing the benzene content of hydrocarbon solvents: distillation, extraction, and hydrotreatment. Distillation and extraction involve the physical separation of aromatics from a hydrocarbon mixture. Hydrotreatment is the chemical reduction of unsaturated hydrocarbons, such as benzene, with hydrogen to produce saturated hydrocarbons.

Of the three methods, hydrotreatment appears to be the most effective means of reducing the content of unsaturated compounds, including benzene. Under moderate hydrotreatment conditions, aromatic compounds can be chemically reduced to completely saturated compounds, and less severe hydrotreatment could be used to convert small amounts of benzene in a liquid

mixture that already contains saturated compounds.

Thus, OSHA preliminarily concludes that it is possible to produce low benzene-containing liquids containing less than 0.1 percent benzene for the solvent users. Therefore, it is technically feasible for the solvent users to comply with the standard by switching to solvents with low benzene concentration.

Short Term Exposure Limit

OSHA's contractor, JRB (Ex. No. 153), has analyzed the efficiencies of the engineering controls and work practices discussed above, and has concluded that the same controls and work practices which will reduce 8-hour TWAs to below the 1.0 ppm level would also be effective in reducing 15-minute STELs to below the 5.0 ppm level, if such a STEL was incorporated into the standard. JRB was able to find only two operations—some maintenance activities and the loading of pure benzene—where meeting a 5.0 ppm STEL may not be possible with engineering controls. In these situations the use of respiratory protection would achieve compliance. OSHA solicits additional information on these operations and the feasibility of a STEL if one is incorporated into the standard. Further discussion of the STEL is located in section X.

Exposure Monitoring

This provision of the proposed standard would require employers to determine whether any employee may be exposed to airborne concentrations of benzene. Measurements would be made by monitoring the breathing zone of one representative employee over an 8-hour period for each job classification and for each shift. OSHA believes that at least two methods are currently available to take these measurements (charcoal tubes and passive dosimeters).

Respiratory Protection

This provision would require employers to provide and ensure the use of respirators when benzene exposures exceed the PELs. The proposed standard would allow employers to use respirators to achieve compliance with the PEL in the following work situations:

- During the installation or implementation of feasible engineering and work practice controls
- Where the employer establishes that engineering and work practice controls are not feasible, such as in maintenance and repair activities, which are intermittent
- When feasible engineering and work practice controls do not exist to reduce exposure to or below the PEL
- In emergencies
- When benzene is used in the workplace less than 30 days per year

OSHA believes that there are a number of currently available respirators on the market that could be used to meet this requirement down to the 1.0 ppm level.

Protective Clothing and Equipment

This provision would require the employer to provide protective clothing and equipment when the employee is exposed to eye or skin contact with benzene. Eye and face protection are currently required by 29 CFR 1910.33 and are easily acquired from suppliers. Other protective clothing that may be required by the standard includes gloves, aprons, coveralls, and footwear, depending on the work situation. These are also currently available on the market.

Only one of the industry sectors, tire manufacturers, may have a problem limiting dermal contact with benzene or benzene-containing liquids. Current practice in this industry sector is to build tires one ply at a time on a rotating drum. A considerable amount of material has been submitted to the docket, in support of the position that it is technologically infeasible to use gloves to limit dermal contact with benzene in this sector, because manual contact with the tacky rubber (i.e., rubber coated with benzene-containing solvent) is necessary for positioning each ply on the drum and for ensuring complete adhesion between plys or between the plys and treads. Even in this industry, however, skin contact can be significantly reduced through the use of either low benzene-containing solvents (less than 0.1 percent) or automated tire building equipment such as that used by the Michelin Tire Corporation. In addition, some barrier creams may help to reduce dermal exposure.

It is clearly feasible for the tire companies to comply with the standard by switching utlimately to solvents with less than 0.1 percent benzene. Most have already reduced the percentage to under 0.5 percent.

Medical Surveillance

These proposed provisions would require initial and semiannual medical examinations for some employees who are exposed to benzene. The initial medical examination would include at least a detailed occupational and medical history, and a complete blood count. Additionally, for workers required to wear respirators at least 30 days a year, a pulmonary function test must be performed every 3 years, and a chest X-ray must be provided every 5 years. Employees exposed to benzene in emergency situations also must be provided with a urinary phenol test at the end of the shift during which the emergency occurred. OSHA believes that all of these examinations are readily available and can be performed at any clinic, doctor's office, or hospital.

E. Cost of Compliance

This section presents OSHA's estimates of the compliance costs that would be incurred by employers in the seven industry sectors primarily affected by the proposed benzene standard. Because there are industry-specific differences in exposure characteristics and equipment usage, cost estimates for each sector were developed separately.

First, a baseline of current industry practice was identified for each sector. This baseline was derived from information on current production methods and hazard control methods obtained during the JRB information-collection efforts and from other submissions to the record. The costs of the engineering controls to achieve each successively lower PEL were then estimated based on the assumption that new controls could be added to those controls already in place.

It should be noted that the lower the target PEL the higher the uncertainty associated with the estimates of effectiveness of the technology and housekeeping and their related costs. OSHA is confident the 1 ppm can generally be reached and maintained on an 8-hour TWA basis, but, is unsure of how close industry can generally approximate a 0.5 ppm on an 8-hour TWA.

Much of the data used for cost estimates were obtained from two basic sources: Information collection from JRB surveys and site visits, and information provided by industry trade associations. Both of these sources rely on input from firms within the various industries. OSHA attempted to corroborate the estimates from other sources such as suppliers of equipment or from independent engineering sources.

Table B summarizes OSHA's compliance cost estimates of the proposed benzene standard with a 1.0 ppm PEL and 0.5 ppm action level. Note, that the "engineering costs" are those costs associated with obtaining the PEL,

and the "non-engineering costs" are those costs associated with the other provisions of the standard, such as medical surveillance, exposure monitoring, training, etc. Annualized costs of capital are the yearly interest and depreciation costs needed to pay for a capital investment over the useful life of the equipment. This takes into account variations in the useful life of each type of equipment as well. The compliance costs attributed to the tire industry are for the engineering control approach (i.e., use of ventilation). OSHA believes that most firms in this sector will actually comply with the standard by using solvents with low benzene concentrations and thereby incur lower costs then were estimated below. Table C provides a sector by sector breakdown of the non-engineering costs of the standard.

TABLE B.—ESTIMATED TOTAL ANNUALIZED COSTS ASSOCIATED WITH THE PROPOSED BENZENE STANDARD (1 PPM PEL AND 0.5 PPM ACTION LEVEL)

[Millions of 1983 dollars]

Sector	Total annualized		
	Engineering costs to achieve the 1 ppm PEL	Non-engineering costs associated with this regulatory alternative [1]	Cost associated with this regulatory alternative [1]
Petrochemical	0.995	1.324	2.319
Petroleum refining	0	2.246	2.246
Coke and coal chemical	4.258	0.786	5.044
Tire manufacturers	0.490	1.025	1.515
Bulk terminals	0.369	1.871	2.240
Bulk plants	2.842	12.534	[2] 15.376
Tank truck	0	0.299	0.299
Total all sectors	8.954	20.085	29.039

[1] Does not include the transitional costs associated with the compliance program.

[2] It should be noted that this cost is divided among approximately 15,000 establishments so the average annualized costs per facility is about $1,000.

Source: Adapted from Meridian Research, 1984.

OSHA has also estimated the costs of compliance for two alternative regulatory proposals, a 0.5 ppm PEL with a 0.1 ppm action level (See Table D), and a 5.0 ppm PEL with a 1.0 ppm action level (see Table E). Note that an action level of 20 percent of the PEL was used for these alternatives rather than 50 percent of the PEL which OSHA has frequently used because of limitations in the data.

A comparison of the three alternatives shows that the estimated costs of lowering the proposed PEL from 5 ppm to 1.0 ppm is approximately $5 million per year. The estimated increased cost of further lowering the PEL from 1.0 ppm to 0.5 ppm is approximately $109 million per year.

TABLE C.—SUMMARY OF ESTIMATED TOTAL ANNUALIZED NON-ENGINEERING COSTS ASSOCIATED WITH THE PROPOSED STANDARD

[Millions of 1983 dollars]

Proposed provisions	Coke and coal chemical producers	Petroleum refineries	Petrochemical producers	Tire manufacturers	Bulk terminals	Bulk plants	Truck transport	Total all sectors
Annual monitoring	0.028	0.068	0.060	0.006	0.239	1.828	0	2.229
Respirator program	0.688	1.313	0.961	0	0.574	4.746	0	8.302
Medical surveillance	0.032	0.696	0.270	0.592	1.058	2.386	0	5.034
Training program	0.036	0.169	0.013	0.427	0	3.574	0.299	4.520
Compliance program	[1] 0.009	[1] 0.044	[1] 0.035	[1] 0.031	[1] 0.367	[1] 2.812	[1] 0.048	[1] 3.346
Total annualized non-engineering costs	[2] 0.786	[2] 2.246	[2] 1.324	[2] 1.025	[2] 1.871	[2] 12.534	[2] 0.299	[2] 20.085

[1] Transitional costs assume to occur only in the first two years following the promulgation of a revised benzene standard.

[2] Does not include costs associated with compliance program.

Source: Adapted from Meridian Research, 1984.

TABLE D.—ESTIMATED TOTAL ANNUALIZED COSTS ASSOCIATED WITH ATTEMPTING TO ACHIEVE THE REGULATORY ALTERNATIVE OF A 0.5 PPM PEL AND 0.1 PPM ACTION LEVEL

[Millions of 1983 dollars]

Sector	Engineering costs to attempt the 0.5 ppm PEL	Non-engineering costs associated with this regulatory alternative [1]	Costs associated with this regulatory alternative [1]
Petrochemical producers	7.937	1.721	9.658
Petroleum refineries	93.425	4.133	87.556
Coke and coal chemical	6.415	0.955	9.370
Tire manufacturers	3.011	3.487	6.498
Bulk terminals	0.851	2.433	3.284
Bulk plants	6.512	13.974	20.486
Tank truck	0.0	0.780	0.780
Total all sectors	110.151	27.483	137.634

[1] Does not include the transitional costs associated with the compliance program.

Source: Adapted from Meridian Research, 1984.

TABLE E.—ESTIMATED TOTAL ANNUALIZED COSTS ASSOCIATED WITH THE REGULATORY ALTERNATIVE OF A 5.0 PPM PEL AND 1.0 PPM ACTION LEVEL

[Millions of 1983 dollars]

Sector	Engineering costs to achieve the 5.0 ppm PEL	Non-engineering costs associated with this regulatory alternative [1]	Costs associated with this regulatory alternative [1]
Petrochemical	0.0	1.204	1.204
Petroleum refining	0.0	1.913	1.913
Coke and coal chemical	4.258	0.766	5.024
Tire manufacturers	0.0	0.611	0.611
Bulk terminals	0.038	1.871	1.909
Bulk plants	0.279	12.534	12.813
Tank truck	0.0	0.299	0.299
Total all sectors	4.575	19.198	23.773

[1] Does not include the transitional costs associated with the compliance program.

Source: Adapted from Meridian Research, 1984.

F. Economic Feasibility Analysis

OSHA's preliminary conclusion is that it is economically feasible for the seven industry sectors and solvent users to comply with the provisions of the proposed benzene standard of a 1.0 ppm PEL and a 0.5 ppm action level. None of these sectors would experience significant economic impacts because of the proposal.

If none of the compliance costs were to be passed forward to consumers, an average firm in each of the four industries characterized by large multi-product firms (e.g., petroleum refining, petrochemical, iron and steel, and tire) would experience an after-tax profit decline of less than 1 percent in its product lines affected by the proposed benzene standard. (This would apply to the iron and steel segment in most years, for example, 1981. The 1982 base year of this analysis, however, was a loss year for this segment and the compliance costs would result in loss increases of less than 1 percent rather than in profit declines.) At the other extreme, if all of the costs associated with the proposed were to be passed forward to the customers so that after-tax profits in these product lines were unchanged, then an average firm in each industry would require price increases of less than 0.1 percent. For example, an

average facility in the petroleum refining or tire manufacturing sectors would have to raise its annual gross revenues by approximately $8,000–$10,000 to offset fully the net compliance costs associated with the proposal. (See table F.)

TABLE F.—ESTIMATED ECONOMIC IMPACTS OF THE PROPOSED BENZENE STANDARD ON AN AVERAGE THE INDUSTRY SECTORS TYPIFIED BY LARGE MULTI-PRODUCT FIRMS

Sector	Total industry after tax profit decline if revenues are unchanged (1000 1982 dollars)	Profit decline of an average firm in industry (percent)	Total industry increased revenues required to fully offset compliance costs (1000 1982 dollars)	Increased revenues required to fully offset compliance costs of an average firm
Petrochemical	(1)	0.15 to 0.88	(1)	0.02 to 0.113
Petroleum refining	1,196	0.02	2,216	0.001
Iron and steel	2,384	[2] 0.20	4,415	0.009
Tire manufacturers	752	0.94	1,393	0.016
Bulk terminals	987	(3)	1,828	0.004

[1] Varies based on the specific type of chemical. See Chapter 6 of the JRB report for details.
[2] This would apply to the iron and steel segment in most years, for example 1981; however, the base year of this analysis (1982) was a loss year for this segment and the compliance costs would result in loss increases (of less than of one percent) rather than profit declines.
[3] OSHA could not obtain profit estimates on these operations. See the text for details.
Source: JRB Associates, 1984.

An average firm in the two sectors characterized by small firms (i.e., the bulk plants and tank sectors) would incur annual compliance costs of approximately $1,200. After taking the permissible tax write-off, these firms would experience an after-tax profit decline of less than 2 percent if none of the compliance costs were to be passed forward to customers, and would require a revenue increase of approximately 0.02 percent to leave after-tax profits unchanged if all of the costs were passed forward to customers (See Table G.)

OSHA believes that the economic impacts estimated under each of the scenarios presented above represent extreme or bounding cases. For example, the after-tax profit declines were based on the assumption that no revenue increases will occur. In actuality, however, because most of the compliance costs are distributed among all firms in each sector, some revenue increases will likely occur to offset potential profit declines. In addition, because a recession year (e.g., 1982) was used as the base year in its analysis, economic impacts are likely to be overestimated. Profits in 1982 were considerably lower than normal in a number of the sectors studied, and as the economy improves, the profits and revenues of many of the firms in these sectors should recover, diminishing the already small economic impacts of the proposed benzene standard.

In fact, in its addendum to the JRB report, Meridian Research states:

TABLE G.—ESTIMATE ECONOMIC IMPACTS OF THE PROPOSED BENZENE STANDARD ON AN AVERAGE FIRM IN THE BULK PLANT AND TANK TRUCK SECTIONS

Industry	Decline in after tax profits of an average firm if revenues are unchanged (1982 dollars)	Percent decline in after tax profits of an average firm if revenues are unchanged	Increased revenue required to fully offset the compliance costs of an average firm (1982 dollars)	Percentage sales increase required to fully offset the compliance costs of an average firm
Bulk plants	649	1.18	927	0.009
Truck transport	656	0.22	1,216	0.01

Source: JRB Associates, 1984.

The JRB report concluded that the economic impact of promulgating any of the alternative benzene standards being considered by OSHA would be limited in all of the industries examined. The improvements in profits experienced by three of these industries (petrochemicals, petroleum refining, and tire manufacturing) in the 1983 will further reduce this impact. In almost all cases, the improvement in these firm's profits from 1982 to 1983 would be sufficient to pay the estimated annualized costs of a revised OSHA standard for benzene manytimes over. (Ex. No. 155).

Meridian was able to collect updated financial information on 10 of the 12 steel companies analyzed by JRB. Meridian concludes that "all of the firms except [for] two showed marked improvement in net income (profits) between the first and fourth quarter of 1983." These two "registered declines due to extraordinary losses caused by write-offs of plant and equipment" (Ex. No. 155).

OSHA believes that these changes are clearly affordable to these industry sectors based on the small size of the costs in relation to both profits and sales. Even allowing for economic impacts of the magnitudes reported above (i.e., profit declines of less than 1 percent), the proposed benzene standard is still unlikely to have any major impact much less a significant influence on the long-term viability of otherwise productive facilities or to cause otherwise profitable firms to leave these industries. Thus, OSHA preliminarily concludes that the proposed benzene standard is economically feasible for firms in these industry sectors.

Solvent users will probably comply with a revised benzene standard by using solvents that are excluded from the scope of the standard. There are processes available to reduce the benzene contamination in solvents to below 0.1 percent. The differences between the prices of the solvents in typical use today and those with less than 0.1 percent benzene expected to be used after the promulgation of a new standard are likely to be small. In addition, since these small price increases will be similar across firms in each industry segment, some of the added costs will likely be passed forward to the customers of the solvent users. Consequently, OSHA preliminarily concludes that the proposed standard is economically feasible for solvent users.

The only potentially significant impacts for the proposed benzene standard that OSHA expects are for the three coke BTX units that convert the light oil produced as a byproduct of coke into various chemicals at coke facilities. Most coke producers that recovery light oil, however, do not separate the oil into its chemical components. They sell it to refineries, where it is separated in refinery BTX units. Refinery separation is inherently more efficient, in part, because of its larger scale. Consequently, over the last couple of decades, most coke facilities have closed their BTX units and sold the light oil to refineries for processing. The remaining BTX units operating in the coke industry are old and inefficient and must compete with the more modern and efficient BTX untis in petroleum refineries. The reason that these three units in the coke-producing sector are able to compete at all may be to a combination of low cost sources of supply and the very low capital costs

associated with equipment that has been completely depreciated years ago. Because of their age and inefficiency, the remaining BTX units are marginal operations which may close irrespective of whether there is a new benzene standard. OSHA, therefore, believes that the compliance costs of the proposed benzene standard at most may be an additional factor affecting the timing of these management decisions. Very few employees work in these operations, and even if they shut down, there may not be a net loss in production and employment because the light oil would be sold to refineries for processing.

OSHA and JRB have performed detailed feasibility analysis for the industry sectors where it is the judgement that the impacts would significant. OSHA's analysis indicates that the impacts in other segments would be minimal. For example, as discussed above, solvent users can achieve compliance by purchasing solvents with low benzene contamination. Comments are requested from any other industry segments on additional impacts, if any, which should be considered prior to issuing a final standard.

G. Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980 (Pub. L. 96-353, 94 Stat. 1164 [5 U.S.C. 601 et seq]), OSHA has given special consideration to the mitigation of the economic impacts of the proposed standard on small entities. OSHA does not anticipate that the proposed standard would adversely affect small entities.

During the process of developing a revised standard for occupational exposure to benzene, OSHA carefully considered size factors such as number of employees, total assets, and gross revenues to assure that the proposed standard would minimize the impact on small firms while protecting workers. In the four industries characterized by large firms (i.e., petrochemical, refining, coke and tire), OSHA does not anticipate any differential impact on the smaller firms, because most of the major costs are roughly proportional to the size of the facilities. For example, the total cost of improving pump seals at a benzene production facility depends on the number of pumps at the facility, and the total cost of reducing exposures at a tire manufacturing plant depends on either the amount of ventilation that must be provided or the amount of low benzene-content solvent used. These factors vary directly with firm production levels. In addition, due to economies of scale, the smaller firms in these sectors are of substantial size in terms of gross revenues and numbers of employees. This section, therefore, concentrates on assessing the economic impacts of the benzene proposal on small firms in the bulk plant and tank truck for-hire sectors.

Bulk plants average 19 full time employees, have average gross assets of $1.3 million, average gross revenues of $10 million, and average after tax profits of $55,000. Based on current information, OSHA believes that the fuels stored at these facilities are primarily contained in closed systems and that employee exposures predominantly occur as the result of 3 operations—maintenance of the equipment, tank qauging, and, loading and unloading of trucks.

Maintenance of the equipment (i.e., loading arms and tanks) results in employee exposures because the normally closed systems must be opened for repairs thereby releasing fuels containing benzene and benzene vapors. Many of these exposures can be minimized by flushing the equipment (i.e., loading arms) with a non-toxic substance before the maintenance personnel begin the actual repair activities. Some activities, such as tank cleaning and tank repair, will necessitate respiratory protection for the workers; however, most of these activities are currently being performed by contract maintenance firms, so that the compliance costs of the benzene standard will be shared among many firms hiring the contractors.

Tank gauging results in employee exposure because benzene vapors are released from the fuels when the tank hatch is opened. These exposures can easily be minimized by requiring employees to stand upwind of the open hatch during the gauging operations.

Loading and unloading operations result in employee exposures because of vapors escaping between the connection in the loading arm and the truck, and because of spills. Techniques to reduce these exposures depend on the type of equipment being employed at the facility.

Many of these companies have already installed vapor control systems on the loading docks. Studies show that exposures average significantly below the proposed action level with this system installed. Therefore, since these employees are protected, OSHA is excluding such operations using vapor controls systems from the standard.

Employers who do not have the system need initially only make a measurement of exposures. This cost will average less than $200 per facility. Most of these employers will find that exposures during the loading and unloading operations are under 0.5 ppm and no further action need be taken, except if process or product changes occur which may increase exposures.

If exposures during these operations are above 0.5 ppm, the employer should experiment with simple work practices to reduce exposures, such as insuring that employees stand up wind of the connections during the operations. (These practices essentially have no costs.) If further measurements show exposures below 0.5 ppm, then no further action is required. If exposures after adoption of work practices are between 0.5 and 1.0 ppm then the employer has two options. One would be to install at a cost of $6,000 per loading arm a closed hatch loading system (most firms will need three). This will reduce exposures under 0.5 ppm and no further action is necessary. It will also substantially reduce environmental benzene and hydrocarbon emissions and reduce the chance of fire. (Many bulk plants already have these installed principally for fire protection.) Alternatively, the employer with exposure between 0.5 and 1.0 ppm can provide employees with the medical surveillance, training and other industrial provisions needed in this case to protect employees. Approximately 1/2 of the employees will be covered at a total cost in the range of $1,000 per year per facility.

If exposures are above 1 ppm, the employers will need to install the closed hatch loading system and remonitor. No further action will probably be needed since OSHA believes this system will reduce exposure below 0.5 ppm. Based on the analysis presented in the JRB report, OSHA believes that less than 4% of the firms in the bulk plant sector will need this system.

For many bulk plants there are no costs or only minor monitoring costs. The small firms in this sector (i.e., those with less than $500,000 in assets) which need to install closed hatch loading arms, will incur an initial capital cost of approximately $19,000 for this equipment and will require a price increase of approximately 0.2 percent in order to maintain their current level of profits and revenue. OSHA believes that these firms will be able to pass forward the 0.2 percent price increase to their customers because most of these firms are located in sparsely populated areas where they do not face much price competition. (Most densely populated areas already require the closed hatch loading systems for fire protection, and are predominantly serviced by bulk terminals, in any case.)

In the tank truck for hire sector, OSHA has not attributed any costs for engineering controls, because the Agency believes that they have been considered in the discussion of other sectors (i.e., refining, petrochemical and bulk storage). OSHA believes that most of the firms in this sector will only incur initial monitoring costs (of approximately $200 per firm), and based on the exposure monitoring will determine that their workers are exposed to less than the 0.5 ppm action level. For these firms no other action will be required. A small percentage of the firms (OSHA believes less than 10 percent based on current data) will determine that their workers are exposed above the proposed 0.5 ppm 8-hour TWA level. These exposures will probably be the result of loading operations at the refining, petrochemical or bulk storage sector, and the unloading operations, some at facilities which are exempt from the scope of the standard (under section (a)(2)(i) such as gas stations). OSHA does not believe that these workers will normally be exposed during the over the road portion of their trips. In order to protect these workers, OSHA proposes to require that they be trained in the proper procedures to minimize exposures during the loading and unloading operations (i.e., standing upwind) and the proper way to handle spills, undergo medical surveillance (at an approximate cost of $100 per worker per year) in order to catch any adverse blood abnormalities, and be periodically remonitored to ensure that they are following correct procedures. Based on information in the docket, OSHA believes that none of the workers in this sector will be exposed above the 1.0 ppm 8-hour TWA, after all of the loading facilities have installed the proper engineering controls (i.e., closed latch loading arms) and all of the drivers are properly trained.

OSHA estimates that for the "small" firms in this industry (i.e., those with total annual revenues of less than $5 million), the training, medical surveillance and monitoring provision will result in a average decline in after-tax profits of less than one tenth of one percent if no costs are passed forward.

OSHA therefore believes the impacts on the small businesses in both of these sectors are minor, and that OSHA has minimized the impacts on small businesses as much as possible while protecting workers.

Small employers currently using solvents contaminated with benzene will generally comply through purchase of solvents which initially have less than 0.5 percent benzene and after 5 years will have less than 0.1 percent benzene. They will then be excluded from the other provisions of the standard and their employees protected because little benzene will be present. As discussed above there are a number of processes available to reduce the benzene concentration in liquids (see Chapter 4 of JRB report.). Some of these solvents are already on the market in the same price range as solvents contaminated with higher concentrations of benzene. One large oil company, for example, presently markets petroleum naphtha with less than 0.1 percent benzene at the same posted price as its untreated naphtha. Though currently some of these low benzene content solvents may be more expensive (JRB estimates hydrotreating will cost approximately 10¢ per gallon), the competitive advantage of solvents with low benzene contents after the promulgation of a new standard will probably lead to the ready availability of such compounds at modest or no increased costs due to economies of scale. This was OSHA's experience with a similar provision in the Vinyl Chloride standard. Solvents are typically a small cost of most businesses, and a small increase in these costs will not appreciably affect employers, since all competitors will be equally affected. The recent substantial increase in solvent costs because of the large increase in petroleum costs have been successfully passed forward by solvent users because these solvents are generally a small cost of business. For these reasons OSHA believes that technically and economically the benzene standard is feasible for and will have no significant impact on small businesses currently using benzene contaminated solvents. Nonetheless, OSHA solicits comments on techniques and approaches it may adopt in the final benzene standard that will minimize any detrimental effects it may have on small businesses.

IX. Conclusion and Permissible Exposure Limit

OSHA considered 4 exposure limits in deciding which level to propose, 5.0 ppm, 1.0 ppm, 0.5 ppm and 0.1 ppm. As discussed above in the Significant Risk section, OSHA's preliminary conclusion is that benzene presents a risk of 44 to 156 excess leukemia deaths per 1000 employees exposed for a working lifetime at 10 ppm, clearly, a significant risk. The proposal to reduce exposures to 1.0 ppm will achieve approximately a 90 percent reduction in risk or 39 to 140 lives saved per 1000 workers who would have been exposed to a working lifetime exposure at 10 ppm, clearly, a substantial reduction in significant risk.

As discussed above in the technical and economic feasibility section, 1.0 ppm appears to be technically feasible with engineering and work practice controls for production operations. It also appears to be economically feasible and would result, if no costs were passed on to purchasers, to at most a 1% reduction in profits of the sectors where the effects are greatest. If all the costs were passed on to purchasers, the maximum average price increase would be 0.1 percent.

Obviously a 5.0 ppm level is also clearly feasible if the 1.0 ppm level is. However based on the risk assessment, a 5.0 ppm level would achieve only a 50 percent reduction in risk, not the 90 percent reduction in risk rates that a 1.0 ppm level achieves. The 1.0 ppm level is a lower and substantially more protective level which OSHA believes on the basis of information before it, to be feasible.

A 0.1 ppm permissible exposure limit does not, on the evidence now before OSHA, appear to be technically feasible to achieve. To attempt to achieve it with engineering controls and work practices would appear to require major redesigns in large, capital intensive facilities such as refineries, coke operations and petrochemical plants and small businesses as well. Many large scale operations would need to be isolated or automated. Making major modifications for a large percentage of facilities in a number of the affected industries would not appear to be technically feasible at this time.

As discussed in the technical feasibility section, many of the same types of engineering and work practice controls which would achieve a 1.0 ppm level could also be used to attempt to achieve a 0.5 ppm level in the industries covered. More extensive use of the same type of controls might achieve the 0.5 ppm in some operations but the record is unclear how extensively 0.5 ppm would be achieved. Comments are requested on this issue.

OSHA believes that the proposal of a 1.0 ppm permissible exposure level with a 0.5 ppm action level would be substantially as protective as and more cost-effective than a 0.5 ppm level in these circumstances. As a result of the action level, OSHA believes many employers, where it is feasible to achieve 0.5 ppm, will choose to achieve those levels with engineering and work practice controls, in order to save on the cost of monitoring, industrial hygiene and medical provisions which are

required for employees exposed over the 0.5 ppm action level.

In this proposal, OSHA has examined the possibilities of altering its previous position putting priority on the use of engineering controls in situations where exposure has exceeded the PEL. Based on its analysis, OSHA is proposing to allow employers the option, under tightly limited circumstances, of controlling benzene exposures through the use of any combination of engineering controls and work practices. Respirators are also permitted in certain situations where engineering controls are deemed to be infeasible (i.e., during maintenance operations) or when benzene is used in the workplace less than 30 days per year. This approach increases the performance orientation of the standard and is intended to promote expanded discussion of the proper mix of engineering control requirements with other control techniques.

OSHA believes that the industrial hygiene, monitoring and medical provisions will provide substantial but not complete additional protection for employees exposed between 1.0 ppm and 0.5 ppm. They will result in less exposure to employees through training, protective clothing and hygiene facilities, and the medical provisions will detect some abnormal blood conditions early, making it possible to reduce any remaining possible incidence of leukemia and aplastic anemia.

For the above reasons, OSHA is proposing the 1.0 ppm permissible exposure limit with a 0.5 ppm action level as needed to reduce substantially a significant risk of leukemia and other diseases and as technically and economically feasible. It will of course, consider all evidence presented in the rulemaking on issues presented including alternate exposure limits.

X. Summary and Explanation of the Proposed Standard

OSHA believes that the proposed requirements set forth in this notice are those, based on currently available data, which are necessary and appropriate to provide adequate protection to employees exposed to benzene. In the development of this proposal, OSHA has carefully considered the input from interested parties given in response to the Request for Information. In addition, numerous reference works, journal articles, and other data, including the previous benzene docket and other data accumulated by OSHA since the initiation of this proceeding have been taken into consideration in the development of this proposed standard.

A. Scope and Application: Paragraph (a)

The proposed standard is to apply to all occupational exposures to benzene with the specific exceptions set forth in the scope and application paragraph. The risk from benzene is, of course, dependent on the degree of exposure and not on the segment of industry where the employee may be employed. However, in some segments and operations, exposures are consistently below the action level because of the nature of the process. In those circumstances, OSHA is proposing an exemption from the proposed new benzene standard. In general, initial monitoring for many operations where the evidence clearly demonstrates that exposures will be consistently below the action level does not appear necessary to protect employees nor cost-effective. The specific exemptions are discussed below.

Paragraph (a)(2)(i) *Fuels.* OSHA is proposing to exempt from the benzene standard the storage, transportation, distribution, dispensing, sale and use of gasoline, motor fuels or other fuels containing benzene as a contaminant or small percentage constituent subsequent to its discharge from bulk wholesale facilities.

Based on data submitted to the docket, OSHA believes that the benzene exposures in the retail gasoline sector are well under the proposed action level. In a 1977 NIOSH report (H-059, Exh. #93A), for example, the preponderance of the service stations surveyed had 8-hour TWA's of less than 0.1 ppm, and only one out of 37 stations surveyed had an 8-hour TWA of greater than 0.2 ppm (0.294 ppm). In a more recent survey submitted by Runion and Scott (Ex. No. 159-67), over 97 percent of the samples taken were below 0.5 ppm; and, although this survey does include some samples greater than the proposed 1.0 ppm PEL (0.9%), OSHA believes that the high readings were probably the result of improper work practices (i.e., standing downwind of the hatch during tank gauging, spills, etc.) and can easily be eliminated. The trend in recent years towards self service stations, should also tend to reduce "occupational" exposures to benzene in this sector.

In addition to having low benzene exposure, the retail gasoline sector is characterized by a large number of facilities (an estimated 155 thousand in 1980 according to A.D. Little, H-059, Exh. No. 5A) with a largely transient work force, making it more difficult to implement many of the non-PEL requirements of the proposed standard (i.e., medical surveillance and training).

Therefore, because the evidence indicates exposures well under the proposed action level, OSHA is proposing to exempt this sector. OSHA is concerned, however, about the recent trend of increasing the benzene content in gasoline in order to boost the octane rating. As the benzene content goes up, employee exposures will increase. OSHA, therefore, solicits information on the appropriateness of including a maximum allowable benzene concentration in gasoline, above which the exclusion will not apply.

OSHA received many comments (Ex. Nos. 142-3, 142-7, 142-10, 142-21, 142-31) urging the exclusion of non-gasoline fuels, such as aviation jet fuel, from the scope of the proposed standard. OSHA believes employee exposures are well under the action level in the distribution of other types of fuel. Therefore, OSHA believes the exemption proposed is appropriate and protective of employees. However, OSHA has less exposure data for these sectors and requests further information on exposure in other sectors and the scope of the exemption.

Section (a)(2)(ii) Storage Facilities

In its 1978 benzene rulemaking process, OSHA proposed that marketing activities of fuels down stream of "bulk terminals" be excluded from the scope of the standard. This resulted in the exemption from the standard, as it was interpreted, of bulk plants which have the same type of operation and fulfill the same function as bulk terminals, (the storage of fuel and the loading of trucks to distribute the fuel to service stations and larger scale users). The basis for not covering the bulk plants was that inadequate notice had been given for their coverage (43 FR 5943; Feb. 10, 1978).

The Agency has received comments on the way the earlier exemption was drafted in response to its request for information under its current rulemaking process. Typical of the comments was the American Petroleum Institute's submission (Ex No. 142-31) which states "OSHA's * * * contractor * * * concluded that this exemption was justified on the basis of very low benzene exposure experienced at the worksites. The difficulty with this exemption was its arbitrariness. It did not cover gasoline "bulk terminals" which are functionally identical (in terms of potential occupational benzene exposure) to the "bulk plants" which were exempted."

OSHA has reexamined the basis of this exemption and concurs with the American Petroleum Institute that the

most appropriate basis for an exemption is exposure levels. If exposures are consistently substantially below the action level, then an exemption would be protective of employees. But if exposures are sometimes below the action level and other times above it or above the PEL, absent other compelling circumstances, a total exemption would not provide adequate protection since many employees would be exposed above the action level. (Obviously if the average exposure is approximately at the action level, approximately half of employees will be exposed above it.)

Therefore, the Agency has proposed to base exemptions on the level of exposures. Two reports (Irving and Grumbles, 1979, (Ex. No. 159–42) and Phillips and Jones, 1978 (Ex. No. 159–63) indicate that bulk plants and terminals with vapor control systems, either top or bottom loading, have average 8 hour TWA exposures substantially below 0.5 ppm (i.e. in the neighborhood of 0.1 ppm) with few 8-hour exposures above the action level, and peak exposures averaging 1 ppm for a 15 minute period. Thus, OSHA concludes that the use of either type of vapor control system will result in average exposures virtually always below the action level and has proposed to exempt from this section loading operations at both bulk plants and terminals which use the vapor control systems on this basis.

However, the same data indicate that bulk plants and terminals without vapor control systems have average 8 hour TWA's in the range of the action level which means many employees would be exposed over the level, and some over the PEL. Therefore, OSHA is not proposing an exemption for bulk plants and terminals which do not have vapor recovered because that would not be sufficiently protective of employees. There are a number of simple inexpensive techniques which can frequently lower exposures below the action level and thereby increase employee protection.

OSHA has carefully crafted the provisions of the standard to minimize the impact of the standard on those bulk plants and terminals which are not exempted and to maximize the cost effectiveness of the standard while protecting employees. This is explained more fully in the Regulatory Flexibility Analysis section of this preamble. In summary, those facilities not exempted must initially monitor. If exposures are below the action level, no further action is needed unless processes change. If exposures are above the action level, simple work practices may succeed in lowering them below the action level, employees will be protected and no further action need be taken by the employer. If these procedures do not succeed in reducing exposures below the PEL, then simple engineering controls are available which will lower exposures to protect employees, reduce fire hazards and provide other benefits.

Section (a)(2)(iii) Intact Containers and Pipelines

OSHA is proposing to exempt from most provisions of the benzene standard sealed containers and pipelines which contain or transport chemicals, which have benzene as a constituent or contaminant. Containers would be covered by the Hazard Communication standard, 29 CFR 1910.1200 (48 FR 53280; Nov. 29, 1983) if they contain more than 0.1 percent benzene. That standard would require, in conjunction with the proposed benzene standard, labeling the containers to indicate that it contained benzene, a carcinogen, employee training specifying what to do if the container was opened or broke, and the supplying of material safety data sheets. Containers carrying less than 0.1 percent benzene are completely exempt from both this and the Hazard Communication standard because of the benzene present in the solution. Obviously, the solution could be covered by the Hazard Communication standard because of other chemicals present.

The basis for this exemption is that sealed containers are unlikely on a regular basis to leak sufficient benzene to expose employees over the action level. The labeling and training provisions of the hazard communication standard already issued will provide sufficient protection in those situations where a container breaks so that employees will know how to handle and clean up a spill safely. The intention of this exemption is to cover warehouses, distributors, supply rooms and similar operations where the chemical containers are stored, transported or sold and not normally opened. However, operations where the containers are opened or the chemicals contained in them are used would be covered because of the possibility of exposure above the action level.

OSHA is proposing to exempt pipelines for similar reasons. They are sealed and exposures tend to be low. This exemption is specifically designed for pipelines which transport gasoline, crude oil and other petroleum products, where the percentage of benzene tends to be under 5 percent so that irregular slight leaks will probably not lead to exposures over the action level on a regular basis. Unlike transportation pipelines, employees in a manufacturing process plant will likely be in the area on a regular basis and slight leaks may lead to regular benzene exposure over the action level. Therefore, this exclusion does not apply to pipes in a manufacturing process which carry benzene or another chemical containing benzene. In addition, since benzene exposures of employees repairing or maintaining transportation pipelines could be substantial, the exemption does not extend to repair or maintenace operations. However, the exemption of pipes from labelling requirements in this standard and from the hazard communication standard does apply in all cases.

The emergency provisions of the benzene standard also will continue to apply to pipeline operators and the handling of sealed containers. This is a performance oriented provision. No specific quantity of benzene spilled or exposure level is stated as constituting an emergency. It is not possible to state such provisions specifically because of the large number of parameters in terms of percentage of benzene, quantity of benzene, size of area and ventilation rate. However, employers who have sufficient benzene present so that a container or pipeline break will lead to higher concentrations of benzene are to keep appropriate respirators present for employees who must clean up the spill (See section (g)(1)(iv)) and a specific medical examination is required for employees who have been exposed to benzene in emergency situations.

OSHA's proposal does not specify a percentage of benzene present in containers or pipeline above which the exemption does not apply. However, the higher the percentage of benzene the greater the likelihood that small leaks could lead to exposures above the PEL on a regular basis and that spills could lead to an emergency. OSHA requests comments on whether a percentage of benzene should be specified above which the exemption does not apply.

Section (a)(2)(iv) Percentage Exclusion

Benzene is a naturally occurring constituent of crude oil and natural gas, and, as such is present in trace quantities in many products made from these substances. The standard will be protective of employees and more cost effective if employers who utilize chemicals, generally solvents with trace amounts of benzene, can be excluded from the standard when there is a high degree of confidence that the trace amounts of benzene present will not lead to airborne exposures over the action level. During its 1978 benzene

rulemaking effort, OSHA received numerous comments on this issue which eventually resulted in the Agency amending its standard to include a "liquid exclusion" provision (43 FR 27962; June 27, 1978). OSHA's position at that time can be summarized as follows:

> OSHA recognizes that the scope of the permanent benzene standard (29 CFR 1910.1028), unamended, is so broad as to encompass work place operations utilizing liquid mixtures with any amount of benzene, however, small (tr. 30) . . . However, because of the ubiquitous nature of benzene, i.e., its presence in a myriad number and type of worksites (benzene is a contaminant in most, if not all petroleum-based liquid mixtures), OSHA believes that it is proper to focus industrial hygiene and medical resources on those operations with higher exposures and which present the greatest potential risk to worker health. This decision is in accord with the evidence developed during the recent rulemaking which revealed the need to and appropriateness of limiting the scope of the standard.

Under its current rulemaking process, OSHA requested additional information on this issue. Many of the comments which were received (Ex. Nos. 142–11, 142–12, 142–31, 142–32) stated that there was no precise scientific formula for setting a liquid exclusion. The American Petroleum Institute for example, stated "the benzene content of a liquid is not the sole—or even the predominant—factor in predicting airborne concentrations. . . . Other facts, including temperature, agitation, ventilation, open versus closed systems, employee work practices, and the relative vapor pressure of the chemical constituents of the mixture, are also important, and may well be the more dominant factors. . . . "(Ex. No. 142–31). This position is supported by Elkins (Ex. No. 142–28) and others.

OSHA agrees that there is no such precise chemical model that would predict an exact percentage of benzene in a mixture which would result in exposures that would remain under the action level. OSHA contracted with JRB chemists to explore whether or not a simplified formula taking into account not only percentage, but quantity of benzene, room dimensions, and simplified assumptions on air exchange rates and temperatures, would give a better correlation with airborne levels and be workable. However, the formulas explored proved to be impracticable and not particularly more likely to lead to better results than a percentage exclusion.

OSHA believes, however, that although no precise formula can be stated, it is important that there be an exemption from the standard because benzene cannot be totally eliminated from many chemicals. The inclusion of all solutions containing benzene under the scope of the standard would require a large amount of industrial hygiene resources and would be very costly, since it would require every employer who uses a chemical with a tiny percentage of benzene present to monitor initially the employees who use that chemical. A properly determined percentage exclusion, however, will lead to lower employee exposures over-all as suppliers are induced to market solvents and other chemicals with smaller percentages of benzene to meet the exclusion, thereby on average lowering benzene exposure for employees working with those chemicals. Thus, OSHA believes that it is necessary to make the best estimate of a percentage exclusion which is likely to keep employee exposure under the action level and yet be feasible.

Many comments addressed the issue of what percent liquid exclusion would result in airborne levels of less than the PEL under typical industrial conditions. Dr. Elkins, for example, stated that "for the sake of simplicity, it is recommended. * * * that the 0.5% exemption percentage be applied [to such liquids] if the airborne permissible exposure limit is 1 ppm * * * "(Ex. No. 142–28). This position is supported by the following: Uniroyal (Ex. No. 142–8), RMS (Ex. No. 142–9), and Firestone (Ex. No. 142–22).

OSHA believes that the 0.5 percent level is too high for the long term. First, OSHA believes the percentage should be set to make it likely that exposures will be below the action level, since employees of exempt employers will not have the benefits of the medical and other provisions which are triggered by the action level.

Secondly, exposure data provided by the United Rubber Workers Union (Ex. No. 145) shows that even with solvents of less than 0.5 percent benzene some 2.8 percent of the workers are exposed to airborne benzene levels above 1.0 ppm and data provided by the National Paint and Coating Association (NPCA) (Ex. No. 142–29) show that almost one percent of the samples taken were above 1.0 ppm as the result of exposure to liquids with less than 0.1 percent benzene. Elkins (Ex. No. 142–28), also recommends that if operations involving heating of the liquids and exposure of large surface areas are carried out, at least a one time monitoring of the area for benzene in air should be done, if the benzene content of the liquids exceeds 0.1 percent. Thus, OSHA believes that the additional protection of a 0.1 percent exclusion is needed to assure that very few employees using excluded solvents are exposed over the action level.

Based on these comments, and the JRB analysis discussed above which shows the feasibility of reducing benzene contamination to below 0.1 percent in solvent, OSHA has preliminarily concluded that excluding work operations which use liquids containing less than 0.1 percent benzene is both feasible and consistent with the employee exposure protection provided by the benzene standard. The standard provides 5 years before this provision takes effect to give time to adopt the processes which would achieve this level. In the interim, the exclusion level is 0.5 percent, which is being achieved now.

Section (a)(2)(v) Oil and Gas Drilling, Production and Servicing Production

OSHA received numerous comments in response to its request for information on this sector (Ex. Nos. 142–1, 142–6, 142–13, 142–31, 142–32, 142–33). Most commenters recommended an exclusion based on monitoring data indicating that exposures at the production sites are believed to be low. Conoco (Ex No. 142–1) for example, states "that both the personnel exposures and the ambient atmosphere at (these production) facilities were primarily in the 0.0–0.30 ppm benzene range . . . (And that) no readings greater than 0.5 ppm could be reproduced.

"In light of this exposure pattern, it is impractical in the extreme to impose . . . [the] requirements for monitoring medical surveillance, and other provisions. . . The burden . . . [of which] is enormous. In oil and gas production activities alone, nearly 700,000 workplaces and perhaps 100,000 workers would be affected." (Ex. No. 142–31.) OSHA concurs with the position that because exposures are consistently below the action level, an exemption is appropriate.

Drilling and Servicing

Some comments also stated that the well drilling and servicing activities should be excluded. OSHA believes that personal benzene exposures during these activities may exceed 1.0 ppm because many of these workers come into contact with crude oil and natural gas (with benzene concentrations as high as 1 to 2 percent) during the course of their work, potentially leading to inhalation exposure greater than the PEL. However, OSHA has no quantitative exposure data for those employees nor data on the possible cost of compliance. Therefore, OSHA does not believe it appropriate at this time to

include these sectors. OSHA solicits additional exposure data and information on the appropriateness of including oil and gas well drilling and servicing activities in the benzene standard.

On December 28, 1983, OSHA proposed a standard to cover safety hazards presented by oil and gas drilling and servicing (48 FR 57202). Hearings were held in July and August of 1984 and the record closed on January 7, 1985. OSHA is now analyzing the record to develop the final standard. If the evidence ultimately demonstrates that drilling and servicing should be covered by a benzene PEL, OSHA requests comments on whether that coverage should be made under a final benzene standard or whether the final oil and gas drilling standard should be amended to include benzene provisions.

Laboratories

The proposed standard as drafted covers laboratories subject to OSHA jurisdiction including quality control and research laboratories. Benzene is a widely used solvent in laboratory procedures. There are also case reports of leukemia associated with benzene exposure in laboratories (Ex. No. 159–35).

Since quality control laboratories in coke, petrochemical, tire, and refinery facilities usually repeat experimental procedures involving liquids containing benzene to test for product uniformity, OSHA requested JRB to study operations in those laboratories. JRB stated that all the laboratories studied had hoods, and that hoods were the appropriate engineering control to reduce employee benzene exposures and that the proposed PEL could be achieved at laboratories utilizing the hoods for experiments involving benzene. Consequently, JRB did not believe there were any engineering costs associated with the proposed benzene standard for quality control laboratories. It was reported that some laboratories did not make use of existing hoods or keep their hoods in good operating condition. For this reason and because quality control laboratories regularly utilizing pure benzene and chemicals containing a percentage of benzene creates a risk if not appropriately handled, OSHA is not proposing an exemption for quality control laboratories. Comments are requested on this issue.

OSHA is also not preliminarily proposing an exemption for research laboratories. However, OSHA requests comments about whether it appropriate to cover such laboratories with the proposed benzene standard either permanently, or until such time as OSHA may issue a generic laboratory standard.

Pure benzene is a commonly used chemical in laboratories for many kinds of experiments. Because of its volatility the potential exists for significant exposure unless it is utilized properly under a hood. Research laboratories should all have properly operating hoods because of the many toxic chemicals in use. This would be the appropriate feasible engineering control which, based on the information from quality control laboratories, would succeed in keeping exposures below the PEL.

OSHA believes that the monitoring requirements of the benzene standard would not be burdensome for research laboratories. A worse case initial monitoring conducted during the expeirment with the greatest use of benzene could determine whether exposures were under the action level. If so, no further action need be taken. If exposures were between the PEL and action level, medical examinations, yearly repeat monitoring and training would be appropriate protections for scientists, research employees, technicians and laboratory helpers for the same reasons as other employees, as discussed in those sections of the preamble. If exposures were over the PEL, it would be appropriate to check the efficiency of the hood and the laboratory (work) practices to lower exposures.

However OSHA recognizes that multiple monitoring for many chemicals may be onerous for research laboratories. The benzene standard will not, by itself, create that problem. A generic laboratory standard would need to face that issue. OSHA is specificlly requesting comments on whether the proposed benzene standard should cover research laboratories at all or in the interim until such time as there is a generic laboratory standard.

Construction and Longshoring

The proposed standard has virtually no impact on construction. The only impact that OSHA is aware of on new construction from the standard is on the use of some solvents contaminated by benzene in construction. However by purchasing solvents with less than initially 0.5 percent benzene contamination and after 5 years 0.1 percent benzene contamination, which as discussed above is feasible and inexpensive, the construction industry will fit within the percentage exclusion and be exempt from the benzene standard.

As discussed above, a frequent source of significant benzene exposure is maintenance operations at refineries, petrochemical plants and other facilities. Engineering controls are often not feasible for these maintenance operations. Exposure during these operations may be relatively high and it is necessary, therefore, that employees wear respirators, receive medical examinations and be protected by the other provisions of the proposed benzene standard. Sometimes such facilities hire outside contractors to perform maintenance operations. The contention is sometimes made that the maintenance operations should be considered to be construction activities and not subject to general industry standards. Since employees of such contractors are subject to the same high levels of benzene exposure and need the same protections as other exposed employees, OSHA proposes to cover these employees under the benzene standard.

To summarize, there will be little impact on construction since complete exemption can be achieved by utilizing solvents with low benzene contamination. However, though the impact of the standard will be low, OSHA believes that construction should not be exempted from the standard. If construction were exempted there would be no requirement that construction employees utilize solvents with a low content of benzene contamination. In addition, a loophole would be opened in the enforcement of the standard if construction were exempted. The distinction, between maintenance and construction activities is often an ambiguous one. The independent contractors who perform maintenance operations clearly need to be covered. If construction were excluded, these maintenance contractors might argue that their work is "construction" and that they are not covered by the standard. By covering construction, this ambiguity does not arise. However, OSHA reiterates that there will be little actual impact on true new construction activities except for the need to purchase solvents with low benzene contamination.

Port facilities handling petroleum products generally handle petroleum products only and these products frequently contain a percentage of benzene. Most facilities are operated by the major oil and petrochemical companies. As discussed in the feasibility section, there are benzene exposures over 1 ppm which may result during the handling of these products. Compliance with the .1 ppm level can be

achieved through the use of engineering controls which are located on the ship or barge.

This is under the jurisdiction of the Coast Guard and not required by the proposed benzene standard. If these controls are not available compliance can be achieved with respirators. As exposures can be over 1 ppm, employees of these facilities need the protection of the benzene standard. Although exposures may not be continuous, they occur on a regular basis. OSHA, therefore, is including this segment in its proposed standard and has covered it in the feasibility analysis. However, the contention can be made that these operations are longshoring rather than general industry. (Since facilities are generally utilized only for petroleum products and employees work there on a full-time basis exposed to benzene, the unique features of longshoring—many different types of cargoes, temporary employment and only occasional exposures do not exist.) Consequently, to avoid that contention, the proposal incorporates the proposed benzene standard into the Part 1918. Comments are of course requested on these issues.

Traditional longshoring operations may involve handling sealed containers holding liquids containing benzene. Those operations are generally exempted by the sealed container exemption. However, training is required to protect employees.

The repair of tankers may lead to high levels of benzene exposure often in confined spaces. Control is possible through tank flushing or via the use of supplied air respirators Consequently, it is proposed to cover ship repairing. In other types of ship repair, there will be little impact, as compliance can be achieved through utilizing solvents with low benzene contamination. Comments are requested on this issue.

Status of 1910.1000 Table Z–2, 10 ppm standard

The current standard for benzene is located in Section 1910.1000, Table Z–2. It is an 8-hour time weighted average of 10 ppm, maximum ceiling concentration of 25 ppm and a peak concentration of 50 ppm. OSHA is proposing to replace the Table Z–2 standard with a new 1 ppm standard as specified in a new section 1910.1028. However, as explained above, exemptions are being given to a number of industry segments. The basis for exemptions are that exposures are virtually always below the action level in those segments. However, the possibility exists that there may be relatively rare circumstances where exposures in the exempted segments are much higher than normal. Consequently, OSHA is proposing to retain the Table Z–2 standard for those segments who are exempted from the proposed new standard to prevent the possibility of gross over exposures. A footnote is proposed to be added to the Table Z–2 entry to indicate this.

B. Definitions: Paragraph (b)

"Action level" is defined as an airborne concentration of benzene of 0.5 ppm calculated as an 8-hour time-weighted average. Where exposures are below the action level of 0.5 ppm, no further action is required of the employer. Above the action level, the monitoring, medical and training provisions of the standard take effect. Of course, the employer is required to keep employees' exposures below the 1.0 ppm permissible exposure limit, and not below the action level.

One purpose of the action level is to relieve the burden on employers by providing a cut-off point for required compliance activities under the standard. In addition, due to the variable nature of employee exposures to airborne concentrations of benzene, the concept of an action level statistically provides a means by which the employer may be assured that the employees will not be exposed to benzene over the permissible exposure limit.

The action level also increases the cost-effectiveness performance orientation of the standard while improving employee protection. Employers who can, in a cost-effective manner, come up with innovative methodology to reduce exposures below the action level, will be encouraged to do so in order to save on the expenses for monitoring, medical and training provisions of the standard. Their employees will be further protected because their exposures will be less than half of the permissible exposure limit. For employers where it is not feasible to lower exposures below the action level, employees above the action level will have protection of medical surveillance, monitoring and training provisions of the standard to give further protection from the effects of benzene.

There are discussions in several other OSHA health standards on the statistical basis for determining the action level. (See, for example, the Acrylonitrile preamble (43 FR 45809, October 3, 1978), and the ETO proposal. (48 FR 17284 April 21, 1983)). Basically, although all measurements taken on a given day may fall below the permissible exposure limit, some possibility exists that on unmeasured days the employee's actual exposure may exceed the permissible exposure limit. According to "Exposure Measurement Action Level and Occupational Environmental Variability," DHEW, PHS, CDC, NIOSH DLCK (December 1975) (Ex. No. 159–49A), where exposure measurements are above one-half of the permissible exposure limit, that is, the action level, the employer cannot reasonably be confident that the employee may not be overexposed. Therefore, requiring periodic employee exposure measurements when the employee is exposed at the action level provides the employer with a reasonable degree of confidence in the results of the measurement program. OSHA's specific choice of setting an action level of one-half the PEL is based on its successful experience in utilizing one-half the PEL as the action level in many standards, such as arsenic, acrylonitrile and vinyl chloride.

The action level is the point at which certain provisions of the proposed standard must be instituted, such as medical surveillance, employee training provisions and monitoring requirements. If on the basis of the results of the initial monitoring or other data, an employer can demonstrate that an employee is exposed to benzene below the action level, the employer may then discontinue compliance activities for that employee. The action level concept thus provides an objective means for an employer to determine if no further actions are required for compliance with the standard.

The action level provides a way of maximizing employee protection in those instances where exposures are possibly significant and minimizing employer obligations by defining the point below which no action is necessary. Use of the action level concept will result in the necessary inclusion of employees under the proposed standard, whose exposures are close to the PEL and for whom further protection is warraned. The action level mechanism will also greatly limit the number of workplaces covered under the standard because employers whose employees are under the action level will be exempt from most provisions of the standard. The action level concept therefore provides an objective means of tailoring different sections of the standard to those employees who are at the greatest risk of developing adverse health effects from exposure to benzene.

The concept of an action level was supported by many commentators to OSHA's Request for Information. In its

comments to the Agency. Uniroyal, Inc. (Ex. No. 142–8) supported the position that if exposures were below a 0.5 ppm level, periodic monitoring should only have to be done at the discretion of the employer. The Rubber Manufacturers Association stated that: "The airborne action level of 0.5 ppm established in the 1977 standard was conceptually appropriate." (Ex. No. 142–9). In response to whether a minimum number of days or hours of exposure to benzene should be required before the provisions concerning monitoring and medical surveillance would become effective, Conoco, Inc. (Ex. No. 142–27) recommended:

> That OSHA handle benzene exposure in the same manner as proposed for occupational exposure to ethylene oxide, in which medical surveillance is not required unless there are 30 days of exposure in a year." "This approach would protect exposed workers while eliminating the difficulty and costs of monitoring casual or temporary employees.

The use of the action level and, in some cases, a 30-day exposure requirement to trigger various provisions of the proposed benzene standard is consistent with other recently published proposed OSHA health standards and final standards e.g., Ethylene Oxide (48 FR 17284, April 21, 1983). Ethylene Dibromide (43 FR 45956, October 7, 1983), and Arsenic (48 FR 1864, January 14, 1983). In addition, the uniformity between this and other standards provides administrative consistency and continuity in developing and implementing compliance strategies for this and other applicable OSHA health standards at individual worksites.

The proposal defines benzene as liquid or gaseous benzene and liquid mixtures containing benzene and benzene vapors released by those liquids (subject to the percentage exclusion discussed above in the scope section). The definition excludes from coverage "unreacted benzene contained in solid materials." The latter is a change from the 1978 standard and intends to clarify some of the concerns raised by commentors. The American Petroleum Institute in its comments (Ex. No. 142–31) raised concerns that if the 1978 standard were interpreted literally, products such as polystyrene containing a few parts per million benzene in the solid form would have to be labeled as a cancer hazard. Other polymer manufacturers reported extremely low levels of benzene vapor emitted from solid products containing very low amounts of unreacted benzene (Ex. No. 142–31, Attachment C, page 6). For example, ARCO stated "Tests conducted by ARCO Polymers on these products . . . demonstrate that even at the point where the highest concentration of benzene would be anticipated, the amount of benzene vapor in the air did not exceed the [0.5 ppm] action level. . . . In all cases but . . . one, if any benzene vapor was emitted it was undetectable using test procedures designed to detect levels as low as five parts per billion."

OSHA's chemical consultants at JRB concur with ARCO's findings and have informed OSHA that in their opinion it would be extermely unlikely that significant quantities of benzene would be emitted from solid materials, except in cases where the solid materials were being burned. Burning these materials would probably release quantities of toxins (such as styrene) with much more acute effects than the quantity of benzene being released. Since it is unlikely that unreacted benzene contained in solids will impose a significant health hazard, OSHA has excluded it from the scope of the standard. The exclusion proposed is intended to omit from the standard's coverage products that contain a very small amount of benzene in bound forms, such that they are incapable of releasing into the workplace, benzene vapors at levels which are greater than a small fraction of the action level.

"Bulk wholesales storage facility" is defined as a "bulk terminal or bulk plant where fuel is stored prior to its delivery to customers". The explanation for this definition is addressed in the Scope and Application section above.

"Day" is defined as any part of a calender day. Therefore, if a requirement is applicable for an employee who is exposed to benzene for 10 days in a calendar year, that requirement becomes applicable to an employee who is exposed to benzene for any part of each of 10 calendar days is a year.

"Emergency" is defined to mean any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may result in an unexpected significant release of benzene. Sections of the proposed standard that include provisions that must be met in case of emergencies include Respiratory Protection, Medical Surveillance, and Employee Information and Training. Every spill or leak does not automatically constitute an emergency situation. The exposure to employees must be high and unexpected. This is a performance oriented provision relying or judgement. It is not possible to specify detailed circumstances which constitute an emergency.

"Employee exposure" is defined as that exposure to airborne benzene which would occur if the employee were not using respiratory protective equipment. This definition is consistent with OSHA's previous use of the term "employee exposure" in other health standards.

C. Permissible Exposure limit: Paragraph (c)

OSHA proposes to revise the permissible exposure limit (PEL) for benzene by amending the current 10 ppm standard contained in 29 CFR 1910.1000, Table Z–2, which also contains an "acceptable ceiling concentration" of 25 ppm and an "acceptable maximum peak concentration" of 50 ppm to apply only where the new standard is not applicable. OSHA proposes to replace these values for most industry segments with an 8-hour time-weighted average Permissible Exposure Limit to airborne concentrations of benzene of 1 ppm. This proposed PEL is based on underlying findings by OSHA that occupational exposure to benzene under current permissible exposure levels presents a significant risk to employees and that the new standard will achieve a significant reduction in that risk. The basis for the proposed permissible 8-hour exposure limit is discussed above in the sections on significant risk, feasibility and choice of proposed exposure limit.

OSHA has been reviewing the scientific principles concerning whether a short term exposure limit (STEL) should be set for a chemical substance. In its recent evaluation of ethylene oxide (EtO) on STEL issues (50 FR 64, January 2, 1985), OSHA received a number of comments on this issue. (See ethylene oxide OSHA Docket No. H–200, Ex. No. 168.) The following examples illustrate some of the concerns expressed in making the determination for the necessity of STEL with regard to EtO. The American Industrial Hygiene Association (AIHA) stated:

> The selection of regulated STEL should not be an arbitrary multiple of the TWA exposure limit but rather should aim at preventing such other adverse effects not othewise prevented by the TWA PEL alone. The two most common examples of such other effects are (1) a disproportionate increase in responses for excursion doses above the TWA (i.e., nonlinear effects) or (2) the onset of an acute response not important near the TWA (e.g., acute irritation versus chronic damage) (Ex. No. 164M).

The American Academy of Industrial Hygiene stated that it would favor the use of a STEL for EtO in conjunction

with a PEL of 1 ppm (as an 8 hr TWA) if either of the following questions could be answered affirmatively:

Does EtO lead to significant acute effects or irritation during brief transients of high exposure encountered in workplaces where a PEL of 1 ppm is being met? (2) Does damage to the receptor (DNA), which is presumed to increase the likelihood of chronic or delayed disease, follow nonlinear kinetics between dose of EtO and response and thereby, weight more heavily the transient high exposures? (Ex. No. 164D.)

The National Institute for Occupational Safety and Health (NIOSH) also discussed the means for determining whether or not a STEL for a substance in necessary. It stated:

There are two concepts that must be explored. The first concept is practicality; the second is necessity . . . the practicality of a short term exposure limit can be described by examination of how workers are most likely to be exposed and whether or not their exposure can be reasonably controlled . . . the issue of the necessity of a short term exposure limit centers on the identification and prevention of adverse health effects. (Ex. No. 164J)

NIOSH made the latter statement in the context that the empirical observation of adverse health effects as a result of short term exposure should constitute the necessity for OSHA to adopt a STEL in order to contain such exposures. The National Institute of Environmental Health Sciences' approach for determining the need for a STEL for a toxic substance was similar to that of NIOSH, i.e., short term levels should be controlled if dose received in such a manner is associated with adverse health effects (Ex. No. 164J)

OSHA seeks comments on the scientific principles it should use to determine the necessity for incorporating a STEL as part of a permissible exposure limit for a toxic substance. With regard to a STEL and benzene, specifically, OSHA requests information on whether a STEL should be incorporated into the benzene standard and if so, what level that STEL should be set at. The following discussion reviews the evidence relevant to a possible STEL for the benzene standard. OSHA requests comment on whether there is sufficient evidence to make inclusion of a STEL appropriate.

Irons of the Chemical Industry Institute of Toxicology recently presented study results on benzene and stated:

Our experimental evidence would highlight a concern that has been focused recently on transient exposure in the occupational environment rather than continuous low level exposure . . . where transient exposure is more important with respect to the individual than constant exposure to some low level or a time weighted average (Ex. No. 159-41A).

In a previous study, Irons had determined that the polyphenolic metabolites of benzene, primarily hydroquinone and catechol, appear to be responsible for benzene immune suppression and bone marrow suppression. Thus, separate mice were administered hydroquinone or catechol both on an intermittent basis and continuously.

Irons stated:

We found if we took the same dose of hydroquinone that we were giving repeatedly for a continuous regimen and gave it for three days and allowed the animals four days to recover, then gave it again, an intermittent exposure, so that over a 30 day period, for example, the animals are receiving approximately 45% of the dose they would have received with continuous exposure, and we have a very pronounced drop in bone marrow cellularity, we have a decrease, a progressive decrease in circulating white counts, primarily associated with the lymphocytes, we have a progressive decrease in erthrocytes, circulating erythocyte counts. We have followed these animals now out to approximately between 6 and 8 weeks. They're beginning to drop dead. . . . with what would be considered a classic aplastic response or aplasia in bone marrow. (Ex. No. 159-41A.)

With repeated administration of the metabolites, only a transient effect which gradually returned to normal was observed. On the basis of these observations, Irons concluded:

Intermittent exposure appears to be much more potent at producing bone marrow effects than is continuous exposure, and it may be that protection of the worker in an occupational setting requires prevention of peak exposures rather than the progressive lowering of the TWA in the absence of regulating or limiting transient exposure situations.

Although two cohort studies of refinery workers did not demonstrate a significantly elevated increased risk of death from leukemia, two case-control studies of leukemia deaths among these cohorts of refinery workers have significantly associated the deaths with specific benzene exposure jobs (Rushton and Alderson, 1981) or with a history of longest employment as general pipefitters (RR=2.7), maintenance and yard pipefitters (RR=2.8), or in utilities (RR=4.6) (Divine and Kaplan, 1983). The mode of benzene exposure in these latter jobs is considered to be through intermittent bursts as pipefitters and utility personnel usually have major responsibilities for repairing broken pipes or leaking seals in streams that may contain from 5% to 100% benzene. Given the limited statistical sensitivity of the case-control studies and yet the identification of a significant association between dying from leukemia and the mode of benzene exposure that may have been experienced by these workers, one could argue that short-term intermittent bursts of benzene may have been more of a factor than continuous low level exposure among these workers. On the other hand, lower elevated relative risks of leukemia that might be associated with general low level exposure may not have been identified because of limited statistical sensitivity.

In the study by Wong (Ex. No. 151A) which demonstrated a dose-response relationship between cumulative benzene exposure and death from lymphatic and hematopoietic cancer, a relative risk of 3.4 was observed for those persons categorized as having experienced maximum peak benzene exposures below 25 ppm. (See more detailed review of the study in section dealing with epidemiologic study results.)

DOW Chemical Company submitted a report to EPA and to NIOSH shortly after the earlier OSHA administrative record on benzene closed in 1978 (Holder, 1978, Ex. No. 159-49). This study demonstrated significantly elevated chromosomal breakage in circulating lymphocytes among 52 workers employed in operations where 8-hour time weighted average benzene concentrations ranged between 2-10 ppm. Peak levels of benzene associated with the TWA concentrations as determined by 2-3 minute sampling periods ranged from 50 to greater than 100 ppm. Ceiling concentrations as determined by 15-minute sampling periods were reported to have been 25 ppm (Holder, 1978, Ex. 159-49). Further analyses by level of exposure indicated elevated chromosomal damage at exposures averaging below 1.0 ppm, as well as a dose-response relationship between chromosomal damage and benzene exposure (Picciano, 1980). Although the frequency of peaking is unknown, Holder implied that the chromosomal damage was due to the peak exposures (Holder, 1978, Ex. 159-49).

In addition, as discussed in Section VI, short term exposures at relatively low levels have caused chromosomal damage in animals. Those include 28 ppm for 4 hours (Tice et al., 1982), (Ex. No. 159-88) 10 ppm for 6 hours (Kligerman, 1984) (Ex. No. 159-47) and 6 ppm for two 8-hour exposures (Cad-El-Karim et al., 1982) (Ex. No. 159-32).

OSHA seeks comment on whether intermittent peak exposures to benzene

carry any greater risk of disease than continuous low level exposures and whether such a determination can or should be based on either experimental data or epidemiologic findings.

In summary, OSHA has noted that the proposal to lower the current PEL from 10 ppm TWA to a 1 ppm TWA is based on feasibility and on risk assessments indicating a significant risk at the current PEL and a significant reduction in risk (though the risk is still significant) by lowering the PEL to an 8-hour TWA of 1 ppm.

Environmental Variability in the Measurement of Benzene

This proposal specifies a permissible exposure limit (PEL) of 1.0 ppm for an 8-hour time-weighted average. The use of the 8-hour time-weighted average as a unit for measuring toxic chemicals has been traditionally followed by OSHA. Because of random variation in exposure in an industrial situation or operation, an employer would need to have average exposures somewhat under the permissible exposure limit to avoid having a percentage of the employee's 8-hour time-weighted exposures over the PEL.

On March 25, 1985, the American Petroleum Institute submitted to OSHA a draft interim report, "Benzene Exposures in the Petroleum Refining Industry" by Spear et al. (1985) (Exs. 179 and 179A). This report suggests that in some areas of petroleum refineries there may be substantial random variation in exposures.

The API recommended that more study be done on the variability issue, although it did not recommend that issuing a proposal be delayed. Rather, API suggested that OSHA give additional consideration to open public comment on alternative PELs at 2 ppm and 5 ppm. OSHA feels that it has met the API recommendations in two ways. First, this preamble (specifically questions 1 and 6) state that the appropriate exposure limit is an issue for this rulemaking and invites public comment on the issue. Secondly, OSHA's feasibility analysis does consider 5, 1, 0.5 and 0.1 ppm as alternative PELs.

OSHA is also considering an alternate approach to respond to situations where there is an unusually high degree of variability in exposures even though the employer has installed engineering controls and instituted work practices designed to keep typical exposures below the PEL. To address this situation, OSHA is considering incorporating a provision in the standard under which a single measurement in excess of the PEL will not necessarily result in issuance of a citation.

Where the employer has made sufficient measurements in the area that indicate that exposures below the PEL occur a large majority of the time at this location and that only on relatively rare occasions does the monitoring show that random variation results in an 8-hour TWA over the PEL, OSHA would re-monitor, if necessary, and would issue a citation only if both OSHA measurements exceeded the PEL. Accordingly, an option OSHA is considering would be that if an employer has made at least five 8 hour time weighted measurements in the same area within a reasonable time that indicates that the average of these measurements is below the PEL, the employer may rebut the presumption of exceedence, provided that the measurements were conducted in accordance with the requirements of the standard and that no valid measurements were excluded from calculating the average. However, under this provision, if the over-exposure is the result of a breakdown of equipment which the employer had knowledge and an opportunity to repair, or because of inadequate training or an inadequate leak detection program, a citation would be appropriate.

OSHA requests comment on this approach to unusually large random variations and on other approaches.

The 1978 final standard for benzene included under the PEL section a paragraph on "dermal and eye exposure limits" which prohibited such exposures. This paragraph has not been included in this proposed standard since the requirement presented feasibility and safety problems for the rubber industry. Provisions for the use of proper personal protective equipment where appropriate to minimize skin and eye contact with benzene are included under paragraph (h) of the standard. See the discussion of the proposed provisions in that section below and in the section on health effects of benzene absorption through the skin.

D. Regulated Areas: Paragraph (d)

The proposed standard contains requirements that regulated areas be established wherever airborne exposures are above the permissible exposure limit, and that access to these areas be regulated and limited to authorized persons. In addition, regulated areas are to be demarcated in any manner that minimizes the number of employees exposed to benzene within these areas. To increase the performance-orientation of the standard and minimize recordkeeping, no detailed requirements are specified on how the regulated areas should be demarcated.

Regulated areas to be established at all worksites where the permissible exposure limit is exceeded, or where the short term exposure limit, 5 ppm averaged over a 15-minute sampling period, is exceeded. It is OSHA's intent to include under this provision areas within worksites where there are frequent leaks, or where exposures may be of high concentration but of short duration, and certain maintenance situations. The purpose of a regulated area is to ensure that employers make employees aware of the presence of benzene at levels above the exposure limits in the workplace. This may be accomplished "in any manner that minimizes the number of employees exposed", such as by posting warning signs. Since the use of respiratory protective equipment is required in regulated areas, the demarcation of such an area is a way to warn employees not to enter these areas, unless they are authorized to do so and only if they are using the proper personal protective equipment.

The establishment of regulated areas is an effective means of limiting the risk of exposure to as few employees as possible. This is consistent with good industrial hygiene practice when exposure to a toxic substance can cause serious health effects. This requirement has additional benefits to employers in that, since the use of personal protective equipment (PPE) is required in these areas, by limiting access to these areas to authorized persons only, the additional obligations imposed by the proposal when PPE is used will be limited to as few persons as possible.

Access to the regulated area is restricted to "authorized persons", that is, those persons required by their job duties to be present in the area; specifically, to those authorized entry by the employer, this proposal, or the OSH Act.

The reasons that regulated areas are to be established at all work areas, where the PEL is exceeded, including maintenance operations, is that it is OSHA's view that the existence of a hazard, rather than the type of operation or work being performed, should be the basis for establishment of a regulated area. Areas where exposures are temporarily over the PEL while maintenance is being performed need to be demarcated to warn employees not needed for repairs to keep out of the areas and warn employees who enter the area to wear respirators to avoid exposures that employees might experience by accidentally walking

through or working in these areas. All that is required is a temporary sign in the area where exposures are over the limit while the maintenance is being performed to remind employees that respirators are needed and to indicate that unprotected people should not enter the area. The regulated area provisions of this proposal standard are similar to other OSHA health standards.

The requirements present in the 1978 final standard to notify the nearest OSHA Area Office of the existence and condition of any regulated areas has been eliminated from this proposal. OSHA is not using this information for compliance purposes and notification by employers of these areas poses a burden on employers that is not providing additional protection for workers. The employer's obligation to maintain regulated areas and limit their access to authorized persons is not lessened by the absence of the requirement to notify the nearest OSHA Area Office.

E. Exposure Monitoring: Paragraph (e)

The proposed standard imposes monitoring requirements pursuant to Section 6(b)(7) of the OSH Act (29 U.S.C. § 655) which mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." The purposes of requiring air sampling for employee exposure to benzene include: preventing the overexposure of employees; the determination of the extent of exposure at the worksite; the identification of the source of exposure to benzene; and collection of exposure data by which the employer can select the proper control methods to be used and to evaluate the effectiveness of the selected methods. Monitoring enables employers to meet the legal obligation of the standard to assure that their employees are not exposed to benzene in excess of the prescribed levels, and to be able to notify employees of their exposure levels, as required by section 8(c)(3) of the Act. In addition, collection of exposure monitoring data enables the examining physician to be informed of employee exposure levels.

Exposure monitoring is also important to determine the exact level of benzene to which employees are exposed. This determines what other requirements of the standard will have to be met. Major sections of the standard are triggered if an employee is exposed above the action level and are not required if the employee is not.

The exposure monitoring provisions require the employer to determine the exposure for each employee exposed to benzene. This does not mean that separate measurements for each employee must be taken but rather "representative employee exposure" is to be determined. Samples must be taken within the employee's breathing zone (also known as "personal breathing zone samples" or just "personal samples") and must represent the employee's exposure to airborne concentrations of benzene over an eight-hour period without regard to the use of respirators. (See "Employee exposure", as defined in the definitions section). Full-shift sampling must be conducted for each job classification in each work area. These samples must consist of at least one sample representative of the entire shift or consecutive samples taken over the length of the shift.

To eliminate unnecessary monitoring and improve the cost-effectiveness of the standard, paragraph (e)(iii) allows employers who can document that exposure levels are the same for similar operations in different work shifts throughout the work day, to sample only the shift for which the highest exposures are expected to occur. This provision was not in the 1978 standard. This provision does not apply to initial monitoring requirements. The employer must be able to demonstrate that employees on the shifts who are not monitored, are not likely to have exposures higher than those of the shifts monitored.

Representative exposure sampling is permitted when there are a number of employees performing essentially the same job under the same conditions. For these types of situations, it may be sufficient to monitor a fraction of such employees in order to obtain data that are "representative" of the remaining employees. As permitted in section (e)(1)(iii), respresentative personal sampling for employees engaged in similar work and exposed to similar benzene levels can be achieved by measuring that member of the exposed group reasonably expected to have the highest exposure. This result would then be attributed to the remaining employees of the group.

Workplace exposure monitoring is initially required of all employers who have a place of employment covered under the scope of this standard. In addition, the proposed standard requires that the initial monitoring be conducted within 60 days of the effective date of the final standard which is 90 days after the publication date. OSHA believes, because of the ready availability of equipment to monitor benzene, that initial monitoring can be completed within 150 days after publication of a final standard. To eliminate unneeded requirements, if an employer has workplace monitoring data from within one year prior to the effective date, those data will be allowed to satisfy the requirements of the initial monitoring.

The results of the initial monitoring represent the data which will be used to determine when further periodic monitoring will be required. If exposures are below the action level, then no further monitoring is required unless processes or products change which are likely to lead to higher exposure. If the initial monitoring results show employee exposures at or above the action level, but at or below the PEL, then the employer must repeat monitoring for these individuals yearly. If exposures are above the PFL, then the employer must remonitor every six months. If, in subsequent monitoring, results indicate that an employee's exposure, as determined by two consecutive measurements taken at least seven days apart, falls from above the PEL to between the PEL and action level, then the monitoring schedule for those employees may change to the less frequently required obligation of monitoring annually. If exposures are found to be below the action level, then monitoring may cease, unless production changes may lead to higher exposures. OSHA believes those frequencies, which are similar to other OSHA standards such as arsenic and the recent ETO and EDB proposals, are sufficient.

The monitoring frequencies allowed in this proposed benzene standard differ substantially from those stated in the 1978 benzene standard. In that standard, if exposures were above the PEL, monitoring was required on a monthly basis. In the development of this proposed standard, OSHA took into consideration the fact that monthly monitoring requirements barely allow sample results to be obtained and evaluated before re-monitoring is to begin all over again. OSHA recognizes the burden placed on employers when disproportionate amounts of sampling are required resulting in the waste of valuable industrial hygiene resources. As stated above, the purpose of monitoring is, among other things, to show the employer what and where the hazardous exposures are and to whom they are occurring; the type of respiratory protective equipment necessary, and in addition, monitoring is a check on the efficiency of engineering controls. However, once the areas are

established where the PEL is exceeded, repeated monitoring on a monthly basis serves little purpose, since the hazard already has been identified and control strategies will have been implemented on the basis of the monitoring results. Areas within the workplace where exposures are to be above the PEL are to be designated and demarcted as regulated areas, and entry is limited into these places to authorized persons who must be wearing appropriate respiratory protective equipment. Therefore, monitoring employees whose exposures are above the PEL once every six months provides the employer with sufficient time to collect and analyze samples, to inform employees of the results, to check on the efficiency of engineering controls and to provide appropriate respiratory protective equipment.

OSHA requires monitoring of employees whose exposures are between the action level and the PEL once every year. Since these employees have been shown to be exposed to levels of benzene below the PEL, re-monitoring on an annual basis provides the employer with data to insure employees and employer that employees are not experiencing any new exposures which may require the use of additional controls. In addition, these measurements remind employees and employers of the continued need to protect against the hazards which could result from exposure to increased benzene levels. The sampling results are also useful to the examining physician (as they would be at any level of exposure) in determining whether the exposed employee is at increased risk. The monitoring frequencies proposed are similar to the frequencies OSHA has proposed in EDB (48 FR 45956, October 7, 1983) and Cotton Dust (48 FR 26962, June 10, 1983).

A new sub-section has been added to the monitoring provisions at (e)(4): Termination of monitoring. Employers are allowed to terminate monitoring of employees for whom initial monitoring results indicate their exposure to be below the action level. Furthermore, if periodic monitoring results indicate, by at least two consecutive measurements taken at least seven days apart, that employee exposures are below the action level, the employer may discontinue monitoring for these employees. OSHA recognizes that monitoring may be a time-consuming, expensive endeavor and therefore offers employers the incentive to be allowed to discontinue monitoring for those employees for whom sampling results indicate exposures below the action level. It is hoped that such a provision to allow the employer to stop monitoring employees whose exposure to benzene falls below the action level will encourage employers to maintain employee exposures to benzene below the action level in their workplaces, thereby keeping exposures to a minimum and saving themselves the time and expense of monitoring and other applicable provisions of the proposal as well.

Employees are protected because additional monitoring is required when there has been a process or production change or a change in control equipment, personnel or work practices which may result in new or additional exposures to benzene. There may also be times within the employer's own workplace when the employee may suspect a change which may result in new or additional benzene exposure; the employer is obligated by paragraph (e)(5) to monitor at these times also.

Comments were received in response to OSHA's Request for Information stating that sampling strategies should be left up to the employer and that monitoring be based on the judgment of an industrial hygienist as to the possibility of exposure to benzene in an area. (See Comment No. 12–25). It was argued in regards to the initial monitoring requirement that the most effective use of industrial hygiene resources and costs associated with an extensive workplace monitoring obligation could be made if qualified industrial hygienists used their professional judgment to determine where to perform initial monitoring. OSHA does not agree with this proposition with regard to initial and periodic monitoring. Not all employers will have qualified industrial hygienists and exposure levels can not be guessed at. OSHA does feel that the professional judgment of an occupational health professional may be relied upon in determining any additional monitoring requirements, as set forth in this paragraph (e)(5). Instead of trying to define each and every situation where the employer must monitor for new or additional exposures to benzene, it is intended by this section that the employers will institute this additional monitoring when the employer has any reason to suspect a change.

The section specifically requires monitoring to be conducted whenever spills, leaks, ruptures or other breakdowns occur. Such occurrence can result in very high exposures. After the clean-up of the spill or repair of the leak, employers must perform redeterminations of airborne exposure levels for those employees who may be exposed at such areas of their worksites. Such redetermination provides one method of ascertaining that proper corrective methods have been instituted and employee exposures are not significantly altered from what they were prior to the leak or spill.

The employer is required to use monitoring and analytical methods which have an accuracy (at a confidence level of 95%) of not less than plus or minus 25% for airborne concentrations of benzene. Methods of measurement are presently available to detect benzene to this accuracy level at levels of 1 ppm and 0.5 ppm, the action level. One such method is described in Appendix B. As discussed in the Appendix, sampling and analysis may also be performed by portable direct reading instruments, real-time continuous monitoring systems, passive dosimeters or other suitable methods. However, the employers have the legal obligation to select a monitoring method which meets the accuracy and precision requirements of the standard under the unique conditions which exist at the employee's worksite.

The proposed standard further requires that employers notify each of their employees in writing, either individually or by posting in an appropriate location accessible to affected employees, the results of personal monitoring samples. The employer is obligated to do this within 15 working days after the receipt of the results. In addition, the written notification must contain the corrective action(s) being taken by the employer that will reduce the employee's workplace exposure to the PEL or below, wherever the PEL is exceeded. This requirement, in keeping with other recently proposed OSHA health standards, allows the employer to post written exposure monitoring results in an easily accessible location, or allows the employer to notify individuals in writing of their monitoring results, whichever better suits that employer's worksite. The requirement to inform employees of the corrective actions the employer is going to take to reduce the exposure level to below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, as required by section 8(c)(3) of the Act.

The employer is also required to allow employees or their designated representatives an opportunity to observe the employee exposure monitoring. This provision is also required by statute (8(c)(3)) and is

provided for in paragraph (m) of the proposal, as is discussed in more detail below.

F. Methods of Compliance: Paragraph (f)

The standard proposes that feasible engineering and work practice controls be the primary method of reducing exposures in production and distribution operations where exposures are continuous in nature. However, the standard recognizes that in many "maintenance and repair activities" and operations where "exposures are intermittent in nature and limited in duration", engineering and work practice controls may not be feasible. Thus, respiratory protection will be the primary means of control. See paragraph (g)(1)(ii). In addition, the proposed standard provides that employers may utilize their choice of control strategies, including respiratory protection, engineering controls, work practices or any combination of these methods when benzene is present in the workplace fewer than 30 days in the year.

In response to the Request for Information, many commenters discussed appropriate compliance strategies. As elaborated below, a number of commenters such as DuPont, PPG and Shell stated that they generally rely on engineering and work practice controls to control benzene and that these controls had generally achieved 1 ppm at their workplaces. However, these and other companies argued that in certain maintenance and repair operations which result in intermittent employee exposures, engineering controls either would not be feasible or be extremely wasteful and that respiratory protection would be appropriate and afford adequate employee protection.

OSHA believes the proposed standard is responsive to these comments and is justified by the circumstances of benzene. Benzene production and the manufacture of chemicals using benzene as a feedstock or containing benzene as a contaminant are often carried out in closed systems where engineering controls are particularly effective. Some very simple engineering controls such as leak detection programs and tightening connections as discussed in the feasibility section may achieve compliance. In addition, excessive concentration of benzene presents a serious fire hazard if operations are not carefully controlled.

The proposed rule's reliance on engineering controls as the primary means of compliance in those operations is, in part, an acknowledgment that a particularly effective method of controlling employee exposure is to control the emission of toxic substances at their source through mechanical means combined with the use of work practices. Good engineering and workpractice controls also help to minimize splashes and spills. An added benefit of these controls is reducing dermal exposure to employees.

In addition, it is very difficult to wear respirators full time in production operations. If active movement is required respirators create safety hazards since they limit vision and communication. They also tend to slip during heavy physical labor and sweat may create skin irritation at the seal.

Specifically in the case of benzene, as discussed in the respirator section, there is no MSHA/NIOSH approved negative pressure respirator for benzene at 1 ppm because benzene has poor odor warning properties below 12–15 ppm and the possibility of filter breakthrough without warning exists. Although OSHA believes the provisions in this proposed standard in regard to filter changing minimizes this problem, nonetheless the problem is sufficiently great to discourage large numbers of employees from wearing respirators when feasible engineering controls exist.

However, OSHA also recognizes that respirators may provide acceptable protection when an employer establishes stringent procedures and then carefully supervises their implementation on a continuous basis. The agency recently published an ANPR (48 FR 7473, February 22, 1983) on methods of compliance requesting comments on all relevant issues related to the circumstances in which it might be appropriate for OSHA to allow greater flexibility in the methods of compliance and to allow greater reliance on work practices and respirators to protect workers from the various airborne contaminants regulated by OSHA. The agency is particularly interested, in conjunction with that initiative and this benzene proposal, in receiving comments, information and data concerning the extent to which respirators may provide effective protection against benzene exposure and to what extent they may be relied upon as a substitute for engineering controls beyond those circumstances described in this proposal.

The standard specifically recognizes that in maintenance and repair operations engineering controls may not be feasible or an efficient use of scarce resources. Thus, respirators are an appropriate control technology. The employer is frequently not going to know where or when breakdowns will occur and since they occur rarely, engineering controls would not be feasible and effective. Employees carrying out the repairs generally do not work in benzene exposure areas frequently and respirator use is intermittent, therefore making it appropriate to rely on the use of respirators as a control strategy. However, mobility is important for maintenance workers and the employer should utilize work practices which assure that maintenance employees wearing respirators can do so safely.

In some benzene operations, employees work in areas where benzene exposures are below the PEL. However, the employee occasionally must go into areas where no employees regularly work but where exposures may be somewhat above the PEL to check gauges or perform other necessary operations. Sometimes in these circumstances there may be cost effective engineering controls such as remote gauging. However in other circumstances the conceivable control methodology would include large scale ventilation which, in such a case, would not be feasible or appropriate because it achieves so little in terms of significantly reducing the overall exposure to employees and it is very costly to attempt. In this type of situation where the exposure is brief and intermittent and hard physical labor may not be needed, respirators can be used relatively effectively. Consequently, paragraph (g)(1)(ii) recognize these as circumstances where respirators may be used because "exposures are intermittent in nature and limited in duration."

In addition, there are some circumstances where exposures are only somewhat above the PEL and where work practices alone may be the appropriate control strategy. As discussed in the regulatory flexibility section, bulk plants and terminals with exposures slightly over the PEL may be able to achieve compliance by adopting work practices such as assuring that workers stand upwind of loading and unloading operations and that employees are carefully trained in proper procedures.

OSHA requests comments on situations where work practices alone are appropriate. The Agency strongly believes that the administrative control of worker rotation is an inappropriate alternative to avoiding the use of engineering controls or respirators. Worker rotation exposes more workers to a carcinogenic substance, (albeit at lower cumulative levels) thereby lowering individual risk, but quite possibly not lowering total risk and placing a larger population at risk.

The proposed standard permits employers who have benzene present in the workplace for 30 or fewer days in a year to comply with the requirement of reducing employee exposure to benzene by using any combination of respirators, engineering and/or work practice controls. Engineering controls may be impractical if used only a few days per year, and, as discussed, respirators present fewer difficulties to the wearer if used intermittently.

OSHA recently issued a final standard for ethylene oxide (EtO) 49 FR 25734 (June 22, 1984; 29 CFR 1910.1047). In the EtO standard OSHA included similar provisions on the general preference for engineering controls. However, OSHA also found that for certain limited operations, engineering controls were generally not feasible for EtO. Therefore, in the EtO standard, OSHA provided for an exemption from the engineering control requirement. This exemption was applicable to a list of operations where the Agency determined that the implementation of such controls was not feasible. See 29 CFR 1910.1047 (f)(1)(iii) at 49 FR 25797 and the discussion at 49 FR 25779.

OSHA believes that the proposed benzene PEL can be achieved in production operations utilizing engineering controls. (Respirators are permitted in maintenance operations where engineering controls are not feasible.) OSHA is not aware of specific production operations where engineering controls would not achieve the benzene PEL. Therefore, OSHA has not included a similar provision in the proposed benzene standard.

OSHA recognizes, however, that situations may exist where the engineering control requirements contained in this proposal may not be technologically or economically feasible. The proposal, therefore, permits the use of respirators as supplementary protection in situations where an employer can demonstrate the infeasibility of engineering and work practice controls. The burden of proof is appropriately placed on the employer to show that engineering and work practice controls are not feasible. The employer is familiar with the workplace operation and is therefore in the best position to evaluate various types of controls as they apply to that particular workplace environment.

OSHA requests information on whether there are production operations covered by the proposed benzene standard where engineering controls generally are not feasible to achieve the PEL. If there are such operations, OSHA request comments on whether specific exemptions listing such operations should be included, similar to the provisions in the EtO standard.

In addition, paragraph (f)(2) requires an employer who has exposures over the PEL to establish and implement a written compliance program which describes the methodology to be used to reduce employee exposure to or below the PEL within his workplace. The plan should provide for this to be accomplished where feasible and required by the standard through engineering and work practice controls. These written plans must be developed so as to include a schedule for implementation and must be furnished upon request for examination and copying to representatives of the Assistant Secretary, representatives of the Director of NIOSH, and affected employees or their representatives. Once a workplace is in compliance with the standard, that is, employee exposures have been reduced to the PEL or below by engineering and/or work practice controls, the compliance plan need not be updated, unless, of course, exposures increase over the PEL in such cases would necessitate that a new compliance plan be drafted. In addition, the compliance plan shall address methods of protection for maintenance workers who are exposed over the PEL.

OSHA proposes that these written compliance plans be revised as appropriate. Appropriate circumstances may include a change in controls or substantially different exposure conditions. The plan need not be updated merely because some controls have been installed since the last update, or because not all have been installed pursuant to the schedule, or because of new monitoring results in exposure measurements which are similar to prior results. However, where new exposure measurements are substantially different, it may be necessary to re-evaluate the compliance plan to ensure the planned controls will alleviate the new or unexpected source of exposure.

As also discussed above, OSHA has carefully reviewed the many comments submitted in response to its "Request for Information" regarding the subject of methods of compliance. Certain companies indicated that the use of engineering and work practice controls installed specifically to reduce personal exposures to benzene would not be necessary, due to low personal and ambient air exposures within their industry. Conoco, Inc. (see Exhibit 142–1) stated: "Engineering and work practice controls established for other purposes (product security, vapor/volume loss control, automatic custody transfer, safety and overall efficiency in operations) have essentially eliminated personnel exposure to airborne benzene or benzene in the liquid." Other commenters cited that the extensive controls specified in proposed EPA regulations would serve as an "effective means" of reducing ambient atmospheric levels of benzene at their petroleum refining operations (see specifically SOHIO, Exhibit No. 142–6). While recognizing the general effectiveness of engineering controls to reduce employee exposures to benzene, SOHIO also pointed out that there were certain working situations and conditions "under which exposure could not be reduced" regardless of how extensive the use of engineering controls was.

This same commenter stated that since "current use of respiratory protection is almost solely for maintenance and non-routine operations, it is doubtful that engineering controls could eliminate the need for respirators." Other oil companies (see Exhibit 142–11, Pennzoil Company) stated they did not want a "rigid hierarchy of control measures" and asked that "employers be given the option to select that method of control which would protect their employees in cost-effective and efficient manner." In its submission, Shell Oil Company (Exhibit 142–13) outlines the engineering and work practice controls used by Shell and other companies operating as oil and chemical processing industries. Shell stated that when these types of controls are coupled with respiratory protection programs, proper personal protective equipment and an effective training and education program, "these engineering and work practice controls are normally adequate to ensure that actual employee exposure does not exceed 1 ppm TWA."

The American Petroleum Institute stated: "While engineering solutions may be the most cost-effective control methods across a broad range of traditional fixed-site manufacturing worksites, OSHA's general policy should incorporate more flexibility to permit the use of other control methods (or combinations of methods) in the almost endless variety of other sites where engineering solutions—while technically feasible—are demonstrably wasteful of finite industrial hygiene resources." It added "Benzene exposure in the petroleum industry contrasts sharply with the traditional fixed-site manufacturing workplace. . . . The workforce is highly mobile, moving continuously from one worksite to another in an outdoor environment. Exposures are episodic and brief in

duration, generally occurring only when closed systems are opened for sampling or bulk transfer, or in the case of leaks or spills."

As discussed above, the agency believes that it has drafted the proposed standard to meet these recommendations. In production operations, and where exposures are relatively continuous, engineering controls are preferred for the reasons stated. For maintenance and other operations where exposures are brief and intermittent, the employer is given greater flexibility to utilize respiratory protection. In this manner, OSHA believes that it has increased the cost-effectiveness of the standard while maintaining worker protection. However, OSHA requests comment on whether employers should be permitted to choose respirators or any other method of compliance in production operations.

In its submission to OSHA, the Rubber Manufacturer's Association (Ex. No. 142–9) stated that its member companies reported 8-hour TWA exposure levels of benzene of 1 ppm or less. Pure benzene is not used in the manufacture of rubber products but is found in trace quantities in petroleum-derived solvents used in rubber manufacture. Regarding the use of engineering controls as a method of compliance to reduce airborne levels of benzene in the rubber industry, the RMA stated that, since levels are "already at 1 ppm or less," further reductions by way of engineering controls would not be feasible due to the fact that "increased ventilation . . . would only increase the need for solvents in many industry applications." The Goodyear Tire and Rubber Company (Ex. No. 142–23) stated: "If increased ventilation were specified to further reduce the already low airborne benzene concentration, the tackifying solvent would evaporate faster, requiring the use of additional solvent." OSHA requires the use of engineering controls to reduce and maintain employee exposures to benzene only to or below the proposed 1 ppm PEL; in instances where airborne levels of benzene are "already at 1 ppm or less", no further use engineering controls would be necessary. Consequently, the proposed standard is responsive to these comments.

In further comments, the Rubber Manufacturers Association stated that most effective way to lower exposure to benzene in the rubber industry would be to "lower, if possible, the amount of benzene contained in the solvents." In agreement with this position was the Firestone Tire and Rubber Company which stated: "Firestone would like to demand solvents which have no benzene." Firestone submitted results of benzene bulk solvent analysis which showed low level benzene contamination in the solvent analyzed: (only three samples contained above 0.5% benzene; out of approximately 212 samples results on solvents received since January, 1978; approximately half of these samples contained 0.1% benzene or less).

OSHA's proposed standard responds to these comments and encourages this approach by granting an exemption if solvents have less than a specified percentage of benzene. As stated in the scope and application section of this proposed standard at section (a)(2)(iv), "Work operations where the only exposure to benzene is from liquid mixtures containing 0.5 percent (0.1 percent after (5 years after promulgation date of final standard)) or less of benzene by volume, or the vapors released from such liquids" are exempted from the provisions of the standard. Clearly then, one way for an employer to protect the employees from excessive exposures to benzene in industries where the source of exposure is from solvents contaminated with benzene is the use in their work processes only those solvents which contain low or no trace levels of benzene. As discussed in the scope and feasibility section and in the JRB report, these percentages are feasible.

In response to OSHA's Request for Information regarding what engineering and work practice controls are available to reduce exposure to benzene, many chemical manufacturing companies submitted a wide variety of engineering control options that may be used in their workplace to reduce airborne benzene concentrations. Concerning the use of engineering controls and their effectiveness, the Monsanto Corporation (Ex. No. 142–17) stated: "The engineering controls available for use to control benzene in the workplace are the same as those available to control acrylonitrile, vinyl chloride or any other volatile organic." Du Pont stated, in its submission (Ex. No. 142–35) that, along with various listed engineering control options, "a number of familiar work practice controls can (and should) be utilized, including extensive training, well-established procedures for particular operations, proper maintenance and good housekeeping. Given an adequate phase-in period, such controls could probably be implemented by Du Pont to operate at 1 ppm." Du Pont pointed out, in further comments, that there were circumstances where "respirators will always be required for some tasks even though engineering controls are in place, whenever the potential for unexpected employee exposure exists (for example, possible equipment failure)." PPG Industries, Inc. (Ex. No. 142–19) agreed with this view, stating that although it had reduced workplace benzene exposures utilizing a variety of engineering and work practice controls, "there are some operations such as unloading, maintenance, and emergency situations where it is not cost effective or feasible to meet low exposure levels solely through engineering controls." The Celanese Fibers Company (Ex. No. 142–16) offered this comment: "employees currently use respirators by exception (leaks, maintenance tanks, etc.). Engineering controls could be used to reduce background concentrations of benzene but not to eliminate all exceptional situations where respirators are now required." As stated above, OSHA believes the proposed standard is responsive to these comments.

Many engineering controls are therefore available to reduce exposures to or below the proposed 1 ppm PEL. These are discussed in greater detail in the Technical Feasibility section above and in the JRB report.

G. Respiratory Protection: Paragraph (g)

The proposed standard requires that whenever respirators are necessary to reduce employee exposure to or below the PEL, the employer must provide respirators appropriate to the exposure level at no cost to the employee. Employers must also assure that respirators are used properly where needed.

Respirators may be necessary to reduce employee exposure where engineering or work practice controls are not feasible. Respirators may be used as supplementary protection if such controls will not achieve the necessary reduction in employee exposure to or below the PEL, while controls are being implemented during emergency situations, and for short duration or intermittent exposures as explained in the body of the standard. Respirator protection is often the only practical method of employee protection in maintenance and repair operations and brief or intermittent operations such as certain gage checking. In addition, the proposal allows the employer the option of using respiratory protection (see (f)(i)(iii)) to control workplace exposures alone or in combination with other controls when benzene is present less than 30 days per year in the workplace.

The proposal contains specific requirements for the use, selection, maintenance, and fitting of respirators along with a table that lists the minimum type of respiratory protection to be provided. It is based on airborne concentrations of benzene in the workplace. The respirators selection table is consistent with the American National Standard Institute's recommendations for respirator protection factors in their consensus standard, Z-88, 2-1980.

For lower concentrations of benzene, OSHA proposes to permit the use of air-purifying respirators provided that the canisters or cartridges are replaced at the beginning of each work shift. Benzene has poor odor warning properties at low levels, and OSHA is aware that MSHA/NIOSH would not approve the use of air-purifying respirators in this situation because users would be unable to detect the benzene if its break through occurs. However, OSHA believes that chemical cartridges or canisters of the type approved by MSHA/NIOSH for use with organic vapors would provide sufficient service life for the intended application as prescribed in Table 1 if replaced with the required frequency. OSHA requests comments on these issues.

Adequate employee protection is achieved by the replacement of the cartridge or canisters. To ensure that cartridges or canisters are changed in time, the employer is required to date the cartridges or canisters when they are installed in the respirators. In addition some cartridges have end-of-service life indicators. When properly designed and constructed, the indicator would give audio or visual warning to the respirator wearer that the cartridge should be changed. Some contaminants absorbed on the sorbents of the cartridges or canisters tend to desorb upon storage. Consequently, immediate breakthrough can occur when the respirator is worn on the next day. Since the desorption characteristics of benzene on the sorbent or on the end-of-service life indicators are known, multi-day use of the cartridges or canisters is not permitted. OSHA solicits information on the desorption characteristics of benzene and the appropriateness of multi-day use respirators that have an end-of-service life indicator.

The proposal permits the use of any full facepiece powered air-purifying respirator (PAPR) with MSHA/NIOSH approved organic vapor canisters for exposures up to 100 ppm. This device contains a blower and a sorbent to purify the contaminated air to breathable air. In order to assure adequate canister capacity, OSHA requires that each organic vapor canister provide a minimum service life of 4 hours when it is tested at 25 °C, 85% relative humidity, 64 liters per minute air flow and at a challenge concentration of 150 ppm benzene. The air flow will be 115 and 170 liters per minute respectively for tight and loose fitting powered air-purifying respirators.

Where employees are exposed to levels of benzene greater than 100 ppm and respirator usage is permitted, positive pressure atmosphere supplying respirators must be used. These respirators use uncontaminated air rather than mechanically cleaning the benzene contaminated atmosphere. OSHA proposes to allow only supplied air or SCBA's which operate in the positive-pressure mode because facepiece leakage is minimal with positive pressure.

Employers may always use a respirator with a higher level of protection in lower concentrations of benzene. For example, a supplied air respirator may be used when exposures are 10 ppm.

The standard permits employees to leave the regulated area to readjust the respirator facepiece to their faces for proper fit. It also permits them to leave the regulated area to wash their faces to avoid petential skin irritation associated with respirator use.

OSHA is requiring fit testing of the respirator because proper fit is essential to the performance of negative pressure air purifying respirators. In this type of respirator, negative-pressure is created within the facepiece when the wearer breathes. This may result in benzene contaminated workplace air entering the facepiece through gaps and leaks in the facepiece seal, instead of passing through the absorbent material. Obtaining a proper respirator fit may require the fit testing of a variety of different mask sizes from several manufacturers to select the facepiece with the best fit (least leakage around the faceseal) for each employee. A properly fitted facepiece will reduce the inhalation leakage to a minimum. Fit testing is especially important for benzene because of benzene's poor odor warning qualities at the level set by the standard.

OSHA is permitting the employer to choose either quantitative or qualitative fit testing to add to the performance orientation of the standard and permit the employer to tailor the testing to the circumstances of the employer's establishment. Protocals for the type of testing the employer the employer chooses are set forth in Appendix E.

Quantitative fit testing is a procedure whereby the level of penetration of a test agent of a known concentration is measured inside the facepiece of the respirator. Quantitative respirator fit testing is generaly recognized as the better methods for determining how well a respirator fits any one individual. It allows the employer to continue testing until the optimum or best fitting respirator is identified and selected for the employee. Quantitative fit testing requires the use of a moderately sophisticated testing equipment and is more expensive than qualitative fit testing to perform, which reduces its usefulness for many worksites. Also testing services may not be available in all parts of the country to provide quantitative fit testing services for small employers.

Qualitative fit testing is a technique whereby a person wearing a respirator is tested to see whether a test agent with a low odor threshold can be detected inside the respirator. Qualitative fit testing is a more subjective test than quantitative testing because it depends on the individuals ability to detect the test agent.

OSHA believes that while quantitative fit testing may have some advantages, qualitative testing which is conducted in accordance with the protocols described in Appendix E accomplishes the intent of the standard to assure that each employee receives and wears the respirator which provides the greatest level of protection. Comments are requested on all aspects of fit testing.

All employees who work in areas with exposure above the PEL more than 10 days per year must be included in a medical surveillance program. This provision ensures those individuals who wear respirators more than a minimal number of times will be in the medical surveillance program. Respirator usage presents an additional burden to the pulmonary system of the employee. This burden may result in symptoms such as shortness of breath, chest pain, dizziness or fatigue. All of these symptoms may be exacerbated by pre-existing lung disease such as chronic bronchitis, emphysema, asthma or peneumoconiosis. It is, therefore, important that all employees who will be wearing respirators more than a minimal number of times be medically screened to determine fitness for respirator usage. OSHA believes that the physician can best accomplish this through a physical examination.

including a pulmonary function test and a chest x-ray.

The employee must be properly trained to wear the respirator, to know why the respirator is needed, and to understand the limitations of the respirator. An understanding of the hazard involved is necessary to enable employees to take steps for their own protection. The respiratory protection program implemented by the employer must conform to that set forth in 29 CFR 1910.134 which contains basic requirements for proper selection, use, cleaning and maintenance of respirators.

H. Protective Clothing and Equipment: Paragraph (h)

The proposed standard requrires the employer to provide and assure the use of personal protective clothing and equipment where appropriate to prevent eye contact and limit dermal exposure to liquid benzene. The equipment is to be provided at no cost to the employee, and includes the use of these items as may be necessary to protect employees at each particular work situation from exposure to benzene; including, where appropriate, such items as face shields, gloves, aprons, coveralls, or footwear.

Contact with liquid benzene irritates the eyes and when there is a realistic possibility of splashing the eyes, precautions are needed. Eye and face protection is currently required by 29 CFR 1910.133, and the types of safety goggles and face shields required by this section to prevent eye and face injury are readily available from safety products companies nationwide.

The requirement in this proposed benene standard has been changed from the 1978 final benzene standard to require personal protective equipment "where appropriate to limit dermal exposure to liquid benzene" instead of the former requirement to provide and assure the use of "impermeable protective clothing and equipment." Dermal contact is to be "limited", and obviously, prevented where possible. The language of this proposal is performance oriented to allow the employer sufficient flexibility to provide the protective equipment for dermal exposure which will be necessary to protect employees in particular work situations. The 1978 provision was in the exposure limit paragraph and it attempted to prevent all skin contact. This proposed standard is intended to minimize not prohibit skin contact. The proposed provision is simple to achieve and is a normal precaution which should be taken with any toxic chemical. Hence, OSHA does not believe a detailed risk assessment for skin absorption is needed.

Essentially the current proposal is performance-oriented and requires the employer to survey the work situation. The following examples illustrate OSHA's intent in carrying out this provision. If the possibility of benzene skin contact is slight, the employer need not provide protective clothing. However, if the employee does become splashed with benzene or other substances containing benzene, the clothing must be immediately removed and the enployee directed to wash the effected area and put on clean clothing.

If the possibility of benzene skin contact is frequent, the employer should examine changing the employer's control methodology since airborne levels are likely to be over the PEL. In addition, the employer then must provide impermeable gloves, other appropriate protective clothing and aprons. They must be washed and changed at appropriate intervals. In addition, they must be sufficiently protective or changed often enough so that benzene wetted clothing is not kept in contact with the skin for more than a few moments. This is what OSHA intends by the concept of limiting skin contact.

This approach grants an employer flexibility to achieve the goal of minimizing benzene contact with the skin in a manner the employer chooses. However, being performance oriented, it is of necessity more general and requires the employer to consider the employer's manufacturing processes to achieve the desired goal in the manner that the employer believes is most efficient. This provision is not intended to allow the employee to come into regular contact with benzene or benzene contaminated substances.

Studies conducted on protective clothing and materials have shown that permeation data depend on benzene concentration, thickness of protective material, temperature, and age of the protective clothing (Weeks and McLeod, 1982; ACGIH, 1983) (Ex. No. 159–4, 159–97). Liquid benzene that may be spilled on aprons, coveralls, or footwear or other protective clothing other than gloves can be wiped off within a few minutes time. Therefore, the materials used to make these types of protective clothes need to be impervious to benzene only for a few minutes. However, the liquid benzene permeability rate for materials used to make gloves needs to be greater since it is less likely that it would be wiped off. Breakthrough times of benzene through various protective clothing materials differ widely, and the choice of material for protection against benzene breakthrough depends on the type of operation involved and length of time of contact, other solvents present, and other factors. There is at least one substance which can be used for making gloves and other protective clothing, viton, which is claimed to have a 900 minute breakthrough time for benzene. OSHA feels, therefore, that the use of personal protective equipment is feasible to prevent eye contact and to limit dermal exposure to benzene in all but one industry sector.

In comments received in response to OSHA's Request for Information, various tire manufacturing companies and the Rubber Manufacturers Association (RMA) contended that, in the tire manufacturing industry, tire builders cannot use gloves of any type. They argued that gloves interfere substantially with tire production and can partially dissolve and become tacky when exposed at or to benzene-containing solvent, thereby creating a safety hazard if a worker's hand became stuck to a rotating unfinished tire.

Tires are typically built one ply at a time on a rotating drum. The industry stated that manual contact with the "tacky" rubber (rubber coated with benzene-containing solvent) is necessary for positioning each ply on the drum and for ensuring complete adhesion between plies or between the plies and treads.

The industry argued that the loss of manual contact necessary for the propoer "feel" would also significantly interfere with the tire builder's ability to build tires safely and with good quality. (Ex. No. 142–9, The RMA, page 10–11)

OSHA has preliminarily concluded that gloves are not a good solution for controlling dermal contact with benzene containing liquids in tire building operations. Tire manufacturers can come into compliance with the standard without using gloves by using solvents initially with less than 0.5 percent benzene and after 5 years with less than 0.1 percent benzene which is feasible as discussed above. However, direct skin contact with hydrocarbon solvents is in general not a good idea because such contact causes the skin to become excessively dry and may cause cracking. Consequently, it is believed advisable to explore the idea of using barrier creams, improve work practices, and the wearing of gloves to avoid such contact where practical.

After the internal draft of the proposed standard and preamble had been completed, OSHA received a letter dated February 16, 1984 from the Rubber Manufacturers Association (Ex. No. 157) concurred in by the United Rubber Workers Union recommending slightly

different provisions to reduce skin absorption. OSHA believes the provisions in the proposed standard on balance meet the concerns of the RMA and URW. However, after considering their more extensive comments and other comments in the public proceeding, OSHA will, of course, make any appropriate changes to the proposed provision.

I. Medical Surveillance: Paragraph (i)

The proposed standard requires that each employer institute a medical surveillance program for all employees who are exposed at or above the action level and below the PEL for 30 or more days per year; for any employee who is exposed above the PEL for 10 days or more per year; and for any employee who was exposed above 10 ppm in the past for more than 30 days in a year while employed by the current employer prior to the effective date of the standard. In addition, medical examinations are to be provided for employees exposed to an emergency situation.

The purpose of medical surveillance is the prevention or detection of abnormalities which may occur in some workers exposed to benzene under the proposed standard. The risk assessment indicates that there is a quantified increased incidence of leukemia. The survey of the literature also indicates that cytopenias and aplastic anemias may occur. For these reasons, OSHA considers regular medical surveillance for benzene workers exposed at or above the action level to be necessary. In addition, there will be a number of workers who have an increased risk of developing leukemia as a result exposure to concentrations above 10 ppm in the past. OSHA requests comments on whether medical examinations are needed for employees who had significant benzene exposure with prior employers.

Yandl's submission to the 1977 benzene hearings reviews a number of papers which indicate that removal from exposure will in most cases result in reversal of cytopenias and the majority of aplasias. There is also evidence from Legge, Hunter, Hamilton and Vigliani that progressive reductions in benzene exposures have resulted in a reduction in cases of benzene hemopathy, including leukemia.

Direct observation of the reduction in cases of leukemia following reduction in exposure is less easy to quantify than other effects on the blood principally because most studies have not had a continuous follow-up for more than 10 years subsequent to reduction or elimination of benzene exposures (Hernberg, Vigliani) (Ex. No. 159–36, 128–15). Goldstein (Ex. Nos. 159–106) is of the opinion that workers previously exposed to air levels higher than 10 ppm benzene should have their blood examined when the new standard is promulgated. Unless these workers are further exposed at or above the action level and fall under the provisions of the standard, routine monitoring on the basis of previous exposures alone is not necessary. Because case recognition by routine monitoring may not necessarily detect leukemia before the clinical manifestations appear, OSHA believes that any individual who develops early signs and symptoms of leukemia, such as fatigue, bruising, bleeding or any other symptoms which might be attributable to benzene exposure should consult the physician who normally carries out routine surveillance as soon as possible.

OSHA concludes from the evidence reviewed that appropriate and adequate medical surveillance as prescribed is essential. The aim of medical surveillance is to detect cytopenias or aplasias due to exposure to benzene at a stage when these conditions are reversible by reducing or eliminating further benzene exposure, and to provide early recognition and possible remission and/or increased survival time for those who have already developed leukemia.

It is recognized that some individuals may be removed for blood dyscrasis such as cytopenias and aplasias not due to benzene exposure. But since these individuals may have compromised bone marrow function, their removal from benzene exposure may prevent the progression of such disease.

In addition, medical surveillance for all workers exposed to benzene above the action level will provide more comprehensive information on the effectiveness of the proposed standard in reducing disease than has previously been possible.

The aim of medical surveillance may be summarized as follows:

1. Early detection and reversal of cytopenias and aplasias.

2. The prevention of some leukemias by reducing dose to the more susceptible workers.

3. Early recognition and treatment of those cases of leukemia which might occur and improvement in remission rate and duration.

4. Better evidence of the effectiveness of the proposed standard.

Salient papers in the medical literature and opinions of scientific and regulatory bodies which have a special bearing on medical surveillance can be found in recent reviews (Ex. Nos. 2–3, 128–59, 126, 159–105). This section presents additional opinions in standard medical and hematological textbooks to explain the reasons for the tests specified and their frequency. The information reflects a consensus of the vast majority of the medical community and forms a basis for the expected toxicity and illness which a medical surveillance program must target for prevention or detection.

The large volume of published medical literature on benzene toxicity unequivocally establishes that chronic exposure to this chemical is causally associated most commonly with acute myelocytic leukemia (AML) and its variants, as well as aplastic anemia and varied combinations of suppression of the erthrocyte count (anemia) and/or the leucocyte cell count (leukopenia) and/or the thrombocyte count (thrombocytopenia). When all of these cell counts are below normal the condition is designated as pancytopenia. Benzene has also been associated to lesser degree with other hematologic disorders, including chronic myelogenous leukemia, acute and chronic lymphatic leukemia, multiple myeloma, paroxysmal nocturnal hemoglobinuria (PNH) and various forms of lymphoma including hodgkins disease.

Cecil's Textbook of Medicine (Ex. No. 159–105) states that "Workers exposed to benzene have an increased risk of acute myelogenous leukemian(AML). In these patients, bone marrow hypoplasia and/or pancytopenia often precede the diagnosis of leukemia."

Harrison's Principles of Medicine (Ex. No. 159–82) states:

> By far the most important manifestation of chronic exposure to benzene is bone marrow depression, which may progress to aplastic anaemia and complete aplasia of the bone marrow. Individual susceptibility to this effect varies greatly and may not become apparent for months after the initial exposure to the poison.

In Cancer Medicine 1982 (Ex. No. 159–26), it is stated that:

> The drugs implicated as leukemogens are all known to cause bone marrow depression and/or aplasia. The only compound with an unequivocal relationship to AML is benzol. Exposure to benzol sometimes seemingly trivial, has been followed by the development of AML with or without the clinically recognized intermediate steps of aplastic anaemia, other cytopenias, myelofibrosis or myeloid metaplasia.

Benzol is synonymous with benzene.

Wintrobe's textbook (Ex. No. 159–102) states:

> A variety of chemicals and drugs have been suggested as possible leukemogenic

agents in human leukemia, but only benzene can be unequivocally implicated. Distrubances of the hematopoietic system, especially marrow aplasia with pancytopenia, in workers chroncially exposed to benzene, have been recognized for many years. The overwhelming predominance of AML or closely related syndromes, ofter preceded by periods of aplasia with pancytopenia, in such workers provides compelling evidence for an etiologic relationship.

Wintrobe further states:

Benzene has been know as a cause of fatal aplastic anaemia since Santesson's description (1897) of 4 cases in workers in a bicycle tire factory . . . . the classic picture of leukopenia, thrombocytopenia, and poisoning by benzene. Among exposed workers the most common abnormality reported was anemia (48%). Next in frequency was macrocytosis (47%), thrombocytopenia (33%) and leukopenia (15%)

Wintrobe adds:

There are great variations in susceptibility to benzene poisoning. Evidence of poisoning may appear in a few weeks or only after many years of exposure, or it may not be discovered until the onset of infection long after exposure has ceased. Any degree of exposure is potentially dangerous.

The chapter on AML in Cancer Medicine (Ex. No. 159–26) includes the following:

The pre-treatment performance status correlates with prognosis. Those with few or no symptoms have a better survival them those with incapacitating symptoms. This is as expected since performance status is a summation of many abnormalities including age, sepsis, hemorrhage and anemia well as the individual's reaction to illness. . . . The presence of infection (defined as a fever greater than 101°F) at the time of diagnosis was correlated with a significant decrease in complete remission and survival time.

The information cited establishes those medical conditions which a surveillance program for benzene exposed employees must be designed to prevent or detect. The screening test for that purpose is a complete blood count (CBC) including a quantitative thrombocyte count. From the information cited above, it seems reasonable to conclude that early detection of a dose related marrow suppression and removal from benzene exposure will in many instances prevent the progression to more serious disease such as aplastic anemia or leukemia.

The medical surveillance program can be divided into four distinct categories: the initial examination, the periodic examination, the additional examination when blood conditions are abnormal and the surveillance examination requirements following an emergency exposure to benzene. OSHA believes that adherence to the requirements of the medical surveillance program will enable the physician to detect adverse health effects of benzene exposure at an early and therefore sometimes correctable stage, and will aid in determining whether an individual can wear a respirator.

Initial Examination

The first examination is to include a detailed occupational and medical history, complete physical examination and pertinent laboratory evaluation. The following areas are to be covered:

Occupational history. Any past exposure to chemicals known to adversely effect the bone marrow or any past hematologic abnormalities which are potentially work related should be recorded, as well as details of any exposure to radiation.

Medical history. Any past illness or abnormality of the hematopoietic system should be carefully evaluated. Any medications used by the worker whose normal or adverse effects impact upon the hematologic or cardiovascular system should be carefully noted. Smoking habits should be recorded.

A complete physical examination.

Laboratory evaluation. A complete blood count, including a thrombocyte count, erythrocyte count, a leukocyte count with differential, hematocrit, hemoglobin and erthrocyte indices. Some physicians believe that a peripheral blood smear is essential to routine medical surveillance. Others are of the opinion that an automated differential count is an appropriate secreening technique. OSHA seeks comments on this.

Additional tests as necessary in the opinion of the examining physician, based on alterations to the components of the blood which may be related to benzene exposure.

For workers who may wear a respirator for more than 30 days in a year, the initial examination is to also include:

A thorough history of difficulties involving the cardiopulmonary system should be noted. A chest x-ray and spirometric test of pulmonary function shall be performed. The spirometry shall be done consistent with the recommendation of the American Thoracic Society, and include at a minimum a forced vital capacity (FVC) and a forced expiratory volume at 1 second (FEV_1). It should be kept in mind that normal values for spirometric tests in blacks can be significantly lower than those for the general population (Ex. Nos. 159–49, 159–107).

During physical examination special attention should be given the eyes (contact lenses or spectacle wearing may cause difficulty with full face mask or half mask wearing respectively and the requirements should be consistent with the respirator standard), ears (perforated tympanic membranes), facial contour (respirator fits), skin (facial irritation from respirators) and cardio pulmonary system.

The purposes of the initial medical examinations are: (1) To establish the current health status of an employee and whether employment in areas with benzene exposure is appropriate, (2) to determine adverse health effects resulting from previous exposures to benzene or other chemicals, or radiation, (3) to provide a baseline against which future occupational health examination results may be measured, and (4) to determine whether the individual can safely wear a respirator. OSHA believes that the described examination will elicit the appropriate information to assess the initial worker health condition and allow for future precise medical monitoring.

The detailed medical history will aid the physician in interpreting the results of the tests. The baseline blood count is important. First, individual counts vary and knowing the individual baseline allows the physician to more prescisely monitor changes which may result from benzene exposures. Secondly, most of the employees monitored will have had prior benzene exposures, many at levels higher than the new PEL. The initial count will provide information for the physician to base a recommendation of whether further benzene exposure is appropriate.

The pulmonary function tests (PFT) and x-ray required as baseline procedures are to assure that those people who are required to a negative pressure respirator will not be compromised by a pulmonary deficit not detected by regular clinical examinations. The pulmonary function test will pick up obstructive and restrictive pulmonary disease while the x-ray is designed to pick up lesions which may be clinically silent. There are various views among members of the medical community as to whether the chest x-ray on the initial and periodic medical examinations should be required by the standard or whether the chest x-rays should be left to the discretion of the examining physician. Therefore, OSHA seeks comments on this issue.

The physicians should, in addition, consider if in their opinion it is necessary to evaluate the worker's ability to wear a respirator during a simulation of the physical stresses of the actual work environment and consider

whether additional laboratory tests such as an electrocardiogram, single breath diffusing capacity or other pulmonary function tests are necessary.

Periodic Examination

OSHA proposes periodic medical examinations to be administered twice yearly in order to detect at an early stage the pathological changes that lead to the more serious diseases caused or aggravated by benzene exposure. By detecting abnormalities early, workers may be removed from further benzene exposure. These measures should prevent significant morbidity and may improve prognosis in individual cases. OSHA's preliminary determination that examinations should be given twice each year is based upon the fact that the serious diseases associated with benzene exposure can develop rapidly and therefore relatively frequent examinations at appropriate intervals are necessary to institute removal and so avoid exposure to a greater total dose.

Specifically, in light of the proven connection between benzene and AML and aplastic anemia and because abnormalities which may precede these diseases are often evident before the onset of the disease and in some cases can be reversed, OSHA believes periodic examinations are necessary for the following reasons.

1. Early detection of marrow suppression before the cell counts are low enough to be life threatening, followed by removal should, in affected persons prevent significant morbidity including hemorrhage or infection or mortality (Ex. No. 142–31).

2. Employee questioning and counseling during the periodic examination to determine possible exposure to other bone marrow toxins (such as alcohol, medications such as butazolidine, chloramphenicol, immunosuppressive and antineoplastic agents), and other chemicals at work, in hobbies and in the home may enable the physician to counsel the employee as to reducing risks.

OSHA believes that by structuring periodic examination around these goals, the overall objective of significantly reducing benzene related adverse health effects can be achieved. As noted above, early detection of abnormalities can extend and save lives. The twice yearly frequency is particularly important in detecting marrow suppression because the normal life span of the red blood cells is 120 days (Ex. No. 159–102), the platelets may be gone in 9 to 12 days (Ex. No. 159–102), and the neutrophils (the most important white blood cell to be suppressed) can be lost in 4 to 10 days (Ex. No. 159–102). Early recognition followed by treatment and/or removal of the worker from any exposure to benzene is expected to decrease the incidence of benzene related diseases or prolong life in cases of leukemia.

OSHA also proposes periodic medical re-evaluation of workers required to wear respirators. The evaluation is necessary because the development of an illness or the use of a new medication which may affect the cardiovascular system must be assessed for its possible bearing on respirator wearing. This will enable the physician to determine whether the individual can safely continue to wear the respirator or whether the employee should be fitted with another type or removed from any area for which a respirator may be necessary.

Pulmonary function tests need not be repeated on an annual basis since no additional information is likely to be derived from such practice but repetition over a three year period is considered to be a reasonable assurance that the worker who is required to wear a respirator has not developed some significant pulmonary disability over the preceding three years. X-rays need not be repeated more frequently than once every five years. Neither of these restrictions preclude the physician from using either PFT's or X-rays more frequently, if in the clinical judgement of the physician they are required.

Additional Examinations

The purpose of the initial and periodic examinations is to screen for employees who have developed abnormalities. When abnormalities in the blood are detected, an additional blood examination shall be carried out to confirm the findings. If the second test shows abnormalities which cause concern to the physician, the employee shall be removed temporarily from exposure to benzene and the examining physician shall refer the employee to a hematologist/internist for further examination unless the examining physician has good reason to believe such additional referral is not needed. The purpose of removal at this stage is to avoid the possibility of deterioration in the employee's blood picture due to continued exposure to benzene. The purpose of consultation with a hematologist/internist is to provide the necessary special tests and expertise to make a diagnosis and to advise on treatment and also advise whether continued or future exposure would be an unacceptable risk to the health of the worker.

Certain abnormalities found through routine screening are of greater significance in a benzene exposed worker and warrant immediate consultation with a specialist. Thrombocytopenia and macrocytosis are considered important but anemia, leukopenia and an abnormal differential count should also alert the physician. In the case of microcytic anemias a thorough search for other causes of this type of anemia should be made prior to deciding that referral to a hematologist/internist is necessary.

Comment to OSHA has indicated that due to the varied geographic availability of hematologists, immediate consultation will not always be possible. In this situation immediate consultation with a board certified/eligible internist will be necessary. Future availability of specialty consultation has been questioned in Dr. Fishbeck's section of the American Petroleum Institutes' submission (Ex. No. 142–31). However, American Medical Association statistics show that as of 31 December 1980 there were 67,979 internal medicine specialists in the United States, clearly enough to permit immediate consultation in any area of the country (Ex. No. 159–6).

The values that OSHA has selected for the lower limits of normal conform with typical recommendations (Appendix A, Ex. No. 159–105. It should be remembered that these suggestions represent 95% confidence intervals, therefore 2.5% of the normal population will have values that fall below these lower limits. Data from the First National Health and Nutrition Examination Survey show variations in the normal range for white cell counts related to age, sex, race, and smoking habits (Ex. No. 159–56). Similarly, variations occur in the normal ranges for other blood elements especially with regard to sex and geography. Thus, all these factors need to be considered when defining acceptable levels of formed blood elements for preemployment assessment as part of routine medical surveillance and for decisions to refer benzene workers to a hematologist/internist. Clearly, an important element in decisionmaking is the preemployment white cell count. Any progressive change in the white cell count or any other blood parameter must be carefully monitored, taking into account not only the precision of the method but also the variation which occurs. A count of 4,000 white blood cells per mm^3 is proposed as the lower limit for normal below which referral is necessary; any value below this also needs to be assessed against the preemployment level taking into account

the factors cited above. Comparison of blood cell counts against the individual's baseline count from a pre-employment or other previous evaluation will be helpful in detecting whether any abnormality exists.

Raised white blood cell counts may be caused by various infections, physical activity and smoking. However, a rapid increase in white blood cells particularly with abnormal differential count may indicate the onset of leukemia. Since such onsets may be sudden and progress rapidly, any benzene exposed worker who feels unwell and mainfests symptoms of fatigue, weakness, loss of appetite, bruising, hemorrhage, or unexplained fever should be encouraged to report at once to a physician. Medical and blood examinations should be carried out immediately. If the physician considers it necessary, the worker may be referred directly to a hematologist/internist since early treatment of leukemia may increase the length of survival.

Setting the upper limit of the white cell count that requires consultation is more difficult. Wintrobe's Clinical Hematology (Appendix A) recommends an upper limit of normal of 10,000 cells/mm^3. However, it has been pointed out that using this value in the working population, where external stresses such as exercise can produce an elevated white cell count with a normal differential count may be problematic. Wintrobe's current textbook (Ex. No. 159–102) also supports this concept.

The main screening goal at the upper limit of normal in this working population is the detection of leukemia. Comments from Cancer Medicine (Ex. No. 159–26) on white cell counts in AML are helpful. Cancer Medicine reports that the median white count of over 1,500 patients with AML was between 15,000 and 20,000/ul. Ten percent of the patients had white counts lower than 2,000/ul. Slightly over one-quarter of the patients had white counts less than 5,000/ul. Cancer medicine also states that, "When the leukocyte level is elevated the circulating cells are usually predominately leukemic."

Therefore, recognizing slightly elevated white cell counts secondary to the working environment OSHA has decided not to recommend an upper level of normal for WBC. Worker protection will be maintained by stipulating that all leukocyte differential counts, with abnormalities in the segmented neutrophil and its precursors require consideration of consultation with a specialist.

OSHA believes that the above guidelines for interpreting the CBC, including consideration of referral to a specialist when counts reach the specified levels, are supported by current medical knowledge and are necessary to adequately protect workers. Some commenters, such as the American Petroleum Institute (Ex. No. 142–31) have criticized similar CBC interpretation guidelines because of the number of evaluations that will be triggered by abnormal blood counts. However, OSHA believes the risks of serious adverse health effects such as leukemia, aplastic anemia, or pancytopenia, coupled with possibility of reversal, treatment and improved prognosis, warrant the above enumerated provisions. The lowering of exposures to 1 ppm will mean that the number of referrals will be small. Of course, OSHA welcomes and encourages public comment on these issues and its final decision will be based on the record evidence.

Emergency Exposures

Following an emergency situation in which a worker is exposed to an excess amount of benzene, documentation of enhanced absorption of benzene through a urinary phenol test is required so that increased medical surveillance can be initiated, if needed. The most extensively used and validated method of detection in this situation is the urinary phenol test (Ex. No. 159–82). Elevated urinary phenol levels can occur without benzene exposure (Ex. No. 159–29), but these rare instances do not detract from the overall effectiveness of the test when overexposure has occurred.

If urinary phenol is high, the employer must provide a complete blood count of the employee at the end of 3 months following emergency exposure to determine if blood abnormalities have developed from the exposure. If they have, a referral to a specialist and treatment may be needed.

Technology permits automated gas-chromatographic analysis for benzene in blood (Ex. No. 159–43). At the levels of exposure currently prevalent in the working environment it appears that measurement of blood benzene (Ex. No. 159–13)) or breath benzene (Ex. No. 159–10) may have valuable potential. Since benzene is rapidly metabolized, the timing of such tests may be critical. Comments are requested on whether such tests should be required.

Additional Provision

This standard provides that all examinations and procedures shall be performed by or under the supervision of a licensed physician without cost to the employee. A physician is the most qualified person to supervise the test, analyze the results and make recommendations.

The proposed standard requires that the employer provide the examining physician with certain information. This includes:

(1) A copy of the regulations and appendices.

(2) A description of the employee's duties as related to exposure.

(3) The employee's representative exposure level.

(4) Information regarding the use of personal protective equipment, and

(5) Information from previous work related medical examinations not otherwise available to the physician.

The purpose of making this information available to the physician is to aid in the evaluation of the employee's health in relation to assigned duties and determine fitness to wear personal protective equipment when required.

For each examination required under this section the employer shall obtain a written opinion from the examining physician which shall include:

1. The physician's opinion as to whether the employee has any detected medical conditions or is taking any medication which would place the employee at increased risk of material impairment from exposure to benzene or from the use of personal protection equipment.

2. An opinion as to the employee's ability to wear a respirator when it is required.

3. A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from benzene exposure which require further explanation or treatment.

The physician shall not reveal in the written opinion given to the employer specific findings of diagnoses unrelated to occupational exposure to benzene. The purpose of this provision is to protect the privacy of the employee by not having the physician reveal non-occupational related conditions to the employer. This provision has been included in prior standards. OSHA requests comments on this provision.

The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt. The requirement that the employee be provided with a copy of the physician's written opinion will ensure that the employee is informed of the results of the medical examination.

Medical Removal

OSHA has proposed that medical removal from further benzene exposure should occur in two circumstances. The

first is temporary removal when the plant physician considers that referral to a hematologist/internist is necessary while waiting for the hematologist/internist report. The justification for temporary medical removal by the plant physician while awaiting consultation by the hematologist/internist is based on the fact that in some cases, blood abnormalities may rapidly progress to serious and possibly life-threatening disease, and continued exposure could risk such an event.

Because of the complex nature of possible early blood changes, the decision to refer an employee to a hematologist/internist is a judgment by the plant physician. A fall in one or more types of blood cells from the individual's own baseline counts, even though still within the laboratory range of normal, may be a significant sign. Indeed, the complexity of the initial blood abnormalities is the reason for referral to a hematologist/internist.

Second, following the findings of the hematologist/internist, it will be necessary to decide whether the employee can return to work involving benzene exposure or whether the employee shall be kept away from further benzene exposure either permanently or until the blood has returned to normal. If removal is temporary, an estimate is to be made of the probable removal period and the times of further follow-up examinations. OSHA considers that at a PEL of 1 ppm such removal procedures will be minimal in number.

There are several reasons for temporary or permanent removal on the advice of the hematologist/internist. Early removal has the best chance of enabling the blood to return to normal. Continued exposure could cause serious progressive and possibly fatal disease, sometimes with rapid onset. As just discussed, blood conditions can deteriorate rapidly during conditions of continuing exposure. Removal and treatment may prevent death, cure illness or improve the employee's condition. Those factors are also discussed at greater length above.

OSHA has not specifically proposed that an employee temporarily or permanently removed from areas of benzene exposure be provided with another job in an area with no benzene exposure. OSHA would expect that employers in a position to do so would do this, and that the details of such a transfer are best left to collective bargaining and employer personnel policies. However, OSHA invites evidence and comment on whether there is health justification for including a provision on this matter and on whether such a provision should be accompanied by wage retention in the standard. OSHA will of course consider all such comment and evidence in determining whether such a provision should be included in a final standard.

J. Communication of benzene hazards to employees: Paragraph (j)

In this proposed benzene standard, OSHA included a new paragraph entitled: "Communication of benzene hazards to employees". This paragraph addresses the issue of transmitting information to employees about the hazards of benzene through the use of: (1) Signs and labels, (2) material safety data sheets, and (3) information and training. Previous OSHA health standards generally included separate paragraphs on employee information and training and signs and labels. This standard incorporates both of those areas into this single paragraph, along with material safety data sheet provisions to be consistent with a recent OSHA rule which addresses these areas.

On November 25, 1983, the Occupational Safety and Health Administration published its final rule on Hazard Communication at 48 FR 53280 (29 CFR 1910.1200). The hazard communication standard requires all chemical manufacturers and importers to assess the hazards of the chemicals they produce or import, and all manufacturing employers to provide information concerning the hazards of such chemicals to their employees. The standard provides that: "This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training."

Since the Hazard Communication Standard "is intended to address comprehensively the issue of evaluating and communicating chemical hazards to employees", OSHA proposes this new paragraph entitled "Communication of benzene hazards to employees" in an effort to avoid repetition of those requirements now comprehensively laid out in § 1910.1200. In addition, this new paragraph has been developed with the intent of avoiding placement of a duplicate administrative burden on those employers attempting to comply with the requirements of several different applicable OSHA health standards, while at the same time providing the necessary protection afforded employees under the provisions for signs and labels, material safety data sheets, and employee information and training. It should be noted that while the communications of benzene hazards paragraph of the benzene standard has been designed to be substantively as consistent as possible with the hazard communications standard, the hazard communication standard addresses the responsibility of employers to downstream employers. The communication of benzene hazards paragraph of the benzene standard only requires that each covered employer make the signs and labels, material safety data sheets and training and information available to that employer's employees. The communication of benzene paragraph of the benzene standard is to cover all industry segments covered by the benzene standard.

The proposed standard requires that regulated areas be posted with signs stating: "Danger, Benzene, Cancer Hazard, Flammable-No Smoking, Authorized Personnel Only, Respirator Required." The proposed standard intends that the posting of these signs will serve as a warning to employees who may otherwise not know they are entering a regulated area. Such warning signs are required to be posted whenever a regulated area exists, that is, whenever the permissible exposure limit is exceeded. For some work sites, regulated areas exist as a permanent situation, where there is an area where exposures cannot be reduced below the PEL by the use of engineering controls. In those situations the signs are needed to warn employees not to enter the area unless they are wearing respirators and unless there is a need for entering the area.

Regulated areas may also exist on a temporary basis, for example, during maintenance and/or emergency situations. The use of warning signs in these types of situations is also important, since a maintenance or emergency situation would represent by nature a new or unexpected exposure to employees who are regularly scheduled to work at these sites. The posting of signs at the occurrence of an emergency or maintenance situation will help to prevent unnecessary exposures to workers who may not otherwise know or expect excessive benzene exposure levels and serves to warn employees of the need to wear respirators. These signs are intended to supplement the training which employees are to receive under the other provisions of this paragraph, since even trained employees need to be reminded of the locations of regulated areas and of the

precautions necessary to be taken before entering these dangerous areas.

The proposed standard specifies the wording of the warning signs for regulated areas in order to assure that the proper warning is given to employees. OSHA feels that the use of the word "Danger" is appropriate, based on the epidemiological evidence of the human carcinogenicity of benzene. "Danger" is used to attract the attention of workers, to alert them to the fact that they are in an area where the permissible exposure limit is exceeded, and to emphasize the importance of the message that follows. The use of the word "Danger" is also consistent with other recent OSHA health standards dealing with carcinogens. The proposed sign requirement also requires that the legend "Respirator Required" be included on the warning sign. While OSHA recognizes that some employees entering the regulated areas may not be exposed above either the 8-hour PEL of 1 ppm or the STEL of 5 ppm as averaged over a 15-minute period, it is still possible that many employees who are assigned to work in these areas may remain in these locations for long enough periods of time so that they would be needlessly overexposed to benzene without the use of respirators. To ensure that these employees are adequately protected, it is necessary that the sign alert them to the need to wear respirators.

The requirements for signs and labels are consistent with section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed. In addition, the OSHA Hazard Communication standard requires that, if a hazardous chemical is regulated by OSHA in a substance-specific health standard, "the chemical manufacturer, importer, distributor or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard." (see 29 CFR 1910.1200(f)(3)). Therefore, this proposed benzene standard, at paragraph (j)(1)(i) states the specific labeling (and sign) requirements that must be used to warn employees of the hazards to which they are exposed.

Paragraph (j)(1)(ii) requires that labels or other appropriate forms of warning must be provided for containers (as defined in the Definitions paragraph of this section) of benzene within the workplace in accordance with the requirements of the Hazard Communication standard. OSHA is proposing a specific labeling requirement which reads: "Caution, Contains Benzene. Cancer Hazard." Paragraph (j)(1)(iii) further requries that this same legend be affixed to containers of benzene leaving the workplace. Again such labeling is to be in accordance with requirements of § 1910.1200(f). As stated in the Scope and Application section of this standard, and, consistent with OSHA's Hazard Communication standard, these labeling requirements do not apply to pipelines.

OSHA also proposes in this proposed benzene standard to require the employer to obtain or develop and to distribute and provide access to a material safety data sheet for benzene in accordance with the requirements of 29 CFR 1910.1200(g). OSHA feels that a properly completed material safety data sheet (MSDS), if readily avaialble to employees, can serve as an excellent, concise source of information regarding the hazards associated with benzene. OSHA's primary intent in this section of the proposed standard, as stated in its recently promulgated Hazard Communication standard, is to ensure that employees will receive as much information as is needed concerning the hazards posed by chemicals in their workplaces. The material safety data sheet ensures that this information will be available to them in a usable, readily accessible and concise form. The material safety sheet also serves as the central source of information to employees and downstream employers who must be provided with the MSDS benzene is produced and shipped out of the plant. In addition, the MSDS serves as the basic source of information on the hazards of benzene essential to the training provisions of this and other applicable health standards.

Chemical manufacturers and importers have the primary responsibility, under the Hazard Communication standard, to develop or prepare the material safety data sheet. The manufacturer or importer is most likely to have the best access to information about the product, and is therefore responsible for disseminating this information to downstream users of the material. For employers whose employee's exposure to benzene is from products received from outside sources, the information necessary for a complete MSDS or the MSDS itself is to be obtained from the manufacturer and made available to affected employees. The requirements for the information that is to be contained on the material safety data sheet are explained in detail at 29 CFR 1910.1200(g).

Paragraph (j)(3) of this proposed benzene standard requires employers to provide employees with information and training on benzene at the time of initial assignment and at least annually thereafter. The training program is to be in accordance with the requirements of the Hazard Communication standard, paragraphs (h)(1) and (2), including specific information required to be provided by that section. In addition, employees are to be provided with an explanation of the contents of Appendices A and B of the final benzene standard. Employees are to be informed where a copy of the final benzene standard is accessible to them, and receive a description of the medical surveillance program required under paragraph (1) of this proposed standard. Employees are also to receive an explanation of the information contained in Appendix C on the medical surveillance guidelines for benzene.

OSHA has determined during other rulemakings that an information and training program, as incorporated in this proposed standard in an overall "Communication of benzene hazards to employees" paragraph, is essential to inform employees of the hazards to which they are exposed and to provide employees with the necessary understanding of the degree to which they themselves can contribute toward minimizing health hazard potential. As part of an overall comunication program for employees, training serves to explain and reinforce the information presented to employees on labels and materials safety data sheets. These written forms of information and warning will only be successful and relevant when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures and therefore reduce the possibility of the occurrence of adverse health effects. Training is essential to an effective overall hazard communication program. Active employee participation in training sessions can result in the effective communication of hazard information to employees which can further result in workers taking conscientious protective actions at their job duties, thereby decreasing the possibility of occupationally-related illnesses and injuries.

OSHA proposes the training provision of this standard to be in performance-oriented, rather than specified and detailed language. The proposed standard, in requiring training to be in accordance with the requirements of 29 CFR 1910.1200, lists the categories of information to be transmitted to employees and not the specific ways that this is to be accomplished.

OSHA believes that the employer is in the best position to determine how the

training he or she is providing is being received and absorbed by the employees. OSHA has therefore laid out the objectives to be met and the intent of its training to ensure employees are made aware of the hazards in their workplace and how they can help to protect themselves. The specifics of how this is to be accomplished are left up to the employer.

In response to OSHA's Request for Information, many comments were received that endorsed this approach. Conoco, Inc. (Ex. No. 142–27) suggested "* * * that OSHA consider that any education and training requirements be in performance language, requiring employers to determine that employees have the necessary health and safety information rather than annual retraining on exactly the same points. "* * * and, "Conoco's experience with the vinyl chloride standard, which details items to be included in annual training, has shown such specification language to be counter-productive because of the required repetition."

Other commenters stated that OSHA's Hazard Communication standard provides important requirements for training provisions and that separate requirements for training would only be redundant, burdensome, and unnecessary, and therefore should not be specifically repeated in the proposed benzene rule. OSHA therefore is proposing to require a training program in accordance with the requirements of 29 CFR 1910.1200 and intends that the use of such performance-oriented requirements will encourage employers to tailor their training needs to their specific workplaces, thereby resulting in the most effective training program suitable for each specific workplace.

K. Recordkeeping: Paragraph (k)

The proposed benzene standard requires employers to maintain exposure measurement records and medical records. These requirements are proposed in accordance with section 8(c) of the Act which requires employers to keep and make available such records as the Secretary may prescribe as necessary or appropriate for the enforcement of the Act, or for developing information regarding occupational accidents and illnesses.

The proposal requires that an exposure monitoring record be established for important data required by paragraph (e) of the proposed standard. Records of employee exposure monitoring results are to be maintained in accordance with OSHA's "Access to Employee Exposure and Medical Records," (29 CFR 1910.20). Records must include the following information: (a) The dates, number, duration, and results of each of the samples taken, including, where appropriate, a description of the procedures used to determine representative employee exposures; (b) a description of the sampling and analytical methods used; (c) a description of the type of respiratory protective equipment worn, if applicable; and (d) the name, social security number, job classification and exposure levels of the employee monitored, and all other employees whose exposure the measurement is intended to represent.

The proposal requires that employee exposure measurement records be maintained for each measurement taken. The record may represent several employee exposure measurements, if representative sampling, as described in section (e), is conducted. Each employee must have access to the exposure monitoring records that represent his or her exposure levels, however. Because the symptoms of disease that have been related to exposure to benzene may not appear for years following an initial exposure, the proposal requires that records of employee exposure measurements be retained for at least 30 years. This requirement is consistent with the retention requirements of the Access to Employee Exposure and Medical Records standard, 29 CFR 1910.20. OSHA believes these records are necessary to assist in the effective evaluation and control benzene in the workplace. As good records are needed for correct diagnoses, and some conditions resulting from benzene exposure are reversible and may not develop for many years, OSHA believes these retention periods are necessary and appropriate to protect the health of benzene-exposed employees.

In addition to records on employee exposure measurements, the employer is required to establish and maintain an accurate individual record for each employee subject to medical surveillance as required by paragraph (i) of the proposed standard. OSHA believes that medical records, like exposure monitoring records, are necessary and appropriate to the enforcement of the standard, to the successful treatment of benzene related disease and the development of information regarding the causes and prevention of illness.

The record shall include: (1) The name and duties of the employee, (2) the employer's copy of all physicians reports on the employee, (3) any employee benzene related medical compliants (4) a copy of the standard and appendices or the reference to the employer's copy (5) a copy of the information provided to physician's and (6) a copy of the employee's medical and work history related to any hematologic toxins. Abnormal changes of blood elements may be affected by different factors and therefore a good medical history will include specification of known hemotologic toxins to which the employee has been exposed. These items constitute information necessary and appropriate for later accurate diagnoses and determinations that the worker is adequately protected under the standard.

The proposed standard requires that medical records are also to be kept for the duration of employment, plus 30 years. This retention period is again consistent with that specified in OSHA's Access to Employee Exposure and Medical Records standard. It is necessary to keep these records for extended periods because of the long latency period commonly associated with carcinogenesis. Cancer often cannot be detected until 20 or 30 years after an initial exposure or initial onset of disease. The extended retention period is also felt to be necessary for the following two reasons: (1) Diagnosis of disease in employees is assisted by having present and past exposure data as well as the results of medical examinations, and (2) the retention of records for extended periods enables a review of the adequacy of the standard at a future date.

The proposal specifies that access to exposure and medical records by employees, designated representatives, and OSHA's shall be in accordance with 29 CFR 1910.20, OSHA's "Access to Employee Exposure and Medical Records" standard. The terms of this standard apply to records required by specific standards, such as this proposed benzene standard, as well as records which are voluntarily created by an employer. Employees and their designated representatives are, in general, allowed unrestricted access to exposure monitoring records. Access to medical records is also provided for employees, and, if the employee has given specific written consent, for the employee's designated representatives. OSHA retains access to both kinds of records, but its access to personally identifiable records is made subject to rules of agency practice and procedure concerning OSHA access to employee medical records, which have been published at 29 CFR 1913.10 (see 45 CF 35384).

The transfer of employee exposure monitoring and medical records is to be in accordance with the provisions of paragraph (h) of 29 CFR 1910.20. If an

employer ceases to do business and there is no successor employer, the employer is to notify NIOSH and transmit the records to the Director of NIOSH for retention, if requested.

OSHA believes the collection and retention of these exposure monitoring and medical records is necessary to protect workers from significant risk and to allow for future assessment of the standard's permissible exposure limit and other provisions. OSHA seeks comment on these specific provisions.

Requirements for recordkeeping under the Paperwork Reduction Act are discussed under Section XII Clearance of Information Collection Requirements.

L. Observation of Monitoring: Paragraph (l)

This proposed benzene standard contains provisions for the observation of exposure monitoring. This provision is in accordance with section 8(c) of the OSH Act which requires that employers provide employees and their representatives with the opportunity to observe monitoring of employee exposures to toxic substances or harmful physical agents. Observation procedures are set forth which require the observer, whether it be an employee or a designated representative, to be provided with the personal protective clothing and equipment that is required to be worn by the employees who are working in the area. The employer is required to assure the use of such clothing and equipement or respirators, and is responsible for requiring that the observer complies with all other applicable safety and health procedures.

M. Effective dates: paragraph (m)

It is proposed that standard become effective 90 days after date of publication in the Federal Register. OSHA proposes that the requirements of paragraphs (a) through (m) of the standard be completed sixty (60) days after the effective date of the final rule except for paragraph (f)(i), which sets forth the requirements for engineering and work practice controls. Consequently employers will have 5 months from publication to accomplish those requirements which OSHA believes is adequate time. Implementation dates for the completion of the engineering and work practice requirements are proposed to be no later than 2 years after the effective date of the final rule. This is to allow affected employers sufficient time to design (where necessary), obtain, and install the necessary control equipment. OSHA solicits comments on the adequacy of these proposed start-up dates.

N. Appendices: Paragraph (n)

Five appendices have been included at the end of this proposed standard. Appendices A, B, C, and D have been included primarily for purposes of information. None of the statements contained in Appendices A, B, C, and D should be construed as establishing a mandatory requirement not otherwise imposed by the standard, or as detracting from an obligation which the standard does impose. However, the protocals for respiratory fit testing in Appendix E are binding.

Appendix A contains information on the description and exposure levels of benzene. Also provided in Appendix A is information on the health hazards associated with exposure, descriptions of protective clothing and equipment, emergency and first aid procedures, medical requirements, provisions for the observation of monitoring, access to exposure and medical records, and precautions for the safe use, handling and storage of benzene.

Appendix B contains "substance technical guidelines" for benzene, including physical and chemical data, spill and leak procedures including waste disposal methods, and other miscellaneous precautions for the safe handling of benzene.

Appendix C contains the medical surveillance guidelines for benzene. Included in these guidelines are a description of the routes of entry, the toxicology and symptoms and signs associated with benzene exposure, information on the treatment of acute toxic effects, and surveillance and preventive considerations, including hematology guidelines which may be useful to physicians in conducting the medical surveillance program required by section (i) of this proposed standard.

Appendix D gives details of the OSHA sampling and analytical methods for use in monitoring emloyee exposures to benzene.

Appendix E gives detailed fit testing procedures that are to be followed for qualitative and quantitative fit testing of negative pressure respirators. Various Protocols for qualitative and quantitative fit tests are outlined in detail.

All the Appendices are designed to aid the employer in complying with the requirements of the standard. Paragraph (j) of this proposed standard on the "communication of benzene hazards to employees" specifically requires that the contents of the standard and Appendices A and B be made available to affected employees. Information contained in Appendix C on medical surveillance is to be explained to affected employees. The information in Apendix C also provides information needed by the physician to evaluate the results of the medical examination.

XI. Environmental Impact

Environmental Assessment Finding of No Significant Impact

The proposed revisions to the benzene standard have been reviewed in accordance with the requiremens of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.), the Council on Environmental Quality (CEQ) NEPA regulations (40 CFR Part 1500), and OSHA's DOL NEPA Compliance procedures (29 CFR Part 11).

As a result of this review, the Assistant Secretary has determined that the proposed rule will not have a significant impact on the external environment. Impacts on the workplace environment are discussed in other portions of this preamble.

In January 1978, OSHA published a Final Environmental Imapct Statement (FEIS) on Benzene. That document concluded that the benzene standard would benefit the workplace environment by reducing benzene exposures, thereby decreasing the incidence of leukemia and other blood abnormalities in workers. Beneficial impacts to the external environment were considered to result from the control of fugitive emissions to the ambient atmosphere. The proposed action was further determined not to have any significant adverse effects on the general quality of the human environment external to the workplace, particularly in terms of ambient air quality, water quality, or solid waste disposal.

Under the present proposed revisions to the benzene standard, there have been some changes in the scope of the standard, the definitions of benzene and benzene mixtures, and in the monitoring provisions as well as some language modifications throughout. The 8-hour time-weighted average (TWA) of 1 part per million (ppm), with a ceiling of 5 ppm over a 15-minute sampling period, remains the same.

Although the scope of the proposal now includes some bulk plants and excludes some bulk terminals (i.e., those using vapor control systems), there does not appear to be any significant environmental effect as a result of this change. The net effect of the standard is to exclude facilities which already have vapor recovery system to reduce benzene emission to the external environment because those systems reduce employee exposure below the 0.5

ppm action level. Some employers who do not already have vapor recovery systems, may be encouraged to install them to reduce exposures of their employees which will also reduce benzene emissions to the external environment.

Worker exposure to benzene emissions occurs during manual tank gauging and open-hatch top loading and unloading operations. During tank gauging procedures, exposures can be reduced or eliminated by work practices. For example, the worker lowering the gauging tape into the tank should stand upwind from the hatch. This work practice would have no impact on the amount of benzene presently emitted to the ambient atmosphere.

During open-hatch loading operations worker exposures could be reduced by the use of closed hatch loading arms. This equipment prevents the release of vapors from the hatch and consequently would be beneficial to the worker and to the external environment. Where bottom hatch loading procedures are used, worker exposure would be reduced since benzene emissions would be diverted from the worker's breathing zone. In these cases, however, there would be no change in present ambient air conditions. Where closed controls such as vapor control systems are implemented there would be no emissions released to the ambient air, thereby having a beneficial effect on the environment. By and large, the overall effect of these controls and work practices on the external environment would not be significant, since most plants and terminals either meet or exceed compliance requirements of the 1 ppm PEL.

The 1978 FEIS also discussed a 1.0 percent exclusion for mixtures (0.1 percent after 1 year from the date of promulgation of the final rule) which intended to exempt from the permanent standard those substances where the benzene content was reduced to the greatest extent possible.

The current proposal revises the percentage-exclusion provision for current mixtures of 0.5 percent and gives employers 5 years, instead of 1 year, from promulgation of the final rule to reformulate products or to find substitutes in order to meet the 0.1 percent level. The exemption of work operations where the only exposure to benzene is from liquid mixtures of 0.1 percent or less of benzene by volume would typically result in worker exposures below the action level. These modifications in this provision are not anticipated to have any significant effects beyond the workplace, but would benefit the environment to the extent that more benezene-containing products would be reformulated or substituted with other less hazardous ones.

The FEIS discussed the implementation of an action level as one alternative to the 1977 proposed action. The major advantage of the action level is to protect employees from potential exposures in excess of the PEL by implementing certain provisions before that PEL is reached or exceeded. This means that employers would be required to institute certain minimum monitoring, medical surveillance, training, and recordkeeping activities at the action level. The implementation of the proposed 0.5 ppm action level is not anticipated to have any significant environmental impact outside of the workplace. As with other work practices and procedures, however, to the extent that they are implemented and are successful in avoiding or eliminating occurrences of accidental spills or improper disposal of wastes there is a potential for some benefit to the external environment.

Other modifications in the language of the proposal and in the monitoring provisions are not anticipated to have a significant effect outside of the workplace.

The conclusions drawn in the 1978 FEIS remain valid and therefore no amended impact statement is required by this OSHA action. The preceding paragraphs and the preamble to the NPRM serve as the environmental assessment and finding of no significant impact. OSHA, of course, reserves the right to perform additional environmental analyses based on information and comments received in response to this notice.

XII. Clearance of Information Collection Requirements

On March 31, 1983, the Office of Management and Budget (OMB) published a new 5 CFR Part 1320, implementing the information collection provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* (48 FR 13666). Part 1320, which became effective on April 30, 1983, sets forth procedures for agencies to follow in obtaining OMB clearance for collection of information requirements contained in proposed rules to OMB not later than the date of publication of the proposal in the **Federal Register.** It also requires agencies to include a statement in the notice of proposed rulemaking, indicating that such information requirements have been submitted to OMB for review under Section 3504 (h) of the Paperwork Reduction Act.

In addition to the above requirements, applicable federal regulations also provide, 5 CFR 1320.4(a), 1320.5(a), and 1320.5(d) respectively as follows:

> An agency shall not engage in a collection of information without obtaining Office of Management and Budget (OMB) approval of the collection of information and displaying a currently valid control number and, unless OMB determines it to be inappropriate, an expiration date.
>
> * * * * *
>
> Notwithstanding any other provision of law, no person shall be subject to any penalty for failure to comply with any information collection request if the request does not display a currently valid OMB control number, or, in the case of an information collection request which is submitted to nine or fewer persons, the request fails to state that for this reason it is not subject to OMB review under the Act.
>
> * * * * *
>
> Whenever a member of the public is protected from imposition of a penalty under this section for failure to comply with a collection of information, such penalty may not be imposed by an agency directly, by an agency through judicial process. Or by any other person through judicial or administrative process.

The sections of the proposed benzene standard which may create recordkeeping requirements are paragraphs (e) exposure monitoring, (f)(2) compliance program, (i) medical surveillance, (j) communication of benzene hazards, and (k) recordkeeping.

In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it will submit the information collection requirements contained in its proposed rule on occupational exposure to benzene to OMB for review under section 3504(h) of that Act. Comments on these information collection requirements may be submitted by interested persons to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for OSHA.

XIII. Public Participation—Notice of Hearings

Comments

Interested persons are invited to submit written data, views, and arguments on all issues with respect to this proposed standard. These comments must be postmarked on or before February 14, 1986, and submitted in quadruplicate to the Docket Officer, Docket No. H-059C, Room N-3670, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, DC 20210. Written submissions must clearly identify the provisions of the proposal which are addressed and the

position taken with respect to each issue.

The data, views, and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

Oral Hearings

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard will be provided at four informal public hearings scheduled to begin at 10:00 A.M. at places and on dates as follows:

Washington, D.C.: March 11, 1986, The Auditorium, Frances Perkins Department of Labor Building, Third and Constitution Avenue NW., Washington, DC 20210.

New Orleans, LA: March 25, 1986, Peach Tree Room, Regency Conference Center (Use 500 Poydras Plaza entrance), Hyatt Regency—New Orleans, At Louisiana Superdome, Poydras at Loyola Avenue, New Orleans, Louisiana 70140 (Telephone: 504–561–1234).

Los Angeles, CA: April 2, 1986, Redondo Room, Sheraton Plaza—La Reina Hotel, 6101 West Century Boulevard, Los Angeles, California 90045–5308 (Telephone: 213–642–1111).

Chicago, IL: April 8, 1986, TWA/NWO Room, Hyatt Regency O'Hare, 9300 West Bryn Mawr Avenue, River Road at Kennedy Expressway, Rosemont, Illinois 60018 (Telephone: 312–696–1234).

All persons desiring to participate at the hearings must file in quadruplicate a notice of intention to appear postmarked on or before February 14, 1986, addressed to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H–059C, Room N–3662, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, DC 20210; telephone 202–523–8024.

The notices of intention to appear which will be available for inspection and copying at the OSHA Docket Office (Room N–3670), telephone 202–523–7894, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The approximate amount of time requested for the presentation;

(4) The specific issues that will be addressed;

(5) A detailed statement of the position that will be taken with respect to each issue addressed;

(6) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and

(7) At which hearing on hearings the party wishes to testify.

Filing of Testimony and Evidence Before Hearings

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of the testimony, including any documentary evidence to be presented at the hearing to the OSHA Division of Consumer Affairs. This material must be received by February 26, 1986 and will be available for inspection and copying at the OSHA Docket Office. Each such submission will be reviewed in light of the amount of time requested in the notice of intention to appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation, and may be requested to return for questioning at a later time.

Conduct of Hearings

The hearings will commence at 10:00 a.m. according to the schedule specified above, with resolution of any procedural matters relating to the proceeding. The hearings will be conducted in accordance with 29 CFR Part 1911 and the prehearing guidelines which will be sent to all persons who file a notice of intention to appear. The hearings will be conducted in as expedited a manner as possible, compatible with a full development of the record and the rights of the parties.

The hearings will be presided over by an Administrative Law Judge who will have all the powers necessary or appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911 and the prehearing guidelines, including the powers:

1. To regulate the course of the proceedings;

2. To dispose of procedural requests, objections, and comparable matters;

3. To confine the presentation to the matters pertinent to the issues raised;

4. To limit the time for questioning;

5. To regulate the conduct of the hearing by appropriate means; and

6. To keep the record open for a reasonable stated time to receive additional written data, views and arguments from any person who has participated in the oral proceeding.

Following the close of the hearings or of any posthearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The Administrative Law Judge does not make or recommend any decisions as to the content of a final standard. The proposed standard will be reviewed in light of all oral and written submissions received as part of the record, and final decisions will be taken by the Assistant Secretary based upon the entire record in this proceeding.

State Plan Applicability

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of a final standard. These States include: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

Authority

This document was prepared under the direction of Patrick R. Tyson, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, DC 20210.

Pursuant to sections 6(b) and 8 of the Occupational Safety and Health Act (29 U.S.C. 655, 657), it is hereby proposed to amend Part 1910 of 29 CFR by adding a new permanent standard for occupational exposure to benzene as § 1910.1028 as set forth below and to make consequential amendments to Table Z–2 of § 1910.1000. In addition, pursuant to section 4(b)(2) of the Act, OSHA has determined that this new standard would be more effective than the corresponding standards now in Subpart B of Part 1910, and in Parts 1915, 1918, and 1926 of Title 29, Code of Federal Regulations. Therefore, these corresponding standards would be superseded by this new § 1910.1028.

List of Subjects in 29 CFR Part 1910

Benzene, Occupational safety and health, Chemicals, Cancer, Health, Risk-assessment.

Signed at Washington, D.C., this 3 day of December 1985.

Patrick R. Tyson,

Acting Assistant Secretary of Labor.

OSHA proposes to amend Part 1910 of Title 29 of the Code of Federal Regulations as follows:

Part 1910—[AMENDED]

1. The authority citation for Subpart Z of Part 1910 would be amended by adding a citation for § 1910.1028 to read as follows:

Authority: Secs. 6, 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Orders 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736) as applicable; and 29 CFR Part 1911;

* * *

§ 1910.1028 also issued under 29 U.S.C. 653

* * * * *

2. A footnote "1" would be added to the word "Benzene" in Table Z-2 of Section 1910.1000 to read as follows:

§ 1910.1000 [Amended]

[1] This standard applies only to the industry segments exempt from the 1 ppm benzene standard of § 1910.1028.

3. It is proposed to add a new § 1910.1028 and Appendices A, B, C, D and E to read as follows:

§ 1910.1028 Benzene.

(a) *Scope and application.* (1) This section applies to all occupational exposures to benzene, Chemical Abstracts Service Registry No. 71-43-2, except as provided for in paragraph (a)(2) of this section.

(2) This section does not apply to:

(i) The storage, transportation, distribution, dispensing, sale or use of gasoline, motor fuels, or other fuels containing benzene subsequent to its final discharge from bulk wholesale storage facilities.

(ii) The work operations at bulk wholesale storage facilities which use vapor control systems for all loading and unloading operations, except for the provisions of 29 CFR 1910.1200 as incorporated into this standard and the emergency provisions of this standard.

(iii) The storage, transportation, distribution or sale of benzene or liquid mixtures containing more than 0.1 percent benzene in intact containers or in transportation pipelines sealed in such a manner as to contain benzene vapors or liquid, except for the provisions of 29 CFR 1910.1200 as incorporated into this standard and the emergency provisions of this standard.

(iv) Containers and pipelines carrying mixtures with less than 0.1 percent benzene.

(v) Work operations where the only exposure to benzene is from liquid mixtures containing 0.5 percent (0.1 percent after (insert date 5 years after publication date of final standard)) or less of benzene by volume, or the vapors released from such liquids.

(vi) Oil and gas drilling, production and servicing operations.

(b) *Definitions.*

"Action level" means an airborne concentration of benzene of 0.5 ppm calculated as an 8-hour time-weighted average.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (1) of this section, or any other person authorized by the Act or regulations issued under the Act.

"Benzene" (C_6H_6) (CAS Registry No. 71-43-2) means liquefied or gaseous benzene. It includes benzene contained in liquid mixtures and the benzene vapors released by these liquids. It does not include unreacted benzene contained in solid materials.

"Bulk wholesale storage facility" means a bulk terminal or bulk plant where fuel is stored prior to its delivery to wholesale customers.

"Container" means any barrel, bottle, can, cylinder, drum, reaction vessel, storage tank, or the like, but does not include piping systems.

"Day" means any part of a calender day.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may or does result in an unexpected significant release of benzene.

"Employee exposure" means exposure to airborne benzene which would occur if the employee were not using respiratory protective equipment.

"Regulated area" means areas where airborne concentrations of benzene are in excess of the permissible exposure limit.

"Vapor control system" means any equipment used for containing the total vapors displaced during the loading of gasoline tank trucks and the displacing of these vapors through a vapor processing system or balancing the vapor with the storage tank. This equipment also includes systems containing the vapors displaced from the storage tank during the unloading of the tank truck which balance the vapors back to the tank truck.

(c) *Permissible exposure limit (PEL).* The employer shall assure that no employee is exposed to an airborne concentration of benzene in excess of one part of benzene per million parts of air (1 ppm) as an 8-hour time-weighted average.

(d) *Regulated areas.*

(1) The employer shall establish a regulated area wherever the airborne concentration of benzene is above the permissible exposure limit.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated in any manner that minimizes the number of employees exposed to benzene within the regulated area.

(e) *Exposure monitoring.*—(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of each employee's average exposure to airborne benzene over an eight hour period.

(ii) Representative employee exposure shall be determined on the basis of at least one sample or consecutive samples covering the full shift for each job classification in each work area.

(iii) Except for initial monitoring as required under paragraph (e)(2), where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer shall only be required to determine representative employee exposure for that operation during the shift that the highest exposure is expected.

(2) *Initial monitoring.* (i) Each employer who has a place of employment covered under paragraph (a)(1) of this section shall monitor each of these workplaces and work operations to determine accurately the airborne concentrations of benzene to which employees may be exposed.

(ii) The initial monitoring required under paragraph (e)(2)(i) of this section shall be completed within 60 days of the effective date of this standard or within 60 days of the introduction of the benzene into the workplace. Where the employer has monitored after (insert

date one year prior to publication of this standard) and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of (e)(2)(i) of this section.

(3) *Periodic monitoring and monitoring frequency.* (i) If the monitoring by paragraph (e)(2)(i) of this section reveals employee exposure at or above the action level but at or below the PEL, the employer shall repeat such monitoring for each such employee at least every year.

(ii) If the monitoring required by paragraph (e)(2) (i) of this section reveals employee exposure above the PEL, the employer shall repeat such monitoring for each such employee at least every six (6) months.

(iii) The employer may alter the monitoring schedule from every six months to annually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee exposure has decreased to the PEL or below.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (e)(2)(i) of this section reveals employee exposure to be below the action level the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (e)(5).

(ii) If the periodic monitoring required by paragraph (e)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level the employer may discontinue the monitoring for that employee, except as otherwise required by paragraph (e)(5).

(5) *Additional monitoring.* (i) The employer shall institute the exposure monitoring required under paragraphs (e)(2) and (e)(3) of this section when there has been a change in the production process, chemicals present, control equipment, personnel or work practices which may result in new or additional exposures to benzene, or when the employer has any reason to suspect a change which may result in new or additional exposures.

(ii) Whenever spills, leaks, ruptures or other breakdowns occur, the employer shall repeat the monitoring which is required by paragraph (e)(2)(i) after a cleanup of the spill or repair of the leak, rupture or other breakdown.

(6) *Accuracy of monitoring.* Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of benzene.

(7) *Employee notification of monitoring results.* (i) The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this standard, notify each employee of these results in writing either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) The written notification required by paragraph (e)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce the employee exposure to or below the PEL, wherever the PEL is exceeded.

(f) *Methods of compliance.*—(1) *Engineering controls and work practices.* (i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to benzene at or below the permissible exposure limit, except to the extent that the employer can establish that these controls are not feasible or where the provisions of paragraphs (f)(1)(iii) or (g)(1) of this section apply.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (g) of this section.

(iii) Where the employer can document that benzene is present in a work area less than a total of 30 days per year, the employer may use engineering controls, work practice controls or respiratory protection or any combination of these controls to reduce employee exposure to benzene to or below the PEL.

(2) *Compliance program.* (i) When any exposures are over the PEL, the employer shall establish and implement a written program to reduce employee exposure to or below the PEL primarily by means of engineering and work practice controls, as required by paragraph (f)(1) of this section. No compliance plan is required if all exposures are under the PEL.

(ii) The written program shall include a schedule for development and implementation of the engineering and work practice controls. These plans shall be reviewed yearly and revised as appropriate based on the most recent exposure monitoring data, to reflect the current status of the program.

(iii) Written plans for these compliance programs shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives.

(g) *Respiratory protection.*—(1) *General.* The employer shall provide respirators, and assure that they are used, where required by this section. Respirators shall be used in the following circumstances.

(i) During the time period necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations for which the employer establishes that engineering and work practice controls are not feasible such as maintenance and repair activities, vessel cleaning, or operations where engineering and work practice controls are infeasible because exposures are intermittent in nature and limited in duration;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the PEL; and

(iv) In work situations where the employer can document that benzene is present in a workarea less than 30 days a year.

(v) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required or allowed under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator as specified in Table 1, and shall assure that the employee uses the respirator provided.

(ii) The employer shall select respirators from among those jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part 11. Negative pressure respirators shall have cartridges or canisters approved by MSHA/NIOSH for organic vapors.

(iii) Any employee who cannot wear a negative pressure respirator shall be given the option of wearing a positive pressure respirator such as a powered air-purifying respirator.

(3) *Respirator program.* The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e) and (f).

(4) *Respirator use.* (i) Where air-purifying respirators (cartridge or canister) are used, the employer shall replace the air purifying element at the beginning of each shift in which they will be used. The employer shall assure that each cartridge is dated at the beginning of use.

(ii) Employees who wear respirators shall be allowed to leave the regulated area to readjust the facepiece or to wash their face and to wipe clean the facepiece on their respirator in order to

minimize potential skin irritation associated with respirator use.

(5) *Respirator fit testing.* (i) The employer shall perform and record the results of either quantitative or qualitative fit tests at the time of initial fitting and at least annually thereafter for each employee wearing a negative pressure respirator. The test shall be used to select a respirator facepiece which exhibits minimum leakage and provides the required protection as prescribed in Table 1.

TABLE 1. RESPIRATORY PROTECTION FOR BENZENE

Airborne concentration of benzene or condition of use	Respirator type
(a) Less than or equal to 10 ppm.	(1) Half-mask chemical cartridge respirator with organic vapor cartridge.
(b) Less than or equal to 50 ppm.	(1) Full facepiece respirator with organic vapor cartridges. (2) Gas mask with chin style canister.
(c) Less than or equal to 100 ppm.	(1) Full facepiece powered air purifying respirator with organic vapor canister.[1]
(d) Less than or equal to 1,000 ppm.	(1) Supplied air respirator with full facepiece in positive pressure mode.
(e) Greater than 1,000 ppm or unknown concentration.	(1) Self-contained breathing apparatus with full facepiece in positive pressure mode. (2) Full facepiece positive-pressure supplied-air respirator with auxiliary self-contained air supply.
(f) Escape	(1) Any organic vapor gas mask; or (2) Any self-contained breathing apparatus with full facepiece.
(g) Firefighting	(1) Full facepiece self-contained breathing apparatus in positive pressure mode.

[1] Canisters must have a minimum service life of four (4) hours when tested at 150 ppm benzene, at 64 LPM, 25°C, and 85% relative humidity for non-powered air purifying respirators. The flow rate shall be 115 LPM and 170 LPM respectively for tight fitting and loose fitting powered air-purifying respirators.

(ii) The employer shall follow the test protocols outlined in Appendix E of this standard for whichever type of fit testing the employer chooses.

(h) *Potective clothing and equipment.* Personal protective clothing and equipment shall be worn where appropriate to prevent eye contact and limit dermal exposure to liquid benzene. Protective clothing and equipment shall be provided by the employer at no cost to the employee and the employer shall assure its use where appropriate. Eye and face protection shall meet the requirements of 29 CFR 1910.133.

(i) *Medical surveillance.*—(1) *General.* (i) The employer shall make available a medical surveillance program for employees who are or may be exposed to benzene at or above the action level 30 or more days per year, for employees who are or may be exposed to benzene at or above the PEL 10 or more days per year, for employees who have been exposed to more than 10 ppm of benzene for 30 or more days in a year prior to the effective date of the standard when employed by their current employer, and for employees who have been exposed to an emergency situation.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and provided without cost to the employee.

(2) *Initial examinations.* (i) Within 60 days of the effective date of this standard, or before the time of initial assignment, the employer shall provide each employee covered by paragraph (i)(1)(i) with a medical examination including the following elements:

(A) A detailed occupational history which includes: (*1*) Past work exposure to benzene or any other hematologic toxins, (*2*) a family history of blood dyscrasias including hematological neoplasms; (*3*) a history of blood dyscrasias including genetically related hemoglobin alterations, bleeding abnormalities, abnormal function of formed blood elements; (*4*) a history of renal or liver dysfunction; (*5*) a history of drugs alcohol and tobacco routinely taken; (*6*) a history of previous exposure to ionizing radiation and (*7*) exposure to marrow toxins outside of the current work situation.

(B) A complete physical examination.

(C) Laboratory tests, including a complete blood count with erythrocyte count, a leukocyte count with differential, a quantitative thrombocyte count, hematocrit, hemoglobin and erythrocyte indices (MCV, MCH, MCHC).

(D) Additional tests as necessary, in the opinion of the examining physician, based on alterations to the components of the blood which may be related to benzene exposure; and

(E) For all workers required to wear respirators for at least 30 days a year, the physical examination shall pay special attention to the cardiopulmonary system and shall include a pulmonary function test and a chest X-ray.

(ii) No initial medical examination is required to satisfy the requirements of paragraph (i)(2)(i) of this section if adequate records show that the employee has been examined in accordance with the procedures of paragraph (i)(2)(i) of this section within the previous six months prior to the effective date of this standard.

(3) *Periodic examinations.* (i) The employer shall provide each employee covered under paragraph (i)(1)(i) of this section with a medical examination at least semi-annually following the initial examination. These periodic examinations shall include at least the following elements:

(A) A brief history regarding any new exposure to potential marrow toxins, changes in drug and alcohol intake, and the appearance of physical signs relating to blood disorders;

(B) A complete blood count with erythrocyte count, a leukocyte count with differential, quantitative thrombocyte count, hemoglobin, hematocrit and erythrocyte indices (MCV, MCH, MCHC); and

(C) Appropriate additional tests as necessary in the opinion of the examining physician in consequence of alterations in the components of the blood or other signs which may be related to benzene exposure.

(ii) Where the employee develops signs and symptoms commonly associated with toxic exposure to benzene, the employer shall provide the employee with an additional medical examination which shall include those elements considered appropriate by the examining physician.

(iii) For persons required to use respirators for at least 30 days a year, a pulmonary function test shall be performed every three (3) years and a chest x-ray every five (5) years; if an X-ray has been taken within the preceding five (5) years it should be examined and need not be repeated. A specific evaluation of the cardiovascular system shall be made at the time of the pulmonary function test.

(4) *Emergency examinations.* (i) If the employee is exposed to benzene in an emergency situation, the employer shall have the employee provide a urinary sample at the end of the employee's shift and have a urinary phenol test performed on it within 72 hours. The urine specific gravity shall be corrected to 1.024.

(ii) If the result of the urinary phenol test is below 75 mg phenol/L of urine, no further testing is required.

(iii) If the result of the urinary phenol test is equal to or greater than 75 mg phenol/L of urine, the employer shall provide the employee with a complete blood count including an erythrocyte count, leukocyte count with differential and thrombocyte count at three (3) months following the emergency exposure.

(iv) If any of the conditions specified in paragraph (1)(5)(i) exists, then the further requirements of paragraph (i)(5) shall be met.

(5) *Additional examinations and referrals.* (i) Where results of the complete blood count required for the initial and periodic examinations indicate the following abnormal

conditions exist, then the blood count shall be repeated within 2 weeks. If the abnormality persists, the examining physician shall refer the employee to a hematologist or an internist for further evaluation unless the physician has good reason to believe such referral is unnecessary.

(A) The hemoglobin level is below 14 grams percent for males or below 12 grams percent for females and the hematocrit is less than 38 for males or less than 35 for females, and/or these indices show a persistent downward trend from the individual's pre-exposure norms; and these findings can not be explained for other medical reasons.

(B) The thrombocyte (platelet) count varies more than 15 percent below the employee's most recent values or falls below 140×10^3 platelets per mm^3.

(C) The leukocyte count is below 4,000 per mm^3, or there is an abnormal differential count.

(ii) In addition to the information required to be provided to the physician under paragraph (i)(6) of this section, the employer shall provide the hematologist or internist with the medical record required to be maintained by paragraph (k)(2) (ii) of this section.

(iii) The hematologist's or internist's evaluation shall include a determination as to the need for additional tests, and the employer shall assure that these tests are provided.

(6) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this regulation and its appendices.

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's actual or representative exposure level;

(iv) A description of any personal protective equipment used or to be used; and

(v) Information from previous employment related medical examinations of the affected employee which is not otherwise available to the examining physician.

(7) *Physician's written opinions.* (i) For each examination under this section, the employer shall obtain and provide the employee with a copy of the examining physician's written opinion within 15 days of its receipt. The written opinion shall include the following:

(A) The occupationally pertinent results of the medical examination and tests;

(B) The physician's opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to benzene;

(C) The physician's recommended limitations upon the employee's exposure to benzene or upon the employee's use of protective clothing or equipment and respirators.

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions resulting from benzene exposure which require further explanation or treatment.

(ii) The written opinion obtained by the employer shall not reveal specific findings or diagnoses unrelated to occupational exposures.

(8) *Medical removal plan.* (i) When a physician makes a referral to a hematologist/internist as required under paragraph (i)(5), the worker shall be temporarily removed from further exposure to benzene at the workplace.

(ii) Following the examination and evaluation by the hematologist/internist, a decision to remove an employee from areas of benzene exposure or to allow the employee to return to areas of benzene exposure shall be made by the physician after consultation with the hematologist/internist. This decision shall be communicated in writing to the employer and employee and shall state the required probable duration of removal from exposure to benzene in the workplace and requirements for future medical examinations to review the decision.

(j) *Communication of benzene hazards to employees.*

(1) *Signs and labels.* (i) The employer shall post signs in regulated areas which bear the following legend:

DANGER

BENZENE

CANCER HAZARD

FLAMMABLE—NO SMOKING

AUTHORIZED PERSONNEL ONLY

RESPIRATOR REQUIRED

(ii) The employer shall ensure that labels or other appropriate forms of warning are provided for containers of benzene within the workplace. There is no requirement to label pipes. The labels shall comply with the requirements of 29 CFR 1910.1200(f) and shall include the following legend:

CAUTION

CONTAINS BENZENE

CANCER HAZARD

(2) *Material safety data sheets.* (i) Employers shall obtain or develop, and shall provide access to their employees, to a material safety data sheet (MSDS) for benzene.

(ii) Employers who are manufacturers or importers shall:

(A) Comply with paragraph (a) of this section, and

(B) Comply with the requirement in OSHA's Hazard Communication Standard, 29 CFR 1910.1200, that they deliver to downstream employers in SIC codes 20–39 an MSDS for benzene.

(3) *Information and training.* (i) The employer shall provide employees with information and training on benzene at the time of initial assignment and at least annually thereafter.

(ii) The training program shall be in accordance with the requirements of 29 CFR 1910.1200(h) (1) and (2), and shall include specific information on benzene for each category of information included in that section.

(iii) In addition to the information required under 29 CFR 1910.1200, the employer shall:

(A) Provide employees with an explanation of the contents of this section, including appendices A and B, and indicate to them where the standard is available and,

(B) Describe the medical surveillance program required under paragraph (i) of this section, and explain the information contained in Appendix C.

(k) *Recordkeeping.*—(1) *Exposure measurements.* (i) The employer shall establish and maintain an accurate record of all measurements required by paragraph (e) of this section, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the procedure used to determine representative employee exposures;

(B) A description of the sampling and analytical methods used;

(C) A description of the type of respiratory protective devices worn, if any; and

(D) The name, social security number, job classification and exposure levels of the employee monitored and all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 30 years, in accordance with 29 CFR 1910.20.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (i) of this section, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name, social security number and description of the duties of the employee;

(B) The employer's copy of the physician's written opinion on the initial, periodic and special examinations, including results of medical examination and all tests, opinions and recommendations;

(C) Any employee medical complaints related to exposure to benzene;

(D) A copy of this standard and its appendices, except that the employer may keep one copy of the standard and its appendices for all employees provided the employer references the standard and its appendices in the medical surveillance record of each employee;

(E) A copy of the information provided to the physician as required by paragraphs (i)(6)(ii) through (i)(6)(v) of this section; and

(F) A copy of the employee's medical and work history related to exposure to benzene or any other hematologic toxins.

(iii) The employer shall maintain this record for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.20.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure monitoring records required by this paragraph shall be provided upon request for examination and copying to employees, employee representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a)–(e) and (g)–(i).

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying, to the subject employee, to anyone having the specific written consent of the subject employee, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(4) *Transfer of records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1019.20(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least 90 days prior to disposal, and transmit them to the Director if requested by the Director within that period.

(l) *Observation of monitoring.*—(1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe the measuring or monitoring of employee exposure to benzene conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) When observation of the measuring or monitoring of employee exposure to benzene requires entry into areas where the use of protective clothing and equipment or respirators is required, the employer shall provide the observer with personal protective clothing and equipment or respirators required to be worn by employees working in the area, assure the use of such clothing and equipment or respirators, and require the observer to comply with all other applicable safety and health procedures.

(m) *Dates.*—(1) *Effective date.* The standard shall become effective (90 days after the date of publication of the final rule in the **Federal Register**).

(2) *Start-up dates.* (i) The requirements of paragraph (a) through (m) of this section, except the engineering control requirements of paragraph (f)(1) shall be completed within sixty (60) days after the effective date of the standard.

(ii) Engineering and work practice controls required by paragraph (f)(1) of this section shall be implemented no later than (2 years after the effective date of the standard).

(n) *Appendices.* The information contained in Appendices A, B, C, and D is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligations. The protocals on respiratory fit testing in Appendix E are mandatory.

Appendix A—Substance Safety Data Sheet, Benzene

I. Substance Identification

A. Substance: Benzene.

B. Permissible Exposure: Except as to the use as fuels of gasoline, motor fuels and other fuels subsequent to discharge from bulk terminals.

1. Airborne: 1 part of benzene vapor per million parts of air (1 ppm), time-weighted average (TWA) for an 8-hour workday.

2. Dermal: Eye contact and skin contact with liquid benzene shall be limited.

C. Appearance and odor: Benzene is a clear, colorless liquid with a pleasant, sweet odor. The odor of benzene does not provide adequate warning of its hazards.

II Health Hazard Data

A. Ways in which benzene affects your health. Benzene can affect your health if you inhale it, or if it comes in contact with your skin or eyes. Benzene is also harmful if you happen to swallow it.

B. Effects of overexposure. 1. Short-term (acute) overexposure: If you are overexposed to high concentrations of benzene, well above the levels where its odor is first recognizable, you may feel breathless, irritable, euphoric, or giddy; you may experience irritation in eyes, nose, and respiratory tract. You may develop a headache, feel dizzy, nauseated, or intoxicated. Severe exposures may lead to convulsions and loss of consciousness.

2. Long-term (chronic) exposure. Repeated or prolonged exposure to benzene, even at relatively low concentrations, may result in various blood disorders, ranging from anemia to leukemia, an irreversible, fatal disease. Many blood disorders associated with benzene exposure may occur without symptoms.

III. Protective Clothing and Equipment

A. Respirators. Respirators are required for those operations in which engineering controls or work practice controls are not feasible to reduce exposure to the permissible level. However, where employers can document that benzene is present in the workplace less than 30 days a year, respirators may be used in lieu of engineering controls. If respirators are worn, they must have joint Mine Safety and Health Administration and the National Institute for Occupational Safety and Health (NIOSH) seal of approval, and cartridge or canisters must be replaced before the end of their service life, or the end of the shift, whichever occurs first. If you experience difficulty breathing while wearing a respirator, you may request a positive pressure respirator from your employer. You must be thoroughly trained to use the assigned respirator, and the training will be provided by your employer.

B. Protective Clothing. You must wear appropriate protective clothing (such as boots, gloves, sleeves, aprons, etc.) over any parts of your body that could be exposed to liquid benzene.

C. Eye and Face Protection. You must wear splash proof safety goggles if it is possible that benzene may get into your eyes. In addition, you must wear a face shield if your face could be splashed with benzene liquid.

IV. Emergency and First Aid Procedures

A. Eye and face exposure. If benzene is splashed in your eyes, wash it out immediately with large amounts of water. If irritation persists or vision appears to be affected see a doctor as soon as possible.

B. Skin exposure. If benzene is spilled on your clothing or skin, remove the contaminated clothing and wash the exposed skin with large amounts of water and soap immediately. Wash contaminated clothing before you wear it again.

C. Breathing. If you or any other person breathes in large amounts of benzene, get the exposed person to fresh air at once. Apply artificial respiration if breathing has stopped. Call for medical assistance or a doctor as soon as possible. Never enter any vessel or confined space where the benzene concentration might be high without proper safety equipment and at least one other person present who will stay outside. A life line should be used.

D. Swallowing. If benzene has been swallowed and the patient is conscious, do not induce vomiting. Call for medical assistance or a doctor immediately.

V. Medical Requirements

If you are exposed to benzene at a concentration at or above 0.5 ppm as an 8-hour time-weighted average, your employer is required to provide a medical examination and history and laboratory tests within 60 days of the effective date of this standard and semiannually thereafter. These tests shall be provided without cost to you. In addition, if you are accidentally exposed to benzene (either by ingestion, inhalation, or skin/eye contact) under conditions known or suspected to constitute toxic exposure to benzene, your employer is required to make special tests available to you.

VI. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to benzene and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear the protective clothing and equipment.

VII. Access to Records

You or your representative are entitled to see the records of measurements of your exposure to benzene upon written request to your employer. Your medical examination records can be furnished to your physician or designated representative upon request by you to your employer.

VIII. Precautions for Safe Use, Handling and Storage

Benzene liquid is highly flammable. It should be stored in tightly closed containers in a cool, well ventilated area. Benzene vapor may form explosive mixtures in air. All sources of ignition must be controlled. Use nonsparking tools when opening or closing benzene containers. Fire extinguishers, where provided, must be readily available. Know where they are located and how to operate them. Smoking is prohibited in areas where benzene is used or stored. Ask your supervisor where benzene is used in your work area and for additional plant safety rules.

Appendix B—Substance Technical Guidelines, Benzene

I. Physical and Chemical Data

A. Substance Identification

1. Synonyms: Benzol, benzole, coal naphtha, cyclohexatriene, phene, phenyl hydride, pyrobenzol. (Benzin, petroleum benzin and Benzine do not contain benzene).

2. Formula: C_6H_6 (CAS Registry Number: 71–43–2).

B. Physical data.

1. Boiling Point (760 mm Hg): 80.1 °C (176 °F)

2. Specific Gravity (water=1): 0.879

3. Vapor Density (air=1): 2.7

4. Melting Point: 5.5 °C (42 °F)

5. Vapor Pressure at 20 °C (68 °F): 75 mm Hg

6. Solubility in Water: .06%

7. Evaporation Rate (ether=1): 2.8

8. Appearance and Odor: Clear, colorless liquid with a distinctive sweet odor.

II. Fire, Explosion, and Reactivity Hazard Data

A. Fire

1. Flash Point (closed cup): −11 °C (12 °F)

2. Autoignition Temperature: 580 °C (1076 °F)

3. Flammable limits in Air, % by Volume: Lower: 1.3%, Upper: 7.5%

4. Extinguishing Media: Carbon dioxide, dry chemical, or foam.

5. Special Fire-Fighting procedures: Do not use solid stream of water, since stream will scatter and spread fire. Fine water spray can be used to keep fire exposed container cool.

6. Unusual fire and explosion hazards: Benzene is a flammable liquid. Its vapors can form explosive mixtures. All ignition sources must be controlled when benzene is used, handled, or stored. Where liquid or vapor may be released, such areas shall be considered as hazardous locations. Benzene vapors are heavier than air; thus the vapors may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which benzene is handled.

7. Benzene is classified as a 1 B flammable liquid for the purpose of conforming to the requirements of 29 CFR 1910.106. A concentration exceeding 3250 ppm is considered a potential fire explosion hazard. Locations where benzene may be present in quantities sufficient to produce explosive or ignitable mixtures are considered Class I Group D for the purposes of conforming to the requirements of 29 CFR 1910.309.

B. Reactivity

1. Conditions contributing to instability: Heat.

2. Incompatibility: Heat and oxidizing materials.

3. Hazardous decomposition products: Toxic gases and vapors (such as carbon monoxide).

III. Spill and Leak Procedures

A. Steps to be taken if the material is released or spilled. As much benzene as possible should be absorbed with suitable materials, such as dry sand or earth. That remaining must be flushed with large amounts of water. Do not flush benzene into a confined space, such as a sewer, because of explosion danger. Remove all ignition sources. Ventilate enclosed places.

B. Waste disposal method. Disposal methods must conform to other jurisdictional regulations. If allowed, benzene may be disposed of: (a) By absorbing it in dry sand or earth and disposing in a sanitary landfill; (b) if small quantities, by removing it to a safe location from buildings or other combustible sources, pouring it in dry sand or earth and cautiously igniting it, (c) if large quantities, by atomizing it in a suitable combustion chamber.

IV. Miscellaneous Precautions

A. High exposure to benzene can occur when transferring the liquid from one container to another. Such operations should be well ventilated and good work practices must be established to avoid spills.

B. Use non-sparking tools to open benzene containers which are effectively grounded and bonded prior to opening and pouring.

C. Employers must advise employees of all plant areas and operations where exposure to benzene could occur. Common operations in which high exposures to benzene may be encountered are: the primary production and utilization of benzene, and transfer of benzene.

Appendix C—Medical Surveillance Guidelines for Benzene

I. Route of Entry

Inhalation; skin absorption.

II. Toxicology

Benzene is primarily an inhalation hazard. Systemic absorption may cause depression of the hematopoietic system and leukemia. Inhalation of high concentrations can affect central nervous system function. Aspiration of small amounts of liquid benzene immediately causes pulmonary edema and hemorrhage of pulmonary tissue. There is some absorption through the skin. Absorption may be more rapid in the case of abraded skin, and benzene may be more readily absorbed if it is present in a mixture or as a contaminant in solvents which are readily absorbed. The defatting action of benzene may produce primary irritation due to repeated or prolonged contact with the skin. High concentrations are irritating to the eyes and the mucous membranes of the nose, and respiratory tract.

III. Signs and Symptoms

There is some benzene absoption through the skin. Direct contact may cause erythema. Repeated or prolonged contact may result in drying, scaling dermatitis, or result in development of secondary skin infections. Local effects of benzene vapor or liquid on the eye are slight. Only at very high concentrations is there any smarting sensation in the eye. Inhalation of high concentrations of benzene may have an initial stimulatory effect on the central nervous system characterized by exhilaration, nervous excitation, and/or giddiness, followed by a period of depression, drowsiness, or fatigue. There may be a sensation of tightness in the chest accompanied by breathlessness and ultimately the victim may lose consciousness. Convulsions and tremors occur frequently, and death may follow from respiratory paralysis or circulatory collapse in a few minutes to several hours following severe exposures.

The detrimental effect on the blood-forming system of prolonged exposure to small quantities of benzene vapor is of extreme importance. The hematopoietic system is the chief target for benzene's toxic effects which are manifested by alterations in the levels of formed elements in the peripheral blood. These effects have been noted to occur at concentrations of benzene which may not cause irritation of mucous membranes, or any unpleasant sensory effects. Early signs and symptoms of benzene morbidity are varied

and often not readily noticed. Such symptoms may also be due to causes other than benzene exposure. Subjective complaints of headache, dizziness, and loss of appetite may precede or follow clinical signs. Bleeding from the nose, gums, or mucous membranes and the development of purpuric spots (small bruises) may occur as the condition progresses. Rapid pulse and low blood pressure in addition to a physical appearance of anemia may accompany a subjective complaint of shortness of breath and excessive tiredness. Clinical evidence of leukopenia, anemia, and thrombocytopenia, singly or in combination, has been frequently reported among the first signs.

Bone marrow may appear normal, aplastic, or hyperplastic and may not in all situations correlate with peripheral blood forming tissues. There are great variations in the susceptibility to benzene morbidity, which prevents the identification of a "typical" blood picture. The onset of effects of prolonged benzene exposure may be delayed for many months or years after the actual exposure has ceased.

IV. Treatment of Acute Toxic Effects

Remove from exposure immediately but do not risk being overcome by fumes yourself. Give oxygen or artificial resuscitation if indicated. Flush eyes and wash skin if contaminated. Symptoms of intoxication may persist following severe exposures. Recovery from mild exposures is usually rapid and complete.

V. Surveilance and Preventive Considerations

A. General

principal effects of benzene exposure forming the basis for this regulation are alterations of the hematopoietic system as reflected by changes in the peripheral blood and leukemia. Consequently, the medical surveillance program is designed to observe on a regular basis, blood indices for early signs of these effects.

Tests must be performed frequently enough to discover individuals who may be unusually sensitive and likely to develop marrow abnormalities, to monitor those who experience accidental overexposure and to provide early detection of delayed evidence of toxicity.

All workers who are or will be exposed to 0.5 parts per million (ppm) or greater benzene as an eight-hour time-weighted average are to be given the opportunity for a medical examination. Initial examinations are to be provided within 30 days of the effective date of this standard or at the time of initial assignment and periodic examinations semiannually thereafter. There are special provisions for medical tests in the event of hematologic abnormalities or for emergency situations.

B. Hematology Guidelines

The following information excerpted from the analysis of Dr. James H. Jandl, Chief of Hematology, Harvard School of Medicine, may be useful to physicians in conducting the medical surveillance program.

A minimum battery of tests is to be performed by strictly standardized methods in the circumstances described above.

1. Red cell, white cell, and platelet counts must be performed using an automated (Coulter) counter. The normal range for the red cell count is approximately 4.4 to 6.0 million cell/mm^3, the values for women being about 0.4 million cells lower than for men. A decline from a normal to a subnormal value, or a rise to a supra-normal value, are indicative of potential toxicity, particularly should there be a decline. The normal total white blood count is approximately 6,200 plus or minus 2,000mm^3. For cigarette smokers the white count will be higher, the upper range of "normal" being approximately 1,000 cells higher than 8,200. Either a decline from normal to subnormal or a rise from normal to supra-normal should be regarded as a potential indication of benzene toxicity. The normal platelet count is 250,000 with a range of 140,000 to 400,000. Counts outside this range should be regarded as possible evidence of benzene toxicity.

If a reticulocyte count is performed using a cover-slip smear (see below), the preferred technique for this purpose is the so-called 'dry method' employing brilliant cresyl blue (BCB) for staining the filaments of reticulum within red cell, and counterstaining with Wright's stain. The extreme range of normal for reticulocytes is 0.4 to 1.5 percent of the red cells, the usual range being 0.5 to 1.2 percent of the red cells, but the typical value is in the range of 0.8 to 1.0 percent. There is an advantage of using the BCB reticulocyte staining technique (followed by counter-staining with Wright's stain) in that visible evidence (i.e., the stained, mounted reticulocyte smears) may be stored, and if kept filed in the dark may later be retrieved for reexamination and comparisons. A decline in reticulocytes to levels of less than 0.4 percent is to be regarded as possible evidence (unless another specific cause is found) of benzene toxicity requiring accelerated surveillance. An increase in reticulocyte levels to above 1.5 percent may also be consistent with (but is not as characteristic of) benzene toxicity.

2. The single most important routine surveillance test in an expert technician's careful examination of the peripheral blood smear. As with the reticulocyte count the smear should be with fresh uncoagulated blood obtained from a needle tip following venipuncture or from a drop of earlobe blood (capillary blood). If necessary, the smear may under certain limited conditions be made from a blood sample anticoagulated with EDTA (but never with oxalate or heparin). When the smear is to be prepared from a specimen of venous blood which has been collected by a commerical Vacutainer ® type tube containing neutral EDTA, the smear should be made as soon as possible after the venesection. A delay of up to 12 hours is permissible between the drawing of the blood specimen into EDTA and the preparation of the smear if the blood is stored at refrigerator (not freezing) temperature. As with the reticulocyte preparations, the smear should be made on cover slips only. Under no circumstances should peripheral blood (or bone marrow aspirate) intended for examination be smeared on microscope slides, a technique which produces artifacts in blood cells and distorts the white cell differential count by severely maldistributing them. Dry blood smear should be stained with Wright's stain which should be filtered at least weekly to remove precipitated dye (saturated completely by methylene blue-eosinate derivates).

3. The minimum mandatory observations to be made from the smear and a discussion of their significance now follows. The observations are:

a. The differential white blood cell count.

b. Description of abnormalities in the appearance of red cells.

c. Description of any abnormalities in the platelets.

d. A careful search must be made by the technician throughout the better areas of every blood smear for immature white cells such as band forms (in more than normal proportion), any number of metamyelocytes, myelocytes or myeloblasts. Any nucleate or multinucleated red blood cells should be reported. Very large "giant" platelets or fragments of megakaryocytes must be recoginzed. Should only a single one of these abnormalities be found, it should be reported.

An increase in the proportion of band forms among the neutrophilic granulocytes is an abnormality deserving special mention for it represents a very early change which should be considered as an early warning of benzene toxicity in the absence of other causative factors (most commonly infection). Likewise, the appearance of metamyelocytes in the absence of other probable cause is to be considered a possible indication of benzene-induced injury.

An upward trend in the number of basophils, which normally do not exceed about 2.0 percentof the total white cells, is to be regarded as possible evidence of benzene toxicity. A rise in the esoinophil count is less specific but also may be suspicious of toxicity if it rises above 6.0 percent of the total white count.

The normal range of monocytes is from 2.0 to 8.0 percent of the total white count with an average of about 5.0 percent. About 20 percent of individuals reported to have mild but persisting abnormalities caused by exposure to benzene show a persisting monocytosis which is sometimes striking. The findings of monocyte count which persists at more than 10 to 12 percent of the normal white cell count (when the total count is normal) or persistence of an absolute monocyte count in excess of 800/mm ^{3} should be regarded as a possible sign of benzene-induced injury.

A less frequent but more serious indication of benzene-induced injury to the bone marrow is the finding in the peripheral blood of the so-called "pseudo" (or acquired) Pelger-Huet anomaly. In this anomaly many, or sometimes the majority, of the neutrophilic granulocytes possess two round nuclear segements—less often one or three round segments—rather than three normally elongated segments. When this anomaly is not hereditary, it is often but not invariably

predictive of subsequent leukemia. However, only about two percent of patients who ultimately develop acute myelogenous leukemia show the acquired Pelger-Huet anomaly.

An uncommon, but ominous sign, one which cannot be detected from the smear, but can be suspected easily by a "sucrose water test" of peripheral blood, is transient paroxysmal nocturnal hemoglobinuria (PNH), which may first occur insidiously during a period of established aplastic anemia and may be followed within one to a few years by the appearance of rapidly fatal acute myelogenous leukemia. Clinical detection of PNH, which occurs in perhaps only one or two percent of those destined to have acute myelogenous leukemia, may be difficult; if the presumptive "sucrose water test" for it is positive, the technician may perform the somewhat more definitive Ham test, also known as the acid-serum hemolysis test.

e. Individuals documented to have developed acute myelogenous leukemia years after initial exposure to benzene, have (see above) progressed through the preliminary phase of hematologic abnormality. In many instances pancytopenia (i.e., a lowering in the counts of all circulating blood cells of bone marrow origin—but not to the extent implied by the term "aplastic anemia") preceded leukemia for many years. Seldom does relative scarcity of a single type blood cell (or of platelets) represent a harbinger of imminent acute leukemia. However, the finding of two or more cytopenias, or of pancytopenia, must be regarded as highly suspicious of more advanced although still reversible, benzene toxicity. When "pancytopenia" develops and becomes associated with the appearance of immature cells (myelocytes, myeloblasts, erythroblasts, etc.), with abnormal cells (pseudo Pelger-Huet anomaly, atypical nuclear heterochromatin, etc.), or with inappropriate elevations of monocytes, basophils, or eosinophils, the findings must be regarded as evidence of benzene overexposure unless proved otherwise. These and other aggregates of alterations are frequently termed "preleukemia," a term whose meaning is good when used retrospectively, but less appropriate when used prospectively, where it has only inferential value. Many severely aplastic patients manifested the ominous finding of 5–10 percent myeloblasts in the marrow, occasional myeloblasts and myelocytes in the blood and 20–30% monocytes; these represented the beginning of recovery rather than the early stage of overt AML. Thus, a considerable proportion of "preleukemias" in benzene poisoning fail to progress to leukemia. Indeed, some have been observed to revert to normal after withdrawal of the afflicted person from toxic exposure. Nonetheless, the chance that "preleukemic" (changes in general) will evolve to leukemia is considerable: at least 20 to 40 percent of persons (only a few of whom were benzene-exposed) with these blood changes develop acute myelogenous leukemia. It is evident (Section III. B.) that isolated cytopenias, pancytopenias and aplastic anemias induced by benzene are reversible and complete recovery occurs on cessation of exposure. However, it is advisable to take these abnormalities seriously. The employee must immediately be removed from any possible exposure to benzene vapor as he continues to be followed. Certain tests may substantiate the person's prospects for progression or regression. One such test would be an examination of the patient's bone marrow. But the decision to perform a bone marrow aspiration or needle biopsy is one that should be made by the hematologist. The findings to be sought there would be: hypoplasia or aplasia; an excess of immature forms; vacuolation in erythroblasts and myelocytes—a phenomenon induced by many toxins apart from benzene, including chloramphenicol and alcohol; and by infections.

The findings of basophilic stippling in circulating red blood cells (usually found in 1 to 5% of red cells during marrow injury), and detection in the bone marrow of what are termed "ringed sideroblasts" must be taken seriously, as they have been noted in recent years to be frequent premonitory signs of subsequent actual leukemia.

In several recent reports dealing with relatively few patients, peroxidase-staining of circulating or marrow neutrophil granulocytes, employing benzidine dihydrochloride, have revealed as a "preleukemic" finding the disappearance of, or diminution in, peroxidase in a sizable proportion of the granulocytes. Granulocyte granules are normally strongly peroxidase positive. A steady decline in leukocyte alkaline phosphatase is also suggestive of early acute leukemia. Exposure to benzene commonly causes an early rise in serum iron, often but not always associated with a fall in the reticulocyte count. Thus serial measurements of serum iron levels provide a means of determining whether or not there is a trend representing sustained suppression of erythropoiesis.

Measurement of serum iron, determination of peroxidase and of alkaline phosphatases activity in peripheral granulocytes can be performed by technical assistants.

Appendix D—Sampling and Analytical Methods for Benzene Monitoring and Measurement Procedures

Measurements taken for the purpose of determining employee exposure to benzene are best taken so that the representative average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Short-time interval samples (or grab samples) may also be used to determine average exposure level if a minimum of five measurements are taken in a random manner over the 8-hour work shift. Random sampling means that any portion of the work shift has the same chance of being sampled as any other. The arithmetic average of all such random samples taken on one work shift is an estimate of an employee's average level of exposure for that work shift. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee). Sampling must be performed by gas adsorption tubes or alternative methods meeting the requirements of the standard, with subsequent chemical analysis by gas chromatography.

There are a number of methods available for monitoring employee exposures to benzene. The sampling and analysis may be performed by collection of the benzene vapor on charcoal adsorption tubes, with subsequent chemical analysis by gas chromatography. Methods meeting the prescribed accuracy and precision requirements are available in the "NIOSH Manual of Analytical Methods." One specific method meeting the prescribed precision and accuracy requirements is NIOSH Method Number S311 which is presented below. Sampling and analysis may also be performed by portable direct reading instruments, real-time continuous monitoring systems, passive dosimeters or other suitable methods. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must have an accuracy, to a 95 percent confidence level, of not less than plus or minus 25 percent for concentrations of benzene greater than or equal to 0.5 ppm.

The following two analytical procedures are presently performed at the OSHA Salt Lake City Analytical Laboratory:

I. OSHA Laboratory Evaluation of NIOSH Method S-311 at Lower Levels

Analyte: Benzene
Matrix: Air
Procedure: Adsorption on charcoal, desorption with carbon disulfide, analysis by GC.

1. Principle of the Method (Reference 1).

1.1. A known volume of air is drawn through a charcoal tube to trap the organic vapors present.

1.2. The charcoal in the tube is transferred to a small, stoppered vial, and the analyte is desorbed with carbon disulfide.

1.3. An aliquot of the desorbed sample is injected into a gas chromatograph.

1.4. The area of the resulting peak is determined and compared with areas obtained from standards.

2. Advantages and disadvantages of the method.

2.1. The sampling device is small, portable, and involves no liquids. Interferences are minimal, and most of those which do occur can be eliminated by altering chromatographic conditions. The samples are analyzed by means of a quick, instrumental method.

2.2. The amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the charcoal tube exceeds 25 percent of that found on the front section, the possibility of sample loss exists.

3. Apparatus

3.1. A calibrated personal sampling pump whose flow can be determined with ±5 percent at the recommend flow rate.

3.2. Charcoal tubes: Glass with both ends flame sealed, 7 cm long with a 6-mm O.D. and a 4-mm I.D., containing 2 sections of 20/40 mesh activated charcoal separating a 2-mm portion of urethane foam. The activated charcoal is prepared from coconut shells and is fired at 600 °C prior to packing. The

adsorbing section contains 100 mg of charcoal, the back-up section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the back-up section. A plug of silanized glass wool is placed in front of the adsorbing section. The pressure drop across the tube must be less than one inch of mercury at a flow rate of 1 liter per minute.

3.3. Gas Chromatograph equipped with a flame ionization detector.

3.4. Column (10-ft × 1/8-in stainless steel) packed with 80/100 Supelcoport coated with 20 percent SP 2100, 0.1 percent CW 1500.

3.5. An electronic integrator or some other suitable method for measuring peak area.

3.6. Two-milliliter sample vials with Teflon-lined caps.

3.7. Microliter syringes: 10-microliter, and other convenient sizes for making standards.

3.8. Pipets: 1.0 mL delivery pipets.

3.9. Volumetric flasks: convenient sizes for making standard solutions.

4. Reagents.

4.1. Chromatographic quality carbon disulfide.

4.2. Benzene, reagent grade.

4.3. An internal standard, such as p-cymene, reagent grade.

4.4. Filtered compressed air.

4.5. Purified hydrogen.

4.6. Purified helium.

5. Procedure.

5.1. Cleaning of equipment. All glassware used for the laboratory analysis should be properly cleaned and free of organics which could interfere in the analysis.

5.2. Calibration of personal pumps. Each pump must be calibrated with a representative charcoal tube in the line.

5.3. Collection and shipping of samples.

5.3.1. Immediately before sampling, break the ends of the tube to provide an opening at least one-half the internal diameter of the tube (2 mm).

5.3.2. The smaller section of the charcoal is used as the backup and should be placed nearest the sampling pump.

5.3.3. The charcoal should be placed in a vertical position during sampling to minimize channeling through the charcoal.

5.3.4. Air being sampled should not be passed through any hose or tubing before entering the charcoal tube.

5.3.5. A sample size of 10 liters is recommended. Sample at a flow rate of approximately 0.05 liters per minute. The flow rate should be known with an accuracy of at least ±5 percent.

5.3.6. The temperature and pressure of the atmosphere being sampled should be recorded.

5.3.7. The charcoal tubes should be capped with the supplied plastic caps immediately after sampling. Plastic caps should be used.

5.3.8. Submit at least one blank tube (a charcoal tube subjected to the same handling procedures, without having any air drawn through it) with each set of samples.

5.3.9. Take necessary shipping and packing precautions to minimize breakage of samples.

5.4. Analysis of samples.

5.4.1. Preparation of samples. In preparation for analysis, each charcoal tube is scored with a file in front of the first section of charcoal and broken open. The glass wool is removed and discarded. The charcoal in the first (larger) section is transferred to a 2-ml vial. The separating section of foam is removed and discarded; the second section is transferred to another capped vial. These two sections are analyzed separately.

5.4.2. Desorption of samples. Prior to analysis, 1.0 mL of desorbing solution is pipetted into each sample container. The desorption solution consists of 0.05 μL internal standard per mL of carbon disulfide. The sample vials are recapped as soon as the solvent is added. Desorption should be done for 30 minutes with occasional shaking.

5.4.3. GC conditions. Typical operating conditions for the gas chromatograph are:

1. 30 mL/min (60 psig) helium carrier gas flow.

2. 30 mL/min (40 psig) hydrogen gas flow to detector.

3. 240 mL/min (40 psig) air flow to detector.

4. 150 °C injector temperature.

5. 250 °C detector temperature.

6. 100 °C Column temperature.

5.4.4. Injection. Solvent flush technique or equivalent.

5.4.5. Measurement of area. The Peak areas are measured by an electronic integrator or some other suitable form of area measurement.

5.4.6. An internal standard procedure is used. The integrator is calibrated to report results in ppm for a 10 liter air sample after correction for desorption efficiency.

5.5. Determination of desorption efficiency.

5.5.1. Importance of determination. The desorption efficiency of a particular compound can vary from one laboratory to another. Thus, it is necessary to determine, at least once, the percentage of the specific compound that is removed in the desorption process, provided the same batch of charcoal is used.

5.5.2. Procedure for determining desorption efficiency. The reference portion of the charcoal tube is removed. To the remaining portion, amounts representing 0.5X, 1X, and 2X and (X represents target concentration) based on a 10 L air sample are injected into several tubes at each level. Dilutions of benzene with carbon tetrachloride are made to allow injection of measurable quantitites. These tubes are then allowed to equilibrate at least overnight. Following equilibration they are analyzed following the same procedure as the samples. Desorption efficiency is determined by dividing the amount of benzene found by amount spiked on the tube.

6. Calibration and standards.

A series of standards, varying in concentration over the range of interest, is prepared and analyzed under the same GC conditions and during the same time period as the unknown samples. Curves are prepared by plotting concentration versus peak area.

7. Calculations.

Since the integrator is programmed to report results in ppm for a 10 liter air sample (corrected for desorption efficiency), the following equation is used:ppm Benzene = (ppm on report)/10 (0.1. x air volume sample in liters).

8. Reference. NIOSH Method S-311.

II. OSHA Laboratory Method No. 12

Analyte: Benzene

Matrix: Bulk Samples

Procedure: Bulk samples are analyzed direct by liquid chromatography.

1. Principle of the method.

1.1. An aliquot of the bulk sample to be analyzed is injected into a liquid chromatograph.

1.2. The peak area for benzene is determined and compared to areas obtained from standards.

2. Advantages and disadvantages of the method.

2.1. The analytical procedure is quick, sensitive, and reproducible.

2.2. Reanalysis of samples is possible.

2.3. Interferences can be circumvented by proper selection of LC parameters.

2.4. Samples must be free of any particulates, etc., that may clog the capillary tubing in the liquid chromatograph. This may require distilling the sample or clarifying with a clarification kit.

3. Apparatus.

3.1. Liquid chromatograph equipped with a UV detector.

3.2. LC Column that will separate benzene from other components in the bulk sample being analyzed. The column used for validation studies was a Waters Bondapack C18, 30 cm c 3.9 mm.

3.3. A clarification kit to remove any particulates in the bulk if necessary.

3.4. A micro-distillation apparatus to distill any samples if necessary.

3.5. An electronic integrator or some other suitable method of measuring peak areas.

3.6. Microliter syringes—10—ul or other convenient sizes for preparing standards, and 10—ul for LC injections.

3.7. Volumetric flasks, 5 mL and other convenient sizes for preparing standards and making dilutions.

4. Reagents.

4.1. Benzene, reagent grade.

4.2. LC grade water, methyl alcohol, and isopropyl alcohol.

5. Collection and shipment of samples.

5.1. Samples should be transported in glass containers with Teflon-lined caps.

5.2. Samples should not be put in the same container used for air samples.

6. Analysis of samples.

6.1. Samples preparation.

If necessary, the samples are distilled or clarified. Samples are analyzed undiluted. If the benzene concentration is out of the working range, suitable dilutions are made with isopropyl alcohol.

6.2. LC conditions.

The typical operating conditions for the liquid chromatography are:

1. Mobile phase—Methyl alcohol/water, 50/50.

2. Analytical wavelength—254 nm.

3. Injection size—10 ul.

6.3. Measurement of peak area and calibration. Peak areas are measured by an integrated or other suitable means. The integrator is calibrated to report results in % benzene with isopropyl alcohol.

7. Calculations.

Since the integrator is programmed to report results in % benzene by volume in an

undiluted sample, the following equation is used:

% Benzene by Volume = AxB

Where:

A = % by volume on report
B = Dilution Factor
(B = 1 for undiluted sample)

Appendix E—Qualitative and Quantitative Fit Testing Procedures

Qualitative Fit Test Protocols

I. Isoamyl Acetate Protocol

A. Odor Threshold Screening

1. Three 1-liter glass jars with metal lids (e.g. Mason or Bell jars) are required.

2. Odor-free water (e.g. distilled or spring water) at approximately 25T1°C shall be used for the solutions.

3. The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1-liter jar and shaking for 30 seconds. This solution shall be prepared new at least weekly.

4. The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated but shall not be connected to the same recirculating ventilation system.

5. The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. Shake for 30 seconds and allow to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution may be used for only one day.

6. A test blank is prepared in a third jar by adding 500 cc of odor free water.

7. The odor test and test blank jars shall be labelled 1 and 2 for jar identification. If the labels are put on the lids they can be periodically peeled, dried off and switched to maintain the integrity of the test.

8. The following instructions shall be typed on a card and placed on the table in front of the two test jars (i.e. 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

9. The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

10. If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test may not be used.

11. If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

B. Respirator Selection

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers. The selection shall include at least five sizes of elastomeric half facepieces, from at least two manufacturers.

2. The selection process shall be conducted in a room separate from the fit-test chamber to prevent odor fatigue. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a "comfortable" respirator. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training or respirator use, as it is only a review.

3. The test subject should understand that the employee is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape and, if fit properly and used properly will provide adequate protection.

4. The test subject holds each facepiece up to the face and eliminates those which obviously do not give a comfortable fit. Normally, selection will begin with a half-mask and if a comfortable fit cannot be found, the subject will be asked to test the full facepiece respirators. (A small percentage of users will not be able to wear any half-mask.)

5. The more comfortable facepieces are noted; the most comfortable mask is donned and *worn at least five minutes* to assess comfort. All donning and adjustments of the facepiece shall be performed by the test subject without assistance from the test conductor or other person. Assistance in assessing comfort can be given by discussing the points in #6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator after donning:

- Positioning of mask on nose.
- Room for eye protection.
- Room to talk.
- Positioning mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

- Chin properly placed.
- Strap tension.
- Fit across nose bridge.
- Distance from nose to chin.
- Tendency to slip.
- Self-observation in mirror.

8. The test subject shall conduct the conventional negative or positive-pressure fit checks (e.g. see ANSI Z88.2–198OA7). Before conducting the negative- or positive-pressure test the subject shall be told to "seat" the mask by rapidly moving the head from side-to-side and up and down, while taking a few deep breaths.

9. The test subject is now ready for fit testing.

10. After passing the fit test, the test subject shall be questioned again regarding the comfort of the respirator. If it has become uncomfortable, another model of respirator shall be tried.

11. The employee shall be given the opportunity to select a different facepiece and be retested if the chosen facepiece becomes increasingly uncomfortable at any time.

C. Fit Test

1. The fit test chamber shall be similar to a clear 55 gal drum liner suspended inverted over a 2 foot diameter frame, so that the top of chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

2. Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

3. After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

4. A copy of the following test exercises and rainbow passage shall be taped to the inside of the test chamber:

Test Exercises

i. Breathe normally.

ii. Breathe deeply. Be certain breaths are *deep* and *regular*.

iii. Turn head all the way from one side to the other. Inhale on each side. Be certain movement is complete. Do not bump the respirator against the shoulders.

iv. Nod head up-and-down. Inhale when head is in the full up position (looking toward ceiling). Be certain motions are complete and made about every second. Do not bump the respirator on the chest.

v. Talking. Talk aloud and slowly for several minutes. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

vi. Jogging in place.

vii. Breathe normally.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

5. Each test subject shall wear the respirator for at least 10 minutes before starting the fit test.

6. Upon entering the test chamber, the test subject shall be given a 6 inch by 5 inch piece of paper towel or other porous absorbent single ply material, folded in half and wetted

with three-quarters of one cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

7. Allow two minutes for the IAA test concentration to be reached before starting the fit-test exercises. This would be an appropriate time to talk with the test subject, to explain the fit test, the importance of cooperation, the purpose for the head exercises, or to demonstrate some of the exercises.

8. Each exercise described in #4 above shall be performed for at least one minute.

9. If at any time during the test, the subject detects the banana-like odor of IAA, the test has failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

10. If the test is failed, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber, and again begin the procedure described in the c(4) through c(8) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

11. If a person cannot pass the fit test described above wearing a half-mask respirator from the available selection, full facepiece models must be used.

12. When a respirator is found that passes the test, the subject breaks the faceseal and takes a breath before exiting the chamber. This is to assure that the reason the test subject is not smelling the IAA is the good fit of the respirator facepiece seal and not olfactory fatigue.

13. When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the area from becoming contaminated, the used towels shall be kept in a self-sealing bag so there is no significant IAA concentration buildup in the test chamber during subsequent tests.

14. At least two facepieces shall be selected for the IAA test protocol. The test subject shall be given the opportunity to wear them for one week to choose the one which is more comfortable to wear.

15. Persons who have successfully passed this fit test with a half-mask respirator may be assigned the use of the test respirator in atmospheres with up to 10 times the PEL of airborne benzene. In atmospheres greater than 10 times, and less than 50 times the PEL (up to 50 ppm), the subject must pass the IAA test using a full face negative pressure respirator. (The concentration of the IAA inside the test chamber must be increased by five times for QLFT of the full facepiece.)

16. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface.

17. If hair growth or apparel interfere with a satisfactory fit, then they shall be altered or removed so as to eliminate interference and allow a satisfactory fit. If a satisfactory fit is still not attained, the test subject must use a positive-pressure respirator such as powered air-purifying respirators, supplied air respirator, or self-contained breathing apparatus.

18. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respirator diseases or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

19. Qualitative fit testing shall be repeated at least every six months.

20. In addition, because the sealing of the respirator may be affected, qualitative fit testing shall be repeated immediately when the test subject has a:

(1) Weight change of 20 pounds or more,

(2) Significant facial scarring in the area of the facepiece seal,

(3) Significant dental changes; i.e.: multiple extractions without prothesis, or acquiring dentures,

(4) Reconstructive or cosmetic surgery, or

(5) Any other condition that may interfere with facepiece sealing.

D. Recordkeeping

A summary of all test results shall be maintained by the employer for 3 years. The summary shall include:

(1) Name of test subject.

(2) Date of testing.

(3) Name of the test conductor.

(4) Respirators selected (indicate manufacturer, model, size and approval number).

(5) Testing agent.

II. Saccharin Solution Aerosol Protocol

A. Respirator Section

Respirators shall be selected as described in section IB (respirator selection) above, except that each respirator shall be equipped with a particulate filter.

B. Taste Threshold Screening

1. An enclosure about head and shoulders shall be used for threshold screening (to determine if the individual can taste saccharin) and for fit testing. The enclosure shall be approximately 12 inches in diameter by 14 inches tall with at least the front clear to allow free movement of the head when a respirator is worn.

2. The test enclosure shall have a three-quarter inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

3. The entire screening and testing procedure shall be explained to the test subject prior to conducting the screening test.

4. During the threshold screening test, the test subject shall don the test enclosure and breathe with open mouth with tongue extended.

5. Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. This nebulizer shall be clearly marked to distinquish it from the fit test solution nebulizer.

6. The threshold check solution consists of 0.83 grams of sodium saccharin, USP in water. It can be prepared by putting 1 cc of the test solution (see C 7 below) in 100 cc of water.

7. To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then is released and allowed to fully expand.

8. Ten squeezes of the nebulizer bulb are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

9. If the first response is negative, ten more squeezes of the nebulizer bulb are repeated rapidly and the test subject is again asked whether the saccharin can be tasted.

10. If the second response is negative ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin can be tasted.

11. The test conductor will take note of the number of squeezes required to elicit a taste response.

12. If the saccharin is not tasted after 30 squeezes (Step 10), the saccharin fit test cannot be performed on the test subject.

13. If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

14. Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

15. The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least every four hours.

C. Fit Test

1. The test subject shall don and adjust the respirator without the assistance from any person.

2. The fit test uses the same enclosure described in IIB above.

3. Each test subject shall wear the respirator for at least 10 minutes before starting the fit test.

4. The test subject shall don the enclosure while wearing the respirator selected in section IB above. This respirator shall be properly adjusted and equipped with a particulate filter.

5. The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

6. A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

7. The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

8. As before, the test subject shall breathe with mouth open and tongue extended.

9. The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same technique as for the taste threshold screening and the same number of squeezes required to elicit a taste response in the screening. (See B8 through B10 above).

10. After generation of the aerosol read the following instructions to the test subject. The test subject shall perform the exercises for one minute each.

i. Breathe normally.

ii. Breathe deeply. Be certain breaths are *deep* and *regular*.

iii. Turn head all the way from one side to the other. Be certain movement is complete. Inhale on each side. Do not bump the respirator against the shoulders.

iv. Nod head up-and-down. Be certain motions are complete. Inhale when head is in the full up position (when looking toward the

ceiling). Do not to bump the respirator on the chest.

v. Talking. Talk aloud and slowly. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

vi. Jogging in place.

vii. Breathe normally.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

11. At the beginning of each exercise, the aerosol concentration shall be replenished using one-half the number of squeezes as initially described in C9.

12. The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

13. If the saccharin is detected the fit is deemed unsatisfactory and a different respirator shall be tried.

14. At least two facepieces shall be selected by the saccharin test protocol. The test subject shall be given the opportunity to wear them for one week to choose the one which is more comfortable to wear.

15. Successful completion of the test protocol shall allow the use of the half mask tested respirator in contaminated atmospheres up to 10 times the PEL of benzene. In other words this protocol may be used to assign protection factors no higher than ten.

16. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface.

17. If hair growth or apparel interfere with a satisfactory fit, then they shall be altered or removed so as to eliminate interference and allow a satisfactory fit. If a satisfactory fit is still not attained, the test subject must use a positive-pressure respirator such as powered air-purifying respirators, supplied air respirator, or self-contained breathing apparatus.

18. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respirator diseases or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

19. Qualitiative fit testing shall be repeated at least every six months.

20. In addition, because the sealing of the respirator may be affected, qualitative fit testing shall be repeated immediately when the test subject has a:

(1) Weight change of 20 pounds or more,

(2) Significant facial scarring in the area of the facepiece seal,

(3) Significant dental changes; i.e.; multiple extractions without prothesis, or acquiring dentures,

(4) Reconstructive or cosmestic surgery, or

(5) Any other condition that may interfere with facepiece sealing.

D. Recordkeeping

A summary of all test results shall be maintained by the employer for 3 years. The summary shall include:

(1) Name of test subject.

(2) Date of testing.

(3) Name of test conductor.

(4) Respirators selected (indicate manufacturer, model, size and approval number).

(5) Testing agent.

III. Irritant Fume Protocol

A. Respirator Selection

Respirators shall be selected as described in section IB above, except that each respirator shall be equipped with a combination of high-efficiency and acid-gas cartridges.

B. Fit Test

1. The test subject shall be allowed to smell a weak concentration of the irritant smoke to familiarize the subject with the characteristic odor.

2. The test subject shall properly don the respirator selected as above, and wear it for at least 10 minutes before starting the fit test.

3. The test conductor shall review this protocol with the test subject before testing.

4. The test subject shall perform the conventional positive pressure and negative pressure fit checks (see ANSI Z88.2 1980). Failure of either check shall be cause to select an alternate respirator.

5. Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part #5645, or equivalent. Attach a short length of tubing to one end of the smoke tube. Attach the other end of the smoke tube to a low pressure air pump set to deliver 200 milliliters per minute.

6. Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep the eyes closed while the test is performed.

7. The test conductor shall direct the stream of irritant smoke from the tube towards the faceseal area of the test subject. The person conducting the test shall begin with the tube at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

8. The test subject shall be instructed to do the following exercises while the respirator is being challenged by the smoke. Each exercise shall be performed for one minute.

i. Breathe normally.

ii. Breathe deeply. Be certain breaths are *deep* and *regular*.

iii. Turn head all the way from one side to the other. Be certain movement is complete. Inhale on each side. Do not bump the respirator against the shoulders.

iv. Nod head up-and-down. Be certain motions are complete and made every second. Inhale when head is in the full up position (looking toward ceiling). Do not bump the respirator against the chest.

v. Talking. Talk aloud and slowly for several minutes. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two end apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

vi. Jogging in Place.

vii. Breathe normally.

9. The test subject shall indicate to the test conductor if the irritant smoke is detected. If smoke is detected, the test conductor shall stop the test. In this case, the tested respirator is rejected and another respirator shall be selected.

10. Each test subject passing the smoke test (i.e. without detecting the smoke) shall be given a sensitivity check of smoke from the same tube to determine if the test subject reacts to the smoke. Failure to evoke a response shall void the fit test.

11. Steps B4, B9, B10 of this fit test protocol shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agents.

12. At least two facepieces shall be selected by the irritant smoke test protocol. The test subject shall be given the opportunity to wear them for one week to choose the one which is more comfortable to wear.

13. Respirators sucessfully tested by the protocol may be used in contaminated atmospheres up to ten times the PEL of benzene.

14. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface.

15. If hair growth or apparel interfere with a satisfactory fit, then they shall be altered or removed so as to eliminate interference and allow a satisfactory fit. If a satisfactory fit is still not attained, the test subject must use a positive-pressure respirator such as powered air-purifying respirators, supplied air respirator, or self-contained breathing apparatus.

16. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respirator diseases or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

17. Qualitive fit testing shall be repeated at least every six months.

18. In addition, because the sealing of the respirator may be affected, qualitative fit testing shall be repeated immediately when the test subject has a:

(1) Weight change of 20 pounds or more,

(2) Significant facial scarring in the area of the facepiece seal,

(3) Significant dental changes; i.e.; multiple extractions without prothesis, or acquiring dentures,

(4) Reconstructive or cosmetic surgery, or

(5) Any other condition that may interfere with facepiece sealing.

D. Recordkeeping

A summary of all test results shall be maintained by the employer for 3 years. The summary shall include:

(1) Name of test subject.

(2) Date of testing.

(3) Name of test conductor.

(4) Respirators selected (indicate manufacturer, model, size and approval number).

(5) Testing agent.

Quantitative Fit Test Procedures

1. General

a. The method applies to the negative-pressure nonpowered air-purifying respirators only.

b. The employer shall assign one individual who shall assume the full responsibility for implementing the respirator quantitative fit test program.

2. Definition

a. "Quantitative Fit Test" means the measurement of the effectiveness of a respirator seal in excluding the ambient atmosphere. The test is performed by dividing the measured concentration of challenge agent in a test chamber by the measured concentration of the challenge agent inside the respirator facepiece when the normal air purifying element has been replaced by an essentially perfect purifying element.

b. "Challenge Agent" means the air contaminant introduced into a test chamber so that its concentration inside and outside the respirator may be compared.

c. "Test Subject" means the person wearing the respirator for quantitative fit testing.

d. "Normal Standing Position" means standing erect and straight with arms down along the sides and looking straight ahead.

e. "Fit Factor" means the ratio of challenge agent concentration outside with respect to the inside of a respirator inlet covering (facepiece or enclosure).

3. Apparatus

a. *Instrumentation.* Corn oil, sodium chloride or other appropriate aerosol generation, dilution, and measurement systems shall be used for quantitative fit test.

b. *Test chamber.* The test chamber shall be large enough to permit all test subjects to freely perform all required exercises without distributing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air yet uniform in concentration throughout the chamber.

c. When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particular filter supplied by the same manufacturer.

d. The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000.

e. The combination of substitute air-purifying elements (if any), challenge agent, and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of PEL to the challenge agent at any time during the testing process.

f. The sampling port on the test specimen respirator shall be placed and constructed so that there is no detectable leak around the port, a free air flow is allowed into the sampling line at all times and so there is no interference with the fit or performance of the respirator.

g. The test chamber and test set-up shall permit the person administering the test to observe one test subject inside the chamber during the test.

h. The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent constant within a 10 percent variation for the duration of the test.

i. The time lag (interval between an event and its being recorded on the strip chart) of the instrumentation may not exceed 2 seconds.

j. The tubing for the test chamber atmosphere and for the respirator sampling port shall be the same diameter, length and material. It shall be kept as short as possible. The smallest diameter tubing recommended by the manufacturer shall be used.

k. The exhaust flow from the test chamber shall pass through a high-efficiency filter before release to the room.

l. When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

4. Procedural Requirements

a. The fitting of half-mask respirators should be started with those having multiple sizes and a variety of interchangeable cartridges and canisters such as the MSA Comfr II–M, Norton M, Survivair M A–O M or Scott-M. Use either of the tests outlined below to assure that the facepiece is properly adjusted.

(1) *Positive pressure test.* With the exhaust port(s) blocked the negative pressure of slight inhalation should remain constant for several seconds.

(2) *Negative pressure test.* With the intake port(s) blocked the negative pressure slight inhalation should remain constant for several seconds.

b. After a facepiece is adjusted, the test subject shall wear the facepiece for at least 5 minutes before conducting a qualitative test by using either of the methods described below and using the exercise regime described in 5.a., b., c., d. and e.

(1) *Isoamyl acetate test.* When using organic vapor cartridges, the test subject who can smell the odor should be unable to detect the odor of isoamyl acetate squirted into the air near the most vulnerable portions of the facepiece seal. In a location which is separated from the test area, the test subject shall be instructed to close her/his eyes during the test period. A combination cartridge or canister with organic vapor and high-efficiency filters shall be used when available for the particular mask being tested. The test subject shall be given an opportunity to smell the odor of isoamyl acetate before the test is conducted.

(2) *Irritant fume test.* When using high-efficiency filters, the test subject should be unable to detect the odor of irritant fume (stannic chloride or titanium tetrachloride ventilation smoke tubes) squirted into the air near the most vulnerable portions of the facepiece seal. The test subject shall be instructed to close her/his eyes during the test period.

c. The test subject may enter the quantitative testing chamber only if she or he has obtained a satisfactory fit by as stated in 4.b. of this Appendix.

d. Before the subject enters the test chamber, a reasonably stable challenge agent concentration shall be measured in the test chamber.

e. Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half-mask and 1 percent for a full facepiece.

f. A stable challenge agent concentration shall be obtained prior to the actual start of testing.

1. Respirator restraining straps may not be overtightened for testing. The straps shall be adjusted by the wearer to give a reasonably comfortable fit typical of normal use.

5. *Exercise Regime.* Prior to entering the test chamber, the test subject shall be given complete instructions as to her/his part in the test procedures. The test subject shall perform the following exercises, in the order given, for each independent test.

a. *Normal Breathing (NB).* In the normal standing position, without talking, the subject shall breathe normally for at least one minute.

b. *Deep Breathing (DB).* In the normal standing position the subject shall do deep breathing for at least one minute pausing so as not to hyperventilate.

c. *Turning head side to side (SS).* Standing in place the subject shall slowly turn his head from side between the extreme positions to each side. The head shall be held at each extreme position for at least 5 seconds. Perform for at least five complete cycles.

d. *Moving head up and down (UD).* Standing in place, the subject shall slowly move his head up and down between the extreme position straight up and the extreme position straight down. The head shall be held at each extreme position for at least 5 seconds. Perform for at least five complete cycles.

e. *Reading (R).* The subject shall read out slowly and loud so as to be heard clearly by the test conductor or monitor. The test subject shall read the "rainbow passage" at the end of this section.

f. *Grimace (G).* The test subject shall grimace, smile, frown, and generally contort the face using the facial muscles. Continue for at least 15 seconds.

g. *Bend over and touch toes (B).* The test subject shall bend at the waist and touch toes and return to upright position. Repeat for at least one minute.

h. *Jogging in place (J).* The test subject shall perform jog in place for at least one minute.

i. *Normal Breathing (NB).* In the normal standing position, without talking, the subject shall breathe normally for at least one minute.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

6. The test shall be terminated whenever any single peak penetration exceeds 5 percent for half-masks and 1 percent for full facepieces. The test subject may be refitted and retested. If two the three required tests are terminated, the fit shall be deemed inadequate. (See paragraph 4.h.).

7. *Calculation of Fit Factors.* a. The fit factor determined by the quantitative fit test equals the average concentration inside the respirator.

b. The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

c. The average peak concentration of the challenge agent inside the respirator shall be the arithmetic average peak concentrations for each of the nine exercises of the test which are computed as the arithmetic average of the peak concentrations found for each breath during the exercise.

d. The average peak concentration for an exercise may be determined graphically if there is not a great variation in the peak concentration during a single exercise.

8. *Interpretation of Test Results.* The fit factor measured by the quantitative fit testing shall be the lowest of the three protection factors resulting from three independent tests.

9. *Other Requirements.* a. The test subject shall not be permitted to wear a half-mask or full facepiece if the minimum fit factor of 250 or 1,250, respectively, cannot be obtained. If hair growth or apparel interfere with a satisfactory fit, then they shall be altered or removed so as to eliminate interference and allow a satisfactory fit. If a satisfactory fit is still not attained, the test subject must use a positive-pressure respirator such as powered air-purifying respirators, supplied air respirator, or self-contained breathing apparatus.

b. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface.

c. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respirator diseases or pulmonary medicine to determine whether the test subject can wear a respirator while performing her or his duties.

d. The test subject shall be given the opportunity to wear the assigned respirator for one week. If the respirator does not provide a satisfactory fit during actual use, the test subject may request another QNFT which shall be performed immediately.

e. A respirator fit factor card shall be issued to the test subject with the following information:

(1) Name.

(2) Date of fit test.

(3) Protection factors obtained through each manufacturer, model and approval number of respirator tested.

(4) Name and signature of the person that conducted the test.

f. Filters used for qualitative or quantitative fit testing shall be replaced weekly, whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily or sooner if there is any indication of breakthrough by the test agent.

10. In addition, because the sealing of the respirator may be affected, quantitative fit testing shall be repeated immediately when the test subject has a:

(1) Weight change of 20 pounds or more,

(2) Significant facial scarring in the area of the facepiece seal,

(3) Significant dental changes; i.e.; multiple extractions without prothesis, or acquiring dentures,

(4) Reconstructive or cosmetic surgery, or

(5) Any other condition that may interfere with facepiece sealing.

11. *Recordkeeping.* a. A summary of all test results shall be maintained for three years. The summary shall include:

(1) Name of test subject.

(2) Date of testing.

(3) Name of the test conductor.

(4) Fit factors obtained from every respirator tested (indicate manufacturer, model, size and approval number).

b. A copy of all test data including the strip chart and results shall be kept for at least five years.

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Tuesday
December 10, 1985

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Parts 91, 121, 125, 129, and 135
Foreign Air Carriers and Operators of Certain Large U.S.-Registered Airplanes; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 121, 125, 129, and 135

[Docket No. 24856; Notice No. 85-24]

Foreign Air Carriers and Operators of Certain Large U.S.-Registered Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This document proposes amendments to ensure that U.S.-registered aircraft leased by foreign persons are maintained in accordance with acceptable maintenance standards, to eliminate the need for certain exemptions to foreign persons who lease U.S.-registered aircraft and to clarify certain rules which were intended to preclude the commingling of noncommon (private) and common-carriage operations. These amendments are necessary to upgrade certain regulations regarding the leasing of U.S.-registered aircraft by foreign persons to meet changing market conditions, to reduce the agency's exemption workload, and to facilitate enforcement of certain private and common-carriage operations. Adopting these proposed amendments would ensure that leased U.S.-registered aircraft are properly maintained and would eliminate the possibility of intermixing private and common-carriage operations by a private operator.

DATE: Comments must be received on or before April 10, 1986.

ADDRESSES: Comments on this proposal are to be marked "Docket No. 24856" and mailed in duplicate to: Federal Aviation Administration: Office of the Chief Counsel, Attn: Rules Docket (AGC-204), Docket No. 24856, 800 Independence Avenue, SW., Washington, DC 20591; or deliver comments in duplicate to: Room 916, 800 Independence Avenue, SW., Washington, DC. Comments may be inspected in Room 916 on weekdays, except Federal holidays between 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Larry Bedore, Project Development Branch (AFO-240), Air Transportation Division, Office of Flight Operations, telephone (202) 426-8096, or Bob Seger, Air Transportation Branch (AWS-330), Aircraft Maintenance Division, Office of Airworthiness, telephone (202) 426-440, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments relating to any significant environmental or economic impact that might result because of the adoption of these proposals may also be submitted. Communications should identify the regulatory docket or notice number and be submitted or delivered in duplicate to the address listed above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 24856." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRM

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-430, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 426-8058. Each communication must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedures.

Background

On October 9, 1980, Part 125 of the Federal Aviation Regulations (FAR) was published in the **Federal Register** (45 FR 67214). With certain exceptions, not germane to the current discussion, Part 125 applies to the operation of all U.S.-registered airplanes having a maximum seating configuration of 20 or more passengers, or a maximum payload configuration of 6,000 pounds or more, unless they are required to be operated under the rules of Part 121, 135, or 137 of the regulations.

Although Part 125 was not intended to provide acceptable safety levels for common-carriage operations, the inspection programs and maintenance requirements of § 125.247 currently apply to U.S.-registered airplanes operated outside the United States by a foreign person. This circumstance arises because § 125.1 states that Part 125 governs operation of a U.S.-registered airplane of the prescribed size unless that operation is required to be conducted under the rules of Part 121, 135, or 137.

At the time Part 125 was published, the FAA was considering rulemaking to revise Part 129—Operations of Foreign Air Carriers. Requiring foreign air carriers to comply with Part 125 immediately was deemed inappropriate in light of the possibility of change to Part 129. Consequently, in adopting Part 125 the agency established a deferred compliance date of January 1, 1983, for foreign air carriers. By Amendments 125-4 (47 FR 44718; October 12, 1982) and 125-5 (49 FR 34815; September 4, 1984), the agency extended the January 1, 1983, compliance date to September 1, 1984, and February 28, 1986, respectively, to provide sufficient time for completion of the proposals contained in this notice.

Subsequent to the adoption of Part 125, the agency has carefully monitored the operating experience of large U.S.-registered airplanes operated under Part 125. The operating experience can be divided into two main areas of interest. First, the frequency with which foreign air carriers operate U.S.-registered airplanes under lease has shown a marked increase. These lease agreements are desirable since they improve the U.S. balance of payments and provide a means for U.S. air carriers to arrange for use of their airplanes during periods of reduced traffic levels. Most foreign air carriers and foreign persons engaged in common-carriage operations have aircraft maintenance program requirements adopted by their domestic governments which are consistent with the international standards in Part I of Annex 6 to the Convention on International Civil Aviation (ICAO). ICAO Annex 6 requires each operator to comply with the terms of the aircraft's certificate of airworthiness and to maintain the aircraft in an airworthy condition. To meet these requirements, each foreign operator of a U.S.-registered aircraft used in common carriage must ensure

that the aircraft is maintained by a qualified organization with a well-trained staff and adequate workshops, equipment and facilities. That organization must also have appropriate maintenance manuals, records, and procedures regarding training, inspection, and release of the aircraft. However, some countries may not have requirements completely consistent with the ICAO aircraft maintenance program requirements. This means that U.S.-registered airplanes operated by foreign air carriers or persons from those countries might not meet those international standards. To allow operation of these aircraft would be inconsistent with U.S. obligations under international agreements for aircraft of its registry. As more fully explained under "Description of Regulatory Proposals," the proposals in this notice, if adopted, would ensure compliance with international airworthiness obligations.

The second main aspect of the operating experience of large U.S.-registered airplanes of the size covered by Part 125 concerns the distinction between common carriage and noncommon carriage. Part 125 was designed to provide a regulatory scheme for an appropriate level of safety for airplanes not used in common carriage. This regulatory intent is stated explicitly in § 125.11. That section prohibits common carriage by a Part 125 certificate holder and declares that any person holding an Air Carrier Operating Certificate is ineligible for a certificate under Part 125. The sole exception to the principle that Part 125 is intended to apply only to noncommon carriage is the case of a foreign person common carrier compelled to operate under the rules of Part 125 by operating a U.S.-registered airplane of the size covered by that part.

Since the adoption of Part 125, the agency has received numerous inquiries from air carriers who desire to hold operations specifications under Part 125. However, the issuance thereof would cause extreme difficulty for the FAA in preserving the distinction between common carriage and noncommon carriage. The FAA would need to expend more time and resources, a result which is incompatible with the agency's staffing levels. Another problem closely related to past operating experience is the fact that some Part 125 operators and foreign air carriers are listing the same airplane on their respective operations specifications. In some cases, common-carriage operations are being disguised as Part 125 operations. Proposals to preserve the intent of Part 125 are more fully explained under "Description of Regulatory Proposals."

Description of Regulatory Proposals

Section 91.161(b)

Section 91.161(a) states that a U.S.-registered civil aircraft operating within or without the United States shall be governed by the maintenance, preventive maintenance, and alterations rules of Subpart C— "Maintenance, Preventive Maintenance, and Alterations." However, § 91.161(b) excepts, from certain requirements of Subpart C, aircraft maintained in accordance with a continuous airworthiness maintenance program as provided in either Part 121, 127, or 135 of the FAR, as appropriate. Section 91.161(b) would be amended to include Part 129 thereby excepting U.S.-registered aircraft operated by a foreign air carrier or foreign person in common-carriage operations. Proposed § 129.14 contains the parallel continuous airworthiness maintenance program requirement necessary to make § 91.161(b) operative.

Section 121.3

This section would be amended by adding a new paragraph (i) that would preclude operation under Part 121 by a person engaged in air transportation of any aircraft listed on any Part 125 operations specifications.

Section 125.1(a)

This section would be amended to delete the reference to paragraph (e), which makes Part 125 applicable to Part 129 operators, as of February 28, 1986, and to clarify the applicability of Part 125 by adding the phrase "when common carriage is not involved" at the end of the sentence.

Section 125.1(b) (1), (3), and (4)

Current § 125.1(b) (1) and (4) excepts from the applicability of Part 125 those U.S.-registered airplanes which are required to be operated under Part 121, 135, or 137. Since one of the objectives of the proposals in this notice is to require U.S.-registered airplanes operated in common carriage by foreign air carriers or foreign persons to be regulated by Part 129 instead of Part 125, this section would be amended by adding Part 129 to the parts already listed. Thus, foreign-registered and U.S.-registered airplanes operated in common carriage by foreign air carriers or foreign persons would be regulated by Part 129. The addition of the words "by a Part 125 certificate holder" in § 125.1(b)(3) is to correct an administrative oversight. The intent of § 125.1(b)(3) is to allow an airplane normally operated under Part 125 to be flown under Part 91 for training, ferrying, positioning, or maintenance purposes.

Section 125.11(a)

This paragraph now provides that no person is eligible for a Part 125 certificate if that person is authorized to operate aircraft under any air carrier operating certificate. This provision implements a basic concept in Part 125; namely; that it was not intended to regulate common carriage. The FAA has received numerous inquiries from persons who desire to hold operations specifications authorizing operations as an air carrier and also to hold operations specifications under Part 125. To allow issuance of dual operations specifications under these circumstances would greatly complicate the FAA's surveillance and enforcement efforts designed to ensure that common carriage is not conducted under Part 125. Accordingly, under the proposed revision to paragraph (a), no person authorized to operate aircraft under an air carrier operating certificate or under air carrier or common carrier operations specifications would be eligible for an operating certificate or operations specifications under Part 125. This proposal and the changes proposed for Parts 121, 129, and 135 should eliminate confusion among regulated persons and eliminate the resulting unnecessary drain on FAA resources used in surveillance and enforcement.

Section 125.11(c)

Consistent with the change proposed in paragraph (a), a new paragraph (c) would be added to prohibit a Part 125 operator from operating or listing on its operations specifications any airplane listed on any operations specifications or other required airplane listing under Part 121, 129, or 135. Corresponding changes also are proposed in §§ 121.3(i), 129.11(c), and 135.11(c) to implement the concept that common carriage and Part 125 operations should be kept separate.

Part 129 Title

The title of Part 129 would be expanded to reflect its application to U.S.-registered aircraft used in common carriage by foreign air carriers or foreign persons. This expansion will permit the maintenance and use of a minimum equipment list (MEL) with respect to those U.S.-registered aircraft not governed by Part 125 and used in common carriage by foreign air carriers or foreign persons. This expansion also ensures a level of maintenance

consistent with U.S. treaty obligations with regard to common-carriage operations of U.S. registered aircraft by foreign air carriers or foreign persons.

Section 129.1

Current § 129.1 would become § 129.1 (a) with a clause added to read: "Except as provided in paragraph (b) of this section. . . ." This clause would create an exception which would be set forth in paragraph (b). Paragraph (b) would require any U.S.-registered aircraft operated by a foreign person outside the United States in common carriage (as that term is customarily understood in the United States) to be maintained according to an acceptable international standard as more fully set forth in proposed § 129.14. For the purpose of Part 129, paragraph (b) would define foreign person as any person, not a citizen of the United States, who operates a U.S.-registered aircraft in common carriage outside the United States. In addition, § 129.1(a) would, based on the sunset of the Civil Aeronautics Board, recognize the role of the Department of Transportation in issuing foreign air carrier permits under Section 402 of the Federal Aviation Act of 1958, as amended, by the Airline Deregulation Act of 1978 and the Civil Aeronautics Board Sunset Act of 1984.

Section 129.11(a)

This paragraph requires each foreign air carrier to conduct its operations within the United States in accordance with operations specifications issued by the Administrator. Operations specifications issued to Part 129 air carriers also require compliance with the aircraft maintenance program requirements of Part I of Annex 6 to the Convention on International Civil Aviation. Incorporating this requirement in Part 129 is appropriate because it would emphasize maintaining an aircraft in accordance with the airworthiness certificate requirements of the State of Registry and will simplify the operations specifications issued to Part 129 foreign air carriers.

Section 129.11(a)(4)

The proposal would require that each foreign carrier list in its operations specifications the registration marking of each U.S.-registered aircraft. As noted above, the FAA has encountered situations in which a U.S.-registered aircraft was simultaneously listed on the operations specifications of a foreign air carrier and a Part 125 operator. This practice hinders the agency's ability to determine which rules apply to a particular operation and greatly complicates the agency's task of detecting the use of subterfuges to conduct unauthorized common-carriage operations. The proposed change should facilitate the agency's surveillance and enforcement efforts and is similar to a current requirement in § 125.31 (b)(2) requiring an operator to list types and registration numbers of airplanes authorized for use.

Section 129.14

This proposed new section would require U.S.-registered aircraft operated in common carriage by any foreign air carrier or any foreign person to meet prescribed maintenance requirements without distinguishing between aircraft operated within or exclusively outside the United States. Currently, a foreign operator who leases a U.S.-registered aircraft from a U.S. air carrier or other person for common carriage must obtain an exemption in order to use the lessor's MEL. The exemption process imposes burdens upon the foreign lessee and the FAA. Under this proposal, foreign operators of most U.S-registered aircraft would be authorized to use an approved MEL. Therefore, this proposal reduces the paperwork burden on the foreign lessee and the FAA, thereby facilitating the FAA's program to reduce unnecessary paperwork and improving operational efficiency. This proposal also would ensure that U.S.-registered aircraft operated by foreign persons would be adequately miantained, and it will therefore carry out U.S. responsibilities under international conventions for airworthiness of U.S.-registered aircraft.

In lieu of petitioning for an exemption to use the lessor's MEL, this proposed new section would permit the foreign air carrier, or foreign person to submit to the appropriate FAA International Field Office or Flight Standards District Office for review and evaluation a copy of the lessor's approved continuous airworthiness maintenance program and either the lessor's MEL, or the lessor's modifications to the lessor's MEL, or the lessee's MEL. In addition, the lessee must show that it is capable of operating under the lessor's maintenance program and meeting the MEL maintenance and operational requirements. After completing its review and evaluation, the appropriate FAA field office will issue a letter of authorization to the foreign air carrier or foreign person to permit operations of the leased aircraft using one of the FAA-approved MELs specified above.

Part 129—Appendix A—Section V.A.5

This proposed amendment conforms the form of application for operations specifications used by foreign air carriers to the requirements of proposed § 129.11(a)(4).

Section 135.11(c)

This new section would prohibit a Part 135 operator from listing on its operations specifications or on the current aircraft list required by § 135.63(a)(3) any aircraft listed on the operations specifications of any Part 125 operator.

Regulatory Evaluation

These proposals clarify the requirements for foreign air carriers operating U.S.-registered aircraft. Eleven specific changes are associated with the proposal. Only one, the proposal for foreign carriers operating U.S.-registered aircraft in the United States to list these aircraft on their operations specifications, involves a new requirement and a minimal cost. The other changes act only to clarify FAA requirements or to rearrange existing requirements within the regulations.

The proposals, if adopted, would establish that foreign air carriers operating U.S.-registered aircraft would not be required to be certificated under Part 125. The proposals also designate maintenance rules for foreign carriers using U.S.-registered aircraft. The proposals also provide for compatibility in Parts 91, 121, 125, 129, and 135.

Since the proposals are basically clarifying, no notable economic consequences are associated with the proposals. If adopted, no cost-incurring actions are required on the part of the governments or carriers affected, except one minor addition to foreign air carrier operations specifications. The proposals will obviate the need for the FAA and certain foreign carriers to go through an unnecessary exemption action. Also, FAA enforcement efficiency will be enhanced by the proposals.

Benefits

The proposals will help to ensure a high degree of safety in common carriage and are in the public interest. The proposals will act to clarify the terms of leasing with foreign air carriers; thus, they will act to facilitate such leasing, which benefits owners of U.S.-registered aircraft.

Conclusion

These proposals provide compatibility among Parts 91, 121, 125, 129, and 135 of the regulations and ensure that all U.S.-registered aircraft meet appropriate requirements based on the type operations (air transportation versus other air commerce) being conducted under FAA-approved operations

specifications. These changes clarify FAA requirements or rearrange existing requirements within the regulations. As a result of clarifying the regulations, these proposals, if adopted, will have a negligible but positive impact on trade opportunities of U.S. and foreign persons who may wish to enter into aircraft lease agreements. Accordingly, the FAA has determined that this document involves a proposed regulation which is not considered to be significant under DOT Regulatory Policies and Procedures (44 CFR Part 11034; February 26, 1979) and is not major as defined in Executive Order 12291. For these reasons and because the proposal will result in negligible costs, as noted above, the FAA certifies that under the criteria of the Regulatory Flexibility Act, this proposed regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities. A copy of the draft regulatory evaluation for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption **"FOR FURTHER INFORMATION CONTACT."**

List of Subjects

14 CFR Part 91

Air carriers, Aviation safety, Safety, Aircraft, Air transportation.

14 CFR Part 121

Aviation safety, Safety, Air carriers, Air transportation, Aircraft, Airplanes, Airspace, Foreign air carriers, Transportation, Common carriers.

14 CFR Part 125

Aircraft, Airplanes, Airworthiness, Air transportation.

14 CFR Part 129

Aircraft, Air carrier, Airworthiness.

14 CFR Part 135

Air carriers, Aviation safety, Safety, Air transportation, Aircraft, Transportation, Airspace, Airplanes.

The Proposed Rule

Accordingly, the Federal Aviation Administration proposes to amend the regulations (14 CFR Parts 91, 121, 125, 129 and 135) as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

1. The authority citation for Part 91 continues as follows:

Authority: 49 U.S.C. 1301(7), 1303, 1344, 1348, 1352 through 1355, 1401, 1421 through 1431, 1471 through 1472, 1502, 1510, 1522, and 2121–2125; Articles 121, 29, 31 and 32(a) of the Convention on International Civil Aviation (61 Stat. 1180); 42 U.S.C. 4321 et seq.; E.O. 11514; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983).

§ 91.161 [Amended]

2. By amending § 91.161(b) by removing the phrase "Part 121, 127, or § 135.411(a)(2)" and inserting the phrase "Part 121, Part 127, Part 129, or § 135.411(a)(2)" in its place.

PART 121—CERTIFICATION AND OPERATIONS: DOMESTIC, FLAG, AND SUPPLEMENTAL AIR CARRIERS AND COMMERCIAL OPERATORS OF LARGE AIRCRAFT

3. The authority citation for Part 121 continues as follows:

Authority: 49 U.S.C. 1354(a), 1355, 1356, 1357, 1401, 1421–1430, 1472, 1485, and 1502; 49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983).

4. By amending § 121.3 by adding a new paragraph (i) to read as follows:

§ 121.3 Certification requirements: General.

* * * * *

(i) No holder of an air carrier operating certificate may operate or list on any required listing of its aircraft any aircraft listed on any operations specifications issued under Part 125.

PART 125—CERTIFICATION AND OPERATIONS: AIRPLANES HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE

5. The authority citation for Part 125 continues as follows:

Authority: 49 U.S.C. 1354, 1421 through 1430 and 1502; 49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983).

6. By amending § 125.1 by removing paragraph (e) and by revising paragraphs (a) and (b) (1), (3), and (4) to read as follows:

§ 125.1 Applicability.

(a) Except as provided in paragraphs (b), (c), and (d) of this section, this part prescribes rules governing the operations of U.S.-registered civil airplanes which have a seating configuration of 20 or more passengers, or a maximum payload capacity of 6,000 pounds or more when common carriage is not involved.

(b) * * *

(1) They are required to be operated under Part 121, Part 129, Part 135, or Part 137 of this chapter;

* * * * *

(3) They are being operated by a Part 125 certificate holder without carrying passengers or cargo under Part 91 for training, ferrying, positioning, or maintenance purposes;

(4) They are being operated under Part 91 by an operator certificated to operate those airplanes under Part 121, Part 135, or Part 137, or are being operated in common carriage outside the United States by a foreign air carrier or foreign person under Part 91 of this chapter; or

* * * * *

7. By amending § 125.11 by revising paragraph (a) and by adding a new paragraph (c) to read as follows:

§ 125.11 Certificate eligibility and prohibited operations.

(a) No person is eligible for a certificate or operations specifications under this part if that person is authorized to operate aircraft under an operating certificate or operations specifications issued under Part 121, Part 129, or Part 135 of this chapter.

* * * * *

(c) No person holding operations specifications under this part may operate or list on its operations specifications any aircraft listed on any operations specifications or other required aircraft listing under Part 121, Part 129, or Part 135.

PART 129—OPERATIONS OF FOREIGN AIR CARRIERS

8. The authority citation for Part 129 continues as follows:

Authority: 49 U.S.C. 1354(a) and 1421; 49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983).

9. By revising the title of Part 129 to read as follows:

PART 129—OPERATIONS: FOREIGN AIR CARRIERS AND FOREIGN OPERATORS OF U.S.-REGISTERED AIRCRAFT ENGAGED IN COMMON CARRIAGE

10. By revising § 129.1 to read as follows:

§ 129.1 Applicability.

(a) Except as provided in paragraph (b) of this section, this part prescribes rules governing the operation within the United States of aircraft of each foreign air carrier holding a permit issued by the Civil Aeronautics Board or the Department of Transportation under section 402 of the Federal Aviation Act of 1958 (49 U.S.C. 1372) or other appropriate economic or exemption authority issued by the Civil Aeronautics Board or the Department of Transportation.

(b) Section 129.14 also applies to U.S.-registered aircraft operated in common carriage by a foreign person or foreign

air carrier solely outside the United States. For the purposes of this part, a foreign person is any person, not a citizen of the United States, who operates a U.S.-registered aircraft in common carriage outside the United States.

11. By amending § 129.11 revising paragraph (a) and by adding a new paragraph (a)(4) and a new paragraph (c) to read as follows:

§ 129.11 Operations Specifications.

(a) Each foreign air carrier shall conduct its operations within the United States in accordance with operations specifications issued by the Administrator under this part and in accordance with the Standards and Recommended Practices contained in Part I (International Commercial Air Transport) of Annex 6 (Operation of Aircraft) to the Convention on International Civil Aviation. Operations specifications shall include:

* * * * *

(4) Regfstration markings of each U.S.-registered aircraft.

* * * * *

(c) No person operating under this part may operate or list on its operation specifications any airplane listed on operations specifications issued under Part 125.

12. By adding a new § 129.14 to read as follows:

§ 129.14 Maintenance and minimum equipment list (MEL) requirements for U.S.-registered aircraft.

(a) Each foreign air carrier and each foreign person operating a U.S.-registered aircraft within or outside the United States in common carriage shall ensure that each aircraft is maintained in accordance with a program acceptable to the Administrator.

(b) The program specified in paragraph (a) of this section must meet the aircraft maintenance program requirements consistent with Part 121 or Part 135 of this chapter, as appropriate.

(c) No foreign air carrier or foreign person may operate a U.S.-registered aircraft with inoperable instruments or equipment unless the following conditions are met:

(1) A Master Minimum Equipment List exists for the aircraft type.

(2) The foreign operator submits for review and approval, its aircraft Minimum Equipment List, based on the Master Minimum Equipment List, to the FAA Flight Standards District Office having geographic responsibility for the operator. The foreign operator must show, before MEL approval can be obtained, that the maintenance procedures used under its maintenance program are adequate to support the use of its MEL.

(3) For leased aircraft maintained and operated under a U.S. operator's continuous airworthiness maintenance program and FAA-approved MEL, the foreign operator submits the U.S. operator's approved continuous airworthiness maintenance program and approved aircraft MEL to the FAA office prescribed in paragraph (c)(2) of this section for review and evaluation. The foreign operator must show that it is capable of operating under the lessor's approved maintenance program and that it is also capable of meeting the maintenance and operational requirements specified in the lessor's approved MEL.

(4) The FAA letter of authorization permitting the operator to use an approved Minimum Equipment List is carried aboard the aircraft. The Minimum Equipment List and the letter of authorization constitute a supplemental type certificate for the aircraft.

(5) The approved Minimum Equipment List provides for the operation of the aircraft with certain instruments and equipment in an inoperable condition.

(6) The aircraft records available to the pilot must include an entry describing the inoperable instruments and equipment.

(7) The aircraft is operated under all applicable conditions and limitations contained in the Minimum Equipment List and the letter authorizing the use of the list.

13. By amending Appendix A of Part 129 by revising Section V., A., by adding a new paragraph 5 to read as follows:

Appendix A—Application for Operations Specifications by Foreign Air Carriers

* * * * *

Section V. Aircraft.

* * *

A. Aircraft.

* * * * *

5. Registration markings of each U.S.-registered aircraft.

* * * * *

PART 135—AIR TAXI OPERATORS AND COMMERCIAL OPERATORS

14. The authority citation for Part 135 continues as follows:

Authority: 49 U.S.C. 1354(a), 1355(a), 1421 through 1431, and 1502; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983).

15. By amending § 135.11 by adding a new paragraph (c) to read as follows:

§ 135.11 Application and issue of certificate and operations specifications.

* * * * *

(c) No person holding operations specifications issued under this part may list on its operations specifications or on the current list of aircraft required by § 135.63(a)(3) any airplane listed on operations specifications issued under Part 125.

Issued in Washington, DC, on December 4, 1985.

William T. Brennan,

Acting Director of Flight Standards.

[FR Doc. 85-29171 Filed 12-9-85; 8:45 am]

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December 10, 1985

Part VI

Department of Housing and Urban Development

Office of the Assistant Secretary for Community Planning and Development

24 CFR Part 511

Rental Rehabilitation Program; Performance Adjustments to Formula Allocations; Interim Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

24 CFR Part 511

[Docket No. R-85-1260; FR-2055]

Rental Rehabilitation Program; Performance Adjustments to Formula Allocations

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Interim rule.

SUMMARY: This rule modifies 24 CFR Part 511, which implements the Rental Rehabilitation Program authorized by section 17 of the United States Housing Act of 1937 (the Act), 42 U.S.C. 1437o. Section 17 was added to the Act by section 301 of the Housing and Urban-Rural Recovery Act of 1983. Section 17(b)(2)(B) of the Act authorizes the Secretary of HUD, beginning with fiscal years after Fiscal Year 1984, to adjust the fund allocation for a city, urban county, consortium, or State administering a rental rehabilitation program by up to 15 percent above or below the amount of its formula-based annual allocation. This adjustment is based on an annual review of the grantee's performance in carrying out program activities under section 17 of the Act. This rule revises § 511.32 of the interim rule concerning the Rental Rehabilitation Program published on April 20, 1984 at 49 FR 16936.

DATES: Effective date: Upon expiration of the first period of 30 calendar days of continuous session of Congress after publication, but not before further notice of the effective date is published in the **Federal Register**.

Comment due date: February 10, 1986.

ADDRESS: Comments should be addressed to the Office of General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410. Comments should refer to the above docket number and title. A copy of each set of comments submitted will be available for public inspection and copying during regular business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Craig S. Nickerson, Director, Rental Rehabilitation Division, Office of Urban Rehabilitation, Room 7164, Department of Housing and Urban Development, at the above address, telephone (202) 755-5970. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 17 of the Act establishes a Rental Rehabilitation Program that provides grants to States and units of general local government to help support the rehabilitation of privately owned real property to be used for primarily residential rental purposes. The program is designed to increase the supply of standard housing units affordable to lower-income families. This is achieved by: (1) Supplying government funds to assist in the rehabilitation of existing units and (2) providing rental housing assistance to lower-income families to help them afford the rent of units in projects assisted with program funds, or find alternative housing.

Under section 17(b)(2)(B), the Secretary is authorized to adjust the allocation for a city, urban county, consortium or State administering a rental rehabilitation program by as much as 15 percent above or below the regular allocation, based upon an annual review of performance. HUD promulgated an interim rule implementing section 17 in the **Federal Register** of April 20, 1984 (49 FR 16936). Section 511.32 of that rule includes a performance adjustment system that implements section 17(b)(2)(B).

This rule substantially revises § 511.32 of the April 1984 interim rule. Although the performance standards in this rule and the April 1984 rule are generally similar, the respective regulations vary significantly in the methodology and specific weights allocated to the various standards. For example, § 511.32 of this rule provides for two threshold standards and six other performance adjustment standards that implement section 17(b)(2) of the Act. (Threshold standards refer to those performance adjustment standards that a grantee must meet to qualify for receiving any points under the other six standards. The rationale for adopting certain performance adjustment standards as thresholds is explained in unit III.A of this preamble.) In contrast, the April 1984 rule does not provide for threshold standards, but rather includes seven performance standards and allocates 65 of 100 total points to a standard that is identical to one of the two threshold standards of this rule, i.e., that at least 80 percent of a grantee's total rehabilitated units under this program are affordable to lower-income families. In addition, this revision to § 511.32 provides a more detailed explanation than was included in the April 1984 rule concerning how the Department will evaluate a grantee's performance in meeting the performance adjustment standards and the method that will be used for making annual formula adjustments for each grantee, beginning in Fiscal Year 1987, assuming there are funds appropriated for the program.

The revised performance adjustment standards in this rule provide direction to grantees regarding important aspects of program implementation, and the measurement of performance will provide essential feedback to grantees to assist them in their program management. It is the Department's intent to use the performance standards to adjust formula funding levels beginning in Fiscal Year 1987, should the Congress appropriate additional funds for the program for that fiscal year. Since the performance standards and the performance adjustment ranking system in this rule would significantly affect the Fiscal Year 1987 adjusted formula funding levels, the Department is publishing these revised performance standards and ranking system as an interim rule. The Department invites public comment on this interim rule for a period of sixty days and will take these comments into account in publishing a final rule.

Under these revisions to 24 CFR 511.32, in order to receive any points under the performance adjustment standards, grantees must pass the following two threshold standards:

Threshold 1—Grantees must have committed rental rehabilitation grant funds to one or more specific local projects during the most recent performance measuring period.

Threshold 2—At least 80 percent of the units in projects rehabilitated with rental rehabilitation grants in the preceding seven performance measuring periods must have rents that are affordable to lower income families.

If a grantee meets these thresholds, its performance will be further evaluated based on the following additional standards:

1. Up to 15 points—For the extent to which more than 80 percent of units in projects rehabilitated with rental rehabilitation grants have rents that are affordable to lower income families.

2. Up to 15 points—For the extent to which rental rehabilitation grants are used to rehabilitate units containing (a) two or more bedrooms and (b) three or more bedrooms.

3. Up to 15 points—For the extent to which units rehabilitated with rental rehabilitation grants were occupied by very low income families before rehabilitation and these families were not displaced.

4. Up to 15 points—For the extent to which the gross amount of total public subsidy funds has been minimized per unit.

5. Up to 15 points—For the extent to which the amount of public subsidy funds as a percentage of total rehabilitation costs has been minimized.

6. Up to 15 points—For the extent to which rental rehabilitation funds have been committed to specific local projects and projects have been completed over the preceding three performance measuring periods. (For a description of the applicable performance measuring periods, see § 511.32(b) of this rule.)

II. Comments on the April 1984 Interim Rule

Comments were received on 24 CFR 511.32 of the April 20, 1984 interim rule. Concerning the affordability standard in 24 CFR 511.32(b)(1), one comment stated that since the grantee cannot control the rents charged through agreements, HUD should drop the performance standard that at least 80 percent of the rehabilitated units remain at or below the fair market rents under the Section 8 Existing Housing Program for the area. Another comment asserted that the grantee should not be penalized for good faith efforts to ensure long term affordability. HUD has determined that this is one of the performance adjustment standards mandated by the Act. The Department has also concluded that the selection of projects with modest rents is critical to the success of the Rental Rehabilitation Program. The selection of appropriate neighborhoods and careful design of the local program will ensure that in the near term, rents will remain affordable, i.e., at or below the fair market rents published by HUD for the Section 8 Existing Housing Program. This is why the threshold and other performance adjustment standards that measure affordability over time weight rents for units completed in the current measuring period more heavily than the rents for units completed in previous years. We believe that a grantee should be able to achieve affordability in the near term by the selection of appropriate neighborhoods and projects and receive proportionately more credit for it.

With respect to § 511.32(b)(5) of the April 1984 interim rule, a comment recommended eliminating from the list of performance standards the standard related to minimizing public subsidies, because it discourages the use of additional public funding. The Rental Rehabilitation Program is not intended to be a heavily subsidized program. The program is designed to encourage maximum leveraging and risk-taking by the private sector. A further discussion of the importance of this private investment factor is presented in unit III of this preamble.

Concerning § 511.32(b)(7), certain comments stated that it would be difficult for HUD to compare the timeliness of the respective grantee's performance because there are many local conditions that have an effect on a grantee's productivity. The Department recognizes that exigencies can occur which would affect the timeliness of performance. However, because funds are limited and the need for rehabilitation resources is very great, expeditious provision of rehabilitated units under the program should be both encouraged and rewarded. Under § 511.32(b)(6) of the revised standards, the timeliness factor for project completion is continued as important to HUD's decisions on rental rehabilitation funding. This revised standard concerns the extent to which rental rehabilitation funds have been committed to specific local projects and projects have been completed over the preceding three performance measuring periods.

With respect to the application of the performance adjustment standards in § 511.32(b) to State grantees, one comment suggested that State grantees should be eligible for the adjustment of rental rehabilitation grant allocations based on the performance of grantees receiving direct allocations from HUD within the State. Under the Rental Rehabilitation Program, States have neither control over nor responsibility for the performance of grantees within the State receiving direct grants from HUD. The Department has determined that States, like cities and urban county grantees, must be held accountable for the quality and efficiency of their own programs and evaluated on their performance as separate grant recipients. Because there are significant differences in 24 CFR Part 511 for the State administration of a rental rehabilitation program in contrast with the program for direct formula grantees, States will be ranked and rated in comparison to other States, not in comparison to all grantees.

III. Amendments to the April 1984 Interim Rule

The performance adjustment standards are intended to provide an incentive for grantees participating in the Rental Rehabilitation Program to receive up to 15 percent above their annual formula allocation for good performance. The use of the performance adjustment standards as a management tool enables the Department to ensure that the priority objectives established for the program are met with a minimum of burdensome front-end regulations. For example, a major program objective is to minimize public subsidy levels and maximize the number of units rehabilitated with limited public resources. This rule does not specify any financing subsidy technique that a grantee must use or the amount of other public funds—such as CDBG funds—that may be used on a project-by-project basis. The revised performance adjustment standards in § 511.32(e) (4) and (5) evaluate how well grantees achieve this objective by measuring the extent to which grantees have minimized the total public dollars invested in projects rehabilitated under the program. The Department has thus established an incentive system to encourage grantees to reach the objectives of the program without imposing prescriptive requirements on any grantee's program design.

In anticipation of the future application of the amended performance adjustment standards in this rule, the Department has designed a comprehensive Cash and Management Information System (C/MI) capable of evaluating a grantee's performance in meeting the standards without imposing burdensome reporting requirements. Most of the necessary data to evaluate a grantee's performance in meeting the performance adjustment standards will be obtained automatically from the C/MI System. This information will be reported routinely by grantees on a project-by-project basis during the year.

The revised performance adjustment standards provide that, beginning in Fiscal Year 1987, HUD may adjust the original formula allocations under §§ 511.30–511.31 for each city, urban county, consortium or State grantee, prior to the actual awarding of the grant. The performance adjustment may be up to 15 percent above or below the formula allocation for that year. Performance adjustments will not be made for units of general local government receiving Rental Rehabilitation Program funds as part of a HUD-administered State program because their grants are not based on formula allocations. However, under § 511.52(b)(1), HUD will consider the grantee's past performance in housing and community development programs, including the Rental Rehabilitation Program, in awarding grants in the HUD-administered State program.

All city, urban county and consortium grantees will be evaluated as a group and ranked in comparison with each other so that the funds provided to these

grantees will "net out" at the national level. That is, there will be no increase or decrease in the total annual funding made available to this category of grantees. Similarly, each State grantee will be evaluated against the overall performance of the other State grantees. State grantee performance adjustments will also "net out" nationally. State performance is evaluated separately because (1) the original formula allocations separate States from other grantees and (2) State programs must operate through a network of comparatively small units of general local government and, therefore, present a very different set of management problems from the other category of grantees.

Section 511.32 (b) and (c) of the amended standards defines the performance measuring period and timing of the review. The performance measuring period is the actual period from September 1–August 31 for which a grantee will be evaluated on how well it met the performance adjustment standards under this section. The closing date of August 31 was selected to give HUD sufficient time to analyze all data, rank grantees, reallocate funds and publish fund announcements as close to the start of the new fiscal year as possible.

Section 511.32(d) of the amended standards identifies the source of data used to make performance adjustments. All data used to make adjustments (except for data received from landlords by survey) will be submitted by grantees to HUD through the Program's C/MI System. Detailed information about projects and the characteristics of tenants in the building prior to rehabilitation is collected on Pre-Rehabilitation Reports submitted when grantees commit funds to specific local projects. Information concerning completed projects is submitted by grantees to the C/MI System within 90 days of project completion. All data entered into the system as of August 31 of each performance measuring period will be used to calculate performance adjustments. Detailed description of the C/MI is provided in CPD Notice 84–8, published in September 17, 1984.

A. Performance Adjustment Thresholds

In order to receive any points on the six performance adjustment standards, grantees must first pass two performance adjustment thresholds which are described at § 511.32(e). These thresholds are based on the key criteria in section 17(b)(2)(B) of the Act, i.e., that the rehabilitation activities are conducted in a timely manner and that the units rehabilitated are affordable to lower-income families. The first of the thresholds requires grantees to have committed funds to one or more specific local projects during the most recent performance measuring period. This threshold is established because grantee commitment of funds to actual projects is necessary to generate data for further rankings and to achieve program objectives. The definition of "commit to specific local projects" in § 511.2 applies to this threshold standard and the performance adjustment standard in paragraph (f)(6) of § 511.32.

The second threshold deals with the provision of units affordable to lower-income families. To pass this threshold, a minimum of 80 percent of the units rehabilitated by a grantee must have rents that are initially, and remain, affordable to lower-income families for a period of up to seven years (for measurement purposes). Affordability ("rents affordable to lower-income families") is defined in 24 CFR 511.2 to mean that the sum of the utility allowance and other rent payable monthly to the owner with respect to a unit is at or below the applicable fair market rents (FMRs), or HUD-approved community-wide exception rents, for the Section 8 Existing Housing Program. Section 511.10(d) generally requires that a grantee selects projects located in neighborhoods where: (1) The median income does not exceed 80 percent of the median income for the area and (2) the unregulated rents are currently affordable to lower-income persons and are likely to remain affordable.

The affordability of rents has been established as a threshold because the provision of affordable housing is central to the purpose and objectives of the Rental Rehabilitation Program. HUD believes that the primary focus of the Program should be on the rehabilitation of a significant number of units that will continue to be affordable to lower-income tenants.

HUD recognizes that while selecting projects with affordable rents at the time rehabilitation occurs is relatively simple, predicting rent levels for seven years is more problematic. (The seven year period was selected because this period is often used by investors and lenders to project rent levels and cash flows for rental housing projects typical of those assisted through this program.) Because of the difficulty in predicting future rents, the affordability calculation will take into consideration the measuring period in which the rehabilitation was completed. A unit completed in the current measuring period will be weighted seven times as much as a project completed seven years ago. As a result, units rehabilitated in recent periods, when rent affordability is easier to predict, will have a significant bearing on whether the 80 percent threshold is met. The following table illustrates the effect the weighting factors might have after a three-year period.

ILLUSTRATIVE CALCULATION FOR A PROJECT REHABILITATED IN SEPT. 1, 1986

	1984 weight 1	1985 weight 2	1986 weight 3	Total
Total projects/units rehabilitated	5/28	11/44	21/104	37/176
Projects/units selected for sample	5/28	10/40	21/104	36/172
Number/percentage of units affordable	21(75%)	32(80%)	99(95%)	152(88%)
Projected number of affordable units	21 (.75×28)	35 (.80×44)	99 (.95×104)	155
Weighted number of affordable units	21(1×21)	70(2×35)	297(3×99)	388
Weighted number of total units	28(1×28)	88(2×44)	312(3×104)	428

$$\text{Performance score for affordable units} = \frac{\text{Weighted number of affordable units}}{\text{Weighted number of total units}} \times 100 \text{ or } \frac{388}{428} \times 100 = 91\%$$

Data on rents being charged on units rehabilitated with program funds for the most recent performance measuring period will be available from current information in the C/MI System. For all preceding periods, however, it will be necessary to obtain current rental data by surveying project owners. The Department will accomplish this by sending a Rental Rehabilitation Program Rent Verification Form to landlords, after receiving OMB clearance of the form. This form will be sent before September 1 of each year and will request information on rents being charged on units rehabilitated with program funds. When received from the landlords, this information will be entered into the C/MI System.

During the first few program years most rehabilitated properties will be surveyed to determine rents being

charged. In later program years, as more units are completed and there is sufficient experience with the program, a statistically generalizable sample of units will be used in the survey. During this later period, if a grantee fails to meet the 80 percent affordability threshold and this calculation is based on sample data, HUD will review the data and determine the precision of the estimate. The Department will consider a grantee to have failed this threshold test only if HUD has determined at a 95 percent confidence level that the true proportion of affordable units in the grantee's projects is less than 80 percent of the total number rehabilitated.

It is expected that most grantees will meet the minimum thresholds. Therefore, it is anticipated that most grantees' allocations will be determined on the basis of the amended performance adjustment standards in § 511.32(f).

B. Performance Adjustment Standards

The first performance adjustment standard (§ 511.32(f)(1)) rewards a grantee for the extent to which it exceeds the minimum threshold requirement that 80 percent of the units rehabilitated under the program are initially, and remain, affordable to lower-income families for a period of up to seven years. A primary objective of the Rental Rehabilitation Program is to increase the supply of standard housing units affordable to lower-income families. It is the Department's intent to provide an incentive to grantees to be extremely careful in their initial selection of neighborhoods and projects so as to ensure that rents charged on units rehabilitated with program funds will remain affordable to lower-income families. A grantee can potentially receive up to fifteen points under this standard, depending on its performance relative to all other grantees nationally.

The revised performance adjustment standard in § 511.32(f)(2) promotes the programmatic and statutory priority to rehabilitate units for families with children. Section 103(c)(2) of the Housing and Community Development Technical Amendments Act of 1984 (Pub. L. 98–479, effective October 17, 1984) revised section 17(c)(3)(A) of the Act to clarify that the Secretary shall assure that an equitable share of funds is used to provide units for families with children, particularly families requiring three or more bedroom units. The Department has determined that the three or more bedroom feature of this amendment can be satisfied if at least 15 percent of the units rehabilitated under the program are units of three or more bedrooms.

The Department is applying the revised performance standard in § 511.32(f)(2) to both Fiscal Years 1984 and 1985 funds, notwithstanding that the specific reference to three-bedroom units in section 17(c)(3)(A) of the Act was effective on October 17, 1984, and is not directly applicable to Fiscal Year 1984 funds. HUD has determined that this position is valid, primarily because section 17(c)(3)(A), prior to the 1984 Amendments, was interpreted in the April 1984 rule (§ 511.10(k)) to require each grantee to make available at least seventy percent of its rental rehabilitation grant amount for units with two *or more* bedrooms. This language does not preclude a three-bedroom standard, and even before the 1984 Amendments, HUD had encouraged grantees to provide units larger than two bedrooms to meet the needs of eligible families with children. In addition, since the performance adjustment system will not be used until Fiscal Year 1987 allocations are made, all grantees should have ample time to give priority to the development of three-bedroom units.

The revised performance standard at § 511.32(f)(2) measures the extent to which a grantee rehabilitates units containing two or more bedrooms and three or more bedrooms. There are two formulas used in order to obtain the result:

$$\text{Percent of units with two or more bedrooms rehabilitated} = \frac{\text{Number of units with two or more bedrooms rehabilitated}}{\text{Total number of units rehabilitated during the performance measuring period}} \times 100$$

$$\text{Percent of units with three or more bedrooms} = \frac{\text{Number of units with three or more bedrooms rehabilitated}}{\text{Total number of units rehabilitated during the performance measuring period}} \times 100$$

The first formula refers to the total number of two or more bedroom units rehabilitated as a percentage of the total units rehabilitated; the second, the total number of three or more bedroom units as a percentage of the total units rehabilitated. In each case, the results are rank-ordered and a score given. The final calculation averages the two scores and ranks this result. The grantee that has performed particularly well in providing two and three or more bedroom units will score well on this standard. The grantee that has not provided three or more bedroom units will probably not score well, as a result of averaging the scores from the two formulas.

The C/MI System will contain information on bedroom size for all units rehabilitated under the program. It will be possible to determine whether the Department's policy for the use of Fiscal Year 1985 funds—that 15 percent of the total units rehabilitated under the program are three or more bedroom units is met.

The amended performance adjustment standard at § 511.32(f)(3) rewards those grantees that target rehabilitation to very low-income families residing in substandard units. Section 17(c)(3)(B) of the Act mandates that a priority be given to projects containing units in substandard condition which are occupied by very low-income families. Section 511.10(*l*) of the April 1984 rule requires that each grantee shall ensure that a priority will be given to rehabilitating projects occupied before rehabilitation by very low-income families. Consequently, the amended performance standard at § 511.32(f)(3) measures the extent to which a grantee rehabilitates units in which very low-income families reside, where these families are not displaced from the project as a result of the rehabilitation. The formula for this performance standard is:

$$\text{Percent of units with very low-income families not displaced from the project} = \frac{\text{Units before rehabilitation occupied by very low income families not displaced from the project}}{\text{Total number of units rehabilitated during the performance measuring period}} \times 100$$

The performance adjustment standards in §§ 511.32(f) (4) and (5) measure the extent to which subsidy dollars have been minimized and

private dollars have been maximized in projects rehabilitated under the program. Because of the limited amount of Rental Rehabilitation Program resources, the Department's objective is to provide an incentive to grantees participating in the program to provide as many standard housing units as possible to lower-income families at the lowest cost. Such an approach is also statutorily encouraged. Section 17(c)(1)(C) of the Act requires grantees to consider and describe in their program descriptions how they will most efficiently use the Federal resources to be made available for the local program. Sections 17(c)(2) (C) and (E) of the Act set limits on the amount of rental rehabilitation dollars that may be invested by a grantee in a project, in order to achieve the objective of providing as many standard housing units as possible with limited resources. Section 17(c)(2)(C) generally requires that grant assistance for any structure not exceed 50 percent of the total costs associated with the rehabilitation of the structure. Section 17(c)(2)(E) generally requires that the amount of rental rehabilitation assistance provided shall not exceed $5,000 per unit, with limited exceptions. In implementing the Act, § 511.10(e) of the April 1984 rule further elaborates on the financial limitations for the use of program funds.

The amended performance adjustment standard in § 511.32(f)(4) rewards those grantees that minimize the gross public subsidies, including public funds other than Rental Rehabilitation Program funds, e.g., Community Development Block Grants or Urban Development Action Grants. Grantees that have the lowest public subsidy per unit will receive the highest score under this standard. The method of calculation for this performance standard is:

$$\text{Per unit with public subsidy} = \frac{\text{Total public dollars reported for all projects completed}}{\text{Total number of units completed during the performance measuring period}}$$

Under § 511.32(f)(5), the performance adjustment standard measures a grantee's ability to minimize the percentage of public funds in relation to total costs for projects rehabilitated under the program. Related to this objective of minimizing public subsidy dollars per unit, is the objective of maximizing the leveraging of private dollars invested in projects. The lower the percentage of public funds, the higher the score that a grantee will receive under this standard. The method of calculation for this performance standard is:

$$\text{Percent of public rehabilitation funds for projects} = \frac{\text{Total public rehabilitation funds, all projects}}{\text{Total rehabilitation costs, all projects}} \times 100$$

Scores for standards in §§ 511.32(f)(4) and 511.32(f)(5) each have a maximum value of fifteen points, totaling 30 points for these two standards. This reflects the high priority the Department places on the ability of grantees to provide the maximum number of standard affordable housing units to lower-income families with the least amount of public subsidy dollars.

It is the Department's intent to spend Rental Rehabilitation Program funds as expeditiously as possible. Under the amended performance adjustment standard at § 511.32(f)(6), a grantee will be measured on the extent to which program funds have been committed to projects and the timely completion of these projects. ("Commit to specific local projects" is defined in § 511.2 of the current regulations.) The method of calculation for this performance standard is:

$$\text{Percent of commitments} = \frac{\text{Total rental rehabilitation funds committed for all projects for the last three performance measuring periods}}{\text{Total adjusted formula share (irrespective of any fund reallocations under § 511.33) for the last three performance measuring periods}} \times 100$$

$$\text{Percent of completions} = \frac{\text{Total rental rehabilitation funds for all projects completed for the last three performance measuring periods}}{\text{Total adjusted formula share (irrespective of any fund reallocations under § 511.33) for the last three performance measuring periods}} \times 100$$

This standard in § 511.32(f)(6) rewards a grantee that has a high level of dollar commitments and project completions in relation to its adjusted formula allocation. Both project commitments and completions have been included in this standard, since they best represent a grantee's progress in carrying out its program. The project commitment and completion scores are averaged together to compute a final score.

A period of up to three years was chosen for review of dollar commitments and completions in order to compensate for the fluctuations that may occur in a specific performance measuring period. For example, a grantee may have started slowly in the early years of the program, but dramatically improved its capacity in the more recent years. The three years are averaged together to show an overall performance capability over the three-year period. The adjusted formula shares shown in the denominator of the two equations represent the annual formula allocation awarded to a grantee for up to three fiscal years after adjustments have been made. It does not include any reallocations of funds that might have occurred from the application of § 511.33 during those years since this would unnecessarily bias the statistics. A superior performer under this standard will have both a

high level of dollar commitments and a high level of project completions in relation to its adjusted formula allocation.

C. Performance Adjustment Ranking System

Section 511.32(g) of the rule sets out the performance adjustment ranking system that will be implemented in Fiscal Year 1987. The ranking system will be used by the Department to readjust the fund allocation for a city, urban county, or consortium, or a State administering a rental rehabilitation program by up to 15 percent above and below the amount of the formula-based annual allocation.

In the ranking system under § 511.32(g), two formulas are included for the calculation of points to a grantee for each adjustment standard in § 511.32(f) and the percent adjustment to the formula allocation for each grantee.

The formula for the calculation of points to grantees for each adjustment standard in § 511.32(f) is stated in § 511.32(g)(3). As an example of a calculation under this formula, assume the following: six grantees; five unique scores under any standard ("factor") in § 511.32(f) with a maximum of 15 points; two of the five grantees with the identical score placing them in rank 2, behind the grantee with the highest score in rank 1. According to the formula, the grantee with the highest score (rank 1) receives a score of 15 points; each of the two grantees with identical scores in rank 2 receives 12 points; and the three grantees with ranks 3, 4, and 5 receive 9 points, 6 points, and 3 points, respectively.

The formula for the calculation of the percent adjustment to the formula allocations for each grantee is stated in § 511.32(g)(5)(i). As an example of a calculation under this formula, assume that there are 80 grantees, but only 61 ranking groups, i.e., 61 unique total scores. In the initial adjustments under § 511.32(g)(5) (iii) and (iv), grantees in ranking group 61 will lose 15 percent of their formula allocation. Similarly, grantees in ranking group 1 will receive an increase of 15 percent. Grantees in ranking group 31 will not have their formula allocations adjusted, because this ranking group represents the median ranking. Grantees in ranking groups 2 and 3 will initially have their formula allocations increased by 14.5 and 14 percent, respectively. Similar calculations will be made for grantees in all other ranking groups.

IV. Sample Calculations for Performance Adjustments

Following is a detailed example of the actual steps that are to be used in establishing whether grantees have met the two thresholds and in measuring relative performance on the adjustment standards. The examples use five fictitious grantees-City A, City B, City C, City D, and City E to illustrate the system. The final score shows the total overall performance of the grantees. (This example does not illustrate the application of the methodology in § 511.32(g) to be used for the actual percentage readjustment of the formula allocations. Examples of certain calculations under § 511.32(g) are provided in unit III.C of this preamble.)

Threshold 1: Funds committed to one or more specific local projects during the most recent performance measuring period.

Commitment of funds	Total committed
City A	$166,000
City B	490,000
City C	360,292
City D	191,000
City E	0

City E will be among those grantees at the bottom of the performance adjustment ranking and will lose up to fifteen percent of its original allocated funds. Further calculations will not be performed.

Threshold 2: 80 percent of units rehabilitated with program funds under 24 CFR Part 511 are and have remained affordable for up to seven years.

- Rental charged on units rehabilitated with program funds must be at or less than published fair market rents or approved community-wide exception rents under the Section 8 Existing Housing Program to be considered affordable.
- After affordable units are determined for each year in which units are completed, both the affordable units and total units rehabilitated are multiplied by the weighting factor. The weighting factor is from one to seven, ranging from a weight of 7 for units rehabilitated in the current year, to a weight of 1 for units rehabilitated 7 years earlier.

Grantee	1984(1)[1]	1985(2)[1]	1986(3)[1]	Weighted total	Percent affordable	Meets threshold
City D						
Affordable	13(1) = 13	17(2) = 34	13(3) = 39	86		
Not affordable	3	3	0			
Total	16(1) = 16	20(2) = 40	13(3) = 39	95	86/95 = 90.53%	Yes.
City B						
Affordable	19(1) = 19	24(2) = 48	25(3) = 75	142		
Not affordable	11	6	1			
Total	30(1) = 30	30(2) = 60	26(3) = 78	168	142/168 = 84.52%	Yes.
City C						
Affordable	18(1) = 18	20(2) = 40	17(3) = 51	109		
Not affordable	7	6	2			
Total	25(1) = 25	26(2) = 52	19(3) = 57	134	108/134 = 81%	Yes.
City A						
Affordable	33(1) = 33	30(2) = 60	10(3) = 30	123		
Not affordable	14	10	5			
Total	47(1) = 47	40(2) = 80	15(3) = 45	172	132/172 = 72%	No.

[1] Weighting factor.

Even though City A spent 95 percent of its money, it will be placed at the bottom of the performance adjustment ranking since it did not meet the affordability threshold. The three cities that will be compared on the performance criteria are thus B, C, and D.

Performance Standard 1

The extent to which more than 80 percent of units rehabilitated are affordable.

- Select grantees that meet the minimum threshold from above calculation.
- Rank grantees from high to low.
- Assign up to fifteen points. Scores are calculated according to the formula in § 511.32(g)(3).

EXAMPLE FOR PERFORMANCE ADJUSTMENT STANDARD NO. 1

Grantees—ranked from highest to lowest	Percent affordable	Score
City D	90.53	15
City B	84.52	10
City C	81	5

Performance Standard 2

The extent to which Rental Rehabilitation grants are used to rehabilitate units containing two or more bedrooms and three or more bedrooms.

• Total number of two-bedroom units or greater divided by total units rehabilitated in most recent performance measuring period. Rank order from highest to lowest and assign numerical score up to 7.5 points.

• Total number of three-bedroom units or greater divided by total units rehabilitated in most recent performance measuring period. Rank order from highest to lowest and assign numerical score up to 7.5 points.

• Add scores together for the above calculations and divided by two for new score. Rerank from high to low and assign final score. Scores are calculated according to the formula in § 511.32(g)(3).

EXAMPLE FOR PERFORMANCE ADJUSTMENT STANDARD NO. 2

[Units with two or more bedrooms]

Grantees—ranked from highest to lowest	Number 2 bedrooms units +	Total units	Percent 2 bedrooms +	Score
City B	20	26	77	7.5
City D	9	13	69	5
City C	13	19	68	2.5

[Units with three or more bedrooms]

Grantees—ranked from highest to lowest	Number 3 bedroom units +	Total units	Percent 3 bedrooms +	Score
City D	5	13	38	7.5
City C	5	19	26	5
City B	5	26	19	2.5

[Averaged score]

Grantees—ranked from highest to lowest	Number 2 bedrooms + score	Number 3 bedrooms + score	Average score	Final score
City D	5	7.5	6.25	15
City B	7.5	2.5	5	10
City C	2.5	5	3.75	5

Performance Standard 3

The extent to which units rehabilitated with Rental Rehabilitation grants were occupied by very low income families before rehabilitation and these families were not displaced from the project.

• Total number of very low income tenants retained from Project Completion Form divided by total units rehabilitated in most recent performance measuring period.

• Rank order from highest to lowest and assign numerical score up to fifteen points. Scores are calculated according to the formula in § 511.32(g)(3).

EXAMPLE OF PERFORMANCE ADJUSTMENT STANDARD NO. 3

Grantee—rank ordered from highest to lowest	Low-income families not displaced	Total units rehabilitated	Percent low-income families not displaced	Final score
City D	13	13	100	15
City B	21	26	81	10
City C	15	19	79	5

Performance Standard 4

The extent to which the gross amount of total public subsidy funds have been minimized per unit.

• Total public dollars invested for all completed projects divided by total units completed for most recent performance measuring year.

• Rank order from lowest to highest and assign numerical score up to fifteen points. Scores are calculated according to the formula in § 511.32(g)(3).

EXAMPLE OF PERFORMANCE ADJUSTMENT STANDARD NO. 4

Grantees—rank ordered from lowest to highest	Total public dollars	Total units rehabilitated	Public dollars per unit rehabilitated	Final score
City D	54,215	13	4,170.00	15
City B	110,000	26	4,230.77	10
City C	97,000	19	5,105.26	5

Performance Standard 5

The extent to which the amount of public subsidy funds as a percentage of total rehabilitation costs have been minimized.

• Total public dollars for all projects divided by total rehabilitation cost for all projects for the most recent performance measuring period.

• Rank order from lowest percent to highest percent and assign numerical score not to exceed fifteen points. Scores are calculated according to the formula in § 511.32(g)(3).

EXAMPLE OF PERFORMANCE ADJUSTMENT STANDARD NO. 5

Grantees—rank ordered from lowest to highest	Total rehabilitation cost	Total public dollars	Public funds as percent of rehabilitation cost (percent)	Final score
City D	$162,645	54,215	33	15
City B	242,500	97,000	40	10
City C	220,000	110,000	50	5

Performance Standard 6

Extent to which rental rehabilitation grant funds have been committed to specific local projects and projects have been completed over the preceding three performance measuring periods.

• Total dollars committed for last three performance measuring periods divided by adjusted formula share (original obligation) for the last three periods.

• Rank order from highest to lowest and assign numerical score not to exceed 7.5 points.

• Total dollars disbursed for completed projects for last three performance measuring periods divided by adjusted formula share (original obligation) for the last three periods.

• Rank order from highest to lowest and assign numerical score not to exceed fifteen points. Scores are calculated according to the formula in § 511.32(g)(3).

• Average the two scores together and assign final score.

EXAMPLE OF PERFORMANCE ADJUSTMENT STANDARD NO. 6

[Commitments]

Grantees—Ranked from highest to lowest	Commitments for 3 periods	Total adjusted formula share for 3 periods	Percent commitments	Final score
City B	$490,000	$505,000	97	7.5
City D	191,000	205,000	93	5
City C	360,292	388,292	92	2.5

[Completions]

Grantees—Ranked from highest to lowest	Completions for 3 periods	Total adjusted formula share for 3 periods	Percent completions	Final score
City D	$182,915	$205,000	89	7.5
City C	331,538	388,292	85	5
City B	413,360	505,000	82	2.5

[Averaged score]

Grantees—Ranked from highest to lowest	Commitment score	Completion score	Average score	Final score
City D	5	7.5	6.25	15
City B	7.5	2.5	5.00	10
City C	2.5	5.00	3.75	5

[Final scores for adjustment standards]

Grantee	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	Final score
City D	15	15	15	15	15	15	90
City B	10	10	10	10	10	10	60
City C	5	5	5	5	5	5	30
City A							0
City E							0

V. Miscellaneous

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50, which implements section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the General Counsel, Rules Docket Clerk, at the above address.

This rule does not constitute a "major rule" as that term is defined in Section 1(b) of the Executive Order on Federal Regulation issued by the President on February 17, 1981 (Executive Order 12291). This rule does not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions, nor does it significantly adversely affect competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Analysis of the rule indicates that it would not have annual effect of the economy of $100 million or more.

Under the provisions of section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601), the Undersigned hereby certifies that this rule does not have significant economic impact on a substantial number of small entities, because statutorily eligible grantees and State recipients are relatively larger cities, urban counties or States and the rental rehabilitation grant amounts to be made available to any grantee are relatively small in relation to other sources of Federal funding for State and local government in relation to private investment in rental housing.

The information collection requirements contained in this rule have been approved by the Office of Management and Budget and assigned approval number 2506–0080.

This rule was listed as item number 912 in the Department's Semiannual Agenda of Regulations published on October 29, 1985 (50 FR 44166, 44200) under Executive Order 12291 and the Regulatory Flexibility Act.

The Catalog of Federal Domestic Assistance program number applicable to this rule is 14.230.

List of Subjects in 24 CFR Part 511

Rental rehabilitation grants, Administrative practice and procedure, Grant programs: Housing and community development, Low and moderate income housing, Reporting and recordkeeping requirements.

Accordingly, 24 CFR Part 511 is amended as follows:

PART 511—RENTAL REHABILITATION GRANT PROGRAM

1. The authority citation for 24 CFR Part 511 continues to read as follows:

Authority: Section 17 of the United States Housing Act of 1937, 42 U.S.C. 1437o; sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

2. Section 511.32 is revised to read as follows:

§ 511.32 Performance adjustments to formula allocation.

(a) *General.* Beginning with Fiscal Year 1987, HUD will adjust the annual allocation for a city, urban county, consortium or State administering a rental rehabilitation program for each fiscal year by up to 15 percent above or below the formula allocation for that year. Adjustments will be based on an annual review of performance in carrying out rental rehabilitation activities using the performance standards described in paragraph (f) of this section, and based on the performance adjustment ranking system described in paragraph (g) of this section. Adjustments will be made for two categories of grantees. All cities, urban counties, and consortia will be ranked in a national rating. Similarly, all States will be compared to each other and ranked according to their performance. All fund allocations in each category will be calculated and adjusted by computer based on the relative ranking of the grantees, so that the upward and downward adjustments "net out" on a national basis.

(b) *Performance measuring period.* The performance measuring period runs from September 1 through August 31 and is used to evaluate grantees on the threshold performance standards identified at § 511.32(e) and additional performance standards at § 511.32(f)(1)–(6). Data entered into the Cash and Management Information (C/MI) System during the performance measuring period will be used to calculate the ranking of the grantees.

(c) *Timing of review.* Performance evaluations will take place as of September 1 of each year beginning September 1, 1985. However, the Department's readjustment of the annual fund allocations based on performance evaluations applying the performance adjustment standards of paragraphs (e) and (f) of this section will not begin until Fiscal Year 1987.

(d) *Source of data.* Data for all the performance standards will be obtained from the information provided by grantees to the Cash and Management Information (C/MI) System. The C/MI System permits HUD to collect detailed project and tenant information in connection with the electronic disbursement of program funds to grantees. All data submitted through the C/MI is collected and processed by HUD Headquarters staff under direction of the Assistant Secretary for Administration. Information collected under the C/MI System has been approved by OMB and assigned approval number 2506–0080.

(e) *Threshold performance standards.* In order to receive any points on the six performance adjustment standards, grantees must pass the following two performance thresholds. Failure to pass these thresholds automatically places grantees at the bottom of the ranking described in paragraph (g) below and results in the loss of 15 percent of their grant funds.

(1) Grantees must have committed rental rehabilitation grants funds to one or more specific local projects during the most recent performance measuring period.

(2) At least 80 percent (calculated on a weighted basis under paragraph (e)(2)(i)) of the units in projects renovated with rental rehabilitation grants in the preceding seven performance measuring periods must have rents that are affordable to lower-income families.

(i) *Method of Calculations.* All rents will be compared to the most recently published (as of September 1) fair market rents under the Section 8 Existing Housing Program or any community-wide exception rents approved by HUD to determine if rents charged are affordable to lower-income families as defined at § 511.2. The percentage of affordable units derived from the sample for each performance measuring period will be projected to

the total number of units completed in each performance measuring period. HUD will assign different weights from one to seven to the data for each performance measuring period which reflects the period in which the project was completed.

(ii) *Source of data.* Project Completion Form of the C/MI System for projects completed in the most recent performance measuring period and HUD-conducted, statistically valid, random sample of rents for representative projects completed in previous periods.

(iii) *Period of evaluation.* Most recent seven performance measuring periods.

(f) *Performance standards.* After a determination by HUD that a grantee passes the two thresholds, its performance is measured in comparison to all other grantees on the following six standards.

(1) Extent to which more than 80 percent of units in projects renovated with rental rehabilitation grants have rents that are affordable to lower-income families.

(i) *Points.* Up to fifteen (15) points.

(ii) *Method of calculations.* See § 511.32(e)(2)(i).

(iii) *Source of data.* See § 511.32(e)(2)(ii).

(iv) *Period of evaluation.* See § 511.32(e)(2)(iii).

(2) Extent to which rental rehabilitation grants are used to rehabilitate units containing two or more bedrooms and three or more bedrooms.

(i) *Points.* Up to fifteen (15) points.

(ii) *Method of calculation.*

(A) The results of grantee's performance on each of the two formulas listed below will be ranked; grantees will receive a score, not to exceed 7.5 points on each formula; and, the two scores will be averaged together to calculate the final score for this performance standard. The percent of units with two or more bedrooms may be calculated by: (*1*) Dividing the number of units with two or more bedrooms rehabilitated by the total number of units rehabilitated during the performance measuring period, and (*2*) multiplying by 100.

(B) The percent of units with three or more bedrooms may be calculated by: (*1*) Dividing the number of units with three or more bedrooms rehabilitated by the total number of units rehabilitated during the performance measuring period, and (*2*) multiplying by 100.

(iii) *Source of data.* Project Completion Report of the C/MI System.

(iv) *Period of evaluation.* Most recent performance measuring period.

(3) Extent to which units rehabilitated with rental rehabilitation grants were occupied by very low income families before rehabilitation and these families were not displaced from the project.

(i) *Points.* Up to fifteen (15) points.

(ii) *Method of calculation.* The percent of units with very low-income families not displaced may be calculated by: (A) Dividing the number of units before rehabilitation occupied by very low income families not displaced by the total number of units rehabilitated during the performance measuring period and (B) multiplying by 100.

(iii) *Source of data.* Project Completion Report of the C/MI System.

(iv) *Period of evaluation.* Most recent performance measuring period.

(4) Extent to which the gross amount of total public subsidy funds has been minimized per unit.

(i) *Points.* Up to fifteen (15) points.

(ii) *Definition of "public funds".* Public funds are any monies invested in a project made available through Federal, State, or local government. Monies raised through tax exempt borrowing will be treated as 80 percent private funding and 20 percent public funding.

(iii) *Method of calculating.* The per unit public subsidy for projects may be calculated by dividing the total public dollars reported for all projects completed by the total number of units completed during the performance measuring period.

(iv) *Source of data.* Project Completion Report of the C/MI System.

(v) *Period of evaluation.* Most recent performance measuring period.

(5) Extent to which the amount of public subsidy funds as a percentage of total rehabilitation costs have been minimized.

(i) *Points.* Up to fifteen (15) points.

(ii) *Method for calculation.* The percent of public subsidy funds as related to total rehabilitation costs may be calculated by: (A) Dividing the total public funds for rental rehabilitation projects by the total rehabilitation cost for the projects and (B) multiplying by 100.

(iii) *Source of data.* Project Completion Report of C/MI System.

(iv) *Period of evaluation.* Most recent performance measuring period.

(6) Extent to which rental rehabilitation grant funds have been committed to specific local projects and to which projects have been completed over the preceding three performance measuring periods.

(i) *Points.* Up to fifteen (15) points.

(ii) *Method for calculation.*

(A) The results of grantee's performance on funds commitment and project completion below will be ranked; grantees will receive a score, not to exceed 7.5 points on each formula; and the two scores will be averaged together to calculate the final score on this performance standard. The percent of funds committed may be calculated by: (*1*) Dividing the total rental rehabilitation dollars committed for projects for the last three performance measuring periods by the total adjusted share (irrespective of any fund reallocations under § 511.33) for the last three performance measuring periods, and (*2*) multiplying by 100.

(B) The percentage of projects completed may be calculated by: (*1*) dividing the total rental rehabilitation funds for all projects completed for the last three performance measuring periods by the total adjusted formula share (irrespective of any fund reallocations under § 511.33) for the last three performance measuring periods, and (*2*) multiplying by 100.

(iii) *Source of data.* For fund commitments, Pre-Rehabilitation Report of C/MI System; for funds to completed projects, Project Completion Report of the C/MI System; for total adjusted formula share, sum of annual grants, including performance adjustments (irrespective of any reallocations made under § 511.33).

(iv) *Period of evaluation.* Most recent three performance measuring periods.

(g) *Ranking and scoring.*

(1) Beginning in Fiscal Year 1987, all grantees that meet the two threshold criteria described at § 511.32(e) will be further evaluated annually on the six performance standards detailed at § 511.32(f). The following provisions describe the ranking system that will be used by the Department in Fiscal Year 1987 to readjust the fund allocation for a city, urban county, consortium, or a State administering a rental rehabilitation program by up to 15 percent above and below the amount of the formula-based annual allocation.

(2) All city, urban county, and consortium grantees will be ranked together and all State grantees will be ranked together so that the reallocations in each of the two groups "net out".

(3) Grantees in each of the two groups identified in paragraph (g)(2) above will be ranked separately on each performance adjustment standard in § 511.32(f) and a score assigned commensurate with the ranking. Points for each standard will be calculated according to the following formula:

Points to Grantee Z for Each Factor in § 511.32(f) =

$$\text{Maximum factor points} - \left[\frac{\text{Maximum factor points}}{\text{Number of unique scores for the factors in § 511.32(f)}} \times (\text{Z's rank} - 1) \right]$$

Scores on all standards then will be added together to establish a total score for each grantee.

(4) In paragraph (g)(3) of this section, "maximum factor points" generally refers to the total of fifteen possible points that may be achieved for meeting each of the six adjustment standards ("factors") in § 511.32(f). However, in the adjustment standard at § 511.32(f)(2), "maximum factor points" refers to a total of 7.5 points to measure the extent that the grants are used to rehabilitate units containing two or more bedrooms and three or more bedrooms, respectively. In addition, in the adjustment standard at § 511.32(f)(6), "maximum factor points" refers to a total of 7.5 points to measure the extent to which the grants have been committed to specific local projects and to which projects have been completed over the preceding 3 performance measuring periods, respectively. "Unique scores for the factor" refers to the total of number of individual scores for eligible grantees for a particular adjustment standard ("factor") that do not duplicate other scores for that factor.

(5) Based on their total scores, grantees in each group (both the group of participating States and the group of grantee cities, urban counties, and consortia) will be ranked. The adjustments to formula allocations will be calculated in the following manner:

(i) All grantees will be ranked according to their scores. Grantees who fail to meet one or both threshold requirements will be placed at the bottom of their respective groups. Grantees with the same score will be given an identical rank and be included in the same group. Initial adjustments will range from negative 15 percent to positive 15 percent based on their rank. Grantees in the group with the highest ranking (those grantees with the highest score achieved under the six adjustment standards in § 511.32(f)) will have their formula allocations raised by 15 percent. Grantees in the group with the lowest ranking (i.e., any grantees who do not meet the two threshold adjustment standards) will have their allocations lowered by 15 percent. Grantees in the group with the median ranking will not have their allocations adjusted. For all other grantees, formula allocations will be adjusted according to the following formula:

Percent Adjustment =

$$15 - \left[\frac{(\text{Rank} - 1) \times 30}{(\text{Total Number of Ranking Groups} - 1)} \right]$$

The multiplier of 30 in the bracketed expression in the formula represents the size of the total interval for the adjustments under § 511.32(g), i.e., the range of percentage adjustments from positive 15 percent to negative 15 percent. If there is an even number of ranking groups, this formula may be adjusted slightly. Initial calculations of adjustments will be made at constant intervals in the range from positive 15 percent to negative 15 percent, with the size of the intervals dependent on the number of ranking groups. However, it may be necessary to recalculate adjustments subject to the qualifications described in paragraph (g)(5) (v) and (vi) of this section.

(ii) Under the methodology of this section, funds withdrawn from grantees with negative scores will be available for transfer to those grantees with positive scores.

(iii) Grantees with the same rank and a negative score will have their original formula allocation reduced by the appropriate percent. (For example, according to this initial adjustment, a grantee with a score of negative 10 percent and an original formula allocation of $200,000 would have its allocation reduced by $20,000.)

(iv) Grantees with the same rank and a positive score will have their original formula allocation increased by the appropriate percent. (For example, according to this initial adjustment, a grantee with a score of positive 10 percent and an original formula allocation of $200,000 would have its allocation increased by $20,000.)

(v) If fund amounts initially withdrawn from grantees with negative scores exceed the funds to be given to grantees with positive scores, the fund amounts that each grantee with a negative score would otherwise lose will be reduced based on prorating each calculated negative adjustment by a ratio determined by dividing the total funds to be distributed to grantees with positive scores by the total funds initially calculated to be withdrawn from grantees with negative scores.

(vi) If fund amounts initially withdrawn from grantees with negative scores are insufficient to reward those grantees with positive scores, the fund amounts that each grantee with a positive score would otherwise receive will be reduced based on prorating each calculated positive adjustment by a ratio determined by dividing the total funds withdrawn from grantees with negative scores by the total funds initially calculated to be distributed to grantees with positive scores.

Dated: November 13, 1985.

Alfred C. Moran,

Assistant Secretary for Community Planning and Development.

[FR Doc. 85-27606 Filed 12-9-85; 8:45 am]

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federal register

Tuesday
December 10, 1985

Part VII

Federal Reserve System

12 CFR Part 207

Purchase of Debt Securities To Finance Corporate Takeovers; Proposed Rules

FEDERAL RESERVE SYSTEM

12 CFR Part 207

[Regulation G; Docket No. R-0562]

Securities Credit by Persons Other Than Banks, Brokers, or Dealers; Purchase of Debt Securities To Finance Corporate Takeovers

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed interpretative rule; request for comment.

SUMMARY: Questions have been raised as to whether the margin requirements in Regulation G apply to the purchase of debt securities that are issued to finance the acquisition of the margin stock of a target company by a shell corporation as part of a takeover attempt. Because this type of transaction clearly involves "purpose credit" as defined in Regulation G and does not involve any direct security agreement, the resolution of the issue turns on whether the purchaser of these securities would be viewed as a person extending credit "indirectly secured" by the margin stock. The Board has proposed an interpretation of Regulation G that concludes that this type of transaction does constitute an extension of credit that is "indirectly secured" by the target company's margin stock unless there is specific evidence, such as a guaranty by the parent of the shell corporation, that would lead to a contrary conclusion. The proposed interpretation further states that for purposes of the interpretation, there is no difference between privately placed and publicly distributed debt securities.

The proposed interpretation declines to conclude that debt securities issued by an operating company with income and substantial assets should be presumed to be "indirectly secured" by the margin stock of the target company. In that circumstance, the proposal states that the purchasers of the debt securities may be relying on sources of repayment other than the margin stock for repayment of the credit.

While the proposed interpretation, which is intended to deal with a relatively limited factual situation, is not ordinarily a matter for public comment, in order to assure that there are no unanticipated effects of the proposed interpretation, the Board is providing a short period for public comment on the terms of the proposal. After consideration of the public comments, the Board intends to take final action with respect to this interpretation by December 31, 1985.

The proposed interpretation, if adopted, would not apply to written contracts to extend credit entered into prior to the effective date of the interpretation. See Federal Reserve Regulatory Service ¶ 5–306.

DATE: Comments must be received by December 23, 1985.

ADDRESS: All comments, which should refer to Docket No. R–0562, should be mailed to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th and Constitution Avenue NW., 20551, or should be delivered to the Office of the Secretary, Room 2200, Eccles Building, 20th and Constitution Avenue NW., between the hours of 8:45 a.m. and 5:15 p.m. weekdays. Comments may be inspected in Room 1122, Eccles Building between 8:45 a.m. and 5:15 p.m. weekdays.

FOR FURTHER INFORMATION CONTACT: Laura Homer, Securities Credit Officer, Division of Banking Supervision and Regulation, (202) 452–2781; or James Michaels, Attorney, Legal Division, (202) 452–3582.

Lists of Subjects in 12 CFR Part 207

Credit, Margin, Margin requirements, Reporting and recordkeeping requirements, Securities.

Pursuant to the Board's authority under sections 7 and 23 of the Securities Exchange Act of 1934 as amended (15 U.S.C. 78 g and w) the Board proposes to adopt the following interpretation and to amend 12 CFR 207.

1. The authority citation for 12 CFR Part 207 continues to read as follows:

Authority: Secs. 3, 7, 8, 17 and 23 of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78c, 78g, 78h, 78q and 78w).

2. Section 207.112 is added to read as follows:

§ 207.112 Purchase of debt securities to finance corporate takeovers.

(a) Questions have been raised as to whether the margin requirements in Regulation G apply to the purchase of debt securities that are issued to finance the acquisition of stock of a target company as part of a takeover attempt.

(b) In some corporate takeovers financed by debt securities, the debt securities would be issued by a shell corporation that is an affiliate of the acquiring company. The typical shell corporation has virtually no operations, and no significant business function other than to acquire and hold stock of a target company. The shell vehicle would use the proceeds of the debt securities to finance a tender offer for the stock of the target company, which typically is margin stock. If the tender offer is successful, the shell corporation seeks to merge with the target company.

(c) Where the stock of the target company is margin stock (as defined in § 207.2(i)), the purchase of the debt securities issued to finance the acquisition clearly involves "purpose credit" (as defined in § 207.2(l)). In addition, such debt securities typically are purchased only by sophisticated investors in very large minimum denominations, so that the purchasers may be "lenders" for purposes of Regulation G. See 12 CFR 207.2(h). Since the debt securities typically contain no direct security agreement involving the margin stock, applicability of the lending restrictions of the Regulation turns on whether the arrangement constitutes an extension of credit that is secured indirectly by margin stock.

(d) As the Board has recognized, "indirect security" can encompass a wide variety of arrangements between lenders and borrowers with respect to margin stock collateral that serve to protect the lenders' interest in assuring that a credit is repaid where the lenders do not have a conventional direct security interest in the collateral. See 12 CFR 221.113. However, a credit is not indirectly secured by margin stock if the lender in good faith has not relied on the margin stock as collateral in extending or maintaining credit. See 12 CFR 207.2(f)(2)(iv).

(e) The Board is of the view that, in the situation described above, the debt securities would be indirectly secured by the margin stock to be acquired by the shell acquisition vehicle. The staff has expressed the view that nominally unsecured credit extended to an investment company, a substantial portion of whose assets consist of margin stock, is indirectly secured by the margin stock. See Federal Reserve Regulatory Service ¶ 5–917.12. This opinion notes that the investment company has substantially no assets other than margin stock to support indebtedness and thus credit could not be extended to such a company in good faith without reliance on the margin stock.

(f) The Board believes that this rationale applies to the debt securities issued by the shell acquisition vehicle described above. At the time the debt securities are issued, the shell corporation has substantially no assets to support the credit other than the margin stock that it has acquired or intends to acquire and has no significant business function other than to hold the stock of the target company in order to facilitate the acquisition. Moreover, it is possible that the shell may hold the

margin stock for a significant and indefinite period of time, if defensive measures by the target prevent consummation of the acquisition. Because of the difficulty in predicting the outcome of a contested takeover at the time that credit is extended to the shell corporation, the Board believes that the purchasers of the debt securities could not, in good faith, lend without reliance on the margin stock. The presumption that the credit is indirectly secured by margin stock in these circumstances would not apply if there is additional, specific evidence that lenders could in good faith rely on other assets to support the credit, such as a guaranty by the shell's parent company that has substantial non-margin stock assets.

(g) The Board's conclusion is also supported by the fact that in these circumstances there is a practical restriction on the ability of a shell corporation to dispose of the margin stock of the target company. "Indirectly secured" is defined in § 207.2(f) of the regulation to include any arrangement under which the customer's right or ability to sell, pledge, or otherwise dispose of margin stock owned by the customer is in any way restricted while the credit remains outstanding. The purchasers of debt securities issued by a shell acquisition vehicle to finance a takeover attempt clearly understand that the shell intends to acquire the margin stock of the target company in order to effect the acquisition of that company. This understanding represents a practical restriction on the ability of the shell corporation to dispose of the target's margin stock and to acquire other assets with the proceeds of the credit.

(h) In addition, questions have been raised as to whether the margin regulations would apply where an operating company, rather than a shell acquisition vehicle, issues debt securities to finance the acquisition of margin stock of a particular company. The Board is of the opinion that in this context, these debt securities, as a general matter, should not necessarily be presumed to be "indirectly secured" by the margin stock of the target company. A borrowing company with business operations would ordinarily have income and substantial assets, without regard to the target's stock, and therefore the purchasers may be relying on sources of repayment other than the target's stock for repayment of the credit. The circumstances of a particular transaction, however, may provide specific evidence, in accordance with 12 CFR § 207.2(f)(1), that a lender has relied upon the margin stock as collateral.

(i) For purposes of this interpretation, the Board does not recognize any difference between privately placed and publicly distributed debt securities. Any credit provided through the purchase of debt securities issued by a shell acquisition vehicle to facilitate a corporate takeover, that is in excess of the threshold levels specified in Regulation G, may require that the purchaser register as a Regulation G lender and that the credit comply with the conditions and limitations of the Regulation.

Board of Governors of the Federal Reserve System, December 6, 1985.

William W. Wiles,

Secretary of the Board.

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