federal register

Thursday
April 9, 1998

Part II

Department of Labor

Mine Safety and Health Administration

30 CFR Parts 72 and 75

Diesel Particulate Matter Exposure of Underground Coal Miners; Proposed Rule

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 72 and 75

RIN 1219–AA74

Diesel Particulate Matter Exposure of Underground Coal Miners

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish new health standards for underground coal mines that use equipment powered by diesel engines.

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

The proposed rule for underground coal mines would require that mine operators install and maintain high-efficiency filtration systems on certain types of diesel-powered equipment. Underground coal mine operators would also be required to train miners about the hazards of dpm exposure.

By separate notice, MSHA will soon propose a rule to reduce dpm exposures in underground metal and nonmetal mines.

DATES: Comments must be received on or before August 7, 1998. Submit written comments on the information collection requirements by August 7, 1998.

ADDRESSES: Comments on the proposed rule may be transmitted by electronic mail, fax, or mail, or dropped off in person at any MSHA office. Comments by electronic mail must be clearly identified as such and sent to this e-mail address: comments@msha.gov. Comments by fax must be clearly identified as such and sent to: MSHA, Office of Standards, Regulations, and Variances, 703–235–5551. Send mail comments to: MSHA, Office of Standards, Regulations, and Variances, Room 631, 4015 Wilson Boulevard, Arlington, VA 22203–1984, or any MSHA district or field office. The Agency will have copies of the proposal available for review by the mining community at each district and field office location, at the National Mine Safety and Health Academy, and at each technical support center. The document will also be available for loan to interested members of the public on an as needed basis. MSHA will also accept written comments from the mining community at the field and district offices, at the National Mine Safety and Health Academy, and at technical support centers. These comments will become a part of the official rulemaking record. Interested persons are encouraged to supplement written comments with computer files or disks; please contact the Agency with any questions about format.

Written comments on the information collection requirements may be submitted directly to the Office of Information and Regulatory Affairs, New Executive Office Building, 725 17th Street, NW., Rm. 10235, Washington, D.C. 20503, Attn: Desk Officer for MSHA.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director; Office of Standards, Regulations, and Variances; MSHA; 703–235–1910.

SUPPLEMENTARY INFORMATION:

I. Questions and Answers About This Proposed Rule

(A) General Information of Interest to the Entire Mining Community

(1) What Actions Are Being Proposed?

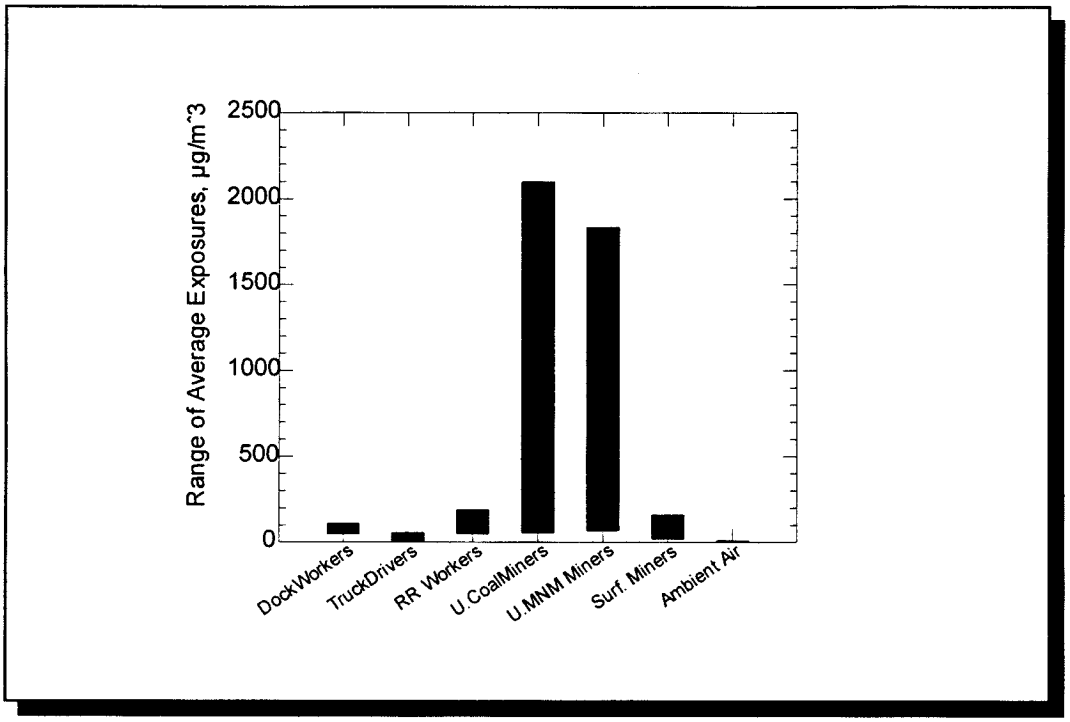
MSHA has determined that action is essential to reduce the exposure of miners to a harmful substance emitted from diesel engines—and that regulations are needed for this purpose in underground mines. This notice proposes requirements for underground coal mines; by separate notice, MSHA will soon propose a rule for underground metal and nonmetal mines.

The harmful substance is known as diesel particulate matter (dpm). As shown in Figure I–1, average concentrations of dpm observed in dieselized underground mines are up to 200 times as high as average environmental exposures in the most heavily polluted urban areas and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups. The best available evidence indicates that exposure to such high concentrations of dpm puts miners at significantly increased risk of incurring serious health problems, including lung cancer.

The goal of the proposed rule is to reduce underground miner exposures to attain the highest degree of safety and health protection that is feasible.

BILLING CODE 4510–43–P

Figure I-1:
Comparative Exposures ($\mu g/m^3$)[1]



[1] Range of average dpm exposures observed at various mines for underground and surface miners compared to range of average exposures reported for other occupations and for urban ambient air. Averages are represented by median observed within mines for mine workers, by median as estimated with geometric mean reported for other occupations, and, for ambient air in urban environments, by the monthly mean estimated for different months and locations in Southern California. The range estimated for urban ambient air is roughly 1 to 10 $\mu g/m^3$. See part III for more detailed information.

Throughout this preamble, exposure information is presented in terms of "whole diesel particulate". Moreover, the information is presented in units of micrograms (μg) per cubic meter of air. However, in many of the references cited, exposure measurements may be expressed as milligrams (mg) per cubic meter of air.

1 mg/m^3 = 1 milligram per cubic meter of air
1 $\mu g/m^3$ = 1 microgram per cubic meter of air
1 milligram = 1000 micrograms.

To convert from milligrams to micrograms, multiply by 1000 -- or move the decimal point three places to the right. For example, 0.15 mg/m^3 = 150 $\mu g/m^3$.

BILLING CODE 4510–43–C

In underground coal mines, MSHA's proposal would require the installation of high-efficiency filters on diesel-powered equipment to trap diesel particles before they enter the mine atmosphere. Following 18 months of education and technical assistance by MSHA after the rule is issued, filters would first have to be installed on permissible diesel-powered equipment. By the end of the following year (i.e., 30 months after the rule is issued), such filters would also have to be installed on any heavy-duty outby equipment. No specific concentration limit would be established in this sector; the proposed rule would require that filters be installed and properly maintained. Miner awareness training on the hazards of dpm would also be required.

MSHA is not at this time proposing a rule applicable to surface mines. As illustrated in Figure I–1, in certain situations the concentrations of dpm at surface mines may exceed those to which rail, trucking and dock workers are exposed. Problem areas identified in this sector include production areas where miners work in the open air in close proximity to loader-haulers and trucks powered by older, out-of-tune diesel engines, or other confined spaces where diesel engines are running. The Agency believes, however, that these problems are currently limited and readily controlled through education and technical assistance. Using tailpipe exhaust extenders, or directing the exhaust across the engine fan, can dilute the high concentrations of dpm that might otherwise occur in areas immediately adjacent to mining equipment. Surface mine operators using or planning to switch to environmentally conditioned cabs to reduce noise exposure to equipment operators might also be able to incorporate filtration features that would protect these miners from high dpm concentrations as well. Completing already planned purchases of new trucks containing cleaner engines may also help reduce the isolated instances of high dpm concentrations at such mines.

The Agency would like to emphasize, however, that surface miners are entitled to the same level of protection as other miners, and that the Agency's risk assessment indicates that even short-term exposures to concentrations of dpm like those observed may result in serious health problems. Accordingly, in addition to providing education and technical assistance to surface mines, the Agency will also continue to evaluate the hazards of diesel particulate exposure at surface mines and will take any necessary action, including regulatory action if warranted, to help the mining community minimize any hazards.

(2) How Is This Notice of Proposed Rulemaking Organized?

The proposed rule for underground coal mines can be found at the end of this Notice. The remainder of this preamble to the proposed rule (**SUPPLEMENTARY INFORMATION**) describes the Agency's rationale for what is being proposed.

Part I consists of twelve ''Questions and Answers.'' The Agency hopes they will provide most of the information you will need to formulate your comments. The first ten of these (Section A) cover general topics. The last two (Section B) contain additional detail about the proposed rule for the underground coal sector, and a discussion of two alternatives on which the Agency would particularly like additional comment.

Part II provides some background information on nine topics that are relevant to this rulemaking. In order, the topics covered are: (1) the role of diesel-powered equipment in mining; (2) the composition of diesel exhaust and diesel particulate; (3) measurement of diesel particulate; (4) reducing soot at the source—EPA regulation of diesel engine design; (5) limiting the public's exposure to soot—EPA ambient air quality standards; (6) controlling diesel particulate emissions in mining—a toolbox; (7) existing mining standards that limit miner exposure to occupational diesel particulate emissions; (8) how other jurisdictions are restricting occupational exposure to diesel soot; and (9) MSHA's initiative to limit miner exposure to diesel particulate—the history of this rulemaking and related actions. Appended to the end of this document is a copy of an MSHA publication, ''Practical Ways to Reduce Exposure to Diesel Exhaust in Mining—A Toolbox,'' which includes additional information on methods for controlling dpm, and a glossary of terms.

Part III is the Agency's risk assessment. The first section presents the Agency's data on current dpm exposure levels in each sector of the mining industry. The second section reviews the scientific evidence on the risks associated with exposure to dpm. The third section evaluates this evidence in light of the Mine Act's statutory criteria.

Part IV is a detailed section-by-section explanation and discussion of the elements of the proposed rule.

Part V is an analysis of whether the proposed rule meets the Agency's statutory obligation to attain the highest degree of safety or health protection for miners, with feasibility a consideration. This part begins with a review of the law and a profile of the coal industry's economic position. This next part explores the extent to which the proposed rule is expected to impact existing concentration levels, reviews significant alternatives that might provide more protection than the rule being proposed but which have not been adopted by the Agency due to feasibility concerns, and then discusses the feasibility of the rule being proposed. Part V draws upon a computer simulation of how the proposed rule in underground coal mines is expected to impact dpm concentrations; accordingly, an Appendix to this discussion provides information about the simulation methodology. The simulation method, which can be performed using a standard spreadsheet program, can be used to model conditions and control impacts in any underground mine; copies of this model are available to the mining community from MSHA.

Part VI reviews several impact analyses which the Agency is required to provide in connection with a proposed rulemaking. This information summarizes a more complete discussion that can be found in the Agency's Preliminary Regulatory Economic Analysis (PREA). Copies of this document are available from the Agency and will be posted on the MSHA Web site (http://www.msha.gov).

Part VII is a complete list of publications referenced by the Agency in the preamble.

(3) What Evidence Does MSHA Have That Current Underground Concentrations of DPM Need To Be Controlled?

The best available evidence MSHA has at this time is that miners subjected to an occupational lifetime of dpm exposure at concentrations we presently find in underground mines face a significant risk of material impairment to their health.

It has been recognized for some time that miners working in close contact with diesel emissions can suffer acute reactions—e.g., eye, nose and throat irritations—but questions have persisted as to what component of the emissions was causing these problems, whether exposure increased the risk of other adverse health effects, and the level of exposure creating health consequences.

In recent years, there has been growing evidence that it is the very small respirable particles in diesel exhaust (dpm) that trigger a variety of

adverse health outcomes. These particles are generally less than one-millionth of a meter in diameter (submicron), and so can readily penetrate into the deepest recesses of the lung. They consist of a core of the element carbon, with up to 1,800 different organic compounds adsorbed onto the core, and some sulfates as well. (A diagram of dpm can be found in part II of this preamble—see Figure II–3). The physiological mechanism by which dpm triggers particular health outcomes is not yet known. One or more of the organic substances adsorbed onto the surface of the core of the particles may be responsible for some health effects, since these include many known or suspected mutagens and carcinogens. But some or all of the health effects might also be triggered by the physical properties of these tiny particles, since some of the health effects are observed with high exposures to any ''fine particulate,'' whether the particle comes from diesel exhaust or another source.

There is clear evidence that exposure to high concentrations of dpm can result in a variety of serious health effects. These health effects include: (i) sensory irritations and respiratory symptoms serious enough to distract or disable miners; (ii) death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer.

By way of example of the non-cancer effects, there is evidence that workers exposed to diesel exhaust during a single shift suffer material impairment of lung capacity. A control group of unexposed workers showed no such impairment, and workers exposed to filtered diesel exhaust (i.e., exhaust from which much of the dpm has been removed) experienced, on average, only about half as much impairment. Moreover, there are a number of studies quantifying significant adverse health effects—as measured by lost work days, hospitalization and increased mortality rates—suffered by the general public when exposed to concentrations of fine particulate matter like dpm far lower than concentrations to which some miners are exposed. The evidence from these fine particulate studies was the basis for recent rulemaking by the Environmental Protection Agency to further restrict the exposure of the general public to fine particulates, and the evidence was given very widespread and close scrutiny before that action was made final. Of particular interest to the mining community is that these fine particulate studies indicate that those who have pre-existing pulmonary problems are particularly at risk. Many individual miners in fact have such pulmonary problems, and the mining population as a whole is known to have such conditions at a higher rate than the general public.

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

Moreover, all of the human occupational studies indicating an increased frequency of lung cancer among workers exposed to dpm involved average exposure levels estimated to be far below the levels observed in underground mines. As noted in Part III, MSHA views extrapolations from animal experiments as subordinate to results obtained from human studies. However, it is noteworthy that dpm exposure levels recorded in some underground mines have been within the exposure range that produced tumors in rats.

Based on the scientific data available in 1988, the National Institute for Occupational Safety and Health (NIOSH) identified dpm as a probable or potential human carcinogen and recommended that it be controlled. Other organizations have made similar recommendations.

MSHA carefully evaluated all the evidence available in light of the requirements of the Mine Act. Based on this evaluation, MSHA has reached several conclusions:

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

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

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

MSHA had its risk assessment independently peer reviewed. The risk assessment presented here incorporates revisions made in accordance with the reviewers recommendations. The reviewers stated that:

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

The proposed rule would reduce the concentration of one type of fine particulate in underground coal mines—that from diesel emissions—but would not explicitly control miner exposure to other fine airborne particulates present underground. In light of the evidence presented in the Agency's risk assessment on the risks that fine particulates in general may pose to the mining population, MSHA would welcome comments as to whether the Agency should also consider restricting the exposure of underground coal miners to all fine particulates, regardless of the source.

(4) Aren't NIOSH and the NCI Working on a Study That Will Provide Critical Information? Why Proceed Before the Evidence Is Complete?

NIOSH and the National Cancer Institute (NCI) are collaborating on a cancer mortality study that will provide additional information about the relationship between dpm exposure levels and disease outcomes, and about which components of dpm may be responsible for the observed health effects. The study is projected to take about seven years. The protocol for the study was recently finalized.

The information the study is expected to generate will be a valuable addition to the scientific evidence on this topic. But given its conclusions about currently available evidence, MSHA believes the Agency needs to take action now to protect miners' health. Moreover, as noted by the Supreme Court in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straightjacket.'' *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 607, 100 S.Ct. 2844 (1980). The Court noted that

when regulating on the edge of scientific knowledge, absolute scientific certainty may not be possible, and ''so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection.'' (*Id.* at 656). This advice has special significance for the mining community, because a singular historical factor behind the enactment of the current Mine Act was the slowness in coming to grips with the harmful effects of other respirable dust (coal dust).

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

(5) What are the Impacts of the Proposed Rule?

Costs. Tables I–1 and I–2 provide cost information. Some explanation is necessary.

Costs consist of two components: ''initial'' costs (e.g., capital costs for equipment, or the one-time costs of developing a procedure), which are then amortized over a period of years in accordance with a standardized formula to provide an ''annualized'' cost; and ''annual'' costs that occur every year (e.g., maintenance or training costs). Adding together the ''annualized'' initial costs and the ''annual'' costs provides the per year costs for the rule.

It should be noted that in amortizing the initial costs, a net present value factor was applied to certain costs: those associated with provisions where mine operators do not have to make capital expenditures until some period of time after the effective date. Detailed information on this point is contained in the Agency's Preliminary Regulatory Economic Analysis (PREA), as are the Agency's cost assumptions.

The costs per year to the underground coal industry are about $10 million. Diesel equipment manufacturers would have a yearly cost increase of about $14,000.

The Agency spent considerable time developing its cost assumptions, which are discussed in detail in the Agency's PREA, and would encourage the mining community to provide detailed comments in this regard so as to ensure these cost estimates are as accurate as possible.

TABLE I–1.—COMPLIANCE COSTS FOR UNDERGROUND COAL MINES

[Dollars + 1,000]

Detail	Large mines (≥20)			Small mines (<20)			Total mines		
	Total [Col. B+C] (A)	Annualized (B)	Annual (C)	Total [Col. E+F] (D)	Annualized (E)	Annual (F)	Total [Col. H+I] (G)	Annualized (H)	Annual (I)
75.1915	$9	$9	$0	$1	$1	$0	$10	$10	$0
72.500(a)	4,910	457	4,453	95	22	73	5,005	479	4,526
72.500(b)	4,768	1,335	3,433	22	12	10	4,790	1,347	3,443
72.510	185	0	185	1	0	1	186	0	186
75.371qq and 75.370	1	1	0	1	1	0	2	2	0
Total	9,873	1,802	8,071	120	36	84	9,993	1,838	8,155

TABLE I–2.—COMPLIANCE COSTS FOR MANUFACTURERS

[Dollars×1,000]

Detail	Manufacturers		
	Total [Col. B+C]	Annualized	Annual
	(A)	(B)	(C)
Part 36	$14	$14	$0
Total	$14	$14	$0

As required by the Regulatory Flexibility Act, MSHA has performed a review of the effects of the proposed rule on ''small entities''. The results—including information about the average cost for mines in each sector with less than 500 employees and mines in each sector with less than 20 miners—are summarized in response to Question 7.

Paperwork

Tables I–3 and I–4 show additional paperwork burden hours which the proposed rule would require. Only those existing or proposed regulatory requirements which would, as a result of this rulemaking, result in new burden hours, are noted. The costs for these paperwork burdens, a subset of the overall costs of the proposed rule, are specifically noted in part VII of the Agency's PREA. Each of these tables shows separately the burden hours on smaller mines—those with less than 20 miners. Table I–3 shows additional paperwork burden hours for underground coal operators.

TABLE I–3.—UNDERGROUND COAL MINE BURDEN HOURS

Detail	Large	Small	Total
75.370	93	9	102
75.371	158	8	166
75.1915	12	1	13
72.510	347	5	352
Total	610	23	633

Table I–4 shows the additional burden hours for diesel equipment manufacturers. All of the manufacturer burden hours will occur once and not recur annually.

TABLE I–4.—DIESEL EQUIPMENT MANUFACTURERS BURDEN HOURS

Detail	Total
Part 36	520
Total	520

Benefits

The proposed rule would reduce the exposure of underground miners to dpm, thereby reducing the risk of adverse health effects and their concomitant effects.

The risks being addressed by this rulemaking arise because some miners are exposed to high concentrations of the very small particles produced by engines that burn diesel fuel. As discussed in part II of the preamble, diesel powered engines are used increasingly in underground mining operations because they permit the use of mobile equipment and provide a full range of power for both heavy-duty and light-duty operations (i.e., for production equipment and support equipment, respectively), while avoiding the explosive hazards associated with gasoline. But underground mines are confined spaces which, despite ventilation requirements, tend to accumulate significant concentrations of particles and gases—both those produced by the mine itself (e.g., methane gas and coal dust liberated by mining operations) and those produced by equipment used in the mine.

As discussed in MSHA's risk assessment (part III of this preamble), the concentrations of diesel particulates to which some underground miners are currently exposed are significantly higher than the concentrations reported for other occupations involving the use of dieselized equipment; and at such concentrations, exposure to dpm by underground miners over a working lifetime is associated with an excess risk of a variety of adverse health effects.

The nature of the adverse health effects associated with such exposures suggests the nature of the savings to be derived from controlling exposure. Acute reactions can result in lost production time for the operator and lost pay (and perhaps medical expenses) for the worker. Hospital care for acute breathing crises or cancer treatment can be expensive, result in lost income for the worker, lost income for family members who need to provide care and lost productivity for their employers, and may well involve government payments (e.g., Social Security disability and Medicare). Serious illness and death lead to long term income losses for the families involved, with the potential for costs from both employers (e.g., workers' compensation payouts, pension payouts) and society as a whole (e.g., government assisted aid programs).

The information available to the Agency suggests that as exposure is reduced, so are the adverse health consequences. For example, data collected on the effects of environmental exposure to fine particulates suggest that reducing occupational dpm exposures by as little as 75 $\mu g/m^3$ (roughly corresponding to a reduction of 25 $\mu g/m^3$ in 24-hour ambient atmospheric concentration) could lead to significant reductions in the risk of various acute responses, including mortality. And chronic occupational exposure has been linked to an estimated 30 to 40 percent increase in the risk of lung cancer. All the quantitative risk models reviewed by NIOSH suggest excess risks of lung cancer of more than one per thousand for miners who have long-term occupational exposures to dpm concentrations in excess of 1000 $\mu g/m^3$, and the epidemiologically-based risk estimates suggest higher risks.

Despite these quantitative indications, quantification of the benefits is difficult. Although increased risk of lung cancer has been shown to be associated with dpm exposure among exposed workers, a conclusive dose-response relationship upon which to base quantification of benefits has not been demonstrated. The Agency nevertheless intends, to the extent it can, to develop an appropriate analysis quantifying benefits in connection with the final rule.

The Agency does not have much experience in quantifying benefits in the case of a proposed health standard (other than its recent proposal on controlling mining noise, where years of compliance data and hearing loss studies provide a much more complete quantitative picture than with dpm). MSHA therefore welcomes suggestions for the appropriate approach to use to quantify the benefits likely to be derived from this rulemaking. Please identify scientific studies, models, and/or assumptions suitable for estimating risk at different exposure levels, and data on numbers of miners exposed to different levels of dpm.

(6) Did MSHA Actively Consider Alternatives to What Is Being Proposed?

Yes. Once MSHA determined that the evidence of risk required a regulatory action, the Agency considered a number of alternative approaches, the most significant of which are reviewed in part V of the preamble.

The consideration of options proceeded in accordance with the requirements of section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (the ''Mine Act''). In promulgating standards addressing toxic materials or harmful physical agents, the Secretary must promulgate standards which most adequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health over his/her working lifetime. In addition, the Mine Act requires that the Secretary, when promulgating mandatory standards pertaining to toxic materials or harmful physical agents, consider other factors, such as the latest scientific data in the field, the feasibility of the standard and experience gained under the Mine Act and other health and safety laws. Thus, the Mine Act requires that the Secretary, in promulgating a standard, attain the highest degree of health and safety protection for the miner, based on the ''best available evidence,'' with feasibility a consideration.

As a result, MSHA seriously considered a number of alternatives that would, if adopted as part of the proposed rule, have provided increased protection—and would also have significantly increased costs. For example, in underground coal mining, the Agency considered requiring filtration of all light-duty diesel-powered equipment as well as heavier equipment. The Agency concluded, however, that such an approach may not be feasible for the underground coal sector at this time, although it is asking for comment as to whether there are some types of light-duty equipment whose dpm emissions should, and could feasibly, be controlled.

MSHA also considered alternatives that would have led to a significantly lower-cost proposal, e.g., increasing the time for mine operators to come into compliance. However, based on the current record, MSHA has tentatively concluded that such approaches would not be as protective as those being proposed, and that the approach proposed is both economically and technologically feasible. As a result, the Agency has not proposed to adopt these alternatives.

MSHA also explored whether to permit the use of administrative controls (e.g., rotation of personnel) and personal protective equipment (e.g., respirators) to reduce the diesel particulate exposure of miners. It is generally accepted industrial hygiene practice, however, to eliminate or minimize hazards at the source before resorting to personal protective

equipment. Moreover, such a practice is generally not considered acceptable in the case of carcinogens since it merely places more workers at risk.

Other alternatives the Agency considered include: establishing a concentration limit for dpm in this sector; requiring filters on some light-duty equipment; and looking at the filter and the engine as a package that has to meet a particular emission standard, instead of requiring that all engines be equipped with a high-efficiency filter. The Agency also spent a considerable amount of time studying whether it could simply propose a concentration limit for dpm in underground coal mines. Such an approach would provide underground coal mine operators with flexibility to elect any combination of engineering controls they wish as long as the concentration of dpm in the mine remains below a set level. At this point in the rulemaking process, however, the Agency is not confident that there is a measurement method for dpm that will provide accurate, consistent and verifiable results at lower concentration levels in underground coal mines. As discussed in detail in part II of this preamble, the problem arises because coal dust contains organic compounds that might be mistaken for dpm in the methods otherwise validated for use at lower dpm concentrations. The Agency is continuing to explore questions about the measurement of dpm in underground coal mines in consultation with NIOSH, and welcomes comment on this issue. However, at this point in the rulemaking process, the Agency believes that the best approach for the underground coal sector would be one which does not require measurement of ambient dpm levels to ascertain compliance or noncompliance.

MSHA recognizes that a specification standard does not allow for the use of future alternative technologies that might provide the same or enhanced protection at the same or lower cost. MSHA welcomes comment as to whether and how the proposed rule can be modified to enhance its flexibility in this regard.

MSHA did consider two alternative specification standards which would provide somewhat more flexibility for coal mine operators. Alternative 1 would treat the filter and engine as a package that has to meet a particular emission standard. Instead of requiring that all engines be equipped with a high-efficiency filter, this approach would provide some credit for the use of lower-polluting engines. Alternative 2 would also provide credit for mine ventilation beyond that required. The Agency believes, however, that these alternatives may be less protective of miners than the alternative proposed, although it is seeking comment on them. More information on these two alternatives can be found in this part in response to Question 12.

(7) What Will the Impact Be on the Smallest Underground Coal Mines? What Consideration Did MSHA Give to Alternatives for the Smallest Mines?

The Regulatory Flexibility Act requires MSHA and other regulatory agencies to conduct a review of the effects of proposed rules on small entities. That review is summarized here; a copy of the full review is included in part VI of this preamble, and in the Agency's PREA. The Agency encourages the mining community to provide comments on this analysis.

The Small Business Administration generally considers a small mining entity to be one with less than 500 employees. MSHA has traditionally defined a small mine to be one with less than 20 miners, and has focused special attention on the problems experienced by such mines in implementing safety and health rules, e.g., the Small Mine Summit, held in 1996. Accordingly, MSHA has separately analyzed the impact of the proposed rule on mines with 500 employees or less, and those with less than 20 miners.

Table I–5 summarizes MSHA's estimates of the average costs of the proposed rule to a small underground coal entity or small underground coal mine.

TABLE I–5.—AVERAGE COST PER SMALL UNDERGROUND COAL MINE

Size	UG Coal <500	UG Coal <20
Cost per mine	$58,000	$8,000

Pursuant to the Regulatory Flexibility Act, MSHA must determine whether the costs of the proposed rule constitute a ''significant impact on a substantial number of small entities.'' Pursuant to the Regulatory Flexibility Act, if an Agency determines that a proposed rule does not have such an impact, it must publish a ''certification'' to that effect. In such a case, no additional analysis is required (5 U.S.C. 605).

In evaluating whether certification is appropriate, MSHA utilized a ''screening test,'' comparing the costs of the proposal to the revenues of the sector involved (only the revenues for underground coal mines are used in this calculation). For underground coal mines, the costs of the proposed rule appear to be significantly less than one percent of revenues—even for mines with less than 20 miners. As a result, MSHA is certifying that the proposed rule for underground coal mines does not have a ''significant impact on a substantial number of small entities,'' and has performed no further analyses.

In promulgating standards, MSHA does not reduce protection for miners employed at small mines. But MSHA does consider the impact of its standards on even the smallest mines when it evaluates the feasibility of various alternatives. For example, a major reason why MSHA concluded it needed to stagger the effective dates of some of the requirements in the proposed rule is to ensure that it would be feasible for the smallest mines to have adequate time to come into compliance.

Consistent with recent amendments to the Regulatory Flexibility Act under SBREFA (the Small Business Regulatory Enforcement Fairness Act), MSHA has already started considering actions it can take to minimize the anticipated compliance burdens of this proposed rule on smaller mines. For example, no equipment filtration would be required for 18 months, and during that time, the Agency plans to provide extensive compliance assistance to the mining community. MSHA intends to focus its efforts on smaller operators in particular to provide training to them and technical assistance on available controls. The Agency will also issue a compliance guide, and continue its current efforts to disseminate educational materials and software. Comment is invited on whether compliance workshops or other such approaches would be valuable.

(8) Why Would the Proposed Rule Require Special Training for Underground Miners Exposed to Diesel Exhaust? And Why Does the Proposed Rule Not Address Medical Surveillance and Medical Removal Protection for Affected Miners?

Training. Diesel particulate exposure has been linked to a number of serious health hazards, and the Agency's risk assessment indicates that the risks should be reduced as much as feasible. It has been the experience of the mining community that miners must be active and committed partners along with government and industry in successfully reducing these risks. Therefore, training miners as to workplace risks is a key component of mine safety and health programs. This rulemaking continues this approach.

Specifically, pursuant to proposed § 72.510, any underground coal miner ''who can reasonably be expected to be

exposed to diesel emissions'' would have to receive instruction in: (a) the health risks associated with dpm exposure; (b) in the methods used in the mine to control diesel particulate concentrations; (c) in identification of the personnel responsible for maintaining those controls; and (d) in actions miners must take to ensure the controls operate as intended. The training is to be provided annually in all mines using diesel-powered equipment, and is to be provided without charge to the miner.

MSHA does not expect this training to be a significant new burden for mine operators. The training required can be provided at minimal cost and with minimal disruption. The proposal would not require any special qualifications for instructors, nor would it specify the minimum hours of instruction. The purpose of the proposed requirement is miner awareness, and MSHA believes this can be accomplished by operators in a variety of ways. In mines that have regular safety meetings before the shift begins, devoting one of those meetings to the topic of diesel particulate would probably be a very easy way to convey the necessary information. Mines not having such a regular meeting can schedule a ''toolbox'' talk for this purpose. MSHA will be developing an outline of educational material that can be used in these settings. Simply providing miners with a copy of MSHA's toolbox, and reviewing how to use it, can cover several of the training requirements.

Operators may choose to include required dpm training under part 48 training as an additional topic. Part 48 training plans, however, must be approved. There is no existing requirement that part 48 training include a discussion of the hazards and control of diesel emissions. While mine operators are free to cover additional topics during the part 48 training sessions, the topics that must be covered during the required time frame may make it impracticable to cover other matters within the prescribed time limits. Where the time is available in mines using diesel-powered equipment, operators should be free to include the dpm instruction in their proposed part 48 training plans. The Agency does not believe special language in the proposed rule is needed to permit this action under part 48, but welcomes comment in this regard.

The proposal would not require the mine operator to separately certify the completion of the diesel particulate training, but some evidence that the training took place would have to be produced upon request. A serial log with the employee's signature is a perfectly acceptable practice in this regard.

Medical surveillance

Another important source of information that miners and operators can use to protect health can come from medical surveillance programs. Such programs provide for medical evaluations or tests of miners exposed to particularly hazardous substances, at the operator's expense, so that a miner exhibiting symptoms or adverse test results can receive timely medical attention, ensure that personal exposure is reduced as appropriate and controls are reevaluated. Sometimes, to ensure that this source of information is effective, medical removal (transfer) protection must also be required. Medical transfer may address protection of a miner's employment, a miner's pay retention, a miner's compensation, and a miner's right to opt for medical removal.

As a general rule, medical surveillance programs have been considered appropriate when the exposures are to potential carcinogens. MSHA has in fact been considering a generic requirement for medical surveillance as part of its air quality standards rulemaking. And MSHA recently proposed a medical surveillance program for hearing, as part of the Agency's proposed rule on noise exposure. (61 FR 66348).

MSHA is not proposing such a program for dpm at this time because it is still gathering information on this issue. The Agency, however, welcomes comments regarding this issue and also, on medical removal.

Specifically, the Agency would welcome comment on the following questions: (a) what kinds of examinations or tests would be appropriate to detect whether miners are suffering ill effects as a result of dpm exposure; (b) the qualifications of those who would have to perform such examinations or tests and their availability; (c) whether such examinations or tests need to be provided and how frequently once the provisions of the rule are in effect; and (d) whether medical removal protections should be a component of a medical surveillance program.

(9) What Are the Major Issues on Which MSHA Wants Comments?

MSHA wants the benefit of your experience and expertise: whether as a miner or mine operator in any mining sector; a manufacturer of diesel-powered engines, equipment, or emission control devices; or as a scientist, doctor, engineer, or safety and health professional. MSHA intends to review and consider all comments submitted to the Agency.

The following list reflects some topics on which the Agency would particularly like information; requests for information on other topics can be found throughout the preamble.

(a) Assessment of Risk/Benefits of the Rule. Part III of this preamble reviews information that the Agency has been able to obtain to date on the risks of dpm exposure to miners. The Agency welcomes your comments on the significance of the material already in the record, and any information that can supplement the record. For example, additional information on existing and projected exposures to dpm and to other fine particulates in various mining environments would be useful in getting a more complete picture of the situation in various parts of the mining industry. Additional information on the health risks associated with exposure to dpm—especially observations by trained observers or studies of acute or chronic effects of exposure to known levels of dpm or fine particles in general, information about pre-existing health conditions in individual miners or miners as a group that might affect their reactions to exposures to dpm or other fine particles, and information about how dpm affects human health—would help provide a more complete picture of the relationship between current exposures and the risk of health outcomes. Information on the costs to miners, their families and their employers of the various health problems linked to dpm exposure, and the prevalence thereof, would help provide a more complete picture of the benefits to be expected from reducing exposure. And as discussed in response to Question and Answer 5, the Agency would welcome advice about the assumptions and approach to use in quantifying the benefits to be derived from this rule.

(b) Proposed Rule. Part IV of this preamble reviews each provision of the proposed rule, part V discusses the economic and technological feasibility of the proposed rule, and part VI reviews the projected impacts of the proposed rule. The Agency would welcome comments on each of these topics.

The Agency would like your thoughts on the specific alternative approaches discussed in part V. The options discussed include: establishing a concentration limit for dpm in this sector; requiring filters on some light-duty equipment; and looking at the filter

and the engine as a package that has to meet a particular emission standard, instead of requiring that all engines be equipped with a high-efficiency filter.

The Agency would also like your thoughts on more specific changes to the proposed rule that should be considered. The Agency is also interested in obtaining as many examples as possible as to the specific situation in individual mines: the composition of the diesel fleet, what controls cannot be utilized due to special conditions, and any studies of alternative controls using the computer spreadsheet described in the Appendix to part V of this preamble. (See Adequacy of Protection and the Feasibility of the Proposed Rule). Information about the availability and costs of various control technologies that are being developed (e.g., high-efficiency ceramic filters), experience with the use of available controls, and information that will help the Agency evaluate alternative approaches for underground coal mines would be most welcome. And the Agency would appreciate information about any unusual situations that might warrant the application of special provisions.

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

(d) Minimizing Adverse Impact of the Proposed Rule. The Agency has set forth its assumptions about impacts (e.g., costs, paperwork, and impact on smaller mines in particular) in some detail in this preamble and in the PREA, and would welcome comments on the methodology. Information on current operator equipment replacement planning cycles, tax, State requirements, or other information that might be relevant to purchasing new engines or control technology would likewise be helpful.

(10) *When Will the Rule Become Effective? Will MSHA Provide Adequate Guidance Before Implementing the Rule?*

Some requirements of the proposed rule would go into effect 60 days after the date of promulgation: specifically, the requirement to provide basic hazard training to miners who are exposed underground to dpm.

The next set of requirements would go into effect 18 months after the date the rule is promulgated. Underground coal mines would have to properly filter permissible diesel-powered equipment.

A year later (30 months after the date of promulgation), underground coal mines would have to properly filter heavy-duty nonpermissible equipment.

MSHA intends to provide considerable technical assistance and guidance to the mining community before the various requirements go into effect, and be sure MSHA personnel are fully trained in the requirements of the rule. A number of actions have already been taken toward this end. The Agency held workshops on this topic in 1995 which provided the mining community an opportunity to share advice on how to control dpm concentrations. The Agency has published a ''toolbox'' of methods available to mining operators to achieve reductions in dpm concentration (a copy is attached as an Appendix at the end of this document). The ''toolbox'' provides information on filter technology as well as on other actions mine operators can take to address dpm concentrations in their mines.

The Agency is committed to issuing a compliance guide for mine operators providing additional advice on implementing the rule. MSHA would welcome suggestions on matters that should be discussed in such a guide. MSHA would also welcome comments on other actions it could take to facilitate implementation, and in particular whether a series of additional workshops would be useful.

(B) Additional Information About the Proposed Rule for Underground Coal Mines

(11) *More Specifically, What Changes Does the Proposal Make to the Current Rules on the Use of Diesel-Powered Equipment in Underground Coal Mines?*

The proposal builds on the changes to part 75 recently adopted in MSHA's final rule ''Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines.'' (61 FR 55412). As a result of these changes, grounded in safety considerations, underground coal mines must already comply with certain rules that have the added benefit of reducing harmful dpm emissions from diesel-powered equipment. These include a requirement that only low-sulfur diesel fuel be used underground, restrictions on the idling of diesel-powered equipment, ensuring that maintenance of diesel-powered equipment is performed only by qualified personnel, weekly tailpipe tests to ensure the engines are operating in approved condition, and the requirement that the entire diesel fleet have approved engines before the year 2000.

The proposed rule would require that all permissible and heavy-duty nonpermissible diesel-powered equipment be equipped with a filtration system that is capable of removing, on average, at least 95% by mass of the particulate emissions coming out of that equipment. These filtration systems must be properly maintained in accordance with manufacturer specifications (e.g., changing paper filters at the proper interval). The permissible equipment must be so equipped within 18 months after the rule becomes final, and the heavy-duty nonpermissible equipment a year later. The mine's ventilation and dust control plan must contain a list of the diesel-powered equipment used in the mine and the filtration system installed on each. And finally, to ensure they can better contribute to dpm reduction efforts, underground coal miners who can reasonably be expected to be exposed to diesel emissions must be annually trained about the hazards associated with that exposure and in the controls being used by the operator to reduce dpm concentrations.

The proposed rule would not require the filtration of light-duty outby diesel equipment. It would not establish a concentration limit for dpm in underground coal mines. And it would not require monitoring of dpm concentrations by either operators or MSHA in this sector. Enforcement of the proposed requirements would be through observation by MSHA inspectors who are at the mine on a regular basis.

MSHA's decision to propose this approach for underground coal mines was driven by two interrelated considerations.

First, the Agency is not confident that there is a measurement method for dpm that will provide accurate, consistent and verifiable results at lower concentration levels in underground coal mines. The available measurement methods for determining dpm concentrations in underground coal mines were carefully evaluated by the Agency, including field testing, before the Agency reached this conclusion. The problems are discussed in detail in part II of this preamble. Basically, coal dust contains compounds that could be mistaken for dpm in the methods that do not exclude organic materials. A size selective impactor minimizes this problem by screening out most of the coal dust before it can reach the filter medium, but doesn't eliminate it. Measuring only the elemental carbon in a sample does provide a way to distinguish dpm from coal dust, but there remain questions about whether a

measured amount of elemental carbon can be equated to a prescribed amount of whole diesel particulate under the variable engine conditions found in actual mining environments. The Agency is continuing to explore questions about the measurement of dpm in underground coal mines in consultation with NIOSH, and welcomes comment on this issue. If at some future time it can be established that a particular measurable component of dpm is responsible for the adverse health effects observed (e.g., the elemental carbon cores), the Agency would evaluate the question of measurement in that light.

Second, filtration systems for the diesel equipment used in this sector are readily available, and if properly maintained can provide generally consistent, highly effective elimination of dpm from underground mine atmospheres.

MSHA's analysis of dpm emissions in underground coal mines indicates that it is currently the permissible equipment used for face haulage that contributes most to high dpm levels, but heavy-duty outby equipment can also generate significant dpm emissions. On the permissible equipment, paper type filtration systems can be installed directly on the tailpipes; accordingly, the rule would require these filters to be installed within 18 months. In the case of outby equipment, scrubbers and cooling system upgrades will need to be added to cool the exhaust before the paper type filters can be installed, or a dry technology system would need to be utilized. The Agency is seeking information as to whether ceramic filters might achieve the required efficiency once a market develops; but at this time, the proposal would provide an additional year for the nonpermissible equipment to be converted and fitted with high efficiency filtration systems.

The proposed rule specifies a laboratory method that equipment manufacturers can use to determine whether a particular filtration system meets the requirement that the system be at least 95% effective in removing dpm.

(12) *Why not Consider a more Flexible Approach Under Which the Filter, the Engine, and the Available Ventilation is Viewed as a Single System that has to Meet a Defined Emission Limit?*

MSHA has considered some approaches along this line. The Agency welcomes comment on such ideas so it can better evaluate whether they provide more protection to underground coal miners.

Alternative 1 would in essence provide some credit in filter selection to those operators who use less polluting engines. Under this approach, the engine and aftertreatment filter would be bench tested as a unit; and if the emissions from the unit are below a certain level per defined volume of air (e.g., 120_{DPM} μg/m^3), the package would be acceptable without regard to the efficiency of just the filter component. Alternative 2 would also provide credit in filter selection for extra ventilation used in an underground coal mine. If the bench test of the combined engine and filter package was conducted at the name plate ventilation, a mine's use of more than that level of ventilation would be factored into the calculation of what package would be acceptable.

One practical effect of these alternatives would be to permit some operators to save the costs of installing heat exchangers or other exhaust-cooling devices on nonpermissible heavy-duty equipment. Such devices are necessary in order for this equipment to be fitted with paper filters—and as noted in response to the previous question, at the moment these are the only filters on the market capable of providing 95% and more filtration capability.

The appropriateness of Alternative 1 is not clear. With the proper equipment to cool the exhaust, a 95% paper filter can be installed on any piece of heavy-duty equipment in coal mines—and of course directly on any permissible piece of equipment. And, as indicated herein, the Agency is tentatively concluding that such an approach is economically feasible as well. Installing a 95% efficient filter on an engine lowers the dpm concentration in the mine more than would installing a less efficient filter. Hence for engines whose emissions can, with a 95% filter, be reduced below 120_{DPM} μg/m^3 or whatever other dpm limit is set under such an approach, the alternative approach may result in less miner protection.

Moreover, it is not clear to MSHA that 95% filtration of the engines used on the majority of permissible machines in underground coal mines can meet an emissions limit of 120_{DPM} μg/m^3 using MSHA's name plate ventilation. These engines are of older design and produce higher concentrations of diesel particulate. Thus adopting a rule with such an emissions limit would in effect require these engines to be replaced with cleaner engines. Of course, it follows that such a rule would be more costly than the one proposed, because it would require the 95% filters plus the replacement of these engines.

The second alternative appears to be less protective in all cases. To provide mines who need extra ventilation for other reasons (e.g., to keep methane in check) with a credit for this fact in determining the required filter efficiency would not reduce dpm concentrations as much as simply requiring a 95% filter.

The Agency welcomes comments on these approaches and information that will help it assess them in light of the requirements of the Mine Act.

II. Background Information

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

(1) The role of diesel-powered equipment in mining;

(2) Diesel exhaust and diesel particulate;

(3) Methods available to measure DPM;

(4) Reducing soot at the source—engine standards;

(5) Limiting the public's exposure to soot — ambient air quality standards;

(6) Controlling diesel particulate emissions in mining—a toolbox;

(7) Existing mining standards that limit miner exposure to occupational diesel particulate emissions;

(8) How other jurisdictions are restricting occupational exposure to diesel soot; and

(9) MSHA's initiative to limit miner exposure to diesel particulates—the history of this rulemaking and related actions.

In addition, an Appendix at the end of this document reprints a recent MSHA publication, ''Practical Ways to Reduce Exposure to Diesel Exhaust in Mining—A Toolbox'', which contains considerable information of interest in this rulemaking.

These topics will be of interest to the entire mining community, even though this rulemaking is specifically confined to the underground coal sector.

(1) *The Role of Diesel-Powered Equipment in Mining.* Diesel engines now power a full range of mining equipment on the surface and underground, in both coal and in metal/nonmetal mining. Many in the mining industry believe that diesel-powered equipment has a number of productivity and safety advantages over electrically-powered equipment. Nevertheless, concern about miner safety and health has slowed the spread of this technology, and in certain states resulted in a complete ban on its use in underground coal mines. As the industry has moved to realize the advantages this equipment may provide, the Agency has endeavored to address

the miner safety and health issues presented.

Historical Patterns of Use

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

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

It was not until 1939 that the first diesel engine was used in the United States mining industry, when a diesel haulage truck was used in a limestone mine in Pennsylvania, and not until 1946 was a diesel engine used in coal mines. Today, however, diesel engines are used to power a wide variety of equipment in all sectors of U.S. mining, such as: air compressor; ambulance; crane truck; ditch digger; foam machine; forklift; generator; grader; haul truck; load-haul-dump machine; longwall retriever; locomotive; lube unit; mine sealant machine; personnel car; hydraulic pump machine; rock dusting machine; roof/floor drill; shuttle car; tractor; utility truck; water spray unit and welder.

Estimates of Current Use

Estimates of the current inventory of diesel engines in the mining industry are displayed in Table II–1. Not all of these engines are in actual use. Some may be retained rather than junked, and others are spares. MSHA has been careful to take this into account in developing cost estimates for this proposed rule; its assumptions in this regard are detailed in the Agency's PREA.

TABLE II–1.—DIESEL EQUIPMENT IN THREE MINING SECTORS

Mine type	No. Mines [2]	No. Mines w/Diesel	No. Engines
Underground Coal	971	[3] 173	[4] 2,950
[1] Small	426	15	50
Large	545	158	2,900
Underground M/NM	261	[5] 203	[6] 4,100
[1] Small	130	82	625
Large	131	121	3,475
Surface Coal	1,673	[7] 1,673	[8] 22,000
[1] Small	1,175	1,175	7,000
Large	498	498	15,000
Surface M/NM	10,474	[9] 10,474	[10] 97,000

Notes on Table II–1:

[1] A mine with less than 20 miners. MSHA traditionally regards mines with less than 20 miners as ''small'' mines, and those with 20 or more miners as ''large'' mines based on differences in operation. However, in examining the impact of the proposed regulations on the mining community, MSHA, consistent with the Small Business Administration definition for small mines, which refers to employers with 500 employees or less, has analyzed impact for this size. This is discussed in the Agency's preliminary regulatory economic analysis for this proposed rule.

[2] Preliminary 1996 MSHA data.

[3] Data from MSHA approval and certification center, Oct.95.

[4] Actual inventory, rounded to nearest 50.

[5] Estimates are based on a January 1998 count, by MSHA inspectors, of underground mines that use diesel powered equipment.

[6] The estimates are based on a January 1998 count, by MSHA inspectors, of diesel powered equipment normally in use.

[7] Based on assumption that all surface coal mines had some diesel powered equipment.

[8] Based on MSHA survey of 25% of surface coal mines.

[9] MSHA assumes all surface M/NM mines use some diesel engines.

[10] Derived by applying ratios (engines per mine) from MSHA survey of surface coal mines to M/NM mines.

As noted in Table II–1, nearly all underground metal and nonmetal mines, and all surface mines, use diesel-powered equipment. This is not true in underground coal mines—in no small measure because, as discussed later in this part, several key underground coal states have for many years banned the use of diesel-powered equipment in such mines.

Neither the diesel engines nor the diesel-powered equipment are identical from sector to sector. This relates to the equipment needs in each sector. This is important information because the type of engine, and the type of equipment in which it is installed, can have important consequences for particulate production and control.

As the horsepower size of the engine increases, the mass of dpm emissions produced per hour increases. (A smaller engine may produce the same or higher levels of particulate emissions per volume of exhaust as a large engine, due to the airflow, but the mass of particulate matter increases with the engine size.) Accordingly, as engine size increases, control of emissions may require additional efforts.

Diesel engines in underground metal and nonmetal mines, and in surface coal mines, range up to 750 HP or greater; by contrast, in underground coal mines, the average engine size is less than 150 HP. The reason for this disparity is the nature of the equipment powered by diesel engines. In underground metal and nonmetal mines, and surface mines, diesel engines are widely used in all types of equipment—both the equipment used under the heavy stresses of production and the equipment used for support. By contrast, the great majority of the diesel usage in underground coal mines is in support equipment. For example, in underground metal and nonmetal mines, of the approximate 4,100 pieces of diesel equipment normally in use, about 1,800 units are for loading and hauling. By contrast, of the approximate 3,000 pieces of diesel equipment in underground coal, MSHA estimates that less than 50 pieces are for coal haulage. The largest diesel engines are used in surface operations; in underground metal and nonmetal mines, the size of the engine can be limited by the size of the shaft opening.

The type of equipment in the sectors also varies in another way that can affect particulate control directly, as well as constrain engine size. In underground coal, equipment that is used in face (production) areas of the coal mine must be MSHA-approved part 36 permissible equipment. These locations are the areas where methane gas is likely to accumulate in higher concentrations. This includes the in-by section starting at the tailpiece (coal dump point) and all returns. Part 36 permissible equipment for coal requires the use of flame arresters on the intake and exhaust systems and surface temperature control to below 302°F. As

discussed in more detail elsewhere in this notice, the cooler exhaust from these permissible pieces of equipment permits the direct installation of particulate filtration devices such as paper type filters that cannot be used directly on engines with hot exhaust. In addition, the permissibility requirements have had the effect of limiting engine size. This is because prior to MSHA's issuance of a diesel equipment rule in 1996, surface temperature control was done by water jacketing. This limited the horsepower range of the permissible engines because manufacturers have not expended resources to develop systems that could meet the 302°F surface temperature limitation using a water jacketed turbocharger.

In the future, larger engines may be used on permissible equipment, because the new diesel rule allows the use of new technologies in lieu of water jacketing. This new technology, plus the introduction of air-charged aftercoolers on diesel engines, may lead to the application of larger size diesel engines for underground coal production units. Moreover, if manufacturers choose to develop this type of technology for underground coal production units, the number of diesel production machines may increase.

There are also a few underground metal and nonmetal mines that are gassy, and these require the use of part 36 permissible equipment. Permissible equipment in metal and nonmetal mines must be able to control surface temperatures to 400° F. MSHA estimates that there are currently less than 15 metal and nonmetal mines classified as gassy and which, therefore, must use part 36 permissible equipment if diesels are utilized in areas where permissible equipment is required. These gassy metal and nonmetal mines have been using the same permissible engines and power packages as those approved for underground coal mines. (MSHA has not certified a diesel engine exclusively for a part 36 permissible machine for the metal and nonmetal sector since 1985 and has certified only one permissible power package; however, that engine model has been retired and is no longer available as a new purchase to the industry). As a result, these mines are in a similar situation as underground coal mines: engine size (and thus dpm production of each engine) is more limited, and the exhaust is cool enough to add the paper type of filtration device directly to the equipment.

In nongassy underground metal and nonmetal mines, and in all surface mines, mine operators can use conventional construction equipment in their production sections without the need for modifications to the machines. Two examples are haulage vehicles and dump trucks. Some construction vehicles may be redesigned and articulated for sharper turns in underground mines; however, the engines are still the industrial type construction engines. As a result, these mines can and do use engines with larger horsepower. At the same time, since the exhaust is not cooled, paper-type filters cannot be added directly to this equipment without first adding a water scrubber, heat exchanger or other cooling device. The same is true for the equipment used in outby areas of coal mines, where the methane levels do not require the use of permissible equipment.

Future Demand and Emissions

MSHA expects there will be more diesel-powered equipment added to the Nation's mines. While other types of power sources for mining equipment are available, many in the mining industry believe that diesel power provides both safety and economic advantages over alternative power sources available today. Not many studies have been done recently on these contentions, and the studies which have been reviewed by MSHA do not clearly support this hypothesis; but as long as this view remains prevalent, continued growth is likely.

There are additional factors that could increase growth. As noted above, permissible equipment can now be designed in such a way to permit the use of larger engines, and in turn more use of diesel-powered production equipment in underground coal and other gassy mines. Moreover, state laws banning the use of diesel engines in the underground coal sector are under attack. As noted in section 8 of this part, until recently, three major underground coal states, Pennsylvania, West Virginia, and Ohio, have prohibited the use of diesel engines in underground coal mines. In late 1996, Pennsylvania passed legislation (PA Senate Bill No. 1643) permitting such use under conditions defined in the statute. West Virginia passed legislation lifting its ban as of May, 1997 (WV House Bill 2890), subject to regulations to be developed by a joint labor-industry commission. This makes the need to address safety and health concerns about the use of such engines very pressing.

In the long term, the mining industry's diesel fleet will become cleaner, even if the size of the fleet expands. This is because the old engines will eventually be replaced by new engines that will emit fewer particulates than they do at present. As discussed in section 4 of this part, EPA regulations limiting the emissions of particulates and various gasses from new diesel engines are already being implemented for some of the smaller engines used in mining. Under a defined schedule, these new standards will soon apply to other new engines, including the larger engines used in mining. Moreover, over time, the emission standards which new engines will have to pass will become more and more stringent. Under international accords, imported engines are also likely to be cleaner: European countries have already established more stringent emission requirements (Needham, 1993; Sauerteig, 1995).

But MSHA believes that turnover of the mining fleet to these new, cleaner engines will take a very long time because the mining industry tends to purchase for mining use older equipment that is being discarded by other industries. In the meantime, the particulate burden on miners as a group is expected to remain at current levels or even grow.

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

The gaseous constituents of diesel exhaust include oxides of carbon, nitrogen and sulfur, alkanes and alkenes (e.g., butadiene), aldehydes (e.g., formaldehyde), monocyclic aromatics (e.g., benzene, toluene), and polycyclic aromatic hydrocarbons (e.g., phenanthrene, fluoranthene). The oxides of nitrogen (NO_X) are worth particular mention because in the atmosphere they can precipitate into particulate matter. Thus, controlling the emissions of NO_X is one way that engine manufacturers can control particulate production indirectly. (See section 4 of this part).

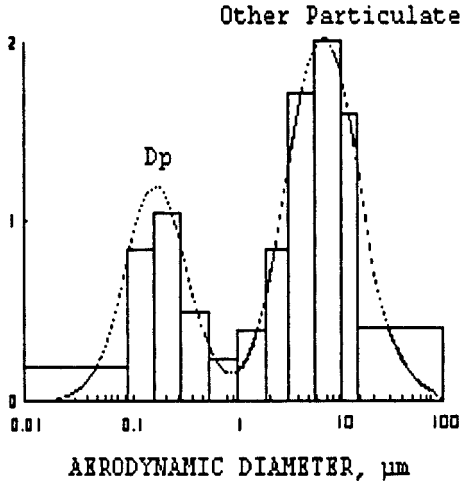
The particulate fraction of diesel exhaust—what is known as soot—is made up of very small individual particles. Each particle consists of an insoluble, elemental carbon core and an

adsorbed, surface coating of relatively soluble organic carbon (hydrocarbon) compounds. There can be up to 1,800 different organic compounds adsorbed onto the elemental carbon core. A portion of this hydrocarbon material is the result of incomplete combustion of fuel; however, the majority is derived from the engine lube oil. In addition, the diesel particles contain a fraction of non-organic adsorbed materials.

Diesel particles released to the atmosphere can be in the form of individual particles or chain aggregates (Vuk, Jones, and Johnson, 1976). In underground coal mines, more than 90% of these particles and chain aggregates are submicrometer in size—i.e., less than 1 micrometer (1 micron) in diameter. In underground metal and nonmetal mines, a greater portion of the aggregates may be larger than 1 micron in size because of the equipment used. Dust generated by mining and crushing of material—e.g., silica dust, coal dust, rock dust—is generally not submicrometer in size.

Figure II–1 shows a typical size distribution of the particles found in the environment of a mine that uses equipment powered by diesel engines (Cantrell and Rubow, 1992). The vertical axis represents relative concentration, and the horizontal axis the particle diameter. As can be seen, the distribution is bimodal, with dpm generally being well less than 1 m in size and dust generated by the mining process being well greater than 1 m. Because of their small size, even when diesel particles are present in large quantities, the environment might not be perceived as ''dusty''. Rather, the perception might be primarily of a vaporous, dirty and smelly ''soot'' or ''smoke''.

Figure II-1 -Typical distribution of dpm relative to distribution of other mining particulates.



The particulate nature of diesel soot has special significance for the mining community, which has a history of significant health and safety problems associated with dusts in the mining atmosphere. As a result of this long experience, the mining community is familiar with the standard techniques to control particulate concentrations. It knows how to use ventilation systems, for example, to reduce dust levels in underground mines. It knows how to water down particulates capable of being impacted by that approach, and to divert particulates away from where miners are actively working. Moreover, the mining community has long experience in the sampling and measurement of particulates—and in all the problems associated therewith. Miners and mine operators are very familiar with sampling devices that are worn by miners during normal work activities or placed in specific locations to collect dust. They understand the significance of sample integrity, the validity of laboratory analysis, and the concept of statistical error in individual samples. They know that weather and mine conditions can affect particulate production, as can changes in mine operations in an area of the mine. MSHA and the former Bureau of Mines have conducted considerable research into these topics. While the mining community has often argued over these points, and continues to do so, the sophistication of the arguments reflects the thorough familiarity of the mining community with particulate sampling and analysis techniques.

(3) *Methods Available to Measure DPM.* There are a number of methods which can measure dpm concentrations with reasonable accuracy when it is at high concentrations and when the purpose is exposure assessment. Measurements for the purpose of compliance determinations must be more accurate, especially if they are to measure compliance with a dpm concentration as low as 200 µg/m^3 or lower. It is with these considerations in mind that MSHA has carefully analyzed

the available methods for measuring dpm.

Comments. In its advanced notice of proposed rulemaking (ANPRM) in 1992, MSHA sought information on whether there are methodologies available for assessing occupational exposures to diesel particulate.

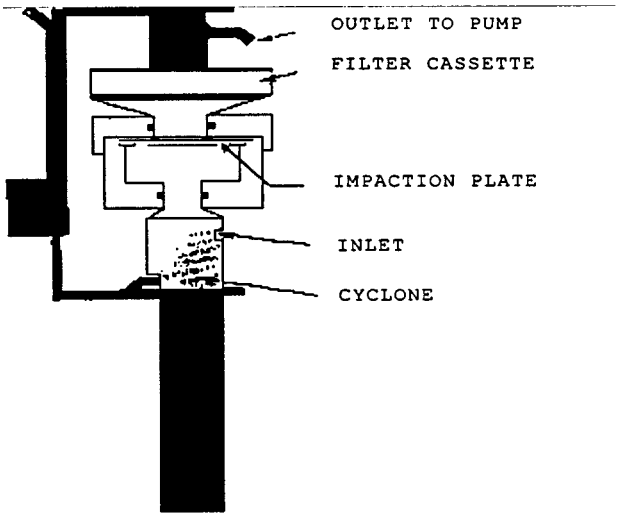
Some commenters argued that at that time there was no validated sampling method for diesel exhaust and there had been no valid analytical method developed to determine the concentration of diesel exhaust. According to the American Mining Congress, (AMC 1992), sampling methods commonly in use were prototypic in nature, were primarily being utilized by government agencies and were subject to interference. Commenters also stated that sampling instrumentation was not commercially available and that the analytical procedures could only be conducted in a limited number of laboratories. Several industry commenters submitted results of studies to support their position on problems with measuring diesel particulate in underground mines. A problem with sampler performance was noted in a study using prototype dichotomous sampling devices. Another commenter indicated that the prototype sampler developed by the former Bureau of Mines (discussed later in this section) for collecting the submicrometer respirable dust was difficult to assemble but easy to use, and that no problems were encountered. Problems associated with gravimetric analysis were also noted in assessing a short term exposure limit (STEL). Another commenter (Morton, 1992) indicated the cost of the sampling was prohibitive.

Another issue addressed by commenters to the 1992 ANPRM was ''Are existing sampling and exposure monitoring methods sufficiently sensitive, accurate and reliable?'' If not, what methods would be more suitable? Some commenters indicated their views that sampling methods had not been validated at that time for compliance sampling. They asserted that, depending on the level of measurement, both the size selective and elemental carbon techniques have some utility. The measurement devices give a precise measurement; however, because of interferants, corrections may need to be made to obtain an accurate measurement. Commenters also expressed the view that all of the sampling devices are sophisticated and require some expertise to assemble and analyze the results, and that MSHA should rely on outside agencies to evaluate and validate the sampling methods. An on-board sampler being developed by Michigan Technological University was the only other emission measurement technology discussed in the comments. However, this device is still in the development stage. Another commenter indicated that the standard should be based on the hazard and that the standard would force the development of measurement technology.

Submicrometer Sampling

The former Bureau of Mines (BOM) submitted information on the development of a prototype dichotomous impactor sampling device that separates and collects the submicrometer respirable particulate from the respirable dust sampled (See Figure II–2).

Figure II- 2
Personal Sampler For Submicrometer Particulate Sampling



The sampling device was designed to help measure dpm in coal mine environments, where, as noted in the last section of this part, nearly all the dpm is submicrometer (less than 1 micron) in size. In its submission to MSHA, the former BOM noted it had redesigned a prototype and had verified the sampler's performance through laboratory and field tests.

As used by the former BOM in its research, the submicrometer respirable particulate was collected on a pre-weighed filter. Post-weighing of the filter provides a measure of the submicrometer respirable particulate. The relative insensitivity of the gravimetric method only allows for a lower limit of detection of approximately 200 $\mu g/m^3$. Because submicrometer respirable particulate can contain particulate material other than diesel particulate, measurements can be subject to interference from other submicrometer particulate material.

NIOSH Method 5040

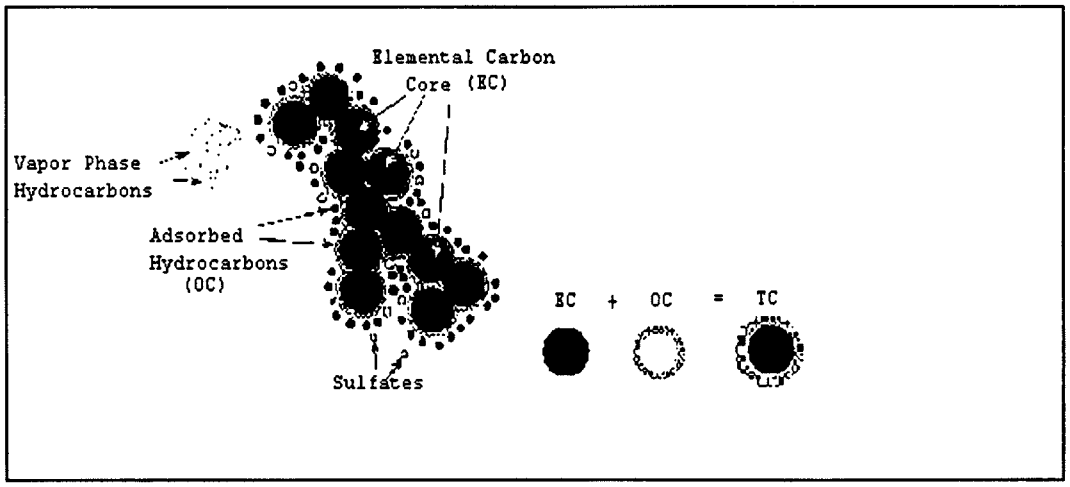
In response to the ANPRM, NIOSH submitted information relative to the development of a sampling and analytical method to assess the diesel particulate concentration in an environment by measuring the amount of total carbon.

As discussed earlier in this part, diesel particulate consists of a core of elemental carbon (EC), adsorbed organic carbon (OC) compounds, sulfates, vapor phase hydrocarbons and traces of other compounds. The method developed by NIOSH provides for the collection of a sample on a quartz fiber filter. The filter is mounted in an open face filter holder that allows for the sample to be uniformly deposited on the filter surface. After sampling, a section of the filter is analyzed using a thermal-optical technique (Birch and Cary, 1996). This technique allows the EC and OC species to be separately identified and quantified. Adding the EC and OC species together provides a measure of the total carbon concentration in the environment. This is indicated diagrammatically in Figure II–3.

Studies have shown that the sum of the carbon (C) components (EC + OC) associated with dpm accounts for 80–85% of the total dpm concentration when low sulfur fuel is used (Birch and Cary, 1996). Since the TC:DPM relationship is consistent, it provides a method for determining the amount of dpm.

The method can detect as little as 1 $\mu g/m^3$ of TC.

Figure II-3
DPM components



Moreover, NIOSH has investigated the method and found it to meet NIOSH's accuracy criterion (NIOSH, 1995); i.e., that measurements come within 25 percent of the true TC concentration at least 95 percent of the time.

NIOSH Method 5040 is directly applicable for the determination of diesel particulate levels in underground metal and nonmetal mines. The only potential sources of carbon in such mines would be organic carbon from oil mist and cigarette smoke. Oil mist may occur when diesel equipment malfunctions or is in need of maintenance. MSHA, currently, has no data as to the frequency of occurrence or the magnitude of the potential interference from oil mist. However, during studies conducted by MSHA to evaluate different methods used to measure diesel particulate concentrations in underground mines, MSHA has not encountered situations where oil mist was found to be an interferant. Moreover, the Agency assumes that full operator implementation of maintenance standards to minimize dpm emissions (which are part of MSHA's proposed rule) will minimize any remaining potential for such interference. MSHA welcomes comments or data relative to oil mist interference. Cigarette smoke is under the control of operators, during sampling times in particular, and hence should not be a consideration.

While samples in underground metal and nonmetal mines could be taken with a submicrometer impactor, this could lead to underestimating the total amount of dpm present. This is because the fraction of dpm particles greater than 1 micron in size in the environment of noncoal mines can be as great as 20% (Vuk, Jones, and Johnson, 1976).

When sampling diesel particulate in coal mines, the NIOSH method recommends that a specialized impactor with a submicrometer cut point, such as the one developed by the former BOM, be used. Use of the submicron impactor minimizes the collection of coal particles, which have an organic carbon content. However, if 10% of coal particles are submicron, this means that up to 200 micrograms of submicrometer coal dust could be collected in face areas under current coal dust standards. Accordingly, for samples collected in underground coal mines, an adjustment may have to be made for interference from submicrometer coal dust; however, outby areas where little coal mine dust is present may not need such an adjustment.

NIOSH further recommends that in using its method in coal mines, the sample only be analyzed for the EC component. Measuring only the EC component ensures that only diesel particulate material is being measured in such cases. However, there are no established relationships between the concentration of EC and total dpm under various operating conditions. (The organic carbon component of dpm can vary with engine type and duty cycle; hence, the amount of whole dpm present for a measured amount of EC may vary). The Agency welcomes data and suggestions that would help it ascertain if and how measurements of

submicrometer elemental carbon could realistically be used to measure dpm concentrations in underground coal mines.

Although NIOSH Method 5040 requires no specialized equipment for collecting a dpm sample, the sample would most probably require analysis by a commercial laboratory. MSHA recognizes that the number of laboratories currently capable of analyzing samples using the thermal-optical method is limited. However, there are numerous laboratories available that have the ability to perform a TC analysis without identifying the different species of carbon in the sample. Total carbon determinations using these laboratories would provide the mine with good information relative to the levels of dpm to which miners are potentially exposed. MSHA believes that once there is a need (e.g., as a result of the requirements of the proposed rule), more commercial laboratories will develop the capability to analyze dpm samples using the thermo-optical analytical method. Currently, the cost to analyze a submicrometer particulate sample for its TC content ranges from $30 to $50. This cost is consistent with costs associated with similar analysis of minerals such as quartz.

RCD Method

Another method, referred to as the Respirable Combustible Dust Method (RCD), has been developed in Canada for measuring dpm concentrations in noncoal mines. Respirable dust is collected with a respirable dust sampler consisting of a 10 millimeter nylon cyclone and a filter capsule containing a preweighed, preconditioned silver membrane filter. Samples are collected at a flow rate of 1.7 liter per minute. The respirable sample collected includes both combustible and noncombustible particulate matter.

Samples collected in accordance with the RCD method require analysis by a commercial laboratory. Total respirable dust is determined gravimetrically by weighing the filter after the sample is collected. After the sample has been subjected to a controlled combustion process at 400°C for two hours, the remainder of the sample is weighed, and the amount of the particulate burned off determined by subtraction. This is the RCD. The combustible particulate matter consists of the soluble organic fraction, the EC core of the dpm, and any other combustible material collected. Thus, only a portion of the RCD is attributable to dpm. Oil mist and other combustible matter collected on the filter are interferants that can affect the accuracy of dpm concentration determination using this method. Because the mass of RCD is determined by weighing, the relative insensitivity of this method is similar to that obtained with the size selective gravimetric method (approximately 200 $\mu g/m^3$).

One commenter (Inco Limited) indicated experience with this method for identifying diesel particulate in their mining operations and suggested that this technique may be appropriate for determining eight hour exposures. Although this method was commonly used by the commenter for assessing dpm levels, concerns for the efficiency of the cyclones used to sample the respirable fraction of the particulate along with interference from oil mist were expressed.

Canada is now experimenting with the use of a submicron impactor with the RCD method.

Sampler Availability

The components for conducting sampling according to the submicrometer and the RCD methods are commercially available, as are those for NIOSH Method 5040, without a submicrometer particulate separator (impactor).

A reusable impactor can be manufactured by machine shops following the design specifications developed by the former U.S. Bureau of Mines (BOM IC 9324, 1992). The use of the size-selective samplers requires some training and laboratory time to prepare the impaction plate and assemble the unit. The cost to manufacture the size-selective units is approximately $35.

In addition, MSHA has requested NIOSH to develop and provide a commercially available disposable submicrometer particulate separator that would be used with existing personal respirable dust sampling equipment. The commercially available separator will be manufactured according to design criteria specified by NIOSH. It is anticipated that other sampling instrument manufacturers will develop commercial units once there is an established need for such a sampling device.

Use of Alternative Surrogates to Assess DPM Concentrations

A number of commenters on the ANPRM indicated that a number of surrogates were available to monitor diesel particulate. Of the surrogates suggested, the most desirable to use would be carbon dioxide because of its ease of measurement. In 1992 the former Bureau of Mines (BOM IC 9324, 1992) reported on research being conducted to investigate the use of CO_2 as a surrogate to assess mine air quality where diesel equipment is utilized. However, because the relationship between CO_2 and other exhaust components depends on the number, type and duty cycle of the engines in operation, no acceptable measurement method based on the use of CO_2 has been developed.

(4) *Reducing Soot at the Source—Engine Standards.* One way to limit diesel particulate emissions is to redesign diesel engines so they produce fewer pollutants. Engine manufacturers around the world are being pressed to do this pursuant to environmental regulations. These cleaner engine requirements are sometimes referred to as tailpipe standards because compliance is measured by checking for pollutants as the exhaust emerges from the engine's tailpipe—before any aftertreatment devices. This section reviews developments in this area, and explains the relationship between the environmental standards on new engines and MSHA engine ''approval'' requirements.

The Clean Air Act and Mobile Sources

The Clean Air Act authorized the Federal Environmental Protection Agency (EPA) to establish nationwide standards for new mobile vehicles, including those powered by diesel engines. These standards are designed, over time, to reduce the volume of certain harmful atmospheric pollutants emanating from mobile sources: particulate matter, nitrogen oxides (which as previously noted, can result in the generation of particulates in the atmosphere), hydrocarbons and carbon monoxide.

California has its own standards. New engines destined for use in California must meet standards under the law of that State. The standards are issued and administered by the California Air Resources Board (CARB). In recent years, EPA and CARB have worked together with industry in establishing their respective standards, so most of them are identical.

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

Engines are generally divided into three broad categories for purposes of

environmental emissions standards, in accordance with the primary use for which the type of engine is designed: (1) cars and light duty trucks (i.e., to power passenger transport); (2) heavy duty trucks (i.e., to power over-the-road hauling); and (3) nonroad vehicles (i.e., to power small equipment, construction equipment, locomotives and other non-highway uses). Engines used in mining equipment are not regulated as a separate category in this regard, but engines in all three categories are engaged in mining work, from generator sets to pickup trucks to huge earth movers and haulers.

New vs. Used

The environmental tailpipe requirements are applicable only to new engines. In the mining industry, used engines are often purchased; and, of course, the existing fleet consists of engines that are not new. Thus, although these tailpipe requirements will bring about gradual reduction in the overall contribution of diesel pollution to the atmosphere, the beneficial effects on mining atmospheres may require a longer timeframe, absent actions to accelerate the turnover of mining fleets to the cleaner engines.

In underground coal mining, MSHA has already taken actions which will have such an effect on the fleet. The diesel equipment rule issued in late 1996 requires that by November 25, 1999, all diesel equipment used in underground coal mines use an approved engine and maintain that engine in approved condition. (30 CFR 75.1907.) MSHA expects this will result in the replacement of about 47 percent of the diesel engines now in the underground coal mine inventory with engines that emit fewer pollutants. The timeframe permitted for the turnover was based upon MSHA's estimates of the useful life in an underground mining environment of the ''outby'' equipment involved.

Technology-Forcing Schedule

As noted above, the exact environmental tailpipe requirements which a new diesel engine must meet varies with the date of manufacture. The Clean Air Act, which was most recently amended in 1990, establishes a schedule for the reduction of particular pollutants from mobile sources. EPA and CARB, working closely with the diesel engine industry, have endeavored to turn this into a regulatory schedule that forces technology while taking into account certain technological realities (e.g., actions taken to reduce particulate emissions may increase NOx emissions, and vice versa). Existing EPA regulations for on-highway engines (both for light duty vehicles and heavy duty trucks) and non-road engines schedule the tailpipe standards that must be met for the rest of this century. Agreements between EPA, CARB and the engine industry are now leading to proposed rules for engine standards to be met during the early part of the next century. These standards will be stricter and will lower the levels of diesel emissions.

Light-Duty Engines

The current regulations on light duty vehicle engines (cars and passenger trucks) were set in 1991. (56 FR 25724). EPA is currently considering proposing new standards for this category. Pursuant to a specific requirement in the Clean Air Act Amendments of 1990, EPA is to study and report to Congress on whether further reductions in this category should be pursued. A public workshop was held in the Spring of 1997. EPA plans provide for a draft report to be available for public comment by Spring of 1998, and a final report completed by July 1998, although a notice of citizen suit has been filed to speed the process. Up-to-date information about the progress of this initiative can be found at the home page for the study (http://www.epa.gov/omswww/tr2home.htm).

On-Highway Heavy Duty Truck Engines

The first phase of the on-highway standards for heavy duty diesel engines was applicable to engines manufactured in 1985. (40 CFR 86.085–11.) For the first time, separate standards for NO_X and hydrocarbons were established. The nitrogen oxides and hydrocarbons are precursors of ground level ozone, a major component of smog. A number of hydrocarbons are also toxic, while nitrogen oxides contribute to the formation of acid rain and can, as previously noted, precipitate into particulate matter. In 1988, a specific standard limiting particulate matter emitted from the heavy duty on-highway diesel engines went into effect. (40 CFR 86.088–11). The Clean Air Act Amendments and the regulations provided for phasing in even tighter controls on NO_X and particulate matter through 1998. Reductions in NO_X took place in 1990 and 1991 and are to occur again in 1998, and reductions in PM took place in 1991 and 1994. Certain types of trucks in particularly polluted urban areas must reach even tighter requirements.

On October 21, 1997, EPA issued a new rule for on-highway engines that will take effect for engine model years starting in 2004. (62 FR 54693.) The rule establishes a combined requirement for NO_X and HC. The combined standard is set at 2.5gm/bhp-hr, which includes a cap of 0.5gm/bhp-hr for HC. Prior to the rule, the EPA, CARB, and the engine manufacturers signed a Statement of Principles (SOP) that agreed on harmonization of the emission standards and the feasible levels that could be achieved. The rule allows manufacturers a choice of two combinations of NO_X and HC, with a net expected reduction in NO_X emissions of 50%. The rule does not require further reductions in tailpipe emissions of PM.

Non-road Engines

Of particular interest to the mining community is the EPA's regulatory work on the standards that will be applicable to non-road engines, for these include the engines used in the heaviest mining equipment.

The 1990 Clean Air Act Amendments specifically directed EPA to study the contribution of nonroad engines to air pollution, and regulate them if warranted. In 1991, EPA released a study that documented higher than expected emission levels across a broad spectrum of nonroad engines and equipment (EPA Fact Sheet, EPA420–F–96–009, 1996). In response, EPA initiated several regulatory programs. One of these set emission standards for land-based nonroad engines greater than 50 horsepower (other than for rail use). Limits are established for tailpipe emissions of hydrocarbons, carbon monoxide, NO_X, and dpm. The limits are phased in from 1996 to 2000: starting in 1996 with nonroad engines from 175 to 750 hp, then smaller engines, and by 2000 the larger nonroad engines. Moreover, in February 1997, restrictions on nonroad engines for locomotives were proposed. (62 FR 6366.)

In September 1996, EPA announced another Statement of Principles (SOP) with the engine industry and CARB on new rounds of restrictions for non-road engines to begin to take place in this century. This led in September 1997 to a proposed rule setting standards for almost all types of engines in this category manufactured after 1999–2006 (the actual year depends on the category). (62 FR 50151.) The applicable standards for an engine category would be gradually tightened through three tiers. They would set a cap on the combined NO_X and HC (similar to the on-highway), set CO standards, and lower standards on PM. The implementation of the final tier of the proposed reductions is subject to a technology review in 2001 to ensure

that the appropriateness of the levels to be set is feasible.

Will the Diesel Engine Industry Meet Mining Industry Requirements?

Concern has been expressed from time to time that the diesel industry might not be able to meet the ever tightening standards on tailpipe emissions, and might, therefore, stop producing certain engines needed by the mining community or other industries (Gushee, 1995). To date, however, such concerns have not been realized. The fact that the most recent regulations have been developed through a consensus process with the engine industry, and that the non-road plan includes a scheduled technology review to ensure the proposed emission standards can really be achieved, suggests that although the EPA standards are technology forcing, diesel engines will continue to be available to meet the needs of the mining community for the foreseeable future. In addition, the nonroad engine agreement with the industry calls for development of a separate research agreement involving stakeholders in the exploration of technologies that can achieve very low emission levels of NO_X and PM ''while preserving performance, reliability, durability, safety, efficiency, and compatibility with nonroad equipment'' (EPA420–F–96–015, September 1996). Also, Vice President Gore has recently noted that the Administration is committed to emissions research that would clean up both the diesels currently on the road, as well as enabling these engines an opportunity to compete as a new generation of vehicles is developed that are far more efficient than today's vehicles (White House Press Release, July 23, 1997). It is always possible, of course, that some new technological problems could emerge that could impact diesel engine availability—e.g., confirmation that some of the newer engines produce high levels of ''nanoparticles'' particulates and that such emissions pose some sort of a health problem. Research of nanoparticles and their health effects is currently a topic of investigation (Bagley et al., 1996).

A related question has been whether the costs of the ''high-tech'' diesel engines will make them unaffordable in practice to the mining community. MSHA believes the new engines will be affordable. The fact that the engine industry has agreed to the new standards, and has some assurance of what the applicable standards will be for the foreseeable future, should help keep costs in check.

In theory, underground mines can control costs by purchasing certain types of new engines that do not have to meet the new EPA standards. The rules on heavy duty on-highway truck engines were not applied to engines intended to be used in underground coal mines (59 FR 31336), and the new proposed rules on nonroad vehicles would likewise not be mandatory for engines intended for any underground mining use. In practice, however, it is not likely that engine manufacturers will produce special engines once they switch over their production lines to meet the new EPA standards, because there are few types and sizes of engines in production for which the mining community is the major market. Moreover, the larger engines (above 750 hp) are specifically covered by the EPA nonroad rules (*Engine Manufacturers Assn.* vs. *EPA*, 88 F.3d 1075, 319 U.S. App.D.C. 12 (1996)).

MSHA Approved Engines

Acting under its own authority to protect miner safety and health, MSHA requires that diesel engines used in certain types of mining operations be ''approved'' as meeting certain tailpipe standards.

In some ways, the standards are akin to those of EPA and CARB. For example, MSHA, CARB and EPA generally use the same tests to check emissions. MSHA uses a steady state, 8-mode test cycle, the same as EPA and CARB use to test engines designed for use in off-road equipment; however, EPA uses a different, transient test for on-highway engines.

But to be approved by MSHA, an engine does not have to be as clean as the newer diesel engines, every generation of which must meet ever tighter EPA and CARB tailpipe standards. Approval of an engine by MSHA merely ensures that the tailpipe emissions from that engine meet certain basic standards of cleanliness—cleaner than the engines which many mines continue to use.

The MSHA approval rules were revised in 1996 (as part of the 1996 rule on the use of diesel equipment in underground coal mines) to provide the mining community with additional information about the cleanliness of the emissions emerging from the tailpipe of various engines. Specifically, the agency now requires that a particulate index (PI) be reported as part of MSHA's engine approval. This index permits operators to evaluate the contribution of a proposed new addition to the fleet to the mine's particulate concentrations.

There is no requirement that approved engines meet a particular PI; rather, the requirement is for information purposes only. In its 1996 rulemaking, MSHA explicitly deferred until this rulemaking the question of whether to require engines used in mining environments to meet a particular PI. (61 FR 55420–21, 55437). The Agency has decided not to take that approach, for the reasons discussed in part V of this preamble.

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

This section provides an overview of EPA rulemaking on particulate matter. For more detailed information, commenters are referred to ''The Plain English Guide to the Clean Air Act,'' EPA 400–K–93–001, 1993, to the ''Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information'', EPA–452/R–96–013, 1996; and, on the latest rule, to EPA Fact Sheets, July 17, 1997. These and other documents are available from EPA's Web site.

Background

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

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

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

TSP

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

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

PM_{10}

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

Some state implementation plans required surface mines to take actions to help the state meet the PM_{10} standard. In particular, some surface mines in Western states were required to control the coarser particles—e.g., by spraying water on roadways to limit dust. The mining industry has objected to such controls, arguing that the coarser particles do not adversely impact health, and has sought to have them excluded from the EPA ambient air standards (Shea, 1995; comments of Newmont Gold Company, March 11, 1997, EPA docket number A–95–54, IV–D–2346).

$PM_{2.5}$

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

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

The basis for the $PM_{2.5}$ NAAQS is a new body of scientific data suggesting that particles in this size range are the ones responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. (A chart of the scientific review process is available on EPA's web site — http://ttnwww.rtpnc.epa.gov/naaqspro/pmnaaqs.gif). The proposed rule resulted in considerable press attention, and hearings by Congress, in which this scientific evidence was further discussed. Following a careful review, President Clinton announced his concurrence with the rulemaking in light of the scientific evidence of risk. However, the implementation schedule for the rule is long enough so that the next review of the science is scheduled to be completed before the states are required to meet the new NAAQS for $PM_{2.5}$—hence, adjustment of the standard is still possible before implementation.

Implications for the Mining Community

As noted earlier in this part, diesel particulate matter is mostly less than 1.0 micron in size. It is, therefore, a fine particulate. The body of evidence of human health risk from environmental exposure to fine particulates must, therefore, be considered in assessing the risk of harm to miners of occupational exposure to one type of fine particulate—diesel particulate. MSHA has accordingly done so in its risk assessment (see part III of this preamble).

(6) *Controlling Diesel Particulate Emissions in Mining—a Toolbox.* Efforts to control diesel particulate emissions have been under review for some time within the mining community, and accordingly, there is considerable practical information available about controls—both in general terms, and with respect to specific mining situations.

Workshops

In 1995, MSHA sponsored three workshops ''to bring together in a forum format the U.S. organizations who have a stake in limiting the exposure of miners to diesel particulate (including) mine operators, labor unions, trade organizations, engine manufacturers, fuel producers, exhaust aftertreatment manufacturers, and academia.'' (McAteer, 1995). The sessions provided an overview of the literature and of diesel particulate exposures in the mining industry, state-of-the-art technologies available for reducing diesel particulate levels, presentations on engineering technologies toward that end, and identification of possible strategies whereby miners' exposure to diesel particulate matter can be limited both practically and effectively. One workshop was held in Beckley, West Virginia on September 12 and 13, and the other two were held on October 6, and October 12 and 13, 1995, in Mt Vernon, Illinois and Salt Lake City, Utah, respectively. A transcript was made. During a speech early the next year, the Deputy Assistant Secretary for MSHA characterized what took place at these workshops:

> The biggest debate at the workshops was whether or not diesel exhaust causes lung cancer and whether MSHA should move to regulate exposures. Despite this debate, what emerged at the workshops was a general recognition and agreement that a health problem seems to exist with the current high levels of diesel exhaust exposure in the mines. One could observe that while all the debate about the studies and the level of risk was going on, something else interesting was happening at the workshops: One by one miners, mining companies, and

manufacturers began describing efforts already underway to reduce exposures. Many are actively trying to solve what they clearly recognize is a problem. Some mine operators had switched to low sulfur fuel that reduces particulate levels. Some had increased mine ventilation. One company had tried a soy-based fuel and found it lowered particulate levels. Several were instituting better maintenance techniques for equipment. Another had hired extra diesel mechanics. Several companies had purchased electronically controlled, cleaner, engines. Another was testing a prototype of a new filter system. Yet another was using disposable diesel exhaust filters. These were not all flawless attempts, nor were they all inexpensive. But one presenter after another described examples of serious efforts currently underway to reduce diesel emissions. (Hricko, 1996).

Toolbox

In March of 1997, MSHA issued, in draft form, a publication entitled ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox''. The draft publication was disseminated by MSHA to all underground mines known to use diesel equipment and posted on MSHA's Web site. Following comment, the toolbox was finalized in the Fall of 1997 and disseminated. For the convenience of the mining community, a copy is reprinted as an Appendix at the end of this document.

The material on controls is organized as a ''toolbox'' so that mine operators have the option of choosing the control technology that is most applicable to their mining operation for reducing exposures to dpm. The Toolbox provides information about nine types of controls that can reduce dpm emissions or exposures: Low emission engines; fuels; aftertreatment devices; ventilation; enclosed cabs; engine maintenance; work practices and training; fleet management; and respiratory protective equipment.

The Estimator

MSHA has developed a model that can help mine operators evaluate the effect of alternative controls on dpm concentrations. The model is in the form of a template that can be used on standard computer spreadsheet programs; as information about a new combination of controls is entered, the results are promptly displayed. A complete description of this model, referred to as ''the Estimator,'' and several examples, are presented in part V of this preamble. MSHA intends to make this model widely available to the mining community, and hopes to receive comments in connection with this rulemaking based on the results of estimates conducted with this model.

History of Diesel Aftertreatment Devices in Mining

For many years, the majority of the experience has been with the use of oxidation catalytic converters (OCCs), but in more recent years both ceramic and paper filtration systems have also been used more widely.

OCCs began to be used in underground mines in the 1960's to control carbon monoxide, hydrocarbons and odor (Haney, Saseen, Waytulonis, 1997). That use has been widespread. It has been estimated that more than 10,000 OCCs have been put into the mining industry over the years (McKinnon, dpm Workshop, Beckley, WV, 1995).

When such catalysts are used in conjunction with low sulfur fuel, there is a reduction of up to 90 percent of carbon monoxide, hydrocarbons and aldehyde emissions, and nitric oxide can be transformed to nitrogen dioxide. Moreover, there is also an approximately 20 percent reduction in diesel particulate mass. The diesel particulate reduction comes from the elimination of the soluble organic compounds that, when condensed through the cooling phase in the exhaust, will attach to the elemental carbon cores of diesel particulate. Unfortunately, this effect is lost if the fuel contains more than 0.05 percent sulfur. In such cases, sulfates can be produced which ''poison'' the catalyst, severely reducing its life. With the use of low sulfur fuel, some engine manufacturers have certified diesel engines with catalytic converter systems to meet EPA requirements for lower particulate levels (see section 4 of this part).

The particulate trapping capabilities of some OCCs are even higher. In 1995, the EPA implemented standards requiring older buses in urban areas to reduce the dpm emissions from rebuilt bus engines. (40 CFR 85.1403). Aftertreatment manufacturers developed catalytic converter systems capable of reducing dpm by 25%. Such systems are available for larger diesel engines common in the underground metal and nonmetal sector.

Other types of aftertreatment devices capable of more significant reductions in particulate levels began to be developed for commercial applications following EPA rules in 1985 limiting diesel particulate emissions from heavy duty diesel engines. The wall flow type ceramic honeycomb diesel particulate filter system was initially the most promising approach (SAE, SP–735, 1988). However, due to the extensive work performed by the engine manufacturers on new technological designs of the diesel engine's combustion system, and the use of low sulfur fuel, particulate traps turned out to be unnecessary to comply with the EPA standards of the time.

While this work was underway, efforts were also being made to transfer this aftertreatment technology to the mining industry. The former Bureau of Mines investigated the use of catalyzed diesel particulate filters in underground mines in the United States (BOM, RI–9478, 1993). The investigation demonstrated that filters could work, but that there were problems associated with their use on individual unit installations, and the Bureau made recommendations for installation of ceramic filters on mining vehicles. But as noted by one commenter at one of the MSHA workshops in 1995, ''while ceramic filters give good results early in their life cycle, they have a relatively short life, are very expensive and unreliable.'' (Ellington, dpm Workshop, Salt Lake City, UT, 1995).

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

Work with ceramic filters in the last few years has led to the development of the ceramic fiber wound filter cartridge (SAE, SP–1073, 1995). The ceramic fiber has been reported by the manufacturer to have dpm reduction efficiencies up to 80 percent. This system has been used on vehicles to comply with German requirements that all diesel engines used in confined areas be filtered. Other manufacturers have made the wall flow type ceramic honeycomb dpm filter system commercially available to meet the German standard. In the case of some engines, a choice of the two types is available; but depending upon horsepower, this may not always be the case.

In the early 1990's, MSHA worked with the former Bureau of Mines and a filter manufacturer to successfully develop and test a pleated paper filter for wet water scrubber systems of permissible diesel powered equipment. The dpm reduction from these filters has been determined in the field by the former BOM to be up to 95% (BOM, IC

9324). The same type of filter has been used in recently developed dry systems for permissible machines, with reported laboratory reductions in dpm of 98% (Paas, dpm Workshop, Beckley WV, 1995).

ANPRM Comments

The ANPRM requested information about several kinds of work practices that might be useful in reducing dpm concentrations. These comments were provided well before the workshops mentioned above, and before MSHA issued its diesel equipment standard for underground coal mines, and are thus somewhat dated. But, solely to illustrate the range of comments received, the following sections review the comments concerning certain work practices—fuel type, fuel additives, and maintenance practices.

Type of Diesel Fuel Required

It has been well established that the quality of diesel fuel influences emissions. Sulfur content, cetane number, aromatic content, density, viscosity, and volatility are interrelated fuel properties which can influence emissions. Sulfur content can have a significant effect on diesel emissions.

Use of low sulfur diesel fuel reduces the sulfate fraction of dpm matter emissions, reduces objectionable odors associated with diesel exhaust and allows oxidation catalysts to perform properly. The use of low sulfur fuel also reduces engine wear and maintenance costs. Fuel sulfur content is a particularly important parameter when the fuel is used in low emission diesel engines. Low sulfur diesel fuel is available nationwide due to EPA regulations. (40 CFR parts 80 and 86.) In MSHA's ANPRM, information was requested on what reduction in concentration of diesel particulate can be achieved through the use of low sulfur fuel. Information was also solicited as to whether the use of low sulfur fuel reduces the hazard associated with diesel emissions.

Responses from commenters stated that there would be a positive reduction in particulate with the use of low sulfur fuel. One commenter stated that the brake specific exhaust emissions (grams/brake horsepower-hour) of particulate would decrease by about 0.06 g/bhp-hr for a fuel sulfur reduction of 0.25 weight percent sulfur. The particulate reduction effect is proportional to the change in sulfur content. Another commenter stated that a typical No. 2 diesel fuel containing 0.25 percent weight sulfur will include 1 to 1.6 grams of sulfate particulate per gallon of fuel consumed. A fuel containing 0.05 percent weight sulfur will reduce sulfate particulate to 0.2–0.3 grams per gallon of fuel consumed, an 80 percent reduction.

In responding to the question on whether reducing the sulfur content of the fuel will reduce the health hazard associated with diesel emissions, several commenters stated that they knew of no evidence that sulfur reduction reduces the hazard of the particulate. MSHA also is not aware of any data supporting the proposition that reducing the sulfur content of the fuel will reduce the health hazard associated with diesel emissions. However, in the preamble to the final rule for the EPA requirement for the use of low sulfur fuel, EPA stated that there were a number of benefits which could be attributed to lowering the sulfur content of diesel fuel. The first area was in exhaust aftertreatment technology. Reductions in fuel sulfur content will result in small reductions in sulfur compounds being emitted. This will cause the whole particulate concentration from the engine to be reduced. However, the number of carbon particles is not reduced, therefore, the total carbon concentration would be the same.

The major benefit of using low sulfur fuel is that the reduction of sulfur allows for the use of some aftertreatment devices such as catalytic converters, and catalyzed particulate traps which were prohibited with fuels of high sulfur content (greater than 0.05 percent sulfur). The high sulfur content led to sulfate particulate that when passed through the catalytic converter or catalyzed traps was changed to sulfuric acid when the sulfates came in contact with water vapor. Using low sulfur fuel permits these devices to be used.

The second area of benefits that the EPA noted was that of reduced engine wear with the use of low sulfur fuel. Reducing engine wear will help maintain engines in their near manufactured condition that would help limit increases in particulate matter due to lack of maintenance or age of the engine.

Other questions posed in the ANPRM requested information concerning the differences in No. 1 and No. 2 diesel fuel regarding particulate formation; the current sulfur content of diesel fuel used in mines; and when would 0.05 percent sulfur fuel be available to the mining industry.

In response to those questions, commenters stated that a difference in No. 1 and No. 2 fuel regarding particulate formation would be that No. 1 fuel typically has less sulfur than No. 2 fuel and would therefore be expected to produce less particulate. Also, the No. 1 fuel has a lower density, boiling range and aromatic content and a higher cetane number. All of these fuel property differences tend to cause lower particulate emissions.

Commenters also stated that the sulfur content of fuels commercially available for diesel-powered equipment can vary from nearly zero to 1 percent. The national average sulfur content for commercial No. 2 diesel fuel is approximately 0.25 percent. One commenter stated that sulfur content varied from region to region and the National Institute of Petroleum and Energy Research survey could be used to get the answers for specific regions.

Commenters noted that low sulfur fuel, less than 0.05 percent sulfur, would be available for on-highway use as mandated by the EPA by October 1993. Also, California requires the statewide availability of 0.05 percent sulfur fuel for all diesel engine applications by the same date. Although the EPA mandate ensures that low sulfur fuel will be available throughout the nation, commenters indicated the availability for off-road and mining application was uncertain at that time.

The ANPRM also requested information on the differences in the per gallon costs among No. 1, No. 2 and 0.05 percent sulfur fuel; how much fuel is used annually in the mining industry; and what would be the economic impact on mining of using 0.05 percent sulfur fuel. In response, commenters stated that No. 1 fuel typically costs the user 10 to 20 percent more than does No. 2 fuel. They also stated that the price of 0.05 percent sulfur fuel will eventually be set by the competitive market conditions. No information was submitted for accurately estimating fuel usage costs to the industry. The economic impact on the mining industry of using 0.05 percent fuel will vary greatly from mine to mine. Factors influencing that cost are a mine's dependence on diesel powered equipment, the location of the mine and existing regulation. Mines relying heavily on diesel equipment will be most impacted.

Another commenter stated that the price for 0.05 percent fuel is forecast to average about 2 cents per gallon higher than the price for typical current No. 2 fuel. Kerosene and No. 1 distillate are forecast as 2 to 4 cents per gallon above 0.05 percent fuel and 4 to 6 cents above current No. 2 fuel. A recent census of mining and manufacturing dated 1987 showed mining industry energy consumption from all sources to total 1968.4 trillion BTU per year. Coal mining alone used 9.96 million barrels

annually of distillate, at a cost of 258.1 million dollars. Included in these quantities was diesel fuel for surface equipment and vehicles at or around the mine site. The commenter also stated that applying a cost increase of 2 cents per gallon to the total industry distillate consumption would increase annual fuel costs by $24.3 million. For coal mining only, the cost increase would be $8.4 million annually.

While MSHA does not have an opinion on the accuracy of the information received in this regard, it is in any event dated. Since the time that the ANPRM was open, the availability of low sulfur fuel has become more common. Comments received at MSHA's Diesel Workshops indicate that low sulfur fuel is readily available and that all that is needed to obtain it is to specify the desired fuel quality on the purchase order. The differences in the fuel properties of No. 1 and No. 2 fuel are consistent with specifications provided by ASTM and other literature information concerning fuel properties.

Fuel Additives

Information relative to fuel additives was requested in MSHA's ANPRM. The ANPRM requested information on the availability of fuel additives that can reduce dpm or additives being developed; what diesel emissions reduction can be expected through the use of these fuel additives; the cost of additives and advantages to their use; and will these fuel additives introduce other health hazards. One commenter stated that cetane improvers and detergent additives can reduce dpm from 0 to 10 percent. The data, however, does not indicate consistent benefits as in the case with sulfur reduction. Oxygenate additives can give larger benefits, as with methanol, but then the oxygenate is not so much an additive as a fuel blend. Another commenter stated the cost depended on the price and concentration of the additive. This commenter estimated the cost to be between three and seven cents per gallon of fuel.

Another commenter stated that some additives are used for reducing injector tip fouling, other alternative additives also are offered specifically for the purpose of reducing smoke or dpm such as organometallic compounds, i.e., copper, barium, calcium, iron or platinum; oxygenate supplements containing alcohols or peroxides; and other proprietary hydrocarbons. The commenter did not quantify the expected reductions in dpm.

The former Bureau of Mines commented on an investigation of barium-based, manganese based, and ferrocene fuel additives. Details of the investigation are found in the literature (BOM, IC 9238, 1990). In general, fuel additives are not widely used by the mining industry to reduce dpm or to reduce regeneration temperatures in ceramic particulate filters. Research has shown aerosol reductions of about 30 percent without significant adverse impacts although new pollutants derived from the fuel additive remain a question.

One commenter stated that a cetane improver and detergent additives should not exceed 1 cent per gallon at the treat rates likely to be used. The use of oxygenates depends on which one and how much but would be perhaps an order of magnitude higher than the use of a cetane improver. One commenter also added that any fuel economy advantages would be very small.

In response to the creation of a health hazard when using additives, one commenter stated that excessive exposure to cetane improver (alkyl nitrates), which is hazardous to humans, requires special handling because of poor thermal stability. Detergent additives are similar to those used in gasoline and probably have similar safety and health issues. Except at low load operation, additives are not likely to result in any significant quantity in the exhaust. Another commenter stated that the effect on human health of new chemical exhaust species that may result from the use of some of these additives has not been determined. Engine manufacturers also are concerned about the use of such products because their effectiveness has not always been adequately demonstrated and, in many cases, the effect on engine durability has not been well-documented for different designs and operating conditions.

MSHA agrees with the commenters that fuel additives can affect engine performance and exhaust emissions. MSHA's experience with additives has shown that they can enhance fuel quality by increasing the cetane number, depressing the cloud point, or in the case of a barium based additive, affect the combustion process resulting in a reduction of particulate output. MSHA's experience also has shown that in most cases the effects of an additive on engine performance or emissions cannot be adequately determined without extensive research. The additives listed on EPA's list of ''registered additives'' meet the requirements of EPA's standards in 40 CFR part 79.

MSHA is concerned about the use of untested fuel additives. A large number of additives are currently being marketed to reduce emissions. These additives include cetane improvers that increase the cetane number of the fuel, which may reduce emissions and improve starting; detergents that are used primarily to keep the fuel injectors clean; dispersants or surfactants that prevent the formation of thicker compounds that can form deposits on the fuel injectors or plug filters. While the use of many of these additives will result in reduced particulate emission, some have been found to introduce harmful agents into the environment. For this reason, it is a good idea to limit the use of additives to those that have been registered by the EPA.

Maintenance Practices

The ANPRM requested information concerning what maintenance procedures are effective in reducing diesel particulate emissions from existing diesel-powered equipment, and what additional maintenance procedures would be required in conjunction with anticipated developments of new diesel particulate reduction technology. Information was also requested about the amount of time to perform the maintenance procedures and if any, loss of production time.

Commenters stated that some maintenance procedures have a very dramatic impact on particulate emissions, while other procedures that are equally important for other reasons have little or no impact at all on particulates. Another commenter stated that maintenance procedures are intended to ensure that the engine operates and will continue to operate as intended. Such procedures will not reduce diesel particulate below that of the new, original equipment. A commenter stated that the diesel engine industry experience has demonstrated that emissions deterioration over the useful life of an engine is minimal.

Commenters stated that depending on the implied technology, the need for additional maintenance will be based on complexity of the control devices. Also, time for maintenance will be dependent on complexity of the control device. Some production loss will occur due to increased maintenance procedures.

MSHA agrees with the commenters' view that maintenance does affect engine emissions, some more dramatically than others. Research has clearly shown that without engine maintenance, all engine emissions will increase greatly. For example, the former Bureau of Mines, in conjunction with Southwest Research, conducted extensive research on the effects of maintenance on diesel engines which indicated this result (BOM contract H–0292009, 1979). MSHA agrees that

emissions increase is minimal over the useful life of the engine only when proper maintenance is performed daily. However, MSHA believes that with the awareness of the increased maintenance, production may not be lost due to the increased time that the machines are able to operate without unwanted down time due to poor maintenance practices.

MSHA's diesel ''toolbox'' includes an extensive discussion on the importance of maintenance. It reminds operators and diesel maintenance personnel of the basic systems on diesel engines that need to be maintained, and how to avoid various problems. It includes suggestions from others in the mining community, and information on their success or difficulties in this regard.

(7) *Existing Mining Standards that Limit Miner Exposure to Occupational Diesel Particulate Emissions.* MSHA already has in place various requirements that help to control miner exposure to diesel emissions in underground mines—including exposure to diesel particulate. These include ventilation requirements, engine approval requirements, and explicit restrictions on the concentration of various gases in the mine environment.

In addition, in 1996, MSHA promulgated a rule governing the use of diesel-powered equipment in underground coal mines. (61 FR 55412). While the primary focus of the rulemaking was to promote the safe use of diesel engines in the hazardous environment of underground coal mines, various parts of the rule will help to control exposure to harmful diesel emissions in those mines. The new rule revised and updated MSHA's diesel engine approval requirements and the ventilation requirements for underground coal mines using diesel equipment, and established requirements concerning diesel fuel sulfur content and the idling, maintenance and emissions testing of diesel engines in underground coal mines.

Background

Beginning in the 1940s, mining regulations were promulgated to promote the safe and healthful use of diesel engines in underground mines. In 1944, part 31 established procedures for limiting the gaseous emissions and establishing the recommended dilution air quantity for mine locomotives that use diesel fuel. In 1949, part 32 established procedures for testing of mobile diesel-powered equipment for non-coal mines. In 1961, part 36 was added to provide requirements for the use of diesel equipment in gassy noncoal mines, in which engines must be temperature controlled to prevent explosive hazards. These rules responded to research conducted by the former Bureau of Mines.

Continued research by the former Bureau of Mines in the 1950s and 1960s led to refinements of its ventilation recommendations, particularly when multiple engines are in use. An airflow of 100 to 250 cfm/bhp was recommended for engines that have a properly adjusted fuel to air ratio (Holtz, 1960). An additive ventilation requirement was recommended for operation of multiple diesel units, which could be relaxed based on the mine operating procedures. This approach was subsequently refined to become a 100–75–50 percent guideline (MSHA Policy Memorandum 81–19MM, 1981). Under this guideline, when multiple pieces of diesel equipment are operated, the required airflow on a split of air would be the sum of: (a) 100 percent of the nameplate quantity for the vehicle with the highest nameplate air quantity requirement; (b) 75 percent of the nameplate air quantity requirement of the vehicle with the next highest nameplate air quantity requirement; and (c) 50 percent of the nameplate airflow for each additional piece of diesel equipment.

Diesel Equipment Rule

On October 6, 1987, MSHA published in the **Federal Register** (52 FR 37381) a notice establishing a committee to advise the Secretary of Labor on health and safety standards related to the use of diesel-powered equipment in underground coal mines. The ''Mine Safety and Health Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines'' (the Advisory Committee) addressed three areas of concern: the approval of diesel-powered equipment, the safe use of diesel equipment in underground coal mines, and the protection of miners' health. The Advisory Committee submitted its recommendations in July 1988.

With respect to the approval of diesel-powered equipment, the Advisory Committee recommended that all diesel equipment except for a limited class, be approved for use in underground coal mines. This approval would involve both safety (e.g., fire suppression systems) and health factors (e.g., maximum exhaust emissions).

With respect to the safe use of diesel equipment in underground coal mines, the Advisory Committee recommended that standards be developed to address the safety aspects of the use of diesel equipment, including such concerns as equipment maintenance, training of mechanics, and the storage and transport of diesel fuel.

The Advisory Committee also made recommendations concerning miner health, discussed later in this section.

As a result of the Advisory Committee's recommendations on approval and safe use, MSHA developed and, on October 25, 1996, promulgated as a final rule, standards for the ''Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines.'' (61 FR 55412).

The October 25, 1996 final rule on diesels focuses on the safe use of diesels in underground coal mines. Integrated requirements are established for the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, maintenance requirements, fire suppression, and design features for nonpermissible machines. While the focus was on safety, certain rules related to emissions are included in the final rule. For example, the final rule requires maintenance on diesel powered equipment. Regular maintenance on diesel powered equipment should keep the diesel engine and vehicle operation at its original or baseline condition. However, as a check that the maintenance is being performed, MSHA wrote a standard for checking the gaseous CO emission levels on permissible and heavy duty outby machines to determine the need for maintenance. The CO check requires that a regular repeatable loaded engine condition be run on a weekly basis and the CO measured. Carbon monoxide is a good indicator of engine condition. If the CO measurement increases to a higher concentration than what was normally measured during the past weekly checks, then a maintenance person would know that either the regular maintenance was missed or a problem has developed that is more significant than could be identified by a general daily maintenance program.

Consistent with the Advisory Committee's recommendation, the final rule, among other things, requires that virtually all diesel-powered engines used in underground coal mines be approved by MSHA. (30 CFR part 7 (approval requirements), part 36 (permissible machines defined), and part 75 (use of such equipment in underground coal mines). The approval requirements, among other things, are designed to require clean-burning

engines in diesel-powered equipment. (61 FR 55417). In promulgating the final rule, MSHA recognized that clean-burning engines are ''critically important'' to reducing toxic gasses to levels that can be controlled through ventilation. (*Id.*). To achieve the objective of clean-burning engines, the rule sets performance standards which must be met for virtually all diesel-powered equipment in underground coal mines (30 CFR part 7).

Consistent with the recommendation of the Advisory Committee, the technical requirements for approved diesel engines include undiluted exhaust limits for carbon monoxide and oxides of nitrogen. (61 FR 55419). As recommended by the Advisory Committee, the limits for these gasses are derived from existing 30 CFR part 36. (61 FR 55419). Also consistent with the recommendation of the Advisory Committee, the final rule requires that as part of the approval process, ventilating air quantities necessary to maintain the gaseous emissions of diesel engines within existing required ambient limits be set. (61 FR 55420). As recommended by the Advisory Committee, the ventilating air quantities are required to appear on the engine's approval plate. (61 FR 55421).

The final rule also implements the Advisory Committee's recommendation that a particulate index be set for diesel engines. (61 FR 55421). Although, as discussed below, there is not yet a specific standard limiting miners' exposure to diesel particulate, the particulate index is nonetheless useful in providing information to the mining community so that operators can compare the particulate levels generated by different engines. (61 FR 55421).

Also consistent with the recommendation of the Advisory Committee, the final rule addresses the monitoring and control of gaseous diesel exhaust emissions. (30 CFR part 70; 61 FR 55413). In this regard, the final rule requires that mine operators take samples of carbon monoxide and nitrogen dioxide. (61 FR 55413, 55430–55431). Samples exceeding an action level of 50 percent of the threshold limits set forth in 30 CFR 75.322, trigger corrective action by the mine operator. (30 CFR part 70, 61 FR 55413). Also consistent with the Advisory Committee's recommendation, the final rule requires that diesel-powered equipment be adequately maintained. (30 CFR 75.1914; 61 FR 55414). Among other things, as recommended by the Advisory Committee, the rule requires the weekly examination of diesel-powered equipment, including testing of undiluted exhaust emissions for certain types of equipment. (30 CFR 75.1914(g)). In addition, consistent with the Advisory Committee's recommendation, operators are required to establish programs to ensure that those performing maintenance on diesel equipment are qualified. (61 FR 55414). As explained in the preamble, maintenance requirements were included because of MSHA's recognition that inadequate equipment maintenance can, among other things, result in increased levels of harmful gaseous and particulate components from diesel exhaust. (61 FR 55413–55414).

Consistent with the Advisory Committee's recommendation, the final rule also requires that underground coal mine operators use low sulfur diesel fuel. (30 CFR 75.1901; 61 FR 55413). The use of low sulfur fuel lowers not only the amount of gaseous emissions, but also the amount of diesel particulate emissions. (*Id.*). To further reduce miners' exposure to diesel exhaust, the final rule prohibits operators from unnecessarily idling diesel-powered equipment. (30 CFR 75.1916(d)).

Also consistent with the recommendation of the Advisory Committee, the final rule establishes minimum air quantity requirements in areas of underground coal mines where diesel-powered equipment is operated. (30 CFR 75.325). As set forth in the preamble, MSHA believes that effective mine ventilation is a key component in the control of miners' exposure to gasses and particulate emissions generated by diesel equipment. (61 FR 55433). The final rule also requires generally that mine operators maintain the approval plate quantity minimum airflow in areas of underground coal mines where diesel-powered equipment is operated. (30 CFR 75.325 [2]).

The diesel equipment rule will help the mining community use diesel-powered equipment more safely in underground coal mines. As discussed throughout this preamble, the diesel equipment rule has many features which, though it was not their primary purpose, will incidently reduce harmful diesel emissions in underground coal mines—including the particulate component of these emissions. (The requirements of the diesel equipment rule are highlighted with a special typeface in MSHA's publication, ''Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox'', reprinted as an Appendix at the end of this document. An example is the requirement in the diesel equipment rule that all engines used in underground coal mines be approved engines, and be maintained in approved condition —thus reducing emissions at the source.

In developing this safety rule, however, MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce those exposure levels in underground coal mines. Moreover, the rule does not apply to the remainder of the mining industry, where the use of diesel machinery is much more intense than in underground coal.

Gas Limits

Various organizations have established or recommended limits for many of the gasses occurring in diesel exhaust. Some of these are listed in Table II–2, together with information about the limits currently enforced by MSHA. MSHA requires mine operators to comply with gas specific threshold limit values (TLV's) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1972 (for coal mines) and in 1973 (for metal and nonmetal mines).

TABLE II–2.—GASEOUS EXPOSURE LIMITS (PPM)

Pollutant	Range of limits recommended		MSHA limits	
			Coal [a]	M/NM [b]
HCHO	[c] 0.016	[d] 0.3	2	2

[2] On December 23, 1997, the National Mining Association and Energy West Mining Company filed petitions for review of the final rule. *National Mining Association* versus *Secretary of Labor*, Nos. 96–1489 and 96–1490. These cases were consolidated and held in abeyance pending discussions between the mining industry and the Secretary. On March 19, 1998, petitioners filed an Unopposed Joint Motion for Voluntary Dismissal. This motion is still pending before the Court.

TABLE II–2.—GASEOUS EXPOSURE LIMITS (PPM)—Continued

CO	[d] 25	50	50	50
CO_2	[c] 5,000	5,000	5,000	5,000
NO_2	[c d e] 25	25	25	25
NO_2	[f] 1	[d] 3	5	5
SO_2	[c d] 2	[e] 5	2	5

Table Notes:
[a] ACGIH, 1972.
[b] ACGIH, 1973.
[c] NIOSH recommended exposure limit (REL), based on a 10-hour, time-weighted average.
[d] ACGIH, 1996.
[e] OSHA permissible exposure limit (PEL).
[f] NIOSH recommends only a 1-ppm, 15-minutes, short-term exposure limit (STEL).

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

(8) *How Other Jurisdictions are Restricting Occupational Exposure to Diesel Soot.* MSHA's proposed rule is the first effort by the Federal government to deal with the special risks faced by workers exposed to diesel exhaust on the job—because, as described in detail in the part III of this preamble, miner exposures are an order of magnitude above those of any other group of workers. But others have been looking at the problem of exposure to diesel soot.

States

As noted in the first section of this part, few underground coal mines now use diesel engines. Several states have had bans on the use of such equipment: Pennsylvania, West Virginia, and Ohio.

Recently, Pennsylvania has replaced its ban with a special law that permits the use of diesel-powered equipment in deep coal mines under certain circumstances. The Pennsylvania statute goes beyond MSHA's new regulation on the use of diesel-powered equipment in underground coal mines. Of particular interest is that it specifically addresses diesel particulate. The State did not set a limit on the exposure of miners to dpm, nor did it establish a limit on the concentration of dpm in deep coal mines. Rather, it approached the issue by imposing controls that will limit dpm emissions at the source.

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

The Pennsylvania law also has a number of other requirements for the safe use of diesel-powered equipment in the particularly hazardous environments of underground coal mines. Many of these parallel the requirements in MSHA's rule. Like MSHA's requirements, they too can result in reducing miner exposure to diesel particulate—e.g., regular maintenance of diesel engines by qualified personnel and equipment operator examinations. The requirements in the Pennsylvania law take into account the need to maintain the aftertreatment devices required to control diesel particulate (see, e.g., section 217–A(b)(6)).

West Virginia has also lifted its ban, subject to rules to be developed by a joint labor-management commission. MSHA understands that pursuant to the West Virginia law lifting the ban, the Commission has only a limited time to determine the applicable rules, or the matter is to be referred to an arbitrator for resolution.

Other Countries

Concerns about air pollution have been a major impetus for most countries' standards on vehicle emissions, including diesel particulate. Most industrialized nations recognize the fundamental principle that their citizens should be protected against recognized health risks from air pollution and that this requires the control of particulate such as diesel exhaust. In November of 1995, for example, the government of the United Kingdom recommended a limit on PM_{10}, and noted it would be taking further actions to limit airborne particulate matter (including a special study of dust from surface minerals workings).

Concerns about international trade have been another impetus. Diesel engines are sold to an international market to power many types of industrial and nonindustrial machinery and equipment. The European Union manufacturers exported more than 50 percent of their products, mainly to South Korea, Taiwan, China, Australia, New Zealand and the United States. Germany and the United Kingdom, two major producers, have pushed for harmonized world standards to level the playing field among the various countries' engine producers and to simplify the acceptance of their products by other countries (Financial Times, 1996). This includes products that must be designed to meet pollution standards. The European Union (EU) is now considering a proposal to set an EU-wide standard for the control of the emission of pollutants from non-road mobile machinery (Official Journal of European Communities, 1995). The proposal would largely track that of the U.S. Environmental Protection Agency's final rule on the Control of Air Pollution Determination of Significance for Nonroad Sources and Emission Standards for New Nonroad Compression-Ignition Engines at or above 37 kilowatts (50 HP)p (discussed in section 3 of this part of the preamble).

A third impetus to action has been the studies of the health effects of worker exposure to diesel exhaust—many of which have been epidemiological studies concerning workers in other countries. As noted in Part III of this preamble, the studies include cohorts of Swedish dock workers and bus garage workers, Canadian railway workers and

miners, French workers, London transport workers, and Danish chimney sweeps.

Below, the agency summarizes some information obtained on exposure limits of other countries. Due to differences in regulatory schemes among nations considering the effects of diesel exhaust, countries which have addressed the issue are more likely to have issued recommendations rather than a mandatory maximum exposure limit. Some of these may have issued mandatory design features for diesel equipment to assist in achieving the recommended exposure level. Measurement systems also vary.

Germany

German legislation on dangerous substances classifies diesel engine emissions as carcinogenic. Therefore, diesel engines must be designed and operated using the latest technology to cut emissions. This always requires an examination to determine whether the respective operations and activities may be carried out using other types of less polluting equipment. If, as a result of the examination, it is decided that the use of diesel engines is necessary measures must be instituted to reduce emissions. Such measures can include low-polluting diesel engines, low sulphur fuels, regular maintenance, and, where technology permits, the use of particulate traps. To reduce exposure levels further, diesel engine emissions may be regulated directly at the source; ventilation systems may be required to be installed.

The use of diesel vehicles in a fully or partly enclosed working space—such as in an underground mine—may be restricted by the government, depending on the necessary engine power or load capacity and on whether the relevant operation could be accomplished using a non-polluting vehicle, e.g., an electrically powered vehicle. When determining whether alternate equipment is to be used, the burden to the operator to use such equipment is also considered.

In April of 1997, the following permissible exposure limits (TRK [3]) for diesel engine emissions were instituted for workplaces in mining.

(1) Non-coal underground mining and construction work: TRK = 0.3 mg/m^3 of colloid dust.[4]

(2) other: TRK = 0.1 mg/m^3 of colloid dust.

(3) The average concentration of diesel engine emissions within a period of 15 minutes should never be higher than four times the TRK value.

The TRK is ascertained by determining the fraction of elemental carbon in the colloid (fine) dust by coulometric analysis. Determining the fraction of elemental carbon always involves the determination of total organic carbon in the course of analysis. If the workplace analysis shows that the fraction of elemental carbon in total carbon (elemental carbon plus organic carbon) is lower than 50%, or is subject to major fluctuations, then the TRK limits total carbon in such workplaces to 0.15 mg/m^3.

Irrespective of the TRK levels, the following additional measures are considered necessary once the concentration reaches 0.1 mg/m^3 colloid dust:

(1) Informing employees concerned;

(2) Limited working hours for certain staff categories;

(3) Special working hours; and

(4) Medical checkups.

If concentrations continue to fail to meet the TRK level, the employer must:

(1) Provide appropriate, effective, hygienic breathing apparatus, and

(2) Ensure that workers are not kept at the workplace for longer than absolutely necessary and that health regulations are observed.

Workers must use the breathing apparatus if the TRK levels for diesel engine emissions at the work place are exceeded. Due to the interference of recognized analysis techniques in coal mining, it is currently impossible to ascertain exposure levels in the air in coal mines. As a consequence, the coal mining authorities require the use of special low-polluting engines in underground mining and impose special requirements on the supply of fresh air to the workplace.

European Standards

On April 21, 1997, the draft of a European directive that applied to emissions from non-road mobile machinery was prepared. The directive proposed technical measures that would result in a reduction in emissions from internal-combustion engines (gasoline and diesel) installed in non-road mobile machinery, and type-approval procedures that would provide uniformity among the member nations for the approval of these engines.

The directive proposed a two-stage process. Stage 1, proposed to begin December 31, 1997, was for three different engine categories:

—A: 130 kW <= P <= 560 kW,

—B: 75 kW <= P < 130. kW,

—C: 37 kW <= P < 75 kW.

Stage 2, proposed to begin December 31, 1999, consisted of four engine categories being phased-in over a four-year period:

— D: after December 31,1999 for engines of a power output of 18 kW <= P < 37 kW,

— E: after December 31, 2000 for engines of a power output of 130 kW<= P <= 560 kW,

—F: after December 31, 2001 for engines of a power output of 75 kW<= P < 130 kW,

—G: after December 31, 2002 for engines of a power output of 37 kW<= P <=75 kW.

The emissions shown in the following table for carbon monoxide, hydrocarbons, oxides of nitrogen and particulates are to be met for the respective engine categories described for stage I.

Net power (P) (kW)	Carbon monoxide (P) (g/kWH)	Hydro-carbon s (HC) (g/kWh)	Oxides of nitrogen (NO_X) (g/kWh)	Particulates (PT) (g/kWh)
130≤P<560	5.0	1.3	9.2	0.54
75≤P<130	5.0	1.3	9.2	0.70
37≤P<75	6.5	1.3	9.2	0.85

The engine emission limits that have to be achieved for stage II are shown in the following table. The emissions limits shown are engine-out limits and are to be achieved before any aftertreatment device is used.

[3] TPK is the technical exposure limit of a hazardous material that defines the concentration of gas, vapour or airborne particulates which is the minimum possible with current technology and which serves as a guide for necessary protective measures and monitoring in the workplace.

[4] Colloid dust is defined as that part of total respirable dust in a workplace that passes the alveolar ducts of the worker.

Net power (P) (kW)	Carbon monoxide (P) (g/kWH)	Hydro-carbons (HC) (g/kWh)	Oxides of nitrogen (NO_X) (g/kWh)	Particulates (PT) (g/kWh)
130≤P<560	3.5	1.0	6.0	0.2
75≤P<130	5.0	1.0	6.0	0.3
37≤P<75	5.0	1.3	7.0	0.4
18≤P<37	5.5	1.5	8.0	0.8

Canada (Related Developments in Canada)

The Mining and Minerals Research Laboratories (MMRL) of the Canada Centre for Mineral and Energy Technology (CANMET), an arm of the Federal Department of Natural Resources Canada (NRCAN), began work in the early 1970s to develop measurement tools and control technologies for diesel particulate matter (dpm). In 1978, I.W. French and Dr. Anne Mildon produced a CANMET-sponsored contract study entitled: ''Health Implications of Exposure of Underground Mine Workers to Diesel Exhaust Emissions.'' In this document, an Air Quality Index (AQI) was developed involving several major diesel contaminants (CO, NO, NO_2, SO_2 and RCD—respirable combustible dust which is mostly dpm). These concentrations were divided by their then current permissible exposure limits, and the sum of the several ratios indicates the level of pollution in the mine atmosphere. The maximum value for this Index was fixed at 3.0. This criterion was determined by the known health hazard associated with small particle inhalation, and the known chemical composition of dpm, among other matters.

Subsequently, in 1986, the Canadian Ad hoc Diesel Committee was formed from all segments of the mining industry, including: mine operators, the labor force, equipment manufacturers, research agencies including CANMET, and Canadian regulatory bodies. The objective was the identification of major problems for research and development attention, the undertaking of the indicated studies, and the application of the results to reduce the impact of diesel machines on the health of underground miners.

In 1990–91, CANMET developed an RCD mine sampling protocol on behalf of the Ad hoc Committee. Then current underground sampling studies indicated an average ratio of RCD to dpm of 1.5. This factor accounted for the presence of other airborne combustible liquids including fuel, lubrication and particularly drilling oils, in addition to the dpm.

The original 1978 French-Mildon study was updated under a CANMET contract in 1990. It recommended that the dpm levels be reduced to 0.5 mg/m^3 (suggesting a corresponding RCD level of 0.75 mg/m^3).

However, in 1991, the Ad hoc Committee decided to set an interim recommended RCD level of 1.5 mg/m^3 (the equivalent 1.0 mg/m^3). This value matched the then recommended, but not promulgated, MSHA ''Ventilation Index'' value for dpm of 1.0 mg/m^3. Consequently, all of the North American mining industry then seemed to be accepting the same maximum levels of dpm.

It should be noted that for coal mine environments or other environments where a non-diesel carbonaceous aerosol is present, RCD analysis is not an appropriate measure of dpm levels.

Neither CANMET nor the Ad hoc Committee is a regulatory body. In Canada, mining is regulated by the individual provinces and territories. However, the federal laboratories provide: research and development facilities, advice based on research and development, and engine/machine certification services, in order to assist the provinces in their diesel-related mining regulatory functions.

Prior to the 1991 recommendation of the Ad hoc Committee, Quebec enacted regulations requiring: ventilation, a maximum of 0.25% sulfur content in diesel fuel; a prohibition on black smoke; exhaust cooling to a maximum temperature of 85°C; and the setting of maximum contaminant levels. Since 1997, new regulations add the CSA Standard for engine certification, a maximum RCD level of 1.5 mg/m^3, and the application of an exhaust treatment system.

Further, after the Ad hoc Committee recommendation was published in 1991 (RCDmax = 1.5 mg/m^3), various provinces took the following actions:

(1) Five provinces—British Columbia, Ontario, Quebec, New Brunswick, and Nova Scotia, and the Northwest Territories, adopted an RCD limit of 1.5 mg/m^3.

(2) Two others, Manitoba and Newfoundland/Labrador, have been adopting the ACGIH TLVs.

(3) Two provinces, Alberta and Saskatchewan, and the Yukon Territory, continue to have no dpm limit.

Most Canadian Inspectorates accept the CSA Standard for diesel machine/engine certification. This Standard specifies the undiluted Exhaust Quality Index (EQI) criterion for calculation of the ventilation in cfm, required for each diesel engine/machine. Fuel sulfur content, type of aftertreatment device and rated engine load factor are on-site, variable factors which may alter the ventilation ultimately required. Diesel fuel may not exceed 0.50% sulfur, and must have a minimum flash point of 52°C. However, most mines in Canada now use fuel containing less than 0.05% sulfur by weight.

In addition to limiting the RCD concentration, Qntario, established rules in 1994 that required diesel equipment to meet the Canadian Standards Association ''Non-Rail-Bound Diesel-Powered Machines for use in Non-Gassy Underground Mines'' (CSA M424.2–M90) Standard, excepting the ventilation assessment clauses. As far as fuel sulfur and flashpoint are concerned, Ontario is intending to change to: Smax = 0.05% from 0.25%, and maximum fuel flash point = 38°C from 52°C.

New Brunswick, in addition to limiting the RCD concentration, requires mine operators to submit an ambient air quality monitoring plan. Diesel engines above 100 horsepower must be certified, and there is a minimum ventilation requirement of 105 cfm/bhp.

Since 1996, the Ad hoc organization and the industry consortium called the Diesel Emissions Evaluation Program (DEEP) have been cooperating in a research and development program designed to reduce dpm levels in mines.

World Health Organization (WHO)

Environmental Health Criteria 171 on ''Diesel Fuel and Exhaust Emissions'' is a 1996 monograph published under joint sponsorship of the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization. The monograph provides a comprehensive review of the literature and evaluates the risks for human health and the

environment from exposure to diesel fuel and exhaust emissions.

The following tables compiled in the monograph show diesel engine exhaust limits for various exhaust components and illustrate that there is international concern about the amount of diesel exhaust being released into the environment.

TABLE II–3.—INTERNATIONAL LIMIT VALUES FOR COMPONENTS OF DIESEL EXHAUST LIGHT-DUTY VEHICLES (G/KM)

Region	Carbon monoxide	Nitrogen oxides	Hydrocarbons	Particulates	Comments
Austria	2.1	0.62	0.25	0.124	≤3.5t; since 1991; from 1995, adoption of European Union standards planned.
Canada	2.1	0.62	0.25	0.12	Since 1987.
European Union	2.72	0.97 (with hydrocarbons).		0.14	Since 1992.
	1.0	0.7		0.08	From 1996.
Finland				Since 1993..	
Japan	2.1	0.7	0.62	None	Since 1986.
	2.1	0.5	0.4	0.2	Since 1994.
Sweden, Norway	2.1	0.62 (city) 0.76 (highway)	0.25	0.124	≤3.5t; from motor year 1992.
Switzerland	2.1	0.62 (city) 0.76 (highway)	0.25	0.124	≤3.5t; since 1988; from 1995, adoption of European Union standard planned.
USA (California)	2.1–5.2	0.2–0.6	0.2–0.3 (except methane).	0.05 (up to 31000 km).	Depending on mileage.
US Environmental Protection Agency.	2.1–2.6	0.6–0.8	0.2	0.05–0.12	Depending on mileage.

TABLE II–4.—INTERNATIONAL LIMIT VALUES FOR COMPONENTS OF DIESEL EXHAUST HEAVY-DUTY VEHICLES (G/KWH)

Region	Carbon monoxide	Nitrogen oxides	Hydro carbons	Particulates	Comments
Austria	4.9	9.0	1.23	0.4	
Canada	15.5	5.0	1.3	0.25	g/bhp-h.
	15.5	5.0	1.3	0.1	g/bhp-h; from 1995–97.
European Union	4.5	8.0	1.1	0.36	Since 1992.
	4.0	7.0	1.1	0.15	From 1995–96.
Japan	7.4	5.0	2.9	0.7	Indirect injection engines.
	7.4	6.0	2.9	0.7	Direct injection engines.
Sweden	4.9	9.0	1.23	0.4	
USA	15.5	5.0	1.3	0.07	g/bhp-h; bus.
	15.5	4.0	1.3	0.1	g/bhp-h; truck.
	15.5	5.0	1.3	0.05	g/bhp-h; bus; from 1998.
	15.5	4.0	1.3	0.1	g/bhp-h; truck; from 1998.

Adapted from Mercedes-Benz AG (1994b).

With respect to the protection of human health, the monograph states that the data reviewed supports the conclusion that inhalation of diesel exhaust is of concern with respect to both neoplastic and non-neoplastic diseases. The monograph found that diesel exhaust ''is probably carcinogenic to humans.'' It also states that the particulate phase appears to have the greatest effect on health, and both the particle core and the associated organic materials have biological activity, although the gas-phase components cannot be disregarded. The monograph recommends the following actions for the protection of human health:

(1) Diesel exhaust emissions should be controlled as part of the overall control of atmospheric pollution, particularly in urban environments.

(2) Emissions should be controlled strictly by regulatory inspections and prompt remedial actions.

(3) Urgent efforts should be made to reduce emissions, specifically of particulates, by changing exhaust train techniques, engine design, and fuel consumption.

(4) In the occupational environment, good work practices should be encouraged, and adequate ventilation must be provided to prevent excessive exposure.

The monograph made no recommendations as to what constitutes excessive exposure.

International Agency for Research on Cancer (IARC)

The carcinogenic risks for human beings were evaluated by a working group convened by the International Agency for Research on Cancer in 1988 (International Agency for Research on Cancer, 1989b). The conclusions were:

(1) There is sufficient evidence for the carcinogenicity in experimental animals of the whole diesel engine exhaust.

(2) There is inadequate evidence for the carcinogenicity in animals of gas-phase diesel engine exhaust (with particles removed).

(3) There is sufficient evidence for the carcinogenicity in experimental animals of extracts of diesel engine exhaust particles.

(4) There is limited evidence for the carcinogenicity in humans of engine exhausts (unspecified as from diesel or gasoline engines).

Overall IARC Evaluation

Diesel engine exhaust is probably carcinogenic to humans (Group 2A).

(9) *MSHA's Initiative to Limit Miner Exposure to Diesel Particulate—a Brief History of this Rulemaking and Related Actions.* As discussed in part III of this preamble, by the early 1980's, the evidence indicating that exposure to diesel exhaust might be harmful to miners, particularly in underground mines, had started to grow. As a result, formal agency actions were initiated to investigate this possibility and to determine what, if any, actions might be appropriate. These actions are summarized here in chronological sequence, without comment as to the basis of any action or conclusion.

In 1984, in accordance with the § 102(b) of the Mine Act, NIOSH established a standing Mine Health Research Advisory Committee to advise it on matters involving or related to mine health research. In turn, that group established a subgroup to determine if:

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

In 1985, MSHA established an Interagency Task Group with the National Institute for Occupational Safety and Health (NIOSH) and the former Bureau of Mines (BOM) to assess the health and safety implications of the use of diesel-powered equipment in underground coal mines. In part, as a result of the recommendation of the Task Group, MSHA, in April 1986, began drafting proposed regulations on the approval and use of diesel-powered equipment in underground coal mines. Also in 1986, the subgroup of the NIOSH advisory committee studying this issue summarized the evidence available at that time as follows:

> It is our opinion that although there are some data suggesting a small excess risk of adverse health effects associated with exposure to diesel exhaust, these data are not compelling enough to exclude diesels from underground mines. In cases where diesel equipment is used in mines, controls should be employed to minimize exposure to diesel exhaust. (Interagency Task Group Report, 1986).

As noted previously in section 7 of this part, in discussing MSHA's diesel equipment rule, on October 6, 1987, pursuant to Section 102(c) of the Mine Act, 30 U.S.C. § 812(c), MSHA appointed an advisory committee ''to provide advice on the complex issues concerning the use of diesel-powered equipment in underground coal mines.'' (52 FR 37381). MSHA appointed nine members to the Advisory Committee. As required by Section 101(a)(1), MSHA provided the Advisory Committee with draft regulations on the approval and use of diesel-powered equipment in underground coal mines. The draft regulations did not include standards setting specific limitations on diesel particulate, nor had MSHA at that time determined that such standards should be promulgated.

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

With respect to diesel particulate, the Advisory Committee recommended that MSHA ''set in motion a mechanism whereby a diesel particulate standard can be set.'' (MSHA, 1988). In this regard, the Advisory Committee determined that because of inadequacies in the data on the health effects of diesel particulate matter and inadequacies in the technology for monitoring the amount of diesel particulate matter at that time, it could not recommend that MSHA promulgate a standard specifically limiting the level of diesel particulate matter. (*Id.* 64–65). Instead, the Advisory Committee recommended that MSHA request NIOSH and the former BOM to prioritize research in the development of sampling methods and devices for diesel particulate. The Advisory Committee also recommended that MSHA request a study on the chronic and acute effects of diesel emissions (*Id.*). In addition, the Advisory Committee recommended that the control of diesel particulate ''be accomplished through a combination of measures including fuel requirements, equipment design, and in-mine controls such as the ventilation system and equipment maintenance in conjunction with undiluted exhaust measurements.'' The Advisory Committee further recommended that particulate emissions ''be evaluated in the equipment approval process and a particulate emission index reported.'' (*Id.* at 9).

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

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

Consistent with the Advisory Committee's research recommendations, MSHA, in September 1988, formally requested NIOSH to perform a risk assessment for exposure to diesel particulate. (57 FR 500). MSHA also requested assistance from NIOSH and the former BOM in developing sampling and analytical methodologies for assessing exposure to diesel particulate in mining operations. (*Id.*). In part, as a result of the Advisory Committee's recommendation, MSHA also participated in studies on diesel particulate sampling methodologies and determination of underground occupational exposure to diesel particulate. A list of the studies requested and reports thereof is set forth in 57 FR 500–501.

On October 4, 1989, MSHA published a Notice of Proposed Rulemaking on approval requirements, exposure monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (54 FR 40950). The proposed rule, among other things, addressed, and in fact followed, the Advisory Committee's recommendation that MSHA promulgate regulations requiring the approval of diesel engines (54 FR 40951), limiting gaseous pollutants from diesel equipment, (*Id.*), establishing ventilation requirements based on approval plate dilution air quantities (54 FR 40990), requiring equipment maintenance (54 FR 40958), requiring that trained personnel work on diesel-powered equipment, (54 FR 40995), establishing fuel requirements,

(*Id.*), establishing gaseous contaminant monitoring (54 FR 40989), and requiring that a particulate index indicating the quantity of air needed to dilute particulate emissions from diesel engines be established. (54 FR 40953).

On January 6, 1992, MSHA published an Advance Notice of Proposed Rulemaking (ANPRM) indicating that it was in the early stages of developing a rule specifically addressing miners' exposure to diesel particulate. (57 FR 500). In the ANPRM, MSHA, among other things, sought comment on specific reports on diesel particulate prepared by NIOSH and the former BOM. (*Id.*). MSHA also sought comment on reports on diesel particulate which were prepared by or in conjunction with MSHA. (57 FR 501). The ANPRM also sought comments on the health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a diesel particulate rule. (57 FR 501). The notice also identified five specific areas where the agency was particularly interested in comments, and about which it asked a number of detailed questions: (1) exposure limits, including the basis therefore; (2) the validity of the NIOSH risk assessment model and the validity of various types of studies; (3) information about non-cancer risks, non-lung routes of entry, and the confounding effects of tobacco smoking; (4) the availability, accuracy and proper use of sampling and monitoring methods for diesel particulate; and (5) the technological and economic feasibility of various types of controls, including ventilation, diesel fuel, engine design, aftertreatment devices, and maintenance by mechanics with specialized training. The notice also solicited specific information from the mining community on ''the need for a medical surveillance or screening program and on the use of respiratory equipment.'' (57 FR 500). The comment period on the ANPRM closed on July 10, 1992.

While MSHA was completing a ''comprehensive analysis of the comments and any other information received'' in response to the ANPRM (57 FR 501), it took several actions to encourage the mining community to begin to deal with this problem, and to provide the knowledge and equipment needed for this task. As described earlier in this part, the Agency held several workshops in 1995, published a ''toolbox'' of controls, and developed a spreadsheet template that allows mine operators to compare the impacts of various controls on dpm concentrations in individual mines.

On October 25, 1996, MSHA published a final rule addressing approval, exhaust monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (61 FR 55412). The final rule addresses and in large part is consistent with the specific recommendations made by the Advisory Committee for limiting underground coal miners' exposure to diesel exhaust. (A further summary of this rule is contained in section 7 of this part).

On February 26, 1997, the United Mine Workers of America petitioned the U.S. Court of Appeals for the D.C. Circuit to issue a writ of mandamus ordering the Secretary of Labor to promulgate a rule on diesel particulate. In Re: International Union, United Mine Workers of America, D.C. Cir. Ct. Appeals, No. 97–1109. The matter was scheduled for oral argument on September 12, 1997. On September 11, 1997, the Court granted the parties' joint motion to continue oral argument and hold the proceedings in abeyance. The Court directed the parties to file status reports or motions to govern future proceedings at 90-day intervals. Pursuant to that order, on March 10, 1998, the Secretary filed a status report.

III. Risk Assessment

Table of Contents

Introduction
1. Exposures of U.S. Miners
a. Underground Coal Mines
b. Underground Metal and Nonmetal Mines
c. Surface Mines
d. Comparison of Miner Exposures to Exposures of Other Groups
2. Health Effects Associated with DPM Exposures
a. Relevancy Considerations
i. Relevance of Health Effects Observed in Animals
ii. Relevance of Health Effects that are Reversible
iii. Relevance of Health Effects Associated with Fine Particulate Matter in Ambient Air
b. Acute Health Effects
i. Symptoms Reported by Exposed Miners
ii. Studies Based on Exposures to Diesel Emissions
iii. Studies Based on Exposures to Particulate Matter in Ambient Air
c. Chronic Health Effects
i. Studies Based on Exposures to Diesel Emissions
A. Chronic Effects Other than Cancer
B. Cancer
i. Lung Cancer
ii. Bladder Cancer
ii. Studies Based on Exposures to Fine Particulate in Ambient Air
d. Mechanisms of Toxicity
i. Effects Other than Cancer
ii. Lung Cancer
A. Genotoxicological Evidence
B. Evidence from Animal Studies
3. Characterization of Risk
a. Material Impairments to Miner Health or Functional Capacity
i. Sensory Irritations and Respiratory Symptoms
ii. Excess Risk of Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes
iii. Lung Cancer
b. Significance of the Risk of Material Impairment to Miners
i. Definition of a Significant Risk
ii. Evidence of Significant Risk at Current Exposure Levels
c. Substantial Reduction of Risk by Proposed Rule
Conclusions

Introduction

MSHA has reviewed the scientific literature to evaluate the potential health effects of diesel particulate at occupational exposures encountered in the mining industry. Based on its review of the currently available information, this part of the preamble assesses the risks associated with those exposures. Additional material submitted for the record will be considered by MSHA before final determinations are made.

Agencies sometimes place risk assessments in the rulemaking record and provide only a summary in the preamble for a proposed rule. MSHA has decided that, in this case, it is important to disseminate a discussion of risk widely throughout the mining community. Therefore, the full assessment is being included as part of the preamble.

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

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

> [a] decision driven activity, directed toward informing choices and solving problems * * * Oversimplifying the science or skewing the results through selectivity can lead to the inappropriate use of scientific information in risk management decisions,

but providing full information, if it does not address key concerns of the intended audience, can undermine that audience's trust in the risk analysis.

MSHA intends this risk assessment to further the rulemaking process. The purpose of a proposed rulemaking is to advise the regulated community of what information the agency is evaluating, how the agency believes it should evaluate that information, and what tentative conclusions the agency has drawn. Comments and guidance from all interested members of the public are encouraged. The risk assessment presented here is meant to facilitate public comment, thus, helping to ensure that final rulemaking is based on as complete a record as possible—on both the evidence itself and the manner in which it is to be evaluated by the Agency. Those who want additional detail are welcome to examine the materials cited in this part, copies of which are included in MSHA's rulemaking record.

While this rulemaking only covers the underground coal sector, this risk assessment was prepared so as to enable MSHA and to assess the risks throughout the mining industry. Accordingly, this information will be of interest to the entire mining community.

MSHA had this risk assessment independently peer reviewed. The risk assessment presented here incorporates revisions made in accordance with the reviewers recommendations. The reviewers stated that:

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

III.1. Exposures of U.S. Miners

Information about U.S. miner exposures comes from published studies and from additional mine surveys conducted by MSHA since 1993.[5] Previously published studies of U.S. miner exposure to dpm are: Watts (1989, 1992), Cantrell (1992, 1993), Haney (1992), and Tomb and Haney (1995). MSHA has also conducted surveys subsequent to the period covered in Tomb and Haney (1995), and the previously unpublished data from those surveys are included here. Overall, the period covered in MSHA's surveys, on which this section is based, is late 1988 through mid 1997.

MSHA's field studies involved measuring dpm concentrations at a total of 48 mines: 25 underground metal and nonmetal (M/NM) mines, 12 underground coal mines, and 11 surface mining operations (both coal and M/NM). At all surface mines and all underground coal mines, dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. With two exceptions, dpm measurements at underground M/NM mines were made using the RCD method (with no submicrometer impactor). Measurements at the two remaining underground M/NM mines were made using the size-selective method, as in coal and surface mines. The various methods of measuring dpm are explained in Part II of this preamble. Weighing errors inherent in the gravimetric analysis required for both size-selective and RCD methods become statistically insignificant at the relatively high dpm concentrations observed.

Each underground study typically included personal dpm exposure measurements for approximately five production workers. Also, area samples were collected in return airways of underground mines to determine diesel particulate emission rates. Operational information such as the amount and type of equipment, airflow rates, fuel, and maintenance was also recorded. In general, MSHA's studies focused on face production areas of mines, where the highest concentrations of dpm could be expected; but, since some miners do not spend their time in face areas, studies were performed in other areas as well, to get a more complete picture of miner exposure. Because of potential interferences from tobacco smoke in underground M/NM mines, samples were not collected on or near smokers.

Table III–1 summarizes key results from MSHA's studies.

The higher concentrations in underground mines were typically found in the haulageways and face areas where numerous pieces of equipment were operating, or where insufficient air was available to ventilate the operation. In production areas and haulageways of underground mines where diesel powered equipment is used, the mean dpm concentration observed was 755 μg/m^3. By contrast, in travelways of underground mines where diesel powered equipment is used, the mean dpm concentration (based on 107 samples not included in Table III–1) was 307 μg/m^3. In surface mines, the higher concentrations were generally associated with truck drivers and front-end loader operators. The mean dpm concentration observed was less than 200 μg/m^3 at all 11 of the surface mines in which measurements were made. More information about the dpm concentrations observed in each sector is presented in the material that follows.

TABLE III–1.—FULL-DIESEL PARTICULATE MATTER CONCENTRATIONS OBSERVED IN PRODUCTION AREAS AND HAULAGEWAYS OF 48 DIESELIZED U.S. MINES. INTAKE AND RETURN AREA SAMPLES ARE EXCLUDED.

Mine type	Number of samples	Mean exposure μg/m^3	Exposure range μg/m^3
Surface	45	88	9–380
Underground Coal	226	644	0–3,650
Underground Metal and Nonmetal	331	830	10–5,570

III.1.a. Underground Coal Mines

Approximately 170 out of the 971 existing underground coal mines currently utilize diesel powered equipment. Of these 170 mines, fewer than 20 currently use diesel equipment for face coal haulage. The remaining mines use diesel equipment for transportation, materials handling and other support operations. MSHA focused its efforts in measuring dpm concentrations in coal mines on mines that use diesel powered equipment for face coal haulage. Twelve mines using diesel-powered face haulage were

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

sampled. Mines with diesel powered face haulage were selected because the face is an area with a high concentration of vehicles operating at a heavy duty cycle at the furthest end of the mine's ventilation system.

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

Figure III–1 displays the range of exposure measurements obtained by MSHA in the field studies it conducted in underground coal mines. A study normally consisted of collecting samples on the continuous miner operator and ramcar operators for two to three shifts, along with area samples in the haulageways. A total of 142 personal samples and 84 area samples were collected. No statistically significant difference was observed in mean dpm concentration between the personal and area samples.

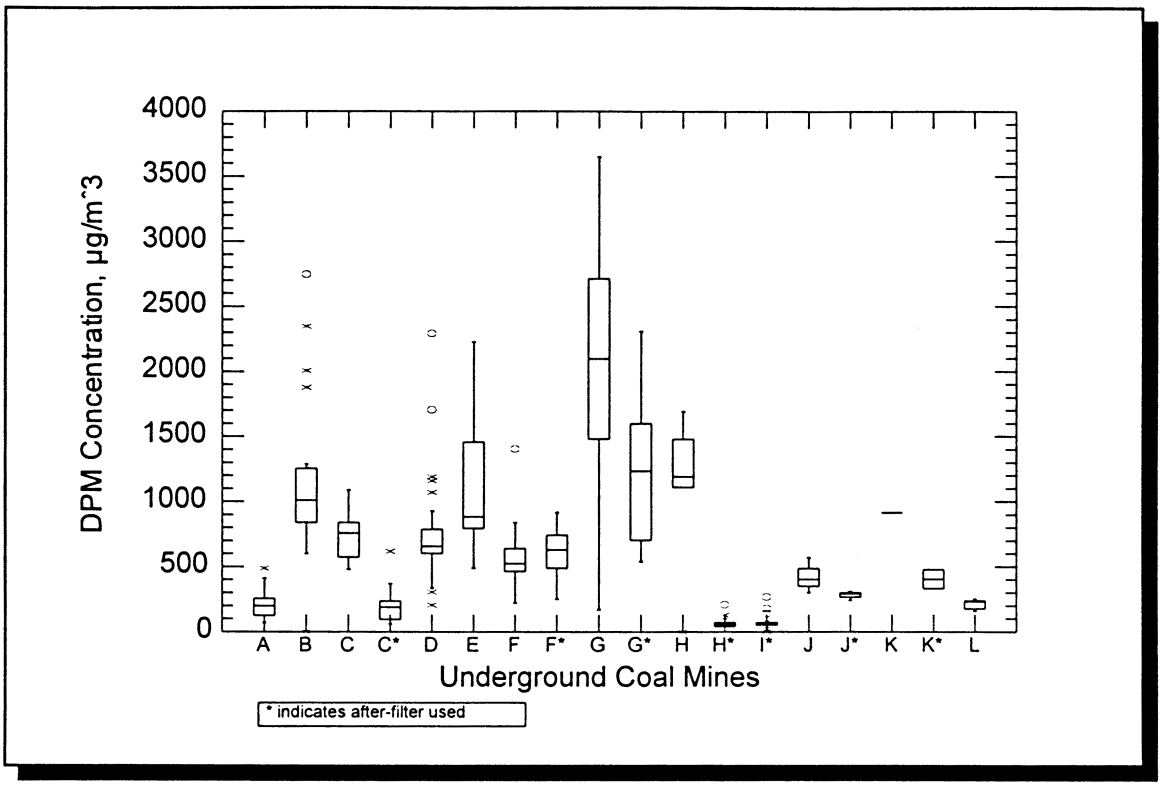


Figure III-1.-- Box plots for dpm concentrations observed at 12 underground coal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points are outliers, representing unusually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

In six mines, measurements were taken both with and without employment of disposable after treatment filters, so that a total of eighteen studies, carried out in twelve mines, are displayed. Without employment of after treatment filters, average observed dpm concentrations exceeded 500 µg/m^3 in eight of the twelve mines and exceeded 1000 µg/m^3 in four.[6]

[6] In coal mine E, the average as expressed by the mean exceeded 1000 µg/m^3, but the median did not.

The highest dpm concentrations observed at coal mines were collected at Mine "G." Eight of these samples were collected during employment of DDEF's, and eight were collected while filters were not being employed. Without filters, the mean dpm concentration observed at Mine "G" was 2052 µg/m^3

(median = 2100 μg/m³). With disposable filters, the mean dropped to 1241 μg/m³ (median = 1235 μg/m³).

Filters were employed in three of the four studies showing median dpm concentration at or below 200 μg/m³. After adjusting for outby sources of dpm, exposures were found to be reduced by up to 95 percent in mines using the DDEF and by up to 50 percent in the mine using the WMF. The higher dpm concentrations observed at the mine using the WMF are attributable partly to the lower section airflow. The only study without filters showing a median concentration at or below 200 μg/m³ was conducted in a mine (Mine "A") which had section airflow approximately ten times the nameplate requirement. The section airflow at the mine using the WMF was approximately the nameplate requirement.

III.1.b. Underground Metal and Nonmetal Mines. Currently there are approximately 260 underground M/NM mines in the United States. Nearly all of these mines utilize diesel powered equipment, and twenty-five of those doing so were sampled by MSHA for dpm. The M/NM studies typically included measurements of dpm exposure for dieselized production equipment operators (such as truck drivers, roof bolters, haulage vehicles) on two to three shifts. A number of area samples were also collected. None of the M/NM mines studied were using diesel particulate afterfilters.

Figure III–2 displays the range of dpm concentrations measured by MSHA in the twenty-five underground M/NM mines studied. A total of 254 personal samples and 77 area samples were collected. No statistically significant difference was observed in mean dpm concentration between the personal and area samples. Personal exposures observed ranged from less than 100 μg/m³ to more than 3500 μg/m³. With the exception of Mine "V", personal exposures were for face workers. Mine "V" did not use dieselized face equipment.

Average observed dpm concentrations exceeded 500 μg/m³ in 17 of the 25 M/NM mines and exceeded 1000 μg/m³ in 12.[7] The highest dpm concentrations observed at M/NM mines were collected at Mine "E". Based on 16 samples, the mean dpm concentration observed at Mine "E" was 2008 μg/m³ (median = 1835 μg/m³). Twenty-five percent of the dpm measurements at this mine exceeded 2400 μg/m³. All four of these were based on personal samples.

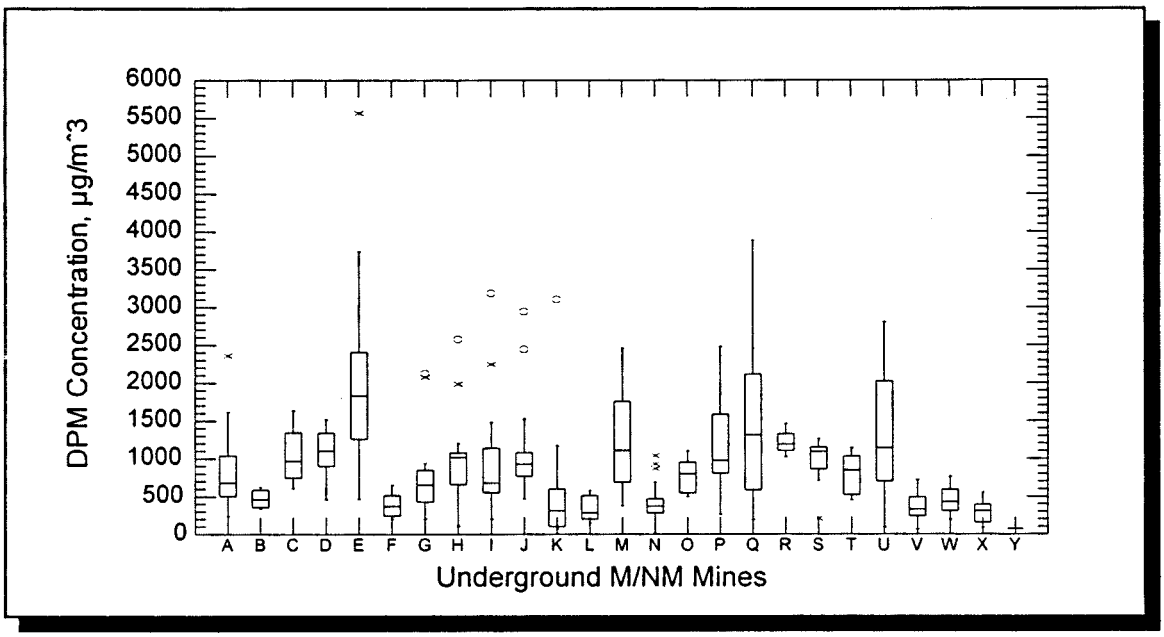


Figure III-2.-- Box plots for dpm concentrations observed at 25 underground metal and nonmetal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points are outliers, representing unusually high or low measurements compared to other observations at the same mine. Measurements at mines other than "D" and "T" were made using RCD method. Measurements at mines "D" and "T" were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. Because of potential interferences from cigarette smoke, samples were not collected on or near smokers.

As with underground coal mines, dpm levels in underground M/NM mines are related to the amount and size of equipment, to the ventilation rate, and to the effectiveness of the diesel particulate control technology employed. In the dieselized M/NM mines studied by MSHA, front-end-loaders were used either to load ore

[7] At M/NM mines C, I, J, and P, the average as expressed by the mean exceeded 100 μg/m³ but the median did not. At N/NM mines H and S, the median exceeded 1000 μg/m³ but the mean did not. At M/NM mine K, the mean exceeded 500 μg/m³, but the median did not.

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

III.1.c. Surface Mines. Currently, there are approximately 12,200 surface mining operations in the United States. The total consists of approximately 1,700 coal mines and 10,500 M/NM mines. Virtually all of these mines utilize diesel powered equipment.

MSHA conducted diesel particulate studies at eleven surface mining operations: eight coal mines and three M/NM mines. To help select those surface facilities likely to have significant dpm concentrations, MSHA first made a visual examination (based on blackness of the filter) of surface mine respirable dust samples collected during a November 1994 study of surface coal mines. This preliminary screening of samples indicated that higher exposures to diesel particulate are typically associated with front-end-loader operators and haulage-truck operators; accordingly, sampling focused on these operations. A total of 45 samples were collected.

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

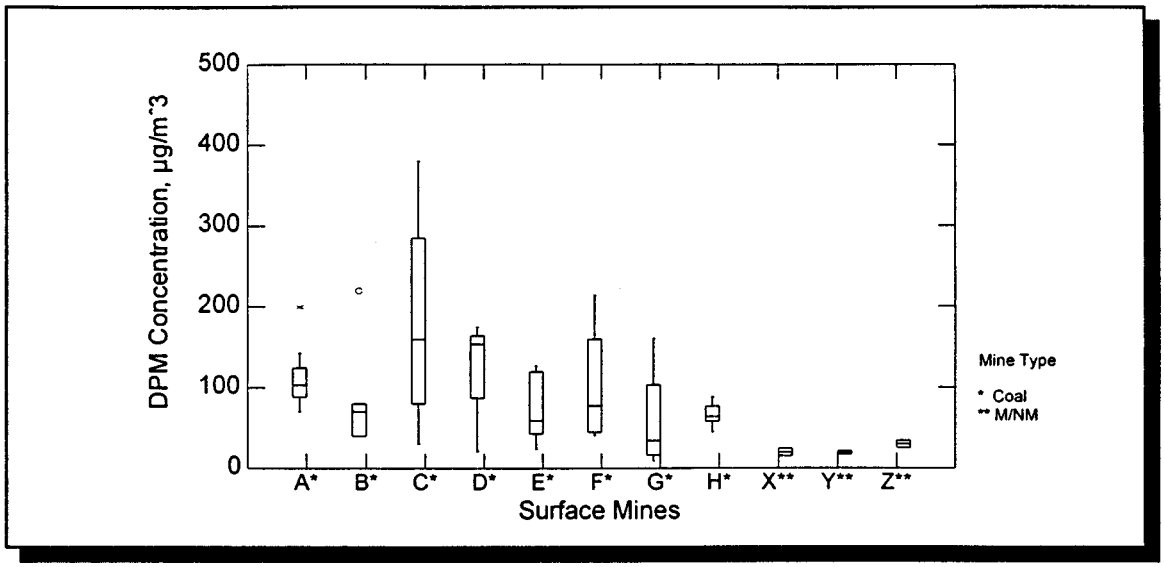


Figure III-3.--Box plots for dpm concentrations observed at 11 surface mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points are outliers, representing unusually high or low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

III.1.d. Comparison of Miner Exposures to Exposures of Other Groups. Occupational exposure to diesel particulate primarily originates from industrial operations employing equipment powered with diesel engines. Diesel engines are used to power ships, locomotives, heavy duty trucks, heavy machinery, as well as a small number of light-duty passenger cars and trucks. NIOSH estimates that approximately 1.35 million workers are occupationally exposed to the combustion products of diesel fuel in approximately 80,000 workplaces in the United States. Workers who are likely to be exposed to diesel emissions include: mine workers; bridge and tunnel workers; railroad workers; loading dock workers; truck drivers; fork-lift drivers; farm workers; and, auto, truck, and bus maintenance garage workers (NIOSH, 1988). Besides miners, groups for which occupational exposures have been reported and health effects have been studied include dock workers, truck drivers, and railroad workers.

As estimated by geometric mean, median occupational exposures reported for dock workers either operating or otherwise exposed to diesel fork lift trucks have ranged from 23 to 55 μg/m³, as measured by submicrometer elemental carbon (NIOSH, 1990; Zaebst et al., 1991). Watts (1995) states that "elemental carbon generally accounts for about 40% to 60% of diesel particulate mass." Assuming that, on average, the submicrometer elemental carbon constituted approximately 50% by mass of the whole diesel particulate, this would correspond to a range of 46 to 110 μg/m³ in median dpm concentrations at various docks.

In a study of dpm exposures in the trucking industry, Zaebst et al. (1991) reported geometric mean concentrations of submicrometer carbon ranging from 2 to 7 μg/m³ for drivers to 5 to 28 μg/m³ for mechanics, depending on weather conditions. Again assuming that, on average, the mass concentration of whole diesel particulate is about twice that of submicrometer elemental carbon, the corresponding range of median dpm concentrations would be 4 to 56 μg/m³.

Exposures of railroad workers to dpm were estimated by Woskie et al. (1988) and Schenker et al. (1990). As measured by total respirable particulate matter other than cigarette smoke, Woskie et al. reported geometric mean concentrations for various occupational categories of exposed railroad workers ranging from 49 to 191 μg/m³.

Figure III–4 shows the range of median dpm concentrations observed for mine workers at different mines compared to the range of median concentrations estimated for dock workers (including forklift drivers at loading docks), truck drivers and mechanics, railroad workers, and urban ambient air. The range for ambient air, 1 to 10 μg/m³, was obtained from Cass and Gray (1995). For dock workers, truck drivers, and railroad workers, the estimated range of median exposures is respectively 46 to 110 μg/m³, 4 to 56 μg/m³, and 49 to 191 μg/m³. The range of medians observed at different underground coal mines is 55 to 2100 μg/m³, with filters employed at mines showing the lower concentrations. For underground M/NM mines, the corresponding range is 68 to 1835 μg/m³, and for surface mines it is 19 to 160 μg/m³.

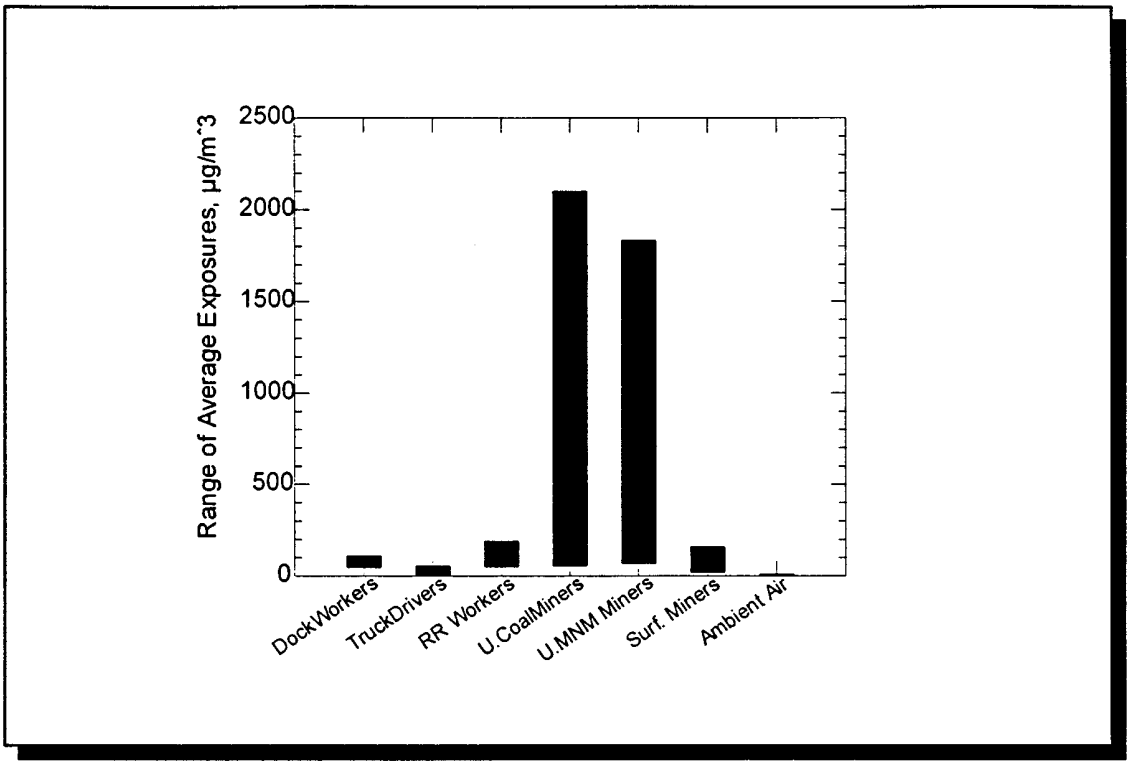


Figure III-4.--Range of average dpm exposures observed at various mines for underground and surface miners compared to range of average exposures reported for other occupations and for urban ambient air. Averages are represented by median observed within mines for mine workers, by median as estimated with geometric mean reported for other occupations, and, for ambient air in urban environments, by the monthly mean estimated for different months and locations in Southern California. The range estimated for urban ambient air is roughly 1 to 10 μg/m³.

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

III.2. Health Effects Associated with DPM Exposures.

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

III.2.a. Relevancy Considerations.

III.2.a.i. Relevance of Health Effects Observed in Animals. Since the lungs of different species may react differently to particle inhalation, it is necessary to treat the results of animal studies with some caution. Evidence from animal studies can nevertheless be valuable, and those respondents to MSHA's ANPRM who addressed this question urged consideration of all animal studies related to the health effects of diesel exhaust.

Unlike humans, laboratory animals are bred to be homogeneous and can be randomly selected for either non-exposure or exposure to varying levels of a potentially toxic agent. This permits setting up experimental and control groups of animals that do not differ biologically prior to exposure. The consequences of exposure can then be determined by comparing responses in the experimental and control groups. After a prescribed duration of deliberate exposure, laboratory animals can also be sacrificed, dissected, and examined. This can contribute to an understanding of mechanisms by which inhaled particles may exert their effects on health. For this reason, discussion of the animal evidence is placed in the section entitled ''Mechanisms of Toxicity'' below.

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

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

Accordingly, MSHA believes that judicious use of evidence from animal studies is appropriate. The extent to which MSHA relies upon such evidence to draw specific conclusions will be

discussed below in connection with those conclusions.

III.2.a.ii. Relevance of Health Effects That Are Reversible. Some reported health effects associated with dpm are apparently reversible—i.e., if the worker is moved away from the source for a few days, the health problem goes away. A good example is eye irritation.

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

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

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

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

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

III.2.a.iii. Relevance of Health Effects Associated with Fine Particulate Matter in Ambient Air. There have been many studies in recent years designed to determine whether the mix of particulate matter in ambient air is harmful to health. The evidence linking particulates in air pollution to health problems has long been compelling enough to warrant direction from the Congress to limit the concentration of such particulates (see part II, section 5 of this preamble). In recent years, the evidence of harmful effects due to airborne particulates has increased, and, moreover, has suggested that ''fine'' particulates (i.e., particles less than 2.5 µm in diameter) are more strongly associated than ''coarse'' particulates (i.e., respirable particles greater than 2.5 µm in diameter) with the adverse health effects observed (EPA, 1996).

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

Nevertheless, there are compelling reasons to consider this body of evidence. Since dpm is a type of respirable particle, information about health effects associated with exposures to respirable particles in general, and especially to fine particulate matter, is certainly relevant, even if difficult to apply directly to dpm exposures. Adverse health effects in the general population have been observed at ambient atmospheric particulate concentrations well below those studied in occupational settings. Furthermore, there is extensive literature showing that occupational dust exposures contribute to Chronic Obstructive Pulmonary Diseases (COPD), thereby compromising the pulmonary reserve of some miners, and that miners experience COPD at a significantly higher rate than the general population (Becklake 1989, 1992; Oxman 1993; NIOSH 1995). This would appear to place affected miners in a subpopulation specifically identified as susceptible to the adverse health effects of respirable particle pollution (EPA, 1996). The Mine Act requires standards that ''* * * most adequately assure on the basis of the best available evidence that *no miner* suffer material impairment of health or functional capacity * * *'' (Section 101(a)(6), emphasis added).

In sum, MSHA believes it would be a serious omission to ignore the body of evidence from air pollution studies and the Agency is, therefore, taking that evidence into account. The Agency would, however, welcome additional scientific information and analysis on ways of applying this body of evidence to miners experiencing acute and/or chronic dpm exposures. MSHA is especially interested in receiving information on whether the elevated prevalence of COPD among miners makes them, as a group, highly susceptible to the harmful effects of fine particulate air pollution, including dpm.

III.2.b. *Acute Health Effects*

Information relating to the acute health effects of dpm includes anecdotal reports of symptoms experienced by exposed miners, studies based on

exposures to diesel emissions, and studies based on exposures to particulate matter in the ambient air. These will be discussed in turn.

III.2.b.i. Symptoms Reported by Exposed Miners. Miners working in mines with diesel equipment have long reported adverse effects after exposure to diesel exhaust. For example, at the workshops on dpm conducted in 1995, a miner reported headaches and nausea among several operators after short periods of exposure (dpm Workshop; Mt. Vernon, IL, 1995). Another miner reported that the smoke from equipment using improper fuel or not well maintained is an irritant to nose and throat and impairs vision. ''We've had people sick time and time again * * * at times we've had to use oxygen for people to get them to come back around to where they can feel normal again.'' (dpm Workshop; Beckley, WV, 1995). Other miners (dpm Workshops; Beckley, WV, 1995; Salt Lake City, UT, 1995), reported similar symptoms in the various mines where they worked.

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

MSHA welcomes additional information about such effects including information from medical personnel who have treated miners and information on work time lost, together with information about the exposures of miners for whom such effects have been observed. The Agency would be especially interested in comparisons of effects observed in workers subjected to filtered exhaust as compared to those subjected to unfiltered exhaust.

III.2.b.ii. Studies Based on Exposures to Diesel Emissions. Several scientific studies have been conducted to investigate acute effects of exposure to diesel emissions.

In a clinical study (Battigelli, 1965), volunteers were exposed to different levels of diesel exhaust and then the degree of eye irritation was measured. Exposure for ten minutes to diesel exhaust produced ''intolerable'' irritation in some subjects while the average irritation score was midway between ''some'' irritation and a ''conspicuous but tolerable'' irritation level. Cutting the exposure by 50% significantly reduced the irritation.

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

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

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

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

To investigate whether removal of the particles from diesel exhaust might reduce the ''acute irritative effect on the lungs'' observed in their earlier study, Ulfvarson and Alexandersson (1990) compared pulmonary effects in a group of 24 stevedores exposed to unfiltered diesel exhaust to a group of 18 stevedores exposed to filtered exhaust, and to a control group of 17 occupationally unexposed workers. Workers in all three groups were nonsmokers and had normal spirometry values, adjusted for sex, age, and height, prior to the experimental workshift.

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

Rudell et al., (1996) carried out a series of double-blind experiments on 12 healthy, non-smoking subjects to investigate whether a particle trap on the tailpipe of an idling diesel engine would reduce acute effects of diesel exhaust, compared with exposure to unfiltered exhaust. Symptoms associated with exposure included headache, dizziness, nausea, tiredness, tightness of chest, coughing, and difficulty in breathing, but the most prominent were found to be irritation of the eyes and nose, and a sensation of unpleasant smell. Among the various pulmonary function tests performed, exposure was found to result in significant changes only as measured by increased airway resistance and specific airway resistance. The ceramic wall flow particle trap reduced the number of particles by 46 percent, but resulted in no significant attenuation of symptoms or lung function effects. The authors concluded that diluted diesel exhaust caused increased symptoms of the eyes and nose, unpleasant smell, and bronchoconstriction, but that the 46 percent reduction in median particle

number concentration observed was not sufficient to protect against these effects in the populations studied.

Wade and Newman (1993) documented three cases in which railroad workers developed persistent asthma following exposure to diesel emissions while riding immediately behind the lead engines of trains having no caboose. None of these workers were smokers or had any prior history of asthma or other respiratory disease. Although this is the only published report MSHA knows of directly relating exposure to diesel emissions with the development of asthma, there have been a number of recent studies indicating that dpm exposure can induce bronchial inflammation and respiratory immunological allergic responses in humans. These are reviewed in Peterson and Saxon (1996) and Diaz-Sanchez (1997).

III.2.b.iii. Studies Based on Exposures to Particulate Matter in Ambient Air. As early as the 1930's, as a result of an incident in Belgium's industrial Meuse Valley, it was known that large increases in particulate air pollution, created by winter weather inversions, could be associated with large simultaneous increases in mortality and morbidity. More than 60 persons died from this incident, and several hundred suffered respiratory problems. The mortality rate during the episode was more than ten times higher than normal, and it was estimated that 3,179 sudden deaths would occur if a similar incident occurred in London. Although no measurements of pollutants in the ambient air during the episode are available, high PM levels were obviously present (EPA, 1996).

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

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

These three episodes ''left little doubt about causality regarding the induction of serious health effects by very high concentrations of particle-laden air pollutant mixtures'' and stimulated additional research to characterize exposure-response relationships (EPA, 1996). Based on several analyses of the 1952 London data, along with several additional acute exposure mortality analyses of London data covering later time periods, the U.S. Environmental Protection Agency (EPA) concluded that increased risk of mortality is associated with exposure to particulate and SO_2 levels in the range of 500–1000 $\mu g/m^3$. The EPA also concluded that relatively small, but statistically significant increases in mortality risk exist at particulate levels below 500 $\mu g/m^3$, with no indications of any specific threshold level yet indicated at lower concentrations (EPA, 1986).

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

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

A total of 38 studies examining relationships between short-term particulate levels and increased mortality, including nine with fine particulate measurements, were published between 1988 and 1996 (EPA, 1996). Most of these found statistically significant positive associations. Daily or several-day elevations of particulate concentrations, at average levels as low as 18–58 $\mu g/m^3$, were associated with increased mortality, with stronger relationships observed in those with preexisting respiratory and cardiovascular disease. Overall, these studies suggest that an increase of 50 $\mu g/m^3$ in the 24-hour average of PM_{10} is associated with a 2.5 to 5-percent increase in the risk of mortality in the general population. Based on Schwartz et al. (1996), the relative risk of mortality in the general population increased by 2.6 to 5.5 percent per 25 $\mu g/m^3$ of fine particulate ($PM_{2.5}$) (EPA, 1996).

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

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

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

and, therefore, had very little power to detect any such association.

III.2.c. Chronic Health Effects

During the 1995 dpm workshops, miners reported observable adverse health effects among those who have worked a long time in dieselized mines. For example, a miner (dpm Workshop; Salt Lake City, UT, 1995), stated that miners who work with diesel ''have spit up black stuff every night, big black—what they call black (expletive) ***[they] have the congestion every night*** the 60-year-old man working there 40 years.'' Scientific investigation of the chronic health effects of dpm exposure includes studies based specifically on exposures to diesel emissions and studies based more generally on exposures to fine particulate matter in the ambient air. Only the evidence from human studies will be addressed in this section. Data from genotoxicology studies and studies on laboratory animals will be discussed later, in the section on potential mechanisms of toxicity.

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

III.2.c.i.A. Chronic Effects Other than Cancer. There have been a number of epidemiological studies that investigated relationships between diesel exposure and the risk of developing persistent respiratory symptoms, (i.e., chronic cough, chronic phlegm, and breathlessness), or measurable loss in lung function. Three studies involved coal miners (Reger et al., 1982; Ames et al., 1984; Jacobson et al., 1988); four studies involved metal and nonmetal miners (Jörgenson & Svensson, 1970; Attfield, 1979; Attfield et al., 1982; Gamble et al., 1983). Three studies involved other groups of workers—railroad workers (Battigelli et al., 1964), bus garage workers (Gamble et al., 1987), and stevedores (Purdham et al., 1987).

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

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

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

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

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

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

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

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

In a study of workers at four diesel bus garages in two cities, Gamble et al. (1987b) investigated relationships between tenure (as a surrogate for cumulative exposure) and respiratory symptoms, chest radiographs, and pulmonary function. The study population was also compared to an unexposed control group of workers with similar socioeconomic background.

After indirect adjustment for age, race, and smoking, the exposed workers showed an increased prevalence of cough, phlegm, and wheezing, but no association was found with tenure. Age- and height-adjusted pulmonary function was found to decline with duration of exposure, but was elevated on average, as compared to the control group.

The number of positive radiographs was too small to support any conclusions. The authors concluded that the exposed workers may have experienced some chronic respiratory effects.

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

In a recent review of these studies, Cohen and Higgins (1995) concluded that they did not provide strong or consistent evidence for chronic, nonmalignant respiratory effects associated with occupational exposure to diesel exhaust. These reviewers stated, however, that ''several studies are suggestive of such effects * * * particularly when viewed in the context of possible biases in study design and analysis.'' MSHA agrees that the studies are inconclusive but suggestive of possible effects.

III.2.c.i.B. Cancer. Because diesel exhaust has long been known to contain traces of carcinogenic compounds (e.g., benzene in the gaseous fraction and

benzopyrene and nitropyrene in the dpm fraction), a great deal of research has been conducted to determine if occupational exposure to diesel exhaust actually results in an increased risk of cancer. Evidence that exposure to dpm increases the risk of developing cancer comes from three kinds of studies: human studies, genotoxicological studies, and animal studies. MSHA places the most weight on evidence from the human epidemiological studies and views the genotoxicological and animal studies as lending support to the epidemiological evidence.

In the epidemiological studies, it is generally impossible to disassociate exposure to dpm from exposure to the gasses and vapors that form the remainder of whole diesel exhaust. However, the animal evidence shows no significant increase in the risk of lung cancer from exposure to the gaseous fraction alone (Heinrich et al., 1986; Iwai et al., 1986; Brightwell et al., 1986). Therefore, dpm, rather than the gaseous fraction of diesel exhaust, is assumed to be the agent associated with an excess risk of lung cancer.

III.2.c.i.B.i. Lung Cancer. Beginning in 1957, at least 43 epidemiological studies have been published examining relationships between diesel exhaust exposure and the prevalence of lung cancer. The most recent published reviews of these studies are by Mauderly (1992), Cohen and Higgins (1995), Stöber and Abel (1996), Morgan et al. (1997), and Dawson et al. (1998). In addition, in response to the ANPRM, several commenters provided MSHA with their own reviews. Two comprehensive statistical ''meta-analyses'' of the epidemiological literature are also available: Lipsett and Alexeeff (1998) and Bhatia et al. (1998). These meta-analyses, which analyze and combine results from the various epidemiological studies, both suggest a statistically significant increase of 30 to 40 percent in the risk of lung cancer, attributable to occupational dpm exposure. The studies themselves, along with MSHA's comments on each study, are summarized in Tables III–4 (24 cohort studies) and III–5 (19 case-control studies).[8] Presence or absence of an adjustment for smoking habits is highlighted, and adjustments for other potentially confounding factors are indicated when applicable.

Some degree of association between occupational dpm exposure and an excess risk of lung cancer was observed in 38 of the 43 studies reviewed by MSHA: 18 of the 19 case-control studies and 20 of the 24 cohort studies. However, the 38 studies reporting a positive association vary considerably in the strength of evidence they present. As shown in Tables III–4 and III–5, *statistically significant* results were reported in 24 of the 43 studies: 10 of the 18 positive case-control studies and 14 of the 20 positive cohort studies.[9] In six of the 20 cohort studies and nine of the 18 case-control studies showing a positive association, the association observed was not statistically significant.

Because workers tend to be healthier than non-workers, the incidence of disease found among workers exposed to a toxic substance may be lower than the rate prevailing in the general population, but higher than the rate occurring in an unexposed population of workers. This phenomenon, called the ''healthy worker effect,'' also applies when the rate observed among exposed workers is greater than that found in the general population. In this case, assuming a study is unbiased with respect to other factors such as smoking, comparison with the general population will tend to *underestimate* the excess risk of disease attributable to the substance being investigated. Several studies drew comparisons against the general population, including both workers and nonworkers, with no compensating adjustment for the healthy worker effect. Therefore, in these studies, the excess risk of lung cancer attributable to dpm exposure is likely to have been underestimated, thereby making it more difficult to obtain a statistically significant result.

Five of the 43 studies listed in Tables III–4 and III–5 are negative—i.e., a lower rate of lung cancer was found among exposed workers than in the control population used for comparison. None of these five results, however, were statistically significant. Four of the five were cohort studies that drew comparisons against the general population and did not take the healthy worker effect into account. The remaining negative study was a case-control study in which vehicle drivers and locomotive engineers were compared to clerical workers.

Two cohort studies (Waxweiler et al., 1973; Ahlman et al., 1991) were performed specifically on groups of miners, and one (Boffetta et al., 1988) addressed miners as a subgroup of a larger population. Although an elevated prevalence of lung cancer was found among miners in both the 1973 and 1991 studies, the results were not statistically significant. The 1988 study found, after adjusting for smoking patterns and other occupational exposures, an 18-percent increase in the lung cancer rate among all workers occupationally exposed to diesel exhaust and a 167-percent increase among miners (relative risk = 2.67). The latter result is statistically significant.

In addition, four case-control studies, all of which adjusted for smoking, found elevated rates of lung cancer associated with mining. The results for miners in three of these studies (Benhamou et al., 1988; Morabia et al., 1992; Siemiatycki et al., 1988) are given little weight because of potential confounding by occupational exposures to other carcinogens. The other study (Lerchen et al., 1987) showed a marginally significant result for underground non-uranium miners, but this was based on very few cases and the extent of diesel exposure among these miners was not reported. Although they do not pertain specifically to mining environments, other studies showing statistically significant results (most notably those by Garshick et al., 1987 and 1988) are based on far more data, contain better diesel exposure information, and are less susceptible to confounding by extraneous risk factors.

Since none of the existing human studies is perfect and many contain major deficiencies, it is not surprising that reported results differ in magnitude and statistical significance. Shortcomings identified in both positive and negative studies include: possible misclassification with respect to exposure; incomplete or questionable characterization of the exposed population; unknown or uncertain quantification of diesel exhaust exposure; incomplete, uncertain, or unavailable history of exposure to tobacco smoke and other carcinogens; and insufficient sample size, dpm exposure, or latency period (i.e., time since exposure) to detect a carcinogenic effect if one exists. Indeed, in their review of these studies, Stöber and Abel (1996) conclude that ''In this field * * *

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

[9] A statistically significant result is a result unlikely to have arisen by chance in the group, or statistical *sample,* of persons being studie. An association arising by chance would have no predictive value for workers outside the sample. Failure to achieve statistical significance in an individual study can arise because of inherent limitations in the study, such as a small number of subjects in the sample or a short period of observation. Therefore, the lack of statistical significance in an individual study does not demonstrate that the results of that study were due merely to chance—only that the study (viewed in isolation) is inconclusive.

epidemiology faces its limits (Taubes, 1995) * * * Many of these studies were doomed to failure from the very beginning.''

Such problems, however, are not unique to epidemiological studies involving diesel exhaust but are common sources of uncertainty in virtually all epidemiological research involving cancer. Indeed, deficiencies such as exposure misclassification, small sample size, and short latency make it difficult to detect a relationship even when one exists. Therefore, the fact that 38 out of 43 studies showed any excess risk of lung cancer associated with dpm exposure may itself be a significant result, even if the evidence in most of those 38 studies is relatively weak.[10] The sheer number of studies showing such an association readily distinguishes this body of evidence from those criticized by Taubes (1995), where weak evidence is available from only a single study.

At the same time, MSHA recognizes that simply tabulating outcomes can sometimes be misleading, since there are generally a variety of outcomes that could render a study positive or negative and some studies use related data sets. Therefore, rather than limiting its assessment to such a tabulation, MSHA is basing its evaluation with respect to lung cancer largely on the two comprehensive meta-analyses (Lipsett and Alexeeff, 1998; Bhatia et al., 1998) described later, in the ''material impairments'' section of this risk assessment. In addition to restricting themselves to independent studies meeting certain minimal requirements, both meta-analyses investigated and rejected publication bias as an explanation for the generally positive results reported.

All of the studies showing negative or statistically insignificant positive associations were either based on relatively short observation or follow-up periods, lacked good information about dpm exposure, involved low duration or intensity of dpm exposure, or, because of inadequate sample size, lacked the statistical power to detect effects of the magnitude found in the ''positive'' studies. As stated by Boffetta et al. (1988, p. 404), studies failing to show a statistically significant association—

> * * * often had low power to detect any association, had insufficient latency periods, or compared incidence or mortality rates among workers to national rates only, resulting in possible biases caused by the 'healthy worker effect.'

Some respondents to the ANPRM argued that such methodological weaknesses may explain why not all of the studies showed a statistically significant association between dpm exposure and an increased prevalence of lung cancer. According to these commenters, if an epidemiological study shows a statistically significant result, this often occurs *in spite of* methodological weaknesses rather than because of them. Limitations such as potential exposure misclassification, inadequate latency, inadequate sample size, and insufficient duration of exposure all make it more difficult to obtain a statistically significant result when a real relationship exists.

On the other hand, Stöber and Abel (1996) argue, long with Morgan et al. (1997) and some commenters, that even in those epidemiological studies showing a statistically significant association, the magnitude of relative or excess risk observed is too small to demonstrate any causal link between dpm exposure and cancer. Their reasoning is that in these studies, errors in the collection or interpretation of smoking data can create a bias in the results larger than any potential contribution attributable to diesel particulate. They propose that studies failing to account for smoking habits should be disqualified from consideration, and that evidence of an association from the remaining studies should be discounted because of potential confounding due to erroneous, incomplete, or otherwise inadequate characterization of smoking histories.

MSHA concurs with Cohen and Higgins (1995), Lipsett and Alexeeff (1998), and Bhatia et al. (1998) in not accepting this view. MSHA does recognize that unknown exposures to tobacco smoke or other human carcinogens, such as asbestos, can distort the results of some lung cancer studies. MSHA also agrees that significant differences in the distribution of confounding factors, such as smoking history, between study and control groups can lead to misleading results. MSHA also recognizes, however, that it is not possible to design a human epidemiological study that perfectly controls for all potentially confounding factors. Some degree of informed subjective judgement is always required in evaluating the potential significance of unknown or uncontrolled factors.

Sixteen of the published epidemiological studies involving lung cancer did, in fact, control or adjust for exposure to tobacco smoke, and some of these also controlled or adjusted for exposure to asbestos and other carcinogenic substances (e.g., Garshick et al., 1987; Steenland et al., 1990; Boffetta et al., 1988). All but one of these 16 epidemiological studies reported some degree of excess risk associated with exposure to diesel particulate, with statistically significant results reported in seven. These results are less likely to be confounded than results from studies with no adjustment. In addition, several of the other studies drew comparisons against internal control groups or control groups likely to have similar smoking habits as the exposed groups (e.g., Garshick et al., 1988; Gustavsson et al., 1990; and Hansen, 1993). MSHA places more weight on these studies than on studies drawing comparisons against dissimilar groups with no controls or adjustments.

According to Stöber and Abel, the potential confounding effects of smoking are so strong that they could explain even statistically significant results observed in studies where smoking was explicitly taken into account. MSHA agrees that variable exposures to non-diesel lung carcinogens, including relatively small errors in smoking classification, could bias individual studies. However, the potential confounding effect of tobacco smoke and other carcinogens can cut in either direction. Spurious positive associations of dpm exposure with lung cancer would arise only if the group exposed to dpm had a greater exposure to these confounders than the unexposed control group used for comparison. If, on the contrary, the control group happened to be more exposed to confounders, then this would tend to make the association between dpm exposure and lung cancer appear negative. Therefore, although smoking effects could potentially distort the results of any single study, this effect could reasonably be expected to make only about half the studies that were explicitly adjusted for smoking come out positive. Smoking is unlikely to have been responsible for finding an excess prevalence of lung cancer in 15 out of 16 studies in which a smoking adjustment was applied. Based on a 2-tailed sign test, this possibility can be rejected at a confidence level greater than 99.9 percent.

Even in the 27 studies involving lung cancer for which no smoking adjustment was made, tobacco smoke and other carcinogens are important confounders only to the extent that the

[10] The high proportion of positive studies is statistically significant according to the 2-tailed sign test, which rejects, at a high confidence level, the null hypothesis that each study is equally likely to be positive or negative. Assuming that the studies are independent, and that there is no systematic bias in one direction or the other, the probability of 38 or more out of 43 studies being either positive or negative is less than one per million under the null hypothesis.

populations exposed and unexposed to diesel exhaust differed systematically with respect to these other exposures. Twenty-three of these studies, however, reported some degree of excess lung cancer risk associated with diesel exposure. This result could be attributed to non-diesel exposures only in the unlikely event that, in nearly all of these studies, diesel-exposed workers happened to be more highly exposed to these other carcinogens than the control groups of workers unexposed to diesel. All five studies not showing any association (Kaplan, 1959; DeCoufle, 1977; Waller, 1981; Edling, 1987; and Bender, 1989) may have failed to detect such a relationship because of too small a study group, lack of accurate exposure information, low duration or intensity of exposure, and/or insufficient latency or follow-up time.

It is also significant that the two most comprehensive, complete, and well-controlled studies available (Garshick et al., 1987 and 1988) both point in the direction of an association between dpm exposure and an excess risk of lung cancer. These studies took care to address potential confounding by tobacco smoke and asbestos exposures. In response to the ANPRM, a consultant to the National Coal Association who was critical of all other available studies acknowledged that these two:

> * * * have successfully controlled for severally [sic] potentially important confounding factors * * * Smoking represents so strong a potential confounding variable that its control must be nearly perfect if an observed association between cancer and diesel exhaust is * * * [inferred to be causal]. In this regard, two observations are relevant. First, both case-control [Garshick et al., 1987] and cohort [Garshick et al., 1988] study designs revealed consistent results. Second, an examination of smoking related causes of death other than lung cancer seemed to account for only a fraction of the association observed between diesel exposure and lung cancer. A high degree of success was apparently achieved in controlling for smoking as a potentially confounding variable. [Submission 87–0–10, Robert A. Michaels, RAM TRAC Corporation, prepared for National Coal Association].

Potential biases due to extraneous risk factors are unlikely to account for a significant part of the excess risk in all studies showing an association. Excess rates of lung cancer were associated with dpm exposure in all epidemiologic studies of sufficient size and scope to detect such an excess. Although it is possible, in any individual study, that the potentially confounding effects of differential exposure to tobacco smoke or other carcinogens could account for the observed elevation in risk otherwise attributable to diesel exposure, it is unlikely that such effects would give rise to positive associations in 38 out of 43 studies. As stated by Cohen and Higgins (1995):

> * * * elevations [of lung cancer] do not appear to be fully explicable by confounding due to cigarette smoking or other sources of bias. Therefore, at present, exposure to diesel exhaust provides the most reasonable explanation for these elevations. The association is most apparent in studies of occupational cohorts, in which assessment of exposure is better and more detailed analyses have been performed. The largest relative risks are often seen in the categories of most probable, most intense, or longest duration of exposure. In general population studies, in which exposure prevalence is low and misclassification of exposure poses a particularly serious potential bias in the direction of observing no effect of exposure, most studies indicate increased risk, albeit with considerable imprecision. [Cohen and Higgins (1995), p. 269].

III.2.c.i.B.ii. Bladder Cancer. With respect to cancers other than lung cancer, MSHA's review of the literature identified only bladder cancer as a possible candidate for a causal link to dpm. Cohen and Higgins (1995) identified and reviewed 14 epidemiological case-control studies containing information related to dpm exposure and bladder cancer. All but one of these studies found elevated risks of bladder cancer among workers in jobs frequently associated with dpm exposure. Findings were statistically significant in at least four of the studies (statistical significance was not evaluated in three).

These studies point quite consistently toward an excess risk of bladder cancer among truck or bus drivers, railroad workers, and vehicle mechanics. However, the four available cohort studies do not support a conclusion that exposure to dpm is responsible for the excess risk of bladder cancer associated with these occupations. Furthermore, most of the case-control studies did not distinguish between exposure to diesel-powered equipment and exposure to gasoline-powered equipment for workers having the same occupation. When such a distinction was drawn, there was no evidence that the prevalence of bladder cancer was higher for workers exposed to the diesel-powered equipment.

This, along with the lack of corroboration from existing cohort studies, suggests that the excessive rates of bladder cancer observed may be a consequence of factors other than dpm exposure that are also associated with these occupations. For example, truck and bus drivers are subjected to vibrations while driving and may tend to have different dietary and sleeping habits than the general population. For these reasons, MSHA does not find that any convincing evidence currently exists for a causal relationship between dpm exposure and bladder cancer.

III.2.c.ii. Studies Based on Exposures to Fine Particulate in Ambient Air.

Longitudinal studies examine responses at given locations to changes in conditions over time, whereas *cross-sectional studies* compare results from locations with different conditions at a given point in time. Prior to 1990, cross sectional studies were generally used to evaluate the relationship between mortality and long-term exposure to particulate matter, but unaddressed spatial confounders and other methodological problems inherent in such studies limited their usefulness (EPA, 1996).

Two recent prospective cohort studies provide better evidence of a link between excess mortality rates and exposure to fine particulate, although the uncertainties here are greater than with the short-term exposure studies conducted in single communities. The two studies are known as the Six Cities study (Dockery et al., 1993), and the American Cancer Society (ACS) study (Pope et al., 1995).[11] The first study followed about 8,000 adults in six U.S. cities over 14 years; the second looked at survival data for half a million adults in 151 U.S. cities for 7 years. After adjusting for potential confounders, including smoking habits, the studies considered differences in mortality rates between the most polluted and least polluted cities.

Both the Six Cities study and the ACS study found a significant association between increased concentration of $PM_{2.5}$ and total mortality.[12] The authors of the Six Cities Study concluded that the results suggest that exposures to fine particulate air pollution ''contributes to excess mortality in certain U.S. cities.'' The ACS study, which not only controlled for smoking habits and various occupational exposures, but also, to some extent, for passive exposure to tobacco smoke, found results qualitatively consistent with those of the Six Cities Study.[13] In the

[11] A third such study only looked at TSP, rather than fine particulate. It did not find a significant association between total mortality and TSP. It is known as the California Seventh Day Adventist study (Abbey et al., 1991).

[12] The Six Cities study also found such relationships at elevated levels of $PM_{15/10}$ and sulfates. The ACS study was designed to follow up on the fine particle result of the Six Cities study, but also looked at sulfates.

[13] The Six Cities study did not find a statistically significant increase in risk among non-smokers, suggesting that this group might not be as sensitive to adverse health effects from exposure to fine

ACS study, however, the estimated increase in mortality associated with a given increase in fine particulate exposure was lower, though still statistically significant. In both studies, the largest increase observed was for cardiopulmonary mortality. Both studies also showed an increased risk of lung cancer associated with increased exposure to fine particulate, but these results were not statistically significant.

The few studies on associations between chronic $PM_{2.5}$ exposure and morbidity in adults show effects that are difficult to separate from PM_{10} measures and measures of acid aerosols. The available studies, however, do show positive associations between particulate air pollution and adverse health effects for those with pre-existing respiratory or cardiovascular disease; and as mentioned earlier, there is a large body of evidence showing that respiratory diseases classified as COPD are significantly more prevalent among miners than in the general population. It also appears that PM exposure may exacerbate existing respiratory infections and asthma, increasing the risk of severe outcomes in individuals who have such conditions (EPA, 1996).

III.2.d. Mechanisms of Toxicity

As described in Part II, the particulate fraction of diesel exhaust is made up of aggregated soot particles. Each soot particle consists of an insoluble, elemental carbon core and an adsorbed, surface coating of relatively soluble organic compounds, such as polycyclic aromatic hydrocarbons (PAH's). When released into an atmosphere, the soot particles formed during combustion tend to aggregate into larger particles.

The literature on deposition of fine particles in the respiratory tract is reviewed in Green and Watson (1995) and U.S. EPA (1996). The mechanisms responsible for the broad range of potential particle-related health effects will vary depending on the site of deposition. Once deposited, the particles may be cleared from the lung, translocated into the interstitium, sequestered in the lymph nodes, metabolized, or be otherwise transformed by various mechanisms.

As suggested by Figure II–1 of this preamble, most of the aggregated particles making up dpm never get any larger than one micrometer in diameter. Particles this small are able to penetrate into the deepest regions of the lungs, called *alveoli*. In the alveoli, the particles can mix with and be dispersed by a substance called *surfactant*, which is secreted by cells lining the alveolar surfaces.

MSHA would welcome any additional information, not already covered in the surveys cited above, on fine particle deposition in the respiratory tract, especially as it might pertain to lung loading in miners exposed to a combination of diesel particulate and other dusts. Any such additional information will be placed into the public record and considered by MSHA before a final rule is adopted.

III.2.d.i. Effects Other than Cancer. A number of controlled animal studies have been undertaken to ascertain the toxic effects of exposure to diesel exhaust and its components. Watson and Green (1995) reviewed approximately 50 reports describing noncancerous effects in animals resulting from the inhalation of diesel exhaust. While most of the studies were conducted with rats or hamsters, some information was also available from studies conducted using cats, guinea pigs, and monkeys. The authors also correlated reported effects with different descriptors of dose. From their review of these studies, Watson and Green concluded that:

(a) Animals exposed to diesel exhaust exhibit a number of noncancerous pulmonary effects, including chronic inflammation, epithelial cell hyperplasia, metaplasia, alterations in connective tissue, pulmonary fibrosis, and compromised pulmonary function.

(b) Cumulative weekly exposure to diesel exhaust of 70 to 80 mg•hr/m^3 or greater are associated with the presence of chronic inflammation, epithelial cell proliferation, and depressed alveolar clearance in chronically exposed rats.

(c) The extrapolation of responses in animals to noncancer endpoints in humans is uncertain. Rats were the most sensitive animal species studied.

Subsequent to the review by Watson and Green, there have been a number of animal studies on allergic immune responses to dpm. Takano et al. (1997) investigated the effects of dpm injected into mice through an intratracheal tube and found manifestations of allergic asthma, including enhanced antigen-induced airway inflammation, increased local expression of cytokine proteins, and increased production of antigen-specific immunoglobulins. The authors concluded that the study demonstrated dpm's enhancing effects on allergic asthma and that the results suggest that dpm is ''implicated in the increasing prevalence of allergic asthma in recent years.'' Similarly, Ichinose et al. (1997) found that five different strains of mice injected intratracheally with dpm exhibited manifestations of allergic asthma, as expressed by enhanced airway inflammation, which were correlated with an increased production of antigen-specific immunoglobulin due to the dpm. The authors concluded that dpm enhances manifestations of allergic airway inflammation and that ''* * * the cause of individual differences in humans at the onset of allergic asthma may be related to differences in antigen-induced immune responses * * *.''

Several laboratory animal studies have been performed to ascertain whether the effects of diesel exhaust are attributable specifically to the particulate fraction. (Heinrich et al., 1986; Iwai et al., 1986; Brightwell et al., 1986). These studies compare the effects of chronic exposure to whole diesel exhaust with the effects of filtered exhaust containing no particles. The studies demonstrate that when the exhaust is sufficiently diluted to nullify the effects of gaseous irritants (NO_2 and SO_2), irritant vapors (aldehydes), CO, and other systemic toxicants, diesel particles are the prime etiologic agents of noncancer health effects. Exposure to dpm produced changes in the lung that were much more prominent than those evoked by the gaseous fraction alone. Marked differences in the effects of whole and filtered diesel exhaust were also evident from general toxicological indices, such as body weight, lung weight, and pulmonary histopathology. This provides strong evidence that the toxic component in diesel emissions producing the effects noted in other animal studies is due to the particulate fraction.

The mechanisms that may lead to adverse health effects in humans from inhaling fine particulates are not fully understood, but potential mechanisms that have been hypothesized for non-cancerous outcomes are summarized in Table III–6. A comprehensive review of the toxicity literature is provided in U.S. EPA (1996).

Deposition of particulates in the human respiratory tract could initiate events leading to increased airflow obstruction, impaired clearance, impaired host defenses, or increased epithelial permeability. Airflow obstruction could result from laryngeal constriction or bronchoconstriction secondary to stimulation of receptors in extrathoracic or intrathoracic airways. In addition to reflex airway narrowing, reflex or local stimulation of mucus secretion could lead to mucus hypersecretion and could eventually lead to mucus plugging in small airways.

Pulmonary changes that contribute to cardiovascular responses include a

particulate; however, the ACS study, with more statistical power, did find an association even for non-smokers.

variety of mechanisms that can lead to hypoxemia, including bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators. Hypoxia can lead to cardiac arrhythmias and other cardiac electrophysiologic responses that, in turn, may lead to ventricular fibrillation and ultimately cardiac arrest. Furthermore, many respiratory receptors have direct cardiovascular effects. For example, stimulation of C-fibers leads to bradycardia and hypertension, and stimulation of laryngeal receptors can result in hypertension, cardiac arrhythmia, bradycardia, apnea, and even cardiac arrest. Nasal receptor or pulmonary J-receptor stimulation can lead to vagally mediated bradycardia and hypertension (Widdicombe, 1988).

In addition to possible acute toxicity of particles in the respiratory tract, chronic exposure to particles that deposit in the lung may induce inflammation. Inflammatory responses can lead to increased permeability and possibly diffusion abnormality. Furthermore, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to an increased risk of thrombus formation in the vascular system (Seaton, 1995). Persistent inflammation, or repeated cycles of acute lung injury and healing, can induce chronic lung injury. Retention of the particles may be associated with the initiation and/or progression of COPD.

III.2.d.ii. Lung Cancer.

III.2.d.ii.A. Genotoxicological Evidence. Many studies have shown that diesel soot, or its organic component, can increase the likelihood of genetic mutations during the biological process of cell division and replication. A survey of the applicable scientific literature is provided in Shirnamé-Moré (1995). What makes this body of research relevant to the risk of cancer is that mutations in critical genes can sometimes initiate, promote, or advance a process of carcinogenesis.

The determination of genotoxicity has frequently been made by treating diesel soot with organic solvents such as dichloromethane and dimethyl sulfoxide. The solvent removes the organic compounds from the carbon core. After the solvent evaporates, the mutagenic potential of the extracted organic material is tested by applying it to bacterial, mammalian, or human cells propagated in a laboratory culture. In general, the results of these studies have shown that various components of the organic material can induce mutations and chromosomal aberrations.

A critical issue is whether whole diesel particulate is mutagenic when dispersed by substances present in the lung. Since the laboratory procedure for extracting organic material with solvents bears little resemblance to the physiological environment of the lung, it is important to establish whether dpm as a whole is genotoxic, without solvent extraction. Early research indicated that this was not the case and, therefore, that the active genotoxic materials adhering to the carbon core of diesel particles might not be biologically damaging or even available to cells in the lung (Brooks et al., 1980; King et al., 1981; Siak et al., 1981). A number of more recent research papers, however, have shown that dpm, without solvent extraction, can cause DNA damage when the soot is dispersed in the pulmonary surfactant that coats the surface of the alveoli (Wallace et al., 1987; Keane et al., 1991; Gu et al., 1991; Gu et al., 1992). From these studies, NIOSH has concluded:

> * * * the solvent extract of diesel soot and the surfactant dispersion of diesel soot particles were found to be active in procaryotic cell and eukaryotic cell *in vitro* genotoxicity assays. The cited data indicate that respired diesel soot particles on the surface of the lung alveoli and respiratory bronchioles can be dispersed in the surfactant-rich aqueous phase lining the surfaces, and that genotoxic material associated with such dispersed soot particles is biologically available and genotoxically active. Therefore, this research demonstrates the biological availability of active genotoxic materials without organic solvent interaction. [Cover letter to NIOSH response to ANPRM.]

From this conclusion, it follows that dpm itself, and not only its organic extract, can cause genetic mutations when dispersed by a substance present in the lung.

The biological availability of the genotoxic components is also supported directly by studies showing genotoxic effects of exposure to whole dpm. The formation of DNA adducts is an important indicator of genotoxicity and potential carcinogenicity. If DNA adducts are not repaired, then a mutation or chromosomal aberration can occur during normal mitosis (i.e., cell replication). Hemminki et al. (1994) found that DNA adducts were significantly elevated in nonsmoking bus maintenance and truck terminal workers, as compared to a control group of hospital mechanics, with the highest adduct levels found among garage and forklift workers. Similarly, Nielsen et al. (1996) found that DNA adducts were significantly increased in bus garage workers and mechanics exposed to dpm as compared to a control group.

III.2.d.ii.B. Evidence from Animal Studies. Bond et al. (1990) investigated differences in peripheral lung DNA adduct formation among rats, hamsters, mice, and monkeys exposed to dpm at a concentration of 8100 $\mu g/m^3$ for 12 weeks. Mice and hamsters showed no increase of DNA adducts in their peripheral lung tissue, whereas rats and monkeys showed a 60 to 80% increase. The increased prevalence of lung DNA adducts in monkeys suggests that, with respect to DNA adduct formation, the human lungs' response to dpm inhalation may more closely resemble that of the rat than that of the hamster or mouse.

Mauderly (1992) and Busby and Newberne (1995) provide reviews of the scientific literature relating to excess lung cancers observed among laboratory animals chronically exposed to filtered and unfiltered diesel exhaust. The experimental data demonstrate that chronic exposure to whole diesel exhaust increases the risk of lung cancer in rats and that dpm is the causative agent. This carcinogenic effect has been confirmed in two strains of rats and in at least five laboratories. Experimental results for animal species other than the rat, however, are either inconclusive or, in the case of Syrian hamsters, suggestive of no carcinogenic effect. This is consistent with the observation, mentioned above, that lung DNA adduct formation is increased among exposed rats but not among exposed hamsters or mice.

The conflicting results for rats and hamsters indicate that the carcinogenic effects of dpm exposure may be species-dependent. Indeed, monkey lungs have been reported to respond quite differently than rat lungs to both diesel exhaust and coal dust (Nikula, 1997). Therefore, the results from rat experiments do not, by themselves, infer any excess risk due to dpm exposure for humans. The human epidemiological data, however, indicate that humans comprise a species that, like rats and unlike hamsters, suffer a carcinogenic response to dpm exposure. Therefore, MSHA considers the rat studies at least relevant to an evaluation of the risk for humans.

When dpm is inhaled, a number of adverse effects that may contribute to carcinogenesis are discernable by microscopic and biochemical analysis. For a comprehensive review of these effects, see Watson and Green (1995). In brief, these effects begin with phagocytosis, which is essentially an attack on the diesel particles by cells called alveolar macrophages. The macrophages engulf and ingest the diesel particles, subjecting them to detoxifying enzymes. Although this is a normal physiological response to the

inhalation of foreign substances, the process can produce various chemical byproducts injurious to normal cells. In attacking the diesel particles, the activated macrophages release chemical agents that attract neutrophils (a type of white blood cell that destroys microorganisms) and additional alveolar macrophages. As the lung burden of diesel particles increases, aggregations of particle-laden macrophages form in alveoli adjacent to terminal bronchioles, the number of Type II cells lining particle-laden alveoli increases, and particles lodge within alveolar and peribronchial tissues and associated lymph nodes. The neutrophils and macrophages release mediators of inflammation and oxygen radicals, which have been implicated in causing various forms of chromosomal damage, genetic mutations, and malignant transformation of cells (Weitzman and Gordon, 1990). Eventually, the particle-laden macrophages are functionally altered, resulting in decreased viability and impaired phagocytosis and clearance of particles. This series of events may result in pulmonary inflammatory, fibrotic, or emphysematous lesions that can ultimately develop into cancerous tumors.

Such reactions have also been observed in rats exposed to high concentrations of fine particles with no organic component (Mauderly et al., 1994; Heinrich et al., 1994 and 1995; Nikula et al., 1995). Rats exposed to titanium dioxide or pure carbon (''carbon-black'') particles, which are not considered to be genotoxic, developed lung cancers at about the same rate as rats exposed to whole diesel exhaust. Therefore, it appears that the toxicity of dpm, at least in some species, may result largely from a biochemical response to the particle itself rather than from specific effects of the adsorbed organic compounds.

Some researchers have interpreted the carbon-black and titanium dioxide studies as also suggesting that (1) the carcinogenic mechanism in rats depends on massive overloading of the lung and (2) that this may provide a mechanism of carcinogenesis specific to rats which does not occur in other rodents or in humans (Oberdörster, 1994; Watson and Valberg, 1996). Some commenters on the ANPRM cited the lack of any link between lung cancer and coal dust or carbon black exposure as evidence that carbon particles, by themselves, are not carcinogenic in humans. Coal mine dust, however, consists almost entirely of particles larger than those forming the carbon core of dpm or used in the carbon-black and titanium dioxide rat studies. Furthermore, although there have been eight studies [14] reporting no excess risk of lung cancer among coal miners (Liddell, 1973; Costello et al., 1974; Armstrong et al., 1979; Rooke et al., 1979; Ames et al., 1983; Atuhaire et al., 1985; Miller and Jacobsen, 1985; Kuempel et al., 1995), five studies have reported an elevated risk of lung cancer for those exposed to coal dust (Enterline, 1972; Rockette, 1977; Correa et al., 1984; Levin et al., 1988; Morfeld et al., 1997). The positive results in two of these studies (Enterline, 1972; Rockette, 1977) were statistically significant. Furthermore, excess lung cancers have been reported among carbon black production workers (Hodgson and Jones, 1985; Siemiatycki, 1991; Parent et al., 1996). MSHA is not aware of any evidence that a mechanism of carcinogenesis due to fine particle overload is inapplicable to humans. Studies carried out on rodents certainly do not provide such evidence.

The carbon-black and titanium dioxide studies indicate that lung cancers in rats exposed to dpm may be induced by a mechanism that does not require the bioavailability of genotoxic organic compounds adsorbed on the elemental carbon particles. These studies do not, however, prove that the only significant agent of carcinogenesis in rats exposed to diesel particulate is the non-soluble carbon core. Nor do the carbon-black studies prove that the only significant mechanism of carcinogenesis due to diesel particulate is lung overload. Due to the relatively high doses administered in the rat studies, it is conceivable that an overload phenomenon masks or parallels other potential routes to cancer. It may be that effects of the genotoxic organic compounds are merely masked or displaced by overloading in the rat studies. Gallagher et al. (1994) exposed different groups of rats to diesel exhaust, carbon black, or titanium dioxide and detected species of lung DNA adducts in the rats exposed to dpm that were not found in the controls or rats exposed to carbon black or titanium dioxide.

Particle overload may provide the dominant route to lung cancer at very high concentrations of fine particulate, while genotoxic mechanisms may provide the primary route under lower-level exposure conditions. In humans exposed over a working lifetime to doses insufficient to cause overload, carcinogenic mechanisms unrelated to overload may dominate, as indicated by the human epidemiological studies and the data on human DNA adducts cited above. Therefore, the carbon black results observed in the rat studies do not preclude the possibility that the organic component of dpm has important genotoxic effects in humans (Nauss et al., 1995).

Even if the genotoxic organic compounds in dpm were biologically unavailable and played no role in human carcinogenesis, this would not rule out the possibility of a genotoxic route to lung cancer (even for rats) due to the presence of dpm particles themselves. For example, as a byproduct of the biochemical response to the presence of dpm in the alveoli, free oxidant radicals may be released as macrophages attempt to digest the particles. There is evidence that dpm can both induce production of active oxygen agents and also depress the activity of naturally occurring antioxidant enzymes (Mori, 1996; Sagai, 1993). Oxidants can induce carcinogenesis either by reacting directly with DNA, or by stimulating cell replication, or both (Weitzman and Gordon, 1990). This would provide a mutagenic route to lung cancer with no threshold. Therefore, the carbon black and titanium dioxide studies cited above do not prove that dpm exposure has no incremental, genotoxic effects or that there is a threshold below which dpm exposure poses no risk of causing lung cancer.

It is noteworthy, however, that dpm exposure levels recorded in some mines have been almost as high as laboratory exposures administered to rats showing a clearly positive response. Intermittent, occupational exposure levels greater than about 500 $\mu g/m^3$ dpm may overwhelm the human lung clearance mechanism (Nauss et al., 1995). Therefore, concentrations at levels currently observed in some mines could be expected to cause overload in some humans, possibly inducing lung cancer by a mechanism similar to what occurs in rats. MSHA would like to receive additional scientific information on this issue, especially as it relates to lung loading in miners exposed to a combination of diesel particulate and other dusts.

As suggested above, such a mechanism would not necessarily be the only route to carcinogenesis in humans and, therefore, would not imply that dpm concentrations too low to

[14] The Agency has recently learned of another report, from the University of Newcastle, Australia, that found no elevated risk of lung cancer among coal miners. Although the Agency has not been able to acquire this report in time to include it in the present risk assessment, it will be reviewed and considered in the risk assessment prior to any final action. The Agency would also welcome information on any additional studies or reports on this issue of which it is not currently aware.

cause overload are safe for humans. Furthermore, a proportion of exposed individuals can always be expected to be more susceptible than normal. Therefore, at lower dpm concentrations, particle overload may still provide a route to lung cancer in susceptible humans. At even lower concentrations, other routes to carcinogenesis in humans may predominate, possibly involving genotoxic effects.

III.3. Characterization of Risk

Having reviewed the evidence of health effects associated with exposure to dpm, MSHA has evaluated that evidence to ascertain whether exposure levels currently existing in mines warrant regulatory action pursuant to the Mine Act. The criteria for this evaluation are established by the Mine Act and related court decisions. Section 101(a)(6)(A) provides that:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

Based on court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that need to be addressed: (1) whether health effects associated with dpm exposure constitute a ''material impairment'' to miner health or functional capacity; (2) whether exposed miners are at significant excess risk of incurring any of these material impairments; and (3) whether the proposed rule will substantially reduce such risks.

The criteria for evaluating the health effects evidence do not require scientific certainty. As noted by Justice Stevens in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straightjacket.'' [*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607, 100 S.Ct. 2844 (1980), hereinafter designated the ''Benzene'' case]. When regulating on the edge of scientific knowledge, certainty may not be possible; and—

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

The statutory criteria for evaluating the health evidence do not require MSHA to wait for absolute precision. In fact, MSHA is required to use the ''best *available* evidence.'' (Emphasis added).

III.3.a. *Material Impairments to Miner Health or Functional Capacity*

From its review of the literature cited in Part III.2, MSHA has tentatively concluded that underground miners exposed to current levels of dpm are at excess risk of incurring the following three kinds of material impairment: (i) sensory irritations and respiratory symptoms; (ii) death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. The basis for linking these with dpm exposure is summarized in the following three subsections.

III.3.a.i. Sensory Irritations and Respiratory Symptoms. Kahn et al. (1988), Battigelli (1965), Gamble et al. (1987a) and Rudell et al. (1996) identified a number of debilitating acute responses to diesel exhaust exposure: irritation of the eyes, nose and throat; headaches, nausea, and vomiting; chest tightness and wheeze. These symptoms were also reported by miners at the 1995 workshops. In addition, Ulfvarson et al. (1987, 1990) found evidence of reduced lung function in workers exposed to dpm for a single shift.

Although there is evidence that such symptoms subside within one to three days of no occupational exposure, a miner who must be exposed to dpm day after day in order to earn a living may not have time to recover from such effects. Hence, the opportunity for a so-called ''reversible'' health effect to reverse itself may not be present for many miners. Furthermore, effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and can, in some cases, be seriously disabling. Also, workers experiencing sufficiently severe sensory irritations can be distracted as a result of their symptoms, thereby endangering other workers and increasing the risk of accidents. For these reasons, MSHA considers such irritations to constitute ''material impairments'' of health or functional capacity within the meaning of the Act, regardless of whether or not they are reversible. Further discussion of why MSHA believes reversible effects can constitute material impairments can be found earlier in this risk assessment, in the section entitled ''Relevance of Health Effects that are Reversible.''

The best available evidence also points to more severe respiratory consequences of exposure to dpm. Significant associations have been detected between acute environmental exposures to fine particulates and debilitating respiratory impairments in adults, as measured by lost work days, hospital admissions, and emergency room visits. Short-term exposures to fine particulates, or particulate air pollution in general, have been associated with significant increases in the risk of hospitalization for both pneumonia and COPD (EPA, 1996).

The risk of severe respiratory effects is exemplified by specific cases of persistent asthma linked to diesel exposure (Wade and Newman, 1993). There is considerable evidence for a causal connection between dpm exposure and increased manifestations of allergic asthma and other allergic respiratory diseases, coming from recent experiments on animals and human cells (Peterson and Saxon, 1996; Diaz-Sanchez, 1997; Takano et al., 1997; Ichinose et al., 1997). Such health outcomes are clearly ''material impairments'' of health or functional capacity within the meaning of the Act.

III.3.a.ii. Excess Risk of Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes. The evidence from air pollution studies identifies death, largely from cardiovascular or respiratory causes, as an endpoint significantly associated with acute exposures to fine particulates. The weight of epidemiological evidence indicates that short-term ambient exposure to particulate air pollution contributes to an increased risk of daily mortality. Time-series analyses strongly suggest a positive effect on daily mortality across the entire range of ambient particulate pollution levels. Relative risk estimates for daily mortality in relation to daily ambient particulate concentration are consistently positive and statistically significant across a variety of statistical modeling approaches and methods of adjustment for effects of relevant covariates such as season, weather, and co-pollutants. After thoroughly reviewing this body of evidence, the U.S. Environmental Protection Agency (EPA) concluded:

> It is extremely unlikely that study designs not yet employed, covariates not yet identified, or statistical techniques not yet developed could wholly negate the large and consistent body of epidemiological evidence * * *.

There is also substantial evidence of a relationship between chronic exposure to fine particulates and an excess (age-adjusted) risk of mortality, especially from cardiopulmonary diseases. The Six Cities and ACS studies of ambient air particulates both found a significant association between chronic exposure to fine particles and excess mortality. In

both studies, after adjusting for smoking habits, a statistically significant excess risk of cardiopulmonary mortality was found in the city with the highest average concentration of fine particulate (i.e., $PM_{2.5}$) as compared to the city with the lowest. Both studies also found excess deaths due to lung cancer in the cities with the higher average level of $PM_{2.5}$, but these results were not statistically significant (EPA, 1996). The EPA concluded that—

> * * * the chronic exposure studies, taken together, suggest there may be increases in mortality in disease categories that are consistent with long-term exposure to airborne particles and that at least some fraction of these deaths reflect cumulative PM impacts above and beyond those exerted by acute exposure events* * * There tends to be an increasing correlation of long-term mortality with PM indicators as they become more reflective of fine particle levels (EPA, 1996).

Whether associated with acute or chronic exposures, the excess risk of death that has been linked to pollution of the air with fine particles like dpm is clearly a ''material impairment'' of health or functional capacity within the meaning of the Act.

III.3.a.iii. Lung Cancer. It is clear that lung cancer constitutes a ''material impairment'' of health or functional capacity within the meaning of the Act. Questions have been raised however, as to whether the evidence linking dpm exposure with an excess risk of lung cancer demonstrates a causal connection (Stöber and Abel, 1996; Watson and Valberg, 1996; Cox, 1997; Morgan et al., 1997; Silverman, 1998).

MSHA recognizes that no single one of the existing epidemiological studies, viewed in isolation, provides conclusive evidence of a causal connection between dpm exposure and an elevated risk of lung cancer in humans. Consistency and coherency of results, however, do provide such evidence. Although no epidemiological study is flawless, studies of both cohort and case-control design have quite consistently shown that chronic exposure to diesel exhaust, in a variety of occupational circumstances, is associated with an increased risk of lung cancer. With only rare exceptions, involving too few workers and/or observation periods too short to have a good chance of detecting excess cancer risk, the human studies have shown a greater risk of lung cancer among exposed workers than among comparable unexposed workers.

Lipsett and Alexeeff (1998) performed a comprehensive statistical meta-analysis of the epidemiological literature on lung cancer and dpm exposure. This analysis systematically combined the results of the studies summarized in Tables III–4 and III–5. Some studies were eliminated because they did not allow for a period of at least 10 years for the development of clinically detectable lung cancer. Others were eliminated because of bias resulting from incomplete ascertainment of lung cancer cases in cohort studies or because they examined the same cohort population as another study. One study was excluded because standard errors could not be calculated from the data presented. The remaining 30 studies were analyzed using both a fixed-effects and a random-effect analysis of variance (ANOVA) model. Sources of heterogeneity in results were investigated by subset analysis; using categorical variables to characterize each study's design; target population (general or industry-specific); occupational group; source of control or reference population; latency; duration of exposure; method of ascertaining occupation; location (North America or Europe); covariate adjustments (age, smoking, and/or asbestos exposure); and absence or presence of a clear healthy worker effect (as manifested by lower than expected all-cause mortality in the occupational population under study).

Sensitivity analyses were conducted to evaluate the sensitivity of results to inclusion criteria and to various assumptions used in the analysis. This included substitution of excluded ''redundant'' studies of same cohort population for the included studies and exclusion of studies involving questionable exposure to dpm. An influence analysis was also conducted to examine the effect of dropping one study at a time, to determine if any individual study had a disproportionate effect on the ANOVA. Potential effects of publication bias were also investigated. The authors concluded:

> The results of this meta-analysis indicate a consistent positive association between occupations involving diesel exhaust exposure and the development of lung cancer. Although substantial heterogeneity existed in the initial pooled analysis, stratification on several factors identified a relationship that persisted throughout various influence and sensitivity analyses * * *.
>
> This meta-analysis provides evidence consistent with the hypothesis that exposure to diesel exhaust is associated with an increased risk of lung cancer. The pooled estimates clearly reflect the existence of a positive relationship between diesel exhaust and lung cancer in a variety of diesel-exposed occupations, which is supported when the most important confounder, cigarette smoking, is measured and controlled. There is suggestive evidence of an exposure-response relationship in the smoking adjusted studies as well. Many of the subset analyses indicated the presence of substantial heterogeneity among the pooled estimates. Much of the heterogeneity observed, however, is due to the presence or absence of adjustment for smoking in the individual study risk estimates, to occupation-specific influences on exposure, to potential selection biases, and other aspects of study design.

A second, independent meta-analysis of epidemiological studies published in peer-reviewed journals was conducted by Bhatia et al. (1998).[15] In this analysis, studies were excluded if actual work with diesel equipment ''could not be confirmed or reliably inferred'' or if an inadequate latency period was allowed for cancer to develop, as indicated by less than 10 years from time of first exposure to end of follow-up. Studies of miners were also excluded, because of potential exposure to radon and silica. Likewise, studies were excluded if they exhibited selection bias or examined the same cohort population as a study published later. A total of 29 independent studies from 23 published sources were identified as meeting the inclusion criteria. After assigning each of these 29 studies a weight proportional to its estimated precision, pooled relative risks were calculated based on the following groups of studies: all 29 studies; all case-control studies; all cohort studies; cohort studies using internal reference populations; cohort studies making external comparisons; studies adjusted for smoking; studies not adjusted for smoking; and studies grouped by occupation (railroad workers, equipment operators, truck drivers, and bus workers). Elevated risks were shown for exposed workers overall and within every individual group of studies analyzed. A positive duration-response relationship was observed in those studies presenting results according to employment duration. The weighted, pooled estimates of relative risk were identical for case-control and cohort studies and nearly identical for studies with or without smoking adjustments. Based on their stratified analysis, the authors argued that—

> the heterogeneity in observed relative risk estimates may be explained by differences between studies in methods, in populations studied and comparison groups used, in latency intervals, in intensity and duration of

[15] To address potential publication bias, the authors identified several unpublished studies on truck drivers and noted that elevated risks for exposed workers observed in these studies were similar to those in the published studies utilized. Based on this and a ''funnel plot'' for the included studies, the authors concluded that there was no indication of publication bias.

exposure, and in the chemical and physical characteristics of diesel exhaust.

They concluded that the elevated risk of lung cancer observed among exposed workers was unlikely to be due to chance, that confounding from smoking is unlikely to explain all of the excess risk, and that ''this meta-analysis supports a causal association between increased risks for lung cancer and exposure to diesel exhaust.''

As discussed earlier in the section entitled ''Mechanisms of Toxicity,'' animal studies have confirmed that diesel exhaust can increase the risk of lung cancer in some species and shown that dpm (rather than the gaseous fraction of diesel exhaust) is the causal agent. MSHA, however, views results from animal studies as subordinate to the results obtained from human studies. Since the human studies show increased risk of lung cancer at dpm levels lower than what might be expected to cause overload, they provide evidence that overload may not be the only mechanism at work among humans. The fact that dpm has been proven to cause lung cancer in laboratory rats is of interest primarily in supporting the plausibility of a causal interpretation for relationships observed in the human studies.

Similarly, the genotoxicological evidence provides additional support for a causal interpretation of associations observed in the epidemiological studies. This evidence shows that dpm dispersed by alveolar surfactant can have mutagenic effects, thereby providing a genotoxic route to carcinogenesis independent of overloading the lung with particles. Chemical byproducts of phagocytosis may provide another genotoxic route. Inhalation of diesel emissions has been shown to cause DNA adduct formation in peripheral lung cells of rats and monkeys, and increased levels of human DNA adducts have been found in association with occupational exposures. Therefore, there is little basis for postulating that a threshold exists, demarcating overload, below which dpm would not be expected to induce lung cancers in humans.

Results from the epidemiological studies, the animal studies, and the genotoxicological studies are coherent and mutually reinforcing. After considering all these results, MSHA has concluded that the epidemiological studies, supported by the experimental data establishing the plausibility of a causal connection, provide strong evidence that chronic occupational dpm exposure increases the risk of lung cancer in humans.

III.3.b. Significance of the Risk of Material Impairment to Miners

The fact that there is substantial evidence that dpm exposure can materially impair miner health in several ways does not imply that miners will necessarily suffer such impairments. This section will consider the significance of the risk faced by miners exposed to dpm.

III.3.b.i. Definition of a Significant Risk. The benzene case, referred to earlier in this section, provides the starting point for MSHA's analysis of this issue. Soon after its enactment in 1970, OSHA adopted a ''consensus'' standard on exposure to benzene, as required and authorized by the OSH Act. The basic part of the standard was an average exposure limit of 10 parts per million over an 8-hour workday. The consensus standard had been established over time to deal with concerns about poisoning from this substance (448 U.S. 607, 617). Several years later, NIOSH recommended that OSHA alter the standard to take into account evidence suggesting that benzene was also a carcinogen. (*Id.,* at 619 *et seq.*). Although the ''evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best,'' OSHA was operating under a policy that there was no safe exposure level to a carcinogen. (*Id.,* at 631). Once the evidence was adequate to reach a conclusion that a substance was a carcinogen, the policy required the agency to set the limit at the lowest level feasible for the industry. (*Id.,* at 613). Accordingly, the Agency proposed lowering the permissible exposure limit to 1 ppm.

The Supreme Court rejected this approach. Noting that the OSH Act requires ''safe or healthful employment,'' the court stated that—

> * * * 'safe' is not the equivalent of 'risk-free' * * * a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm. Therefore, before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. [Id., at 642, italics in original.]

The court went on to explain that it is the Agency that determines how to make such a threshold finding:

> First, the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe.' [*Id.,* at 655.]

The court noted that the Agency's ''* * * determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' (*Id.,* note 62.)

III.3.b.ii. Evidence of Significant Risk at Current Exposure Levels. In evaluating the significance of the risks to miners, a key factor is the very high concentrations of diesel particulate to which a number of those miners are currently exposed—compared to ambient atmospheric levels in even the most polluted urban environments, and to workers in diesel-related occupations for which positive epidemiological results have been observed. Figure III–4 compared the range of median dpm exposures measured for mine workers at various mines to the range of geometric means (i.e., estimated medians) reported for other occupations, as well as to ambient environmental levels. Figure III–5 presents a similar comparison, based on the highest mean dpm level observed at any individual mine, the highest mean level reported for any occupational group other than mining, and the highest monthly mean concentration of dpm estimated for ambient air at any site in the Los Angeles basin.[16] As shown in Figure III–5, underground miners are currently exposed at mean levels up to 10 times higher than the highest mean exposure reported for other occupations, and up to 100 times higher than comparable environmental levels of diesel particulate.

[16] For comparability with occupational lifetime exposure levels, the environmental ambient air concentration has been multiplied by a factor of approximately 4.7. This factor reflects a 45-year occupational lifetime with 240 working days per year, as opposed to a 70-year environmental lifetime with 365-days per year, and assumes that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day.