As a practical matter, MSHA believes that most existing heavy duty equipment will utilize commercially available hot gas filters (*e.g.,* ceramic cell, wound fiber, sintered metal, etc.) to comply with the final limit. All the existing fleet can reach the interim limit with such a filter; some will not need one. MSHA determined that all but a few can reach the final limit with such a filter.

The rule provides that MSHA may rely upon the test results of organizations who perform filtration efficiency tests. In this regard, MSHA will accept the results of filter tests performed by VERT. VERT is an acronym for Verminderung der Emissionen von Realmaschinen in Tunnelbau, a consortium of several European agencies conducting diesel emission research in connection with major planned tunneling projects in Austria, Switzerland and Germany. VERT was established to advance hot gas filter technology due to concerns in Europe about dpm levels. This gave VERT the opportunity to acquire the necessary filter evaluation expertise. A wide range of commercially available hot gas filters have been tested by VERT and the filtration efficiency determined. The Secretary may also accept filter efficiency test results from other testing organizations that can demonstrate a high level of expertise in filter evaluation (see § 72.503(c) of the final rule).

Operators using the DST'' system with the catalytic convertor on heavy duty equipment, or the Jeffrey dry exhaust system, will also be deemed in compliance with the final rule, since test results conducted in the same manner as the requirement in the final rule demonstrate that those systems can reduce the emissions from all existing heavy duty engines to below the limit. Filtration devices whose filter efficiency has not been demonstrated by testing on a diesel engine can be evaluated following the procedures in 30 CFR 72.503 of this part added by this rulemaking.

MSHA will publish on its web site a list of tested control devices and their performance. Compliance will be determined by reference to this data—there will be no in-mine testing.

The standard may also be met through the use of newer, cleaner engines in some heavy duty equipment with low horsepower engines. There are already many engines approved for non-permissible use in underground coal mines that will enable heavy duty equipment to limit emissions, thus allowing the use of lower efficiency filters. MSHA is also considering approaches that would expedite the approval of additional engines based on evidence that such engines meet EPA standards which ensure the engines are at least as clean as required under MSHA approval standards.

(3) What are the requirements for generators and compressors?

The final rule provides that generators and compressors meet the same dpm emissions standards as heavy duty equipment. Thus, generators and compressors will ultimately not be permitted to emit more than 2.5 grams per hour of dpm. Generators and compressors introduced into the fleet of an underground coal mine more than 60 days after the final rule is published will have to meet an interim emissions limit of 5.0 g/hr. Generators and compressors in the existing fleet will have 30 months to meet the interim standard of 5.0 grams per hour of dpm. After an additional 18 months (4 years in all), all generators and compressors underground will have to meet the final standard of 2.5 grams per hour of dpm.

Although the proposed rule would not have covered generators and compressors, MSHA explicitly asked the mining community if there were types of light duty equipment that should, because of operating characteristics, be treated like heavy duty equipment. Generators and compressors generate more dpm emissions than other light-duty equipment based on their known duty cycle and type of work for which they are designed; indeed, they use engines whose horsepower often exceeds that in permissible equipment. Accordingly, MSHA has determined they should be covered by this rulemaking.

MSHA's inventory indicates that the 34 generators and 29 compressors constitute less than 3% of the underground light duty diesel fleet. The existing compressors are using engines which should meet the standard's interim and final requirements with a commercially available hot gas filter.

Generators and compressors will be able to utilize the same technologies as heavy duty machines to comply with this standard. This will include hot gas filters or paper filters, as appropriate. Smaller generators and compressors may utilize the clean engine technologies.

(4) What are the requirements for other nonpermissible equipment?

The final rule provides that any piece of nonpermissible light-duty equipment introduced into an underground coal mine more than 60 days after the date of publication of the rule must not emit more than 5.0 grams per hour of dpm. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another, but it does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

The final rule does not impose any new requirements on the existing nonpermissible light-duty fleet (except for generators and compressors as noted above).

While new light duty equipment would not have been covered by the proposed rule, MSHA explicitly asked the mining community if it would be feasible to cover such new light duty equipment, even if it were not feasible to set limits for all light duty equipment. MSHA has determined that it is feasible to require that newly introduced light duty equipment meet the same 5 gr/hr standard as new heavy duty equipment.

To facilitate compliance with this standard, light duty equipment which uses an engine meeting certain EPA standards listed in the MSHA rule will be deemed to automatically meet the MSHA dpm standard for newly introduced light-duty equipment. For example, any ''heavy duty highway engine'' produced after 1994 will be deemed to meet this dpm standard. The agency has determined that there are already MSHA approved engines available in a full range of horsepower sizes that can meet the EPA standards listed in this final rule.

In practice, what this rule does is simply ensure that very old engines with few, if any, emission controls are not added to a mine's current light duty fleet, thus accelerating the turnover to a newer generation of technology.

(5) Is there a summary of the applicable requirements and effective dates?

All of the emissions standards established by MSHA's final rule are summarized in Table I–1.

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Table I-1

Type of Equipment	Emissions Limit	When Applicable (from date final rule published)
Permissible		
newly introduced	2.5 grams per hour	60 days
existing fleet	2.5 grams per hour	18 months
Heavy duty nonpermissible		
newly introduced	5.0 grams per hour	60 days
existing fleet (interim)	5.0 grams per hour	30 months
existing fleet (final)	2.5 grams per hour	4 years
Generators and compressors	same as heavy duty	same as heavy duty
Other light duty nonpermissible		
newly introduced	5.0 grams per hour (or listed EPA standards)	60 days
entire fleet	no requirements	

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(6) What other requirements are contained in the final rule for underground coal mines?

Miners have to be trained annually in the risks of dpm exposure and in control methods being used at the mine. Also, certain information about diesel engines and aftertreatment devices has to be added to the mine ventilation plan. The paperwork requirements added by this rule are small—on average, less than 7 hours in the first year and 4 hours per year thereafter for a mine operator that uses diesel powered equipment. Furthermore, manufacturers of diesel powered equipment will incur burden hours only during the first year that the rule is in effect in order to amend existing MSHA approvals. During the first year that the rule is in effect the average manufacturer will incur 70 paperwork burden hours.

(7) Will the final rule eliminate any health risks to miners resulting from the use of diesel powered equipment underground?

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain after the rule is fully implemented.

MSHA considered establishing stricter standards for certain types of equipment, and covering more light duty equipment, but concluded that such actions would either be technologically or economically infeasible for the coal mining industry as a whole at this time. As MSHA takes actions to facilitate the introduction of newer and cleaner engines underground, and as control technologies continue to develop, additional reductions in dpm levels may become feasible for the industry as a whole. MSHA will continue to monitor developments in this area.

(8) What are the costs and benefits of the final rule?

Costs

Table I–2 summarizes the compliance costs to mine operators that use diesel powered equipment for each section of the rule; total compliance costs are about $7 million a year. Table I–3 summarizes the compliance costs to mine operators that use diesel powered equipment by mine size (*i.e.,* mines employing fewer than 20 workers, mines employing between 20 and 500 workers, and mines employing more than 500 workers). In addition, there is a total annualized cost to diesel equipment manufacturers of $30,030.

MSHA's full Regulatory Economic Analysis, (REA) from which Tables I–2 and I–3 are derived, provides considerable detail on the assumptions MSHA used in developing these cost estimates, and on the costs associated with the controls required for particular engines in the current fleet. For example, MSHA is estimating that for a Caterpillar 3304 PCNA in a heavy duty piece of equipment, an operator will have to spend about $4,500 a year to achieve compliance with the limits for that equipment (hot gas filter, cost annualized, plus annual costs of regeneration). Copies of MSHA's full (REA) analysis are in the record and are available to the mining community upon request.

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Table I-2:
Total Yearly Compliance Costs for Mine Operators

Requirement	Total Yearly Industry Cost
Section 72.500 (Permissible Equipment)	$ 4,468,965
Section 72.501 (Heavy Duty Equipment)	$ 2,278,970
Section 72.502 (Light Duty Equipment)	$ 121,391
Section 72.503 (Filter Maintenance Training)	$ 2,971
Section 72.510 (Miner Health Training)	$ 196,209
Section 75.520 (Diesel Equipment Inventory)	$ 2,327
TOTAL	$ 7,070,833

Table I-3:
Total Cost By Mine Size Class

	Number of Employees		
	< 20	20 to 500	> 500
Compliance Costs	$7,411	$6,087,732	$975,690

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Benefits

Benefits of the rule include reductions in lung cancer. In the long run, as the mining population turns over, MSHA estimates that a minimum of 1.8 lung cancer deaths will be avoided per year.[1]

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

(9) What actions has MSHA taken, and what additional actions does it plan to take, to facilitate compliance with this rule?

This rule is a continuation of efforts by MSHA to help the mining community deal with the use of diesel engines in mining. The diesel equipment rule, now in effect, has itself contributed to the reduction of diesel exhaust emissions through the use of low sulfur diesel fuel, the requirement that all engines underground be approved, and improved maintenance. In one case, testimony was presented by a mine operator that timely engine maintenance, triggered by the weekly undiluted exhaust emissions test required by the new regulation, has greatly reduced carbon monoxide emissions from diesel equipment. These properly tuned engines will generate less particulate. MSHA has devoted workshops specifically to dpm control, issued a Toolbox of control methods to assist the mining community in this regard, and developed a computerized Estimator to help individual mines evaluate the impact of alternative approaches of controlling dpm emissions. The agency has verified the efficiency of the current generation of paper filters, and has sponsored work on the measurement of dpm in ambient mine atmospheres.

This final rule includes certain provisions to facilitate compliance—*e.g.,* authorizing MSHA to rely on the testing requirements of organizations like VERT, and permitting compliance with certain EPA requirements to be deemed as compliance with the requirements in this rule for newly introduced light duty equipment. The agency is, as described above, planning to take action in consultation with the mining community to facilitate the approval, and in particular the approval for permissible use, of a newer, cleaner generation of diesel engines. The agency will be preparing a compliance guide for this rule, and posting a variety of useful information on its web site. If necessary, additional workshops may be scheduled. In addition, MSHA is ready to provide special technical assistance to those who are planning to bring new engines or equipment underground in the next few months.

(10) Are surface mines addressed in this rule?

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

II. Background Information

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

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

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

(3) The difficulties in measuring ambient dpm in underground coal mines;

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

(5) The impact on emissions of MSHA approval standards and environmental tailpipe standards;

(6) Methods for controlling dpm emissions in underground coal mines;

(7) Existing standards for underground coal mines that limit miner exposure to diesel emissions;

(8) Information on how certain states are restricting occupational exposure to diesel particulate matter; and

(9) A history of this rulemaking.

Material on these subjects which was available to MSHA at the time of the proposed rulemaking was included in Part II of the preamble that accompanied the proposed rule (63 FR 17501 *et seq.*). This version has been updated to reflect the record, to discuss certain issues relevant to underground coal mines in more detail, and reorganized as appropriate.

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

Diesel engines, first developed about a century ago, now power a full range of mining equipment. However at this time, less than 20% of underground coal mines (fewer than 150 underground coal mines) utilize this technology. Equipment powered by other sources (electrical power delivered by cable or trolley, and battery power) continues to predominate in this mining sector. Moreover, unlike in other mining sectors, most of the current diesel fleet in underground coal mines consists of light-duty support vehicles, and only limited numbers of the equipment used in digging or hauling coal is powered by diesel engines.

Many in the mining industry believe that diesel-powered equipment has productivity and safety advantages over equipment powered by other sources. Others cite evidence to the contrary, and several key underground coal mining states continue to ban or significantly restrict the use of diesel-powered equipment in underground coal mines. The use of diesel engines to power equipment in underground coal mining is increasing and appears likely to continue to do so absent significant improvement in other power technologies.

Historical Overview of Diesel Power Use in Mining. As discussed in the notice of proposed rulemaking, the diesel engine was developed in 1892 by the German engineer Rudolph Diesel. It was originally intended to burn coal dust with high thermodynamic efficiency. Later, the diesel engine was modified to burn middle distillate petroleum (diesel fuel). In diesel engines, liquid fuel droplets are injected

[1] This lower bound figure could significantly underestimate the magnitude of the health benefits. For example, the estimate based on the mean value of all the studies examined is 13 lung cancer deaths avoided per year.

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 an efficient lightweight diesel power unit was developed. 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 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 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. Production equipment includes vehicles such as haultrucks and shuttle cars, load-haul-dump units, face drills, and explosives trucks. Diesel engines are also used in support equipment including generators and air compressors, ambulances, crane trucks, ditch diggers, foam machines, forklifts, graders, locomotives, longwall component carriers, lube units, mine sealant machines, personnel carriers, hydraulic power units, rock dusting machines, roof drills, tractors, utility trucks, water spray units, and welders.

Current Patterns of Diesel Power Use in Underground Coal Mining. The underground coal mining sector is not as reliant upon diesel power as are other mining sectors. While nearly all underground metal and nonmetal mines, and nearly all surface mines, use diesel-powered equipment, less than 20% of underground coal mines use it. Table II–1 provides further information on the current inventory.

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Table II-1. Diesel Equipment in Underground Coal Mines

Mine size	# Mines	# Mines w/Diesel	# Engines
Small[a]	382	7	20
Large	528	138	3,101
All	910	145	3,121

Notes on Table II-1:
(a) A "small" mine is one with less than 20 miners.

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The great majority of the diesel engines used in underground coal mines are used to power support equipment, rather than production equipment. This is in sharp contrast to other sectors. For example, in underground metal and nonmetal mines, of the approximate 4,100 pieces of diesel equipment normally in use at the time of MSHA's proposal, nearly half of the units were estimated to be used for loading and hauling. By contrast, of the approximately 3,000 pieces of diesel equipment in use in underground coal mines, MSHA estimates that fewer than 10% are used for coal loading and haulage. Moreover, because of space constraints and other operating conditions in underground coal mines, virtually all coal loading and hauling equipment has engines less than 200 horsepower; by contrast, virtually all such equipment in metal and nonmetal mines has engines greater than 200 horsepower and ranging to more than 750 horsepower or greater. As a result, the average horsepower of diesel engines powering equipment in underground coal mines is much less than the average engine in underground metal and nonmetal mines and all surface mines. This is significant because, other things being equal, lower horsepower engines are going to produce less dpm emissions by mass than higher horsepower engines.

The engines in underground coal mines can be divided into three categories recognized under existing MSHA regulations: ''permissible'', ''heavy-duty nonpermissible'', and ''light-duty nonpermissible.'' In this final dpm rule, MSHA is establishing different requirements for each of these categories. Accordingly, some background on this categorization is needed.

Use of Diesel Engines in Permissible Equipment. Under existing regulations, equipment, whether powered by diesel engines or electricity, that is used in areas of the mine where methane gas is likely to be present in dangerous concentrations must be MSHA-approved ''permissible'' equipment.

Permissible diesel powered equipment for use in coal mines is provided with special equipment to prevent the ignition of methane. This special equipment includes flame arresters and special treatment of flanges and joints. Since diesel engines normally have very hot surface temperatures and hot exhaust gas that can constitute an ignition source, permissible diesels must be provided with a means to maintain the temperatures of surfaces and the exhaust gas below 302°F.

MSHA regulations are very specific in defining those areas of the mine where permissible equipment is required. Generally, permissible equipment is required where the coal mining is actually being performed, because the mining process typically liberates methane. These areas are commonly referred to as ''inby'' areas. In some cases, however, permissible equipment is required to be used in other areas of the mine. For example, only permissible diesel-powered equipment may be used in return aircourses. The permissible equipment provides an additional level of fire protection because of the strict temperature controls on the equipment surface and exhaust. This increased protection is required because of the potential for the accumulation of dangerous levels of methane in these aircourses.

MSHA's January 2000 inventory indicates that of the 3,121 diesel powered pieces of equipment in underground coal mines, 528 units are permissible pieces. The emissions generated by permissible equipment make a significant contribution to dpm concentrations in the mines where they are functioning. This is because the equipment has large engines, works hard and continuously in locations generally far from ventilation sources, and in close quarters with miners.

Moreover, the engines which have to date been approved for permissible use are among those which emit the highest levels of dpm (in grams/hour): the Caterpillar 3304, Caterpillar 3306 (available in two horsepower sizes), the Deutz D916–6, and the Isuzu QD–100. The Deutz D916–6 is still used in underground coal mines, however, it is no longer in production. MSHA recently approved the Caterpillar 3306PCTA permissible, the first approved turbocharged engine.

Diesel engines in the horsepower ratings required to power permissible equipment are now available in new low emissions technology engines. However, none of them has been approved for use on permissible equipment because no applications for MSHA approval have been received. This situation may reflect a lack of adequate incentives for engine and equipment manufacturers to incur the development costs to meet MSHA permissibility requirements or to pay the fees required for approval.

MSHA is developing programs that would facilitate the availability of engines that utilize the latest technologies to reduce gaseous and particulate emissions for use in permissible equipment. Current engine designs that utilize low emissions technologies are currently approved by MSHA in nonpermissible form.

One of the programs that MSHA is considering would follow the precedent established in the recently published diesel equipment rule. To facilitate compliance with this dpm rule, MSHA is considering funding the additional emissions testing needed to gain permissibility approval, previously approved, non-permissible engines that utilize low emissions technology engines, or waiving the normal fees that the Agency charges for the administrative and technical evaluation portion of the approval process.

Alternatively, MSHA may relax, as an interim measure, the requirement that engine approvals be issued only to engine manufacturers. Under this program an equipment manufacturer could utilize an engine, approved by MSHA as nonpermissible, in a permissible power package. MSHA would ensure that the additional emissions tests required for permissible engines are conducted as part of the power package approval process. Provisions of the two programs could be combined.

While the availability of cleaner engines would help reduce the dpm emissions from the permissible fleet, there are aftertreatment filters available for such equipment that are both highly efficient and relatively low cost. As discussed in more detail in section 6 of this part, because the exhaust temperature of these permissible pieces of equipment must be cooled for safety reasons, aftertreatment devices whose filtration media consists of paper can be directly installed on this equipment. Paper filters exposed to uncooled exhaust pose a fire and ignition hazard.

Use of Diesel Engines in Nonpermissible Equipment. In those areas of an underground coal mine where methane concentrations can be limited through the control of ventilation air, permissible equipment is not required. Generally, this is the case in areas away from the face, often referred to as ''outby'' areas. Most equipment operating in underground coal mines is ''nonpermissible'' equipment.

Nonpermissible equipment is divided into several categories for purposes of the diesel equipment rules that currently apply in underground coal mines (30 CFR part 75). In pertinent part, those rules provide:

§ 75.1908 Nonpermissible diesel-powered equipment; categories

(a) Heavy-duty diesel-powered equipment includes—

(1) Equipment that cuts or moves rock or coal;

(2) Equipment that performs drilling or bolting functions;

(3) Equipment that moves longwall components;

(4) Self-propelled diesel fuel transportation units and self-propelled lube units; or

(5) Machines used to transport portable diesel fuel transportation units or portable lube units.

(b) Light-duty diesel-powered equipment is any diesel-powered equipment that does not meet the criteria of paragraph (a) * * *

(c) * * *.

(d) Diesel-powered ambulances and fire fighting equipment are a special category of equipment that may be used underground only in accordance with the mine fire fighting and evacuation plan * * *.

MSHA's inventory indicates that of the 3,121 diesel powered pieces of equipment, 497 are heavy duty nonpermissible pieces, 66 are generators and air compressors, and 2,030—that is, about two-thirds of the total underground coal diesel fleet at present—are other light duty nonpermissible pieces.

The rationale for the division of nonpermissible dieselized equipment into these classes requires some background here because in this rulemaking on dpm, MSHA proposed making a significant distinction between the requirements applicable to each class.

The division resulted from MSHA's 1996 regulation establishing safety rules for the use of dieselized equipment in underground coal mines (the general history and purpose of which are summarized in section 9 of this Part). As discussed in the preamble to the final diesel safety rule (61 FR 55459–61), the purpose of the categorization was to take the diversity of nonpermissible equipment into account in establishing regulatory requirements relevant to safety. The final categorization scheme for nonpermissible equipment developed over the course of time in response to public comments to the proposed rule.

Equipment falling within the heavy duty category is typically used for extended periods during a shift on a continuous, rather than an intermittent, basis. Heavy duty equipment also moves heavy loads or performs considerable work. Accordingly, to ensure such equipment could operate in a safe manner, the safety rule required that each piece of heavy duty equipment:

> * * * has to be equipped with an automatic fire suppression system addressing the additional fire risks resulting from the way this equipment is used. Heavy-duty equipment also produces greater levels of gaseous contaminants, and under the final rule is therefore subject to weekly undiluted exhaust emissions tests * * * and is included in the air quantity calculation of ventilation of diesel-powered equipment * * *. (61 FR 55461)

It is important to note that there are other types of underground coal mining equipment which, although they have operating characteristics much like heavy duty equipment, were not designated as such under the diesel equipment rule. That is because such equipment (*e.g.,* generators and compressors) is considered as portable equipment and special requirements were established in that rule to address the hazards presented by that equipment.

Ambulances and fire-fighting equipment which use diesel engines have operating characteristics like light-duty equipment, but under the diesel equipment rule are considered a special category of equipment that does not have to meet the requirements of that rule. The equipment in this category must only be used in emergencies or fire drills and in compliance with fire fighting and evaluation plan requirements. Consequently, such equipment is not required to have an approved engine or power package or comply with the design and performance requirements of §§ 75.1909 and 75.1910 (61 FR 55461).

Under the diesel equipment rule, heavy-duty equipment may be used to perform light-duty work; but equipment that is classified as light-duty may not be used, even intermittently, to perform the functions listed in paragraphs (a)(1) through (a)(5) of 30 CFR 75.1908 because it is not required to have the automatic fire suppression system that MSHA determined was necessary for such kinds of work. (Id.) As noted in the preamble, two machines of the same model could fall into different equipment categories depending on how they are used. Although of the same design, they do not present the same risk of fire because of the way in which they are used, nor do they produce the same quantities of exhaust contaminants:

> ''* * * machines that are operated for extended periods of time under heavy load generate more contaminants than machines that are not.'' (Id.)

It was for this reason—the rate of contaminant generation—that in proposing a rule to limit the concentration of dpm in underground coal mines, MSHA proposed making a distinction between heavy-duty equipment and light-duty equipment. MSHA proposed requiring heavy-duty nonpermissible equipment and permissible equipment to be equipped with filters capable of removing 95% of the dpm emitted by the engines in those pieces of equipment. The proposal did not include any controls for the dpm emitted from light-duty equipment nor for ambulances and fire-fighting equipment. As noted in section 9 of this part, the Agency asked the mining community to comment on the Agency's assumptions and consider some options in this regard. The record on this matter and MSHA's final decision are discussed in Part IV.

Whether categorized as heavy-duty or light-duty, the engine exhaust from nonpermissible equipment is not required to be cooled for safety reasons like exhaust from permissible equipment. Accordingly, this means that paper-type filters cannot be added directly to nonpermissible equipment without first adding a water scrubber or heat exchanger; otherwise, the paper would burn. As a result, control devices that are designed to filter hot exhaust gases (*e.g.,* ceramic filters) provide a cost effective alternative for dpm control with nonpermissible equipment.

Does Diesel Power Have Advantages Over Alternative Sources of Power for Equipment Used in Underground Coal Mines? As pointed out by a commenter, a number of power sources for mining equipment have been tried in the mining industry only to be rejected for various reasons (*e.g.,* gasoline engines, cables, and compressed air). Today, this commenter continued, there are three general ways of powering mining equipment: electric power (delivered by electric trailing cables or by trolley wires), on-board battery power, and diesel. Table II–2 reproduces a list provided by this commenter as to his view of some of the ''advantages and challenges'' of these power sources; MSHA is reproducing this list as a convenient summary, but does not necessarily agree or disagree with each specific entry.

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Table II-2

One Commenter's Comparison of Power Sources

Power Type	Electric w/trailing cable	Electric w/trolley wire	Battery	Diesel
Necessary infra-structure	electric power centers must be available at all areas where this type of electric trailing cable equipment is used	trolley wires and rails must be available at all areas where electric trolley wire equipment is used	battery charging stations must be available within the operating range of all battery powered equipment	refueling stations must be available within the operating reach of all diesel powered equipment
Availability of power source	the machine must be within reach and tethered to the electric power center	the machine must be connected to the energized electric trolley wire	the machine must be within reach of the charging station once the battery is depleted, usually at least once a shift	the vehicle is driven to a refueling station or a refueling vehicle is driven to the vehicle - refueling is typically performed every 1-3 shifts
Mobility	the range is limited by the reach of the trailing capable and is usually less than 500 feet	limited to areas with energized trolley wires	good as long as the battery is charged, weak when the battery charge is low	excellent and unlimited mobility in all properly ventilated areas of the mine
Operating time between service	uninterrupted until the trailing cable extent has been reached	uninterrupted as long as operating within reach of the trolley wire	may be less than a shift - multiple batteries are normally needed	at least one full shift, often several shifts
Safety concerns	electrocution hazard from damaged energized cables, back injuries from lifting and moving heavy cables	electrocution hazard from contact with energized trolley wires, open sparks	fire hazard during recharging the batteries; battery acid spills, hydrogen release	fuel spills, health concerns, acid exhaust emissions
Conclusions	prone to back injuries and electrocution risk	hazardous and prone to electrocution risk	prone to fire risk	requires emission controls

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Some in the mining industry strongly favor the use of diesel engines to power equipment in underground coal mines. A representative of a company with four underground coal mines testified that it has 200 pieces operated by diesel power, and is continuing to add more. Another commenter stated that diesel is the power source of choice for moving personnel and supplies in large underground mines where coal is moved by conveyor belt.

A number of commenters asserted that diesel-powered equipment has productivity and safety advantages over electrically-powered and battery-powered equipment.

One commenter argued that diesel reduces the risks associated with the use of electrical equipment by eliminating the need for trolley wires, trolley poles and trailing cables that cause injuries, accidents and fatalities—shocks, electrocutions, burns, fires, tripping or being struck by trolley poles, and also reduce the number of material handling injuries. This commenter also argued that unlike electrical power, diesel use does not restrict mining plans or the mining cycle because operations are not hampered by cable length or time consuming power moves, provide greater flexibility in underground travel routes, and make equipment moves from one area of a mine to another more efficient. This commenter further claimed that compared to battery-powered mining equipment (which arguably provides the same flexibility), diesels can haul coal more efficiently over longer distance, provide more power, and eliminate time-consuming battery change-out time.

Another commenter noted the increased potential for fatalities and injuries in underground coal mines when trolley wires are present, and further that trolley wires restrict ventilation in one entry.

Another commenter noted the difficulties of evacuating miners in the event of emergencies over the large distances in some underground mines using sources of power that were more prone to failure than diesel.

Another commenter asserted that all of the 18 employees who had died since 1972 as a result of exposed overhead direct current trolley lines could have lived if diesel power had been in use, and pointed to examples of fires initiated by trolley wires with associated loss of productivity. This commenter also noted that battery powered equipment has been known to cause injuries, and explosions both from its production of hydrogen gas and from sparks igniting methane in the mine atmosphere.

Commenters also note that many asserted safety risks associated with the use of diesel powered equipment in underground coal mines have now been addressed as a result of MSHA's safety rules.

Other commenters, however, pointed out that there are a number of the nation's most productive underground coal mines (including both those using longwall and those using room and pillar mining techniques) which do not use this technology. These commenters challenged industry claims that diesel power is necessary for business to survive. Some also noted that miners are trained to protect themselves better from safety hazards that accompany the use of electrical power, like tripping on cables and electrical hazards, but are not able to protect themselves from health hazards they cannot see. In this regard, the hearing transcripts are replete with reminders by underground coal miners of their concern about what they are breathing in light of the tragic experience with black lung disease.

As indicated by MSHA in the preamble to the proposed rule (63 FR 17503), not many studies done recently address the contentions that diesel power provides safety and/or productivity advantages, and the studies which have been reviewed by MSHA do not clearly support this hypothesis.

Outlook for Use of Diesel Engines To Power Equipment in Underground Coal Mines

The use of diesel engines to power equipment in underground coal mining is increasing. In fact, since this rulemaking was proposed, MSHA's inventory has recorded an increase of about 5% in the number of diesel-powered pieces of equipment at the roughly 145 coal mines using diesel power underground. This trend appears likely to continue, absent significant improvement in other power technologies.

Several key underground coal mining states—Ohio, Pennsylvania and West Virginia—continue to ban or significantly restrict the use of diesel-powered equipment in underground coal mines (as discussed in section 8 of this Part). There are 339 underground coal mines in these states. If the current restrictions in these States were relaxed, in accordance with the expressed interest of industry groups toward this end, many of these underground coal mines are likely to begin using diesel to power some equipment.

Full implementation of MSHA's recent rules for the safe use of diesel-powered equipment in underground coal mines (discussed in section 7 of this part), is also likely to lead to increased diesel use because they resolve certain safety concerns that discouraged the mining community from using such equipment more widely. Another factor suggesting that the use of diesel power will expand is that both miners and mine operators are concerned about the future of their industry.

On the other hand, operators as well as miners have acknowledged that potential health hazards associated with the use of diesel power must be addressed if its use is to become widespread. Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that the underground coal mining sector as a whole cannot feasibly reduce dpm concentrations further at this time. Nevertheless, the efforts by US and overseas environmental regulators to restrict dpm and other diesel emissions into the environment, discussed in sections 4, 5 and 6 of this Part, are leading to technological improvements in engines, fuel and filters that will help reduce this risk.

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

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

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

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

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

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

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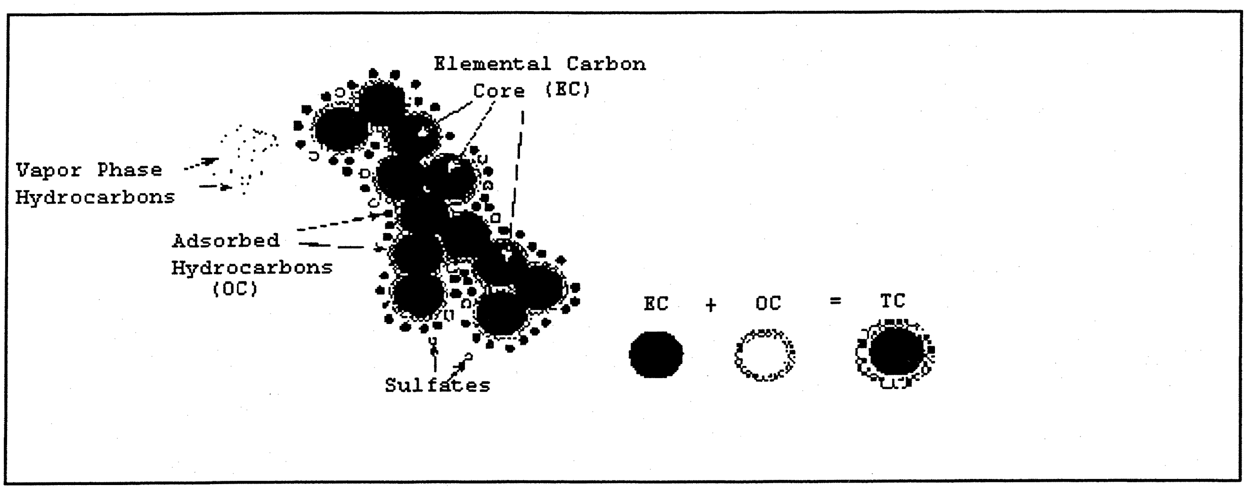
Figure II-1
DPM components



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

As can be seen, the distribution is bimodal, with dpm generally less than 1 μm in size, and dust generated by the mining process greater than 1 μm.

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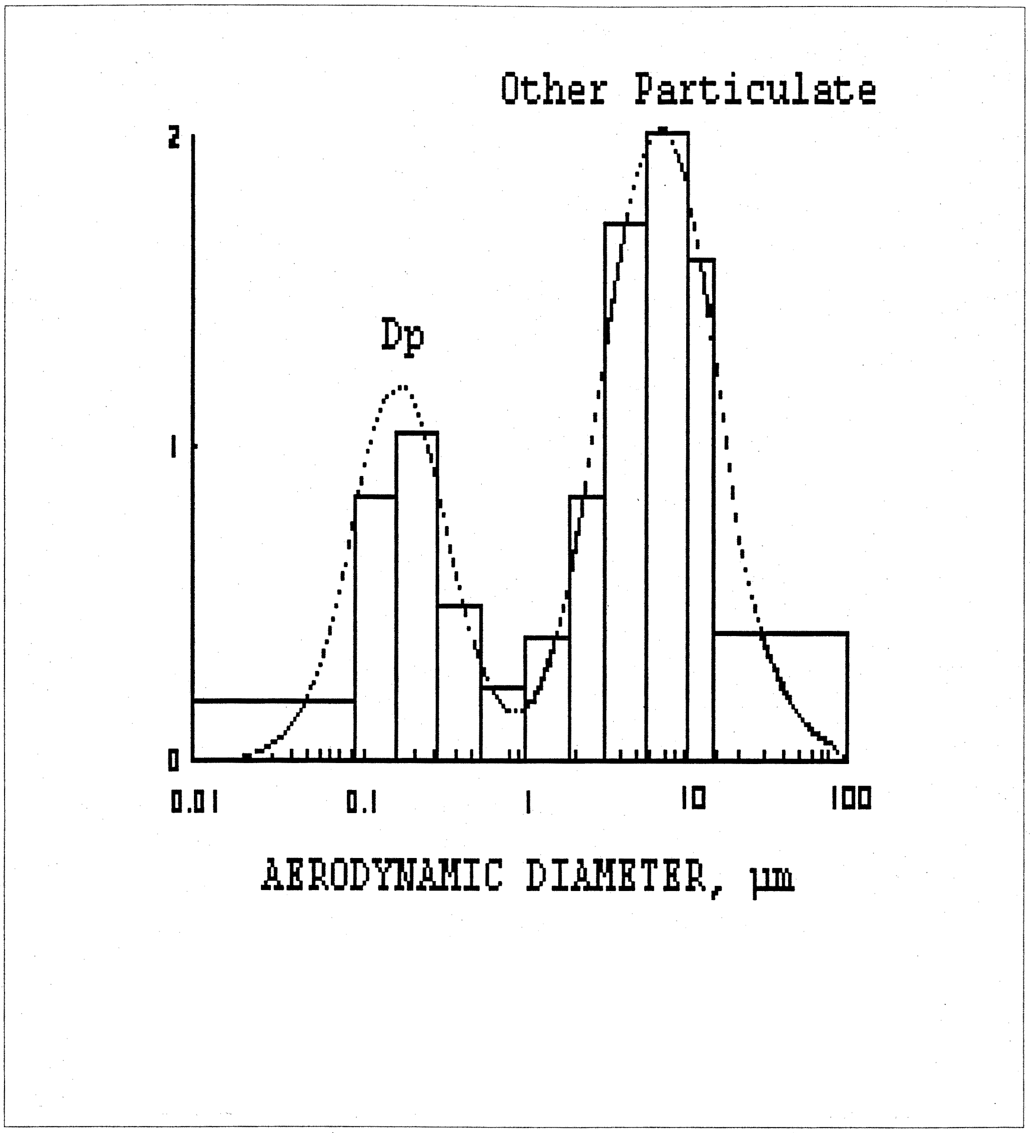
Figure II-2 -Typical distribution of dpm relative to distribution of other mining particulates.



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

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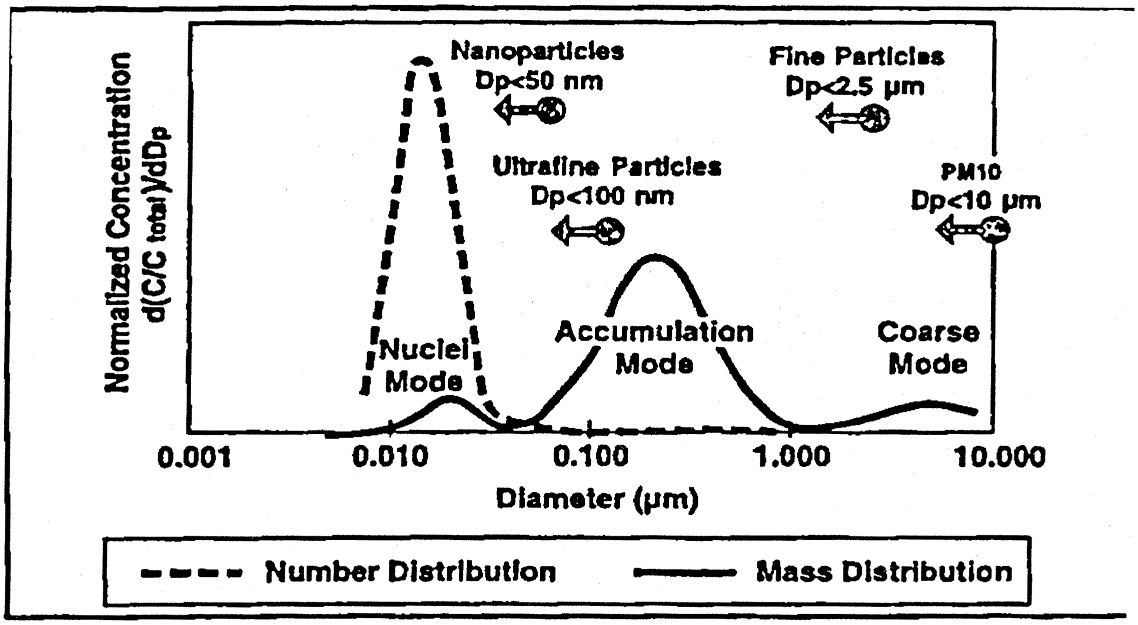
Figure II-3



Diesel particulate size distribution.

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

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

(3) The Difficulties of Measuring Ambient DPM in Underground Coal Mines.

As it indicated in its notice of proposed rulemaking to limit the concentrations of dpm in underground coal mines (63 FR 17498, 17500), MSHA decided not to propose a rule to require the measurement of ambient dpm levels in underground coal mines in order to determine compliance. The Agency observed that while there are a number of methods which can measure ambient dpm at high concentrations in underground coal mines with reasonable accuracy. When the purpose is exposure assessment, MSHA does not believe any of these methods provide the accuracy that would be required to measure ambient dpm levels in underground coal mines at lower concentrations.

In particular, MSHA expressed concern about potential difficulties in using the available methods to distinguish between dpm and submicron coal mine dust (63 FR 17506–17507). While the use of an available impactor device can prevent larger particles from entering the sampler (*e.g.,* carbonates), albeit at the expense of eliminating the larger fraction of dpm as well, there are limits on the extent to which it can help MSHA distinguish how much of the fine particulate reaching the sampler is coal dust and how much is dpm. To make the distinction analytically, NIOSH method 5040 would have to be adjusted so that only the elemental carbon is determined. However, as MSHA noted, there are no established relationships between the concentration of elemental carbon 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 elemental carbon may vary. Accordingly, MSHA concluded that it was "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" (63 FR 17500).

Since there has been no disagreement with MSHA's initial conclusion about the current availability of an accurate, consistent and verifiable method of measuring dpm concentration levels in underground coal mines, the final rule is not dependent on ambient air measurements. MSHA has proposed using such a method for underground metal and nonmetal mines, and the validity of the measurement was the subject of much comment; accordingly, a more complete discussion of this topic will be found in the preamble of the final rule for underground metal and nonmetal mines.

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

Pursuant to the Clean Air Act, the Federal Environmental Protection Agency (EPA) is responsible for setting air pollution standards to protect the public from toxic air contaminants. These include standards to limit exposure to particulate matter. The pressures to comply with these limits have an impact upon the mining industry, which emits 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's rulemaking efforts to limit the ambient air concentration of particulate matter, including its recent particular focus on diesel and other fine particulates. Additional and up-to-date information about the most current rulemaking in this regard is available on an EPA's Web site, http://www.epa.gov/ttn/oarpg/naaqsfin/.

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

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

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

Implementation of each national standard is the responsibility of the states. Each must develop a state implementation plan that ensures air quality in the state consistent with the ambient air quality standard. Thus, each state has a great deal of flexibility in targeting particular modes of emission (*e.g.,* mobile or stationary, specific industry or all, public sources of emissions vs. private-sector sources), and in what requirements to impose on polluters. However, EPA must approve the state plans pursuant to criteria it establishes, and then take measurements of pollution 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''.

Total Suspended Particulates (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 mix 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.

Particulates Less than 10 Microns in Diameter (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 PM_{10} limit of 50 $\mu g/m^3$, and a 24-hour PM_{10} limit of 150 $\mu g/m^3$. 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 the levels of 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).

Particulate Less than 2.5 Microns in Diameter ($PM_{2.5}$). The next EPA scientific review was completed in 1996. A proposed rule was published in November of 1996, and, after public hearings and review by the Office of Management and Budget, a final rule was promulgated on July 18, 1997 (62 FR 38651).

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

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

A majority of the DC Circuit Court, however, agreed with challenges to the EPA's determination to keep the existing requirements on PM_{10} as a surrogate for the coarser particulates in this category (those particulates between 2.5 and 10 microns in diameter); instead, the Court ordered EPA to develop a new standard for this size category.

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; in some regions of the country, diesel particulate generated by highway and off-road vehicles constitutes a significant portion of the ambient fine particulate (June 16, 1997, PM–2.5 Composition and Sources, Office of Air Quality Planning and Standards, EPA). As noted in Part III of this preamble, some of the scientific studies of health risk from fine particulates used to support the EPA rulemaking were conducted in areas where the major fine particulate was from diesel emissions. Accordingly, MSHA has concluded that it must consider the body of evidence of human health risk from environmental exposure to fine particulates in assessing the risk of harm to miners of occupational exposure to diesel particulate, and did so in its risk assessment (see part III of this preamble). Comments on the appropriateness of this conclusion by MSHA, are reviewed in Part III.

(5) *The impact on emissions of MSHA approval standards and environmental tailpipe standards.*

MSHA requires that the gaseous emissions from all diesel engines used in underground coal mines meet certain minimum standards of cleanliness; only engines which meet those standards are ''approved'' for use in underground coal mines. The 1996 diesel equipment safety rule required that all engines in the underground mining fleet be approved engines. Thus, these rules set a ceiling for various types of diesel gas emissions. But diesel engines do not have to meet a dpm emissions standard to be ''approved'' for underground use.

Engine emissions of dpm are however, restricted by Federal environmental regulations, supplemented in some cases by State restrictions. Over time, these regulations have required, and are continuing to require, that new diesel engines meet tighter and tighter standards on dpm emissions. As these cleaner engines replace or supplement older engines in underground coal mines, they can lead to a significant reduction in the amount of dpm emitted by the underground fleet.

This section reviews developments in this area. Although this subject was discussed in the preamble of the proposed dpm rule (63 FR 17507), this review here updates the relevant information.

MSHA Approval Requirements for Engines Used in Underground Coal Mines. MSHA requires that all diesel engines used in underground coal mines be ''approved'' by MSHA for such use, and be maintained by operators in approved condition. Among other things, approval of an engine by MSHA ensures that engines exceeding certain pollutant standards are not used in underground coal mines. MSHA sets the standards for such approval, establishes the testing criteria for the approval process, and administers the tests. The costs to obtain approval of an engine are usually borne by the engine manufacturer or equipment manufacturer.

MSHA's 1996 diesel equipment rule (discussed in more detail in section 7 of this Part) made significant changes to diesel engine requirements for underground coal mines. The new rule required the entire underground coal fleet to convert to approved engines no later than November 1999. Accordingly, by the time this rule to limiting dpm exposure goes into effect, all diesel engines in underground coal mines are expected to be approved engines.

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

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

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

In the proposed dpm rule, MSHA indicated that given that the equipment rule was recently promulgated, it did not yet have enough information to determine the feasibility of a requirement that certain engines meet a specific PI in order to be used underground (63 FR 17564). MSHA received comments on this subject during the hearings and thereafter; the Agency's response to these comments is included in Part IV of this preamble.

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

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

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

Diesel engines are generally divided into three broad categories for purposes of engine emissions standards, in accordance with the primary use for which the type of engine is designed: (1) Light duty vehicles and light duty trucks (*i.e.,* trucks under 8500 lbs GVWR, which include pick-up trucks and SUVs. EPA has also established a class of ''medium duty passenger vehicles'' which include passenger vehicles over 8500 lbs. These vehicles, mostly large SUVs, are treated like light-duty trucks for the purposes of emission standards; (2) heavy duty highway engines (*i.e.,* those designed primarily to power trucks) greater than 8500 lbs GVWR) which range from the largest pick-up trucks to over the road trucks); and (3) nonroad vehicles (*i.e.,* those engines designed primarily to power small equipment, construction equipment, locomotives, farm equipment and other non-highway uses).

The terms ''heavy duty'' and ''light duty'' are used differently by EPA and MSHA. The category of an engine for purposes of environmental regulations is not the same as the category of mining equipment in which it is used. The engine categories used by EPA have been established with reference to normal transportation uses. But as explained in section 1 of this Part, MSHA has established a classification system for underground coal mining equipment based on how that equipment is used in mining. This system includes ''permissible'' equipment (required where explosive methane gas may be present in significant quantities) and two categories of ''nonpermissible'' equipment known as ''heavy duty nonpermissible'' and ''light duty nonpermissible''. Accordingly, ''heavy duty'' engines might be used in ''light duty'' nonpermissible equipment.

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

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

EPA Emission Standards for Light-Duty Vehicles and Light Duty Trucks. Although vehicle engines in these categories are not currently approved for use in underground coal mines, it might be sought in the future. Accordingly, some information about the applicable environmental regulations is provided here.[2]

Current light-duty vehicles generally comply with the Tier 1 and National LEV emission standards. Particulate-matter emission limits are found in 40 CFR part 86. In 1999, EPA issued new Tier 2 standards that will be applicable to light-duty cars and trucks beginning in 2004. With respect to pm, the new rules phase in tighter emissions limits to parts of production runs for various subcategories of these engines over several years; by 2009, all light duty trucks must limit pm emissions to a maximum of 0.02 g/mi (40 CFR 86.1811–04(c)). Engine manufacturers may, of course, produce complying engines before the various dates required.

EPA Emissions Standards for Heavy-Duty Highway Engines. In 1988, a standard limiting particulate matter emitted from the heavy duty highway diesel engines went into effect, limiting dpm emissions to 0.6 g/bhp-hr. The Clean Air Act Amendments of 1990 and associated regulations provided for phasing in even tighter controls on NO_X and particulate matter through 1998. Thus, engines had to meet ever tighter standards for NO_X in model years 1990, 1991 and 1998; and tighter standards for PM in 1991 (0.25 g/bhp-hr) and 1994 (0.10 g/bhp-hr). The latter remains the standard for PM from these engines for current production runs (40 CFR 86.094–11(a)(1)(iv)(B)). Since any heavy duty highway engine manufactured since 1994 must meet this standard, there is a supply of engines available today which meet this standard. These engines are used in commercial mining pickup trucks.

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

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

Nonroad diesel engines were not subjected to emission controls as early as other diesel engines. The 1990 Clean Air Act Amendments specifically directed EPA to study the contribution of nonroad engines to air pollution, and regulate them if warranted (Section 213 of the Clean Air Act). In 1991, EPA released a study that documented higher than expected emission levels across a broad spectrum of nonroad engines and equipment (EPA Fact Sheet, EPA420–F–96–009, 1996). In response, EPA initiated several regulatory programs. One of these set Tier 1 emission standards for larger land-based nonroad engines (other than for rail use). Limits were established for engine emissions of

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

hydrocarbons, carbon monoxide, NO_X, and dpm. The limits were phased in over model years from 1996 to 2000. With respect to particulate matter, the rules required that starting in model year 1996, nonroad engines from 175 to 750 hp meet a limit on pm emissions of 0.4 g/bhp-hr, and that starting in model year 2000, nonroad engines over 750 hp meet the same limit.

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

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

Table II–3 provides a full list of the EPA required particulate matter limitations on nonroad diesel engines for tier 1 and 2. For example, a nonroad engine of 175 hp produced in 2001 must meet a standard of 0.4 g/hp-hr; a similar engine produced in 2003 or thereafter must meet a standard of 0.15 g/hp-hr.

TABLE II–3.—EPA NONROAD ENGINE PM REQUIREMENTS

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

The Impact of MSHA and EPA Engine Emission Standards on the Underground Coal Mining Fleet. In the mining industry, engines and equipment are often purchased in used condition, and frequently rebuilt. Thus, many of the diesel engines in an underground coal mine's fleet today may only meet older environmental emission standards, or no environmental standards at all. Although the environmental tailpipe requirements on dpm are already bringing about a reduction in the overall contribution of dpm to the general atmosphere, the beneficial effects of the EPA regulations on mining atmospheres will be slower absent incentive or regulatory actions that accelerate the turnover of mining fleets to engines that emit less dpm. Moreover, while the requirement that all underground coal mine engines be ''MSHA approved'' is leading to a less polluting fleet than would otherwise be the case, there are many approved engines that do emit significant levels of pollution, and in particular dpm. As noted in the discussion of MSHA's approval requirements, the Agency is taking internal actions to ensure that these requirements do not inadvertently slow the introduction of cleaner engine technology.

It should be noted that in theory, underground mines can still purchase certain types of new engines that do not have to meet EPA standards. For example, the current rules on nonroad diesel engines state that they do not apply to engines intended to be used in underground coal and metal and nonmetal mines (40 CFR 89.1(b)). Moreover, it is not uncommon for engine manufacturers to take a model submitted for EPA testing and adjust the horsepower or other features for use in a mining application. In recent years, however, engine manufacturers have significantly cut back on such adjustments because the mining community is not a major market. Accordingly, MSHA believes that most of the diesel engines that will be available for underground mines in the future will meet the applicable EPA standard. In addition, many of the recently approved engines by MSHA currently meet the tier II nonroad pm standards.

The Question of Nanoparticles. Comments received from several commenters on the proposed rule for diesel particulate matter exposure of underground coal miners raised questions relative to ''nanoparticles;'' i.e., particles found in the exhaust of diesel engines that are less than 50 nanometers (nm) in diameter.

One commenter was concerned about recent indications that nanoparticles may pose more of a health risk than the larger particles that are emitted from a diesel engine. This commenter submitted information demonstrating that nanoparticles emitted from the engine could be removed effectively from the exhaust using aftertreatment devices such as ceramic traps.

Another commenter was concerned that MSHA's proposed rule for underground coal mines is based on removing 95% of the particulate by mass. He believed that this reduction in mass was attributed to those particles greater than 0.1μm but less than 1μm and did not address the recent scientific hypothesis that it may be the very small nanopaticles that are responsible for adverse health effects. Based on the recent scientific information on the potential health effects resulting from exposure to nanoparticles, this commenter did not believe that potential the risk of cancer would be reduced if exposure levels to nanoparticles increased. He indicated that studies suggest that the increase in nanoparticles will exceed 6 times their current levels.

Current environmental emission standards established by EPA and CARB, and the particulate index calculated by MSHA, focus on the total mass of diesel particulate matter emitted by an engine—for example, the number of grams per some unit of measure (i.e. grams/brake-horsepower). Thus, the technology under development by the engine industry to meet the standards accordingly focuses on reducing the mass of dpm emitted from the engine. There is some evidence, however, that some aspects of this new technology, particularly fuel injection, is resulting in an increase in the number of nanoparticles emitted from the engine.

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

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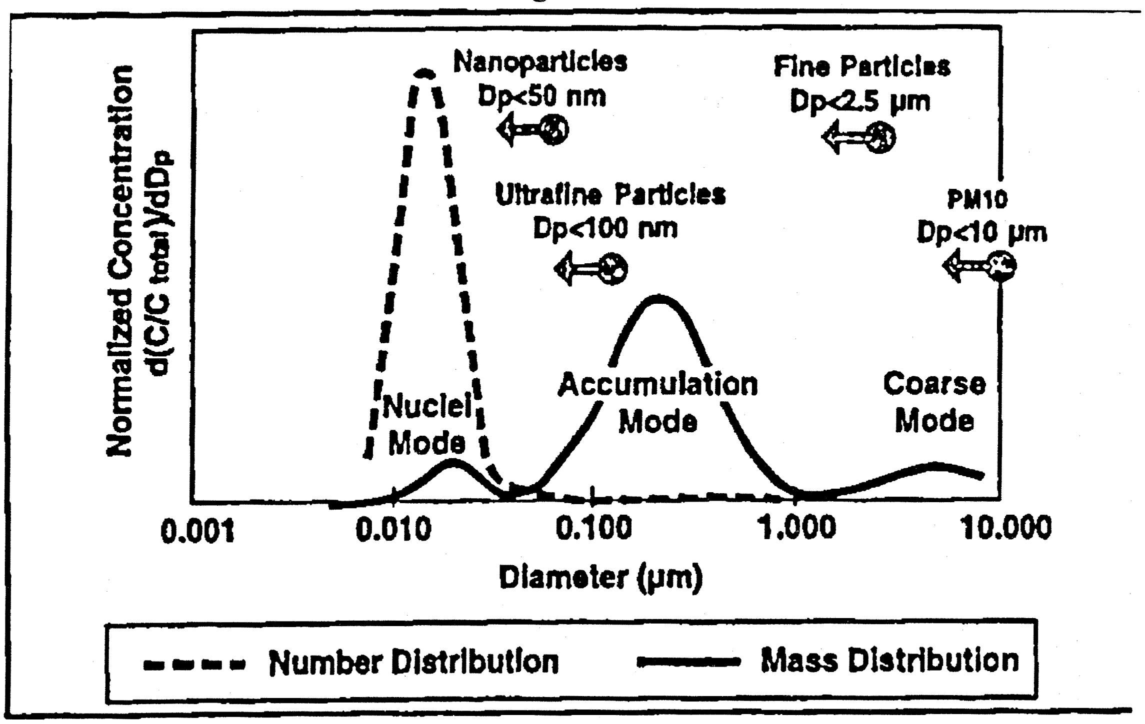
Figure II-3



Diesel particulate size distribution.

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

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

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

As discussed in Part III, the available evidence on the risks for dpm exposure do not currently include enough data to draw conclusions about the risks of exposure to significant numbers of very small particles. Research on nanoparticles and their health effects is currently a topic of investigation. As there have been few measurements of the number of particles emitted (as opposed to mass), it will be very difficult for epidemiologists to extrapolate information in this regard.

Based on the comments received and a review of the literature currently available on the nanoparticle issue, MSHA believes that promulgation of the final rules for underground coal and metal and nonmetal mines is necessary to protect miners. The nanoparticle issues discussed above will not be answered for some time because of the extensive research required to address the questions raised. MSHA's rules will require the application of exhaust aftertreatment devices on nearly all of the most polluting engines. The application of these measures will reduce the number of nanoparticles as well as the mass of the larger particles to which a miner will be exposed—miners wanted aftertreatment on all machines for this purpose.

(6) Other Methods for Controlling DPM in Underground Coal Mines

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

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

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

Emissions aftertreatment devices. One of the most discussed approaches to controlling dpm emissions involves the use of devices placed on the end of the tailpipe to physically trap diesel particulate emissions and thus limit their discharge into the mine atmosphere. These aftertreatment devices are often referred to as ''particle traps'' or ''soot traps,'' but the term filter is also used. The two primary categories of particulate traps are those composed of ceramic materials (and thus capable of handling uncooled exhaust), and those composed of paper materials (which require the exhaust to first be cooled). Typically, the latter are designed for conventional permissible equipment which have water scrubbers installed which cool the exhaust. However, another alternative that is now used in coal mines is ''dry system technology'' which cools the diesel exhaust with a heat exchanger and then uses a paper filter. In addition, ''oxidation catalytic converters,'' devices used to limit the emission of diesel gases, and ''water scrubbers,'' devices used to cool the emission of diesel gases, are discussed here as well, because they also can have effect on limiting particle emission.

Water Scrubbers. Water scrubbers are devices added to the exhaust system of diesel equipment. Water scrubbers are essentially metal boxes containing water through which the diesel exhaust gas passes. The exhaust gas is cooled, generally to below 170 degrees F. A small fraction of the unburned hydrocarbons is condensed and remains in the water with some of the dpm. Tests conducted by the former Bureau of Mines and others indicate that no more than 20 to 30 percent of the dpm is removed. However, MSHA has no definitive evidence on the amount of dpm reduction that can be achieved with a particular water scrubber. The water scrubber does not remove the carbon monoxide, the oxides of nitrogen, or other gaseous emission that remains a gas at room temperature, so their effectiveness as aftertreatment devices is limited.

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

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

Oxidation Catalytic Converters (OCCs). Oxidation catalytic converters (OCCs) were among the first devices added to diesel engines in mines to reduce the concentration of harmful gaseous emissions discharged into the mine environment. OCCs began to be used in underground mines in the 1960's to control carbon monoxide, hydrocarbons and odor (Haney, Saseen, Waytulonis, 1997). Their use has been widespread. It has been estimated that more than 10,000 OCCs have been put into the mining industry over the last several years (McKinnon, dpm Workshop, Beckley, WV, 1995).

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

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

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

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

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

Recently, as described elsewhere in this preamble, the EPA required that diesel fuel used for over the road trucks contain no more than 500 ppm (0.05 percent) sulfur. This action made low sulfur fuel available throughout the United States. MSHA, in its recently promulgated regulations for the use of diesel powered equipment in underground coal mines required that this low sulfur fuel be used. When the low sulfur fuel is burned in an engine and passed through a converter with a moderately active catalyst, only small amounts of SO_2 and additional sulfate based particulate are created. However, when a very active catalyst is used, to lower the operating temperature of the converter or to enhance the CO removal efficiency, even the low sulfur fuel has sufficient sulfur present to create an SO_2 and sulfate based particulate problem. Consequently, as discussed later in this section, the EPA has notified the public of its intentions to promulgate regulations that would limit the sulfur content of future diesel fuel to 15 ppm (0.0015 percent) for on-highway use in 2006.

The particulate removal capabilities of some OCCs are significant in gravimetric terms. In 1995, the EPA implemented standards requiring older buses in urban areas to reduce the dpm emissions from rebuilt bus engines (40 CFR 85.1403). Aftertreatment manufacturers developed catalytic converter systems capable of reducing dpm by 20%. Such systems are available for larger diesel engines common in the underground metal and nonmetal sector. However, as has been pointed out by Mayer, the portion of particulate mass that seems to be impacted by OCCs is the soluble component, and this is a smaller percentage of particulate mass in utility vehicle engines than in automotive engines. Moreover, some measurements indicate that more than 40% of NO is converted to more toxic NO_2, and that particulate mass actually increases using an OCC at full load due to the formation of sulfates. In summation, Mayer concluded that the OCCs do not reduce the combustion particulates, produce sulfate particulates, or have unfavorable gaseous phase reactions increasing toxicity, and that the positive effects are irrelevant for construction site diesel engines. He concludes that the negative effects outweigh the benefits (Mayer).

The Phase 1 interim data report of the Diesel Emission Control-Sulfur Effects (DECSE) Program (a joint government-industry program established to explore lower sulfur content that is discussed in more detail later in this section) similarly indicates that testing of OCCs under certain operating conditions can increase dpm emissions due to an increase in the sulfate fraction. (DECSE Program Summary, Dec. 1999) Another commenter also notes that oxidation catalytic activity can increase sulfates under certain operating temperatures, and that oxidation is a part of aftertreatment systems approaches like the DST® and some ceramic traps. But this commenter asserts that the sulfate production occurs at an operating mode that is seldom seen in real operation.

Other commenters during the rulemaking strongly supported the use of OCCs to reduce particulate and other diesel emissions. They argue that the OCCs result in significant reductions in dpm and in dpm generating gases. One commenter noted that with a clean engine, an OCC might well reduce particulates enough to meet any requirements established by MSHA.

However, another commenter noted that OCCs and ceramic traps can fail when used at higher altitude mines due to the lower oxygen content in the exhaust system. Another commenter asserted that OCCs are not effective at low temperature, although they are improving. Accordingly, this commenter indicated that OCCs have an impact only on light duty equipment when the equipment is working, not when it is idling, and are virtually useless on permissible equipment because of the low exhaust temperatures achieved through cooling. Despite a specific request from MSHA at the rulemaking hearings, no data were provided by OCC advocates to demonstrate that they can perform well at the lower temperatures normally found in light duty equipment.

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

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

The wall flow type ceramic honeycomb diesel particulate filter system was initially the most promising approach (SAE, SP–735, 1988). This consisted of a ceramic substrate encased in a shock-and vibration-absorbing material covered with a protective metal shell. The ceramic substrate is arranged in the shape of a honeycomb with the openings parallel to the centerline. The ends of the openings of the honeycomb cells are plugged alternately. When the exhaust gas flows through the particulate trap, it is forced by the plugged end to flow through the ceramic wall to the adjacent passage and then out into the mine atmosphere. The ceramic material is engineered with pores in the ceramic material sufficiently large to allow the gas to pass through without placing excessive back pressure on the engine, but small enough to trap the particulate on the wall of the ceramic material. Consequently, these units are called wall flow traps.

Work with ceramic filters in the last few years has led to the development of the ceramic fiber wound filter cartridge (SAE, SP–1073, 1995). The ceramic fiber has been reported by the manufacturer to have dpm reduction efficiencies up to 80 percent. This system has been used on vehicles to comply with German requirements that exhaust from 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. One commenter noted that a total exhaust, wall-flow, ceramic filter developed in Canada in collaboration with a US firm has been successfully demonstrated underground with a reduction of between 60% and 90% of particulate matter.

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

These devices proved to be quite effective in removing particulate, achieving particulate removal efficiencies of greater than 90 percent.

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

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

Reservations regarding their usefulness and practicality remain. One commenter stated 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.'' Another commenter reported unsuccessful experiments with ceramic filters in 1991 due to their inability to regenerate at low temperatures, lack of reliability, high cost of purchase and installation, and short life. Another reported that ceramics would not work at higher altitudes because of lower oxygen content in the exhaust system. Another commenter pointed out that elevated operating temperatures in certain engine modes can result in sulfates adding as much as 50% to total particulate mass, and asserted that ceramic traps alone were unable to offset this effect on their own.

In response to the proposed rule, MSHA received information and claims about the current efficiency of such technologies. One commenter, representing those who manufacture emissions controls, and referring to technologies other than low temperature paper filters—such as higher temperature disposable paper filters, ceramic monolith diesel particulate filters, wound ceramic fiber filters, and metal fiber filters—asserted that there were technologies which could achieve in excess of 95% filtration efficiency under ''many operating conditions.'' Another commenter submitted copies of information provided to that commenter by individual manufacturers of emission control systems, many of which made similar claims. Another commenter, however, questioned manufacturer claims, asserting big differences had been observed between such claims an independent 8-mode tests.

It appears that two groups in particular have been doing some research comparing the efficiency of recent ceramic models: the University of West Virginia, as part of that State's efforts to develop rules on the use of diesel-powered equipment underground; and VERT (Verminderung der Emissionen von Realmaschinen in Tunnelbau), a consortium of several European agencies conducting research in connection with major planned tunneling projects in Austria, Switzerland and Germany to protect occupational health and subsequent legislation in each of the three countries restricting diesel emissions in tunneling (in both cases, background on the regulatory efforts of the jurisdictions involved is discussed in section 8 of this part).

The legislature of the State of West Virginia enacted the West Virginia Diesel Act, which created the West Virginia Diesel Commission and set forth an administrative vehicle to allow and regulate the use of diesel equipment in underground coal mines in that state. West Virginia University was appropriated funds to test diesel exhaust controls, as well as an array of diesel particulate filters. The University was asked to provide technical support and data necessary for the Commission to make decisions on standards for emission controls.

The University provided data on four different engines and an assortment of configurations of available control devices, both hot gas filters and the DST® system (a system which, first cools the exhaust, then runs it through a paper filter). The range of collection efficiencies reported for the ceramic filters and oxidation catalysts combined fell between 65% and 78%. The highest collection efficiency obtained using the ISO 8 mode test cycle (test cycle described in rule) was 81% on the DST® system. The University reported problems with this system that would account for the lower than expected efficiency for a paper filter type system. A commenter who spoke for the Commission at MSHA's public hearing expressed serious reservations of the 95% collection efficiency of MSHA's proposed rule and believed it was not achievable with technology based on the University's current work. The WV Commission also provided MSHA a detailed proposal for setting a laboratory diesel particulate standard of 0.5 milligram per cubic meter. As discussed in part IV, this is similar to the Pennsylvania standard, but without a strict filter efficiency value, and as further discussed in part IV, MSHA's approach in this final rule is similar.

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

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

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

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

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

Subsequently, VERT has evaluated additional commerically available filter systems. A list of recently evaluated hot gas filters are shown in Table II–4. The filtration efficiency, expressed on a gravimetric basis is shown in the column headed ''PMAG—without additive''. The filtration efficiencies determined by VERT for these 6 filter systems range from 80.7% to 94.5%. The average efficiency of these filters is 87%. MSHA will be updating the list of VERT's evaluated systems as they become available.

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Table II-4

Efficiency of Diesel Particulate Traps VERT-Certification Test

Average 4 operation points, ISO 8187

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

[1] Small melting damage

[2] Uncertain data

[3] Coulometry is optional for VERT certification test

PMAG: Efficiency according to Total Particulate Mass PM

PZAG: Efficiency according to Integrated Particulate Count (20 - 300 nm) PZ

ECAG: Efficiency according to Elementary Carbon EC (2 state Coulometry)

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

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

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

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

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

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

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

A very active catalyst applied to the particulate trap surfaces and a very active catalyst in a catalytic converter installed upstream of the trap can create a situation in which the trap performs less efficiently than expected. Burning low sulfur diesel fuel, containing less than 500 ppm sulfur, will result in the creation of significant quantities of sulfates in the exhaust gas. These sulfates will still be in the gaseous state when they reach the ceramic trap and will pass through the trap. These sulfates will condense later forming diesel particulate. Special care must be taken in the selection of the catalyst formulation to ensure that sulfate formation is avoided. This problem does not occur in systems designed with a catalytic converter upstream of a water scrubber. The gaseous phase sulfates will condense when contacting the water in the scrubber and will not be discharged into the mine atmosphere. Thus far, no permissible diesel packages have been approved which incorporate a catalytic converter upstream of the water scrubber. One research project conducted by the former Bureau of Mines which attempted this arrangement was unsuccessful. In attempting to maintain a surface temperature less than the 300 degrees Fahrenheit (required for permissibility purposes) the exhaust gas was be cooled to the point that the catalytic converter did not reach the necessary operating temperature. It would appear that a means to isolate the catalytic converter from the exhaust gas water jacket is necessary for the arrangement to function as intended.

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

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

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

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

VERT has also published information on the extent of dpm filter usage in Europe as evidence that the filter technology has attained wide spread acceptance. MSHA believes this information is relevant to coal and metal/nonmetal mining because the tunneling equipment on which these filters are installed is similar to metal/nonmetal equipment and can be applied to heavy duty equipment in coal mining operations. VERT stated that over 4,500 filter systems have been deployed in England, Scandinavia, and Germany. Deutz Corporation has deployed 400 systems (Deutz's design) with full flow burners for regeneration of filters installed on engines between 50–600kw. The Oberland-Mangold company has approximately 1,000 systems in the field. They have accumulated an average of 8,400 operating hours in forklift trucks, 10,600 operating hours in construction site engines, and 19,200 operating hours in stationary equipment. The Unikat company has introduced in Switzerland over 250 traps since 1989 and 3,000 worldwide with some operating more than 20,000 hours. In German industry, approximately 1,500 traps in forklifts are installed annually.

Paper filters. In 1990, the former Bureau of Mines conducted a project to develop a means to reduce the amount of dpm emitted from permissible diesel powered equipment using technologies that were available commercially and that could be applied to existing equipment. The project was conducted with the cooperation of an equipment manufacturer, a mine operator, and MSHA. In light of the fact that all permissible diesel powered equipment, at that time, utilized water scrubbers to meet the MSHA approval requirements, the physical characteristics of the exhaust from that type of equipment were the basis for the selection of candidate technologies. The technology selected for development was the pleated media filter or paper filter as it came to be called. The filter selected was an intake air cleaner normally used for over the road trucks. That filter was acceptable for use with permissible diesel equipment because the temperature of the exhaust gas from the water scrubber was less than 170 degrees F, well below the ignition point of the filter material. Recognizing that under some operating modes, water would be discharged along with the exhaust, a water trap was installed in the exhaust stream before it passed through the filter. After MSHA conducted a thorough permissibility evaluation of the modified system, this filter was installed on a permissible diesel coal haulage vehicle and a series of in-mine trials were conducted. It was determined, by in mine ambient gravimetric sampling, that the particulate filter reduced dpm emissions by 95 percent compared with the same machine without the filter. The test results showed that the filters would last between one and two shifts, depending on how hard the equipment worked. (BOM, IC 9324).

Following the successful completion of the former Bureau of Mines mine trial, several equipment manufacturers applied for and received MSHA approval to offer the paper filter kits as options on a number of permissible diesel machines. These filter kits were installed on other machines at the mine where the original tests were conducted, and later, on machines at other mines.

Despite the initial reports on the high efficiency of paper filters, during the hearings and in the comments on this rulemaking a number of commenters questioned whether, in practice, paper filters could achieve efficiencies on the order of 95% when used on existing permissible equipment. In order to determine whether it could verify those concerns, MSHA contracted with the Southwest Research Institute to verify the ability of such a paper filter to reduce the dpm generated by a typical engine used in permissible equipment. The results of this verification investigation are reviewed in Part IV of this preamble. They confirmed that commercially available paper filters are capable of achieving very high efficiencies.

Another commenter noted that the volatile fraction of particulate is not trapped by hot gas filters, but rather passes through the filter in gaseous form. The volatile fraction consists of, among other components, gaseous forms of sulfur compounds, lube oil and the high boiling point fraction of unburned fuel. These components condense in the mine atmosphere as diesel particulate. The commenter asserted that the process of volatilization is reduced in the water cooled exhaust, but it is present nevertheless.

MSHA recognizes that the volatile fraction of dpm passes through hot gas filters. This volatile fraction later condenses in the mine atmosphere and is collected on particulate samplers. This is not the case with hot gas filters that utilize a catalytic converter. The volatile fraction is oxidized in the catalytic converter and the gases produced do not condense as particulate. Paper filters are typically used with water scrubbers or heat exchangers, both of which condense the volatile fraction into dpm before the exhaust gas reaches the paper filter. This allows the paper filter to trap the condensed volatile fraction.

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

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

The dry system can operate on any grade without the problems encountered by water scrubbers. Furthermore, there is no problem with fog created by operation of the water scrubber. Dry systems have been installed and are operating successfully on diesel haulage equipment, longwall component carriers, longwall component extraction equipment, and in nonpermissible form, on locomotives. However, as pointed out by commenters, requiring the use of a dry system on all mining equipment would be expensive, cumbersome, and in many cases would require considerable engineering measures that might render them infeasible.

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

Two manufacturers have received approval for diesel power packages that are configured as described above; Paas Technologies, (under various corporate designations including Minecraft and a registered trade name, Dry Systems Technology, or DST®) and Jeffrey Mining Equipment Company (currently Long-Airdox-Jeffrey).

The design of the dry system manufactured by DST® includes a catalytic converter. However, with respect to the basic Paas Technologies system, without a catalytic converter, the initial reported laboratory reductions in dpm were dramatic: up to 98%.

During the hearings, however, there were many questions about the applicability of the early results to MSHA's proposed requirement that emissions of certain equipment be reduced 95% by mass. It was indicated by a commenter that the original Paas Technology dry system tests with a paper filter were performed at West Virginia University used high sulfur fuel which is currently prohibited in underground coal mines. The commenter stated that the University tested different fuels containing varying sulfur contents and the results indicated a fluctuation in overall dpm emission results. The commenter stated the difference in dpm collection efficiency by the filter was on the order of 12 to 15%. Another commenter stated the difference in dpm reduction using a 0.37 percent fuel sulfur and a 0.04 percent fuel sulfur was about 22 percent. This commenter further stated that other published papers from Europe report the same dpm reductions with varying fuel sulfur levels, approximately 15 to 20 percent reduction.

As was stated ealier, Paas Technologies has further developed its system by the adding a catalytic converter in the exhaust before the particulate paper filter. Paas Technologies have developed a technique whereby the catalytic converter is mounted so that the exhaust gas temperature remains high enough for the converter to operate effectively while complying with the MSHA surface temperature requirement. In addition to removing most of the carbon monoxide, the catalytic converter removes most of the unburned hydrocarbons before they are cooled and condensed. This feature extends the operating life of the filter. Any sulfate formed in the catalytic converter or in the engine combustion process condenses to a solid form as the exhaust gas passes through the heat exchanger and is collected in the particulate filter.

Paas Technologies submitted a detailed set of test results on a 94hp MWM D–916–6 test engine equipped with a Model M38 DST ® Management System, which included the catalytic converter, for the rulemaking record. These tests were conducted by Southwest Research Institute using an 8-mode test, with ASTM No. 2–D diesel fuel. Both the test cycle and test fuel (low sulfur) conformed with the test procedure detailed in the proposed rule and in this final rule. In idle mode, the dpm emissions were reduced about 90%; in mode 5, the dpm emissions were down 99%; on average of the 8 modes, the dpm emissions were reduced by 97%.

The Jeffrey system, which does not utilize a catalytic converter, was the subject of the MSHA verification initiative, noted in part IV. The verification was conducted in such a way as to test filter efficiency separately from whole system, with the low sulfur fuel required for coal mine use and without a catalytic converter. The verification confirmed that the paper filter has a dpm removal efficiency greater than 95 percent.

This data submitted to the rulemaking record demonstrates that paper filters used on dry systems can achieve a filtration efficiency that allows equipment to meet the 2.5 gm/hr standard with low sulfur diesel fuel both with and without a catalytic converter in the system.

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

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

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

Moreover, planned Tier 3 standards for nonroad vehicles would require similar action (64 FR 26143). (For more information on the EPA planned engine standards, see section 5 of this Part). The EPA noted that the European Union has adopted new specifications for diesel fuel that would limit it to 50 ppm by 2005, (an interim limit of 350 ppm by this year), that the entire diesel fuel supply in the United Kingdom should soon be at 50 ppm, and that Japan and other nations were working toward the same goal (64 FR 26148).

In the ANPRM, EPA specifically noted that while continuously regenerating ceramic filters have shown considerable promise for limiting dpm emissions even at fairly low exhaust temperatures, the systems were fairly intolerant of fuel sulfur. Accordingly, the agency hopes to gather information on whether or not low sulfur fuel was needed for effective PM control (64 FR 26150). EPA’s proposed rule was published in May 2000 and EPA issued final regulations addressing emissions standards (December 2000) for new model year 2007 heavy-duty diesel engines and the low-sulfur fuel rule. The regulations require ultra-low sulfur fuel be phased in during 2006–2009.

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

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

Several commenters in this rulemaking suggested other fuel formulations which could have a beneficial effect on dpm emissions. One commenter encouraged the use of FRF, Fire Resistant Fuel, which has various safety features as well as lower NO_X and PM, and noted it is under study for use by the military.

Another commenter noted the development of a catalytic ignition system that permits the engines to operate on alternative fuels which greatly reduce harmful emissions. For example, using a water-methanol mix, the commenter noted dramatic reductions in harmful emissions of NO_X, CO and HC over a gasoline, spark ignition engine. This commenter also noted that the ignition system could operate on a diesel engine, but provided no information about emissions reductions by its use.

Meyer reports the results of a test by VERT of a special synthetic fuel containing neither sulfur nor bound nitrogen nor aromatics, with a very high

Cetane index. The fuel performed very well, but produced only abut 10% fewer particulates than low sulfur diesel fuel, nor did it show any improvement in diminishing nonparticulate emissions.

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

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

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

MSHA has evaluated the efficiency of cab filters for diesel particulate reduction. Several different types of filter media have been tested in underground mines. These include standard filter paper and high efficiency filter paper. Filter papers can reduce diesel particulate exposures by 60 percent to 90 percent. When changing filter media, it is necessary to make sure that the airflow into the cab is not reduced and that the airflow through an air conditioning system is not reduced.

Although the installation of a cab does not relieve the mine operator from the responsibility of complying with the equipment dpm limits, cabs provide assistance in complying with noise and respirable dust regulations. Cabs protect the equipment operator protection from dpm, respirable dust and noise exposures.

(7) Existing Standards for Underground Coal Mines That Assist in Limiting Miner Exposure to Diesel Emissions

MSHA already has in place various requirements that indirectly help to control miner exposure to diesel emissions in underground mines—including exposure to diesel particulate. The first such requirements were developed in the 1940's; the most recent went into full effect only in November, 1999. It is important to understand these requirements because they form the base upon which this new rule is overlaid.

Early developments. In 1944, part 31 established procedures for limiting the gaseous emissions from diesel powered equipment 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 were drafted in response 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 for engines that have a properly adjusted fuel to air ratio was recommended (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 approval plate quantity for the vehicle with the highest approval plate air quantity requirement; (b) 75 percent of the approval plate air quantity requirement of the vehicle with the next highest approval plate air quantity requirement; and (c) 50 percent of the approval plate airflow for each additional piece of diesel equipment.

Limitations on Diesel Gasses. MSHA has limits on some of the gasses produced in diesel exhaust. These are listed in Table II–5, for both coal mines and metal/nonmetal mines, together with information about the recommendations in this regard of other organizations. As indicated in the table, MSHA requires mine operators to comply with gas specific threshold limit values (TLV®s) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1972 (for coal mines) and in 1973 (for metal and nonmetal mines).

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TABLE II-5

GASEOUS EXPOSURE LIMITS (PPM)

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

Table Notes:

A) ACGIH, 1972

B) ACGIH, 1973

C) NIOSH recommended exposure limit (REL), based on a 10-hour, time-weighted average

D) ACGIH, 1996

E) OSHA permissible exposure limit (PEL)

F) NIOSH recommends only a 1-ppm, 15-minutes, short-term exposure limit (STEL)

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To change an MSHA exposure limit, regulatory action is required because the rule does not provide for their automatic updating. In 1989, MSHA proposed changing some of these gas limits in the context of a proposed rule on air quality standards (54 FR 35760). Following opportunity for comment and hearings, a portion of that proposed air quality rule (concerning control of drill dust and blasting) was promulgated. As a result of a recent legal action, MSHA's efforts to revise the specific limits for those gases emitted by diesel engines have been placed under the continued supervision of a federal court of appeals. This action is discussed in more detail in section 9 of this Part.

Diesel Equipment Rule for Underground Coal Mines. On October 25, 1996, MSHA promulgated standards for the ''Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines'' (61 FR 55412). The history of this ''diesel equipment rule'' (sometimes referred to here as the ''diesel safety rule'' to help distinguish it from this rulemaking which is oriented toward health) is set forth as part of the history of this rulemaking (see section 9 of this part).

The diesel equipment rule focuses on the safe use of diesels in underground coal mines. Integrated requirements are established for the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines.

Certain requirements were included in the diesel equipment rule that are directly related to reducing diesel emissions. For example, the diesel equipment rule requires that the emissions of permissible and heavy duty equipment be tested weekly. The tests are conducted using instrumentation and the tests are conducted with the engines operated at a loaded condition which is representative of actual operation. The results are monitored and recorded. Higher than normal emissions readings indicate that the engines and equipment are not being maintained in approved condition. Although some of these requirements help reduce dpm emissions, they were not included in the rule for that specific purpose.

Lower-emission engines. The diesel equipment rule requires that virtually all diesel-powered engines used in underground coal mines be approved by MSHA; see 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, 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. To achieve the objective of clean-burning engines, the rule sets performance standards which must be met by virtually all diesel-powered equipment in underground coal mines.

As noted in section 5 of this part, the technical requirements for approved diesel engines focus on limiting the amount of various gases that an engine can emit, including undiluted exhaust limits for carbon monoxide and oxides of nitrogen (61 FR 55419). The limits for these gasses are derived from existing 30 CFR part 36.

The diesel equipment rule also provides that the particulate matter emitted by approved engines be determined during the testing required to gain approval. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates what air quantity is necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air. The purpose of the PI requirement is discussed in more detail in section 5 of this part.

Gas Monitoring. The diesel equipment rule also addresses the monitoring and control of gaseous diesel exhaust emissions (30 CFR part 70; 61 FR 55413). In this regard, the rule requires that mine operators take samples of carbon monoxide and nitrogen dioxide as part of existing onshift workplace examinations (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).

Engine Maintenance. The diesel equipment rule requires that diesel-powered equipment be maintained in safe and approved condition (30 CFR 75.1914; 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).

The rule also requires the weekly examination of diesel-powered equipment (30 CFR 75.1914(g)). To determine if more extensive maintenance is required, the rule further requires a weekly check of the gaseous CO emission levels on permissible and heavy duty outby machines. The CO check requires that the engine be operated at a repeatable loaded condition and the CO measured. The carbon monoxide concentration in the exhaust provides a good indication of engine condition. If the CO measurement increases to a higher concentration than what was normally measured during the past weekly checks, then a maintenance person would know that a problem has developed that requires further investigation.

In addition, operators are required to establish programs to ensure that those performing maintenance on diesel equipment are qualified (61 FR 55414).

Fuel. The diesel equipment rule also requires that underground coal mine operators use diesel fuel with a sulfur content of 0.05% (500 ppm) or less (30 CFR 75.1910(a); 61 FR 55413). Some types of exhaust aftertreatment technology designed to lower hazardous diesel emissions work more effectively when the sulfur content of the fuel is low. More effective aftertreatment devices will result in reduced hydrocarbons, carbon monoxide, and particulate levels. Low sulfur fuel also greatly reduces the sulfate production from the catalytic converters currently in use in underground coal mines thereby decreasing exhaust particulate. To further reduce miners' exposure to diesel exhaust, the final rule prohibits operators from unnecessarily idling diesel-powered equipment (30 CFR 75.1916(d).

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

Impact of the diesel equipment rule on dpm. The diesel equipment rule is helping the mining community use diesel-powered equipment more safely in underground coal mines. Moreover, the diesel equipment rule has many features which reduce the emission and concentration of harmful diesel emissions in underground coal mines—including the particulate component of these emissions.

During the public hearings on the equipment rule, miners complained about the high concentrations of diesel emissions at the section loading point and in the areas of the mine where longwall equipment is being installed or removed. Accordingly, MSHA established, in that rule, provisions which would address miners' concerns.

The equipment rule required that the approval plate ventilation quantity be provided at the section loading point. The loading point is also identified as a location where regular air quality samples are required to be taken. Corrective action is required if the samples of CO and NO_2 exceeded more than one half the allowable concentration limit of these gases.

Longwall equipment installations and removals are handled in a similar manner. The diesel emissions from all of the equipment in the area of the mine where the longwall move is being made are required to be considered in establishing the amount of ventilation air to be provided. A specific location where that quantity is to be measured is established. Additionally, the same air quality sampling program required for section loading points is required for areas of the mine where the longwall move is to take place.

Permissible haulage vehicles contribute the largest quantities of emissions at the section loading point. Longwall moves are typically carried out by permissible and heavy duty equipment such as shield carriers, mules, and locomotives which produce large quantities of diesel emissions. Emissions from these vehicles are reduced by the use of approved engines, low sulfur fuel, the loaded repeatable engine condition testing, regular maintenance by trained personnel and the ventilation and sampling provisions of the diesel equipment rule.

Because the effective dates for provisions of the diesel equipment regulations are staggered, the full impact of the new rules was not known at the time the dpm hearings were held. MSHA expects that the concentrations of diesel emissions at the section loading point and during longwall moves will be reduced as these provisions are fully implemented.

In developing the diesel equipment rule, however, MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines. It was understood that the agency would be taking a separate look at the health risks of dpm exposure. (61 FR 55420).

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

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

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

Pennsylvania. As indicated in section 1, Pennsylvania essentially had a ban on the use of diesel-powered equipment in underground coal mines for many years. As noted by one commenter, diesel engines were permitted provided the request was approved by the Secretary of the Department of Environmental Protection but no request was ever approved.

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

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

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

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

One commenter described the difficulty in efforts to get a small outby unit approved under the current Pennsylvania law. Accordingly, the industry has indicated that it would seek additional changes in the Pennsylvania diesel law. Commenters representing miners indicated that they were also involved in these discussions.

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

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

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

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

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

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

(9) History of this Rulemaking

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

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

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

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

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

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

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

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

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

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

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

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

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

On October 4, 1989, MSHA published a Notice of Proposed Rulemaking on approval requirements, exposure monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (54 FR 40950). The proposed rule, among other things, addressed, and in fact followed, the MSHA Diesel 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 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. 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 thereof; (2) the validity of the NIOSH risk assessment model and the validity of various types of studies; (3) information about non-cancer risks, non-lung routes of entry, and the confounding effects of tobacco smoking; (4) the availability, accuracy and proper use of sampling and monitoring methods for diesel particulate; and (5) the technological and economic feasibility of various types of controls, including ventilation, diesel fuel, engine design, aftertreatment devices, and maintenance by mechanics with specialized training. The notice also solicited specific information from the mining community on ''the need for a medical surveillance or screening program and on the use of respiratory equipment.'' (57 FR 500). The comment period on the ANPRM closed on July 10, 1992.

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

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

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

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

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

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

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

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

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

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

Proposed Rulemaking on Dpm. On April 9, 1998, MSHA published a proposed rule to "reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter" (63 FR 17492).

MSHA went to some lengths to ensure the mining community would be able to review and comment on the proposed rule. The agency made 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. MSHA also provided the opportunity for comments to be accepted from the mining community at each of those locations, as well as through mail, e-mail and fax to the national office. MSHA also distributed the proposal to all underground mines, to mining associations and other interested parties. A copy was also posted on MSHA's website.

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

The notice of proposed rulemaking reviewed and discussed the comments received in response to the ANPRM, including information on such control approaches as fuel type, fuel additives, and maintenance practices (63 FR 17512–17514). For the convenience of the mining community, a copy of MSHA's Toolbox was also reprinted as an Appendix at the end of the notice of proposed rulemaking (63 FR 17580 *et seq.*). A complete description of the Estimator, and several examples, were also presented in the preamble of the proposed dpm rule (63 FR 17565 *et seq.*).

The proposed dpm rule was fairly simple. In addition to miner training, the proposed rule would have required aftertreatment filters on all permissible equipment and, subsequently, on all heavy duty nonpermissible equipment. Throughout the preamble, MSHA discussed a number of other approaches that might have merit in limiting the concentration of dpm in underground coal mines. MSHA made it very clear to the mining community that the rule being proposed represented only one of the approaches which might ultimately be required by the final rule and on which comment was being solicited by the proposed rulemaking notice.

For example, the agency noted the following:

> "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 * * *. (There are) 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." (63 FR 17498)

These alternatives were further discussed in a separate Question and Answer (#12). The agency was also clear it would welcome comment on "whether there are some types of light-duty equipment whose dpm emissions should, and could feasibly, be controlled", and "whether it would be feasible for this sector to implement a requirement that any new light-duty equipment added to a mine's fleet be filtered" Question and Answer (#6) (63 FR 17556).

MSHA also discussed and welcomed comment on a number of other alternatives: *e.g.,* restricting the exposure of underground coal mines to all fine particulates regardless of source (63 FR 17495); and the use of administrative controls (*e.g.,* rotation of personnel) and personal protective equipment (*e.g.,* respirators) to reduce the dpm exposure of miners. The Agency also sought comments on its risk assessment, presented in full in the preamble to the proposed rule (Part III). As noted therein, this was the first risk assessment ever performed by the agency to be peer reviewed. Such a review is not required under the agency's statute, but MSHA took the time to obtain such a review in this instance due to significant disagreement within the mining community about the health risks of exposure to dpm (63 FR 17521).

MSHA also asked for comment on its economic assumptions in the preamble. Two of the Questions and Answers (#5 and #7) were specifically devoted to cost impacts, including those on small mines. MSHA also specifically requested all members of the mining community to consider using the Estimator in developing comments on the proposed rulemaking (63 FR 17565).

On July 14, 1998, in accordance with the National Environmental Protection Act, MSHA published a notice in the **Federal Register** seeking comment on its preliminary determination that the proposed rule would not have a significant environmental impact (63 FR 37796).

The initial comment period was scheduled to last for 120 days until August 7, 1998. In response to requests from the public, on August 5, 1998, MSHA extended the initial comment period on the proposed rule (and the comment period on its preliminary determination of no significant environmental impact) for an additional 60 days, until October 9, 1998 (63 FR 41755). That notice also announced MSHA's intent to hold public hearings on the proposal.

On October 19, 1998, MSHA announced in the **Federal Register** locations of four public hearings on the proposed rule. The agency further announced that the close of the post-hearing comment period and rulemaking record would be on February 16, 1999 (63 FR 55811).

In November 1998, MSHA held hearings in Salt Lake City, Utah and Beckley, West Virginia. In December 1998, hearings were held in Mt. Vernon, Illinois, and Birmingham, Alabama.

These hearings were well attended. Testimony was presented by individual miners, representatives of miners, individual coal companies, mining industry associations, representatives of engine and equipment manufacturers and one individual manufacturer. Members of the mining community participating had an extensive opportunity to hear and respond to alternative views; some participated in several hearings. They also had an opportunity to engage in direct dialogue with members of MSHA's rulemaking committee-responding to questions and asking questions on their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about the need for diesel powered equipment in this sector, the risks associated with its use, the need for regulation in this sector, alternative approaches (including but not limited to those on which MSHA specifically sought comment), and the technological and economic feasibility of various alternatives.

During the hearings, MSHA made a number of requests that information provided at the hearing be supplemented by submission of cited sources, additional data, and in particular for data to support assertions made about various control technologies. MSHA again solicited information concerning the agency's cost assumptions, for the results of studies using MSHA's Estimator model, and also asked for any data on a number of other points. For example, the agency requested further information on the size distribution of particles from cleaner engines, on the viability of a fine particulate standard in lieu of a dpm standard, for a list of any studies concerning the risks of dpm or lack thereof, and data on equipment upgrades.

On February 12, 1999, (64 FR 7144) MSHA published a notice in the **Federal Register** announcing: (1) The availability of three additional studies discussed in the preamble of the proposed rule but not available at the time of publication; and (2) the extension of the post-hearing comment period and close of record for 60 additional days, until April 30, 1999.

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

On July 8, 1999, MSHA published a notice in the **Federal Register** correcting technical errors in the preamble discussion on the Diesel Emission Control Estimator formula in the Appendix to Part V of the proposed rulemaking notice, and correcting Figure V–5 of the preamble. Comments on these changes were solicited by July 26, 1999, the close of the rulemaking record (64 FR 36826). The Estimator model was subsequently published in the literature.

The rulemaking record closed on July 26, 1999, fifteen months after the date the proposed rule was published for public notice. The comments, like the hearings, reflected extensive participation in this effort by the full range of interests in the mining community and covered a full range of ideas and alternatives.

On June 30, 2000, the rulemaking record was reopened for 30 days in order to obtain public comment on certain additional documents which the agency determined should be placed in the rulemaking record. Those documents were MSHA's paper filter verification studies and the recent information from VERT on the performance of hot gas filters mentioned in section 6 of this Part. In addition, the notice provided an opportunity for comment on additional documents being placed in the rulemaking record for a related rulemaking for underground metal and nonmetal mines, and an opportunity to comment on some additional documents on risk being placed in both records. In this regard, the notice reassured the mining community that any comments filed on risk in either rulemaking proceeding would be placed in both records, since the two rulemakings utilize the same risk assessment.

Other Related Activity. On September 3, 1999, the United States Court of Appeals for the District of Columbia Circuit issued its decision on writ of mandamus sought by the United Mine Workers to compel MSHA to issue final regulations controlling gaseous emissions in the exhaust of diesel engines used in underground coal mines. (190 F.3d 545.) The UMWA argued that such action should have been completed some years before as part of MSHA's air quality rulemaking to update emissions limits on hundreds of exposure limits. The Court found that the Agency was in violation of the statute's requirement that the Secretary must either promulgate final regulations, or explain her decision not to promulgate them, within ninety days of the certification of the record of a hearing if one is held or the close of the public comment period if a hearing is not held 30 U.S.C. 811(a)(4). However, the Court declined to immediately issue the mandamus order sought in this case because, among other factors: (a) The UMWA agreed that the diesel equipment rules alone may have the desired effect of reducing exposure to these gases; (b) the UMWA further agreed that the control of diesel particulate matter and respirable mine dust rank as higher rulemaking priorities for MSHA; and (c) MSHA submitted a tentative schedule for such rulemaking that the court found to be reasonable. However, the court retained jurisdiction of the case to ensure MSHA would move forward on this matter, and ordered several reports by the agency on its progress on December 31, 1999, June 30, 2000, December 31, 2000, and December 31, 2001.

III. Risk Assessment

Introduction

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

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

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

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

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

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

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

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

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

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

1. Exposures of U.S. Miners

Information about U.S. miner exposures comes from published studies and from additional mine investigations conducted by MSHA since 1993.[3] Previously published studies of exposures to dpm among U.S. miners are: Watts (1989, 1992), Cantrell (1992, 1993), Haney (1992), and Tomb and Haney (1995). MSHA has also conducted investigations subsequent to the period covered in Tomb and Haney (1995), and the previously unpublished data through mid-1998 are included here. Both the published and unpublished studies were placed in the record with the proposal, giving MSHA's stakeholders the opportunity to analyze and comment on all of the exposure data considered.

MSHA's field studies involved measuring dpm concentrations at a total of 50 mines: 27 underground metal and nonmetal (M/NM) mines, 12 underground coal mines, and 11 surface mining operations (both coal and M/NM). At all surface mines and all underground coal mines, dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. With few exceptions, dpm measurements at underground M/NM mines were made using the Respirable Combustible Dust (RCD) method (with

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

no impactor). At two of the underground M/NM mines, measurements were made using the total carbon (TC) method, and at one, RCD measurements were made in one year and TC measurements in another. Measurements at the two remaining underground M/NM mines were made using the size-selective method, as in coal and surface mines.[4] Weighing errors inherent in the gravimetric analysis required for both size-selective and RCD methods become statistically insignificant at the relatively high dpm concentrations observed.

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

Each underground study typically included personal dpm exposure measurements for approximately five production workers. Also, area samples were collected in return airways of underground mines to determine diesel particulate emission rates.[5] Operational information such as the amount and type of equipment, airflow rates, fuel, and maintenance was also recorded. Mines were selected to obtain a wide range of diesel equipment usage and mining methods. Mines with greater than 175 horsepower and less than 175 horsepower production equipment were sampled. Single and multiple level mines were sampled. Mine level heights ranged from eight to one-hundred feet. In general, MSHA's studies focused on face production areas of mines, where the highest concentrations of dpm could be expected; but, since some miners do not spend their time in face areas, samples were collected in other areas as well, to get a more complete picture of miner exposure. Because of potential interferences from tobacco smoke in underground M/NM mines, samples were not collected on or near smokers.

Table III–1 summarizes key results from MSHA's studies. The higher concentrations in underground mines were typically found in the haulageways and face areas where numerous pieces of equipment were operating, or where airflow was low relative to the amount of equipment operating. In production areas and haulageways of underground mines where diesel powered equipment was used, the mean dpm concentration observed was 644 µg/m³ for coal and 808 µg/m³ for M/NM. In travelways of underground mines where diesel powered equipment was used, the mean dpm concentration (based on 112 area samples not included in Table III–1) was 517 µg/m³ for M/NM and 103 µg/m³ for coal. In surface mines, the higher concentrations were generally associated with truck drivers and front-end loader operators. The mean dpm concentration observed was less than 200 µg/m³ at all eleven of the surface mines in which measurements were made. More information about the dpm concentrations observed in each sector is presented in the material that follows.

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

Mine type	Number of mines	Number of samples	Mean exposure (µg/m³)	Standard error of mean (µg/m³)	Exposure range (µg/m³)
Surface	11	45	88	11	9–380
Underground Coal[a]	12	226	644	41	0–3.650
Underground Metal and Nonmetal	27	355	808	39	10–5.570

Note: Intake and return area samples are excluded.

a. Underground Coal Mines

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

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

Figure III–1 displays the range of exposure measurements obtained by MSHA in the field studies it conducted in underground coal mines. A study

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

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

normally consisted of collecting samples on the continuous miner operator and coal haulage vehicle operators for two to three shifts, along with area samples in the haulageways. A total of 142 personal samples and 84 area samples were collected, excluding any area samples taken in intake or return airways.

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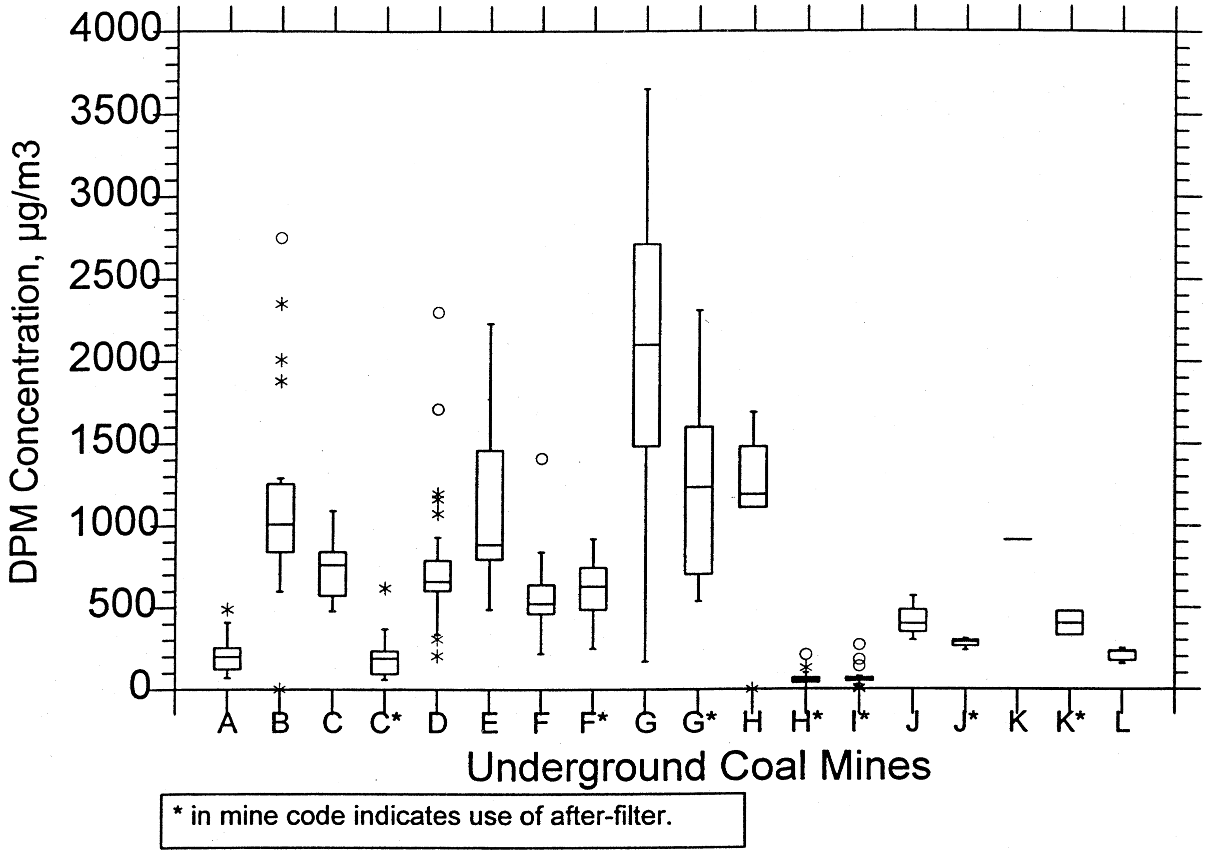

Figure 5 Box plots (Tukey, 1977) for dpm concentrations observed at 12 underground coal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[6] A total of 19 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. Although the three highest of these were from area samples, nine of the 19 measurements exceeding 1500 µg/m³ were from personal samples.

In six mines, measurements were taken both with and without use of disposable after-treatment filters, so that a total of eighteen studies, carried out in twelve mines, are displayed. Without use of after-treatment filters, average observed dpm concentrations exceeded 500 µg/m³ in eight of the twelve mines and exceeded 1000 µg/m³ in four.[7] At five of the twelve mines, all dpm measurements were 300 µg/m³ or greater in the absence of after-treatment filters.

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

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

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

employment of WMFs, the mean dropped to 1241 μg/m³ (median = 1235 μg/m³).

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

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

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

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

At lower concentrations, or shorter sampling times, random variability in the gravimetric determination of weight gain becomes significant, compared to the weight of dust accumulated on the filter. For this reason, MSHA has rejected the use of the gravimetric size-selective method for enforcement purposes.[8] This does not mean, however, that MSHA has ''discredited'' this method for other purposes, including detection of very high dpm concentrations at coal mines (i.e., greater than 500 μg/m³) and estimation of average dpm concentrations, based on multiple samples, when coal mine dust concentrations are not excessive. On the contrary, MSHA regards the gravimetric size-selective method as a useful tool for detecting and monitoring very high dpm concentrations and for estimating average exposures.

b. Underground Metal and Nonmetal Mines

Currently there are approximately 265 underground M/NM mines in the United States. Nearly all of these mines utilize diesel powered equipment, and 27 of those doing so were sampled by MSHA for dpm.[9] The M/NM studies typically included measurements of dpm exposure for dieselized production equipment operators (such as truck drivers, roof bolters, haulage vehicles) on two to three shifts. A number of area samples were also collected. None of the M/NM mines studied were using diesel particulate afterfilters.

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

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

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

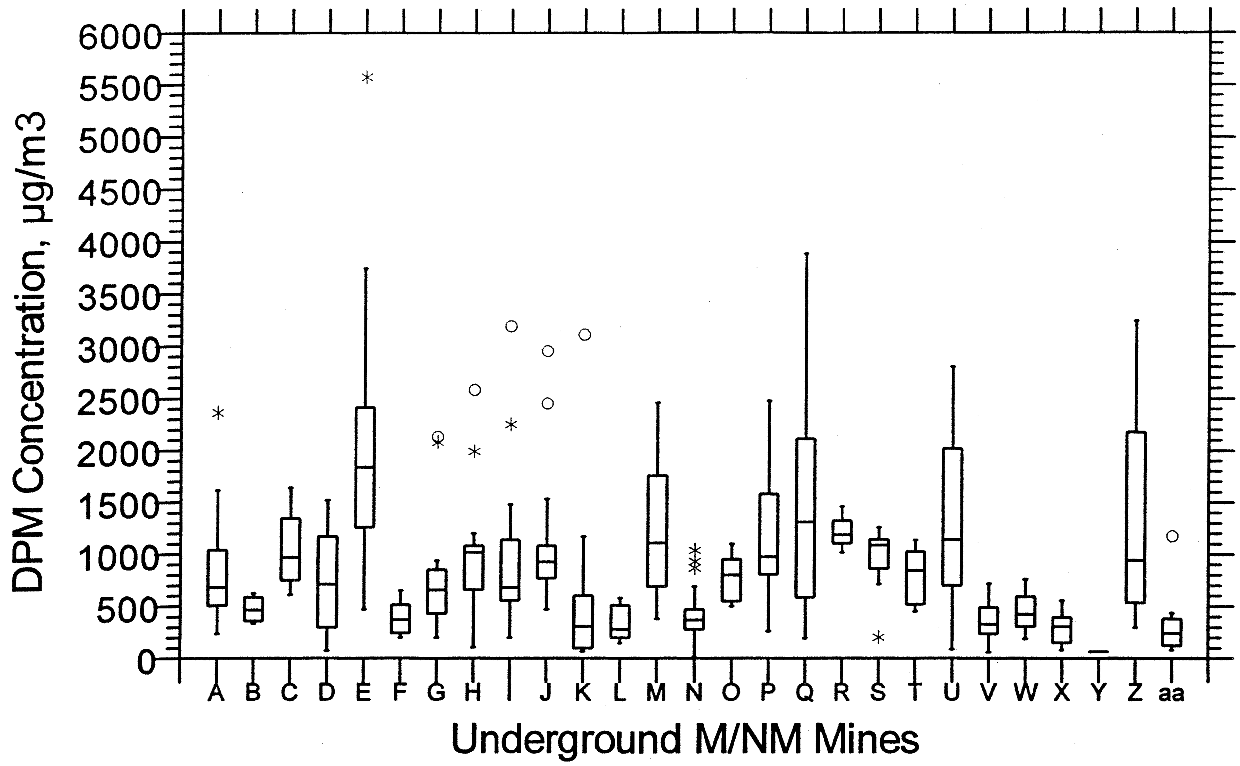

Figure 6 Box plots (Tukey, 1977) for dpm concentrations observed at 27 underground metal and nonmetal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at same mine. Measurements at Mine "T" and on one visit to mine "D" were made using the size-selective method, based on gravimetric determinationof the amount of submicrometer dust collected with an impactor. Measurements on another visit to mine "D" and at Mines "Z" and "aa" were made using TC method. All other measurements were made using RCD method. Because of potential interferences from cigarette smoke, samples were not collected on or near smokers.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[10] A total of 45 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. The three highest of these, all exceeding 3500 µg/m³, were from personal samples. Of the 45 measurements exceeding 1500 µg/m³, 30 were from personal samples and 15 were from area samples.

Average observed dpm concentrations exceeded 500 µg/m³ in 18 of the 27 underground M/NM mines and exceeded 1000 µg/m³ in 12.[11] At eight of the 27 mines, all dpm measurements exceeded 300 µg/m³. The highest dpm concentrations observed at M/NM mines were collected at Mine ''E''. Based on 16 samples, the mean dpm concentration observed at Mine ''E'' was 2008 µg/m³ (median = 1835 µg/m³). Twenty-five percent of the dpm measurements at this mine exceeded 2400 µg/m³. All four of these were based on personal samples.

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

Some commenters argued that, because of the limited number of underground M/NM mines sampled by MSHA, ''* * * results of MSHA's admittedly non-random sample cannot be extrapolated to other mines.'' [MARG] More specifically, IMC Global claimed that since only 25 [now 27] of about 260 underground M/NM mines were sampled,[12] then ''if the * * * measurements are correct, this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector and then only for certain unlisted commodities.''[13] IMC Global went on to suggest that MSHA should ''perform sufficient additional exposure monitoring * * * to show that the diesel particulate exposures are representative of the entire industry before promulgating regulations that will be applicable to the entire industry.''

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

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

MSHA also disagrees with the premise that 27 [or 25 as in the proposal] is an inherently insufficient number of mines to sample for the purpose of identifying an industry-wide dpm exposure problem that would justify regulation. The between-mine standard deviation of the 27 mean concentrations observed within mines was 450 µg/m³. Therefore, the standard error of the estimated grand mean, based on the variability observed between mines, was

$$450/\sqrt{27} = 87\ \mu g/m^3.$$[14]

MSHA considers this degree of uncertainty to be acceptable, given that the overall mean concentration observed exceeded 800 µg/m³.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

c. Surface Mines

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

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

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

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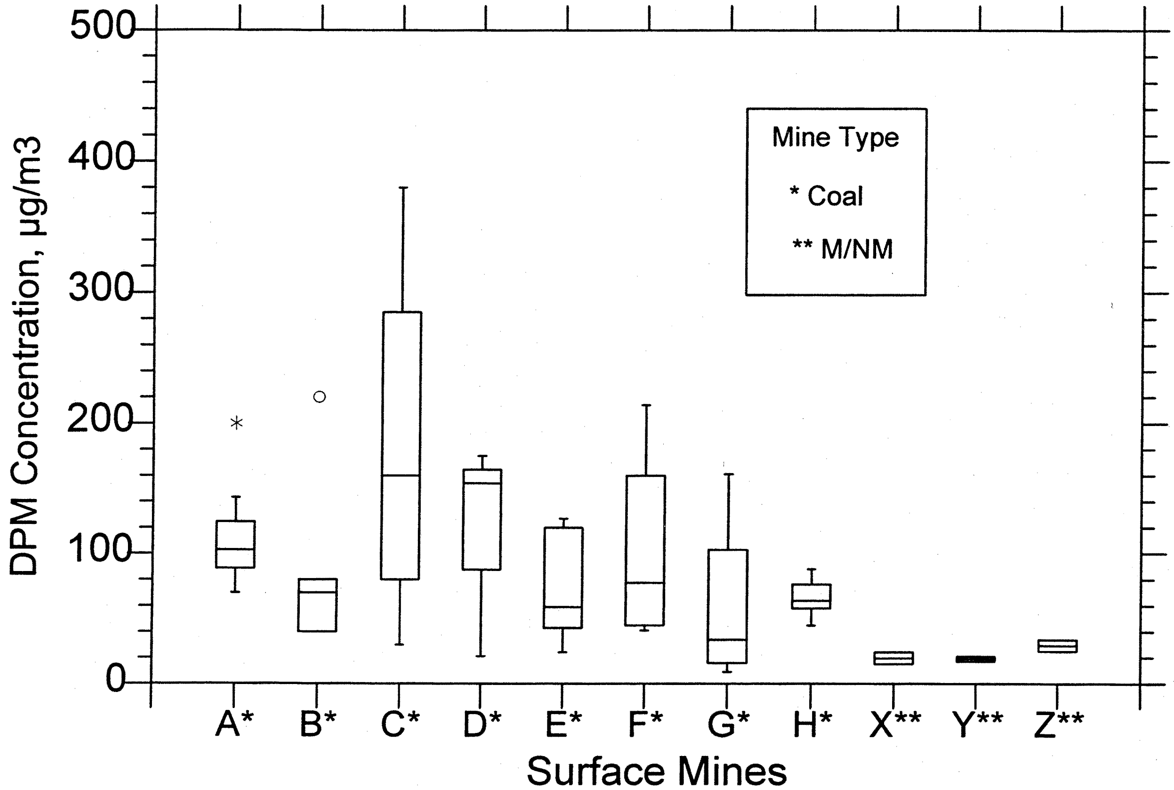

Figure 7Box plots (Tukey, 1977) for dpm concentrations observed at 11 surface mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ✳ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. Because of potential interferences from cigarette smoke, samples were not collected on smokeres who worked inside enclosures.

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d. Miner Exposures Compared to Exposures of Other Groups

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

As estimated by the reported geometric mean,[15] the median site-specific occupational exposures for loading dock workers operating or otherwise exposed to unfiltered diesel fork lift trucks ranged from 23 to 55 μg/m^3, as measured by submicrometer elemental carbon (EC) (NIOSH, 1990). Reported geometric mean concentrations of submicrometer EC ranged from 2.0 to 7.0 μg/m^3 for truck drivers and from 4.8 to 28 μg/m^3 for truck mechanics, depending on weather conditions (Zaebst et al., 1991).

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

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

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

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

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

Still, MSHA agrees with IMC Global that better estimates of dpm exposure levels are attainable by applying conversion factors more specifically related to the separate categories within the trucking industry: dock workers, truck drivers, and truck mechanics. Based on a total of 63 field measurements, the mean ratios (in percent) of EC to total carbon (TC) reported for these three categories were 47.3, 36.6, and 34.2, respectively (Zaebst et al., 1991).[16] As explained elsewhere in this preamble, TC amounts to approximately 80 percent, by weight, of total dpm. Therefore, each of these ratios must be multiplied by 0.8 in order to estimate the corresponding percentage of EC in dpm.

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

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

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

Figure III–4 compares the range of median dpm concentrations observed for mine workers within different mines to a range of dpm exposure levels estimated for urban ambient air and to the ranges of median dpm concentrations estimated for loading dock workers operating or otherwise exposed to diesel fork lift trucks, truck drivers, truck mechanics, and railroad workers. The range for ambient air, 1 to 10 μg/m^3, was obtained from Cass and Gray (1995). For dock workers, truck drivers, truck mechanics, and railroad workers, the estimated ranges of median dpm exposures are, respectively: 61 to 145 μg/m^3, 6.8 to 24 μg/m^3, 18 to 102 μg/m^3 and 49 to 191 μg/m^3. The range of median dpm concentrations observed at different underground coal mines is 55 to 2100 μg/m^3, with filters employed at mines showing the lower concentrations.[17] For underground M/NM mines, the corresponding range is 68 to 1835 μg/m^3, and for surface mines it is 19 to 160 μg/m^3. Since each range plotted is a range of median values or (for ambient air) mean values, the plots do not encompass all of the individual measurements reported.

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

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

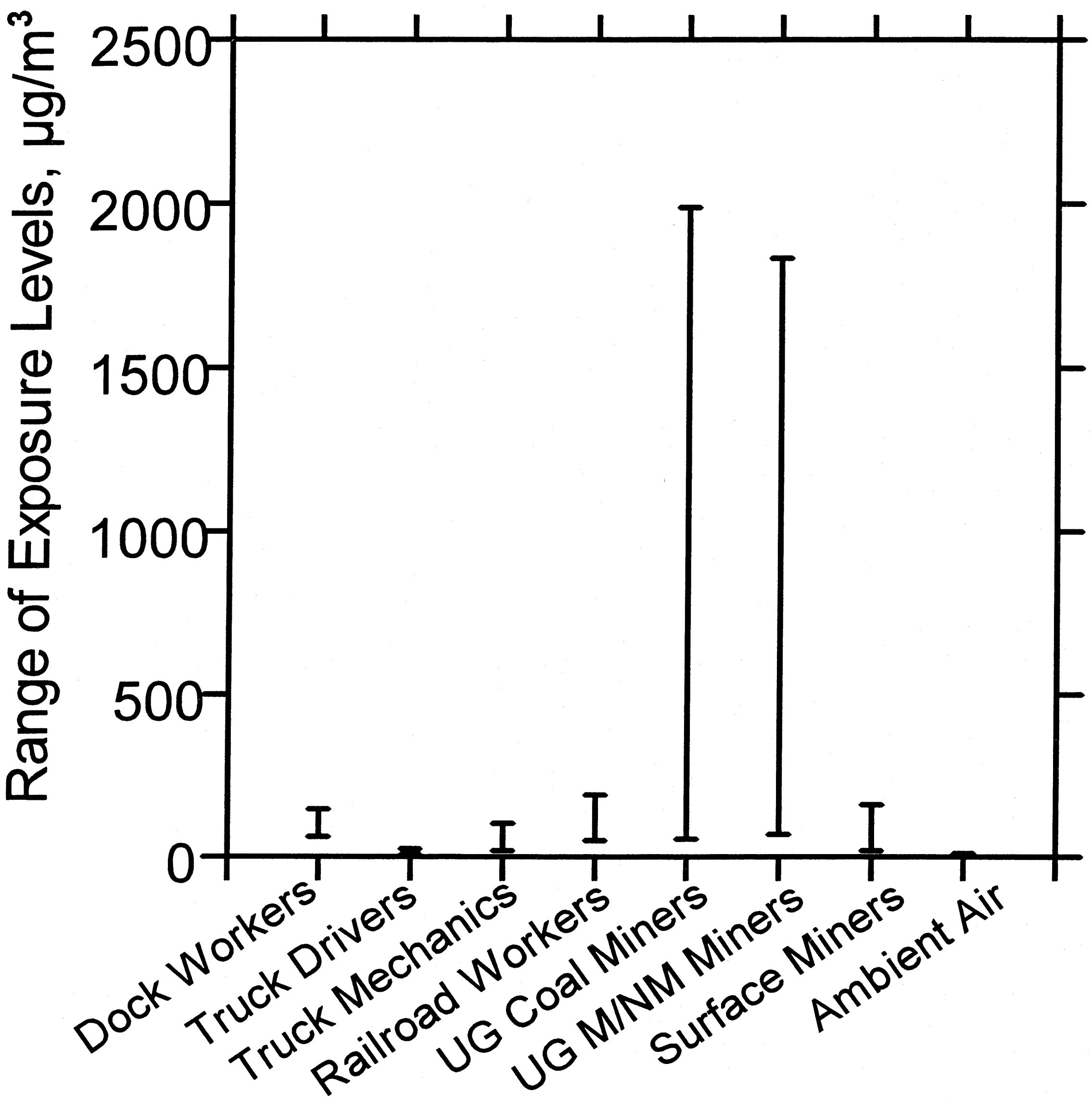

Figure III-4. — Range of median dpm exposure levels observed within various mines for underground and surface miners compared to range of median dpm exposure levels estimated for other occupations. Range of dpm exposure levels for ambient air is for urban environments only and is based on the monthly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

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As shown in Figure III–4, some miners are exposed to far higher concentrations of dpm than are any other populations for which exposure data have been reported. Indeed, median dpm concentrations observed in some underground mines are up to 200 times as high as mean environmental exposures in the most heavily polluted urban areas,[18] and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups.

Several commenters objected to Figure III–4 and, more generally, to MSHA's comparison of dpm exposure levels for miners against the levels reported for other occupations. The objections to MSHA's method of estimating ranges of median dpm exposure for job categories within the trucking industry have already been discussed and addressed above. Other objections to the comparison were based on claims of insufficient accuracy in the RCD and gravimetric size selective measurements MSHA used to measure dpm levels for miners. MSHA considers its use of these methods appropriate for purposes of this comparison and has responded to criticisms of the dpm measurements for miners in Subsections 1.a and 1.b of this risk assessment.[19]

Some commenters objected to MSHA's basing a characterization of dpm exposures to miners on data spanning a ten-year period. These commenters contended that, in at least some M/NM mines, dpm levels had improved substantially during that period. No data were submitted, however, to support the premise that dpm exposures throughout the mining industry have declined to the levels reported for other occupations. As stated in the proposal and emphasized above, MSHA's dpm measurements were not technically designed as a random or statistically representative sample of the industry. They do show, however, that very high exposures have recently occurred in some mines. For example, as shown in Figure III–2, more than 25 percent of MSHA's dpm measurements exceeded 2000 $\mu g/m^3$ at underground M/NM mines ''U'' and ''Z''—and these measurements were made in 1996–7. In M/NM mines where exposures are actually commensurate with other industries already, little or nothing would need to be changed to meet the exposure limits.

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

2. Health Effects Associated With Dpm Exposures

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

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

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

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

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

A fourth report (Glenn *et al.*, 1983) summarized results from the overall research program of which the coal mine studies were a part. This health and environmental research program included not only coal miners, but also workers at potash, trona, salt, and metal mines. All subjects were given chest radiographs and spirometric tests and were questioned about respiratory symptoms, smoking and occupational history. In conjunction with these medical evaluations, industrial hygiene surveys were conducted to characterize the mine environments where diesel equipment was used. Diesel exhaust exposure levels were characterized by area and personal samples of NO2 (and, in some cases, additional gasses), aldehydes, and both respirable and total dust. For the evaluations of acute effects, exposure measures were based on the shift concentrations to which the examined workers were exposed. For the evaluations of chronic effects, exposures were usually estimated by summing the products of time spent in various locations by each miner by concentrations estimated for the various locations. Results of studies on acute effects in salt mines were reported by Gamble *et al.* (1978) and are considered

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

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

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

a. Relevancy Considerations

i. Animal Studies

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

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

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

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

One commenter objected to MSHA's reference to using animal studies as a ''check'' on epidemiologic studies. This commenter emphasized that animal studies provide far more than just corroborative information and that researches use epidemiologic and animal studies ''* * * to help understand different aspects of the carcinogenic process.'' [20] MSHA does not dispute the utility of animal studies in helping to provide an understanding of toxicological processes and did not intend to belittle their importance for this purpose. In fact, MSHA places the bulk of its discussion of these studies in a section entitled ''Mechanisms of Toxicity.'' However, MSHA considers the use of animal studies for corroborating epidemiologic associations to be also important—especially with respect to ruling out potential confounding effects and helping to establish causal linkages. Animal studies make possible a degree of experimental design and statistical rigor that is not attainable in human studies.

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

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

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

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

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

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

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

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

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

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

findings and to identify and explore potential mechanisms of toxicity.

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

ii. Reversible Health Effects

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

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

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

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

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

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

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

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

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

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

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

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

iii. Health Effects Associated with $PM_{2.5}$ in Ambient Air

There have been many studies in recent years designed to determine whether the mix of particulate matter in ambient air is harmful to health. The evidence linking particulates in air pollution to health problems has long been compelling enough to warrant direction from the Congress to limit the concentration of such particulates (see part II, section 5 of this preamble). In recent years, the evidence of harmful effects due to airborne particulates has increased, suggesting that ''fine'' particulates (i.e., particles less than 2.5

µm in diameter) are more strongly associated than ''coarse'' respirable particulates (i.e., particles greater than 2.5 µm but less than 10 µm in diameter) with the adverse health effects observed (EPA, 1996).

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

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

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

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

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

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

b. Acute Health Effects

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

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

i. Symptoms Reported by Exposed Miners

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

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

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

Other miners working at dieselized coal mines testified at those hearings that they had personally experienced eye irritation and/or respiratory ailments immediately after exposure to diesel exhaust, and they attributed these ailments to their exposure. For example, one miner attributed a case of pneumonia to a specific episode of unusually high exposure. (Birm., 1998) The safety and training manager of the mining company involved noted that ''there had been a problem recognized in review with that exhaust system on that particular piece of equipment'' and that the pneumonia may have developed due to ''idiosyncracy of his lungs that respond to any type of a respiratory irritant.'' The manager suggested that this incident should not be generalized to other situations but provided no evidence that the miner's lungs were unusually susceptible to irritation.[21]

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

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

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

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

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

In comments submitted for this rulemaking, the NMA pointed out, as has MSHA, that the evidence presented in this subsection is anecdotal. The NMA, further, suggested that the cited article by Kahn *et al.* typified this kind of evidence in that it was ''totally devoid of any correlation to actual exposure levels.'' A lack of concurrent exposure measurements is, unfortunately, not restricted to anecdotal evidence; and MSHA must base its evaluation on the available evidence. MSHA recognizes the scientific limitations of anecdotal evidence and has, therefore, compiled and considered it separately from more formal evidence. MSHA nevertheless considers such evidence potentially valuable for identifying acute health hazards, with the understanding that confirmation requires more rigorous investigation.[22]

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

> * * * neglects to include in the preamble the article's description of the conditions under which the ''overexposures'' occurred, *e.g.,* ''poor engine maintenance, poor maintenance of emission controls, prolonged idling of machinery, engines pulling heavy loads, use of equipment during times when ventilation was disrupted (such as during a move of longwall machinery), use of several pieces of equipment exhausting into the fresh-air intake, and use of poor quality fuel. The NMA asserted that these conditions, cited in the article, ''have been addressed by MSHA's final standards for diesel equipment in underground coal mines issued October 25, 1996.''[23] Furthermore, despite its reservations about anecdotal evidence:

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

The NMA provided no evidence, however, that elimination of the conditions described by Kahn *et al.*, or implementation of the 1996 diesel regulations for coal mines, would reduce dpm levels sufficiently to prevent the sensory irritations and respiratory symptoms described. MSHA completed an analysis of the impact of the 1996 diesel regulations for underground coal mines (See Part II, Section 7). We do expect that the concentrations of diesel emissions at the section loading point and during longwall moves will be reduced as these provisions are fully implemented. These dpm levels, though reduced, are still above the exposures expected to cause sensory irritations and respiratory symptoms (See Section 3(d)(5)). MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines when developing the 1996 underground coal diesel regulations. It was understood that the agency would be taking a separate look at the health risks of dpm exposure. In addition, the NMA did not provide evidence that these are the only conditions under which complaints of sensory irritations and respiratory symptoms occur, or explain why eliminating them would reduce the need to prevent excessive exposures under other conditions.

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

ii. Studies Based on Exposures to Diesel Emissions

Several experimental and statistical studies have been conducted to investigate acute effects of exposure to

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

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

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

diesel emissions. These more formal studies provide data that are more scientifically rigorous than the anecdotal evidence presented in the preceding subsection. Unless otherwise indicated, diesel exhaust exposures were determined qualitatively.

In a clinical study (Battigelli, 1965), volunteers were exposed to three concentrations of diluted diesel exhaust and then evaluated to determine the effects of exposure on pulmonary resistance and the degree of eye irritation. The investigators stated that ''levels utilized for these controlled exposures are comparable to realistic values such as those found in railroad shops.'' No statistically significant change in pulmonary function was detected, but exposure for ten minutes to diesel exhaust diluted to the middle level produced ''intolerable'' irritation in some subjects while the average irritation score was midway between ''some'' irritation and a ''conspicuous but tolerable'' irritation level. Diluting the concentration by 50% substantially reduced the irritation. At the highest exposure level, more than 50 percent of the volunteers discontinued the experiment before 10 minutes because of ''intolerable'' eye irritation.

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

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

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

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

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

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

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

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

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

Diaz-Sanchez *et al.* (1994) challenged healthy human volunteers by spraying

300 μg dpm into their nostrils.[24] Immunoglobulin E (IgE) binds to mast cells where it binds antigen leading to secretion of biologically active amines (*e.g.,* histamine) causing dilation and increased permeability of blood vessels. These amines are largely responsible for clinical manifestations of such allergic reactions as hay fever, asthma, and hives. Enhanced IgE levels were found in nasal washes in as little as 24 hours, with peak production observed 4 days after the dpm was administered.[25] No effect was observed on the levels of other immunoglobulin proteins. The selective enhancement of local IgE production was demonstrated by a dramatic increase in IgE-secreting cells. The authors suggested that dpm may augment human allergic disease responses by enhancing the production of IgE antibodies. Building on these results, Diaz-Sanchez *et al.* (1996) measured cytokine production in nasal lavage cells from healthy human volunteers challenged with 150 μg dpm sprayed into each nostril. Based on the responses observed, including a broad increase in cytokine production, along with the results of the 1994 paper, the authors concluded that dpm exposure contributes to enhanced local IgE production and thus plays a role in allergic airway disease.

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

iii. Studies Based on Exposures to Particulate Matter in Ambient Air

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

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

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

These three episodes ''left little doubt about causality in regard to the induction of serious health effects by very high concentrations of particle-laden air pollutant mixtures'' and stimulated additional research to characterize exposure-response relationships (EPA, 1996). Based on several analyses of the 1952 London data, along with several additional acute exposure mortality analyses of London data covering later time periods, the U.S. Environmental Protection Agency (EPA) concluded that increased risk of mortality is associated with exposure to combined particulate and SO_2 levels in the range of 500–1000 $\mu g/m^3$. The EPA also concluded that relatively small, but statistically significant increases in mortality risk exist at particulate (but not SO_2) levels below 500 $\mu g/m_3$, with no indications of a specific threshold level yet indicated at lower concentrations (EPA, 1986).

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

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

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

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

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

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

[†] All references are from EPA, 1996

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

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

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

References from EPA, 1996, Staff Report

[A] Schwartz et al. (1996a)
[B] Burnett et al. (1994)
[C] Burnett et al. (1995) O_3
[D] Thurston et al. (1992, 1994)
[E] Neas et al. (1995)
[F] Ostro et al. (1993)
[G] Schwartz et al. (1994)
[P] Ostro et al. (1991)
[Q] Koenig et al. (1993)

† Min/Max 24-hr PM indicator level shown in parentheses unless otherwise noted as (±S.D.), 10 and 90 percentile (10,90).
* Change per 100 nmoles/m^3.
** Change per 20 $\mu g/m^3$ for $PM_{2.5}$; per 5 $\mu g/m^3$ for $PM_{2.5}$ sulfur; per 25 nmoles/m^3 for H^+.
*** 50th percentile value (10,90 percentile).
**** Coefficient and SE in parenthesis.

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

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

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

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

c. Chronic Health Effects

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

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

i. Studies Based on Exposures to Diesel Emissions

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

(1) Chronic Effects Other Than Cancer

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

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

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

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

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

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

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

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

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

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

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

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

(2) Cancer

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

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

(a) Lung Cancer

MSHA evaluated 47 epidemiologic studies examining the prevalence of lung cancer within groups of workers occupationally exposed to dpm. This includes four studies not included in MSHA's risk assessment as originally proposed.[26] The earliest of these studies was published in 1957 and the latest in 1999. The most recent published reviews of these studies are by Mauderly (1992), Cohen and Higgins (1995), Muscat and Wynder (1995), IPCS (1996), Stöber and Abel (1996), Cox (1997), Morgan et al. (1997), Cal–EPA (1998), ACGIH (1998), and U.S. EPA (1999). In response to both the ANPRM and the 1998 proposals, several commenters also provided MSHA with

[26] One of these studies (Christie et al., 1995) was cited in the discussion on mechanisms of toxicity but not considered in connection with studies involving dpm exposures. Several commenters advocated that it be considered. The other three were published in 1997 or later. Johnston et al. (1997) was introduced to these proceedings in 64 FR 7144. Säverin et al. (1999) is the published English version of a Germany study submitted as part of the public comments by NIOSH on May 27, 1999. The remaining study is Brüske-Hohlfeld et al. (1999).

their own reviews of many of these studies. In arriving at its conclusions, MSHA considered all of these reviews, including those of the commenters, as well as the 47 source studies available to MSHA.

In addition, MSHA relied on two comprehensive statistical ''meta-analyses'' [27] of the epidemiologic literature: Lipsett and Campleman (1999) thru [28] and Bhatia et al. (1998).[29] These meta-analyses, which weight, combine, and analyze data from the various epidemiologic studies, were themselves the subject of considerable public comment and are discussed primarily in Subsection 3.a.iii of this risk assessment. The present section tabulates results of the studies and addresses their individual strengths and weaknesses. Interpretation and evaluation of the collective evidence, including discussion of potential publication bias or any other systematic biases, is deferred to Subsection 3.a.iii.

Tables III–4 (27 cohort studies) and III–5 (20 case-control studies) identify all 47 known epidemiologic studies that MSHA considers relevant to an assessment of lung cancer risk associated with dpm exposure.[30] These tables include, for each of the 47 studies listed, a brief description of the study and its findings, the method of exposure assessment, and comments on potential biases or other limitations. Presence or absence of an adjustment for smoking habits is highlighted, and adjustments for other potentially confounding factors are indicated when applicable. Although MSHA constructed these tables based primarily on its own reading of the 48 source publications, the tables also incorporate strengths and weaknesses noted in the literature reviews and/or in the public comments submitted.

Some degree of association between occupational dpm exposure and an excess prevalence of lung cancer was reported in 41 of the 47 studies reviewed by MSHA: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Despite some commenters' use of conflicting terminology, which will be addressed below, MSHA refers to these 41 studies as ''positive.'' The 22 positive cohort studies in Table III–4 are identified as those reporting a relative risk (RR) or standardized mortality ratio (SMR) exceeding 1.0. The 19 positive case-control studies in Table III–5 are identified as those reporting an RR or odds ratio (OR) exceeding 1.0. A study does not need to be statistically significant (at the 0.05 level) or meet all criteria described, in order to be considered a ''positive'' study. The six remaining studies were entirely negative: they reported a deficit in the prevalence of lung cancer among exposed workers, relative to whatever population was used in the study as a basis for comparison. These six negative studies are identified as those reporting no relative risk (RR), standard mortality ratio (SMR), or odds ratio (OR) greater than 1.0.[31]

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

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

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

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

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

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

Table III-4. — Summary of information from 27 cohort studies on lung cancer and occupational exposure to diesel exhaust.

Study	Occupation	No. of Subjects	Follow-up period	Exposure Assessment	Smk. Adj.	Findings[a]	Stat. Sig.[b]	Comments
Ahlberg et al. (1981)	Male truck drivers	35,883	1961-73	Occupation only		RR = 1.33 for drivers of "ordinary" trucks.	*	Risk relative to males employed in trades thought to have no exposure to "petroleum products or other chemicals." Comparison controlled for age and province of residence (Sweden). Based on comparison of smoking habits between truck drivers and general Stockholm population, authors concluded that excess rate of lung cancer could not be entirely attributed to smoking.
Ahlman et al. (1991)	Underground sulfide ore miners	597	1968-86	Job histories from personnel records. Measurements of alpha energy concentration from radon daughters at each mine worked.		RR = 1.45 overall. RR = 2.9 for 45-64 age group. (calculated by MSHA)		Age-adjusted relative risk compared to males living in same area of Finland. No excess observed among 338 surface workers at same mines, with similar smoking and alcohol consumption, based on questionnaire. Based on calculation of expected lung cancers due to radon, excess risk attributed by author partly to radon exposure and partly to diesel exhaust & silica exposure.
Balarajan & McDowall (1988)	Professional drivers	3,392	1950-84	Occupation only		SMR = 0.86 for taxi drivers. SMR = 1.42 for bus drivers. SMR = 1.59 for truck drivers.	*	Possibly higher rates of smoking among bus and truck drivers than among taxi drivers.
Bender et al. (1989)	Highway maintenance workers	4,849	1945-84	Occupation only		SMR = 0.69		No adjustment for healthy worker effect.
Boffetta et al. (1988)	Railroad worker Truck drivers Heavy Eq. Op's. Miners	2,973 16,208 855 2,034	1982-84	Occupation and diesel exposure by questionnaire	✔	RR = 1.24 for truck drivers. RR = 1.59 for railroad workers. RR = 2.60 for heavy Eq. Op's. RR = 2.67 for miners.	 * *	Risk relative to workers reporting that they never worked in these four occupations and were never occupationally exposed to diesel exhaust. Adjusted for age and smoking only.
	All workers	476,648				RR = 1.05 for 1-15 years. RR = 1.21 for 16+ years.		Based on self-reported exposure, relative to unexposed workers. Adjusted for occupational exposures to asbestos, coal and stone dusts, coal tar & pitch, and gasoline exhaust (in addition to age and smoking). Possible biases due to volunteered participation and elevated lung cancer rate among 98,026 subjects with unknown dpm exposure.
Christie et al. (1994, 1995)	Coal miners	23,630	1973-92	Occupation only		SMR = 0.76		No adjustment for healthy worker effect. Cohort includes workers who entered workforce up through 1992. SMR reported to be greater than for occupationally unexposed petroleum workers.

Dubrow & Wegman (1984)	Truck & tractor drivers	not reported	1971-73	Occupation only		sMOR = 1.73 based on 176 deaths.	*	Excess cancers observed over the entire respiratory system and upper alimentary tract.
Edling et al. (1987)	Bus workers	694	1951-83	Occupation only		SMR = 0.7 for overall cohort		Small size of cohort lacks statistical power to detect excess risk of lung cancer. No adjustment for healthy worker effect.
Garshick et al. (1988, 1991)	Railroad workers	55,395 (1991 report)	1959-80	Job in 1959 & years of diesel exposure since 1959		RR = 1.31 for 1-4 years. RR = 1.28 for 5-9 years. RR = 1.19 for 10-14 years. RR = 1.40 for 15 or more years.	* * * *	Adjusted for attained age (1991 report). Cumulative diesel exposure-years lagged by 5 years. Subjects with likely asbestos exposure excluded from cohort. Statistically significant results corroborated if 12,872 shopworkers and hostlers possibly exposed to asbestos are also excluded. Missing 12% of death certificates. Cigarette smoking judged to be uncorrelated with diesel exposure within cohort. Higher RR for each exposure group if shopworkers and hostlers are excluded.
Guberan et al. (1992)	Professional drivers	1,726	1961-86	Occupation only		SMR = 1.50	*	Approximately 1/3 to 1/4 of cohort reported to be long-haul truck drivers. SMR based on regional lung cancer mortality rate.
Gustafsson et al. (1986)	Dock workers	6,071	1961-80	Occupation only		SMR = 1.32 (mortality). SMR = 1.68 (morbidity).	* *	No adjustment for healthy worker effect.
Gustavsson et al. (1990)	Bus garage workers	708	1952-86	Semi-quantitative, based on job history & exposure intensity estimated for each job.		SMR = 1.22 for overall cohort. SMR = 1.27 for highest-exposed subgroup.		Lack of statistical significance may be attributed to small size of cohort.
Hansen (1993)	Truck drivers	14,225	1970-80	Occupation only		SMR = 1.60 for overall cohort. Some indication of increasing SMR with age (i.e., greater cumulative exposure).	*	Compared to unexposed control group of 38,301 laborers considered to "resemble the group of truck drivers in terms of work-related demands on physical strength and fitness, educational background, social class, and life style." Correction for estimated differences in smoking habits between cohort and control group reduces SMR from 1.60 to 1.52. Results judged "unlikely *** [to] have been seriously confounded by smoking habit differences."

Howe et al. (1983)	Railroad workers	43,826	1965-77	Jobs classified by diesel exposure		RR = 1.20 for "possibly exposed." RR = 1.35 for "probably exposed."	* *	Risk is relative to unexposed subgroup of cohort. Similar results obtained for coal dust exposure. Possible confounding with asbestos and coal dust.
Johnston et al. (1997)	Underground coal miners	18,166	1950-85	Quantitative, based on detailed job history & surrogate dpm measurements	✔	mine-adjusted model: RR = 1.156 per g-hr/m^3 mine-unadjusted model: RR = 1.227 per g-hr/m^3		Risk is relative to unexposed workers in cohort. Adjusted for age, smoking habit & intensity, mine site, and cohort entry date. Mine site highly correlated with dpm exposure. Both models lag exposure by 15 years.
Kaplan (1959)	Railroad workers	Approx. 32000	1953-58	Jobs classified by diesel exposure		SMR=0.88 for operationally exposed. SMR = 0.72 for somewhat exposed. SMR = 0.80 for rarely exposed.		No adjustment for healthy worker effect. Clerks (in rarely exposed group) found more likely to have had urban residence than occupationally exposed workers. No attempt to distinguish between diesel and coal-fired locomotives. Results may be attributable to short duration of exposure and/or inadequate follow-up time.
Leupker & Smith (1978)	Truck drivers	183,791	May-July, 1976	Occupation only		SMR = 1.21		Lack of statistical significance may be due to inadequate follow-up period. Retirees excluded from cohort, so lung cancers occurring after retirement were not included.
Lindsay et al. (1993)	Truck drivers	not reported	1965-79	Occupation only		SMR = 1.15	*	
Menck & Henderson (1976)	Truck drivers	34,800 estimated	1968-73	Occupation only		SMR = 1.65	*	Number of subjects in cohort estimated from census data.
Raffle (1957)	Transport engineers	2,666 estimated from manyears at risk	1950-55	Occupation only		SMR = 1.42		SMR calculated by combining data presented for four quadrants of London. Excluded most retirees and lung cancers occurring after retirement.
Rafnsson & Gunnarsdottir (1991)	Truck drivers	868	1951-88	Occupation only		SMR = 2.14	*	No trend of increasing risk with increased duration of employment or increased follow-up time. Based on survey of smoking habits in cohort compared to general male population, and fact that there were fewer than expected deaths from respiratory disease, authors concluded that differences in smoking habits were unlikely to be enough to explain excess rate of lung cancer. However, not all trucks were diesel prior to 1951, and there is possible confounding by asbestos exposure.

Rushton et al. (1983)	Bus maintenance workers	8,480	5.9 yrs (mean)	Occupation only		SMR = 1.01 for overall cohort. SMR = 1.33 for "general hand" subgroup.	 *	Short follow-up period. SMR based on comparison to national rates, with no adjustment for regional or socioeconomic differences, which could account for excess lung cancers observed among general hands. No adjustment for healthy worker effect.
Säverin et al. (1999)	Underground potash miners	5,536	1970-94	Quantitative, based on TC measurements & detailed job history		RR = 2.17 for highest compared to least exposed categories. RR=1.03 to 1.225 per mg-yr/m^3, depending on statistical model & inclusion criteria.		Based on routine measurements, miners determined to have had no occupational exposure to radon progeny. Authors judged asbestos exposure minor, with negligible effects. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Schenker et al. (1984)	Railroad workers	2,519	1967-79	Job histories, with exposure classified as unexposed, high, low, or undefined.		RR = 1.50 for low exposure subgroup. RR = 2.77 for high exposure subgroup.		Risk relative to unexposed subgroup. Jobs considered to have similar socioeconomic status. Differences in smoking calculated to be insufficient to explain findings. Possible confounding by asbestos exposure.
Waller (1981)	Bus workers	16,828 Est. from manyears at risk	1950-74	Occupation only		SMR = 0.79 for overall cohort.		Lung cancers occurring after retirement or resignation from London Transport Authority were not counted. No adjustment for healthy worker effect.
Waxweiler et al. (1973)	Potash miners	3,886	1941-67	Miners classified as underground or surface		SMR = 1.1 for both underground and surface miners.		No adjustment for healthy worker effect. SMR based on national lung cancer mortality, which is about 1/3 higher than lung cancer mortality rate in New Mexico, where miners resided. Authors judged this to be balanced by smoking among miners. A substantial percentage of the underground subgroup may have had little or no occupational exposure to diesel exhaust.
Wong et al. (1985)	Heavy equipment operators	34,156	1964-78	Job histories, latency, & years of union membership		SMR = 0.99 for overall cohort. SMR = 1.07 for ≥20 yr member. SMR = 1.12 for ≥20 yr. latency. SMR = 1.30 for 4,075 "normal" retirees. SMR = 3.43 for "high exposure" dozer operators with 15-19 yr union membership & ≥20 yr latency.	 * *	Increasing trend in SMR with latency and (up to 15 yr) with duration of union membership. No adjustment for healthy worker effect.

[a] RR = Relative Risk; SMR = Standardized Mortality Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.

[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

Table III-5. — Summary of published information from 20 case-control studies on lung cancer and exposure to diesel exhaust.

Study	Cases	Controls	No. of Cases	No. of Controls	Exposure Assessment	Matching Smk.	Matching Additional	Findings[a]	Stat. Sig.[b]	Comments
Benhamou et al. (1988)	Histologically confirmed lung cancers	Non-tobacco related diseases	1,625	3,091	Occupational history by questionnaire.	✔	Sex, age at diagnosis, hospital, interviewer.	RR = 2.14 for miners RR = 1.42 for professional drivers.	* *	Mine type not reported. No evidence of an increase in risk with duration of exposure
Boffetta et al. (1990)	Hospitalized males with histologically confirmed lung cancer	Hospitalized males with no tobacco related disease	2,584	5,099	Occupation classified by probability of diesel exposure	✔	Sex, age within 2 yr, hospital, year of interview.	OR = 0.95 for 13 jobs with probable exposure. OR = 1.49 for more than 30 yr in "probable" jobs.		Adjusted for race, asbestos exposure, education, & number of cigarettes per day.
			477	846	Occupational history & duration of diesel exposure by interview			OR = 1.21 for any self-reported diesel exposure. OR = 2.39 for more than 30 yr of self-reported diesel exposure.		
Brüske-Hohlfeld et al. (1999)	Cytologically and/or histologically confirmed lung cancers	Randomly selected from compulsory registries of residents.	3,498	3,541	Occupational history by interview; total duration of diesel exposure compiled from individual job episodes.	✔	Sex, age, region of residence.	OR = 1.43 for any occupational diesel exposure during lifetime. OR = 1.56 for West German professional drivers post-1955. OR = 2.88 for > 20 yr in "traffic-related" jobs other than driving. OR = 6.81 for > 30 yr as full-time driver of farm tractors. OR = 4.30 for > 20 yr as heavy equipment operator.	* * * * *	Adjusted for cumulative smoking & asbestos exposure. All interviews conducted directly with cases and controls. Lack of elevated risk for East German professional drivers attributed to relatively low traffic density & low proportion of vehicles with diesel engines in East Germany. Non-driving "traffic-related jobs" include switchmen & operators of diesel locomotives & forklifts.
Buiatti et al. (1985)	Histologically confirmed lung cancers	Patients at same hospital	376	892	Occupational history from interview	✔	Sex, age, admission date.	OR = 1.8 for taxi drivers.		Adjusted for current and past smoking patterns and for asbestos exposure.

Coggon et al. (1984)	Lung cancer deaths of males under 40	Deaths from other causes in males under 40	598	1,180	Occupation from death certificate, classified as high, low, or no diesel exposure		Sex, death year, region, and birth year (approx.)	RR = 1.3 for all jobs with diesel exposure. RR=1.1 for jobs classified as high exposure.	*	Only most recent full-time occupation recorded on death certificate.
Damber & Larsson (1985)	Male patients with lung cancer	One living and one deceased without lung cancer	604	1,071	Job, with tenure, from mailed questionnaire	✔	Sex, death year, age, municipality	RR = 1.9 for non-smoking truck drivers aged <70 yr. RR = 4.5 for non-smoking truck drivers aged ≥70 yr.	*	Ex-smokers who did not smoke for at least last 10 years included with non-smokers.
DeCoufle et al. (1977)	Male patients with lung cancer	Non-neoplastic disease patients	6,434	Not reported	Occupation only, from questionnaire	✔	Unmatched	RR = 0.92 for bus, taxi, and truck drivers. RR = 0.94 for locomotive engineers.		Selected occupation compared to clerical workers. Positive associations found before smoking adjustment.
Emmelin et al. (1993)	Deaths from primary lung cancer among dock workers	Dock workers without lung cancer	50	154	Semi-quantitative from work history & records of diesel fuel usage	✔	Date of birth, port, and survival to within 2 years of case's diagnosis of lung cancer	RR = 1.6 for "medium" duration of exposure. RR = 2.9 for "high" duration of exposure.		Increasing relative risk also observed using exposure estimates based on machine usage & diesel fuel consumption. Confounding from asbestos may be significant.
Garshick et al. (1987)	Deaths with primary lung cancer among railroad workers	Deaths from other than cancer, suicide, accidents, or unknown causes	1,256	2,385	Job history and tenure combined with current exposure levels measured for each job	✔	Date of birth and death	RR = 1.41 for 20+ diesel-years in workers aged ≤ 64 yr. RR = 0.91 for 20+ diesel-years in workers aged ≥65 yr.	*	Adjusted for asbestos exposure. Older workers had relatively short diesel exposure, or none.
Gustavsson et al. (1990)	Deaths from lung cancer among bus garage workers	Non-cases within cohort mortality study	20	120	Semi-quantitative based on job, tenure, & exposure class for each job		Born within two years of case.	RR = 1.34, 1.81, and 2.43 for increasing cumulative diesel exposure categories, relative to lowest exposure category.	*	Authors judged smoking habits to be similar for different exposure categories. RR did not increase with increasing asbestos exposure
Hall & Wynder (1984)	Hospitalized males with lung cancer	Hospitalized males with no tobacco-related diseases	502	502	Usual occupation by interview	✔	Age, race, hospital, and hospital room status	RR = 1.4 for jobs with diesel exposure. RR = 1.9 for heavy equipment operators & repairmen.		Confounding with other occupational exposures possible.

Hayes et al. (1989)	Lung cancer deaths pooled from 3 studies	Various -- lung disease excluded	2,291	2,570	Occupational history by interview	✔	Sex, age, and either race or area of residence	OR = 1.5 for ≥10 yr truck driving. OR = 2.1 for ≥10 yr operating heavy equipment. OR = 1.7 for ≥10 yr bus driving.	*	OR adjusted for birth-year cohort and state of residence (FL, NJ, or LA), in addition to average cigarette use. Smaller OR for <10 yr in these jobs.
Lerchen et al. (1987)	New Mexico residents with lung cancer	Medicare recipients	506	771	Occupational history, industry, & self-reported exposure, by interview	✔	Sex, age, ethnicity	OR = 0.6 for ≥1 yr occupational exposure to diesel exhaust. OR = 2.1 for underground non-uranium mining.		Small number of cases and controls in diesel-exposed jobs. Possibly insufficient exposure duration. Not matched on date of birth or death.
Milne et al. (1983)	Lung cancer deaths	Deaths from any other cancer	925	6,565	Occupation from death certificate		None	OR = 3.5 for bus drivers. OR = 1.6 for truck drivers.	*	Inadequate latency allowance.
Morabia et al. (1992)	Male lung cancer patients	Patients without lung cancer or other tobacco-related condition	1,793	3,228	Job, with coal and asbestos exposure durations, by interview	✔	Race, age, hospital, and smoking history	OR = 2.3 for miners. OR = 1.1 for bus drivers. OR = 1.0 for truck or tractor drivers.	.	Mine type not specified. Potential confounding by other occupational exposures for miners.
Pfluger and Minder (1994)	Professional drivers	Workers in occupational categories with no known excess lung cancer risk.	284	1,301	Occupation only, from death certificate.		None.	OR = 1.48 for professional drivers.	*	Stratified by age. Indirectly adjusted for smoking, based on smoking-rate for occupation.
Siemiatycki et al. (1988)	Squamous cell lung cancer patients by type of lung cancer	Other cancer patients	359	1,523	Semi-quantitative, from occupational history by interview, & exposure class for each job	✔	None	OR = 1.2 for diesel exposure; OR = 2.8 for mining.		Stratified by age, socioeconomic status, ethnicity, and blue- vs. white-collar job history. Examination of files indicated that most miners "were exposed to diesel exhaust for short periods of time." Mining included quarrying, so result is likely to be confounded by silica exposure.

Steenland et al. (1990, 1992, 1998)	Deaths from lung CA among Teamsters	Deaths other than lung or bladder cancer or motor vehicle accidents	996	1,085	Occupational history and tenure from next-of-kin, supplemented by IH data	✔	Time of death within 2 years	OR = 1.27 for diesel truck drivers with 1-24 yr tenure.		Years of tenure not necessarily all at main job (i.e., diesel truck driver).
								OR = 1.26 for diesel truck drivers with 25-34 yr tenure.		
								OR = 1.89 for diesel truck drivers with ≥35 yr tenure.	*	OR adjusted for asbestos exposure.
								OR = 1.50 for truck mechanics with ≥18 yr tenure after 1959.		
Swanson et al. (1993) See also Burns & Swanson (1991)	Histologically confirmed Detroit metro area lung cancers	Colon or rectal cancer cases	3,792 males 5,935 total	1,966 males 3,956 total	Occupational history from interview	✔	None	OR = 1.4 for heavy truck drivers with 1-9 yr tenure.		OR for truck drivers & RR workers is for white males, relative to corresponding group with <1 yr tenure, adjusted for age at diagnosis. Pattern of increasing risk with duration of employment also reported for black male railroad workers, based on fewer cases. (1993 report)
								OR = 1.6 for heavy truck drivers with 10-19 yr tenure.		
								OR = 2.5 for heavy truck drivers with ≥20 yr tenure.	*	
								OR = 1.2 for railroad workers with 1-9 yr tenure.		
								OR = 2.5 for railroad workers with ≥10 yr tenure.	*	
								OR = 2.98 for mining industry workers.	*	OR for mining machinery operators and mining is for all males, adjusted for race and age at diagnosis. Type of mining not reported. Potential confounding by other occupational exposures. (1991 report)
								OR = 5.03 for mining machinery operators.	*	
Williams et al. (1977)	Male lung cancer patients	Other male cancer patients	432	2,817	Main lifetime occupation from interview	✔	Sex	OR = 1.52 for male truck drivers.		Controlled for age, race, alcohol use, and socioeconomic status. Unexplained discrepancies in reported number of controls.

[a] RR = Relative Risk; OR = Odds Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.

[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

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(i) Evaluation Criteria

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

(1) power of the study to detect an exposure effect;

(2) composition of comparison groups;

(3) exposure assessment;

(4) statistical significance; and

(5) potential confounders.

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

Power of the Study

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

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

Some of the 41 positive studies also had little power, either because they included relatively few exposed workers (*e.g.,* Lerchen et al., 1987, Ahlman et al., 1991; Gustavsson et al., 1990) or an inadequate latency allowance or follow-up period (*e.g.,* Leupker and Smith (1978); Milne, 1983; Rushton et al., 1983). In those based on few exposed workers, there is a strong possibility that the positive association arose merely by chance.[32] The other studies, however, found increased prevalence of lung cancer despite the relatively short periods of latency and follow-up time involved. It should be noted that, for reasons other than lack of power, MSHA places very little weight on the Milne and Rushton studies. As mentioned in Table III–4, the Rushton study compared the cohort to the national population, with no adjustment for regional or socioeconomic differences. This may account for the excess rate of lung cancers reported for the exposed ''general hand'' job category. The Milne study did not control for potentially important ''confounding'' variables, as explained below in MSHA's discussion of that criterion.

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

Composition of Comparison Groups

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

In several of the studies, a group identified with diesel exposure may have systematically included workers who, in fact, received little or no occupational diesel exposure. For example, a substantial percentage of the ''underground miner'' subgroup in Waxweiler et al. (1973) worked in underground mines with no diesel equipment. This would have diluted any effect of dpm exposure on the group of underground miners as a whole.[33] Similarly, the groups classified as miners in Benhamou et al. (1988), Boffetta et al. (1988), and Swanson et al. (1993) included substantial percentages of miners who were probably not occupationally exposed to diesel emissions. Potential effects of exposure misclassification are discussed further under the criterion of ''Exposure Assessment'' below.

Selection bias refers to systematic differences in characteristics of the comparison groups due to the criteria and/or methods used to select those included in the study. For example, three of the cohort studies (Raffle, 1957; Leupker and Smith, 1976; Waller, 1981) systematically excluded retirees from the cohort of exposed workers—but not

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

from the population used for comparison. Therefore, cases of lung cancer that developed after retirement were counted against the comparison population but not against the cohort. This artificially reduced the SMR calculated for the exposed cohort in these three studies.

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

MSHA judged that seven of the 20 available case-control studies were susceptible to this type of selection bias because controls were drawn from a population of ''other deaths'' or ''other patients.'' [34] These control groups were likely to have over-represented cases of cardiovascular disease, which is known to be highly correlated with smoking and is possibly also correlated with occupation. The only case-control study not reporting a positive result (DeCoufle et al., 1977) fell into this group of seven. The remaining 13 case-control studies all reported positive results.

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

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

Many of the 41 positive studies also drew comparisons against the general population with no compensating adjustment for the healthy worker effect. But the healthy worker effect can influence results even when the age-adjusted mortality or morbidity rate observed among exposed workers is greater than that found in the general population. In such studies, comparison with the general population tends to reduce the excess risk attributable to the substance being investigated. For example, Gustafsson et al. (1986), Rushton et al. (1983), and Wong et al. (1985) each reported an unadjusted SMR exceeding 1.0 for lung cancer in exposed workers and an SMR significantly less than 1.0 for all causes of death combined. Since the SMR for all causes is less than 1.0, there is evidence of a healthy worker effect. Therefore, the SMR reported for lung cancer was probably lower than if the comparison had been made against a more similar population of unexposed workers. Bhatia et al. (1998) constructed a simple estimate of the healthy worker effect evident in these studies, based on the SMR for all causes of death except lung cancer. This estimate was then used to adjust the SMR reported for lung cancer. For the three positive studies mentioned, the adjustment raised the SMR from 1.29 to 1.48, from 1.01 to 1.23, and from 1.07 to 1.34, respectively. [35]

Exposure Assessment

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

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

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

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

The highest rank, with respect to this criterion, is reserved for studies having quantitative, concurrent exposure measurements for specific workers or for specific jobs coupled with detailed work histories. Only two studies (Johnston et al., 1997 and Säverin et al., 1999) fall into this category.[36] Both of these recent cohort studies took smoking habits into account. These

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

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

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

studies both reported an excess risk of lung cancer associated with dpm exposure.

The second rank is defined by semi-quantitative exposure assessments, based on job history and an estimated exposure level for each job. The exposure estimates in these studies are crude, compared to those in the first rank, and they are subject to many more kinds of error. This severely restricts the utility of these studies for QRA (i.e., for quantifying the change in risk associated with various specified exposure levels). For purposes of hazard identification and characterization, however, crude exposure estimates are better than no exposure estimates at all. MSHA places two cohort studies and five case-control studies into this category.[37] All seven of these studies reported an excess risk of lung cancer risk associated with diesel exposure. Thus, results were positive in all nine studies with quantitative or semi-quantitative exposure assessments.

The next rank belongs to those studies with only enough information on individual workers to construct estimates of exposure duration. Although these studies present no data relating excess risk to specific exposure levels, they do provide excess risk estimates for those working a specified minimum number of years in a job associated with diesel exposure. One cohort study and five case-control studies fall into this category, and all six of them reported an excess risk of lung cancer.[38] With one exception (Benhamou et al. 1988), these studies also presented evidence of increased age-adjusted risk for workers with longer exposures and/or latency periods.

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

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

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

Statistical Significance

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

As explained earlier, MSHA classifies a reported RR, SMR, or OR (i.e., the point estimate of relative risk) as ‘‘positive’’ if it exceeds 1.0 and ‘‘negative’’ if it is less than or equal to 1.0. By common convention, a positive result is considered statistically significant if its 95-percent confidence interval does not overlap 1.0. If all other relevant factors are equal, then a statistically significant positive result provides stronger evidence of an underlying relationship than one that is not statistically significant. On the other hand, a study must meet two requirements in order to provide statistically significant evidence of no positive relationship: (1) the upper limit of its 95-percent confidence interval must not exceed 1.0 by an appreciable amount[39] and (2) it must have allowed for sufficient exposure, latency, and follow-up time to have detected an existing relationship.

As shown in Tables III–4 and III–5, statistically significant positive results were reported in 25 of the 47 studies: 11 of the 19 positive case-control studies and 14 of the 22 positive cohort studies. In 16 of the 41 studies showing a positive association, the association observed was not statistically significant. Results in five of the six negative studies were not statistically significant. One of the six negative studies (Christie et al., 1995, in full version), reported a statistically significant deficit in lung cancer for miners. This study, however, provided for no minimum period of exposure or latency and, therefore, lacked the power necessary to provide statistically significant evidence.[40]

Whether or not a study provides statistically significant evidence is dependent upon many variables, such as study size, adequate follow-up time (to account for enough exposure and latency), and adequate case ascertainment. In the ideal world, a

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

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

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

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

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

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

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

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

Potential Confounders

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

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

The first approach requires a high degree of control over the two groups being compared (exposed and unexposed in a cohort study; with and without lung cancer in a case-control study). For example, the effects of age in a case-control study can be controlled by matching each case of lung cancer with one or more controls having the same year of birth and age in year of diagnosis or death. Matching on age is never perfect, because it is generally not feasible to match within a day or even a month. Similarly, the effects of smoking in a case-control study can be imperfectly controlled by matching on smoking habits to the maximum extent possible.[41] In a cohort study, there is no confounding unless the exposed cohort and the comparison group differ with respect to a potential confounder. For example, if both groups consist entirely of never-smokers, then smoking is not a confounder in the study. If both groups contain the same percentage of smokers, then smoking is still an important confounder to the extent that smoking intensity and history differ between the two groups. In an attempt to minimize such differences (along with potentially important differences in diet and lifestyle) some studies restrict comparisons to workers of similar socioeconomic status and area of residence. Studies may also explicitly investigate smoking habits and histories and forego any adjustment of results if these factors are found to be homogeneously distributed across comparison groups. In that case, smoking would not actually appear to function as a confounder, and a smoking adjustment might not be required or even desirable. Nevertheless, a certain amount of smoking data is still necessary in order to check or verify homogeneity. The study's credibility may also be an important consideration. Therefore, MSHA agrees with the HEI's expert panel that even when smoking appears not to be a confounder,

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

However, this does not mean that a study cannot, by means of an efficient study design and/or statistical verification of homogeneity,

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

demonstrate adequate control for smoking without applying a smoking adjustment.

The second approach to dealing with a confounder requires knowledge or estimation both of the differences in group composition with respect to the confounder and of the effect that the confounder has on lung cancer. Ideally, this would entail specific, quantitative knowledge of how the variable affects lung cancer risk for each member of both groups being compared. For example, a standardized mortality ratio (SMR) can be used to adjust for age differences when a cohort of exposed workers with known birth dates is compared to an unexposed reference population with known, age-dependent lung cancer rates.[42] In practice, it is not usually possible to obtain detailed information, and the effects of smoking and other known confounders cannot be precisely quantified.

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

It should be noted, first of all, that five of the six negative studies neither matched nor adjusted for smoking.[43] But more importantly, MSHA concurs with IARC (1989), Cohen and Higgins (1995), IPCS (1996), CAL–EPA (1998), ACGIH (1998), Bhatia et al. (1998), and Lipsett and Campleman (1999) in not accepting the view that studies should automatically be disqualified from consideration because of potential confounders. MSHA recognizes that unknown exposures to tobacco smoke or other human carcinogens can distort the results of some lung cancer studies. MSHA also recognizes, however, that it is not possible to design a human epidemiologic study that perfectly controls for all potential confounders. It is also important to note that a confounding variable does not necessarily inflate an observed association. For example, if the exposed members of a cohort smoke less than the reference group to which they are compared, then this will tend to reduce the apparent effects of exposure on lung cancer development. In the absence of evidence to the contrary, it is reasonable to assume that a confounder is equally likely to inflate or to deflate the results.

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

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

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

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

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

In contrast with the two cases cited, the purpose of this risk assessment is not to establish civil liabilities for personal injury. MSHA's concern is with reducing the risk of lung cancer, not with establishing the specific cause of lung cancer for an individual miner. The excess risk of an outcome, given an excessive exposure, is not the same thing as the likelihood that an excessive exposure caused the outcome in a given case. To understand the difference, it may be helpful to consider two analogies: (1) The likelihood that a given death was caused by a lightning strike is relatively low, yet exposure to lightning is rather hazardous; (2) a specific smoker may not be able to prove that his or her lung cancer was

[42] Since these rates may vary by race, geographic region, or other factors, the validity of this adjustment depends heavily on choice of an appropriate reference population. For example, Waxweiler et al. (1973) based SMRs for a New Mexico cohort on national lung cancer mortality rates. Since the national age-adjusted rate of lung cancer is about ⅓ higher than the New Mexico rate, the reported SMRs were roughly ¾ of what they would have been if based on rates specific to New Mexico.

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

''more likely than not'' caused by radon exposure, yet radon exposure significantly increases the risk—especially for smokers. Lung cancer has a variety of alternative causes, but this fact does not reduce the risk associated with any one of them.

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

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

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

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

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

(ii) Studies Involving Miners

In the proposed risk assessment, MSHA identified seven epidemiologic studies reporting an excess risk of lung cancer among miners thought to have been exposed occupationally to diesel exhaust. As stated in the proposal, two of these studies specifically investigated miners, and the other five treated miners as a subgroup within a larger population of workers.[44] MSHA placed two additional studies specific to exposed coal miners (Christie et al., 1995; Johnston et al.,1997) into the public record with its Feb. 12, 1999 **Federal Register** notice. Another study,[45] investigating lung cancer in exposed potash miners, was introduced by NIOSH at the Knoxville public hearing on May 27, 1999 and later published as Säverin et al., 1999. Finally, one study reporting an excess risk of lung cancer for presumably exposed miners was listed in Table III–5 as originally published, and considered by MSHA in its overall assessment, but inadvertently left out of the discussion on studies involving miners in the previous version of this risk assessment.[46] There are, therefore, available to MSHA a total of 11 epidemiologic studies addressing the risk of lung cancer for miners, and five of these studies are specific to miners.

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

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

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

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

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

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

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

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

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

respirable silica dust, making it difficult to isolate the effects of a potential carcinogen.

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

With their post-hearing comments, the NMA and MARG submitted critiques by Dr. Peter Valberg and Dr. Jonathan Borak of six reports involving miners (see Footnote 42). Drs. Valberg and Borak both noted that the six studies reviewed lacked information on diesel exposure and were vulnerable to confounders and exposure misclassification. For these reasons, Dr. Valberg judged them ''particularly poor in identifying what specific role, if any, diesel exhaust plays in lung cancer for miners.'' He concluded that they do not ''implicate diesel exposure per se as strongly associated with lung cancer risk in miners.'' Similarly, Dr. Borak suggested that, since they do not relate adverse health effects in miners to any particular industrial exposure, ''the strongest conclusion that can be drawn from these six studies is that the miners in the studies had an increased risk of lung cancer.''

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

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

Case-Control Studies

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

Burns and Swanson (1991)[47] reported elevated lung cancer risk for miners and especially mining machine operators, which the authors attributed to diesel exposure. Potential confounding by other carcinogens associated with mining make the results inconclusive, but the statistically significant odds ratio of 5.0 reported for mining machine operators is high enough to cause concern with respect to diesel exposures, especially in view of the significantly elevated risks reported in the same study for other diesel-exposed occupations. The authors noted that the ''occupation most likely to have high levels of continuous exposure to diesel exhaust and to experience that exposure in a confined area has the highest elevated risks: mining machine operators.''

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

Cohort Studies

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

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

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

Boffetta et al. (1988) investigated mortality in a cohort of male volunteers who enrolled in a prospective study conducted by the American Cancer Society. Lung cancer mortality was analyzed in relation to self-reported diesel exhaust exposure and to employment in various occupations identified with diesel exhaust exposure, including mining. After adjusting for smoking patterns,[48] there was a statistically significant excess of 167 percent (RR = 2.67) in lung cancers among 2034 workers ever employed as miners, compared to workers never employed in occupations associated with diesel exposure. No analysis by type of mining was reported. Other findings reported from this study are discussed in the next subsection.

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

Several commenters reiterated two caveats expressed by the study's authors and noted in Table III–4. These are (1) that the study is susceptible to selection biases because participants volunteered and because the age-adjusted mortality rates differed between those who provided exposure information and those who did not; and (2) that all exposure information was self-reported with no quantitative measurements. Since these caveats are not specific to mining and pertain to most of the study's findings, they will be addressed when this study's overall results are described in the next subsection.

One commenter, however (Mr. Mark Kaszniak of IMC Global), argued that selection bias due to unknown diesel exposure status played an especially important role in the RR calculated for miners. About 21 percent of all participants provided no diesel exposure information. Mr. Kaszniak noted that diesel exposure status was unknown for an even larger percentage of miners and suggested that the RR calculated for miners was, therefore, inflated. He presented the following argument:

> In the miner category, this [unknown diesel exposure status] accounted for 44.2% of the study participants, higher than any other occupation studied. This is important as this group experienced a higher mortality for all causes as well as lung cancer than the analyzed remainder of the cohort. If these persons had been included in the ''no exposure to diesel exhaust group,'' their inclusion would have lowered any risk estimates from diesel exposure because of their higher lung cancer rates. [IMC Global post-hearing comments]

This argument, which was endorsed by MARG, was apparently based on a misunderstanding of how the comparison groups used to generate the RR for mining were defined.[49] Actually, persons with unknown diesel exposure status were included among the miners, but excluded from the reference population. Including sometime miners with unknown diesel exposure status in the ''miners'' category would tend to mask or reduce any strong association that might exist between highly exposed miners and an increased risk of lung cancer. Excluding persons with unknown exposure status from the reference population had an opposing effect, since they happened to experience a higher rate of lung cancer than cohort members who said they were unexposed. Therefore, removing ''unknowns'' from the ''miner'' group and adding them to the reference group could conceivably shift the calculated RR for miners in either direction. However, the RR reported for persons with unknown diesel exposure status, compared to unexposed persons, was 1.4 (ibid., p. 412)—which is smaller than the 2.67 reported for miners. Therefore, it appears more likely that the RR for mining was deflated than inflated on account of persons with unknown exposure status.

Although confounders and selection effects may have contributed to the 2.67 RR reported for mining, MSHA believes this result was high enough to support a dpm effect, especially since elevated lung cancer rates were also reported for the three other occupations associated with diesel exhaust exposure. Dr. Borak stated without justification that ''[the] association between dpm and lung cancer was confounded by age, smoking, and other occupational exposures * * *.'' He ignored the well-documented adjustments for age and smoking. Although it does not provide strong or direct evidence that dpm exposure was responsible for any of the increased risk of lung cancer observed among miners, the RR for miners is consistent with evidence provided by the rest of the study results.

Ahlman et al. (1991) studied cohorts of 597 surface miners and 338 surface workers employed at two sulfide ore mines using diesel powered front-end loaders and haulage equipment. Both of these mines (one copper and one zinc) were regularly monitored for alpha energy concentrations (i.e., due to radon progeny), which were at or below the Finish limit of 0.3 WL throughout the study period. The ore in both mines contained arsenic only as a trace element (less than 0.005 percent). Lung cancer rates in the two cohorts were compared to rates for males in the same province of Finland. Age-adjusted excess mortality was reported for both lung cancer and cardiovascular disease among the underground miners, but not among the surface workers. None of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on the alpha energy concentration measurements made for the two mines, the authors calculated that not all of the excess lung cancer for the underground miners was attributable to radon exposure. Based on a questionnaire, the authors found similar underground and surface age-specific smoking habits and alcohol consumption and determined that ''smoking alone cannot explain the difference in lung cancer mortality between the [underground] miners and surface workers. Due to the small size of the cohort, the excess lung cancer mortality for the underground miners was not statistically significant. However, the authors concluded that the portion of excess lung cancer not attributable to radon exposure could be explained by the combined effects of diesel exhaust and silica exposure. Three of the ten lung cancers reported for underground miners were experienced by conductors of diesel-powered ore trains.

Christie et al. (1994, 1995) studied mortality in a cohort of 23,630 male Australian (New South Wales, NSW)

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[48] During the public hearing on May 25, 1999, Mr. Mark Kaszniak of IMC Global incorrectly asserted that ''smoking was treated in a simplistic way in this study by using three categories: smokers, ex-smokers, and non-smokers.'' The study actually used five categories, dividing smokers into separate categories for 1–20 cigarettes per day, 21 or more cigarettes per day, and exclusively pipe and/or cigar smoking.

[49] During the public hearing on May 25, 1999, Mr. Kaszniak stated his belief that, for miners, the ''relative risk calculation excluded that 44% of folks who did not respond to the questionnaire with regards to diesel exposure.'' Contrary to Mr. Kaszniak's belief, however, the ''miners'' on which the 2.67 RR was based included all 2034 cohort members who had ever been a miner, regardless of whether they had provided diesel exposure information (see Boffetta et al., 1988, p. 409).

Furthermore, the 44.2-percent nonrespondent figure is not pertinent to potential selection bias in the RR calculation reported for miners. The group of 2034 ''sometime'' miners used in that calculation was 65 percent larger than the group of 1233 ''mainly'' miners to which the 44-percent nonrespondent rate applies. The reference group used for comparison in the calculation consisted of all cohort members ''with occupation different from those listed [i.e., railroad workers, truck drivers, heavy equipment operators, and miners] and not exposed [to diesel exhaust].'' The overall nonrespondent rate for occupations in the reference group was about 21 percent (calculated by MSHA from Table VII of Boffetta et al., 1988).

coal mine workers who entered the industry after 1972. Although the majority of these workers were underground miners, most of whom were presumably exposed to diesel emissions, the cohort included office workers and surface (''open cut'') miners. The cohort was followed up through 1992. After adjusting for age, death rates were lower than those in the general male population for all major causes except accidents. This included the mortality rate for all cancers as a group (Christie et al., 1995, Table 1). Lower-than-normal incidence rates were also reported for cancers as a group and for lung cancer specifically (Christie et al., 1994, Table 10).

The investigators noted that the workers included in the cohort were all subject to pre-employment physical examinations. They concluded that ''it is likely that the well known 'healthy worker' effect * * * was operating'' and that, instead of comparing to a general population, ''a more appropriate comparison group is Australian petroleum industry workers.'' (Christie et al., 1995) In contrast to the comparison with the population of NSW, the all-cause standardized mortality ratio (SMR) for the cohort of coal miners was greater than for petroleum workers by a factor of over 20 percent—i.e., 0.76 vs. 0.63 (ibid., p. 20). However, the investigators did not compare the cohort to petroleum workers specifically with respect to lung cancer or other causes of death. Nor did they adjust for a healthy worker effect or make any attempt to compare mortality or lung cancer rates among workers with varying degrees of diesel exposure within the cohort.

Despite the elevated SMR relative to petroleum workers, several commenters cited this study as evidence that exposure to diesel emissions was not causally associated with an increased risk of lung cancer (or with adverse health effects associated with fine particulates). These commenters apparently ignored the investigators' explanation that the low SMRs they reported were likely due to a healthy worker effect. Furthermore, since the cohort exhibited lower-than-normal mortality rates due to heart disease and non-cancerous respiratory disease, as well as to cancer, there may well have been less tobacco smoking in the cohort than in the general population. Therefore, it is reasonably likely that the age-adjusted lung cancer rate would have been elevated, if it had been adjusted for smoking and for a healthy worker effect based on mortality from causes other than accidents or respiratory disease. In addition, the cohort SMR for accidents (other than motor vehicle accidents) was significantly above that of the general population. Since the coal miners experienced an elevated rate of accidental death, they had a lower-than-normal chance to die from other causes or to develop lung cancer. The investigators made no attempt to adjust for the competing, elevated risk of death due to occupational accidents.

Given the lack of any adjustment for smoking, healthy worker effect, or the competing risk of accidental death, the utility of this study in evaluating health consequences of Dpm exposure is severely limited by its lack of any internal comparisons or comparisons to a comparable group of unexposed workers. Furthermore, even if such adjustments or comparisons were made, several other attributes of this study limit its usefulness for evaluating whether exposure to diesel emissions is associated with an increased risk of lung cancer. First, the study was designed in such a way as to allow inadequate latency for a substantial portion of the cohort. Although the cohort was followed up only through 1992, it includes workers who entered the workforce at the end of 1992. Therefore, there is no minimum duration of occupational exposure for members of the cohort. Approximately 30 percent of the cohort was employed in the industry for less than 10 years, and the maximum duration of employment and latency combined was 20 years. Second, average age for members of the cohort was only 40 to 50 years (Christie et al., p. 7), and the rate of lung cancer was based on only 29 cases. The investigators acknowledged that ''it is a relatively young cohort'' and that ''this means a small number of cancers available for analysis, because cancer is more common with advancing age * * *.'' They further noted that ''* * * the number of cancers available for analysis is increasing very rapidly. As a consequence, every year that passes makes the cancer experience of the cohort more meaningful in statistical terms.'' (ibid., p. 27) Third, miners's work history was not tracked in detail, beyond identifying the first mine in which a worker was employed. Some of these workers may have been employed, for various lengths of time, in both underground and surface operations at very different levels of diesel exposure. Without detailed work histories, it is not possible to construct even semi-quantitative measures of diesel exposure for making internal comparisons within the cohort.

One commenter (MARG) claimed that this (NSW) study ''* * * reflects the latest and best scientific evidence, current technology, and the current health of miners'' and that it ''is not rational to predicate regulations for the year 2000 and beyond upon older scientific studies * * *.'' For the reasons stated above, MSHA believes, to the contrary, that the NSW study contributes little or no information on the potential health effects of long-term dpm exposures and that whatever information it does contribute does not extend to effects, such as cancer, expected in later life.

Furthermore, three even more recent studies are available that MSHA regards as far more informative for the purposes of the present risk assessment. Unlike the NSW study, these directly address Dpm exposure and the risk of lung cancer. Two of these studies (Johnston et al., 1997; Säverin et al., 1999), both incorporating a quantitative Dpm exposure assessment, were carried out specifically on mining cohorts and will be discussed next. The third (Brüske-Hohlfeld et al., 1999) is a case-control study not restricted to miners and will be discussed in the following subsection. In accordance with MARG's emphasis on the timeliness of scientific studies, MSHA places considerable weight on the fact that all three—the most recent epidemiologic studies available—reported an association between diesel exposure and an increased risk of lung cancer.

Johnston et al. (1997) studied a cohort of 18,166 coal miners employed in ten British coal mines over a 30-year period. Six of these coal mines used diesel locomotives, and the other four were used for comparison. Historical NO_X and respirable dust concentration measurements were available, having routinely been collected for monitoring purposes. Two separate approaches were taken to estimate dpm exposures, leading to two different sets of estimates. The first approach was based on NO_X measurements, combined with estimated ratios between dpm and NO_X. The second approach was based on complex calculations involving measurements of total respirable dust, ash content, and the ratio of quartz to dust for diesel locomotive drivers compared to the ratio for face workers (ibid., Figure 4.1 and pp 25–46). These calculations were used to estimate dpm exposure concentrations for the drivers, and the estimates were then combined with traveling times and dispersion rates to form estimates of dpm concentration levels for other occupational groups. In four of the six dieselized mines, the NO_X-based and dust-based estimates of dpm were in generally good agreement, and they were combined to form time-independent estimates of shift average dpm concentration for individual seams and occupational groups within each mine. In the fifth mine, the PFR measurements were judged unreliable for reasons extensively discussed in the report, so the NO_X-based estimates were used. There was no NO_X exposure data for the sixth mine, so they used dust-based estimates of dpm exposure.

Final estimates of shift-average dpm concentrations ranged from 44 µg/m³ to 370 µg/m³ for locomotive drivers and from 1.6 µg/m³ to 40 µg/m³ for non-drivers at various mines and work locations (ibid.,Tables 8.3 and 8.6, respectively). These were combined with detailed work histories, obtained from employment records, to provide an individual estimate of cumulative dpm exposure for each miner in the cohort. Although most cohort members (including non-drivers) had estimated cumulative exposures less than 1 g-hr/m³, some members had cumulative exposures that ranged as high as 11.6 g-hr/m³ (ibid., Figure 9.1 and Table 9.1).

A statistical analysis (time-dependent proportional hazards regression) was performed to examine the relationship between lung cancer risk and each miner's estimated cumulative dpm exposure (unlagged and lagged by 15 years), attained age, smoking habit, mine, and cohort entry date. Smoking habit was represented by non-smoker, ex-smoker, and smoker categories, along with the average number of cigarettes smoked per day for the smokers. Pipe tobacco consumption was expressed by an equivalent number of cigarettes per day.

In their written comments, MARG and the NMA both mischaracterized the results of this study, apparently confusing it with a preliminary analysis of the same cohort. The preliminary analysis (one part of what Johnston et al. refer to as the ''wider mortality study'') was summarized in Section 1.2 (pp 3–5) of the 105-page report at issue, which may account for the confusion by MARG and the NMA.[50]

Contrary to the MARG and NMA characterization, Johnston et al. found a positive, quantitative relationship between cumulative dpm exposure (lagged by 15 years) and an excess risk of lung cancer, after controlling for age, smoking habit, and cohort entry date. For each incremental g-hr/m³ of cumulative occupational dpm exposure, the relative risk of lung cancer was estimated to increase by a factor of 22.7 percent. Adjusting for mine-to-mine differences that may account for a portion of the elevated risk reduced the estimated RR factor to 15.6 percent. Therefore, with the mine-specific adjustment, the estimated RR was 1.156 per g-hr/m³ of cumulative dpm exposure. It follows that, based on the mine-adjusted model, the estimated RR for a specified cumulative exposure is 1.156 raised to a power equal to that exposure. For example, $RR = (1.156)^{3.84} = 1.74$ for a cumulative dpm exposure of 3.84 g-hr/m³, and $RR = (1.156)^{7.68} = 3.04$ for a cumulative dpm exposure of 7.68 g-hr/m³.[51] Estimates of RR based on the mine-unadjusted model would substitute 1.227 for 1.156 in these calculations.

Two limitations of this study weaken the evidence it presents of an increasing exposure-response relationship. First, although the exposure assessment is quantitative and carefully done, it is indirect and depends heavily on assumptions linking surrogate measurements to dpm exposure levels. The authors, however, analyzed sources of inaccuracy in the exposure assessment and concluded that ''the similarity between the estimated * * * [dpm] exposure concentrations derived by the two different methods give some degree of confidence in the accuracy of the final values * * *.'' (ibid., pp. 71–75) Second, the highest estimated cumulative dpm exposures were clustered at a single coal mine, where the SMR was elevated relative to the regional norm. Therefore, as the authors pointed out, this one mine greatly influences the results and is a possible confounder in the study. The investigators also noted that this mine was ''* * * found to have generally the higher exposures to respirable quartz and low level radiation.'' Nevertheless, MSHA regards it likely that the relatively high dpm exposures at this mine were responsible for at least some of the excess mortality. There is no apparent way, however, to ascertain just how much of the excess mortality (including lung cancer) at this coal mine should be attributed to high occupational dpm exposures and how much to confounding factors distinguishing it (and the employees working there) from other mines in the study.

The RR estimates based on the mine-unadjusted model assume that the excess lung cancer observed in the cohort is entirely attributable to dpm exposures, smoking habits, and age distribution. If some of the excess lung cancer is attributed to other differences between mines, then the dpm effect is estimated by the lower RR based on the mine-adjusted model.

For purposes of comparison with the findings of Säverin et al.(1999), it will be useful to calculate the RR for a cumulative dpm exposure of 11.7 g-hr/m³ (i.e., the approximate equivalent of 4.9 mg-yr/m³ TC).[52] At this exposure level, the mine-unadjusted model produces an estimated $RR = (1.227)^{11.7} = 11$, and the mine-adjusted model produces an estimated $RR = (1.156)^{11.7} = 5.5$.

Säverin et al. (1999) studied a cohort of male potash miners in Germany who had worked underground for at least one year after 1969, when the mines involved began converting to diesel powered vehicles and loading equipment. Members of the cohort were selected based on company medical records, which also provided bi-annual information on work location for each miner and, routinely after 1982, the miner's smoking habits. After excluding miners whose workplace histories could not be reconstructed from the medical records (5.5 percent) and miners lost to follow-up (1.9 percent), 5,536 miners remained in the cohort. Within this full cohort, the authors defined a sub-cohort consisting of 3,258 miners who had ''worked underground for at least ten years, held one single job during at least 80% of their underground time, and held not more than three underground jobs in total.''

The authors divided workplaces into high, medium, and low diesel exposure categories, respectively corresponding

[50] Since MARG and the NMA both stressed the importance of a quantitative exposure assessment, it is puzzling that they focused on a crude SMR from the preliminary analysis and ignored the quantitative results from the subsequent analysis. Johnston et al. noted that SMRs from the preliminary analysis were consistent ''with other studies of occupational cohorts where a healthy worker effect is apparent.'' But even the preliminary analysis explored a possible surrogate exposure-response relationship, rather than simply relying on SMRs. Unlike the analysis by Johnston et al., the preliminary analysis used travel time as a surrogate measure of dpm exposure and made no attempt to further quantify dpm exposure concentrations. (ibid.,p.5)

[51] Assuming an average dpm concentration of 200 µg/m³ and 1920 work hours per year, 3.84 g-hr/m³ and 7.68 g-hr/m³ correspond to 10 and 20 years of occupational exposure, respectively.

[52] This value represents 20 years of cumulative exposure for the most highly exposed category of workers in the cohort studied by Säverin et al.

As explained elsewhere in this preamble, TC constitutes approximately 80 percent of total dpm. Therefore, the TC value of 4.9 mg-yr/m³ presented by Säverin et al. must first be divided by 0.8 to produce a corresponding dpm value of 6.12 mg-yr/m³. To convert this result to the units used by Johnston et al., it is then multiplied by 1920 work hours per year and divided by 1000 mg/g to yield 11.7 g-hr/m³. This is nearly identical to the maximum cumulative dpm exposure estimated for locomotive drivers in the study by Johnston et al. (See Johnston et al., op cit., Table 9.1.)

to production, maintenance, and workshop areas of the mine. Each of these three categories was assigned a representative respirable TC concentration, based on an average of measurements made in 1992. These averages were 390 µg/m³ for production, 230 µg/m³ for maintenance, and 120 µg/m³ for workshop. Some commenters expressed concern about using average exposures from 1992 to represent exposure throughout the study. The authors justified using these measurement averages to represent exposure levels throughout the study period because ''the mining technology and the type of machinery used did not change substantially after 1970.'' This assumption was based on interviews with local engineers and industrial hygienists.

Thirty-one percent of the cohort consented to be interviewed, and information from these interviews was used to validate the work history and smoking data reconstructed from the medical records. The TC concentration assigned to each work location was combined with each miner's individual work history to form an estimate of cumulative exposure for each member of the cohort. Mean duration of exposure was 15 years. As of the end of follow-up in 1994, average age was 49 years, average time since first exposure was 19 years, and average cumulative exposure was 2.70 mg-y/m³.

The authors performed an analysis (within each TC exposure category) of smoking patterns compared with cumulative TC exposure. They also analyzed smoking misclassification as estimated by comparing information from the interviews with medical records. From these analyses, the authors determined that the cohort was homogeneous with respect to smoking and that a smoking adjustment was neither necessary nor desirable for internal comparisons. However, they did not entirely rule out the possibility that smoking effects may have biased the results to some extent. On the other hand, the authors concluded that asbestos exposure was minor and restricted to jobs in the workshop category, with negligible effects. The miners were not occupationally exposed to radon progeny, as documented by routine measurement records.

As compared to the general male population of East Germany, the cohort SMR for all causes combined was less than 0.6 at a 95-percent confidence level. The authors interpreted this as demonstrating a healthy worker effect, noting that ''underground workers are heavily selected for health and sturdiness, making any surface control group incomparable.'' Accordingly, they performed internal comparisons within the cohort of underground miners. The RR reported for lung cancer among miners in the high-exposure production category, compared to those in the low-exposure workshop category, was 2.17. The corresponding RR was not elevated for other cancers or for diseases of the circulatory system.

Two statistical methods were used to investigate the relationship between lung cancer RR and each miner's age and cumulative TC exposure: Poisson regression and time-dependent proportional hazards regression. These two statistical methods were applied to both the full cohort and the subcohort, yielding four different estimates characterizing the exposure-response relationship. Although a high confidence level was not achieved, all four of these results indicated that the RR increased with increasing cumulative TC exposure. For each incremental mg-yr/m³ of occupational TC exposure, the relative risk of lung cancer was estimated to increase by the following multiplicative factor: [53]

Method	RR per mg-yr/m³	
	Full cohort	Sub-cohort
Poisson	1.030	1.139
Proportional Hazards	1.112	1.225

Based on these estimates, the RR for a specified cumulative TC exposure (X) can be calculated by raising the tabled value to a power equal to X. For example, using the proportional hazards analysis of the subcohort, the RR for X = 3.5 mg-yr/m³ is $(1.225)^{3.5} = 2.03$.[54] The authors calculated the RR expected for a cumulative TC exposure of 4.9 mg-yr/m³, which corresponds to 20 years of occupational exposure for miners in the production category of the cohort. These miners were exposed for five hours per 8-hour shift at an average TC concentration of 390 µg/m³. The resulting RR values were reported as follows:

Method	RR for 4.9 mg-yr/m³	
	Full cohort	Sub-cohort
Poisson	1.16	1.89
Proportional Hazards	1.68	2.70

This study has two important limitations that weaken the evidence it presents of a positive correlation between cumulative TC exposure and the risk of lung cancer. These are (1) potential confounding due to tobacco smoking and (2) a significant probability (i.e., greater than 10 percent) that a correlation of the magnitude found could have arisen simply by chance, given that it were based on a relatively small number of lung cancer cases.

Although data on smoking habits were compiled from medical records for approximately 80 percent of the cohort, these data were not incorporated into the statistical regression models. The authors justified their exclusion of smoking from these models by showing that the likelihood of smoking was essentially unrelated to the cumulative TC exposure for cohort members. Based on the portion of the cohort that was interviewed, they also determined that the average number of cigarettes smoked per day was the same for smokers in the high and low TC exposure categories (production and workshop, respectively). However, these same interviews led them to question the accuracy of the smoking data that had been compiled from medical records. Despite the cohort's apparent homogeneity with respect to smoking, the authors noted that smoking was potentially such a strong confounder that ''even small inaccuracies in smoking data could cause effects comparable in size to the weak carcinogenic effect of diesel exhaust.'' Therefore, they excluded the smoking data from the analysis and stated they could not entirely rule out the possibility of a smoking bias. MSHA agrees with the authors of this report and the HEI Expert Panel (op cit.) that even a high degree of cohort homogeneity does not rule out the possibility of a spurious correlation due to residual smoking effects. Nevertheless, because of the cohort's homogeneity, the authors concluded that ''the results are unlikely to be substantially biased by confounding,'' and MSHA accepts this conclusion.

The second limitation of this study is related to the fact that the results are based on a total of only 38 cases of lung cancer for the full cohort and 21 cases for the subcohort. In their description of this study at the May 27, 1999, public

[53] MSHA *determined* these values by calculating the antilog, to the base e, of each corresponding estimate of α reported by Säverin et al. (op cit.) in their Tables III and IV. The cumulative exposure unit of mg-yr/m³ refers to the average TC concentration experienced over a year's worth of 8-hour shifts.

[54] This is the estimated risk relative not to miners in the workshop category but to a theoretical age-adjusted baseline risk for cohort members accumulating zero occupational TC exposure.

hearing, NIOSH noted that the ''lack of [statistical] significance may be a result of the study having a small cohort (approximately 5,500 workers), a limited time from first exposure (average of 19 years), and a young population (average age of 49 years at the end of follow-up).'' More cases of lung cancer may be expected to occur within the cohort as its members grow older. The authors of the study addressed statistical significance as follows:

* * * the small number of lung cancer cases produced wide confidence intervals for all measures of effect and substantially limited the study power. We intend to extend the follow-up period in order to improve the statistical precision of the exposure-response relationship. [Säverin et al., op cit.]

Some commenters stated that due to these limitations, data from the Säverin et al. study should not be the basis of this rule. On the other hand, NIOSH commented that ''[d]espite the limitations discussed * * * the findings from the Säverin et al. (1999) study should be used as an alternative source of data for quantifying the possible lung cancer risks associated with Dpm exposures.'' As stated earlier, MSHA is not relying on any single study but, instead, basing its evaluation on the weight of evidence from all available data.

(iii) Best Available Epidemiologic Evidence

Based on the evaluation criteria described earlier, and after considering all the public comment that was submitted, MSHA has identified four cohort studies (including two from U.S.) and four case-control studies (including three from U.S.) that provide the best currently available epidemiologic evidence relating dpm exposure to an increased risk of lung cancer. Three of the 11 studies involving miners fall into this select group. MSHA considers the statistical significance of the combined evidence far more important than confidence levels for individual studies. Therefore, in choosing the eight most informative studies, MSHA placed less weight on statistical significance than on the other criteria. The basis for MSHA's selection of these eight studies is summarized as follows:

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STUDY	STATISTICAL SIGNIFICANCE (at 95% Conf.)	COMPARISON GROUPS	EXPOSURE ASSESSMENT	CONTROLS ON POTENTIAL CONFOUNDING
Boffetta et al. 1988 (cohort)	YES	Internal Comparison	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking, and, in some analyses, for occupational exposures to asbestos, coal & stone dusts, coal tar & pitch, and gasoline exhaust.
Boffetta et al. 1990 (case-control)	NO	Matched within hospital on smoking, age, year of interview.	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking habit and intensity, asbestos exposure, race, and education.
Brüske-Hohlfeld et al. 1999 (case-control)	YES	Matched on sex, age, and region of residence.	Total duration of occupational diesel exposure based on detailed job history.	Adjustments for current and past smoking patterns, cumulative amount smoked (packyears), and asbestos exposure.
Garshick et al. 1987 (case-control)	YES	Matched within cohort on dates of birth and death.	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Adjustments for lifetime smoking and asbestos exposure.
Garshick et al. 1988, 1991 (cohort)	YES	Internal Comparison	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Subjects with likely or possible asbestos exposure excluded from cohort. Cigarette smoking determined to be uncorrelated with diesel exposure within cohort.
Johnston et al. 1997 (cohort)	NO (marginal)	Internal Comparison	Quantitative, based on surrogate exposure measurements and detailed employment records.	Adjustments for age, smoking habit & intensity, mine site, and cohort entry date.
Säverin et al. 1999 (cohort)	NO	Internal Comparison	Quantitative, based on TC exposure measurements and detailed employment records.	Adjustment for age. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Steenland et al. 1990, 1992, 1998 (case-control)	YES	Matched within cohort on date of death within 2 years.	Semi-quantitative, based on job history and subsequent EC measurements.	Adjustments for age, smoking, and asbestos exposure. Dietary covariates were tested and found not to confound the analysis.

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Six entirely negative studies were identified earlier in this risk assessment. Several commenters objected to MSHA's treatment of the negative studies, indicating that they had been discounted without sufficient justification. To put this in proper perspective, the six negative studies should be compared to those MSHA has identified as the best available epidemiologic evidence, with respect to the same evaluation criteria. (It should be noted that the statistical significance of a negative study is best represented by its power.) In accordance with those criteria, MSHA discounts the evidentiary significance of these six studies for the following reasons:

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STUDY	POWER	COMPARISON GROUPS	EXPOSURE ASSESSMENT	CONTROLS ON POTENTIAL CONFOUNDING
Bender et al. 1989 (cohort)	Relatively small cohort (N = 4849)	External comparison; No adjustment for healthy worker effect.	Job only: highway maintenance workers.	Disparate comparison groups with no smoking adjustment.
Christie et al. 1996 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Industry only: combined all underground and surface workers at coal mines.	Disparate comparison groups with no smoking adjustment
DeCoufle et al. 1977 (case-control)	Inadequate latency allowance.	Cases not matched with controls.	Job only: (1) Combined bus, taxi, and truck drivers; (2) locomotive engineers.	Age differences not taken into account.
Edling et al. 1987 (cohort)	Small cohort (N = 694)	External comparison; No adjustment for healthy worker effect.	Job only: bus workers.	Disparate comparison groups with no smoking adjustment
Kaplan 1959 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Jobs classified by diesel exposure. No attempt to differentiate between diesel and coal-fired locomotives.	Disparate comparison groups with no smoking adjustment
Waller 1981 (cohort)	Acceptable.	External comparison; No adjustment for healthy worker effect; Selection bias due to excluding retirees from cohort.	Job only: bus workers.	Disparate comparison groups with no smoking adjustment

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Other studies proposed as counter-evidence by some commenters will be addressed in the next subsection of this risk assessment.

The eight studies MSHA identified as representing the best available epidemiologic evidence all reported an elevated risk of lung cancer associated with diesel exposure. The results from these studies will now be reviewed, along with MSHA's response to public comments as appropriate.

Boffetta et al., 1988

The structure of this cohort study was summarized in the preceding subsection of this risk assessment. The following table contains the main results. The relative risks listed for duration of exposure were calculated with reference to all members of the cohort reporting no diesel exposure, regardless of occupation, and adjusted for age, smoking pattern, and other occupational exposures (asbestos, coal and stone dusts, coal tar and pitch, and gasoline exhausts). The relative risks listed for occupations were calculated for cohort members that ever worked in the occupation, compared to cohort members never working in any of the four occupations listed and reporting no diesel exposure. These four relative risks were adjusted for age and smoking pattern only. Smoking pattern was coded by 5 categories: never smoker; current 1–20 cigarettes per day; current 21 or more cigarettes per day; ex-smoker of cigarettes; current or past pipe and/or cigar smoker.

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Main results from Boffetta et al., 1988

(RRs by duration adjusted for age, smoking, and other occupational exposures;

Occupational RRs adjusted for age and smoking only)

Self-Reported Duration of Exposure to Diesel Exhaust (years)	Lung Cancer RR	95-Percent Confidence Interval
1 to 15	1.05	0.80 - 1.39
16 or more	1.21	0.94 - 1.56
Occupation		
Truck Drivers	1.24	0.93 - 1.66
Railroad Workers	1.59	0.94 - 2.69
Heavy Equipment Operators	2.60	1.12 - 6.06
Miners	2.67	1.63 - 4.37

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In addition to comments (addressed earlier) on the RR for miners in this study, IMC Global submitted several comments pertaining to the RR calculated for persons who explicitly stated that they had been occupationally exposed to diesel emissions. This RR was 1.18 for persons reporting any exposure (regardless of duration) compared to all subjects reporting no exposure. MSHA considers the most important issue raised by IMC Global to be that 20.6 percent of all cohort members did not answer the question about occupational diesel exhaust exposure during their lifetimes, and these subjects experienced a higher age-adjusted mortality rate than the others. As the authors of this study acknowledged, this ''could introduce a substantial bias in the estimate of the association.'' (Boffetta et al., 1988, p.412).

To show that the impact of this bias could indeed be substantial, the authors of the study addressed one extreme possibility, in which all ''unknowns'' were actually unexposed. Under this scenario, excluding the ''unknowns'' would have biased the calculated RR upward by a sufficient amount to explain the entire 18-percent excess in RR. This would not, however, explain the higher RR for persons reporting more than 16 years exposure, compared to the RR for persons reporting 1 to 15 years. Moreover, the authors did not discuss the opposite extreme: if all or most of the ''unknowns'' who experienced lung cancer were actually exposed, then excluding them would have biased the calculated RR downward. There is little basis for favoring one of these extremes over the other.

Another objection to this study raised by IMC Global was:

> All exposure information in the study was self-reported and not validated. The authors of the study have no quantitative data or measurements of actual diesel exhaust exposures.

MSHA agrees with IMC Global and other commenters that a lack of quantitative exposure measurements limits the strength of the evidence this study presents. MSHA believes, however, that the evidence presented is nevertheless substantial. The possibility of random classification errors due to self-reporting of exposures does not explain why persons reporting 16 or more years of exposure would experience a higher relative risk of lung cancer than persons reporting 1 to 15 years of exposure. This difference is not statistically significant, but random exposure misclassification would tend to make the effects of exposure less conspicuous. Nor can self-reporting explain why an elevated risk of lung cancer would be observed for four occupations commonly associated with diesel exposure.

Furthermore, the study's authors did perform a rough check on the accuracy of the cohort's exposure information. First, they confirmed that, after controlling for age, smoking, and other occupational exposures, a statistically significant relationship was found between excess lung cancer and the cohort's self-reported exposures to asbestos. Second they found no such association for self-reported exposure to pesticides and herbicides, which they considered unrelated to lung cancer (*ibid.*, pp. 410–411).

IMC Global also commented that the ''* * * study may suffer from volunteer bias in that the cohort was healthier and less likely to be exposed to important risk factors, such as smoking or alcohol.'' They noted that this possibility ''is supported by the U.S. EPA in their draft Health Assessment Document for Diesel Emissions.''

The study's authors noted that enrollment in the cohort was nonrandom and that participants tended to be healthier and less exposed to various risk factors than the general population. These differences, however, would tend to reduce any relative risk for the cohort calculated in comparison to the external, general population. The authors pointed out that external comparisons were, therefore, inappropriate; but ''the internal comparisons upon which the foregoing analyses are based are not affected strongly by selection biases.'' (ibid.)

Although the 1999 EPA draft notes potential volunteer bias, it concludes: ''Given the fact that all diesel exhaust exposure occupations * * * showed elevated lung cancer risk, this study is suggestive of a causal association.'' [55] (EPA, 1999, p. 7–13) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

[55] In his review of this study for the NMA, Dr. Peter Valberg stated: ''This last sentence reveals EPA's bias; the RRs for truck drivers and railroad workers were not statistically elevated.'' Contrary to Dr. Valberg's statement, the RRs were greater than 1.0 and, therefore, were ''statistically elevated.'' Although the elevation for these two occupations was not statistically significant at a 95-percent confidence level, the EPA made no claim that it was. Under a null hypothesis of no real association, the probability should be ½ that the RR would exceed 1.0 for an occupation associated with diesel exposure. Therefore, under the null hypothesis, the probability that the RR would exceed 1.0 for all four such occupations is $(1/2)^4 = 0.06$. This corresponds to a 94-percent confidence level for rejecting the null hypothesis.

Boffetta et al., 1990

This case-control study was based on 2,584 male hospital patients with histologically confirmed lung cancer, matched with 5099 male patients with no tobacco-related diseases. Cases and controls were matched within each of 18 hospitals by age (within two years) and year of interview. Information on each patient, including medical and smoking history, occupation, and alcohol and coffee consumption, was obtained at the time of diagnosis in the hospital, using a structured questionnaire. For smokers, smoking data included the number of cigarettes per day. Prior to 1985, only the patient's usual job was recorded. In 1985, the questionnaire was expanded to include up to five other jobs and the length of time worked in each job. After 1985, information was also obtained on dietary habits, vitamin consumption, and exposure to 45 groups of chemicals, including diesel exhaust.

The authors categorized all occupations into three groups, representing low, possible, and probable diesel exhaust exposure. The ''low exposure'' group was used as the reference category for calculating odds ratios for the ''possible'' and ''probable'' job groups. These occupational comparisons were based on the full cohort of patients, enrolled both before and after 1985. A total of 35 cases and 49 controls (all enrolled after the questionnaire was expanded in 1985) reported a history of diesel exposure. The reference category for self-reported diesel exposure consisted of a corresponding subset of 442 cases and 897 controls reporting no diesel exposure on the expanded questionnaire. The authors made three comparisons to rule out bias due to self-reporting of exposure: (1) No difference was found between the average number of jobs reported by cases and controls; (2) the association between self-reported asbestos exposure was in agreement with previously published estimates; and (3) no association was found for two exposures (pesticides and fuel pumping) considered unrelated to lung cancer (*ibid.*, p. 584).

Stöber and Abel (1996) identified this study as being ''of eminent importance owing to the care taken in including the most influential confounding factors and analyses of dose-effect relationships.'' The main findings are presented in the following table. All of these results were obtained using logistic regression, factoring in the estimated effects of age, race, years of education, number of cigarettes per day, and asbestos exposure (yes or no). An elevated risk of lung cancer was reported for workers with more than 30 years of either self-reported or ''probable'' diesel exposure. The authors repeated the occupational analysis using ''ever'' rather than ''usual'' employment in jobs classified as ''probable'' exposure, with ''remarkably similar'' results (*ibid.,* p. 584).

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Main results from Boffetta et al., 1990

(adjusted for age, race, education, smoking, and asbestos exposure)

Self-Reported Duration of Exposure to Diesel Exhaust (years)	Lung Cancer Odds Ratio	95-Percent Confidence Interval
1 to 15	0.90	0.40 - 1.99
16 to 30	1.04	0.44 - 2.48
31 or more	2.39	0.87 - 6.57
Likelihood of Exposure		
19 jobs with "possible" exposure	0.92	0.76 - 1.10
13 jobs with "probable" exposure	0.95	0.78 - 1.16
1 to 15 years in "probable" jobs	0.52	0.15 - 1.86
16 to 30 years in "probable" jobs	0.70	0.34 - 1.44
31 or more years in "probable" jobs	1.49	0.72 - 3.11

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The study's authors noted that most U.S. trucks did not have diesel engines until the late 1950s or early 1960s and that many smaller trucks are still powered by gasoline engines. Therefore, they performed a separate analysis of truck drivers cross-classified by self-reported diesel exposure ''to compare presumptive diesel truck drivers with nondiesel drivers.'' After adjusting for smoking, the resulting OR for diesel drivers was 1.25, with a 95-percent confidence interval of 0.85 to 2.76 (*ibid.,* p. 585).

Brüske-Hohlfeld et al., 1999

This was a pooled analysis of two case-control studies on lung cancer in Germany. The data pool consisted of 3,498 male cases with histologically or cytologically confirmed lung cancer and 3,541 male controls randomly drawn from the general population. Cases and controls were matched for age and region of residence. For the pooled analysis, information on demographic characteristics, smoking, and detailed job and job-task history was collected by personal interviews with the cases and controls, using a standardized questionnaire.

Over their occupational lifetimes, cases and controls were employed in an average of 2.9 and 2.7 different jobs, respectively. Jobs considered to have had potential exposure to diesel exhaust were divided into four groups: Professional drivers (including trucks, buses, and taxis), other ''traffic-related'' jobs (including switchmen and operators of diesel locomotives or diesel forklift trucks), full-time drivers of farm tractors, and heavy equipment operators. Within these four groups, each episode of work in a particular job was classified as being exposed or not exposed to diesel exhaust, based on the written description of job tasks obtained during the interview. This exposure assessment was done without knowledge of the subject's case or control status. Each subject's lifetime duration of occupational exposure was compiled using only the jobs determined to have been diesel-exposed. There were 264 cases and 138 controls who accumulated diesel exposure exceeding 20 years, with 116 cases and 64 controls accumulating more than 30 years of occupational exposure.

For each case and control, detailed smoking histories from the questionnaire were used to establish smoking habit, including consumption of other tobacco products, cumulative smoking exposure (expressed as pack-years), and years since quitting smoking. Cumulative asbestos exposure (expressed as the number of exposed working days) was assessed based on 17 job-specific questionnaires that supplemented the main questionnaire.

The main findings of this study, all adjusted for cumulative smoking and asbestos exposure, are presented in the following table. Although the odds ratio for West German professional drivers was a statistically significant 1.44, as shown, the odds ratio for East German professional drivers was not elevated. As a possible explanation, the authors noted that after 1960, the number of vehicles (cars, busses, and trucks) with diesel engines per unit area was about five times higher in West Germany than in East Germany. Also, the higher OR shown for professional drivers first exposed after 1955, compared to earlier years of first exposure, may have resulted from the higher density of diesel traffic in later years.

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Main results from Brüske-Hohlfeld et al., 1999

(controlled for age; adjusted for smoking and asbestos exposure)

Occupational Exposure to Diesel Exhaust	Lung Cancer Odds Ratio	95-Percent Confidence Interval
Any During Lifetime	1.43	1.23 - 1.67
West German Professional Drivers	*1.44*	*1.18 - 1.76*
First exposed before 1946	1.32	0.68 - 2.07
First exposed 1946 - 1955	1.49	0.96 - 1.88
First exposed after 1955	1.56	1.21 - 2.03
"Traffic-Related" Jobs other than Driving	*1.53*	*1.04-2.24*
4 to 10 years	1.18	0.6 - 2.4†
11 to 20 years	2.49	1.1 - 5.6†
More than 20 years	2.88	1.1 - 7.2†
Full-Time Drivers of Farm Tractors	*1.29*	*0.78 - 2.14*
11 to 20 years	1.51	0.4 - 3.8‡
21 to 30 years	3.67	1.0 - 13‡
More than 30 years	6.81	1.1 - 40‡
Heavy Equipment Operators	*2.31*	*1.44 - 3.70*
More than 20 years	4.30	statistically significant (interval not reported)

† Confidence limits estimated from Fig. 1 of Brüske-Hohlfeld et al. (1999).

‡ Confidence limits estimated from Fig. 2 of Brüske-Hohlfeld et al. (1999).

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As the authors noted, a strength of this study is the good statistical power resulting from having a significant number of workers exposed to diesel emissions for more than 30 years. Another strength is the statistical treatment of potential confounders, using quantitative measures of cumulative smoking and asbestos exposures.

Although they did not rely solely on job title, and differentiated between diesel-exposed and unexposed work periods, the authors identified limitations in the assessment of diesel exposure, ''under these circumstances leading to an odds ratio that is biased towards one and an underestimation of the true [relative] risk of lung cancer.'' A more quantitative assessment of diesel exposure would tend to remove this bias, thereby further elevating the relative risks. Therefore, the authors concluded that their study ''showed a statistically significant increase in lung cancer risk for workers occupationally exposed to [diesel exhaust] in Germany with the exception of professional drivers in East Germany.''

Garshick et al., 1987

This case-control study was based on 1,256 primary lung cancer deaths and 2,385 controls whose cause of death was not cancer, suicide, accident, or unknown. Cases and controls were drawn from records of the U.S. Railroad Retirement Board (RRB) and matched within 2.5 years of birth date and 31 days of death date. Selected jobs, with and without regular diesel exposure, were identified by a review of job titles and duties and classified as ''exposed'' or ''unexposed'' to diesel exhaust. For 39 jobs, this exposure classification was confirmed by personal sampling of current respirable dust concentrations, adjusted for cigarette smoke, at four different railroads. Jobs for which no personal sampling was available were classified based on similarities in location and activity to sampled jobs.

A detailed work history for each case and control was obtained from an annual report filed with the RRB. This was combined with the exposure classification for each job to estimate the lifetime total diesel exposure (expressed as ''diesel-years'') for each subject. Years spent not working for a railroad, or for which a job was not recorded, were considered to be unexposed. This amounted to 2.4% of the total worker-years from 1959 to death or retirement.

Because of the transition from steam to diesel locomotives in the 1950s, occupational lifetime exposures were accumulated beginning in 1959. Since many of the older workers retired not long after 1959 and received little or no diesel exposure, separate analyses were carried out for subjects above and below the age of 65 years at death. The group of younger workers was considered to be less susceptible to exposure misclassification.

Detailed smoking histories, including years smoked, cigarettes per day, and years between quitting and death, were obtained from next of kin. Based on job history, each case and control was also classified as having had regular, intermittent, or no occupational asbestos exposure.

The main results of this study, adjusted for smoking and asbestos exposure, are presented in the following table for workers aged less than 65 years at the time of their death. All of these results were obtained using logistic regression, conditioned on dates of birth and death. The odds ratio presented in the shaded cell for 20 years of unlagged exposure was derived from an analysis that modeled diesel-years as a continuous variable. All of the other odds ratios in the table were derived from analyses that modeled cumulative exposure categorically, using workers with less than five diesel-years of exposure as the reference group. Statistically significant elevations of lung cancer risk were reported for the younger workers with at least 20 diesel-years of exposure or at least 15 years accumulated five years prior to death. No elevated risk of lung cancer was observed for the older workers, who were 65 or more years old at the time of their death. The authors attributed this to the fact, mentioned above, that many of these older workers retired shortly after the transition to diesel-powered locomotives and, therefore, experienced little or no occupational diesel exposure. Based on the results for younger workers, they concluded that ''this study supports the hypothesis that occupational exposure to diesel exhaust increases lung cancer risk.''

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Main results from Garshick et al., 1987, for workers aged less than 65 years at death

(controlled for dates of birth and death; adjusted for cigarette smoking and asbestos exposure).

Diesel Exposure (no lag)	**Lung Cancer Odds Ratio**	**95-Percent Confidence Interval**
0 - 4 diesel-years	1	N/A (reference group)
5 - 19 diesel-years	1.02	0.72 - 1.45
20 diesel-years (diesel exposure modeled as continuous variable)	1.41	1.06 - 1.88
20 or more diesel-years	1.64	1.18 - 2.29
Diesel Exposure (accumulated at least 5 years before death)		
0 - 4 diesel-years	1	N/A (reference group)
5 - 14 diesel-years	1.07	0.69 - 1.66
15 or more diesel-years	1.43	1.06 - 1.94

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In its 1999 draft Health Assessment Document for Diesel Emissions, the U.S. EPA noted various limitations of this study but concluded that "compared with previous studies [i.e., prior to 1987] * * *, [it] provides the most valid evidence that occupational diesel exhaust emission exposure increases the risk of lung cancer." (EPA, 1999, p. 7–33) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

The EMA objected to this study's determination of smoking frequency based on interviews with next of kin, stating that such determination "generally results in an underestimate, as it has been shown that cigarette companies manufacture 60% more product than public surveys indicate are being smoked."

A tendency to mischaracterize smoking frequency would have biased the study's reported results if the degree of under- or over-estimation varied systematically with diesel exposure. The EMA, however, submitted no evidence that the smoking under-estimate, if it existed at all, was in any way correlated with cumulative duration of diesel exposure. In the absence of such evidence, MSHA finds no reason to assume differential mis-reporting of smoking frequency.

Even more importantly, the EMA failed to distinguish between "public surveys" of the smokers themselves (who may be inclined to understate their habit) and interviews with next of kin. The investigators specifically addressed the accuracy of smoking data obtained from next of kin, citing two studies on the subject. Both studies reported a tendency for surrogate respondents to overestimate, rather than underestimate, cigarette consumption. The authors concluded that "this could exaggerate the contribution of cigarette smoking to lung cancer risk if the next of kin of subjects dying of lung cancer were more likely to report smoking histories than were those of controls." (ibid, p.1246)

IMC Global, along with Cox (1997) objected to several methodological features of this study. MSHA's response to each of these criticisms appears immediately following a summary quotation from IMC Global's written comments:

(A) The regression models used to analyze the data assumed without justification that an excess risk at any exposure level implied an excess risk at all exposure levels.

The investigators did not extrapolate their regression models outside the range supported by the data. Furthermore, MSHA is using this study only for purposes of hazard identification at exposure levels at least as high as those experienced by workers in the study. Therefore, the possibility of a threshold effect at much lower levels is irrelevant.

(B) The regression model used did not specify that the exposure estimates were imperfect surrogates for true exposures. As a result, the regression coefficients do not bear any necessary relationship to the effects that they try to measure.

As noted by Cox (op cit.), random measurement errors for exposures in an univariate regression model will tend to bias results in the direction of no apparent association, thereby masking or reducing any apparent effects of exposure. The crux of Cox's criticism, however, is that, for statistical analysis of the type employed in this study, random errors in a multivariate exposure (such as an interdependent combination of smoking, asbestos, and diesel exposure) can potentially bias results in either direction. This objection fails to consider the fact that a nearly identical regression result was obtained for the effect of diesel exposure when smoking and asbestos exposure were removed from the model: OR = 1.39 instead of 1.41. Furthermore, even with a multivariate exposure, measurement errors in the exposure being evaluated typically bias the estimate of relative risk downward toward a null result. Relative risk is biased upwards only when the various exposures are interrelated in a special way. No evidence was presented that the data of this study met the special conditions necessary for upward bias or that any such bias would be large enough to be of any practical significance.

C) The * * * analysis used regression models without presenting diagnostics to show whether the models were appropriate for the date.

MSHA agrees that regression diagnostics are a valuable tool in assuring the validity of a statistical regression analysis. There is nothing at all unusual, however, about their not having been mentioned in the published report of this study. Regression diagnostics are rarely, if ever, published in epidemiologic studies making use of regression analysis. This does not imply that such diagnostics were not considered in the course of identifying an appropriate model or checking how well the data conform to a given model's underlying assumptions. Evaluation of the validity of any statistical analysis is (or should be) part of the peer-review process prior to publication.

D) The * * * risk models assumed that 1959 was the effective year when DE exposure started for each worker. Thus, the analysis ignored the potentially large differences in pre-1959 exposures among workers. This modeling assumption makes it impossible to interpret the results of the study with confidence.

MSHA agrees that the lack of diesel exposure information on individual workers prior to 1959 represents an important limitation of this study. This limitation, along with a lack of quantitative exposure data even after 1959, may preclude using it to determine, with reasonable confidence, the shape or slope of a quantitative exposure-response relationship. Neither of these limitations, however, invalidates the study's finding of an elevated lung cancer risk for exposed workers. MSHA is not basing any quantitative risk assessment on this study and is relying on it, in conjunction with other evidence, only for purposes of hazard identification.

E) The risk regression models * * * assume, without apparent justification, that all exposed individuals have identical dose-response model parameters (despite the potentially large differences in their pre-1959 exposure histories). This assumption was not tested against reasonable alternatives, *e.g.*, that individuals born in different years have different susceptibilities * * *

Cases and controls were matched on date of birth to within 2.5 years, and separate analyses were carried out for the two groups of younger and older workers. Furthermore, it is not true that the investigators performed no tests of reasonable alternatives even to the assumption that younger workers shared the same model parameters. They explored and tested potential interactions between smoking intensity and diesel exposure, with negative results. The presence of such interactions would have meant that the response to diesel exposure differed among individuals, depending on their smoking intensity.

One other objection that Cox (op. cit.) raised specifically in connection with this study was apparently overlooked by IMC Global. To illustrate what he considered to be an improper evaluation of statistical significance when more than one hypothesis is tested in a study, Cox noted the finding that for workers aged less than 65 years at time of death, the odds ratio for lung cancer was significantly elevated at 20 diesel-years of exposure. He then asserted that this finding was merely

* * * an instance of a whole family of statements of the form ''Workers who were A years or younger at the time of death and who were exposed to diesel exhaust for Y years had a significantly increased relative odds ratios for lung cancer. The probability of at least one false positive occurring among the multiple hypotheses in this family corresponding to different combinations of A (*e.g.*, no more than 54, 59, 64, 69, 74, 79, etc. years old at death) and durations of exposure (*e.g.*, Y = 5, 10, 15, 20, 25, etc. years) is not limited to 5% when each combination of A and Y values is tested at a p = 5% significance level. For example, if 30 different (A, Y) combinations are considered, each independently having a 5% probability of a false positive (*i.e.*, a reported 5% significance level), then the probability of at least one false positive occurring in the study as a whole is p = 1 − (1 − 0.05) 30 = 78%. This p-value for the whole study is more than 15 times greater than the reported significance level of 5%.

MSHA is evaluating the cumulative weight of evidence from many studies and is not relying on the level of statistical significance attached to any single finding or study viewed in isolation. Furthermore, Cox's analysis of the statistical impact of multiple comparisons or hypothesis tests is flawed on several counts, especially with regard to this study in particular. First, the analysis relies on a highly unrealistic assumption that when several hypotheses are tested within the same study, the probabilities of false positives are statistically independent. Second, Cox fails to distinguish between those hypotheses or comparisons suggested by exploration of the data and those motivated by prior considerations. Third, Cox ignores the fact that the result in question was based on a statistical regression analysis in which diesel exposure duration was modeled as a single continuous variable. Therefore, this particular result does not depend on multiple hypothesis-testing with respect to exposure duration. Fourth, and most importantly, Cox assumes that age and exposure duration were randomly picked for tested from a pool of interchangeable possibilities and that the only thing distinguishing the combination of ''65 years of age'' and ''20 diesel-years of exposure'' from other random combinations was that it happened to yield an apparently significant result. This is clearly not the case. The investigators divided workers into only two age groups and explained that this division was based on the history of dieselization in the railroad industry—not on the results of their data analysis. Similarly, the result for 20 diesel-years of exposure was not favored over shorter exposure times simply because 20 years yielded a significant result and the shorter times did not. Lengthy exposure and latency periods are required for the expression of increased lung cancer risks, and this justifies a focus on the longest exposure periods for which sufficient data are available.

Garshick et al., 1988; Garshick, 1991

In this study, the investigators assessed the risk of lung cancer in a cohort of 55,407 white male railroad workers, aged 40 to 64 years in 1959, who had begun railroad work between 1939 and 1949 and were employed in one of 39 jobs later surveyed for exposure. Workers whose job history indicated likely occupational exposure to asbestos were excluded. Based on the subsequent exposure survey, each of the 39 jobs represented in the cohort was classified as either exposed or unexposed to diesel emissions. The cohort was followed through 1980, and

1,694 cases of death due to lung cancer were identified.

As in the 1987 study by the same investigators, detailed railroad job histories from 1959 to date of death or retirement were obtained from RRB records and combined with the exposure classification for each job to provide the years of diesel exposure accumulated since 1959 for each worker in the cohort. Using workers classified as ''unexposed'' within the cohort to establish a baseline, time-dependent proportional hazards regression models were employed to evaluate the relative risk of lung cancer for exposed workers. Although the investigators believed they had excluded most workers with significant past asbestos exposures from the cohort, based on job codes, they considered it possible that some workers classified as hostlers or shop workers may have been included in the cohort even if occupationally exposed to asbestos. Therefore, they carried out statistical analyses with and without shop workers and hostlers included.

The main results of this study are presented in the following table. Statistically significant elevations of lung cancer risk were found regardless of whether or not shop workers and hostlers were included. The 1988 analysis adjusted for age in 1959, and the 1991 analysis adjusted, instead, for age at death or end of follow-up (i.e., end of 1980).[56] In the 1988 analysis, any work during a year counted as a diesel-year if the work was in a diesel-exposed job category, and the results from the 1991 analysis presented here are based on this same method of compiling exposure durations. Exposure durations excluded the year of death and the four prior years, thereby allowing for some latency in exposure effects. Results for the analysis excluding shop workers and hostlers were not presented in the 1991 report, but the report stated that ''similar results were obtained.'' Using either method of age adjustment, a statistically significant elevation of lung cancer risk was associated with each exposure duration category. Using ''attained age,'' however, there was no strong indication that risk increased with increasing exposure duration. The 1991 report concluded that ''there appears to be an effect of diesel exposure on lung cancer mortality'' but that ''because of weaknesses in exposure ascertainment * * *, the nature of the exposure-response relationship could not be found in this study.''

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Main results from Garshick et al., 1988 and Garshick, 1991.

Exposure Duration (diesel-years, last 5 years excluded)	Full Cohort		Shopworkers & Hostlers Excluded	
	Relative Risk	95% Conf. Int.	Relative Risk	95% Conf. Int.
1 - 4	1.20	1.01 - 1.44	1.34	1.08 - 1.65
	1.31	1.09 - 1.57	N.R.	N.R.
5 - 9	1.24	1.06 - 1.44	1.33	1.12 - 1.58
	1.28	1.09 - 1.49	N.R.	N.R.
10 - 14	1.32	1.13 - 1.56	1.33	1.10 - 1.60
	1.19	1.002 - 1.41	N.R.	N.R.
15 or more	1.72	1.27 - 2.33	1.82	1.30 - 2.55
	1.40	1.03 - 1.90	N.R.	N.R.

Top entry within each cell is from 1988 analysis, adjusted for age in 1959. Bottom entry is from 1991 analysis, adjusted for age at death or end of follow-up (“attained age”). N.R. means “not reported.”

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Some commenters noted that removing the shop workers and hostlers from the analysis increased the relative risk estimates. Dr. Peter Valberg found this ''paradoxical,'' since workers in these categories had later been found to experience higher average levels of diesel exposure than other railroad workers.

This so-called paradox is likely to have resulted simply from exposure misclassification for a significant portion of the shop workers. The effect was explained by Garshick (1991) as follows:

[1] Also, the 1991 analysis excluded 12 members of the cohort due to discrepancies between work history and reported year of death, leaving 55,395 railroad workers included in the analysis.

* * * shop workers who worked in the diesel repair shops shared job codes with workers in non-diesel shops where there was no diesel exhaust * * *. Apparent exposure as a shop worker based on the job code was then diluted with workers with the same job code but without true exposure, making it less likely to see an effect in the shop worker group. In addition, workers in the shop worker group of job codes tended to have less stable career paths * * * compared to the other diesel exposure categories.

So although many of the shopworkers may have been exposed to relatively high dpm concentrations, many others were among the lowest-exposed workers or were even unexposed because they spent their entire occupational lifetimes in unexposed locations. This could readily account for the increase in relative risks calculated when shop workers were excluded from the analysis.

Dr. Valberg also noted that, according to Crump 1999), mortality rates for cirrhosis of the liver and heart disease were significantly elevated for ''train riders,'' who were exposed to diesel emissions, as compared to other members of the cohort, who were less likely to be exposed. It is also the train riders who account, primarily, for the elevated risk of lung cancer associated with diesel exposure in the overall cohort. Dr. Valberg interpreted this as suggesting that ''lifestyle'' factors such as diet or smoking habits, rather than diesel exposure, were responsible for the increased risk of lung cancer observed among the diesel-exposed workers.

Dr. Valberg presented no evidence that, apart from diesel exposure, the train riders differed systematically from the other workers in their smoking habits or in other ways that would be expected to affect their risk of lung cancer. Therefore, MSHA views the suggestion of such a bias as speculative. Even if lifestyle factors associated with train ridership were responsible for an increased risk of cirrhosis of the liver or heart disease, this would not necessarily mean that the same factors were also responsible for the increased risk of lung cancer. Still, it is hypothetically possible that systematic differences, other than diesel exposure, between train riders and other railroad workers could account for some or even all of the increased lung cancer risk. That is why MSHA does not rely on this, or any other, single study in isolation.

Some commenters, including the NMA, objected to this study on grounds that it failed to control for potentially confounding factors, principally smoking. The NMA stated that this ''has rendered its utility questionable at best.'' As explained earlier, there is more than one way in which a study can control for smoking or other potential confounders. One of the ways is to make sure that groups being compared do not differ with respect to the potential confounder. In this study, workers with likely asbestos exposure were excluded from the cohort, stability of workers within job categories was well documented, and similar results were reported when job categories subject to asbestos exposure misclassification were excluded. In their 1988 report, the investigators provided the following reasons to believe that smoking did not seriously affect their findings:

* * * the cohort was selected to include only blue-collar workers of similar socioeconomic class, a known correlate of cigarette smoking * * *, in our case-control study [Garshick et al.,1987], when cigarette smoking was considered, there was little difference in the crude or adjusted estimates of diesel exhaust effects. Finally, in the group of 517 current railroad workers surveyed by us in 1982 * * *, we found no difference in cigarette smoking prevalence between workers with and without potential diesel exhaust exposure. [Garshick et al.,1988]

Since relative risks were based on internal comparisons, and the cohort appears to have been fairly homogeneous, MSHA regards it as unlikely that the association of lung cancer with diesel exposure in this study resulted entirely from uncontrolled asbestos or smoking effects. Nevertheless, MSHA recognizes that differential smoking patterns may have affected, in either direction, the degree of association reported in each of the exposure duration categories.

Cox (1997) re-analyzed the data of this study using exploratory, nonparametric statistical techniques. As quoted by IMC Global, Cox concluded that ''these methods show that DE [i.e., dpm] concentration has no positive causal association with lung cancer mortality risk.'' MSHA believes this quotation (taken from the abstract of Cox's article) overstates the findings of his analysis. At most, Cox confirmed the conclusion by Garshick (1991) that these data do not support a positive exposure-response relationship. Specifically, Cox determined that inter-relationships among cumulative diesel exposure, age in 1959, and retirement year make it ''impossible to prove causation by eliminating plausible rival hypotheses based on this dataset.'' (Cox, 1997; p.826) Even if Cox's analysis were correct, it would not follow that there is no underlying causal connection between dpm exposure and lung cancer. It would merely mean that the data do not contain internal evidence implicating dpm exposure as the cause, rather than one or more of the variables with which exposure is correlated. Cox presented no evidence that any ''rival hypotheses'' were more plausible than causation by dpm exposure. Furthermore, it may simply be, as Garshick suggested, that an underlying exposure-response relationship is not evident ''because of weaknesses in exposure ascertainment.'' (Garshick, 1991, op cit.) None of this negates the fact that, after adjusting for either age in 1959 or ''attained'' age, lung cancer was significantly more prevalent among the exposed workers.

Along similar lines, many commenters pointed out that an HEI expert panel examined the data of this study (HEI, 1999) and found that it had very limited use for quantitative risk assessment (QRA). Several of these commenters mischaracterized the panel's findings. The NMA, for example, drew the following unjustified conclusion from the panel's report: ''In short, * * * the correct interpretation of the Garshick study is that any occupational increase in lung cancer among train workers was not due to diesel exposures.''

Contrary to the NMA's characterization, the HEI Expert Panel's report stated that the data are

* * * consistent with findings of a weak association between death from lung cancer and occupational exposure to diesel exhaust. Although the secondary exposure-response analyses * * * are conflicting, the overall risk of lung cancer was elevated among diesel-exposed workers. [ibid., p.25]

The panel agreed with Garshick (1991) and Cox (1997) that the data of this study do not support a positive exposure-response relationship. Like Garshick and unlike Cox, however, the panel explicitly recognized that problems with the data could mask such a relationship and that this does not negate the statistically significant finding of elevated risk among exposed workers. Indeed, the panel even identified several factors, in addition to weak exposure assessment as suggested by Garshick, that could mask a positive relationship: unmeasured confounding variables such as cigarette smoking, previous occupational exposures, or other sources of pollution; a ''healthy worker survivor effect''; and differential misclassification or incomplete ascertainment of lung cancer deaths. (HEI, 1999; p.32)

Positive exposure-response relationships based on these data were reported by the California EPA (OEHHA, 1998). MSHA recognizes that those findings were sensitive to various assumptions and that other investigators have obtained contrary results. The West Virginia Coal Association, paraphrasing Dr. Peter Valberg, concluded that although the two studies by Garshick et al. "* * * may represent the best in the field, they fail to firmly support the proposition that lung cancer risk in workers derives from exposure to dpm." At least one commenter (IMC Global) apparently reached a considerably stronger conclusion that they were of no value whatsoever, and urged MSHA to "discount their results and not consider them in this rulemaking." On the other hand, in response to the ANPRM, a consultant to the National Coal Association who was critical of all other studies available at the time acknowledged that these two:

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

To a limited extent, MSHA agrees with Dr. Valberg and the West Virginia Coal Association: these two studies—like every real-life epidemiologic study—are not "firmly" conclusive when viewed in isolation. Nevertheless, MSHA believes that they provide important contributions to the overall body of evidence. Whether or not they can be used to quantify an exposure-response relationship, these studies—among the most comprehensive and carefully controlled currently available—do show statistically significant increases in the risk of lung cancer among diesel-exposed workers.

Johnston et al. (1997)

Since it focused on miners, this study has already been summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The tabled relative risk estimates presented for cumulative exposures greater than 1000 mg-hr/m^3 (i.e., 1 g-hr/m^3) were calculated by MSHA based on the regression coefficients reported by the authors. The conversion from mg-hr/m^3 to mg-yr/m^3 assumes 1,920 occupational exposure hours per year. Although 6.1 mg-yr/m^3 Dpm roughly equals the cumulative exposure estimated for the most highly exposed locomotive drivers in the study, the relative risk associated with this exposure level is presented primarily for purposes of comparison with findings of Säverin et al. (1999).

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Main results from Johnston et al., 1997.

Cumulative dpm exposure	Mine-adjusted Model (15-yr lag)		Mine-unadjusted Model (15-yr lag)	
	Relative Risk	95% Conf. Interval	Relative Risk	95% Conf. Interval
1000 mg-hr/m^3 (≈ 0.521 mg-yr/m^3)	1.156	0.90 - 1.49	1.227	1.00 - 1.50
1920 mg-hr/m^3 (≈ 1 mg-yr/m^3)	1.321	Not Reported	1.479	Not Reported
11,700 mg-hr/m^3 (≈ 6.1 mg-yr/m^3)	5.5	Not Reported	11.0	Not Reported

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In its post-hearing comments, MARG acknowledged that this study "found a 'weak association' between lung cancer and respiratory diesel particulate exposure" but failed to note that the estimated relative risk increased with increasing exposure. MARG also stated that the association was "deemed non-significant by the researchers" and that "no association was found among men with different exposures working in the same mines." Although the mine-adjusted model did not support 95-percent confidence for an increasing exposure-response relationship, the mine-unadjusted model yielded a statistically significant positive slope at this confidence level. Furthermore, since the mine-adjusted model adjusts for differences in lung cancer rates between mines, the fact that relative risk increased with increasing exposure under this model indicates (though not at a 95-percent confidence level) that the risk of lung cancer increased with exposure among men with different exposures working in the same mines.

Säverin et al. (1999)

Since this study, like the one by Johnston et al., was carried out on a cohort of miners, it too was summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The relative risk estimates and confidence intervals at the mean exposure level of 2.7 mg-yr/m^3 TC (total carbon) were calculated by MSHA, based on values of α and corresponding confidence intervals presented in Tables III and IV of the published report (ibid., p.420). The approximate equivalency between 4.9 mg-yr/m^3 TC and 6.1 mg-yr/m^3 dpm assumes that, on average, TC comprises 80 percent of dpm.

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Main results from Säverin et al., 1999.

	Relative Risk	95% Confidence Interval
Highest Compared to Least Exposed Worker Category	2.17	0.79 - 5.99

Cumulative Total Carbon Exposure	Proportional Hazards (Cox) Model*		Poisson Model*	
	Relative Risk	95% Conf. Interval	Relative Risk	95% Conf. Interval
2.7 mg-yr/m^3 TC (i.e., cohort mean)	1.33 1.73	0.67 - 2.64 0.70 - 4.30	1.08 1.42	0.59 - 1.99 0.65 - 3.92
4.9 mg-yr/m^3 TC (≈ 6.1 mg-yr/m^3 Dpm)	1.68 2.70	0.49 - 5.8 0.52 - 14.1	1.16 1.89	0.38 - 3.3 0.46 - 11.9

* Top entry in each cell is based on full cohort; bottom entry is based on subcohort, which was restricted to miners who worked underground at least ten years, with at least 80 percent of employment in same job, etc.

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These results are not statistically significant at the conventional 95-percent confidence level. However, the authors noted that the relative risk calculated for the subcohort was consistently higher than that calculated for the full cohort. They also considered the subcohort to have a superior exposure assessment and a better latency allowance than the full cohort. According to the authors, these factors provide ''some assurance that the observed risk elevation was not entirely due to chance since improving the exposure assessment and allowing for latency effects should, in general, enhance exposure effects.''

Steenland et al., (1990, 1992, 1998)

The basis for the analyses in this series was a case-control study comparing the risk of lung cancer for diesel-exposed and unexposed workers who had belonged to the Teamsters Union for at least twenty years (Steenland et al., 1990). Drawing from union records, 996 cases of lung cancer were identified among more than 10,000 deaths in 1982 and 1983. For comparison to these cases, a total of 1,085 controls was selected (presumably at random) from the remaining deaths, restricted to those who died from causes other than lung cancer, bladder cancer, or motor vehicle accident. Information on work history, duration and intensity of cigarette smoking, diet, and asbestos exposure was obtained from next of kin. Detailed work histories were also obtained from pension applications on file with the Teamsters Union.

Both data sources were used to classify cases and controls according to a job category in which they had worked the longest. Based on the data obtained from next of kin, the job categories were diesel truck drivers, gasoline truck drivers, drivers of both truck types, truck mechanics, and dock workers. Based on the pension applications, the principal job categories were long-haul drivers, short-haul or city drivers, truck mechanics, and dock workers. Of the workers identified by next of kin as primarily diesel truck drivers, 90 percent were classified as long-haul drivers according to the Teamster data. The corresponding proportions were 82 percent for mechanics and 81 percent for dock workers. According to the investigators, most Teamsters had worked in only one exposed job category. However, because of the differences in job category definitions, and also because the next of kin data covered lifetimes whereas the pension applications covered only time in the Teamsters Union, the investigators found it problematic to fully evaluate the concordance between the two data sources.

In the 1990 report, separate analyses were conducted for each source of data used to compile work histories. The investigators noted that ''many trucking companies (where most study subjects worked) had completed most of the dieselization of their fleets by 1960, while independent drivers and nontrucking firms may have obtained diesel trucks later. * * * '' Therefore, they specifically checked for associations between increased risk of lung cancer and occupational exposure after 1959 and, separately, after 1964. In the 1992 report, the investigators presented, for the Union's occupational categories used in the study, dpm exposure estimates based on subsequent measurements of submicrometer elemental carbon (EC) as reported by Zaebst et al. (1991). In the 1998 report, cumulative dpm exposure estimates for individual workers were compiled by combining the individual work histories obtained from the Union's records with the subsequently measured occupational exposure levels, along with an evaluation of historical changes in diesel engine emissions and patterns of diesel usage. Three alternative sets of cumulative exposure estimates were considered, based on alternative assumptions about the extent of improvement in diesel engine emissions between 1970 and 1990. A variety of statistical models and techniques were then employed to investigate the relationship between estimated cumulative dpm exposure (expressed as EC) and the risk of lung cancer. The authors pointed out that the results of these statistical analyses depended heavily on ''very broad assumptions'' used to generate the estimates of cumulative dpm exposure. While acknowledging this limitation, however, they also evaluated the sensitivity of their results to various changes in their assumptions and found these changes to have little impact on the results.

The investigators also identified and addressed several other limitations of this study as follows:

(1) possible misclassification smoking habits by next of kin, (2) misclassification of exposure by next of kin, (3) a relatively small non-exposed group (n = 120) which by chance may have had a low lung cancer risk, and (4) lack of sufficient latency (time since first exposure) to observe a lung cancer excess. On the other hand, next-of-kin data on smoking have been shown to be reasonably accurate, non-differential misclassification of exposure * * * would only bias our findings toward * * * no association, and the trends of increased risk with increased duration of employment in certain jobs would persist even if the non-exposed group had a higher lung cancer risk. Finally, the lack of potential latency would only make any positive results more striking. (Steenland et al., 1990)

The main results from the three reports covering this study are summarized in the following table. All of the analyses were controlled for age, race, smoking (five categories), diet, and asbestos exposure as reported by next of kin. Odds ratios for the occupations listed were calculated relative to the odds of lung cancer for occupations other than truck driver (all types), mechanic, dock worker, or other potentially diesel exposed jobs (Steenland et al., 1990, Appendix A). The exposure-response analyses were carried out using logistic regression. Although the investigators performed analyses under three different assumptions for the rate of engine emissions (gm/mile) in 1970, they considered the intermediate value of 4.5 gm/mile to be their best estimate, and this is the value on which the results shown here are based. Under this assumption, cumulative occupational EC exposure for all workers in the study was estimated to range from 0.45 to 2,440 µg-yr/m³, with a median value of 373 µg-yr/m³. The estimates of relative risk (expressed as odds ratios) presented for EC exposures of 373 µg-yr/m³, 1000 µg-yr/m³, and 2450 µ-yr/m³ were calculated by MSHA based on the regression coefficients reported by the authors for five-year lagged exposures (Steenland et al. 1998, Table II).

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Main results from Steenland et al., (1990, 1992, 1998)

Principal Occupation	Mean 1990 EC Concentration (μg/m³)	Duration of Employment	Lung Cancer Odds Ratio	95-percent Conf. Interval
Diesel truck driver	N.A.	35 or more years*	1.89	1.04 - 3.42
Short-haul driver	5.4	18 or more years after 1959	1.79	0.94 - 3.42
Long-haul driver	5.1	18 or more years after 1959	1.55	0.97 - 2.47
		13 or more years after 1964	1.64	1.05 - 2.57
Truck mechanic	26.6	18 or more years after 1959	1.50	0.59 - 3.40

Cumulative Occupational Exposure (μg-yr/m³, lagged 5 years)**			Lung Cancer Odds Ratio	95-percent Conf. Interval
EC	TC ≈ 2•EC	Dpm ≈ TC/0.8 ≈ 2.5•EC		
0 - 169	0 - 338	0 - 422	1.08	0.72 - 1.63
169 - 257	338 - 514	422 - 642	1.10	0.74 - 1.65
257 - 331	514 - 662	642 - 827	1.36	0.90 - 2.04
more than 331	more than 662	more than 827	1.64	1.09 - 2.49

			Lung Cancer Odds Ratio‡	
		Logistic regression model ➜	Simple Cum. Exposure	Log of Cum. Exposure
373	746	932	1.16	1.41
1,000	2,000	2,500	1.48	1.66
2,450	4,900	6,100	2.59	1.93

*Although primary occupation was driving diesel trucks, employment duration includes years driving any type of truck.

**Conversions between EC, TC, and Dpm assume that, on average, TC ≈ 2•EC and TC ≈ 0.8•DPM.

‡ Calculated by MSHA from regression coefficients presented by Steenland et al. (1990), Table II. Statistically significant regression coefficients reported for both models (95% Conf. level). Tabled results for Log(Cum. exposure) model have been adjusted for lifetime background exposure of 65 μg-yr/m³ assumed in regression analysis.

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Under the assumption of a 4.5 gm/mile emissions rate in 1970, the cumulative EC exposure of 2450 µg–yr/m³ (≈ 6.1 mg–yr/m³ Dpm) shown in the table closely corresponds to the upper limit of the range of data on which the regression analyses were based (Steenland et al., 1998, p. 224). However, the relative risks (i.e., odds ratios) calculated for this level of occupational exposure are presented primarily for purposes of comparison with the findings of Johnston et al. (1997) and Säverin et al. (1999). At a cumulative Dpm exposure of approximately 6.1 mg—yr/m³, it is evident that the Johnston models predict a far greater elevation in lung cancer risk than either the Säverin or Steenland models. A possible explanation for this is that the Johnston data included exposures of up to 30 years in duration, and the statistical models showing an exposure-response relationship allowed for a 15-year lag in exposure effects. The other two studies were based on generally shorter diesel exposures and allowed less time for latent effects. In Subsection 3.b.ii(3) of this risk assessment, the quantitative results of these three studies will be further compared with respect to exposure levels found in underground mines.

Several commenters noted that the HEI Expert Panel (HEI, 1999) had identified uncertainties in the diesel exposure assessment as an important limitation of the exposure-response analyses by Steenland et al. (1998) and had recommended further investigation before the quantitative results of this study were accepted as conclusive. In addition, Navistar International Transportation (NITC) raised a number of objections to the methods by which diesel exposures were estimated for the period between 1949 and 1990 (NITC, 1999). In general, the thrust of these objections was that exposures to diesel engine emissions had been overestimated, while potentially relevant exposures to gasoline engine emissions had been underestimated and/or unduly discounted.[57]

As mentioned above, the investigators recognized that these analyses rely on ''broad assumptions rather than actual [concurrent] measurements,'' and they proposed that the ''results should be regarded with appropriate caution.'' While agreeing with both the investigators and the HEI Expert Panel that these results should be interpreted with appropriate caution, MSHA also agrees with the Panel ''* * * that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 39) In this context, MSHA considers it appropriate to regard the 1998 exposure-response analyses as contributing to the weight of evidence that dpm exposure increases the risk of lung cancer, even if the results are not conclusive when viewed in isolation.

Some commenters also noted that the HEI Expert Panel raised the possibility that the method for selecting controls in this study could potentially have biased the results in an unpredictable direction. Such bias could have occurred because deaths among some of the controls were likely due to diseases (such as cardiovascular disease) that shared some of the same risk factors (such as tobacco smoking) with lung cancer. The Panel presented hypothetical examples of how this might bias results in either direction. Although the possibility of such bias further demonstrates why the results of this study should be regarded with ''appropriate caution,'' it is important to distinguish between the mere possibility of a control-selection bias, evidence that such a bias actually exists in this particular study, and the further evidence required to show that such bias not only exists but is of sufficient magnitude to have produced seriously misleading results. Unlike the commenters who cited the HEI Expert Panel on this issue, the Panel itself clearly drew this distinction, stating that ''no direct evidence of such bias is apparent'' and emphasizing that ''even though these examples [presented in HEI (1999), Appendix D] could produce misleading results, it is important to note that they are only hypothetical examples. Whether or not such bias is present will require further examination.'' (HEI, 1999, pp. 37–38) As the HEI showed in its examples, such bias (if it exists) could lead to underestimating the association between lung cancer and dpm exposure, as well as to overestimating it. Therefore, in the absence of evidence that control-selection bias actually distorted the results of this study one way or the other, MSHA considers it prudent to accept the study's finding of an association at face value.

One commenter (MARG) noted that information on cigarette smoking, asbestos exposure, and diet in the trucking industry study was obtained from next of kin and stated that such information was ''likely to be unreliable.'' By increasing random variability in the data, such errors could widen the confidence intervals around an estimated odds ratio or reduce the confidence level at which a positive exposure-response relationship might be established. However, unless such errors were correlated with diesel exposure or lung cancer in such a way as to bias the results, they would not, on average, inflate the estimated degree of association between diesel exposure and an increased risk of lung cancer. The commenter provided no reason to suspect that errors with respect to these factors were in any way correlated with diesel exposure or with the development of lung cancer.

Some commenters pointed out that EC concentrations measured in 1990 for truck mechanics were higher, on average, than for truck drivers, but the mechanics, unlike the drivers, showed no evidence of increasing lung cancer risk with increasing duration of employment. NITC referred to this as a ''discrepancy'' in the data, assuming that ''cumulative exposure increases with duration of employment such that mechanics who have been employed for 18 or more years would have greater cumulative exposure than workers who have been employed for 1–11 years.'' (NITC, 1999)

Mechanics were included in the logistic regression analyses (Steenland et al., 1998) showing an increase in lung cancer risk with increasing cumulative exposure. These analyses pooled the data for all occupations by estimating exposure for each worker based on the worker's occupation and the particular years in which the worker was employed. There are at least three reasons why, for mechanics viewed as a separate group, an increase in lung cancer risk with increasing dpm exposure may not have been reflected by increasing duration of employment.

First, relatively few truck mechanics were available for analyzing the relationship between length of employment and the risk of lung cancer. Based on the union records, 50 cases and 37 controls were so classified; based on the next-of-kin data, 43 cases and 41 controls were more specifically classified as diesel truck mechanics

[57] Many of the issues NITC raised in its critique of this study depend on a peculiar identification of Dpm exclusively with elemental carbon. For example, NITC argued that ''more than 65 percent of the total carbon to which road drivers (and mechanics) were exposed consisted of organic (i.e., non-diesel) carbon, further suggesting that some other etiology caused or contributed to excess lung cancer mortality in these workers.'' (NITC, 1999, p. 16) Such lines of argument, which depend on identifying organic carbon as ''non-diesel,'' ignore the fact that Dpm contains a large measure of organic carbon compounds (and also some sulfates), as well as elemental carbon. Any adverse health effects due to the organic carbon or sulfate constituents of Dpm would nonetheless be due to Dpm exposures.

(Steenland et al., 1990). In contrast, 609 cases and 604 controls were classified as long-haul drivers (union records). This was both the largest occupational category and the only one showing statistically significant evidence of increasing risk with increasing employment duration. The number of mechanics included in the study population may simply not have been sufficient to detect a pattern of increasing risk with increasing length of employment, even if such a pattern existed.

The second part of the explanation as to why mechanics did not exhibit a pattern similar to truck drivers could be that the data on mechanics were more subject to confounding. After noting that ''the risk for mechanics did not appear to increase consistently with duration of employment,'' Steenland et al. (1990) further noted that the mechanics may have been exposed to asbestos when working on brakes. The data used to adjust for asbestos exposure may have been inadequate to control for variability in asbestos exposure among the mechanics.

Third, as noted by NITC, the lung cancer risk for mechanics (adjusted for age, race, tobacco smoking, asbestos exposure, and diet) would be expected to increase with increasing duration of employment only if the mechanics' cumulative dpm exposure corresponded to the length of their employment. None of the commenters raising this issue, however, provided any support for this assumption, which fails to consider the particular calendar years in which mechanics included in the study were employed. In compiling cumulative exposure for an individual worker, the investigators took into account historical changes in both diesel emissions and the proportion of trucks with diesel engines—so the exposure level assigned to each occupational category was not the same in each year. In general, workers included in the study neither began nor ended their employment in the same year. Consequently, workers with the same duration of employment in the same occupational category could be assigned different cumulative exposures, depending on when they were employed. Similarly, workers in the same occupational category who were assigned the same cumulative exposure may not have worked the same length of time in that occupation. Therefore, it should not be assumed that duration of employment corresponds very well to the cumulative exposure estimated for workers within any of the occupational categories. Furthermore, in the case of mechanics, there is an additional historical variable that is especially relevant to actual cumulative exposure but was not considered in formulating exposure estimates: the degree of ventilation or other means of protection within repair shops. Historical changes in shop design and work practices, as well as differences between shops, may have caused more exposure misclassification among mechanics than among long-haul or diesel truck drivers. Such misclassification would tend to further obscure any relationship between mechanics' risk of lung cancer and either duration of employment or cumulative exposure.

(iv) Counter-Evidence

Several commenters stated that, in the proposal, MSHA had dismissed or not adequately addressed epidemiology studies showing no association between lung cancer and exposures to diesel exhaust. For example, the EMA wrote:

> MSHA's discussion of the negative studies generally consists of arguments to explain why those studies should be dismissed. For example, MSHA states that, ''All of the studies showing negative or statistically insignificant positive associations * * * lacked good information about dpm exposure * * *'' or showed similar shortcomings. 63 Fed. Reg. at 17533. The statement about exposure information is only partially true, for, in fact, very few of any of the cited studies (the ''positive'' studies as well) included any exposure measurements, and none included concurrent exposures.

It should, first of all, be noted that the statement in question on dpm exposure referred to the issue of any diesel exposure—not to quantitative exposure measurements, which MSHA acknowledges are lacking in most of the available studies. In the absence of quantitative measurements, however, studies comparing workers known to have been occupationally exposed to unexposed workers are preferable to studies not containing such comparisons. Furthermore, two of the studies now available (and discussed above) utilize essentially concurrent exposure measurements, and both show a positive association (Johnston et al., 1997; Säverin et al., 1999).

MSHA did not entirely ''dismiss'' the negative studies. They were included in both MSHA's tabulation (see Tables III–4 and III–5) and (if they met the inclusion criteria) in the two meta-analyses cited both here and in the proposal (Lipsett and Campleman, 1999, and Bhatia et al., 1998). As noted by the commenter, MSHA presented reasons (such as an inadequate latency allowance) for why negative studies may have failed to detect an association. Similarly MSHA gave reasons for giving less weight to some of the positive studies, such as Benhamou et al. (1988), Morabia et al. (1992), and Siemiatycki et al., 1988. Additional reasons for giving less weight to the six entirely negative studies have been tabulated above, under the heading of ''Best Available Epidemiologic Evidence.'' The most recent of these negative studies (Christie et al., 1994, 1995) is discussed in detail under the heading of ''Studies Involving Miners.''

One commenter (IMC Global) listed the following studies (all of which MSHA had considered in the proposed risk assessment) as ''examples of studies that reported negative associations between [dpm] exposure and lung cancer risk'':

- Waller (1981). This is one of the six negative studies discussed earlier. Results were likely to have been biased by excluding lung cancers occurring after retirement or resignation from employment with the London Transit Authority. Comparison was to a general population, and there was no adjustment for a healthy worker effect. Comparison groups were disparate, and there was no adjustment for possible differences in smoking frequency or intensity.
- Howe et al. (1983). Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risk for workers classified as ''possibly exposed'' or ''probably exposed'' to diesel exhaust. MSHA recognizes that these results may have been confounded by asbestos and coal dust exposures.
- Wong et al. (1985). The investigators reported a statistically insignificant deficit for lung cancer in the entire cohort and a statistically significant deficit for lung cancer in the less than 5-year duration group. However, since comparisons were to a general population, these deficits may be the result of a healthy worker effect, for which there was no adjustment. Because of the latency required for development of lung cancer, the result for ''less than 5-year duration'' is far less informative than the results for longer durations of employment and greater latency allowances. Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risks for ''normal'' retirees (SMR = 1.30) and for ''high exposure'' dozer operators with 15–19 years of union membership and a latency allowance of at least 20 years (SMR = 3.43).
- Edling et al. (1987). This is one of the six negative studies discussed

earlier. The cohort consisted of only 694 bus workers and, therefore, lacked statistical power. Furthermore, comparison was to a general, external population with no adjustment for a healthy worker effect.

• Garshick (1988). The reason the commenter (IMC Global) gave for characterizing this study as negative was: ''That the sign of the association in this data set changes based on the models used suggests that the effect is not robust. It apparently reflects modeling assumptions more than data.'' Contrary to the commenter's characterization, however, the finding of increased lung cancer risk for workers classified as diesel-exposed did not change when different methods were used to analyze the data. What changed, depending on modeling assumptions, was the shape and direction of the exposure-response relationship among exposed workers (Cal-EPA, 1998; Stayner et al., 1998; Crump, 1999; HEI, 1999). MSHA agrees that the various exposure-response relationships that have been derived from this study are highly sensitive to data modeling assumptions. This includes assumptions about historical patterns of exposure, as well as assumptions related to technical aspects of the statistical analysis. However, as noted by the HEI Expert Panel, the study provides evidence of a positive association between exposure and lung cancer despite the conflicting exposure-response analyses. Even though different assumptions and methods of analysis have led to different conclusions about the utility of this study for quantifying an exposure-response relationship, ''the overall risk of lung cancer was elevated among diesel-exposed workers'' (HEI, 1999, p. 25).

Another commenter (MARG) cited a number of studies (all of which had already been placed in the public record by MSHA) that, according to the commenter, ''reflect either negative health effects trends among miners or else failed to demonstrate a statistically significant positive trend correlated with dpm exposure.'' It should be noted that, as explained earlier, failure of an individual study to achieve statistical significance (i.e., a high confidence level for its results) does not necessarily prevent a study from contributing important information to a larger body of evidence. An epidemiologic study may fail to achieve statistical significance simply because it did not involve a sufficient number of subjects or because it did not allow for an adequate latency period. In addition to this general point, the following responses apply to the specific studies cited by the commenter.

• Ahlman et al. (1991). This study is discussed above, under the heading of ''Studies Involving Miners.'' MSHA agrees with the commenter that this study did not ''establish'' a relationship between diesel exposure and the excess risk of lung cancer reported among the miners involved. Contrary to the commenter's characterization, however, the evidence presented by this study does incrementally point in the direction of such a relationship. As mentioned earlier, none of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on measurements of the alpha energy concentration at the mines, and a comparison of smoking habits between underground and surface miners, the authors concluded that not all of the excess lung cancer for the underground miners was attributable to radon daughter exposures and/or smoking. A stronger conclusion may have been possible if the cohort had been larger.

• Ames et al. (1984). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter repeated MSHA's statement (in the proposed risk assessment) that the investigators had not detected any association of chronic respiratory effects with diesel exposure, but ignored MSHA's observation that the analysis had failed to consider baseline differences in lung function or symptom prevalence. Furthermore, as acknowledged by the investigators, diesel exposure levels in the study population were low.

• Ames et al. (1983). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Unlike the Australian mines studied by Christie et al. (1995), the coal mines included in this study were not extensively dieselized, and the investigators did not relate their findings to diesel exposures.

• Ames et al. (1982). As noted earlier under the heading of ''Acute Health Effects,'' this study, which did not attempt to evaluate cancer or other chronic health effects, detected no statistically significant relationship between diesel exposure and pulmonary function. However, the authors noted that this might have been due to the low concentrations of diesel emissions involved.

• Armstrong et al. (1979). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. As pointed out by the commenter, comparisons were to a general population. Therefore, they were subject to a healthy worker effect for which no adjustment was made. The commenter further stated that ''diesel emissions were not found to be related to increased health risks.'' However, diesel emissions were not mentioned in the report, and the investigators did not attempt to compare lung cancer rates in exposed and unexposed miners.

• Attfield et al. (1982). MSHA has taken the results of this study into account, under the heading of ''Chronic Effects other than Cancer.''

• Attfield (1979). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Although the results were not conclusive at a high confidence level, miners occupationally exposed to diesel exhaust for five or more years exhibited an increase in various respiratory symptoms, as compared to miners exposed for less than five years.

• Boffetta et al. (1988). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' The commenter stated that ''the study obviously does not demonstrate risks from dpm exposure.'' If the word ''demonstrate'' is taken to mean ''conclusively prove,'' then MSHA would agree that the study, viewed in isolation, does not do this. As explained in the earlier discussion, however, MSHA considers this study to contribute to the weight of evidence that dpm exposure increases the risk of lung cancer.

• Costello *et al.* (1974). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Since comparisons were to a general population, they were subject to a healthy worker effect for which no adjustment was made. Diesel emissions were not mentioned in the report.

• Gamble and Jones (1983). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' The commenter did not address MSHA's observation that the method of statistical analysis used by the investigators may have masked an association of respiratory symptoms with diesel exposure.

• Glenn *et al.* (1983). As summarized by the commenter, this report reviewed NIOSH medical surveillance on miners exposed to dpm and found that ''* * * neither consistent nor obvious trends implicating diesel exhaust in the mining atmosphere were revealed.'' The authors noted that ''results were rather mixed,'' but also noted that ''levels of diesel exhaust contaminants were generally low,'' and that ''overall tenure in these diesel equipped mines was fairly short.'' MSHA acknowledges the commenter's emphasis on the report's 1983 conclusion: ''further research on this subject is needed.'' However, the authors also pointed out that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group. In the potash, salt and trona groups, these excesses were substantial.'' The miners included in the studies summarized by this report would not have been exposed to Dpm for sufficient time to exhibit a possible increase in the risk of lung cancer.

• Johnston *et al.* (1997). This study is discussed in two places above, under the headings ''Studies Involving Miners'' and ''Best Available Epidemiologic Evidence.'' MSHA disagrees with the commenter's assertion that ''the study does not support a health risk from dpm.'' This was not the conclusion drawn by the authors of the study. As explained in the earlier discussion, this study, one of the few containing quantitative estimates of cumulative dpm exposures, provides evidence of increasing lung cancer risk with increasing exposure.

• Jörgenson and Svensson (1970). MSHA discussed this study, which did not attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' Contrary to the commenter's characterization, the investigators reported higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among the underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine.

• Kuempel (1995); Lidell (1973); Miller and Jacobsen (1985). As discussed later in this risk assessment, under the heading of ''Mechanisms of Toxicity,'' these three studies were among the nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. The extent, if any, to which workers involved in these studies were occupationally exposed to diesel emissions was not documented, and diesel emissions were not mentioned in any of these reports.

• Morfeld *et al.* (1997). The commenter's summary of this study distorted the investigators' conclusions. Contrary to the commenter's characterization, this is one of eight studies that showed an increased risk of lung cancer for coal miners, as discussed later in this risk assessment under the heading of ''Mechanisms of Toxicity.'' For lung cancer, the relative SMR, which adjusts for the healthy worker effect, was 1.11. (The value of 0.70 cited by the commenter was the unadjusted SMR.) The authors acknowledged that the relative SMR obtained by the ''standard analysis'' (*i.e.,* 1.11) was not statistically significant. However, the main object of the report was to demonstrate that the ''standard analysis'' is insufficient. The investigators presented evidence that the 1.11 value was biased downward by a ''healthy-worker-survivor-effect,'' thereby masking the actual exposure effects in these workers. They found that ''all the evidence points to the conclusion that a standard analysis suffers from a severe underestimate of the exposure effect on overall mortality, cancer mortality and lung cancer mortality.'' (Morfeld *et al.,* 1997, p. 350)

• Reger (1982). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of ''Chronic Effects other than Cancer.'' As summarized by the commenter, ''diesel-exposed miners were found to have more cough and phlegm, and lower pulmonary function,'' but the author found that ''the evidence would not allow for the rejection of the hypothesis of health equality between exposed and non-exposed miners.'' The commenter failed to note, however, that miners in the dieselized mines, had worked underground for less than 5 years on average.

• Rockette (1977). This is one of eight studies, discussed under ''Mechanisms of Toxicity,'' showing an increased risk of lung cancer for coal miners. As described by the commenter, the author reported SMRs of 1.12 for respiratory cancers and 1.40 for stomach cancer. MSHA agrees with the commenter that ''the study does not establish a dpm-related health risk,'' but notes that dpm effects were not under investigation. Diesel emissions were not mentioned in the report, and, given the study period, the miners involved may not have been occupationally exposed to diesel exhaust.

• Waxweiler (1972). MSHA's discussion of this study appears earlier in this risk assessment, under ''Studies Involving Miners.'' As noted by the commenter, the slight excess in lung cancer, relative to the general population of New Mexico, was not statistically significant. The commenter failed to note, however, that no adjustment was made for a healthy worker effect and that a substantial percentage of the underground miners were not occupationally exposed to diesel emissions.

(v) Summation

Limitations identified in both positive and negative studies include: lack of sufficient power, inappropriate comparison groups, exposure misclassification, statistically insignificant results, and potential confounders. As explained earlier, under ''Evaluation Criteria,'' weaknesses of the first three of these types can reasonably be expected, for the most part, to artificially decrease the apparent strength of any observed association between diesel exposure and increased risk of lung cancer. Statistical insignificance and potential confounders may, in the absence of evidence to the contrary, be regarded as neutral on average. The weaknesses that have been identified in these studies are not unique to epidemiologic studies involving lung cancer and diesel exhaust. They are sources of uncertainty in virtually all epidemiologic research.

Even when there is a strong possibility that the results of a study have been affected by confounding variables, it does not follow that the effect has been to inflate rather than deflate the results or that the study cannot contribute to the weight of evidence supporting a putative association. As cogently stated by Stöber and Abel (op cit., p. 4), ''* * * associations found in epidemiologic studies can always be, at least in part, attributed to confounding.'' Therefore, an objection grounded on potential confounding can always be raised against any epidemiologic study. It is well known that this same objection was, in the past, raised against epidemiologic studies linking lung cancer and radon exposure, lung cancer and asbestos dust exposure, and even lung cancer and tobacco smoking.

Some commenters have now proposed that virtually every existing epidemiologic study relating lung cancer to dpm exposure be summarily discredited because of susceptibility to confounding or other perceived weaknesses. Given the practical difficulties of designing and executing an epidemiologic study, this is not so much an objection to any specific study as it is an attack on applied epidemiology in general. Indeed, in their review of these studies, Stöber and Abel (1996) conclude that.

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

For important ethical reasons, however, tightly controlled lung cancer experiments cannot be performed on humans. Therefore, despite their inherent limitations, MSHA must rely on the weight of evidence from epidemiologic studies, placing greatest weight on the most carefully designed and executed studies available.

(b) Bladder Cancer

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

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

This, along with the lack of corroboration from existing cohort studies, suggests that the excessive rates of bladder cancer observed may be a consequence of factors other than dpm exposure that are also associated with these occupations. For example, truck and bus drivers are subjected to vibrations while driving and may tend to have different dietary and sleeping habits than the general population. For these reasons, MSHA does not find that convincing evidence currently exists for a causal relationship between dpm exposure and bladder cancer. MSHA received no public comments objecting to this conclusion.

ii. Studies Based on Exposures to $PM_{2.5}$ in Ambient Air

Prior to 1990, the relationship between mortality and long-term exposure to particulate matter was generally investigated by means of cross-sectional studies, but unaddressed spatial confounders and other methodological problems inherent in such studies limited their usefulness (EPA, 1996).[58] Two more recent prospective cohort studies provide better evidence of a link between excess mortality rates and exposure to fine particulate, although some of the uncertainties here are greater than with the short-term studies conducted in single communities. The two studies are the ''Six Cities'' study (Dockery et al., 1993), and the American Cancer Society (ACS) study (Pope et al., 1995).[59] The first study followed about 8,000 adults in six U.S. cities over 14 years; the second looked at survival data for half a million adults in 151 U.S. cities for 7 years. After adjusting for potential confounders, including smoking habits, the studies considered differences in mortality rates between the most polluted and least polluted cities.

Both the Six Cities study and the ACS study found a significant association between chronically higher concentrations of $PM_{2.5}$ (which includes dpm) and age-adjusted total mortality.[60] 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.[61] In the ACS study, however, the estimated increase in mortality associated with a given increase in fine particulate exposure was lower, though still statistically significant. In both studies, the largest increase observed was for cardiopulmonary mortality.

Both studies also showed an increased risk of lung cancer associated with increased exposure to fine particulate. Although the lung cancer results were not statistically significant, they are consistent with reports of an increased risk of lung cancer among workers occupationally exposed to diesel emissions (discussed above).

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

d. Mechanisms of Toxicity

Four topics will be addressed in this section of the risk assessment: (i) the agent of toxicity, (ii) clearance and deposition of dpm, (iii) effects other than cancer, and (iv) lung cancer. The section on lung cancer will include discussions of the evidence from (1) genotoxicity studies (including bioavailability of genotoxins) and (2) animal studies.

i. Agent of Toxicity

As described in Part II of this preamble, the particulate fraction of diesel exhaust is made up of aggregated soot particles, vapor phase hydrocarbons, and sulfates. Each soot particle consists of an insoluble, elemental carbon core and an adsorbed, surface coating of relatively soluble organic compounds, such as polycyclic aromatic hydrocarbons (PAHs). Many of these organic carbon compounds are

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[58] Unlike *longitudinal studies,* which examine responses at given locations to changes in conditions over time, *cross-sectional studies* compare results from locations with different conditions at a given point in time.

[59] A third such study, the California Seventh Day Adventist study (Abbey et al., 1991), investigated only TSP, rather than fine particulate. It did not find significant excess mortality associated with chronic TSP exposures.

[60] The Six Cities study also found such relationships at elevated levels of PM_{10} and sulfates. The ACS study was designed to follow up on the fine particle results of the Six Cities Study, and also investigated sulfates separately. As explained earlier in this preamble, sulfates may be a significant constituent of dpm, depending on the type of diesel fuel used.

[61] The Six Cities study did not find a statistically significant increase in risk among non-smokers, suggesting that non-smokers might be less sensitive than smokers to adverse health effects from fine particulate exposures; however, the ACS study, with more statistical power, did find significantly increased risk even for non-smokers.

suspected or known mutagens and/or carcinogens. For example, nitrated PAHs, which are present in dpm, are potent mutagens in microbial and human cell systems, and some are known to be carcinogenic to animals (IPCS, 1996, pp. 100–105).

When released into an atmosphere, the soot particles formed during combustion tend to aggregate into larger particles. The total organic and elemental carbon in these soot particles accounts for approximately 80 percent of the dpm mass. The remaining 20 percent consists mainly of sulfates, such as H_2SO_4 (sulfuric acid).

Several laboratory animal studies have been performed to ascertain whether the effects of diesel exhaust are attributable specifically to the particulate fraction. (Heinrich *et al.,* 1986, 1995; Iwai *et al.,* 1986; Brightwell *et al.,* 1986). These studies compare the effects of chronic exposure to whole diesel exhaust with the effects of filtered exhaust containing no particles. The studies demonstrate that when the exhaust is sufficiently diluted to nullify the effects of gaseous irritants (NO_2 and SO_2), irritant vapors (aldehydes), CO, and other systemic toxicants, diesel particles are the prime etiologic agents of noncancer health effects. Exposure to dpm produced changes in the lung that were much more prominent than those evoked by the gaseous fraction alone. Marked differences in the effects of whole and filtered diesel exhaust were also evident from general toxicological indices, such as body weight, lung weight, and pulmonary histopathology.

These studies show that, when the exhaust is sufficiently diluted, it is the particles that are primarily responsible for the toxicity observed. However, the available studies do not completely settle the question of whether the particles might act additively or synergistically with the gases in diesel exhaust. Possible additivity or interaction effects with the gaseous portion of diesel exhaust cannot be completely ruled out.

One commenter (MARG) raised an issue with regard to the agent of toxicity in diesel exhaust as follows:

> MSHA has not attempted to regulate exposure to suspected carcinogens contained in dpm, but has opted instead, in metal/non-metal mines, to regulate total carbon (''TC'') as a surrogate for diesel exhaust, without any evidence of adverse health effects from TC exposure. * * * Nor does the mere presence of suspected carcinogens, in minute quantities, in diesel exhaust require a 95 percent reduction of total diesel exhaust [sic] in coal mines. If there are small amounts of carcinogenic substances of concern in diesel exhaust, those substances, not TC, should be regulated directly on the basis of the risks (if any) posed by those substances in the quantities actually present in underground mines. [MARG]

First, it should be noted that the ''suspected carcinogens'' in diesel exhaust to which the commenter referred are part of the organic fraction of the total carbon. Therefore, limiting the concentration of airborne total carbon attributable to dpm, or removing the soot particles from the diesel exhaust by filtration, are both ways of effectively limiting exposures to these suspected carcinogens. Second, the commenter seems to have assumed that cancer is the only adverse health effect of concern and that the only agents in dpm that could cause cancer are the ''suspected carcinogens'' in the organic fraction. This not only ignores non-cancer health effects associated with exposures to dpm and other fine particles, but also the possibility (discussed below) that, with sufficient deposition and retention, soot particles themselves could promote or otherwise increase the risk of lung cancer—either directly or by stimulating the body's natural defenses against foreign substances.

The same commenter [MARG] also stated that ''* * * airborne carbon has not been shown to be harmful at levels currently established in MSHA's dust rules. If the problem is dpm, as MSHA asserts, then it is not rationally addressed by regulating airborne carbon.'' MSHA's intent is to limit dpm exposures in M/NM mines by regulating the submicrometer carbon from diesel emissions—not any and all airborne carbon. MSHA considers its approach a rational means of limiting dpm exposures because most of the dpm consists of carbon (approximately 80 percent by weight), and because using low sulfur diesel fuel will effectively reduce the sulfates comprising most of the remaining portion. The commenter offered no practical suggestion of a more direct, effective, and rational way of limiting airborne dpm concentrations in M/NM mines. Furthermore, direct evidence exists that the risk of lung cancer increases with increasing cumulative occupational exposure to dpm as measured by total carbon (Säverin *et al.,* 1999, discussed earlier in this risk assessment).

ii. Deposition, Clearance, and Retention

As suggested by Figure II–1 of this preamble, most of the aggregated particles making up dpm are no larger than one micrometer in diameter. Particles this small are able to penetrate into the deepest regions of the lungs, called *alveoli.* In the alveoli, the particles can mix with and be dispersed by a substance called *surfactant,* which is secreted by cells lining the alveolar surfaces.

The literature on deposition of fine particles in the respiratory tract was reviewed in Green and Watson (1995) and U.S. EPA (1996). The mechanisms responsible for the broad range of potential particle-related health effects varies depending on the site of deposition. Once deposited, the particles may be cleared from the lung, translocated into the interstitium, sequestered in the lymph nodes, metabolized, or be otherwise chemically or physically changed by various mechanisms. Clearance of dpm from the alveoli is important in the long-term effects of the particles on cells, since it may be more than two orders of magnitude slower than mucociliary clearance (IPCS, 1996).

IARC (1989) and IPCS (1996) reviewed factors affecting the deposition and clearance of dpm in the respiratory tracts of experimental animals. Inhaled PAHs adhering to the carbon core of dpm are cleared from the lung at a significantly slower rate than unattached PAHs. Furthermore, there is evidence that inhalation of whole dpm may increase the retention of subsequently inhaled PAHs. IARC (op cit.) suggested that this can happen when newly introduced PAHs bind to dpm particles that have been retained in the lung.

The evidence points to significant differences in deposition and clearance for different animal species (IPCS, 1996). Under equivalent exposure regimens, hamsters exhibited lower levels of retained Dpm in their lungs than rats or mice and consequently less pulmonary function impairment and pulmonary pathology. These differences may result from a lower intake rate of Dpm, lower deposition rate and/or more rapid clearance rate, or lung tissue that is less susceptible to the cytotoxicity of Dpm. Observations of a decreased respiration in hamsters when exposed by inhalation favor lower intake and deposition rates.

Retardation of lung clearance, called ''overload'' is not specific to dpm and may be caused by inhaling, at a sufficiently high rate, dpm in combination with other respirable particles, such as mineral dusts typical of mining environments. The effect is characterized by (1) an overwhelming of normal clearance processes, (2) disproportionately high retention and loading of the lung with particles, compared to what occurs at lower particle inhalation rates, (3) various pathological responses; generally including chronic inflammation, epithelial hyperplasia and metaplasia, and pulmonary fibrosis; and sometimes including lung tumors.

In the proposed risk assessment, MSHA requested additional information, not already covered in the sources cited above, on fine particle deposition in the respiratory tract, especially as it might pertain to lung loading in miners exposed to a combination of diesel particulate and other dusts. In response to this request, NIOSH submitted a study that investigated rat lung responses to chronic inhalation of a combination of coal dust and diesel exhaust, compared to coal dust or dpm alone (Castranova et al., 1985). Although this report did not directly address deposition or clearance, the investigators reported that another phase of the study had shown that ''particulate clearance, as determined by particulate accumulation in the lung, is inhibited after two years of exposure to diesel exhaust but is not inhibited by exposure to coal dust.''

iii. Effects Other Than Cancer

A number of controlled animal studies have been undertaken to ascertain the toxic effects of exposure to diesel exhaust and its components. Watson and Green (1995) reviewed approximately 50 reports describing noncancerous effects in animals resulting from the inhalation of diesel exhaust. While most of the studies were conducted with rats or hamsters, some information was also available from studies conducted using cats, guinea pigs, and monkeys. The authors also correlated reported effects with different descriptors of dose, including both gravimetric and non-gravimetric (*e.g.,* particle surface area or volume) measures. From their review of these studies, Watson and Green concluded that:

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

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

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

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

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

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Table III-6. — Hypothesized mechanisms of particulate toxicity†

Response	Description
Increased Airflow Obstruction	PM exposure may aggravate existing respiratory symptoms which feature airway obstruction. PM-induced airway narrowing or airway obstruction from increased mucous secretion may increase abnormal ventilation/perfusion ratios in the lung and create hypoxia. Hypoxia may lead to cardiac arrhythmias and other cardiac electrophysiologic responses that in turn may lead to ventricular fibrillation and ultimately cardiac arrest. For those experiencing airflow obstruction, increased airflow into non-obstructed areas of the lung may lead to increased particle deposition and subsequent deleterious effects on remaining lung tissue, further exacerbating existing disease processes. More frequent and severe symptoms may be present or more rapid loss of function.
Impaired Clearance	PM exposure may impair clearance by promoting hypersecretion of mucus which in turn results in plugging of airways. Alterations in clearance may also extend the time that particles or potentially harmful biogenic aerosols reside in the tracheobronchial region of the lung. Consequently alterations in clearance from either disturbance of the mucociliary escalator or of macrophage function may increase susceptibility to infection, produce an inflammatory response, or amplify the response to increased burdens of PM. Acid aerosols impair mucociliary clearance.
Altered Host Defense	Responses to an immunological challenge (e.g., infection), may enhance the subsequent response to inhalation of nonspecific material (e.g., PM). PM exposure may also act directly on macrophage function which may not only affect clearance of particles but also increase susceptibility and severity of infection by altering their immunological function. Therefore, depression or over-activation of the immune system, caused by exposure to PM, may be involved in the pathogenesis of lung disease. Decreased respiratory defense may result in increased risk of mortality from pneumonia and increased morbidity (e.g., infection).
Cardiovascular Perturbation	Pulmonary responses to PM exposure may include hypoxia, bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators that can contribute to cardiovascular perturbation. Inhaled particles could act at the level of the pulmonary vasculature by increasing pulmonary vascular resistance and further increase ventilation/perfusion abnormalities and hypoxia. Generalized hypoxia could result in pulmonary hypertension and interstitial edema that would impose further workload on the heart. In addition, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to increased risk of thrombus formation in the vascular system. Finally, direct stimulation by PM of respiratory receptors found throughout the respiratory tract may have direct cardiovascular effects (e.g., bradycardia, hypertension, arrhythmia, apnea and cardiac arrest).
Epithelial Lining Changes	PM or its pathophysiological reaction products may act at the alveolar capillary membrane by increasing the diffusion distances across the respiratory membrane (by increasing its thickness) and causing abnormal ventilation/perfusion ratios. Inflammation caused by PM may increase "leakiness" in pulmonary capillaries leading eventually to increased fluid transudation and possibly to interstitial edema in susceptible individuals. PM induced changes in the surfactant layer leading to increased surface tension would have the same effect.
Inflammatory Response	Diseases which increase susceptibility to PM toxicity involve inflammatory response (e.g., asthma, COPD, and infection). PM may induce or enhance inflammatory responses in the lung which may lead to increased permeability, diffusion abnormality, or increased risk of thrombus formation in vascular system. Inflammation from PM exposure may also decrease phagocytosis by alveolar macrophages and therefore reduce particle clearance. (See discussions above for other inflammatory effects from PM exposure.)

† This table was derived from information in EPA (1996) 11:179-185; 13:67-72; and Appendix D of EPA staff report.

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

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

Some commenters mistakenly attributed the sensory irritant effects of diesel exhaust entirely to its gaseous components. The mechanism by which constituents of dpm can cause sensory irritations in humans is much better understood than the mechanisms for other adverse health effects due to fine particulates. In essence, sensory irritants are ''scrubbed'' from air entering the upper respiratory tract, thereby preventing a portion from penetrating more deeply into the lower respiratory tract. However, the sensory irritants stimulate trigeminal nerve endings, which are located very close to the oro-nasal mucosa and also to the watery surfaces of the eye (cornea). This produces a burning, painful sensation. The intensity of the sensory irritant response is related to the irritant concentration and duration of exposure. Differences in relative potency are observed with different sensory irritants. Acrolein and formaldehyde are examples of highly potent sensory irritants which, along with others having low molecular weights (acids, aldehydes), are often found in the organic fraction of dpm (Nauss et al., 1995). They may be adsorbed onto the carbon-based core or released in a vapor phase. Thus, mixtures of sensory irritants in dpm may impinge upon the eyes and respiratory tract of miners and produce adverse health effects.

It is also important to note that mixtures of sensory irritants in dpm may produce responses that are not predicted solely on the basis of the individual chemical constituents. Instead, these irritants may interact at receptor sites to produce additive, synergistic, or antagonistic effects. For example, because of synergism, dpm containing a mixture of sensory irritants at relatively low concentrations may produce intense sensory responses (i.e., responses far above those expected for the individual irritants). Therefore, the irritant effects of whole dpm cannot properly be evaluated by simply adding together the known effects of its individual components.

As part of its public comments on the proposed preamble, NIOSH submitted a study (Hahon et al., 1985) on the effects of diesel emissions on mice infected with influenza virus. The object of this study was to determine if exposure to diesel emissions (either alone or in combination with coal dust) could affect resistance to pulmonary infections. The investigators exposed groups of mice to either coal dust, diesel emissions, a combination of both, or filtered air (control group) for various durations, after which they were infected with influenza. Although not reflected by excess mortality, the severity of influenza infection was found to be more pronounced in mice previously exposed to diesel emissions than in control animals. The effect was not intensified by inhalation of coal dust in combination with those emissions.

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

Takenaka et al. (1995) investigated mechanisms by which dpm may act to cause allergenic effects in human cell cultures. The investigators reported that application of organic dpm extracts over a period of 10 to 14 days increased IgE production from the cells by a factor of up to 360 percent. They concluded that enhanced IgE production in the human airway resulting from the organic fraction of dpm may be an important factor in the increasing incidence of allergic airway disease. Similarly, Tsien et al. (1997) investigated the effects of the organic fraction of dpm on IgE production in human cell cultures and found that application of the organic extract doubled IgE production after three days in cells already producing IgE.

Sagai et al. (1996) investigated the potential role of dpm-induced oxygen radicals in causing pulmonary injuries. Repeated intratracheal instillation of dpm in mice caused marked infiltration of inflammatory cells, proliferation of goblet cells, increased mucus secretion, respiratory resistance, and airway constriction. The results indicated that oxygen radicals, induced by intratracheally instilled dpm, can cause responses characteristic of bronchial asthma.

Lovik et al (1997) investigated inflammatory and systemic IgE responses to dpm, alone and in combination with the model allergen ovalbumin (OA), in mice. To determine whether it was the elemental carbon core or substances in the organic fraction of dpm that were responsible for observed allergenic effects, they compared the effects of whole dpm with those of carbon black (CB) particles of comparable size and specific surface area. Although the effects were slightly greater for dpm, both dpm and CB were found to cause significant, synergistic increases in allergenic responses to the OA, as expressed by inflammatory responses of the local lymph node and OA-specific IgE production. The investigators concluded that both dpm and CB synergistically enhance and prolong inflammatory responses in the lymph nodes that drain the site of allergen deposition. They further concluded that the elemental carbon core contributes substantially to the adjuvant activity of dpm.

Diaz-Sanchez et al. (1994, 1996, 1997) conducted a series of experiments on human subjects to investigate the effects of dpm on allergic inflammation as measured by IgE production. The studies by Takenaka et al. (op cit.) and Tsien et al. (op cit.) were also part of this series but were based on human cell cultures rather than live human volunteers. A principal objective of these experiments was to investigate the pathways and mechanisms by which dpm induces allergic inflammation. The investigators found that the organic fraction of dpm can enhance IgE production, but that the major polyaromatic hydrocarbon in this fraction (phenanthrene) can enhance IgE without causing inflammation. On the other hand, when human volunteers were sprayed intranasally with carbon particles lacking the organic compounds, the investigators found a large influx of cells in the nasal mucosa but no increase in IgE. These results suggest that while the organic portion of dpm is not necessary for causing irritation and local inflammation, it is the organic compounds that act on the immune system to promote an allergic response.

Salvi et al. (1999) investigated the impact of diesel exhaust on human airways and peripheral blood by exposing healthy volunteers to diesel exhaust at a concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Following exposure, they found significant evidence of acute inflammatory responses in airway lavage and also in the peripheral blood. Some commenters expressed a belief that the gaseous, rather than particulate, components of diesel exhaust caused these effects. The investigators noted that the inflammatory responses observed could not be attributed to NO_2 in the diesel exhaust because previous studies they had conducted, using a similar experimental protocol, had revealed no such responses in the airway tissues of volunteers exposed to a higher concentration of NO_2, for a longer duration, in the absence of dpm. They concluded that ''[i]t therefore seems more likely that the particulate component of DE is responsible.''

iv. Lung Cancer

(1) Genotoxicity Studies

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

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

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

> * * * the solvent extract of diesel soot and the surfactant dispersion of diesel soot particles were found to be active in procaryotic cell and eukaryotic cell *in vitro* genotoxicity assays. The cited data indicate that respired diesel soot particles on the surface of the lung alveoli and respiratory bronchioles can be dispersed in the surfactant-rich aqueous phase lining the surfaces, and that genotoxic material associated with such dispersed soot particles is biologically available and genotoxically active. Therefore, this research demonstrates the biological availability of active genotoxic materials without organic solvent interaction. [Cover letter to NIOSH response to ANPRM, 1992].

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

One commenter (IMC Global) noted that Wallace et al. (1987) used aged dpm samples from scrapings inside an exhaust pipe and contended that this was not a realistic representation of dpm. The commenter further argued that the two studies cited by Gu et al. involved ''direct application of an unusually high concentration gradient'' that does not replicate normal conditions of dpm exposure.

MSHA agrees with this commenter's general point that conditions set up in such experiments do not duplicate actual exposure conditions. However, as a follow-up to the Wallace study, Keane *et al.* (op cit) demonstrated similar results with both exhaust pipe soot and particles obtained directly from an exhaust stream. With regard to the two Gu studies, MSHA recognizes that any well-controlled experiment serves only a limited purpose. Despite their limitations, however, these experiments provided valuable information. They avoided solvent extraction. By showing that solvent extraction is not a necessary condition of dpm mutagenicity, these studies provided incremental support to the hypothesis of bioavailability under more realistic conditions. This possibility was subsequently tested by a variety of other experiments, including experiments on live animals and humans.

For example, Sagai et al. (1996) showed that whole dpm produced active oxygen radicals in the trachea of live mice, but that dpm stripped of organic compounds did not. Whole dpm caused significant damage to the lungs and also high mortality at low doses. According to the investigators, most of the toxicity observed appeared to be due to the oxygen radicals, which can also have genotoxic effects. Subsequently, Ichinose *et al.* (1997b) examined the relationship between tumor response and the formation of oxygen radicals in the lungs of mice injected with dpm. The mice were treated with sufficiently high doses of dpm to produce tumors after 12 months. As in the earlier study, the investigators found that the dpm generated oxygen radicals, even in the absence of biologically activating systems (such as macrophages), and that these oxygen radicals were implicated in the lung toxicity of the dpm. The authors concluded that ''oxidative DNA damage induced by the repeated DEP [*i.e.*, dpm] treatment could be an important factor in enhancing the mutation rate leading to lung cancer.''

The formation of DNA adducts is an important indicator of genotoxicity and potential carcinogenicity. Adduct formation occurs when molecules, such as those in dpm, attach to the cellular DNA. These adducts can negatively affect DNA transcription and/or cellular duplication. If DNA adducts are not repaired, then a mutation or chromosomal aberration can occur during normal mitosis (*i.e.*, cell replication) eventually leading to cancer cell formation. IPCS (1996) contains a survey of animal experiments showing DNA adduct induction in the lungs of experimental animals exposed to diesel exhaust.[62] MSHA recognizes that such studies provide limited information regarding the bioavailability of organics, since positive results may well have been related to factors associated with lung particle overload. However, the bioavailability of genotoxic dpm components is also supported by human studies showing genotoxic effects of exposure to whole dpm. DNA adduct formation and/or mutations in blood cells following exposure to dpm, especially at levels insufficient to induce lung overload, can be presumed to result from organics diffusing into the blood.

Hemminki *et al.* (1994) found that DNA adducts were significantly elevated in lymphocytes of nonsmoking bus maintenance and truck terminal workers, as compared to a control group of hospital mechanics, with the highest adduct levels found among garage and forklift workers. Hou et al. (1995) reported significantly elevated levels of DNA adducts in lymphocytes of non-smoking diesel bus maintenance workers compared to a control group of unexposed workers. Similarly, Nielsen *et al.* (1996) found that DNA adducts were significantly increased in the blood and urine of bus garage workers and mechanics exposed to dpm as compared to a control group.

One commenter (IMC Global) acknowledged that ''the studies conducted by Hemminiki [Hemminiki et al, 1994] showed elevations in lymphocyte DNA adducts in garage workers, bus maintenance workers and diesel forklift drivers'' but argued that ''these elevations were at the borderline of statistical significance.'' Although results at a higher level of confidence would have been more persuasive, this does not negate the value of the evidence as it stands. Furthermore, statistical significance in an individual study becomes less of an issue when, as in this case, the results are corroborated by other studies.

IMC Global also acknowledged that the Nielsen study found significant differences in DNA adduct formation between diesel-exposed workers and controls but argued that ''the real source of genotoxins was unclear, and other sources of exposure, such as skin contact with lubricating oils could not be excluded.'' As is generally the case with studies involving human subjects, this study did not completely control for potential confounders. For this reason, MSHA considers it important that several human studies—not all subject to confounding by the same variables—found elevated adduct levels in diesel-exposed workers.

IMC Global cited another human study (Qu *et al.,* 1997) as casting doubt on the genotoxic effects of diesel exposure, even though this study (conducted on Australian coal miners) reported significant increases in DNA adducts immediately after a period of intense diesel exposure during a longwall move. As noted by the commenter, adduct levels of exposed miners and drivers were, prior to the longwall move, approximately 50% higher than for the unexposed control group; but differences by exposure category were not statistically significant. A more informative part of the study, however, consisted of comparing adducts in the same workers before and after a longwall move, which involved ''intensive use of heavy equipment, diesel powered in these mines, over a 2–3 week period.'' MSHA emphasizes that the comparison was made on the same workers, because doing so largely controlled for potentially confounding variables, such as smoking habits, that may be a factor when making comparisons between different persons. After the period of ''intensive'' exposure, statistically significant increases were observed in both total and individual adducts. Contrary to the commenter's characterization of this study, the investigators stated that their analysis ''provides results in which the authors have a high level of confidence.'' They concluded that ''given the * * * apparent increase in adducts during a period of intense DEE [*i.e.*, diesel exhaust emissions] exposures it would be prudent to pay particular attention to keeping exposures as low as possible, especially during LWCO [*i.e.*, ''longwall change out''] operations.'' Although the commenter submitted this study as counter-evidence, it actually provides significant, positive evidence that high dpm exposures in a mining environment can produce genotoxic effects.

The West Virginia Coal Association submitted an analysis by Dr. Peter Valberg, purporting to show that ''* * * the quantity of particle-bound mutagens that could potentially contact lung cells under human exposure scenarios is very small.'' According to Dr. Valberg's calculations, the dose of organic mutagens deposited in the lungs of a worker occupationally exposed (40 hours per week) to 500 $\mu g/m^3$ of dpm would be equivalent in potency to smoking about one cigarette per month.[63] Dr. Valberg indicated that a person smoking at this level would generally be classified a nonsmoker, but he made no attempt to quantify the carcinogenic effects. Nor did he compare this exposure level with levels of exposures to environmental tobacco smoke that have been linked to lung cancer.

Since the commenter did not provide details of Dr. Valberg's calculation, MSHA was unable to verify its accuracy or evaluate the plausibility of key assumptions. However, even if the equivalence is approximately correct, using it to discount the possibility that dpm increases the risk of lung cancer relies on several questionable assumptions. Although their precise role in the analysis is unclear because it was not presented in detail, these assumptions apparently include:

(1) That there is a good correlation between genotoxicity dose-response and carcinogenicity dose-response. Although genotoxicity data can be very useful for identifying a carcinogenic hazard, carcinogenesis is a highly complex process that may involve the interaction of many mutagenic, physiological, and biochemical responses. Therefore, the shape and slope of a carcinogenic dose-response relationship cannot be readily predicted from a genotoxic dose-response relationship.

(2) That only the organic fraction of dpm contributes to carcinogenesis. This contradicts the findings reported by Ichinose et al. (1997b) and does not take into account the contribution that inflammation and active oxygen radicals induced by the inorganic carbon core of dpm may have in promoting lung cancers. Multiple routes of carcinogenesis may operate in human lungs—some requiring only the various organic mutagens in dpm and others involving induction of free radicals by the elemental carbon core, either alone or in combination with the organics.

(3) That the only mutagens in dpm are those that have been identified as mutagenic to bacteria and that the

[62] Some of these studies will be discussed in the next subsection of this risk assessment.

[63] The only details provided for this calculation pertained to ajusting 8-hour occupational exposures. Dr. Valberg adjusted the 500 $\mu g/m^3$ concentration for an 8-hour occupational exposure to a supposedly equivalent 24-hour continuous concentration of 92 $\mu g/m^3$. This adjustment ignored differences in breathing rates between periods of sleep, leisure activities, and heavy work. Even under the unrealistic assumption of homogeneous breathing rates, the calculation appears to be erroneous, since (500 $\mu g/m^3$) × (40 hours/week) is nearly 30 percent greater than (92 $\mu g/m^3$) × (168 hours/week). Also, Dr. Valberg stated that the calculation assumed a deposition fraction of 20 percent for dpm but did not state what deposition fraction was being assumed for the particles in cigarette smoke.

mutagenic constituents of dpm have all been identified. One of the most potent of all known mutagens (3-nitrobenzanthrone) was only recently isolated and identified in dpm (Enya et al., 1997).

(4) That the mutagenic components of dpm have the same combined potency as those in cigarette smoke. This ignores the relative potency and amounts of the various mutagenic constituents. If the calculation did not take into account the relative amounts and potencies of all the individual mutagens in dpm and cigarette smoke, then it oversimplified the task of making such a comparison.

In sum, unlike the experimental findings of dpm genotoxicity discussed above, the analysis by Dr. Valberg is not based on empirical evidence from dpm experiments, and it appears to rely heavily on questionable assumptions. Moreover, the contention that active components of dpm are not available in sufficient quantities to cause significant mutagenic damage in humans appears to be directly contradicted by the empirical evidence of elevated DNA adduct levels in exposed workers (Hemminki et al., 1994; Hou et al., 1995; Nielsen et al., 1996; Qu et al., 1997).

(2) Animal Inhalation Studies

When dpm is inhaled, a number of adverse effects that may contribute to carcinogenesis are discernable by microscopic and biochemical analysis. For a comprehensive review of these effects, see Watson and Green (1995). In brief, these effects begin with phagocytosis, which is essentially an attack on the diesel particles by cells called alveolar macrophages. The macrophages engulf and ingest the diesel particles, subjecting them to detoxifying enzymes. Although this is a normal physiological response to the inhalation of foreign substances, the process can produce various chemical byproducts injurious to normal cells. In attacking the diesel particles, the activated macrophages release chemical agents that attract neutrophils (a type of white blood cell that destroys microorganisms) and additional alveolar macrophages. As the lung burden of diesel particles increases, aggregations of particle-laden macrophages form in alveoli adjacent to terminal bronchioles, the number of Type II cells lining particle-laden alveoli increases, and particles lodge within alveolar and peribronchial tissues and associated lymph nodes. The neutrophils and macrophages release mediators of inflammation and oxygen radicals, which have been implicated in causing various forms of chromosomal damage, genetic mutations, and malignant transformation of cells (Weitzman and Gordon, 1990). Eventually, the particle-laden macrophages are functionally altered, resulting in decreased viability and impaired phagocytosis and clearance of particles. This series of events may result in pulmonary inflammatory, fibrotic, or emphysematous lesions that can ultimately develop into cancerous tumors.

IARC (1989), Mauderly (1992), Busby and Newberne (1995), IPCS (1996), Cal-EPA (1998), and US EPA (1999) reviewed the scientific literature relating to excess lung cancers observed among laboratory animals chronically exposed to filtered and unfiltered diesel exhaust. The experimental data demonstrate that chronic exposure to whole diesel exhaust increases the risk of lung cancer in rats and that dpm is the causative agent. This carcinogenic effect has been confirmed in two strains of rats and in at least five laboratories. Experimental results for animal species other than the rat, however, are either inconclusive or, in the case of Syrian hamsters, suggestive of no carcinogenic effect. In two of three mouse studies reviewed by IARC (1989), lung tumor formation (including adenocarcinomas) was increased in the exposed animals as compared to concurrent controls; in the third study, the total incidence of lung tumors was not elevated compared to historical controls. Two more recent mouse studies (Heinrich et al., 1995; Mauderly et al., 1996) have both reported no statistically significant increase in lung cancer rates among exposed mice, as compared to contemporaneous controls. Monkeys exposed to diesel exhaust for two years did not develop lung tumors, but the short duration of exposure was judged inadequate for evaluating carcinogenicity in primates.

Bond et al. (1990a) investigated differences in peripheral lung DNA adduct formation among rats, hamsters, mice, and monkeys exposed to dpm at a concentration of 8100 μg/m³ for 12 weeks. Mice and hamsters showed no increase of DNA adducts in their peripheral lung tissue, whereas rats and monkeys showed a 60 to 80-percent increase. The increased prevalence of lung DNA adducts in monkeys suggests that, with respect to DNA adduct formation, the human lungs' response to dpm inhalation may more closely resemble that of rats than that of hamsters or mice.

The conflicting carcinogenic effects of chronic dpm inhalation reported in studies of rats, mice, and hamsters may be due to non-equivalent delivered doses or to differences in response among species. Indeed, monkey lungs have been reported to respond quite differently than rat lungs to both diesel exhaust and coal dust (Nikula, 1997). Therefore, the results from rat experiments do not, by themselves, establish that there is any excess risk due to dpm exposure for humans. However, the human epidemiologic and genotoxicity (DNA adduct) data indicate that humans comprise a species that, like rats, do suffer a carcinogenic response to dpm exposure. This would be consistent with the observation, mentioned above, that lung DNA adduct formation is increased among exposed rats but not among exposed hamsters or mice. Therefore, although MSHA recognizes that there are important differences between rats and humans (as there are also between rats and hamsters or mice), MSHA considers the rat studies relevant to an evaluation of human health risks.

Reactions similar to those observed in rats inhaling dpm have also been observed in rats inhaling fine particles with no organic component (Mauderly et al., 1994; Heinrich et al., 1994, 1995; Nikula et al., 1995). Rats exposed to titanium dioxide (TiO_2) or pure carbon (''carbon black'') particles, which are not considered to be genotoxic, exhibited similar pathological responses and developed lung cancers at about the same rate as rats exposed to whole diesel exhaust. Carbon black particles were used in these experiments because they are physically similar to the inorganic carbon core of dpm but have negligible amounts of organic compounds adsorbed to their surface. Therefore, at least in some species, it appears that the lung cancer toxicity of dpm may result largely from a biochemical response to the core particle itself rather than from specific, genotoxic effects of the adsorbed organic compounds.[64]

One commenter stated that, in the proposed risk assessment, MSHA had neglected three additional studies suggesting that lung cancer risks in animals inhaling diesel exhaust are unrelated to genotoxic mechanisms. One of these studies (Mauderly et al.,

[64] NIOSH commented as follows: ''Data cited by MSHA in support of this statement are not comparable. Rats were exposed to dpm at 4 mg/m³ for 2 years (Mauderly et al. 1987; Brightwell et al. 1989), in contrast to rats exposed to $Ti0_2$ at 250 mg/m³ for two years [reference to article (Lee et al. 1985) not cited by MSHA]. It is not apparent that the overload mechanism that is proposed to be responsible for tumors in the $Ti0_2$ exposed rats could also have been responsible for the tumors seen in the dpm exposed rats at 62-fold lower exposure concentrations.'' In the reports cited by MSHA, levels of $Ti0_2$ and/or carbon black were commensurate with dpm levels.

1996) did not pertain to questions of genotoxicity but has been cited in the discussion of mouse studies above. The other two studies (Randerath et al., 1995 and Belinsky et al., 1995) were conducted as part of the cancer bioassay described in the 1994 article by Mauderly et al. (cited in the preceding paragraph). In the Randerath study, the investigators found that no DNA adducts specific to either diesel exhaust or carbon black were induced in the lungs of rats exposed to the corresponding substance. However, after three months of exposure, the total level of DNA adducts and the levels of some individual adducts were significantly higher in the diesel-exposed rats than in the controls. In contrast, multiple DNA adducts thought to be specific to diesel exhaust formed in the skin and lungs of mice treated topically with organic dpm extract. These results are consistent with the findings of Mauderly et al. (1994, op cit.). They imply that although the organic compounds of diesel exhaust are capable of damaging cellular DNA, they did not inflict such damage under the conditions of the inhalation experiment performed. The report noted that these results do not rule out the possibility of DNA damage by inhaled organics in ''other species or * * * [in] exposure situations in which the concentrations of diesel exhaust particles are much lower.'' In the Belinsky study, the investigators measured mutations in selected genes in the tumors of those rats that had developed lung cancer. This study did not succeed in elucidating the mechanisms by which dpm and carbon black cause lung tumors in rats. The authors concluded that ''until some of the genes involved in the carcinogenicity of diesel exhaust and carbon black are identified, a role for the organic compounds in tumor development cannot be excluded.''

The carbon-black and TiO_2 studies discussed above indicate that lung cancers in rats exposed to dpm may be induced by a mechanism that does not require the bioavailability of genotoxic organic compounds adsorbed on the elemental carbon particles. Some researchers have interpreted these studies as also suggesting that (1) the carcinogenic mechanism in rats depends on massive overloading of the lung and (2) that this may provide a mechanism of carcinogenesis involving a threshold effect specific to rats, which has not been observed in other rodents or in humans (Oberdorster, 1994; Watson and Valberg, 1996). Some commenters on the ANPRM cited the lack of a link between lung cancer and coal dust or carbon black exposure as evidence that carbon particles, by themselves, are not carcinogenic in humans. Coal mine dust, however, consists almost entirely of particles larger than those forming the carbon core of dpm or used in the carbon black and $Ti0_2$ rat studies. Furthermore, although there have been nine studies reporting no excess risk of lung cancer among coal miners (Liddell, 1973; Costello et al., 1974; Armstrong et al., 1979; Rooke et al., 1979; Ames et al., 1983; Atuhaire et al., 1985; Miller and Jacobsen, 1985; Kuempel et al., 1995; Christie et al., 1995), eight studies have reported an elevated risk of lung cancer for those exposed to coal dust (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Correa et al., 1984; Levin et al., 1988; Morabia et al., 1992; Swanson et al., 1993; Morfeld et al., 1997). The positive results in five of these studies (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Morabia et al., 1992; Swanson et al., 1993) were statistically significant. Morabia et al. (op cit.) reported increased risk associated with duration of exposure, after adjusting for cigarette smoking, asbestos exposure, and geographic area. Furthermore, excess lung cancers have been reported among carbon black production workers (Hodgson and Jones, 1985; Siemiatycki, 1991; Parent et al., 1996). After a comprehensive evaluation of the available scientific evidence, the World Health Organization's International Agency for Research on Cancer concluded: ''Carbon black is possibly carcinogenic to humans (Group 2B).'' (IARC, 1996)

The carbon black and TiO_2 animal studies cited above do not prove there is a threshold below which dpm exposure poses no risk of causing lung cancer in humans. They also do not prove that dpm exposure has no incremental, genotoxic effects. Even if the genotoxic organic compounds in dpm were biologically unavailable and played no role in human carcinogenesis, this would not rule out the possibility of a genotoxic route to lung cancer (even for rats) due to the presence of the particles themselves. For example, as a byproduct of the biochemical response to the presence of particles in the alveoli, free oxidant radicals may be released as macrophages attempt to digest the particles. There is evidence that dpm can both induce production of reactive oxygen agents and also depress the activity of naturally occurring antioxidant enzymes (Mori, 1996; Ichinose et al., 1997; Sagai et al., 1996). Oxidants can induce carcinogenesis either by reacting directly with DNA, or by stimulating cell replication, or both (Weitzman and Gordon, 1990). Salvi et al. (1999) reported acute inflammatory responses in the airways of human exposed to dpm for one hour at a concentration of 300 $\mu g/m^3$. Such inflammation is associated with the production of free radicals and could provide routes to lung cancer with even when normal lung clearance is occurring. It could also give rise to a ''quasi-threshold,'' or surge in response, corresponding to the exposure level at which the normal clearance rate becomes overwhelmed (lung overload).

Oxidant activity is not the only mechanism by which dpm could exert carcinogenic effects in the absence of mutagenic activity by its organic fraction. In its commentary on the Randerath study discussed above, the HEI's Health Review Committee suggested that dpm could both cause genetic damage by inducing free oxygen radicals and also enhance cell division by inducing cytokines or growth hormones:

> It is possible that diesel exhaust exerts its carcinogenic effects through a mechanism that does not involve direct genotoxicity (that is, formation of DNA adducts) but involves proliferative responses such as chronic inflammation and hyperplasia arising from high concentrations of particles deposited in the lungs of the exposed rats. * * * Phagocytes (macrophages and neutrophils) released during inflammatory reactions ''produce reactive oxygen species that can damage DNA. * * * Particles (with or without adsorbed PAHs) may thus induce oxidative DNA damage via oxygen free radicals. * * * Alternatively, activated phagocytes may release cytokines or growth factors that are known to increase cell division. Increased cell division has been implicated in cancer causation. * * * Thus, in addition to oxidative DNA damage, increased cell proliferation may be an important mechanism by which diesel exhaust and other insoluble particles induce pulmonary carcinogenesis in the rat. [Randerath et al., 1995, p.55]

Even if lung overload were the primary or sole route by which dpm induced lung cancer, this would not mean that the high dpm concentrations observed in some mines are without hazard. It is noteworthy, moreover, that dpm exposure levels recorded in some mines have been almost as high as laboratory exposures administered to rats showing a clearly positive response. Intermittent, occupational exposure levels greater than about 500 $\mu g/m^3$ dpm may overwhelm the human lung clearance mechanism (Nauss et al., 1995). Therefore, concentrations at the even higher levels currently observed in some mines could be expected to cause overload in some humans, possibly inducing lung cancer by a mechanism similar to what occurs in rats. In addition, a proportion of exposed individuals can always be expected to be more susceptible than normal to clearance impairments and lung overload. Inhalation at even moderate levels may significantly impair clearance, especially in susceptible individuals. Exposures to cigarette smoke and respirable mineral dusts may further depress clearance mechanisms and reduce the threshold for overload. Consequently, even at dpm concentrations far lower than 500 μg/m³ dpm, impaired clearance due to dpm inhalation may provide an important route to lung cancer in humans, especially if they are also inhaling cigarette smoke and other fine dusts simultaneously. (Hattis and Silver, 1992, Figures 9, 10, 11)

Furthermore, as suggested above, lung overload is not necessarily the only route to carcinogenesis in humans. Therefore, dpm concentrations too low to cause overload still may present a hazard. In humans exposed over a working lifetime to doses insufficient to cause overload, carcinogenic mechanisms unrelated to overload may operate, as indicated by the human epidemiologic studies and the data on human DNA adducts cited in the preceding subsection of this risk assessment. It is possible that overload provides the dominant route to lung cancer at high concentrations of fine particulate, while other mechanisms emerge as more relevant for humans under lower-level exposure conditions.

The NMA noted that, in 1998, the US EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that there is ''no evidence that the organic fraction of soot played a role in rat tumorigenesis at any exposure level, and considerable evidence that it did not.'' According to the NMA, this showed ''* * * it is the rat data—not the hamster data—that lacks relevance for human health assessment.''

It must first be noted that, in MSHA's view, all of the experimental animal data on health effects has relevance for human health risk assessment—whether the evidence is positive or negative and even if the positive results cannot be used to quantify human risk. The finding that different mammalian species exhibit important differences in response is itself relevant for human risk assessment. Second, the passage quoted from CASAC pertains to the route for tumorigenesis in rats and does not discuss whether this does or does not have relevance to humans exposed at high levels. The context for the CASAC deliberations was ambient exposure conditions in the general environment, rather than the higher occupational exposures that might impair clearance rates in susceptible individuals. Third, the comment assumes that only a finding of tumorigenesis attributable to the organic portion of dpm would elucidate mechanisms of potential health effects in humans. This ignores the possibility that a mechanism promoting tumors, but not involving the organics, could operate in both rats and humans. Induction of free oxygen radicals is an example. Fourth, although there may be little or no evidence that organics contributed to rat tumorigenesis in the studies performed, there is evidence that the organics contributed to increases in DNA adduct formation. This kind of activity could have tumorigenic consequences in humans who may be exposed for periods far longer than a rat's 3-year lifetime and who, as a consequence, have more time to accumulate genetic damage from a variety of sources.

Bond et al. (1990b) and Wolff et al. (1990) investigated adduct formation in rats exposed to various concentrations of either dpm or carbon black for 12 weeks. At the highest concentration (10 mg/m³), DNA adduct levels in the lung were increased by exposure to either dpm or carbon black; but levels in the rats exposed to dpm were approximately 30 percent higher. Gallagher et al. (1994) exposed different groups of rats to diesel exhaust, carbon black, or TiO_2 and detected no significant difference in DNA adduct levels in the lung. However, the level of one type of adduct, thought to be derived from a PAH, was elevated in the dpm-exposed rats but not found in the control group or in rats exposed to carbon black or TiO_2.

These studies indicate that the inorganic carbon core of dpm is not the only possible agent of genetic damage in rats inhaling dpm. After a review of these and other studies involving DNA adducts, IPCS (1996) concluded that ''Taken together, the studies of DNA adducts suggest that some organic chemicals in diesel exhaust can form DNA adducts in lung tissue and may play a role in the carcinogenic effects. * * * however, DNA adducts alone cannot explain the carcinogenicity of diesel exhaust, and other factors, such as chronic inflammation and cell proliferation, are also important.''

Nauss et al. (1995, pp. 35–38) judged that the results observed in the carbon black and TiO2 inhalation studies on rats do not preclude the possibility that the organic component of dpm has important genotoxic effects in humans. More generally, they also do not prove that lung overload is necessary for dpm-induced lung cancer. Because of the relatively high doses administered in some of the rat studies, it is conceivable that an overload phenomenon masked or even inhibited other potential cancer mechanisms. At dpm concentrations insufficient to impair clearance, carcinogenesis may have followed other routes, some possibly involving the organic compounds. At these lower concentrations, or among rats for which overload did not occur, tumor rates for dpm, carbon black, and TiO_2 may all have been too low to make statistically meaningful comparisons.

The NMA argued that ''MSHA's contention that lung overload might ''mask'' tumor production by lower doses of Dpm has been convincingly rebutted by recognized experts in the field,'' but provided no convincing explanation of why such masking could not occur. The NMA went on to say:

> The [CASAC] Panel viewed the premises that: a) a small tumor response at low exposure was overlooked due to statistical power; and b) soot-associated organic mutagens had a greater effect at low than at high exposure levels to be without foundation. In the absence of supporting evidence, the Panel did not view derivation of a quantitative estimate of human lung cancer risk from the low-level rat data as appropriate.

MSHA is not attempting to ''derive a quantitative estimate of human lung cancer risk from the low-level rat data.''

Dr. Peter Valberg, writing for the West Virginia Coal Association, provided the following argument for discounting the possibility of other carcinogenic mechanisms being masked by overload in the rat studies:

> Some regulatory agencies express concern about the mutagens bound to dpm. They hypothesize that, at high exposure levels, genotoxic mechanisms are overwhelmed (masked) by particle-overload conditions. However, they argue that at low-exposure concentrations, these organic compounds could represent a lung cancer risk. Tumor induction by mutagenic compounds would be characterized by a linear dose-response and should be detectable, given enough exposed rats. By using a ''meta-analysis'' type of approach and combining data from eight long-term rat inhalation studies, the lung tumor response can be analyzed. When all dpm-exposed rats from lifetime-exposure studies are combined, a threshold of response (noted above) occurs at approximately 600 μg/m³ continuous lifetime exposure (approximately 2,500 μg/m³ of occupational exposure). Additional statistical analysis of only those rats exposed to low concentrations of dpm confirms the absence of a tumorigenic effect below that threshold. Thus, even data in rats (the most sensitive laboratory species) do not support the hypothesis that particle-bound organics cause tumors.

MSHA finds that this analysis relies on several questionable and unsupported assumptions and that, for the following reasons, the possibility remains that organic compounds in inhaled dpm may, under the right exposure conditions, contribute to its carcinogenic effects:

(1) The absence of evidence for an organic carbon effect is not equivalent to evidence of the absence of such an effect. Dr. Valberg did not demonstrate that enough rats were exposed, at levels insufficient to cause overload, to ensure detection of a 30- to 40-percent increase in the risk of lung cancer. Also, the normal lifespan of a rat whose lung is not overloaded with particles may, because of the lower concentrations involved, provide insufficient time for the organic compounds to express carcinogenic effects. Furthermore, low bioavailability of the organics could further reduce the likelihood that a carcinogenic sequence of mutations would occur within a rat's relatively short lifespan (i.e., at particle concentrations too low to cause overload).

(2) If the primary mechanism for carcinogenesis requires a reduced clearance rate (due to overload), then acute exposures are important, and it may not be appropriate to represent equivalent hazards by spreading an 8-hour occupational exposures over a 24-hour period. For example, eight hours at 600 $\mu g/m^3$ would have different implications for lung clearance than 24 hours at 200 $\mu g/m^3$.

(3) Granting that the rat data cannot be used to extrapolate risk for humans, these data should also not be used to rule out mechanisms of carcinogenesis that may operate in humans but not in rats. Clearance, for example, may operate differently in humans than in rats, and there may be a gradual rather than abrupt change in human overload conditions with increasing exposure. Also, at least some of the organic compounds in dpm may be more biologically available to the human lung than to that of the rat.

(4) For experimental purposes, laboratory rats are deliberately bred to be homogeneous. This is done, in part, to deliberately minimize differences in response between individuals. Therefore, individual differences in the threshold for lung overload would tend to be masked in experiments on laboratory rats. It is likely that human populations would exhibit, to a far greater extent than laboratory rats, a range of susceptibilities to lung overload. Also some humans, unlike the laboratory rats in these experiments, place additional burdens on their lung clearance by smoking.

One commenter (MARG) concluded that ''[t]here is * * * no basis for extrapolating the rat results to human beings; the animal studies, taken together, do not justify MSHA's proposals.''

MSHA is neither extrapolating the rat results to make quantitative risk estimates for humans nor using them, in isolation, as a justification for these regulations. MSHA does regard it as significant, however, that the evidence for an increased risk of lung cancer due to chronic dpm inhalation comes from both human and animal studies. MSHA agrees that the quantitative results observed for rats in existing studies should not be extrapolated to humans. Nevertheless, the fact that high dpm exposures for two or three years can induce lung cancer in rats enhances the epidemiologic evidence that much longer exposures to miners, at concentrations of the same order of magnitude, could also induce lung cancers.

3. Characterization of Risk

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

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

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

Some commenters argued that the link between dpm exposure and material health impairments is questionable, and that MSHA should wait until additional scientific evidence becomes available before concluding that there are health risks due to such exposure warranting regulatory action. For example, MARG asserted that ''[c]ontrary to the suggestions in the [proposed] preamble, a link between dpm exposure and serious illness has never been established by reliable scientific evidence.'' [65] MARG continued as follows:

> Precisely because the scientific evidence * * * is inconclusive at best, NIOSH and NCI are now conducting a * * * [study] to determine whether diesel exhaust is linked to illness, and if so, at what level of exposure. * * * MARG is also funding an independent parallel study.
>
> * * * Until data from the NIOSH/NCI study, and the parallel MARG study, are available, the answers to these important questions will not be known. Without credible answers to these and other questions, MSHA's regulatory proposals * * * are premature * * *.''

For reasons explained below, MSHA does not agree that the collective weight of scientific evidence is ''inconclusive at best.'' Furthermore, the criteria for evaluating the health effects evidence do not require scientific certainty. As noted by Justice Stevens in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a ''mathematical straitjacket.'' [*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607, 100 S.Ct. 2844 (1980), hereinafter designated the ''Benzene'' case]. The Court recognized that regulation may be necessary even when scientific knowledge is not complete; and—

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

[65] MARG supported this assertion by claiming that ''[t]he EPA reports which MSHA references in its preamble were found 'not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines' by EPA's Clean Air Scientific Advisory Committee. [reference to CASAC (1998)]'' Contrary to MARG's claim, CASAC (1998) did not review any of the 20 EPA documents MSHA cited in the proposed preamble. Instead, the document reviewed by CASAC (1998) was an unpublished draft of a health risk assessment on diesel exhaust (EPA, 1998), to which MSHA made no reference. Since MSHA has not relied in any way on this 1998 draft document, its ''scientific adequacy'' is entirely irrelevant to this rulemaking.

In response to the 1998 CASAC review, EPA modified its draft risk assessment (EPA, 1999), and CASAC subsequently reviewed the 1999 draft (CASAC, 2000). CASAC found the revised draft much improved over the previous version and agreed that even environmental exposure to diesel emissions is likely to increase the risk of lung cancer (CASAC, 2000). CASAC endorsed this conclusion for dpm concentrations in ambient air, which are lower, by a factor of more than 100, than the levels observed in some mines (see Fig. III–4).

Moreover, the statutory criteria for evaluating health effects do not require MSHA to wait for incontrovertible evidence. In fact, MSHA is required to set standards based on the ''best *available* evidence'' (emphasis added).

a. Material Impairments to Miners' Health or Functional Capacity

MSHA recognizes that there is considerable disagreement, among knowledgeable parties, in the interpretation of the overall body of scientific research and medical evidence related to human health effects of dpm exposures. One commenter for example, interpreted the collective evidence as follows:

> * * * the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health. * * * there is *clear* evidence that diesel particulate exposure can cause lung cancer (as well as other serious non-malignant diseases) among workers in a variety of occupational settings. While no body of scientific evidence is ever completely definitive, the evidence regarding diesel particulate is particularly strong * * *. [Michael Silverstein, MD, State of Washington Dept. of Labor and Industries]

Other commenters, including several national and regional organizations representing the mining industry, sharply disagreed with this interpretation. For example, one commenter stated that ''[i]n our opinion, the best available evidence does not provide substantial or credible support for the proposal.'' Several commenters argued that evidence from within the mining industry itself was especially weak.[66] A representative of one mining company that had been using diesel equipment for many years commented: ''[t]o date, the medical history of our employees does not indicate a single case of lung cancer, chronic illness, or material impairment of health due to exposure to diesel exhaust. This appears to be the established norm throughout the U.S. coal mining industry.'' This commenter, however, submitted no evidence comparing the rate of lung cancer or other material impairment among exposed miners to the rate for unexposed miners (or comparable workers) of similar age, smoking habits, and geographic location.

With due consideration to all oral and written testimony, comments, and evidence submitted during the rulemaking proceedings, MSHA conducted a review of the scientific literature cited in Part III.2. Based on the combined weight of the best available evidence, MSHA has concluded that underground miners exposed to current levels of dpm are at excess risk of incurring the following three kinds of material impairment: (i) Sensory irritations and respiratory symptoms (including allergenic responses); (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. The next three subsections will respectively explain MSHA's basis for linking these effects with dpm exposure.

i. Sensory Irritations and Respiratory Symptoms (Including Allergenic Responses)

Kahn et al. (1988), Battigelli (1965), Gamble et al. (1987a), and Rudell et al. (1996) identified a number of debilitating acute responses to diesel exhaust exposure. These responses included irritation of the eyes, nose and throat; headaches, nausea, and vomiting; chest tightness and wheeze. These symptoms were also reported by miners at the 1995 workshops and the public hearings held on these proceedings in 1998. In addition, Ulfvarson et al. (1987, 1990) reported evidence of reduced lung function in workers exposed to dpm for a single shift. The latter study supports attributing a portion of the reduction to the dpm in diesel exhaust. After reviewing this body of literature, Morgan et al. (1997) concluded ''it is apparent that exposure to diesel fumes in sufficient concentrations may lead to [transient] eye and nasal irritation'' and ''a transient decline of ventilatory capacity has been noted following such exposures.''

One commenter (Nevada Mining Association) acknowledged there was evidence that miners exposed to diesel exhaust experienced, as a possible consequence of their exposure, ''acute, short-term or 'transitory' irritation, such as watering eyes, in susceptible individuals * * *''; but asserted that ''[a]ddressing any such transient irritant effects does not require the Agency's sweeping, stringent PEL approach [in M/NM mines].''

Although there is evidence that such symptoms subside within one to three days of no occupational exposure, a miner who must be exposed to dpm day after day in order to earn a living may not have time to recover from such effects. Hence, the opportunity for a so-called ''reversible'' health effect to reverse itself may not be present for many miners. Furthermore, effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and can, in some cases, be seriously disabling. Also, workers experiencing sufficiently severe sensory irritations can be incapacitated or distracted as a result of their symptoms, thereby endangering themselves and other workers and increasing the risk of accidents. For these reasons, MSHA considers such irritations to constitute ''material impairments'' of health or functional capacity within the meaning of the Act, regardless of whether or not they are reversible. Further discussion of why MSHA believes reversible effects can constitute material impairments can be found above, in Subsection 2.a.2 of this risk assessment.

The best available evidence also points to more severe respiratory consequences of exposure to dpm. Significant statistical associations have been detected between acute environmental exposures to fine particulates and debilitating respiratory impairments in adults, as measured by lost work days, hospital admissions, and emergency room visits (see Table III–3). Short-term exposures to fine particulates, or to particulate air pollution in general, have been associated with significant increases in the risk of hospitalization for both pneumonia and COPD (EPA, 1996).

The risk of severe respiratory effects is exemplified by specific cases of persistent asthma linked to diesel exposure (Wade and Newman, 1993). Glenn et al. (1983) summarized results of NIOSH health evaluations among coal, salt, trona, and potash miners and reported that ''all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group.'' There is persuasive evidence for a causal connection between dpm exposure and increased manifestations of allergic asthma and other allergic respiratory diseases, coming from recent experiments on animals and human cells (Takenaka et al., 1995; Lovik et al., 1997; Takano et al., 1997; Ichinose et al., 1997a). Based on controlled experiments on healthy human volunteers, Diaz-Sanchez et al. (1994, 1996, 1997), Peterson and Saxon (1996), and Salvi et al. (1999) reported significant increases in various markers of allergic response resulting from exposure to dpm.

Peterson and Saxon (1996) reviewed the scientific literature on the

[66] At the public hearing on May 11, 1999, a commenter representing MARG suggested there is evidence that miners exposed to dpm experience adverse health effects at lower-than-normal rates. According to this commenter, ''[s]ignificantly, the human studies conducted in the mining industry reveal a negative propensity for diesel particulate matter-related health effects.'' These studies drew comparisons against an external reference population and failed to adjust for the ''healthy worker effect.'' (See MSHA's discussion of this effect, especially as manifested in the study by Christie et al., 1995, in Subsection 2.c.i(2)(a) of this risk assessment.)

relationship between PAHs and other products of fossil fuel combustion found in dpm and trends in allergic respiratory disease. They found that the prevalences of allergic rhinitis (''hay fever'') and allergic asthma have significantly increased with the historical increase in fossil fuel combustion and that laboratory data support the hypothesis that certain organic compounds found in dpm ''* * * are an important factor in the long-term increases in the prevalence in allergic airway disease.'' Similarly, much of the research on allergenic responses to dpm was reviewed by Diaz-Sanchez (1997), who concluded that dpm pollution in the ambient environment ''may play an important role in the increased incidence of allergic airway disease.'' Morgan et al. (1997) noted that dpm ''* * * may be partly responsible for some of the exacerbations of asthma'' and that ''* * * it would be wise to err on the side of caution.'' Such health outcomes are clearly ''material impairments'' of health or functional capacity within the meaning of the Act.

ii. Premature Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes

The evidence from air pollution studies identifies death, largely from cardiovascular, cardiopulmonary, or respiratory causes, as an endpoint significantly associated with acute exposures to fine particulates ($PM_{2.5}$—see Table III–3). The weight of epidemiologic evidence indicates that short-term ambient exposure to particulate air pollution contributes to an increased risk of daily mortality (EPA, 1996). Time-series analyses strongly suggest a positive effect on daily mortality across the entire range of ambient particulate pollution levels. Relative risk estimates for daily mortality in relation to daily ambient particulate concentration are consistently positive and statistically significant across a variety of statistical modeling approaches and methods of adjustment for effects of relevant covariates such as season, weather, and co-pollutants. The mortality effects of acute exposures appear to be primarily attributable to combustion-related particles in $PM_{2.5}$ (such as dpm) and are especially pronounced for death due to pneumonia, COPD, and IHD (Schwartz et al., 1996). After thoroughly reviewing this body of evidence, the U.S. Environmental Protection Agency (EPA) concluded:

It is extremely unlikely that study designs not yet employed, covariates not yet identified, or statistical techniques not yet developed could wholly negate the large and consistent body of epidemiologic evidence * * *. [EPA, 1996]

There is also substantial evidence of a relationship between chronic exposure to fine particulates ($PM_{2.5}$) and an excess (age-adjusted) risk of mortality, especially from cardiopulmonary diseases. The Six Cities and ACS studies of ambient air particulates both found a significant association between chronic exposure to fine particles and excess mortality. In some of the areas studied, $PM_{2.5}$ is composed primarily of dpm; and significant mortality and morbidity effects were also noted in those areas. In both studies, after adjusting for smoking habits, a statistically significant excess risk of cardiopulmonary mortality was found in the city with the highest average concentration of $PM_{2.5}$ as compared to the city with the lowest. Both studies also found excess deaths due to lung cancer in the cities with the higher average level of $PM_{2.5}$, but these results were not statistically significant (EPA, 1996). The EPA concluded that—

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

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

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that ''MSHA appears to regard all particulates smaller than 2.5 $\mu g/m^3$ as equivalent.'' He argued that ''dpm and other ultra-fine particulates represents only a small proportion of ambient particulate samples,'' that ''chronic cough, chronic phlegm, and chronic wheezing reflect mainly tracheobronchial effects,'' and that tracheobronchial deposition is highly dependent on particle size distribution.

No part of Dr. Borak's argument is directly relevant to MSHA's identification of the risk of death from cardiovascular, cardiopulmonary, or respiratory causes faced by miners exposed to high concentrations of dpm. First, MSHA does not regard all fine particulates as equivalent. However, dpm is a major constituent of $PM_{2.5}$ in many of the locations where increased mortality has been linked to $PM_{2.5}$ levels. MSHA regards dpm as presenting a risk by virtue of its comprising a type of $PM_{2.5.}$ Second, the studies MSHA used to support the existence of this risk specifically implicate fine particles (*i.e.,* $PM_{2.5}$), so the percentage of dpm in ''total suspended particulate emissions'' (which includes particles even larger than PM_{10}) is not relevant. Third, the chronic respiratory symptoms listed by Dr. Borak are not among the material impairments that MSHA has identified from the $PM_{2.5}$ studies. Much of the evidence pertaining to excess mortality is based on acute—not chronic—ambient exposures of relatively high intensity. In the preceding subsection of this risk assessment, MSHA identified various respiratory symptoms, including allergenic responses, but the evidence for these comes largely from studies on diesel emissions.

As discussed in Section 2.a.iii of this risk assessment, many miners smoke tobacco, and miners experience COPD at a significantly higher rate than the general population. This places many miners in two of the groups that EPA (1996) identified as being at greatest risk of premature mortality due to particulate exposures.

iii. Lung Cancer

It is clear that lung cancer constitutes a ''material impairment'' of health or functional capacity within the meaning of the Act. Therefore, the issue to be addressed in this section is whether there is sufficient evidence (*i.e.,* enough to warrant regulatory action) that occupational exposure to dpm causes the risk of lung cancer to increase.

In the proposed risk assessment, MSHA noted that various national and international institutions and governmental agencies had already classified diesel exhaust or particulate as a probable human carcinogen. Considerable weight was also placed on two comprehensive meta-analyses of the epidemiologic literature, which had both found that the combined evidence supported a causal link. MSHA also acknowledged, however, that some reviewers of the evidence disagreed with MSHA's conclusion that, collectively, it strongly supports a causal connection. As examples of the opposing viewpoint, MSHA cited Stöber and Abel (1996), Watson and Valberg (1996), Cox (1997), Morgan *et al.* (1997), and Silverman (1998). As stated in the proposed risk assessment, MSHA considered the opinions of these reviewers and agreed that no individual study was perfect: Even the strongest of the studies had limitations when viewed in isolation. MSHA nevertheless concluded (in the proposal) that the best available epidemiologic studies, supported by experimental data showing toxicity, collectively provide strong evidence that chronic dpm exposure (at occupational levels) actually does increase the risk of lung cancer in humans.

Although miners and labor representatives generally agreed with MSHA's interpretation of the collective evidence, many commenters representing the mining industry strongly objected to MSHA's conclusion. Some of these commenters also expressed dissatisfaction with MSHA's treatment, in the proposed risk assessment, of opposing interpretations of the collective evidence—saying that MSHA had dismissed these opposing views without sufficient explanation. Some commenters also submitted new critiques of the existing evidence and of the meta-analyses on which MSHA had relied. These commenters also emphasized the importance of two reports (CASAC, 1998 and HEI, 1999) that both became available after MSHA completed its proposed risk assessment.

MSHA has re-evaluated the scientific evidence relating lung cancer to diesel emissions in light of the comments, suggestions, and detailed critiques submitted during these proceedings. Although MSHA has not changed its conclusion that occupational dpm exposure increases the risk of lung cancer, MSHA believes that the public comments were extremely helpful in identifying areas of MSHA's discussion of lung cancer needing clarification, amplification, and/or additional supportive evidence.

Accordingly MSHA has re-organized this section of the risk assessment into five subsections. The first of these provides MSHA's summary of the collective epidemiologic evidence. Second is a description of results and conclusions from the only two existing peer-reviewed and published statistical meta-analyses of the epidemiologic studies: Bhatia *et al.* (1998) and Lipsett and Campleman (1999). The third subsection contains a discussion of potential systematic biases that might tend to shift all study results in the same direction. The fourth evaluates the overall weight of evidence for causality, considering not only the collective epidemiologic evidence but also the results of toxicity experiments. Within each of these first four subsections, MSHA will respond to the relevant issues and criticisms raised by commenters in these proceedings, as well as by other outside reviewers. The final subsection will describe general conclusions reached by other reviewers of this evidence, and present some responses by MSHA about opposing interpretations of the collective evidence.

(1) Summary of Collective Epidemiologic Evidence

As mentioned in Section III.2.c.i(2)(a) and listed in Tables III–4 and III–5, MSHA reviewed a total of 47 epidemiologic studies involving lung cancer and diesel exposure. Some degree of association between occupational dpm exposure and an excess rate of lung cancer was reported in 41 of these studies: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Section III.2.c.1(2)(a) explains MSHA's criteria for evaluating these studies, summarizes those on which MSHA places greatest weight, and explains why MSHA places little weight on the six studies reporting no increased risk of lung cancer for exposed workers. It also contains summaries of the studies involving miners, addresses criticisms of individual studies by commenters and reviewers, and discusses studies that, according to some commenters, suggest that dpm exposure does not increase the risk of lung cancer.

Here, as in the earlier, proposed version of the risk assessment, MSHA was careful to note and consider limitations of the individual studies. Several commenters interpreted this as demonstrating a corresponding weakness in the overall body of epidemiologic evidence. For example, one commenter [Energy West] observed that ''* * * by its own admission in the preamble * * * most of the evidence in [the epidemiologic] studies is relatively weak'' and argued that MSHA's conclusion was, therefore, unjustified.

It should first be noted that the three most recent epidemiologic studies became available too late for inclusion in the risk assessment as originally written. These three (Johnston et al., 1997; Säverin et al., 1999; Brüske-Hohlfeld, 1999) rank among the strongest eight studies available (see Section III.2.c.1(2)(a)) and do not have the same limitations identified in many of the other studies. Even so, MSHA recognizes that no single one of the existing epidemiologic studies, viewed in isolation, provides conclusive evidence of a causal connection between dpm exposure and an elevated risk of lung cancer in humans. Consistency and coherency of results, however, do provide such evidence. An appropriate analogy for the collective epidemiologic evidence is a braided steel cable, which is far stronger than any of the individual strands of wire making it up. Even the thinnest strands can contribute to the strength of the cable.

(a) Consistency of Epidemiologic Results

Although no epidemiologic study is flawless, studies of both cohort and case-control design have quite consistently shown that chronic exposure to diesel exhaust, in a variety of occupational circumstances, is associated with an increased risk of lung cancer. Furthermore, as explained earlier in this risk assessment, limitations such as small sample size, short latency, and (usually) exposure misclassification reduce the power of a study. These limitations make it more difficult to detect a relationship even when one exists. Therefore, the sheer number of studies showing a positive association readily distinguishes those studies criticized by Taubes (1995), where weak evidence is available from only a single study. With only rare exceptions, involving too few workers and/or observation periods too short to have a good chance of detecting excess cancer risk, the human studies have shown a greater risk of lung cancer among exposed workers than among comparable unexposed workers.

Moreover, the fact that 41 out of 47 studies showed an excess risk of lung cancer for exposed workers may itself be a significant result, even if the evidence in most of those 41 studies is relatively weak. Getting ''heads'' on a single flip of a coin, or two ''heads'' out of three flips, does not provide strong evidence that there is anything special about the coin. However, getting 41 ''heads'' in 47 flips would normally lead one to suspect that the coin was weighted in favor of heads. Similarly, results reported in the epidemiologic literature lead one to suspect that the underlying relationship between diesel exposure and an increased risk of lung cancer is indeed positive.

More formally, as MSHA pointed out in the earlier version of this risk assessment, the high proportion of positive studies is statistically significant according to the 2-tailed sign test. Under the ''null hypothesis'' that there is no systematic bias in one direction or the other, and assuming that the studies are independent, the probability of 41 or more out of 47 studies being either positive or negative is less than one per ten million. Therefore, the sign test rejects, at a very high confidence level, the null hypothesis that each study is equally likely to be positive or negative. This means that the collective results, showing increased risk for exposed workers, are statistically significant at a very high confidence level—regardless of the statistical significance of any individual study.

MSHA received no comments directly disputing its attribution of statistical significance to the collective epidemiologic evidence based the sign test. However, several commenters objected to the concept that a number of inconclusive studies can, when viewed collectively, provide stronger evidence than the studies considered in isolation. For example, the Engine Manufacturers Association (EMA) asserted that—

> [j]ust because a number of studies reach the same conclusion does not make the collective sum of those studies stronger or more conclusive, particularly where the associations are admittedly weak and scientific difficulties exist in each. [EMA]

Similarly, IMC Global stated that—

> * * * IMC Global does not consider cancer studies with a relative risk of less than 2.0 as showing evidence of a casual relationship between Dpm exposure and lung cancer.* * * Thus while MSHA states [in the proposed risk assessment; now updated to 41 out of 47] that 38 of 43 epidemiologic studies show some degree of association between occupational Dpm exposures and lung cancer and considers that fact significant, IMC Global does not. [IMC Global]

Although MSHA agrees that even statistically significant consistency of epidemiologic results is not sufficient to establish causality, MSHA believes that consistency is an important part of establishing that a suspected association is causal.[67] Many of the commenters objecting to MSHA's emphasis on the collective evidence failed to distinguish the strength of evidence in each individual study from the strength of evidence in total.

Furthermore, weak evidence (from just one study) should not be confused with a weak effect. As Dr. James Weeks pointed out at the public hearing on Nov. 19, 1998, a 40-percent increase in lung cancer is a strong effect, even if it may be difficult to detect in an epidemiologic study.

Explicable differences, or heterogeneity, in the magnitudes of relative risk reported from different studies should not be confused with inconsistency of evidence. For example, as described by Silverman (1998), one of the available meta-analyses (Bhatia et al., 1998) ''examined the primary sources of heterogeneity among studies and found that a main source of heterogeneity is the variation in diesel exhaust exposure across different occupational groups.'' Figures III–9 and III–10, taken from Cohen and Higgins (1995), respectively show relative risks reported for the two occupations on which the most studies are available: railroad workers and truck drivers.

Each of these two charts compares results from studies that adjusted for smoking to results from studies that did not make such an adjustment. For each study, the point plotted is the estimated relative risk or odds ratio, and the horizontal line surrounding it represents a 95-percent confidence interval. If the left endpoint of a confidence interval exceeds 1.0, then the corresponding result is statistically significant at a 95-percent confidence level.

The two charts show that the risk of lung cancer has consistently been elevated for exposed workers and that the results are not significantly different within each occupational category. Differences in the magnitude and statistical significance of results within occupation are not surprising, since the groups studied differed in size, average exposure intensity and duration, and the time allotted for latent effects.

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[67] With respect to IMC Global's blanket rejection of studies showing a relative risk less than 2.0, please see also the related discussions in Subsection 2.c.i(2)(a) above, under the heading of ''Potential Confounders,'' and in Subsection 3.a.iii(3) below, entitled ''Potential Systematic Biases.''

Figure III-5

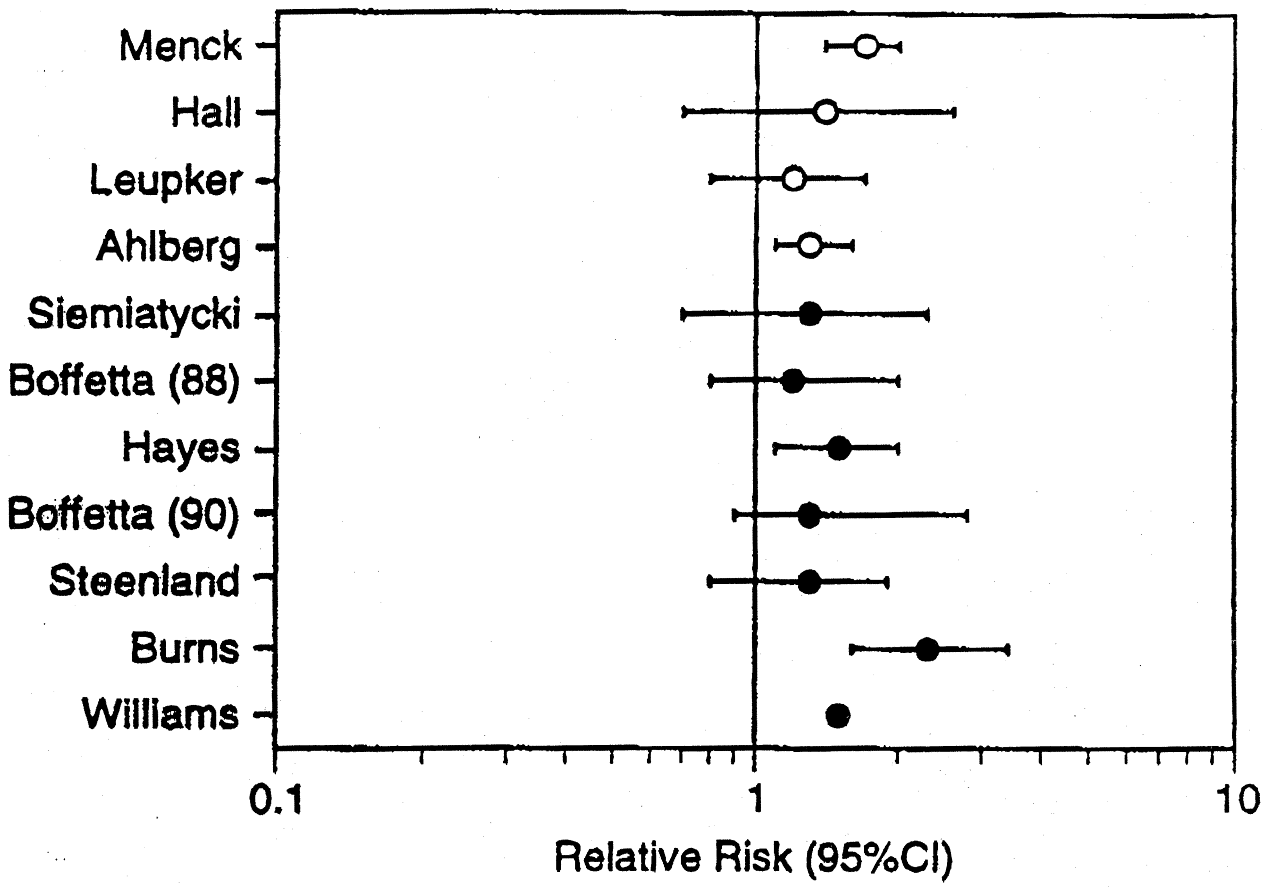

Figure , Lung cancer and exposure to diesel exhaust in truck drivers. ● = RR adjusted for cigarette smoking; ○ = RR not adjusted for cigarette smoking. For the study by Williams, CIs were not reported and could not be calculated. For the Steenland study, the data were gathered from union reports of long-haul truckers; for the Boffetta (1988) study, the data were self-reported by diesel truck drivers; and for the Siemiatycki study, they were self-reported by heavy-duty truck drivers (personal communication).

Figure III–6

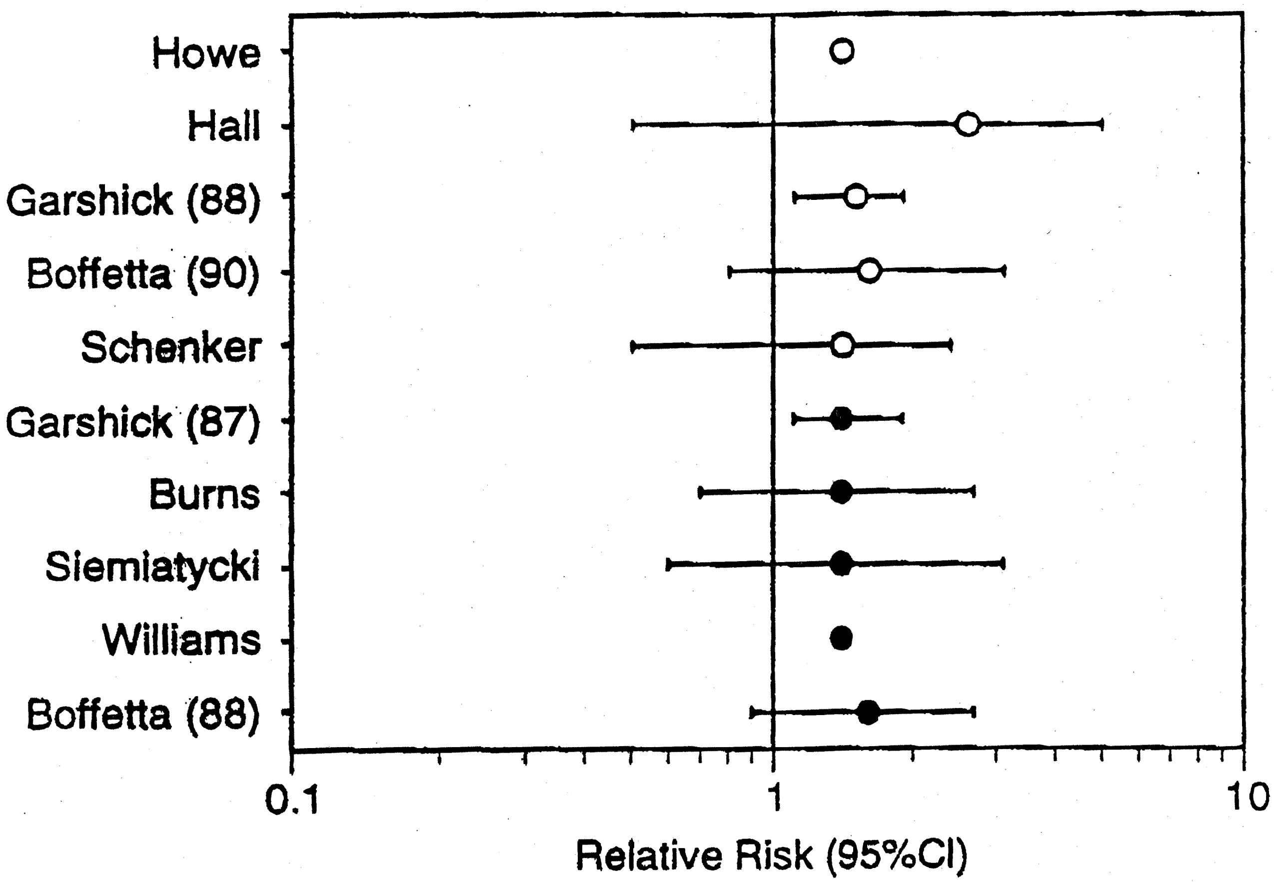

Figure . Lung cancer and exposure to diesel exhaust in railroad workers. ● = RR adjusted for cigarette smoking; ○ = RR not adjusted for cigarette smoking. For the two studies by Howe and Williams, CIs were not reported and could not be calculated.

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As documented in Subsection 2.c.i(2)(a) of risk assessment, all of the studies showing negative associations were either based on relatively short observation or follow-up periods, lacked good information about dpm exposure, involved low duration or intensity of dpm exposure, or, because of inadequate sample size or latency allowance, lacked the power to detect effects of the magnitude found in the ''positive'' studies. Boffetta et al. (1988, p. 404) noted that, in addition, studies failing to show a statistically significant association—

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

Some commenters noted that limitations such as insufficient duration of exposure, inadequate latency allowance, small worker populations, exposure misclassification, and comparison to external populations with no adjustment for a healthy worker effect may explain why not all of the studies showed a statistically significant association between dpm exposure and an increased prevalence of lung cancer. According to these commenters, if an epidemiologic study shows a statistically significant result, this often occurs in spite of methodological weaknesses rather than because of them. MSHA agrees that limitations such as those listed make it more difficult to obtain a statistically significant result when a real relationship exists.

(b) Best Available Epidemiologic Evidence

As explained above, it is statistically significant that 41 of the 47 available epidemiologic studies reported an elevated risk of lung cancer for workers exposed to dpm. MSHA finds it even more informative, however, to examine the collective results of the eight studies identified in Section III.2.c.i(2)(a) as providing the best currently available epidemiologic evidence. These studies, selected using the criteria described earlier, are: Boffetta et al. (1988), Boffetta et al. (1990), Brüske-Hohlfeld et al. (1999), Garshick et al. (1987), Garshick et al. (1988,1991), Johnston et al. (1997), Steenland et al. (1990,1992,1998), and Säverin et al. (1999). All eight of these studies reported an increased risk of lung cancer for workers with the longest diesel exposures and for those most likely to have been exposed, compared to unexposed workers. Tables showing the results from each of these studies are provided in Section III.2.c.1(2)(a).

The sign test of statistical significance can also be applied to the collective results of these eight studies. If there were no underlying association between exposure to diesel exhaust and an increased risk of lung cancer, or anything else systematically favoring a positive result, then there should be equal probabilities (equal to one-half) that any one of these eight studies would turn out positive or negative. Therefore, under the null hypothesis that positive and negative results are equally likely, the probability that all eight studies would show either a positive or a negative association is $(0.5)^8 = 0.0039$, or 0.39 percent. This shows that the collective results of the eight studies comprising the best available epidemiologic evidence are statistically significant at a confidence level exceeding 99 percent (i.e., $100 - 2 \times 0.39$).

When the risk of disease or death increases in response to higher cumulative exposures, this is described by a ''positive'' exposure-response relationship. Like consistency of results, the existence of a positive exposure-response relationship is important in establishing that the exposures in question actually cause an increase in risk. Among the eight studies MSHA has identified as comprising the best available epidemiologic evidence, there are five that provide evidence of increasing lung cancer risk with increasing cumulative exposure: Boffetta, et al. (1990), Brüske-Hohlfeld et al. (1999), Johnston et al. (1997), Säverin et al. (1999), and Steenland et al. (1990, 1992, 1998). The results supporting such a relationship are provided in the table accompanying discussion of each of these studies in Section III.2.c.i(2)(a).

Although some have interpreted the results from the two studies by Garshick et al. as also providing evidence of a positive exposure-response relationship (*e.g.,* Cal-EPA, 1998), this interpretation is highly sensitive to the statistical models and techniques used to analyze the data (HEI, 1999; Crump 1999). Therefore, for purposes of this risk assessment, MSHA is not relying on Garshick et al. (1987) or Garshick et. al (1988, 1991) to demonstrate the existence of a positive exposure-response relationship. MSHA used the study for purposes of hazard identification only. The Garshick studies contributed to the weight of evidence favoring a causal interpretation, since they show statistically significant excesses in lung cancer risk for the exposed workers.

The relative importance of the five studies identified in demonstrating the existence of a positive exposure-response relationship varies with the quality of exposure assessment. Boffetta et al. (1990) and Brüske-Hohlfeld et al. (1999) were able to show such a relationship based on the estimated duration of occupational exposure for exposed workers, but quantitative measures of exposure intensity (i.e., dpm concentration) were unavailable. Although duration of exposure is frequently used as a surrogate of cumulative exposure, it is clearly preferable, as many commenters pointed out, to base estimates of cumulative exposure and exposure-response analyses on quantitative measurements of exposure levels combined with detailed work histories. Positive exposure-response relationships based on such data were reported in all three studies: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999).

(c) Studies With Quantitative or Semiquantitative Exposure Assessments

Several commenters stressed the fact that most of the available epidemiologic studies contained little or no quantitative information on diesel exposures and that those studies containing such information (such as Steenland et al., 1998) generated it using questionable assumptions. Some commenters also faulted MSHA for insufficiently addressing this issue. For example, one commenter stated:

> * * * the Agency fails to highlight the lack of acceptable (or any) exposure measurements concurrent with the 43 epidemiology studies cited in the Proposed Rule.* * * the lack of concurrent exposure data is a significant deficiency of the epidemiology studies at issue and is a major factor that prevents application of those epidemiology results to risk assessment. [EMA]

MSHA agrees that the nature and quality of exposure information should be an important consideration in evaluating the strength of epidemiologic evidence. That is why MSHA included exposure assessment as one of the criteria used to evaluate and rank studies in Section 2.c.1(2)(a) of this risk assessment. Two of the most recent studies, both conducted specifically on miners, utilize concurrent, quantitative exposure data and are included among the eight in MSHA's selection of best available epidemiologic evidence (Johnston et al., 1997 and Säverin et al., 1999). As a practical matter, however, epidemiologic studies rarely have concurrent exposure measurements; and, therefore, the commenter's line of reasoning would exclude nearly all of the available studies from this risk assessment—including all six of the negative studies. Since Section 101(a)(6) of the Mine Act requires MSHA to consider the ''best available evidence'' (emphasis added), MSHA has not excluded studies with less-than-ideal exposure assessments, but, instead, has taken the quality of exposure assessment into account when evaluating them. This approach is also consistent with the recognition by the HEI Expert Panel on Diesel Emissions and Lung Cancer that ''regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available'' (HEI, 1999; p. 39).

The degree of quantification, however, is not the only relevant consideration in evaluating studies with respect to exposure assessment. MSHA also considered the likely effects of potential exposure misclassification. As expressed by another commenter:

> * * * [S]tudies that * * * have poor measures of exposure to diesel exhaust have problems in classification and will have weaker results. In the absence of information that misclassification is systematic or differential, in which case study results would be biased towards either positive or no-effect level, it is reasonable to assume that misclassification is random or nondifferentiated. If so,* * * study results are biased towards a risk ratio of 1.0, a ratio showing no association between diesel exhaust exposure and the occurrence of lung cancer. [Dr. James Weeks, representing UMWA]

In her review of Bhatia et al. (1998), Silverman (1998) proposed that ''[o]ne approach to assess the impact of misclassification would be to exclude studies without quantitative or semiquantitative exposure data.'' According to Dr. Silverman, this would leave only four studies among those considered by Dr. Bhatia: Garshick et al. (1988), Gustavsson et al. (1990), Steenland et al. (1992), and Emmelin et al. (1993).[68] All four of these studies showed higher rates of lung cancer for the workers estimated to have received the greatest cumulative exposure, as compared to workers who had accumulated little or no diesel exposure. Statistically significant results were reported in three of these four studies. Furthermore, the two more recent studies utilizing fully quantitative exposure assessments (Johnston et al., 1997; Säverin et al., 1999) were not evaluated or otherwise considered in the articles by Drs. Bhatia and Silverman. Like the other four studies, these too reported elevated rates of lung cancer for workers with the highest cumulative exposures. Specific results from all six of these studies are presented in Tables III–4 and III–5.

Once again, the sign test of statistical significance can be applied to the collective results of the four studies identified by Dr. Silverman plus the two more recent studies with quantitative exposure assessments. As before, under the null hypothesis of no underlying effect, the probability would equal one-half that any one of these six studies would turn out positive or negative. The probability that all six studies would show either a positive or a negative association would, under the null hypothesis, be $(0.5)^6 = 0.0156$, or 1.56 percent. This shows that the collective results of these six studies, showing an elevated risk of lung cancer for workers estimated to have the greatest cumulative exposure, are statistically significant at a confidence level exceeding 96 percent (i.e., $100 - 2 \times 1.56$).

As explained in the previous subsection, three studies showing evidence of increased risk with increasing exposure based on quantitative or semi-quantitative exposure assessments are included in MSHA's selection of best available epidemiologic evidence: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999). Not only do these studies provide consistent evidence of elevated lung cancer risk for exposed workers, they also each provide evidence of a positive exposure-response relationship—thereby significantly strengthening the case for causality.

(d) Studies Involving Miners

Eleven studies involving miners are summarized and discussed in Section 2.c.i(2)(a) of this risk assessment. Commenters' observations and criticisms pertaining to the individual studies in this group are also addressed in that section. Three of these studies are among the eight in MSHA's selection of best available epidemiologic evidence: (Boffetta et al., 1988; Johnston et al., 1997; Säverin et al., 1999). All three of these studies provide evidence of an increased risk of lung cancer for exposed miners. Although MSHA places less weight on the remaining eight studies, seven of them show some evidence of an excess lung cancer risk among the miners involved. The remaining study (Christie et al., 1995) reported a greater all-cause SMR for the coal miners involved than for a comparable population of petroleum workers but did not compare the miners to a comparable group of workers with respect to lung cancer.

The NMA submitted a review of six of these studies by Dr. Peter Valberg, who concluded that ''[t]hese articles do not implicate diesel exhaust, per se, as strongly associated with lung cancer in miners * * * The reviewed studies do not form a consistent and cohesive picture implicating diesel exhaust as a major risk factor for miners.'' Similarly, Dr. Jonathan Borak reviewed six of the studies on behalf of MARG and concluded:

> [T]he strongest conclusion that can be drawn from these six studies is that the miners in those studies had an increased risk of lung cancer. These studies cannot relate such increased [risk] to any particular industrial exposure, lifestyle or combination of such factors.

Apparently, neither Dr. Valberg nor Dr. Borak disputed MSHA's observation that the miners involved in the studies they reviewed exhibited, overall, an excess risk of lung cancer. It is possible that any excess risk found in epidemiologic studies may be due to extraneous unknown or uncontrolled risk factors (i.e., confounding variables). However, neither Drs. Valberg or Borak, nor the NMA or MARG, offered evidence, beyond a catalog of speculative possibilities, that the excess lung cancer risk for these miners was due to anything other than dpm exposure.

Nevertheless, MSHA agrees that the studies reviewed by Drs. Valberg and Borak do not, by themselves, conclusively implicate dpm exposure as the causal agent. Miners are frequently exposed to other occupational hazards associated with lung cancer, such as radon progeny, and it is not always possible to distinguish effects due to dpm exposure from effects due to these other occupational hazards. This is part of the reason why MSHA did not restrict its consideration of evidence to epidemiologic studies involving miners. What implicates exposure to diesel exhaust is the fact that diesel-exposed workers in a variety of different occupations, under a variety of different working conditions (including different types of mines), and in a variety of different geographical areas consistently exhibit an increased risk of lung cancer.

Drs. Valberg and Borak did not review the two studies that utilize quantitative dpm exposure assessments: Johnston et al. (1997) and Saverin et al. (1999). In recently received comments Dr. Valberg, writing for the NMA brought up four issues on the Saverin et al. 1999. These issues were potential exposure misclassification, potential flaws in the sampling method, potential smoker

[68] Emmelin et al. (1993) was considered but excluded from the meta-analysis by Bhatia et al. (1998) for reasons explained by the authors.

misclassification, and insufficient latency. Two of these issues have already been extensively discussed in section 2.c.i.2.a.ii and therefore will not be repeated here. Dr. Valberg suggested that the potential flaw in the sampling method would tend to over-estimate exposure and that there was insufficient latency. If, in fact, both of these issues are relevant, they would act to UNDERESTIMATE the lung cancer risk in this cohort instead of OVERESTIMATE it. MSHA regards these, along with Boffetta et al. (1988), Burns and Swanson (1991),[69] and Lerchen et al. (1987) to be the most informative of the available studies involving miners. Results on miners from these five studies are briefly summarized in the following table, with additional details provided in Section 2.c.1(2)(a) and Tables III–4 and III–5 of this risk assessment. The cumulative exposures at which relative risks from the Johnston and Säverin studies are presented are equivalent, assuming that TC constitutes 80 percent of total dpm. The cumulative dpm exposure of 6.1 mg-yr/m^3 is the multiplicative product of exposure duration and dpm concentration for the most highly exposed workers in each of these two studies.

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Results from best available studies involving miners.

Study	Mine Type	Exposure Assessment	Smoking Adjustm't	Result
Boffetta et al. (1988)	various	Occupational history	yes	RR = 2.67 for miners, compared to workers never employed in diesel -exposed occupations.†
Burns and Swanson (1991)	unknown	Occupational history	yes	OR = 5.03 for mining machinery operators.†
Johnston et al. (1997)	UG coal	Occupational history & indirect dpm measurements	yes	For cumulative dpm exposure = 6.12 mg-yr/m^3 : RR = 5.5 using mine-adjusted statistical model; RR= 11.0 using mine-unadjusted statistical model.
Lerchen et al. (1987)	various	Occupational history	yes	OR = 2.1 for underground non-uranium mining.
Säverin et al. (1999)	UG potash	Occupational history & TC measurements	smoking uncorrelated with TC within cohort	RR = 2.17 for most highly exposed group, compared to least exposed group. For cumulative TC exposure = 4.9 mg-yr/m^3 : RR = 1.16 to 2.70 depending on statistical model.

†Statistically significant at a 95-percent confidence level.

Although MSHA places less weight on the studies by Burns and Swanson and by Lerchen than on the other three, it is significant that the five best available studies involving miners all support an increased risk of lung cancer attributable to dpm exposure.

(2) Meta-Analyses

MSHA recognizes that simply tabulating epidemiologic studies as positive or negative can sometimes be misleading. There are generally a variety of outcomes that could render a study positive or negative, some studies contain different analyses of related data sets, some studies involve multiple

[69] Listed in Table III–5 under Swanson et al., 1993.

comparisons of various subgroups, and the studies differ widely in the reliability of their results. Therefore, MSHA is not limiting its assessment of the epidemiologic evidence to such a tabulation or relying only on the sign test described above. MSHA has also considered the results of two statistical meta-analyses covering most of the available studies (Lipsett and Campleman, 1999; Bhatia et al., 1998). These meta-analyses weighted and pooled independent results from those studies meeting certain inclusion requirements to form overall estimates of relative risk for exposed workers based on the combined body of data. In addition to forming pooled estimates of the effect of diesel exposure, both meta-analyses analyzed sources of heterogeneity in the individual results and investigated but rejected publication bias as an explanation for the generally positive results reported. Both meta-analyses derived a statistically significant increase of 30 to 40 percent in the risk of lung cancer, attributable to occupational dpm exposure.

Lipsett and Campleman (1999) systematically analyzed and combined results from most of the studies summarized in Tables III–4 and III–5. Forty-seven studies published between 1957 and 1995 were identified for initial consideration. Some studies were excluded from the pooled analysis because they did not allow for a period of at least 10 years for the development of clinically detectable lung cancer. Others were excluded because of bias resulting from incomplete ascertainment of lung cancer cases in cohort studies or because they examined the same cohort population as another study. One study was excluded because standard errors could not be calculated from the data presented. The remaining 30 studies, contributing a total of 39 separate estimates of exposure effect (for distinct occupational groups within studies), were analyzed using a random-effects analysis of variance (ANOVA) model.

Potential effects of publication bias (i.e., the likelihood that papers with positive results may be more likely to be published than those with negative results) were investigated by plotting the logarithm of relative risk estimated from each study against its estimated precision, as expressed by the inverse of its standard error. According to the authors, the resulting ''funnel plot'' was generally consistent with the absence of significant publication bias, although there were relatively few small-scale, statistically insignificant studies. The investigators performed a further check of potential publication bias by comparing results of the included studies with the only relevant unpublished report that became available to them during the course of their analysis. Smoking-adjusted relative risks for several diesel-exposed occupations in the unpublished study were, according to the investigators, consistent with those found in the studies included in the meta-analysis.

Each of the 39 separate estimates of exposure effect was weighted by a factor proportional to its estimated precision. Sources of heterogeneity in results were investigated by subset analysis—using categorical variables to characterize each study's design, target population (general or industry-specific), occupational group, source of control or reference population, latency, duration of exposure, method of ascertaining occupation, location (North America or Europe), covariate adjustments (age, smoking, and/or asbestos exposure), and absence or presence of a clear healthy worker effect (as manifested by lower than expected all-cause mortality in the occupational population under study).

Sensitivity analyses were conducted to evaluate the sensitivity of results to inclusion criteria and to various assumptions used in the analysis. This included (1) substitution of excluded ''redundant'' studies of the same cohort population for the included studies and (2) exclusion of studies involving questionable exposure to dpm. An influence analysis was also conducted to examine the effect of dropping one study at a time, to determine if any individual study had a disproportionate effect on results of the ANOVA.

The pooled relative risk from all 39 exposure effects (estimated from 30 studies) was RR = 1.33, with a 95-percent confidence interval (CI) extending from 1.21 to 1.46. For the subgroup of 13 smoking-adjusted exposure effects (nine studies) from populations ''most likely to have had substantial exposure'' to dpm, the pooled effect was RR = 1.47, with a CI from 1.29 to 1.67. Based on the all of the various analyses they conducted, the authors concluded:

> Although substantial heterogeneity existed in the initial pooled analysis, stratification on several factors substantially reduced heterogeneity, producing subsets of studies with increased relative risk estimates that persisted through various influence and sensitivity analyses. * * *
>
> In studies that adjusted for confounding by cigarette smoking, not only did the positive association between diesel exhaust exposure and lung cancer persist but the pooled risk estimate showed a modest increase, with little evidence of heterogeneity.
>
> * * * [T]his meta-analysis provides quantitative evidence consistent with several prior reviews, which have concluded that the epidemiologic evidence supports a causal relationship between occupational exposure to diesel exhaust and lung cancer. [Lipsett and Campleman, 1999]

The other meta-analysis was conducted by Bhatia et al. (1998) on epidemiologic studies published in peer-reviewed journals between 1957 and 1993. In this analysis, studies were excluded if actual work with diesel equipment ''could not be confirmed or reliably inferred'' or if an inadequate latency period was allowed for cancer to develop, as indicated by less than 10 years from time of first exposure to end of follow-up. Studies of miners were also excluded, because of potential exposure to radon and silica. Likewise, studies were excluded if they exhibited selection bias or examined the same cohort population as a study published later. A total of 29 independent results on exposure effects from 23 published studies were identified as meeting the inclusion criteria.

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

After assigning each of the 29 separate estimates of exposure effect a weight proportional to its estimated precision, Bhatia et al. (1998) used a fixed-effects ANOVA model to calculate pooled relative risks based on the following groupings: all 29 results; all case-control studies; all cohort studies; cohort studies using internal reference populations; cohort studies making external comparisons; studies adjusted for smoking; studies not adjusted for smoking; and studies grouped by occupation (railroad workers, equipment operators, truck drivers, and bus workers). Elevated risks of lung cancer were shown for exposed workers overall and within every individual group of studies analyzed. A positive duration-response relationship was observed in those studies presenting results according to employment duration. The weighted, pooled estimates of relative risk were identical for case-control and cohort studies and nearly identical for studies with or without smoking adjustments.

The pooled relative risk from all 29 exposure effects (estimated from 23 studies) was RR = 1.33, with a 95-percent confidence interval (CI), adjusted for heterogeneity, extending from 1.24 to 1.44. For just the smoking-adjusted studies, it was 1.35 (CI: 1.20 to 1.52); and for cohort studies making internal comparisons, it was 1.43 (CI: 1.29 to 1.58). Based on their evaluation of the all the analyses on various subgroups, Bhatia et al. (1998) concluded that the elevated risk of lung cancer observed among exposed workers was unlikely to be due to chance, that confounding from smoking was unlikely to explain all of the excess risk, and that ''this meta-analysis supports a causal association between increased risks for lung cancer and exposure to diesel exhaust.''

The pooled relative risks estimated in both meta-analyses equal 1.33 and exceed 1.4 for studies making internal comparisons, or comparisons to similar groups of workers. Both meta-analyses found these results to be statistically significant, meaning that they cannot be explained merely by random or unexplained variability in the risk of lung cancer that occurs among both exposed and unexposed workers. Although both meta-analyses relied, by necessity, on an overlapping selection of studies, the inclusion criteria were different and some studies included in one meta-analysis were excluded from the other. They used different statistical models for deriving a pooled estimate of relative risk, as well as different means of analyzing heterogeneity of effects. Nevertheless, they derived the same estimate of the overall exposure effect and found similar sources of heterogeneity in the results from individual studies.[70] One commenter observed that—

> Lung cancer relative risks for occupational ''control groups'' vary over a range from 0.4 to 2.7 * * *. Therefore, the level of relative risks being reported in the Dpm epidemiology fall within this level of natural variation. [IMC Global]

This argument is refuted by the statistical significance of the elevation in risk detected in both meta-analyses in combination with the analyses accounting for heterogeneity of exposure effects.

The EMA objected that MSHA's focus on these two meta-analyses ''presents an incomplete picture because the counter-arguments of Silverman (1998) were not discussed in the same detail.'' IMC global also faulted MSHA for dismissing Dr. Silverman's views without adequate explanation.

In her review,[71] Dr. Silverman characterized Bhatia et al. (1998) as a ''careful meta-analysis'' and acknowledged that it ''add[s] to the credibility that diesel exhaust is carcinogenic * * *.'' She also explicitly endorsed several of its most important conclusions. For example, Dr. Silverman stated that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' She suggested, however, that Bhatia et al. (1998) ''ultimately do not resolve the question of causality.'' (Silverman, 1998)

Dr. Silverman imposed an extremely high standard for what is needed to ultimately resolve the question of causality. The precise question she posed, along with her answer, was as follows:

> Has science proven causality beyond any reasonable doubt? Probably not. [Silverman, 1998, emphasis added.]

Neither the Mine Act nor applicable case law requires MSHA to prove causality ''beyond any reasonable doubt.'' The burden of proof that Dr. Silverman would require to close the case and terminate research is not the same burden of proof that the Mine Act requires to warrant protection of miners subjected to far higher levels of a probable carcinogen than any other occupational group. In this risk assessment, MSHA is evaluating the collective weight of the best available evidence—not seeking proof ''beyond any reasonable doubt.''[72]

The EMA objected to MSHA's reliance on the two meta-analyses because of ''* * * serious deficiencies in each'' but did not, in MSHA's opinion, identify any such deficiencies. The EMA pointed out that ''most of the original studies in each were the same, and the few that were not common to each were not of significance to the outcome of either meta-analysis.'' MSHA does not regard this as a deficiency. Since the object of both meta-analyses was to analyze the available epidemiologic evidence linking dpm exposure with lung cancer, using defensible inclusion criteria, it is quite understandable that they would rely on overlapping information. The principal differences were in the types and methods of statistical analysis used, rather than in the data subjected to analysis; and MSHA considers it informative that different approaches yielded very similar results and conclusions. It is noteworthy, moreover, that both of the meta-analyses explicitly addressed the EMA's concern by performing analyses on various different sub-groupings of the available studies. The sensitivity of results to the inclusion criteria was also explicitly investigated and considered. MSHA believes that the conclusions of these meta-analyses did not depend on unreasonable inclusion or exclusion criteria.

The EMA also argued that—

> [a] meta-analysis cannot compensate for basic deficiencies in the studies used to create the meta-analysis, and this fact is not clearly stated by MSHA. Instead, MSHA follows the tack of the meta-analysis authors, who claim that the meta-analysis somehow overcomes deficiencies of the individual studies selected and presents a stronger case. This is simply not true. [EMA]

MSHA agrees that a meta-analysis cannot correct for all deficiencies that may be present in individual studies. It can, however, correct for certain types of deficiencies. For example, individual studies may lack statistical power because of small study populations. By pooling results from several such studies, a meta-analysis may achieve a level of statistical significance not attainable by the individual studies. Furthermore, both of the meta-analyses used well-defined inclusion criteria to screen out those studies with the most severe deficiencies. In addition, they both found that it was the more rigorous and technically more valid studies that reported the strongest associations between excess lung cancer and dpm exposure. They also performed separate analyses that ruled out inflationary effects of such ''deficiencies'' as lack of a smoking adjustment. For example,

[70] Several commenters suggested that because the two meta-analyses both received direct or indirect funding from the same governmental agency, they were not independently conducted. These commenters speculated that Dr. Allan Smith, a co-author of Cal-EPA (1998) and Bhatia et al. (1998), contributed to both meta-analyses. Although an earlier version of Lipsett and Campleman (1999) appeared as an appendix to Cal-EPA (1998), commenters provided no evidence that Dr. Smith contributed anything to that appendix. Dr. Smith is not listed as a co-author of Lipsett and Campleman (1999).

[71] Silverman (1998) reviewed Bhatia et al. (1998) but not Lipsett and Campleman (1999) or the earlier version of that meta-analysis (Lipsett and Alexeeff, 1998) cited in MSHA's proposed preamble.

[72] It is noteworthy that, in describing research underway that might resolve the issue of causality, Dr. Silverman stressed the need for studies with quantitative exposure measurements and stated that ''underground miners may, in fact, be the most attractive group for study because their exposure to diesel exhaust is at least five times greater than that of previously studied occupational groups.'' (Silverman, 1998) She then mentioned a study on underground miners in Germany that had recently been initiated. The study of German underground potash miners (Säverin et al., 1999), published after Dr. Silverman's article, utilizes quantitative exposure measurements and is included in MSHA's selection of best available epidemiologic evidence (see Section 3.a.iii(1)(a) of this risk assessment). MSHA also includes in that selection another underground miner study utilizing quantitative exposure measurements (Johnston et al., 1997). The 1997 study was available prior to Dr. Silverman's article but is not listed among her references.

Lipsett and Campleman (1999) reported a pooled RR = 1.43 for 20 smoking-adjusted results, as compared to a pooled RR = 1.25 for 19 results with no smoking adjustment.

IMC Global and MARG submitted five specific criticisms of the meta-analyses, to which MSHA will respond in turn.

(1) publication bias

> * * * both studies * * * rely only on published studies. * * * the authors rely on statistical analysis in an attempt to uncover possible publication bias.* * * the only safeguard to protect against possible publication bias is to seek out unpublished results * * *. [IMC Global]

Both meta-analyses compared the results of published and unpublished studies and found them to be similar. Bhatia et al. (1998) found several unpublished studies of lung cancer among truck drivers that ''* * * were not included in our analysis; however the risk ratios of these studies are similar to the [sic] those in published studies among truck drivers.'' (Bhatia et al., p. 90) Lipsett and Campleman (1999) checked ''[s]moking-adjusted relative risks for several diesel-exposed occupations'' in an unpublished report on U.S. veterans and found them ''* * * consistent with those reported here.'' They remarked that ''although publication bias cannot be completely ruled out, it is an unlikely explanation for our findings.'' (Lipsett and Campleman, p. 1015) In addition to comparing results directly against unpublished studies, both meta-analyses used the statistical method of ''funnel plots'' as an indirect means of checking for the existence of significant publication bias. It should also be noted that MSHA did not exclude unpublished studies from this risk assessment.

(2) Selection Bias

> * * * [the] meta-analyses have to provide a much more convincing rationale as to why all miners were excluded even when the confounders that are mentioned are not likely or important, for example in studies conducted in potash and salt mines. * * * IMC Global sees no reason why the older studies of potash workers [Waxweiler *et al.*, 1973] and more recent studies on New South Wales coal miners [Christie *et al.*, 1995] should not be included * * *. [IMC Global]
>
> Studies were selectively included or excluded, without good or sufficient explanation. [MARG]

Contrary to the commenters' characterization, both meta-analyses listed each study excluded from the analysis of pooled relative risk and gave a good reason for its exclusion. For example, both meta-analyses excluded studies that failed to allow for a minimum 10-year latency period for lung cancer to develop after first exposure. With respect to the exclusion of all studies on miners, Bhatia et al. (1998) pointed out that ''[s]ince studies of miners often indicate higher relative risks for lung cancer than those considered in this meta-analysis, this was a conservative exclusion.'' Even if studies on miners had been considered, Waxweiler et al. (1973) and Christie et al. (1995) would have been excluded from both meta-analyses because of their failure to meet the 10-year minimum latency requirement.

(3) Lack of Actual Exposure Data

> * * * [N]ondifferential exposure or disease misclassification can sometimes produce bias away from the null * * * Thus, tests for heterogeneity performed in both these meta-analyzes won't detect or correct this problem. [IMC Global]

Lipsett and Campleman acknowledged that ''[e]xposure misclassification is a problem common to all studies of cancer and diesel emissions. In no case were there direct measurements of historical diesel exhaust exposures of the subjects.'' However, as Dr. Silverman pointed out in her review, ''* * * this bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates toward the null value. Thus the summary RR of 1.33 may be an underestimate of the true lung cancer effect associated with diesel exposure.'' (Silverman, 1998)

(4) Smoking as a Confounder

> * * * The use of data manipulation and modeling adjustments in both these meta-analyses cannot rectify the flaws in the initial studies. [IMC Global]
>
> * * * misclassification of this exposure [cigarette smoking] could result in residual confounding of individual studies and, consequently, metaanalyses, of those studies. [MARG]

Contrary to the commenter's suggestion, neither of the meta-analyses made any attempt to manipulate or adjust the data in order to rectify what the commenter regards as ''flaws'' in the way smoking or other potential confounders were treated in the initial studies. Both meta-analyses, however, compared the pooled RR for studies with a smoking adjustment to the pooled RR for studies without any such adjustment. Both meta-analysis calculated a pooled RR for the smoking-adjusted studies greater than or equal to that for the unadjusted studies. In addition, Bhatia et al. (1998) analyzed the impact of the smoking adjustment for the subgroup of studies reporting results both with and without such an adjustment and found that the ''small reduction in the pooled RR estimates would not be consistent with a major effect from residual confounding.'' Dr. Silverman concluded that ''[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer.'' (Silverman, 1998)

(5) Inadequate Control in the Underlying Studies for Diet

> As noted by Lipsett and Campleman, ''Diet may also confound the diesel-lung cancer association.'' The researchers also caution that this risk factor was not controlled for in the nearly 50 diesel studies they examined. [MARG]

Since inhalation is the primary route of dpm exposure, and the lung is the primary target organ, MSHA considers potential dietary confounding to be of minor importance in the diesel-lung cancer association. Lipsett and Campleman acknowledged that diet might be a relevant consideration for long-haul truck drivers, but stated that ''diet would probably not be an important confounder in studies of other occupations, particularly those using internal or other occupationally active reference populations.'' Studies making internal comparisons, or comparisons to similar groups of workers, are unlikely to be seriously confounded by dietary differences, because the groups of workers being compared are likely to have very similar dietary habits, on average. The pooled relative risk for cohort studies making comparisons internally or to other active workers was 1.48 (95% CI = 1.28 to 1.70). (Lipsett and Campleman, 1999, Table 3) This was considerably higher than the pooled RRs for studies making comparisons against regional or national populations, where dietary differences (and also differences with respect to other potential confounders) would be more important.

(3) Potential Systematic Biases

Citing failure to account for dietary differences as an example, some commenters argued that the meta-analyses may simply propagate weaknesses shared by the individual studies. These commenters contended that many of the studies MSHA considered in this risk assessment share methodological similarities and that, therefore, a ''deficiency'' causing bias in one study would probably also bias many other studies in the same direction. According to these commenters, no matter how great a majority of studies report a 30- to 40-percent increase in the risk of lung cancer for exposed workers, the possibility of systematic bias prevents the collective evidence from being strong or sufficient.

Although this point has some theoretical foundation, it has no basis in fact for the particular body of epidemiologic evidence relating lung cancer to diesel exposure. The studies considered were carried out by many different researchers, in different countries, using different methods, and involving a variety of different occupations. Elevated risk was found in cohort as well as case-control studies, and in studies explicitly adjusting for potential confounders as well as studies relying on internal comparisons within homogeneous populations. The possibility that systematic bias explains these results is also rendered less plausible by results from studies of a radically different type: the elevated risk of lung cancer associated with chronic environmental exposures to $PM_{2.5}$ (Dockery et al. 1993; Pope et al., 1995).

Furthermore, the commenters advancing this argument presented no evidence that the studies shared any deficiencies of a type that would systematically shift results in the direction of showing a spurious association. As explained in Subsection 2.c.i(2)(a), exposure misclassification, healthy worker effect, and low power due to insufficient latency generally have the opposite effect—systematically diluting and masking results. Although many studies may share a similar susceptibility to bias by dietary differences or residual smoking effects,[73] there is no reason to expect that such effects will consistently bias results in the same direction, across all occupations and geographic regions.

Associations between dpm exposure and excess lung cancer are evident in a wide variety of occupational and geographical contexts, and it is unlikely that all (or most) would be biased in the same direction by lifestyle effects. There is no reason to suppose that, in nearly all of these studies, exposed subjects were more likely than unexposed subjects to have lifestyles (apart from their occupations) that increased their risk of lung cancer. On the other hand, exposures to other occupational carcinogens, such as asbestos dust, radon progeny, and silica, could systematically cause studies in which they are not taken into account to exhibit spurious associations between lung cancer and occupational diesel exhaust exposures. Silica dust and radon progeny are frequently present in mining environments (though not usually in potash mines), and this was the reason that studies on miners were excluded from the two meta-analyses.

IMC Global argued that because of the possibility of being misled by systematic biases, epidemiologic evidence can be used to identify only those hazards that, at a minimum, double the risk of disease (i.e., RR ≥ 2.0). IMC Global explained this viewpoint by quoting an epidemiologist as follows:

> * * * [E]pidemiologic methods can only yield valid documentation of large relative risks. Relative risks of low magnitude (say, less than 2) are virtually beyond the resolving power of the epidemiologic microscope. We can seldom demonstrably eliminate all sources of bias, and we can never exclude the possibility of unidentified and uncontrolled confounding. If many studies—preferably based on different methods—are nevertheless congruent in producing markedly elevated relative risks, we can set our misgivings aside. If however, many studies produce only modest increases, those increases may well be due to the same biases in all the studies. [Dr. Samuel Shapiro, quoted by IMC Global]

It is important to note that, unlike IMC Global, Dr. Shapiro did not suggest that results of RR < 2.0 be counted as ''negative.'' He contended only that low RRs do not completely rule out the possibility of a spurious association due to unidentified or uncontrolled confounding. More importantly, however, this restriction would allow workers to be exposed to significant risks and is, therefore, unacceptable for regulatory purposes. For purposes of protecting miners from lung cancer, certainty is not required; and an increase in the relative risk of less than 100 percent can increase the absolute risk of lung cancer by a clearly unacceptable amount. For example, if the baseline risk of lung cancer is six per thousand, then increasing it by 33 percent amounts to an increase of two per thousand for exposed workers.

IMC Global went on to argue that—

> * * * only a few of these studies have relative risks that exceed 2.0, and some of the studies that do exceed 2.0 exhibit biases that make them unsuitable for rulemaking purposes in our opinion. * * * Thus, in IMC Global's opinion, the epidemiologic evidence demonstrates an artificial association that can be explained through common biases probably due to smoking habits and lifestyle factors. [IMC Global]

This line of reasoning leaps from the possibility that systematic biases might account for observed results to a conclusion that they actually do so. Furthermore, after proposing to allow for possible biases by requiring that only relative risks in excess of 2.0 be counted as positive evidence, IMC Global has ignored its own criterion and discounted results greater than 2.0 for the same reason. Contrary to IMC Global's claim that ''only a few of the studies have relative risks that exceed 2.0,'' Tables III–4 and III–5 show 23 separate results greater than 2.0, applying to independent categories of workers in 18 different studies.

According to Stöber and Abel (1996), the potential confounding effects of smoking are so strong that ''residual smoking effects'' could explain even statistically significant results observed in studies where smoking was explicitly taken into account. MSHA agrees that variable exposures to non-diesel lung carcinogens, including relatively small errors in smoking classification, could bias individual studies. However, the potential confounding effect of tobacco smoke and other carcinogens can cut in either direction. Spurious positive associations of dpm exposure with lung cancer would arise only if the group exposed to dpm had a greater exposure to these confounders than the unexposed control group used for comparison. If, on the contrary, the control group happened to be more exposed to confounders, then this would tend to make the association between dpm exposure and lung cancer appear negative. Therefore, although smoking effects could potentially distort the results of any single study, this effect could reasonably be expected to make only about half the studies that were explicitly adjusted for smoking come out positive. Smoking is unlikely to have been responsible for finding an excess prevalence of lung cancer in 17 out of 18 studies in which a smoking adjustment was applied. Based on a 2-tailed sign test, this possibility can be rejected at a confidence level greater than 99.9 percent.

Even in the 29 studies for which no smoking adjustment was made, tobacco smoke and other carcinogens were important confounders only to the extent that the populations exposed and unexposed to diesel exhaust differed systematically with respect to these other exposures. Twenty-four of these studies, however, reported some degree of excess lung cancer risk for the diesel-exposed workers. This result could be attributed to other occupational carcinogens only in the unlikely event that, in nearly all of these studies, diesel-exposed workers happened to be more highly exposed to these other carcinogens than the control groups of workers unexposed to diesel.

Like IMC Global, Stöber and Abel (1996) do not, in MSHA's opinion, adequately distinguish between a possible bias and an actual one.

[73] The term ''residual smoking effects'' refers to the potentially confounding effects of smoking that may remain after a smoking adjustment has been made.

Potential biases due to extraneous risk factors are unlikely to account for a significant part of the excess risk in all studies showing an association. Excess rates of lung cancer were associated with dpm exposure in all epidemiologic studies of sufficient size and scope to detect such an excess. Although it is possible, in any individual study, that the potentially confounding effects of differential exposure to tobacco smoke or other carcinogens could account for the observed elevation in risk otherwise attributable to diesel exposure, it is unlikely that such effects would give rise to positive associations in 41 out of 47 studies. As stated by Cohen and Higgins (1995):

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

Several commenters identified publication bias as another possible explanation for the heavy preponderance of studies showing an elevated risk of lung cancer for exposed workers. As described earlier, both of the available meta-analyses investigated and rejected the hypothesis of significant publication bias affecting the overall results. This was based on both a statistical technique using ‘‘funnel plots’’ and a direct comparison between results of published and unpublished studies. Commenters presented no evidence that publication bias actually exists in this case. After the 1988 NIOSH and 1989 IARC determinations that diesel exhaust was a ‘‘potential’’ or ‘‘probable’’ human carcinogen, negative results would have been of considerable interest, and, in the absence of any evidence specifically applying to dpm studies, there is no reason to assume they would not have been published.

(4) Causality

MSHA must draw its conclusions based on the weight of evidence. In the absence of any statistical evidence for differential confounding or significant publication bias, the weight of epidemiologic evidence strongly favors a causal connection. On the one side, it is evident that virtually all of the studies that adjusted for smoking and other known confounders, or controlled for them by comparing against similar groups of workers, showed positive associations (i.e., relative risk or odds ratio > 1.0). Also on this side of the balance are all eight of the studies MSHA identified as comprising the best available human evidence. These include three studies reporting positive exposure-response relationships based on quantitative dpm exposure assessments: two recent studies specifically on underground miners (one coal and one potash) and one on trucking industry workers.[74] On the other side of the balance is the possibility that publication bias or other systematic biases may have been responsible for some unknown portion of the overall 30- to 40-percent elevation in lung cancer risk observed—a possibility that, while conceivable, is based on speculation. After considering other viewpoints (addressed here and in the next subsection), MSHA has accepted what in its view is the far more likely alternative: that the vast majority of epidemiologic studies showed an elevated risk in association with occupational exposures to diesel exhaust because such exposures cause the risk of lung cancer to increase. The toxicity experiments discussed in Subsection 2.d.iv of this risk assessment support the causal interpretation that MSHA has placed on the associations observed in epidemiologic studies.

In this risk assessment, MSHA is basing its conclusions primarily on epidemiologic studies. However, the results obtained from animal studies confirm that diesel exhaust can increase the risk of lung cancer in some species and help show that dpm (rather than the gaseous fraction of diesel exhaust) is the causal agent. The fact that dpm has been proven to cause lung cancer in laboratory rats only under conditions of lung overload does not make the rat studies irrelevant to miners. The very high dpm concentrations currently observed in some mines could impair or even overwhelm lung clearance for miners already burdened by respirable mineral dusts, thereby inducing lung cancer by a mechanism similar to what occurs in rats (Nauss et al., 1995). It must also be noted, however, that most of the human studies show an increased risk of lung cancer at dpm levels lower than what might be expected to cause overload. Therefore, the human studies suggest that overload is not a necessary condition for dpm to induce or promote lung cancer among humans. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. Animal studies provide evidence that inhalation of dpm has related effects, such as induction of free oxygen radicals, that could promote the development of human lung cancers by mechanisms not requiring lung overload. (See Sec. III.2.d.iv(2).)

Similarly, the weight of genotoxicity evidence helps support a causal interpretation of the associations observed in the epidemiologic studies. This evidence shows that dpm dispersed by alveolar surfactant can have mutagenic effects, thereby providing a genotoxic route to carcinogenesis that is independent of overloading the lung with particles. After a comprehensive review of the evidence, IPCS (1996) concluded that both the particle core and the associated organic materials have biological activity. The biological availability of carcinogens present in the organic portion of dpm may, however, differ significantly in different species. Chemical byproducts of phagocytosis, which occurs even when the lung is not overloaded, may provide another genotoxic route. Inhalation of diesel emissions has been shown to cause DNA adduct formation in peripheral lung cells of rats and monkeys, and increased levels of human DNA adducts have been found in association with occupational exposures. (See Sec. III.2.d.iv(1)) None of this evidence suggests that a lung cancer threshold exists for humans exposed to dpm, despite its importance in the rat model. Nor does this evidence suggest that lung overload is necessary for dpm to induce lung cancer in humans. Indeed, lung overload may be only one of many mechanisms through which lung cancer is produced in humans.

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

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that MSHA's determination that results from the

[74] These studies (respectively: Johnston et al., 1997; Säverin et al., 1999; Steenland et al., 1998) are discussed in detail in Subsection 2.c.i(2)(a) of this risk assessment.

epidemiologic and toxicity studies were ''coherent and mutually reinforcing'' involved circular reasoning. He supported this assertion by incorrectly attributing to MSHA the view that ''most of the individual [epidemiologic] studies are not very good'' and that their suggestion of an association between dpm and lung cancer is ''made credible in light of the animal data.'' To complete his argument that MSHA relied on circular reasoning, Dr. Borak then suggested that the epidemiologic data provided MSHA's sole basis for considering the animal data relevant to humans. In a similar vein, Kennecott Minerals claimed there was an ''absence of toxicological support for epidemiologic findings that are themselves inconclusive.''

Contrary to Dr. Borak's assertion, MSHA has not characterized most of the epidemiologic studies as ''not very good.'' Nor has MSHA suggested that the epidemiologic evidence would not be credible or plausible in the absence of supporting animal data. As Dr. Borak correctly noted, MSHA acknowledged that ''none of the existing human studies is perfect'' and that ''no single one of the existing epidemiological studies, viewed in isolation, provides conclusive evidence of a causal connection * * *.'' That a study is not ''perfect,'' however, does not imply that it is ''not very good.'' MSHA's position has consistently been that, as demonstrated by the two available meta-analyses, the collective epidemiologic evidence is not merely credible but statistically significant and indicative of a causal association. Although MSHA views the toxicity data as supporting and reinforcing the epidemiologic evidence, MSHA believes that the collective epidemiologic evidence is highly credible in its own right.

Furthermore, MSHA does not consider the animal data relevant to humans simply because of the positive epidemiologic evidence. The animal evidence is also credible in its own right. As MSHA has repeatedly pointed out, dust concentrations in some mines have been measured at levels of the same order of magnitude as those found to have caused lung cancer in rats. Such high exposures, especially when combined with occupational exposures to respirable mineral dusts and exposures to particles in tobacco smoke, could overload the human lung and promote lung cancer by a mechanism similar to that hypothesized for rats. (Hattis and Silver, 1992, Figures 9, 10, 11). Also, many of the animal experiments have elucidated genotoxic effects that, while apparently not responsible for the excess lung cancers observed for rats, may be responsible for some or all of the excess risk reported for humans.

MSHA has not relied on circular reasoning. If either the animal data or the toxicity data had failed to show any link between dpm and effects implicated in the induction or promotion of lung cancer, then MSHA's conclusion would have been weakened. The existence of experimental evidence confirming that there is such a link is not imaginary and is logically independent of the epidemiologic evidence. Therefore, contrary to Dr. Borak's characterization, the ''coherency and reinforcement'' arising from the epidemiologic, animal, and genotoxicity data are not the product of circular reasoning. A more apt description is that the three sources of evidence, like three legs of a tripod, support the same conclusion.

Many commenters argued that a causal connection between dpm exposure and an increased human risk of lung cancer should not be inferred unless there is epidemiologic evidence showing a positive exposure-response relationship based on quantitative measures of cumulative dpm exposure. MSHA does not agree that a quantitative exposure-response relationship is essential in establishing causality. Such a relationship is only one of several factors, such as consistency and biological plausibility, that epidemiologists examine to provide evidence of causality. As mentioned earlier, however, there are three studies providing quantitative exposure-response relationships. One of these studies (Steenland et al., 1998) controlled for age, race, smoking, diet, and asbestos exposure, but relied on ''broad assumptions'' to estimate historical exposure levels from later measurements. Two of the studies, however, (Johnston et al., 1997, and Säverin et al., 1999) utilized measurements that were either contemporaneous with the exposures (Johnston) or that were made under conditions very similar to those under which the exposures took place (Säverin). Both of these studies were conducted on underground miners. The Säverin study used exposure measurements of total carbon (TC). All three of the studies combined exposure measurements for each job with detailed occupational histories to form estimates of cumulative dpm exposure; and all three reported evidence of increasing lung cancer risk with increasing cumulative exposure.

Several commenters, expressing and endorsing the views of Dr. Peter Valberg, incorrectly asserted that the epidemiologic results obtained across different occupational categories were inconsistent with a biologically plausible exposure-response relationship. For example, MARG argued that—

> It is biologically implausible that, if Dpm were (causally) increasing lung cancer risk by 50% for a low exposure (say, truck drivers), then the lung cancer risk produced by Dpm exposure in more heavily exposed worker populations (railroad shop workers) would fall in this same range of added risk. The added lung-cancer risk for bus garage workers is half that of either railroad workers or truck drivers, but Dpm concentrations are considerably higher. [MARG]

Earlier, MARG had argued to the contrary that, due to their lack of concurrent exposure measurements, these studies could not reliably be used for hazard identification. MARG then attempted to use them to perform the rather more difficult task of making quantitative comparisons of relative risk. If cumulative exposures are unknown, as MARG argued elsewhere, then there is little basis for comparing responses at different cumulative exposures.

In an analysis submitted by the West Virginia Coal Association, Dr. Valberg extended this argument to miners as follows:

> * * * If dpm concentrations for truck drivers is in the range of 5–50 μg/m³, then we can assign the 0.49 excess risk (Bhatia's meta-analysis result) to the 5–50 μg/m³ exposure. Hence, dpm concentrations for miners in the range of 100–2,000 μg/m³ should have yielded excess risks forty times larger, meaning that the RR for exposed miners would be expected to be about 21 (i.e., 1 + 19.6), whereas reported risk estimates are less than 3 (range from 0.74 2.67). Such an utter lack of concordance argues against a causal role for dpm in the reported epidemiologic associations.

Based on a similar line of reasoning, IMC Global asserted that ''* * * the assumptions that MSHA used to develop [Figure III–4] * * * do not make sense in the context of a dose-response relationship between lung cancer and Dpm exposure.'' This was one of the reasons IMC Global gave for objecting to MSHA's comparison (in Section III.1.d) of exposure levels measured for miners to those reported for different occupations. IMC Global proposed that, as a consequence of this argument, MSHA should delete this comparison from its risk assessment.

MSHA sees three major flaws in Dr. Valberg's argument and rejects it for the following reasons:

(1) The argument glosses over the important distinction between exposure concentrations (intensity) and cumulative exposure (dose). Total

cumulative exposure is the product of intensity and duration of exposure. Depending on duration, high intensity exposure may result in similar (or even lower) cumulative exposure than low intensity exposure. Furthermore, different industries, in different nations, introduced diesel equipment at different times. The studies being considered were carried out in a variety of different countries and covered a variety of different historical periods. Therefore, the same number of years in different studies can correspond to very different durations of occupational exposure.

Many of the miners in the studies Dr. Valberg considered may have been occupationally exposed to dpm for relatively short periods of time or even not at all. Various forms of exposure misclassification would tend to obscure any exposure-response relationship across industries. Such obscuring would result from both exposure misclassification within individual studies and also variability in the degree of exposure misclassification in different industries.

Furthermore, the exposure levels or intensities assigned to the various occupations would not necessarily be proportional to cumulative exposures, even if the average number of years of exposure were the same. Different job conditions, such as longer-than-average work hours, could have major, variable impacts on cumulative exposures. For example, lower dpm concentrations have been measured for truck drivers than for other occupationally-exposed workers. However, the truck drivers studied, due to their work conditions may have been in their trucks for longer than the standard 40-hour work week and therefore have larger cumulative dpm exposures. Truck drivers commonly congregate in parking areas and sleep in their trucks with the engines idling, thereby disproportionately increasing their cumulative dpm exposures compared to miners and other types of workers.

(2) The commenters advancing this argument assumed that an exposure-response relationship spanning occupations at different levels of exposure intensity would take the form of a straight line. This assumption is unwarranted, since carcinogens do not necessarily follow such a simple pattern across a broad range of exposure levels. There is little basis for assuming that the relationship between cumulative dpm exposures and the relative risk of lung cancer would appear as a straight line when plotted against exposure levels that may differ by a factor of 100. Steenland et al. (1998) reported a better statistical ''fit'' to the data using a model based on the logarithm of cumulative exposure as compared to simple cumulative exposure. Even across the relatively limited range of exposures within the trucking industry, the logarithmic exposure model exhibits pronounced curvature towards the horizontal at the higher cumulative exposures (Steenland et al., 1998, Fig. 5). If this model is extrapolated out to the much higher exposures currently found in underground mining, then (as shown in Subsection 3.b.ii(3)(b) of this risk assessment) it diverges even more from a straight-line model. Toxicological evidence of curvature in the dose-response relationship has also been reported (Ichinose et al., 1997b, p.190).

Furthermore, the exposure-response pattern may depend on other aspects of exposure, besides how much is accumulated. For example, the National Research Council (NRC) has adopted a risk model for radon-induced lung cancer in which the relative risk (RR) at any age depends on both accumulated exposure and the rate (reflecting the intensity of exposure) at which total exposure was accumulated. In this model, which was derived empirically from the epidemiologic data, exposures accumulated over long time periods at relatively low rates result in a greater risk of lung cancer than the same total exposures accumulated over shorter time periods at relatively higher rates (NRC, 1999). A similar effect for dpm could cause apparent anomalies in the pattern of relative risks observed for occupations ranked simply with respect to the intensity of their average exposures.

(3) Mean exposures and relative risks reported for miners involved in the available studies were mischaracterized. Although dpm levels as high as 2000 $\mu g/m^3$ have been measured in some mines, the levels at most mines surveyed by MSHA were substantially lower (see Figures III–1 and III–2). The average levels MSHA measured at underground mines were 808 $\mu g/m^3$ and 644 $\mu g/m^3$ for M/NM and coal mines using diesel equipment for face haulage, respectively (Table III–1). However, these were not necessarily the levels experienced by miners involved in the available studies. The mean TC exposure concentration reported by Säverin et al. (1999), for work locations having the highest mean concentration, was 390 $\mu g/m^3$—corresponding to a mean dpm concentration of about 490 $\mu g/m^3$. In the only other study involving miners for which exposure measurements were available, Johnston et al. (1997) reported dpm concentrations for the most highly exposed category of workers (locomotive drivers), ranging from 44 $\mu g/m^3$ to 370 $\mu g/m^3$. Therefore, the mean dpm concentration experienced by the most highly exposed miners involved in these two studies was not ''forty times larger'' than the level imputed to truck drivers, but closer to seven times larger.[75] Applying Dr. Valberg's procedure, this yields an ''expected'' relative risk of about 4.4 for the underground miners who happened to work at mines included in these particular studies $(1 + 7 \times (0.49))$. Miners exposed at higher levels would, of course, face a greater risk.

Dr. Valberg asserted that the highest relative risk reported for miners was 2.67 (from Boffetta et al., 1988). Dr. Valberg failed to note, however, that the upper 95-percent confidence limit for miners' relative risk in this study was 4.37, so that this result hardly qualifies as an ''utter lack of concordance'' with the 4.4 ''expected'' value for miners. Furthermore, even higher relative risks for miners have been reported in other studies. Burns and Swanson (1991) reported 5.0 for operators of mining machinery, with an upper 95-percent confidence limit of 16.9. The relative risk estimated for the most highly exposed miners in the study by Johnston et al. (1997) was either 5.5 or 11.0, depending on the statistical model used. These results appear to be quite consistent with the data for truck drivers.

(5) Other Interpretations of the Evidence. After reviewing the same body of scientific evidence as MSHA, Dr. Peter Valberg came to a very different conclusion with respect to the likelihood of causality:

> Flawed methodology (lack of adequate control for smoking); values for relative risks (''RR'') that are low and often not statistically elevated above 1.0; inadequate treatment of sources of variability; reliance on multiple comparisons; and inadequate control over how authors choose to define dpm exposure surrogates (that is, job category within a profession, cumulative years of work, age at time of exposure, etc.), all undermine the assignment of causality to dpm exposure.

On the other hand, many scientific organizations and governmental agencies have reviewed the available epidemiologic and toxicological evidence for carcinogenicity and, in accordance with MSHA's conclusion, identified dpm as a probable human carcinogen—at levels far lower than those measured in some mines—or

[75] The estimate of seven times larger dpm exposure in miners is the result of averaging data from Säverin et al. (1999) with data from Johnston et al. (1997) and comparing the combined average miner exposure to the average truck driver dpm exposure.

placed it in a comparable category. These include:

Year

2000 National Toxicology Program (NTP);
1999 (tentative) U.S. Environmental Protection Agency (EPA);
1998 (tentative) (American Conference of Governmental Industrial Hygienists (ACGIH); Currently on Y2K NIC list. Probable vote in 10/2000;
1998 California Environmental Protection Agency (Cal–EPA);
1998 Federal Republic of Germany;
1996 International Programme on Chemical Safety (IPCS), a joint venture of the World Health Organization, the International Labour Organization, and the United Nations Environment Programme;
1989 International Agency for Research on Cancer (IARC);
1988 National Institute for Occupational Safety and Health (NIOSH)

Nevertheless, several commenters strongly objected to MSHA's conclusion, claiming that the evidence was obviously inadequate and citing scientific authorities who, they claimed, rejected MSHA's inference of a causal connection. In some cases, views were inaccurately attributed to these authorities, and misleading quotations were presented out of context. For example, the Nevada Mining Association stated that its own review of the scientific literature led to—

> * * * the only reasonable conclusion possible: there is no scientific consensus that there is a causal link between dpm exposure and lung cancer. The HEI [1999 Expert Panel] report concludes that the causal link between diesel exhaust and lung cancer remains unproven, and that further study and analysis are clearly required. [Nevada Mining Assoc.]

Although HEI (1999) recommended further study and analysis for purposes of quantitative risk assessment, the report contains no findings or conclusions about the ''causal link.'' To the contrary, the report explicitly states that the panel ''. . . was not charged to evaluate either the broad toxicologic or epidemiologic literature concerning exposure to diesel exhaust and lung cancer for hazard identification purposes, which has been done by others.'' (HEI, 1999, p. 1) Furthermore, the HEI panel ''. . . recognize[d] that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999, p. 20)

MARG, along with the Nevada Mining Association and several other commenters, mischaracterized the Expert Panel's findings as extending beyond the subject matter of the report. This report was limited to evaluating the suitability of the data compiled by Garshick et al. (1987, 1988) and Steenland et al. (1990, 1992, 1998) for quantitative risk assessment. Contrary to the characterization by these commenters, HEI's Expert Panel explicitly stated:

> [The Panel] was not charged to evaluate the broad toxicologic or epidemiologic literature for hazard identification purposes, which has been done by others. State, national, and international agencies have all reviewed the broader animal and human evidence for carcinogenicity and, in either their draft or final reports, have all identified diesel exhaust as [a] probable human carcinogen or placed it in a comparable category.'' [HEI, 1999, p. 1]

The Panel then identified most of the organizations and governmental institutions listed above (HEI, 1999, p. 8).

One commenter (MARG) also grossly misrepresented HEI (1999) as having stated that ''the available epidemiologic work has 'study design flaws, including uncontrolled, confounding and lack of exposure measures, leading to a lack of convincing evidence.' '' (MARG post-hearing comments) The opinion falsely attributed to HEI was taken from a sentence in which HEI's Diesel Epidemiology Expert Panel was describing opinions expressed in ''[s]ome reviews critical of these data.'' (HEI, 1999, p. 10) The Panel did not suggest that these opinions were shared by HEI or by any members of the Panel. In fact, the cited passage came at the end of a paragraph in which the Panel cited a larger number of other review articles that had ''discusse[d] this literature in depth'' and had expressed no such opinions. In the same paragraph, the Panel confirmed that ''[t]he epidemiologic studies generally show higher risks of lung cancer among persons occupationally exposed to diesel exhaust than among persons who have not been exposed, or who have been exposed to lower levels or for shorter periods of time.'' (HEI, 1999, p. 10)

Several commenters noted that the U.S. EPA's Clean Air Scientific Advisory Committee (CASAC) issued a report (CASAC, 1998) critical of the EPA's 1998 draft Health Assessment Document for Diesel Emissions (EPA, 1998) and rejecting some of its conclusions. After the HEI (1999) Expert Panel report was published, the EPA distributed a revised draft of its Health Assessment Document (EPA, 1999). In the 1999 draft, the EPA characterized human exposures to diesel exhaust as ''highly likely'' to be carcinogenic to humans at ambient (i.e., environmental) exposure levels. After reviewing this draft, CASAC endorsed a conclusion that, at ambient levels, diesel exhaust is likely to be carcinogenic to humans. Although CASAC voted to recommend that the designation in the EPA document be changed from ''highly likely'' to ''likely,'' this change was recommended specifically for ambient rather than occupational exposures. The CASAC report states that ''[a]lthough there was mixed opinion regarding the characterization of diesel emissions as 'highly likely' to be a human carcinogen, the majority of the Panel did not agree that there was sufficient confidence (i.e., evidence) to use the descriptor 'highly' in regard to environmental exposures.'' (CASAC, 2000, emphasis added)

MSHA recognizes that not everyone who has reviewed the literature on lung cancer and diesel exposure agrees about the collective weight of the evidence it presents or about its implications for regulatory decisions. IMC Global, for example, stated:

> After independently reviewing most [of the] * * * epidemiologic studies, the literature reviews and the two meta-analyzes, IMC Global believes * * * MSHA has misrepresented the epidemiologic evidence in the Proposed Rule. The best conclusion that we can reach based on our review of this information is that different reputable studies reach conflicting conclusions * * *. [IMC Global]

IMC Global continued by expressing concern that MSHA had ''dismissed'' opposing arguments critical of the positive studies, especially ''regarding lack of statistical significance; small magnitudes of relative risk * * *; and the impact of confounding factors, especially smoking * * * . [IMC Global]''

MSHA has addressed these three issues, as they relate to the evaluation of individual studies, in Section 2.c.i(2)(a) of this preamble. The argument that confounding factors such as smoking may have been systematically responsible for the positive results was discussed above, under the heading of ''Potential Systematic Biases.'' Statistical significance of the collective evidence is not the same thing as statistical significance of individual studies. Application of the sign test, as described Subsection 3.a.iii(1) above, is one way that MSHA has addressed statistical significance of the collective evidence. Another approach was also described above, under the heading of ''Meta-Analyses.''

IMC Global quoted Morgan et al. (1997) as concluding that ''[a]lthough there have been a number of papers suggesting that diesel fumes may act as a carcinogen, the weight of the evidence is against this hypothesis.'' This conclusion was based largely on the authors' contention, shared by IMC Global, that the epidemiologic results were inconsistent and of insufficient strength (i.e., RR < 2.0) to rule out spurious associations due to potential confounders. MSHA, on the other hand, interprets the epidemiologic studies as remarkably consistent, given their various limitations, and has argued that the strength of evidence from individual studies is less important than the strength of evidence from all studies combined. Dr. Debra Silverman has referred to the ''striking consistency'' of this evidence. (Silverman, 1998)

Ironically, Morgan et al. point out many of the very limitations in individual studies that may actually explain why the studies do not yield entirely equivalent results. The 1997 Morgan article was written before the meta-analyses became available and resolved many, if not all, of the apparent inconsistencies in the epidemiologic results. Since none of the existing human studies is perfect and many contain important limitations, it is not surprising that reported results differ in magnitude and statistical significance. The meta-analyses described earlier showed that the more powerful and carefully designed studies tended to show greater degrees of association. MSHA has addressed the joint issues of consistency and strength of association above, under the heading of ''Consistency of Epidemiologic Evidence.''

The Engine Manufacturers Association (EMA) quoted Cox (1997) as concluding: ''* * * there is no demonstrated biological basis for expecting increased risk at low to moderate levels of [diesel] exposure.'' (Cox, 1997, as quoted by EMA] The EMA, however, prematurely terminated this quotation. The quoted sentence continues: ''* * * low to moderate levels of exposure (those that do not lead to lasting soot deposits, chronic irritation, and perhaps GSH enzyme depletion in the lung).'' MSHA does not regard concentrations of dpm exceeding 200 $\mu g/m^3$ as ''low to moderate,'' and the EMA presented no evidence that the effects Dr. Cox listed do not occur at the high exposure levels observed at some mines. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. The deleted caveat ending the quotation is especially important in a mining context, since mine atmospheres generally contain respirable mineral dusts that may diminish clearance rates and contribute to meeting thresholds for chronic irritation and inflammation leading to oxidative damage. Based on miners' testimony at the public hearings and workshops, there is, in fact, reason to believe that exposed miners experience lasting soot deposits and chronic irritation as a result of their exposures.

With respect to the epidemiologic evidence, the EMA quoted Dr. Cox as concluding: ''* * * among studies that demonstrate an increased relative risk, it appears plausible that uncontrolled biases in study design and data analysis methods can explain the statistical increases in relative risk without there being a true causal increase.'' (Cox, 1997, quoted by EMA) Dr. Cox refers to non-causal explanations for positive epidemiologic results as ''threats to causal inference.'' In considering Dr. Cox's discussion of the evidence, it is important to bear in mind that his purpose was ''* * * not to establish that any (or all) of these threats do explain away the apparent positive associations between [dpm] and lung cancer risk * * * but only to point out that they plausibly could * * *.'' (Cox, 1997, p. 813) Dr. Cox's stated intent was to identify non-causal characteristics of positive studies that could potentially ''explain away'' the positive results. This is a relatively simple exercise that could misleadingly be applied to even the strongest of epidemiologic studies. As stated earlier, no epidemiologic study is perfect, and it is always possible that unknown or uncontrolled risk factors may have given rise to a spurious association. Neither the EMA nor Dr. Cox pointed out however, that there are characteristics common to the negative studies that plausibly explain why they came out negative: insufficient latency allowance, nondifferential exposure misclassification, inappropriate comparison groups (including healthy worker effect, negative confounding by smoking or other variables. A similar approach could also be used to explain why many of the positive studies did not exhibit stronger associations. As observed by Dr. Silverman, ''an unidentified negative confounder may have produced bias across studies, systematically diluting RRs.''

b. Significance of the Risk of Material Impairment to Miners

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

i. Meaning of Significant Risk

(1) Legal Requirements

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

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

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

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

> First, the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2%

benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe.' [*Id.,* at 655].

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

Some commenters contended that the concept of significant risk, as enunciated by the Supreme Court in the Benzene case, requires support by a quantitative dose-response relationship. For example, one commenter argued as follows:

* * * OSHA had contended in * * * [the benzene] case that ''because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response curve at this time''. 448 U.S. at 632–633. The court rejected the Agency's attempt to support a standard based upon speculation that ''the benefits to be derived from lowering'' the permissible exposure level from 10 to 1 ppm were 'likely' to be 'appreciable'.'' 448 U.S. at 654.

One year after the Benzene case, the Court in American Textile Mfr's Inst. v. Donovan, 452 U.S. 490 (1981), upheld OSHA's ''cotton dust'' standard for which a dose-response curve had been established by the Agency. The Court relied upon the existence of such data to find that OSHA had complied with the Benzene mandate, stating: ''In making its assessment of significant risk, OSHA relied on dose-response curve data * * * It is difficult to imagine what else the agency could do to comply with this Court's decision in the Benzene case.'' Id. at 505, n. 25. See also Public Citizen Research Group v. Tyson, 796 F. 2d 1479, 1496, 1499 (D.C. Cir. 1986) (where a dose response curve was constructed for the ethylene oxide standard and the agency [had] gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk); United Steelworkers of America v. Marshall, 647 F. 2d 1189, 1248 (D.C. Cir. 1980), cert. denied , 453 U.S. 913 (1981) (where in promulgating a new lead standard ''OSHA amassed voluminous evidence of the specific harmful effects of lead at particular blood levels and correlated these blood lead levels with air lead levels''). [NMA]

A dose-response relationship has been established between exposure to $PM_{2.5}$ (of which dpm is a major constituent) and the risk of death from cardiovascular, cardiopulmonary, or respiratory causes (Schwartz et al.,1996; EPA, 1996). Furthermore, three different epidemiologic studies, including two carried out specifically on mine workers, have reported evidence of a quantitative relationship between dpm exposure and the risk of lung cancer (Johnston et al., 1997, Steenland et al., 1998, Säverin et al., 1999). However, the Secretary has carefully reviewed the legal references provided by the commenters and finds there is no requirement in the law that the determination of significant risk be based on such a relationship. The cited court rulings appear to describe sufficient means of establishing a significant risk, rather than necessary ones. Indeed, as stated earlier in this section, the Benzene court explained that:

* * * the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. * * * the Agency has no duty to calculate the exact probability of harm * * *.

The Agency has set forth the evidence and rationale behind its decision to propose a rule restricting miner exposure to dpm, obtained an independent peer review of its assessment of that evidence, published the evidence and tentative conclusions for public comment, held hearings, kept the record open for further comments for months after the hearings, and re-opened the record so that stakeholders could comment on the most recent evidence available. Throughout these proceedings, the Agency has carefully considered all public comments concerning the evidence of adverse health effects resulting from occupational dpm exposures. Based on that extensive record, and the considerations noted in this section, the Agency is authorized under the statute and relevant precedents to act on this matter—despite the fact that a more conclusive or definitively established exposure-response relationship might help address remaining doubts among some members of the mining community.

As the Supreme Court pointed out in the benzene case, the appropriate definition of significance also depends on policy considerations of the Agency involved. In the case of MSHA, those policy considerations include special attention to the history of extraordinary occupational risks leading to the Mine Act. That history is intertwined with the toll to the mining community of silicosis and coal workers' pneumoconiosis (CWP or ''black lung''), along with billions of dollars in Federal expenditures.

(2) Standards and Guidelines for Risk Assessment

Several commenters suggested that this risk assessment, as originally proposed, deviated from established risk assessment guidelines, because it did not provide a sufficiently quantitative basis for evaluating the significance of miners's risks due to their dpm exposures. One of these commenters (Dr. Jonathan Borak) maintained that a determination of significant risk based on a ''qualitative'' assessment ''has no statistical meaning.''

MSHA recognizes that a risk assessment should strive to provide as high a degree of quantification and certainty as is possible, given the best available scientific evidence. However, in order to best protect miners' health, it is not prudent to insist on a ''perfect'' risk assessment. Nor is it prudent to delay assessing potentially grave risks simply because the available data may be insufficient for an ideal risk assessment. The need for regulatory agencies to act in the face of uncertainty was recognized by the HEI's Diesel Epidemiology Expert Panel as follows: ''The Panel recognizes that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available.'' (HEI, 1999) When there is good, qualitative evidence—such as the sight and smell of heavy smoke—that one's house is on fire, an inference of significant risk may be statistically meaningful even without quantitative measurements of the smoke's density and composition.

Moreover, as will be demonstrated below, the question of whether a quantitative assessment is or is not essential is, in this case, moot: this risk assessment does, in fact, provide a quantitative evaluation of how significant the risk is for miners occupationally exposed to dpm.

ii. Significance of Risk for Underground Miners Exposed to Dpm

An important measure of the significance of a risk is the likelihood that an adverse effect actually will occur. A key factor in the significance of risks that dpm presents to miners is the very high dpm concentrations to which a number of those miners are currently exposed—compared to ambient atmospheric levels in even the most polluted urban environments, and to workers in diesel-related occupations for which positive epidemiologic results have been reported. Figure III–4 compared the range of median dpm exposure levels measured for mine workers at various mines to the range of medians estimated for other occupations, as well as to ambient environmental levels. Figure III–11 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.[76] As shown in Figure III–11, underground miners are currently exposed at mean levels up to 10 times higher than the highest mean exposure reported for other occupations, and up to 100 times higher than the highest mean environmental level even after adjusting the environmental level upwards to reflect an equivalent occupational exposure.

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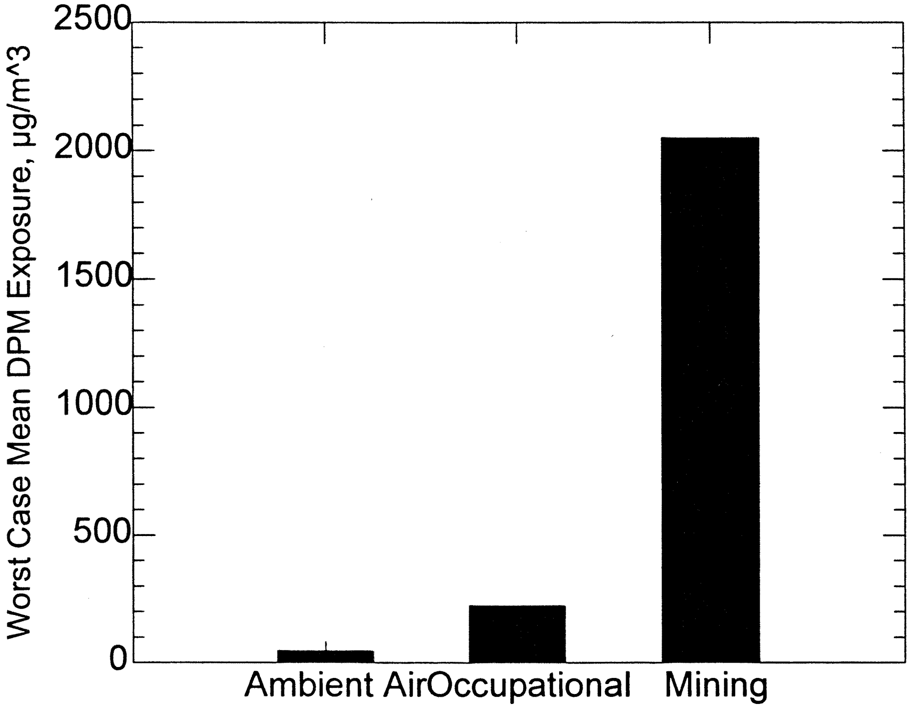

Figure III-11. — Worst case observed or reported mean diesel particulate exposure concentrations for urban ambient air, occupations other than mining, and mining. Worst case for mining is mean dpm measured within an underground mine. Worst case for occupations other than mining is mean respirable particulate matter, other than cigarette smoke, reported for railroad workers classified as hostlers (Woskie et al., 1988). Worst case for ambient air is mean estimated for peak months at most heavily polluted site in Los Angeles area (Cass and Gray, 1995), multiplied by 4.7 to adjust for comparability with occupational lifetime exposure levels. For additional information on means and ranges see Section III.1.d.

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Given the significant increases in mortality and other acute health effects associated with increments of 25 µg/m^3 in fine particulate concentration (see Table III–3), the relative risk of acute effects for some miners (especially those already suffering respiratory problems) appears to be extremely high. Acute responses to dpm exposures have been detected in studies of stevedores, whose exposures were likely to have been less than one tenth the exposure of some miners on the job. Likewise, the risk of lung cancer due to dpm exposure would appear to be far greater for those underground miners who are exposed at such high levels than for other workers or general urban populations.

Several commenters asserted that current dpm exposures in underground mines are lower than they were when MSHA conducted its field surveys and that MSHA had not taken this into account when assessing the significance of dpm risk to miners. A related comment was that MSHA had not designed its sampling studies to provide a statistically representative cross section of the entire industry but had nevertheless used the results in concluding that the risk to underground miners was significant.

In accordance with § 101.(a)(6) of the Mine Act, MSHA is basing this risk assessment on the best available evidence. None of the commenters provided evidence that dpm levels in underground coal mines had declined significantly since MSHA's field studies, or provided quantitative estimates of any purported decline in average dpm concentrations, or submitted data that would better represent the range of dpm concentrations to which underground miners are typically exposed at the present time. Although MSHA's field studies were not designed to be statistically representative in a way that

[76] 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.

can be readily quantified, they were performed at locations selected, according to MSHA's best engineering judgement, to be typical of the type of diesel equipment used. Furthermore, as will be shown below, MSHA's evaluation of the significance of risks presented to underground miners by their dpm exposures does not rely on the highest levels, or even the average levels, that MSHA has measured. As documented in Section 1.d of this risk assessment, some of the highest of MSHA's measurements were made as recently as 1996–1997. In 1996 MSHA published the diesel equipment safety rule that focused primarily on the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines. In developing this diesel equipment safety rule for underground coal mines, however, MSHA did not explicitly consider the health risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels. It was understood that the agency would be evaluating the health risks of dpm exposure at a later date. (61 FR 55420). With the implementation of the diesel safety rule in underground coal mines, MSHA believes that dpm concentrations may have declined, in the past two to three years. It is important to note, as is shown below, the cancer risks of dpm exposure are clearly significant even at a concentration of 300 µg/m³—less than half of the average level that MSHA observed in its field studies. However, MSHA also believes that a reduction in exposure of more than 50 percent is highly implausible, even with the safety standard implemented. It is also important to note that the diesel equipment rule applied only to underground coal mines and not underground metal/nonmetal mines.

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A number of other governmental and nongovernmental bodies have concluded that, even at the far lower levels evident in other occupational environments or in ambient air, the health risks of dpm exposure are of sufficient significance that exposure should be limited:

(1) In 1988, after a thorough review of the scientific literature, the National Institute for Occupational Safety and Health (NIOSH) recommended that diesel exhaust be controlled to the *lowest feasible exposure level*. The document did not contain a recommended exposure limit.

(2) In 1996, the Federal Republic of Germany classified dpm as "probably carcinogenic for humans" and established legally binding technical limits on dpm concentrations in occupational environments. The classification requires that the "best available technology" be used for emission reduction. The technical concentration limits, applying to all workplaces except coal mines, are the lowest limits thought to be feasible in Germany with current technology. Expressed as limits on elemental carbon (EC), they are: 300 µg/m³ for tunneling and non-coal mining; 100 µg/m³ for all other workplaces (except coal mines).

(3) An ad hoc committee of the Canada Centre for Mineral and Energy Technology (CANMET) has recommended that a limit of 500 µg/m³ RCD be adopted as a goal for underground mining environments.

(4) The International Programme on Chemical Safety (IPCS), which is a joint venture of the World Health Organization, the International Labour Organisation, and the United Nations Environment Programme, performed a comprehensive evaluation of the scientific evidence linking diesel exhaust with adverse health effects (IPCS, 1996). IPCS concluded that inhalation of diesel exhaust is of concern with respect to both neoplastic and non-neoplastic diseases and that the particulate phase appears to have the greatest effect on health. As a result of this evaluation, the IPCS recommended that "in the occupational environment, good work practices should be encouraged, and adequate ventilation must be provided to prevent excessive exposure."

(5) In light of the significant health risks associated with environmental exposures to fine particulates ($PM_{2.5}$), in 1997 the U.S. Environmental Protection Agency revised national air quality standards regulating PM to include $PM_{2.5}$ in the ambient air. Diesel particulate matter was a major constituent of $PM_{2.5}$ in many of the areas forming the basis of the EPA's health risk assessment. (EPA, 1996)

(6) In 1998, the California Environmental Protection Agency identified dpm as a toxic air contaminant, as defined in their Health and Safety Code, Section 39655. According to that section, a toxic air contaminant is an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health. This conclusion, unanimously adopted by the California Air Resources Board and its Scientific Review Panel on Toxic Air Contaminants, initiates a process of evaluating strategies for reducing dpm concentrations in California's ambient air.

(7) In 1999, the American Conference of Governmental Industrial Hygienists (ACGIH) proposed a Threshold Limit Value of 50 µg/m³ for the dpm component of diesel exhaust and placed dpm on its Notice of Intended Changes. This ACGIH proposal was based on a determination that occupational exposure levels exceeding 50 µg/m³ would present a significant "incremental" or excess risk of lung cancer.

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Earlier in this risk assessment, MSHA identified three types of material impairment that can result from occupational exposures to dpm. The next three subsections present the Agency's evaluation of how much of a risk there is that miners occupationally exposed to dpm will actually incur such consequences. Each part addresses the risk of incurring one of the three types of material impairment identified earlier.

(1) Sensory Irritations and Respiratory Symptoms (including allergenic responses)

It is evident from the direct testimony of numerous miners working near diesel equipment that their exposures pose a significant risk of severe sensory irritations and respiratory symptoms.

This was underscored during the workshops and public hearings by several miners who noted that such effects occurred immediately and consistently after episodes of intense exposure (Section 2.b.i). There is also persuasive experimental evidence that exposure at levels found in underground mines frequently cause eye and nose irritation (Rudell et al., 1996) and pulmonary inflammation (Salvi et al., 1999). Section 2.a.ii and 3.a.i of this risk assessment explain why these effects constitute ''material impairments'' under the Mine Act and why they threaten miners' safety as well as health. Therefore, it is clear that even short-term exposures to excessive concentrations of dpm pose significant risks.

MSHA's quantitative evaluation of how significant the risks of sensory irritations and respiratory symptoms are for miners is limited, by the quantitative evidence available, to acute respiratory symptoms linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies.MSHA recognizes that, for miners exposed to dpm, this type of risk cannot be quantified with great confidence or precision based on the available evidence. This is because $PM_{2.5}$ is not solely comprised of dpm and also because miners, as a group, have different demographic and health characteristics from the general populations involved in the relevant studies. However, MSHA believes that the quantitative evidence suffices to establish a lower bound on the significance of this type of risk to miners exposed to dpm. Even at this lower bound, which is likely to substantially underestimate the degree of risk, the probability that a miner's occupational exposure to dpm will cause adverse respiratory effects is clearly significant.

As shown in Table III–3, the risk of acute lower respiratory tract symptoms has been reported to increase, at a 95-percent confidence level, by 15 to 82 percent (RR = 1.15 to 1.82) for each incremental increase of 20 μg/m³ in the concentration of $PM_{2.5}$ in the ambient air. This means that the relative risk estimated for a given $PM_{2.5}$ concentration ranges between $(1.15)^k$ and $(1.82)^k$, where k = the concentration of $PM_{2.5}$ divided by 20 μg/m³. For example, for a $PM_{2.5}$ concentration of 40 μg/m³, the RR is estimated to be between $(1.15)^2$ and $(1.82)^2$, or 1.32 to 3.31. MSHA believes that part of the reason why the range is so wide is that the composition of $PM_{2.5}$ varied in the data from which the estimates were derived.

MSHA acknowledges that there are substantial uncertainties involved in converting 24-hour environmental exposures to 8-hour occupational exposures. However, since mining often involves vigorous physical activity (thereby increasing breathing depth and frequency) and sleep is characterized by reduced respiration, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. If it is assumed that the acute respiratory effects of inhaling dpm at a concentration of 60 μg/m³ over an 8-hour workshift are at least as great as those at a concentration of 20 μg/m³ over a 24-hour period, then it is possible to estimate a lower bound on the relative risk of such effects.

Based solely on the fact that dpm consists almost entirely of particles much smaller than 2.5 micrometers in diameter, the dpm would be expected to penetrate the lower respiratory tract at least as effectively as $PM_{2.5}$. Also, given the complex chemical composition of dpm, and its generation within a confined space, there is no reason to suspect that dpm in an underground mining environment is less potent than ambient $PM_{2.5}$ in inducing respiratory symptoms. Under these assumptions, a short-term environmental exposure to $PM_{2.5}$ at a concentration of 20 μg/m³ would correspond to a short-term occupational exposure to dpm at a concentration of 60 μg/m³. Consequently, the RR at an occupational exposure level of Y μg/m³ would equal the RR calculated for an ambient exposure level of $20 \times (Y/60)$ μg/m³. For example, the relative risk (RR) of acute lower respiratory symptoms at an occupational exposure level of 300 μg/m³ dpm would, at a minimum, correspond to the RR at an ambient exposure level equal to 5×20 μg/m³ $PM_{2.5}$. (See Table III–3) A dpm concentration of 300 μg/m³ happens to be the level at which Salvi et al. (1999) found a marked pulmonary inflammatory response in healthy human volunteers after just one hour of exposure.

Under these assumptions, the risk of lower respiratory tract symptoms for a miner exposed to dpm for a full shift at a concentration of 300 μg/m³ or more, would be at least twice the risk of ambient exposure (i.e., RR = $(1.15)^5$ = 2.01). This would imply that for miners exposed to dpm at or above this level, the risk of acute lower respiratory symptoms would double, at a minimum. The Secretary considers such an increase in risk to be clearly significant.

(2) Premature Death From Cardiovascular, Cardiopulmonary, or Respiratory Causes

As in the case of respiratory symptoms, the nature of the best available evidence limits MSHA's quantitative evaluation of how large an excess risk of premature death, due to causes other than lung cancer, there is for miners exposed to dpm. As before, this evidence consists of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. Therefore, the analysis is subject to similar uncertainties. However, also as before, MSHA believes that the quantitative evidence suffices to place a lower bound on the increase in risk of premature mortality for miners occupationally exposed to dpm. As will be shown below, even this lower bound, which is likely to substantially underestimate the degree of increase, indicates that a miner's occupational exposure to dpm has a clearly significant impact on the likelihood of premature death.

Schwartz et al. (1996) found an average increase of 1.5 percent in daily mortality associated with each increment of 10 μg/m³ in the daily concentration of fine particulates. Higher increases were estimated specifically for ischemic heart disease (IHD: 2.1 percent), chronic obstructive pulmonary disease (COPD: 3.3 percent), and pneumonia (4.0 percent). The corresponding 95-percent confidence intervals for the three specific estimates were, respectively, 1.4% to 2.8%, 1.0% to 5.7%, and 1.8% to 6.2%, per increment of 10 μg/m³ in daily $PM_{2.5}$ exposure. Within the range of dust concentrations studied, the response appeared to be linear, with no threshold. The investigators checked for but did not find any consistent or statistically stable relationship between increased mortality and the atmospheric concentration of ''coarse'' respirable particles—i.e., those with aerodynamic diameter greater than 2.5 micrometers but less than 10 micrometers.

As explained earlier, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. Therefore, under the same assumptions made in the previous subsection, the 24-hour average concentrations of $PM_{2.5}$ measured by Schwartz et al. are no more potent, in their impact on mortality risk, than eight-hour average concentrations that are three times as high. As discussed in Section 2.a.iii of this risk assessment, underground miners may be less, equally, or more susceptible than the general population to the acute mortality effects of fine particulates such as dpm. However, miners who smoke tobacco and/or suffer various respiratory ailments fall into groups identified as likely to be especially sensitive (EPA, 1996). Consequently, for such miners occupationally exposed to dpm, the relative risk of each type of premature mortality would be at least equal to the corresponding lower 95-percent confidence limit specified above.

Therefore, MSHA estimates that, on average, each increment of 30 μg/m^3 in the dpm concentration to which miners are exposed increases the risk of premature death due to IHD, COPD, and pneumonia by a factor of at least 1.4 percent, 1.0 percent, and 1.8 percent, respectively. A lower bound on the increased risk expected at an occupational dpm concentration greater than 30 μg/m^3, is obtained by raising the relative risks equivalent to these factors (i.e., 1.014, 1.01, and 1.018) to a power, k, equal to the ratio of the concentration to 30 μg/m^3. For a concentration of 300 μg/m^3, k = 10; so MSHA estimates the lower bounds on relative risk to be: $(1.014)^{10} = 1.149$ for IHD; $(1.01)^{10} = 1.105$ for COPD; and $(1.018)^{10} = 1.195$ for pneumonia. This means that for miners exposed to dpm at or above this level, MSHA expects the risks to increase by at least 14.9 percent for IHD, 10.5 percent for COPD, and 19.5 percent for pneumonia. The Secretary considers increases of this magnitude to be clearly significant, since the causes of death to which they apply are not rare among miners.

(3) Lung Cancer

In contrast to the two types of risk discussed above, the available epidemiologic data can be used to relate the risk of lung cancer directly to dpm exposures. Therefore, the significance of the lung cancer risk can be evaluated without having to make assumptions about the relative potency of dpm compared to the remaining constituents of $PM_{2.5}$. This removes an important source of uncertainty present in the other two evaluations.

There are two different ways in which the significance of the lung cancer risk may be evaluated. The first way is based on the relative risk of lung cancer observed in the best available epidemiologic studies involving miners (identified as such in Subsections 3.a.iii(1)(b) and (d) of this risk assessment). As will be explained below, this approach leads to an estimated tripling of lung cancer risk for miners exposed to dpm, compared to a baseline risk for unexposed miners. The second way is to calculate the lung cancer risk expected at exposure levels MSHA has observed in underground mines, assuming a specified occupational lifetime and using the exposure-response relationships estimated for underground miners by Johnston et al. (1997) and Säverin et al. (1999). As will be explained further below, this second approach yields a wide range of estimates, depending on which exposure-response relationship and statistical model is used. All of the estimates, however, show at least a doubling of baseline lung cancer risk, assuming dpm exposure for a 45-year occupational lifetime at the average concentration MSHA has observed. Most of the estimates are much higher than this. If the exposure-response relationship estimated for workers in the trucking industry by Steenland et al. (1998) is extrapolated to the much higher exposure levels for miners, the resulting estimates fall within the range established by the two mine-specific studies, thereby providing a degree of corroboration. Since lung cancer is not a rare disease, the Secretary considers even the very lowest estimate—a doubling of baseline risk—to represent a clearly significant risk.

Both of these methods provide quantitative estimates of the degree by which miners' risk of lung cancer is increased by their occupational dpm exposures. The estimate based on exposure-response relationships is more refined, in that it ties the increased risk of lung cancer to specific levels of cumulative dpm exposure. However, this added refinement comes at the price of an additional source of uncertainty: the accuracy of the exposure-response relationship used to calculate the estimate. This additional uncertainty is reflected, in MSHA's evaluation, by a broad range of relative risk estimates, corresponding to the range of exposure-response relationships derived using different statistical models and epidemiologic data. The next two subsections present the details of MSHA's two approaches to analyzing lung cancer risk for miners exposed to dpm, along with MSHA's responses to the relevant public comments.

(a) Risk Assessment Based on Studies Involving Miners

As one commenter pointed out, the epidemiologic evidence showing an elevated risk of lung cancer for exposed workers is mostly based on occupations estimated to experience far lower exposure levels, on average, than those observed in many underground mines:

> * * * [U]nderground coal, metal and non-metal miners face a significant risk of lung cancer from occupational exposure to diesel particulate. Numerous epidemiologic studies of workers exposed to levels far below those experienced by coal, metal and non-metal miners have found the risk for exposed workers to be 30–50% greater than for unexposed workers. [Washington State Dept. of Labor and Industries]

Indeed, although MSHA recognizes that results from animal studies should be extrapolated to humans with caution, it is noteworthy that dpm exposure levels recorded in some underground mines (see Figures III–1 and III–2) have been well within the exposure range that produced tumors in rats (Nauss et al., 1995).

Both existing meta-analyses of the human studies relating dpm exposure and lung cancer excluded studies on miners but presented evidence showing that, averaged across all other occupations, dpm exposure is responsible for an increase of about 40 percent in lung cancer risk (See Section 3.a.iii(2) of this risk assessment). Even a 40-percent increase in the risk of lung cancer would clearly be significant, since this would amount to more than two cases of lung cancer per year per thousand miners at risk, and to an even greater risk for smoking miners. The best available evidence, however, indicates (1) that exposure levels in underground mines generally exceed exposures for occupations included in the meta-analyses and (2) that lung cancer risks for exposed miners are elevated to a greater extent than for other occupations.

As Dr. Valberg and other commenters pointed out, the epidemiologic studies used in the meta-analyses involved much lower exposure levels than those depicted for mines in Figures III–1 and III–2. The studies supporting a 40-percent excess risk of lung cancer were conducted on populations whose average exposure is estimated to be less than 200 μg/m^3—less than one tenth the average concentration MSHA observed in some underground mines. More specifically, average exposure levels in the two most extensively studied industries—trucking (including loading dock workers) and railroads—have been reported to be far below the levels observed in underground mining environments. For workers at docks employing diesel forklifts—the occupational group estimated to be most highly exposed within the trucking industry—the highest average dpm concentration reported was about 55 μg/m^3 EC at an individual dock (NIOSH, 1990). As explained in Subsection 1.d of this risk assessment, this corresponds to less than 150 µg/m³ of dpm, on average. Published dpm measurements for railworkers have generally also been less than 150 µg/m³ (measured as respirable particulate matter other than cigarette smoke). The reported mean of 224 µg/m³ for hostlers displayed in Figure III–11 represents only the worst-case occupational subgroup (Woskie et al., 1988). In contrast, in the study on underground potash miners by Säverin et al. (1999), the mean TC concentration measured for production areas was 390 µg/m³—corresponding to a mean dpm concentration of about 490 µg/m³. As shown in Table III–1, the mean dpm exposure level MSHA observed in underground production areas and haulageways was 644 µg/m³ for coal mines and 808 µg/m³ for M/NM.

In accordance with the higher exposure levels for underground miners, the five studies identified in Section III.3.a.iii(1)(d) as comprising the best available epidemiologic evidence on miners all show that the risk of lung cancer increased for occupationally exposed miners by substantially more than 40 percent. The following table presents the relative risk (RR) of lung cancer for miners in these studies, along with the geometric mean based on all five studies:

Study	Relative risk of lung cancer
Boffetta et al., 1988	2.67
Burns & Swanson, 1991	5.03
Johnston et al., 1997 (mine-adjusted model applied at highest cumulative exposure)	5.50
Lerchen et al., 1987	2.1
Säverin et al., 1999 (highest vs least exposed)	2.17
Geometric mean	3.2

As shown in this table, the estimated RR based on these five studies is 3.2 for miners exposed to dpm. In other words, the risk of lung cancer for the highly exposed miners is estimated to be 3.2 times that of a comparable group of occupationally unexposed workers. The geometric mean RR remains 3.2 if the two studies on which MSHA places less weight (by Burns & Swanson and by Lerchen) are excluded from the calculation. This represents a 220-percent increase in the risk of lung cancer for exposed miners, in contrast to the 40-percent increase estimated, on average, for other occupationally exposed workers. The Secretary believes that a 40-percent increase in the risk of lung cancer already exceeds, by a wide margin, the threshold for a clearly significant risk. However, a 220-percent increase to more than three times the baseline rate is obviously of even greater concern.

Some commenters questioned whether increased lung cancer risks of this magnitude were plausible, since they were not aware of any unusually high lung cancer rates among workers at mines with which they were familiar and which used diesel equipment. There are several reasons why an elevated risk of lung cancer might not currently be conspicuous among U.S. miners exposed to dpm. Lung cancer not only may require a latency period of 30 or more years to develop, but it may also not develop until beyond the normal retirement age of 65 years. Cases of lung cancer developing after retirement may not all be known to members of the mining community. Also, in a population that includes many tobacco smokers, it may be difficult to discern cases of lung cancer specifically attributable to dpm exposure when they first begin to become prevalent. Two commenters expressed some of the relevant considerations as follows. Although they were referring to coal miners, the same points apply to M/NM miners.

> Because the latency period for lung cancer is so long, and diesel-powered equipment has only been used extensively in U.S. coal mines for about 25 years, the epidemic may well be progressing unnoticed. [UMWA]
>
> If Dpm exposure will cause cancer, there is a huge population of miners here in the West that have already been exposed. Considering the latency periods indicated by MSHA, these miners should be beginning to develop cancers. [Canyon Fuels]

(b) Risk Assessment Based on Miners' Cumulative Exposure

Although it is evident that underground miners currently face a significant risk of lung cancer due to their occupational exposure to dpm, there are certain advantages in utilizing an exposure-response relationship to quantify the degree of risk at specific levels of cumulative exposure. As some commenters pointed out, for example, dpm exposure levels may change over time due to changes in diesel fuel and engine design. The extent and patterns of diesel equipment usage within mines also has changed significantly during the past 25 years, and this has affected dpm exposure levels as well. Furthermore, exposure levels at the mines involved in epidemiologic studies were not necessarily typical or representative of exposure levels at mines in general. A quantitative exposure-response relationship provides an estimate of the risk at any specified level of cumulative exposure. Therefore, using such a relationship to assess risk under current or anticipated conditions factors in whatever differences in exposure levels may be relevant, including those due to historical changes.

(i) Exposure-Response Relationships from Studies Outside Mining

Stayner et al. (1998) summarized quantitative risk assessments based on exposure-response relationships for dpm published through 1998. These assessments were broadly divided into those based on human studies and those based on animal studies. Depending on the particular studies, assumptions, statistical models, and methods of assessment used, estimates of the exact degree of risk varied widely even within each broad category. However, as presented in Tables III and IV of Stayner et al. (1998), all of the very different approaches and methods published through 1998 produced results indicating that levels of dpm exposure measured at some underground mines present an unacceptably high risk of lung cancer for miners—a risk significantly greater than the risk they would experience without the dpm exposure.[77]

Quantitative risk estimates based on the human studies were generally higher than those based on analyses of the rat inhalation studies. As indicated by Tables 3 and 4 of Stayner et al. (1998), a working lifetime of exposure to dpm at 500 µg/m³ yielded estimates of excess lung cancer risk ranging from about 1 to 200 excess cases of lung cancer per thousand workers based on the rat inhalation studies and from about 50 to 800 per thousand based on the epidemiologic assessments. Stayner et al. (1998) concluded their report by stating:

> The risk estimates derived from these different models vary by approximately three orders of magnitude, and there are substantial uncertainties surrounding each of

[77] In comments submitted by MARG, Dr. Jonathan Borak asserted that MSHA had ''misrepresented the findings of a critical study'' by stating that all methods showed an ''unacceptably high risk'' at exposure levels found at some mines. Dr. Borak claimed that Stayner et al. (1998) had described an analysis by Crump et al. ''that reached an opposite conclusion.'' Dr. Borak failed to distinguish between a finding of high risk and a finding of changes in that risk corresponding to changes in estimated exposures. The findings to which Dr. Borak referred pertained only to the exposure-response relationship within the group of exposed workers. Garshick (1981), Crump (1999), and HEI (1999) all noted that the risk of lung cancer was nevertheless elevated among the exposed workers, compared to unexposed workers in the same cohort, and they all identified reasons why the data used in this study might fail to detect a positive exposure-response relationship among the exposed workers.

these approaches. Nonetheless, the results from applying these methods are consistent in predicting relatively large risks of lung cancer for miners who have long-term exposures to high concentrations of DEP [i.e., dpm]. This is not surprising given the fact that miners may be exposed to DEP [dpm] concentrations that are similar to those that induced lung cancer in rats and mice, and substantially higher than the exposure concentrations in the positive epidemiologic studies of other worker populations.

Restricting attention to the exposure-response relationships derived from human data, Table IV of Stayner et al. (1998) presented estimates of excess lung cancer risk based on exposure-response relationships derived from four different studies: Waller (1981) as analyzed by Harris (1983); Garshick et al. (1987) as analyzed by Smith and Stayner (1991); Garshick et al. (1988) as analyzed by California EPA (1998); and Steenland et al. (1998). Harris (1983) represented upper bounds on risk; and all of the other estimates represented the most likely value for risk, given the particular data and statistical modeling assumptions on which the estimate was based. Three different ranges of estimates were presented from the California EPA analysis, corresponding to various statistical models and assumptions about historical changes in dpm exposure among the railroad workers involved. As mentioned above and in the proposed version of this risk assessment, the low end of the range of estimates was 50 lung cancers per 1000 workers occupationally exposed at 500 µg/m³ for a 45-year working lifetime. This estimate was one of those based on railroad worker data from Garshick et al. (1988).

Several commenters objected to MSHA's reliance on any of the exposure-response relationships derived from the data compiled by Garshick et al. (1987) or Garshick et al. (1988). These objections were based on re-analyses of these data by Crump (1999) and HEI (1999), using different statistical methods and assumptions from those used by Cal-EPA (1998). For example, the NMA quoted HEI (1999) as concluding:

> At present, the railroad worker cohort study * * * has very limited utility for QRA [quantitative risk assessment] of lifetime lung cancer risk from exposure to ambient levels of diesel exhaust * * * [NMA, quoting HEI (1999)]

From this, the NMA argued as follows:

> What then is the relevance of this data to the proceedings at issue? Simply put, there is no relevance. The leading epidemiologist [sic], including Dr. Garshick himself, now agree that the data are inappropriate for conducting risk assessment. [NMA]

MSHA notes that the HEI (1999) conclusion cited by the NMA referred to quantitative risk assessments at ambient, not occupational, exposure levels. Also, HEI (1999) did not apply its approach (i.e., investigating the correlation between exposure and relative risk within separate job categories) to the Armitage-Doll model employed by Cal-EPA in some of its analyses. (Results using this model were among those summarized in Table IV of Stayner et al., 1998). Therefore, the statistical findings on which HEI (1999) based its conclusion do not apply to exposure-response relationships estimated using the Armitage-Doll model. Furthermore, although HEI concluded that the railroad worker data have ''very limited utility for QRA * * * at ambient levels'' [emphasis added], this does not mean, even if true, that these data have ''no relevance'' to this risk assessment, as the NMA asserted. Even if they do not reliably establish an exposure-response relationship suitable for use in a quantitative risk assessment, these data still show that the risk of lung cancer was significantly elevated among exposed workers. This is the only way in which MSHA is now using these data in this risk assessment.

In the proposed risk assessment, MSHA did not rely directly on the railroad worker data but did refer to the lowest published quantitative estimate of risk, which happened, as of 1998, to be based on those data. MSHA's reasoning was that, even based on the lowest published estimate, the excess risk of lung cancer attributable to dpm exposure was clearly sufficient to warrant regulation. If risk assessments derived from the railroad worker data are eliminated from consideration, the lowest estimate remaining in Table IV of Stayner et al. (1998) is obviously even higher than the one that MSHA used to make this determination in the proposed risk assessment. This estimate (based on one of the analyses performed by Steenland et al., 1998) is 89 excess cases of lung cancer per year per thousand workers exposed at 500 µg/m³ for a 45-year working lifetime.

HEI (1999) also evaluated the use of the Steenland data for quantitative risk assessment, but did not perform any independent statistical analysis of the data compiled in that study. Some commenters pointed out HEI's reiteration of the cautionary remark by Steenland et al. (1998) that their exposure assessment depended on ''broad assumptions.'' The HEI report did not rule out the use of these data for quantitative risk assessment but suggested that additional statistical analyses and evaluations were desirable, along with further development of exposure estimates using alternative assumptions. MSHA has addressed comments on various aspects of the analysis by Steenland et al., including the exposure assumptions, in Section 2.c.i(2)(a) of this risk assessment.

One commenter noted that Steenland et al. (1998) had recognized the limitations of their analysis and had, therefore, advised that the results ''should be viewed as exploratory.'' The commenter then asserted that MSHA had nevertheless used these results as ''the basis for a major regulatory standard'' and that ''[t]his alone is sufficient to demonstrate that MSHA's proposal lacks the necessary scientific support.'' [Kennecott Minerals]

The Secretary does not accept the premise that MSHA should exclude ''exploratory'' results from its risk assessment, even if it is granted that those results depend on broad assumptions possibly requiring further research and validation before they are widely accepted by the scientific community. Steenland et al. (1998) estimated risks associated with specific cumulative exposures, based on estimates of historical exposure patterns combined with data originally described by Steenland et al., 1990 and 1992. Regardless of whether the cumulative exposure estimates used by Steenland et al. (1998) are sufficiently reliable to permit pinpointing the risk of lung cancer at any given exposure level, the quantitative analysis indicates that as cumulative exposure increases, so does the risk. Therefore, the 1998 analysis adds significantly to the weight of evidence supporting a causal relationship. However, MSHA did not use or propose to use exposure-response estimates derived by Steenland et al. (1998) as the sole basis for any regulatory standard.

The exposure-response relationships presented by Steenland et al. were derived from exposures estimated to be far below those found in underground mines. As Stayner et al. (1998) point out, questions are introduced by extrapolating an exposure-response relationship beyond the exposures used to determine the relationship. The uncertainties implicit in such extrapolation are demonstrated by comparing results from two statistical models based on five-year lagged exposures—one using simple cumulative exposure and the other using the natural logarithm of cumulative exposure (Steenland et al., 1998, Table II).

Assuming that, on average, EC comprises 40 percent of total dpm,[78] the formula for calculating a relative risk (RR) using Steenland's simple cumulative exposure model is

$$RR = \exp(0.4\times 0.389\times CumExp),$$

where CumExp is occupationally accumulated dpm exposure (expressed in mg-yr/m³), ignoring the most recent five years. Again assuming EC=0.4×dpm, the corresponding formula using Steenland's Log(CumExp) model is

$$RR = \exp(0.1803 \times (\mathrm{Log}(0.4 \times 1000 \times CumExp + BG) - \mathrm{Log}(BG))),$$

still ignoring occupational dpm exposure in the most recent five years.[79]

The risk estimates from these two models are similar at the cumulative exposure levels estimated for workers involved in the study, but the projected risks diverge markedly at the higher exposures projected for underground miners exposed to dpm for a 45-year occupational lifetime. For example, a cumulative dpm exposure of 2.5 mg-yr/m³ (i.e., 45 years of occupational exposure at an average dpm concentration of about 55.6 µg/m³) is within the range of cumulative exposures from which these exposure-response relationships were estimated. At this level of cumulative exposure, the models (both lagged five years) yield relative risk estimates of 1.48 (based on simple cumulative exposure) and 1.64 (based on the logarithm of cumulative exposure, with BG=70 µg-yr/m³). On the other hand, 45 years of occupational exposure at an average dpm concentration of 808 µg/m³ amounts to a cumulative dpm exposure of 36,360 µg-yr/m³, or about 36.4 mg-yr/m³. At this level, which lies well beyond the range of data used by Steenland et al. (1998), the simple and logarithmic exposure models produce relative risk estimates of about 300 and 2.6, respectively.

Despite the divergence of these two models at high levels of cumulative exposure, they can provide a useful check of excess lung cancer risks estimated using exposure-response relationships developed from other studies. For highly exposed miners, the Steenland models both produce estimates of lung cancer risk within the range established by the two miner studies discussed below. This corroborates the upper and lower limits on such risk as estimated by the various statistical models used in those two studies.

(ii) Exposure-Response Relationships From Studies on Miners

As described in Section 2.c.i(2)(a) of this risk assessment, two epidemiologic studies, both conducted on underground miners, provide exposure-response relationships based on fully quantitative dpm exposure assessments. Johnston et al. (1997) conducted their study on a cohort of 18,166 underground coal miners, and Säverin et al. (1999) conducted theirs on a cohort of 5,536 underground potash miners. Each of these studies developed a number of possible exposure-response relationships, depending on the statistical model used for analysis and, in the case of Säverin et al. (1999), inclusion criteria for the cohort analyzed. For purposes of this risk assessment, MSHA has converted the units of cumulative exposure in all of these exposure-response relationships to mg-yr/m³.

Two exposure-response relationships derived by Johnston et al. (1997) are used in this risk assessment, based on a ''mine-adjusted'' and a ''mine-unadjusted'' statistical model. In both of these models, cumulative dpm exposure is lagged by 15 years.[80] This reflects the long latency period required for development of lung cancer and means that the most recent 15 years of exposure are ignored when the relative risk of lung cancer is estimated. The exposure-response relationships, as reported by the investigators, were expressed in terms of g-hr/m³ of cumulative dpm exposure. MSHA has converted the exposure units to mg-yr/m³ by assuming 1920 work hours per year.

Two different methods of statistical analysis were applied by Säverin et al. (1999) to both the full cohort and to a subcohort of 3,258 miners who had worked underground, in relatively stable jobs, for at least ten years. Thus, the investigators developed a total of four possible exposure-response relationships from this study. Since they were based on measurements of total carbon (TC), these exposure-response relationships were expressed in terms mg-yr/m³ of cumulative TC exposure. MSHA has converted the exposure units to mg-yr/m³ of cumulative dpm exposure by assuming that, on average, TC comprises 80 percent of total dpm.

The following table summarizes the exposure-response relationships obtained from these two studies. Each of the quantitative relationships is specified by the unit relative risk (RR) per mg-yr/m³ of cumulative dpm exposure. To calculate the relative risk estimated for a given cumulative dpm exposure (CE), it is necessary to raise the unit RR to a power equal to CE. For example, if the unit RR is 1.11 and CE = 20, then the estimated relative risk is $(1.11)^{20} = 8.1$. Therefore, the estimated relative risk of lung cancer increases as CE increases. For the two Johnston models, CE does not include exposure accumulated during the 15 years immediately prior to the time in a miner's life at which the relative risk is calculated.

EXPOSURE-RESPONSE RELATIONSHIPS OBTAINED FROM TWO STUDIES ON UNDERGROUND MINERS

Study and statistical model	Unit RR per mg-yr/m³ dpm
Säverin et al. (1999):†	
Poisson, full cohort	1.024
Cox, full cohort	1.089
Poisson, subcohort	1.110
Cox, subcohort	1.176
Johnston et al. (1997):‡	
15-year lag, mine-adjusted	1.321
15-year lag, mine-unadjusted	1.479

† Unit RR calculated from Tables III and IV, assuming TC = 0.8×dpm.

‡ Unit RR calculated from Table 11.2, assuming 1920 work hours per year.

For example, suppose a miner is occupationally exposed to dpm at an average level of 500 µg/m³. Then each year of occupational exposure would contribute 0.5 mg-yr/m³ to the miner's cumulative dpm exposure. Suppose also that this miner's occupational exposure

[78] The assumption is that, on average, EC = TC/2 and TC = 0.8×dpm.

[79] BG, expressed in µg-yr/m³, accounts for an assumed background (i.e., non-occupational) EC exposure level of 1.0 µg/m³. At age 70, after a 45-year worklife and an additional 5-year lag after retirement, BG is assumed to equal 70 µg-yr/m³. ''Log'' refers to the natural logarithm, and ''exp'' refers to the antilogarithm of the subsequent quantity.

[80] The 15-year lagged mine-unadjusted and mine-adjusted models are respectively denoted by M/03 and M/06 in Table 11.2 of Johnston et al. (1997). As explained earlier, the individual mines considered in this study differed significantly with respect to both dpm exposures and lung cancer experience. The investigators could not determine exactly how much, if any, of the increased lung cancer risk associated with dpm exposure depends on other, unknown factors differentiating the individual mines. The mine-adjusted model allocates a significant number of the lung cancers otherwise attributable to dpm exposure to the ''norm'' for specific mines. Therefore, if the differences in lung cancer prevalence between mines is actually due to corresponding differences in mean dpm exposure, then this model will mask a significant portion of the risk due to dpm exposure. After adjusting for miners' age and smoking habits, the mine-unadjusted model attributes differences in the prevalence of lung cancer between mines to corresponding differences in mean dpm exposure. However, the mine-adjusted model has the advantage of taking into account differences between mines with respect to potentially confounding factors, such as radon progeny and silica levels.

begins at age 45 and continues for 20 years until retirement at age 65. Consequently, at or above age 65, this hypothetical miner would have accumulated a total of 10 mg-yr/m^3 of occupational dpm exposure. According to the Säverin-Cox-subcohort model, the relative risk estimated for this miner after retirement is RR = $(1.176)^{10}$ = 5.1. This means that, at or above age 65, the retired miner's risk of lung cancer is estimated (by this model) to be about five times that of another retired miner having the same age and smoking history but no occupational dpm exposure.

Since the two Johnston models exclude exposure within the last 15 years, it is instructive to calculate the relative risk using these models for the same hypothetical retiree at age 75. Since this miner retired at age 65, immediately after 20 years of occupational exposure, the cumulative exposure used in applying the Johnston models must be reduced by the 2.5 mg-yr/m^3 accumulated from age 60 to age 65. Therefore, according to the Johnston mine-adjusted model, the relative risk estimated for this retired miner at age 75 is RR = $(1.321)^{7.5}$ = 8.1. At age 80 or above, however, this model predicts that the relative risk would increase to RR = $(1.321)^{10}$ = 16.2.

The six exposure-response relationships obtained from these two studies establish a range of quantitative risk estimates corresponding to a given level of cumulative dpm exposure. This range provides lower and upper limits on the risk of lung cancer for workers exposed at the given level, relative to similar workers who were not occupationally exposed. The lower limit of this range is established by Säverin's full cohort Poisson model. Therefore, the lowest estimate of relative risk after 45 years of occupational dpm exposure is RR = $(1.024)^{45 \times 0.644}$ = 2.0 at a mean concentration of 644 µg/m^3 or RR = $(1.024)^{45 \times 0.808}$ = 2.4 at mean concentration of 808 µg/m^3. These exposure levels correspond to the averages presented in Table III–1 for underground coal and underground M/NM mines, respectively.

A relative risk of 2.0 amounts to a doubling of the baseline lung cancer risk, and all of the models project relative risks of at least 2.0 after 45 years of exposure at these levels. Therefore, MSHA expects that underground miners exposed to dpm at these levels for a full 45-year occupational lifetime would, at a minimum, experience lung cancer at a rate twice that of unexposed but otherwise similar miners. Five of the six statistical models, however, predict a relative risk much greater than 2.0 after 45 years at a mean dpm concentration of 644 µg/m^3. The second-lowest estimate of relative risk, for example, is RR = $(1.089)^{45 \times 0.644}$ = 11.8, predicted by Säverin's full cohort Cox model.[81]

In the next subsection of this risk assessment, relative risks will be combined with baseline lung cancer and mortality data to estimate the lifetime probability of dying from lung cancer due to occupational dpm exposure.

[81] Some commenters contended that MSHA cannot establish a reliable exposure-response relationship because of potential interferences in MSHA's dpm concentration measurements. More specifically, some of these commenters claimed that MSHA's dpm measurements in underground coal mines were significantly inflated by submicrometer coal dust.

As explained in Subsection 1.a of this risk assessment, the sampling device MSHA used to measure dpm in underground coal mines was designed specifically to allow for the submicrometer fraction of coal dust. Both the size-selective and RCD methods are reasonably accurate when dpm concentrations exceed 300 µg/m^3. Moreover, neither of these methods was used to establish the exposure-response relationships presented by Säverin et al. (1999) or Johnston et al. (1997).

(iii) Excess Risk at Specific Dpm Exposure Levels

The ‘‘excess risk’’ discussed in this subsection refers to the lifetime probability of dying from lung cancer resulting from occupational exposure to dpm for 45 years. This probability is expressed as the expected excess number of lung cancer deaths per thousand miners occupationally exposed to dpm at a specified level. The excess is calculated relative to baseline, age-specific lung cancer mortality rates taken from standard mortality tables. In order to properly estimate this excess, it is necessary to calculate, at each year of life after occupational exposure begins, the expected number of persons surviving to that age with and without dpm exposure at the specified level. At each age, standard actuarial adjustments must be made in the number of survivors to account for the risk of dying from causes other than lung cancer.

Table III–7 shows the excess risk of death from lung cancer estimated across the range of exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). Estimates based on the 5-year lagged models from Steenland et al. (1998) fall within this range and are included for comparison. Based on each of the eight statistical models, the excess risk was estimated at four levels of dpm exposure: 200 µg/m^3, 500 µg/m^3, 644 µg/m^3 (the mean dpm concentration observed by MSHA at underground coal mines, as shown in Table III–1), and 808 µg/m^3 (the mean dpm concentration observed by MSHA at underground M/NM mines, as shown in Table III–1).

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Table III-7. — Lifetime excess risk of lung cancer mortality at specific Dpm exposure levels.

Study and Statistical Model	Excess Lung Cancer Deaths per 1000 Occupationally Exposed Workers†			
	200 µg/m³	500 µg/m³	644 µg/m³	808 µg/m³
Säverin et al. (1999)				
Poisson, full cohort	15	44	61	83
Cox, full cohort	70	280	422	577
Poisson, subcohort	93	391	563	693
Cox, subcohort	182	677	761	802
Steenland et al. (1998)				
5-year lag, log of cumulative exposure	67	89	95	101
5-year lag, simple cumulative exposure	159	620	721	771
Johnston et al. (1997)				
15-year lag, mine-adjusted	313	724	770	800
15-year lag, mine-unadjusted	513	783	811	830

† Assumes 45-year occupational exposure at 1920 hours per year from age 20 to retirement at age 65. Lifetime risk of lung cancer adjusted for competing risk of death from other causes and calculated through age 85. Baseline lung cancer and overall mortality rates from NCHS (1996).

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All of the estimates in Table III–7 assume that occupational exposure begins at age 20 and continues until retirement at age 65. Excess risks were calculated through age 85 as in Table IV of Stayner et al. (1998). Table III–7 differs from Table IV of Stayner et al. in that results from Johnston et al. and Säverin et al. are substituted for results based on the two studies by Garshick et al. Nevertheless, at 500 µg/m³, the range of excess risks shown in Table III–7 is nearly identical to the range (50 to 810 µg/m³) presented in Table IV of Stayner et al. (1998).

MSHA considers the exposure levels shown in Table III–1 to be typical of current conditions in underground coal mines using diesel face equipment. At the mean dpm concentration observed by MSHA at underground M/NM mines (808 µg/m³), the eight estimates range from 83 to 830 excess lung cancer deaths per 1000 affected miners. At the mean dpm concentration observed by MSHA at underground coal mines (644 µg/m³), the estimates range from 61 to 811 excess lung cancer deaths per 1000 affected miners. MSHA recognizes that these risk estimates involved extrapolation beyond the exposure experience of the miner cohorts in Säverin et al. (1999) and Johnston et al. (1997). However, the degree of extrapolation was less for those two studies than the extrapolation that was necessary for the diesel-exposed truck drivers in Steenland et al. The lowest excess lung cancer risk in dpm exposed miners found in Table III–7 is 61/1000 per 45-year working lifetime. Based on the quantitative rule of thumb established in the benzene case, this estimate indicates a clearly significant risk of lung cancer attributable to dpm exposure at current levels. [*Industrial Union* vs. *American Petroleum*; 448 U.S. 607, 100 S.Ct. 2844 (1980)].

c. The Rule's Expected Impact on Risk

MSHA strongly disagrees with the views of some commenters who asserted that the proposed rules would provide no known or quantifiable health benefit to mine workers. On the contrary, MSHA's assessment of the best available evidence indicates that reducing the very high exposures currently existing in underground mines will significantly reduce the risk of three different kinds of material impairment to miners: (1) Acute sensory irritations and respiratory symptoms (including allergenic responses); (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (3) lung cancer. Furthermore, as will be shown below, the reduction in lung cancer risk expected as a result of the rule can readily be quantified based on the estimates of excess risk at exposure levels given in Table III–7.

Even though the coal rule is an equipment based standard limiting emissions to 5.0 gm/hr and 2.5 gm/hr dpm output, MSHA estimates that these emissions limits will result in ambient dpm concentration in an underground coal mines of approximately 200 µg/m³. MSHA believes this is a reasonable estimate to use in light of several sample calculations which indicate that using available controls in underground mining sections with dirty equipment can reduce emissions to that level or further. For example, in part IV of this preamble, MSHA discusses the comparison of the machine-based standard in this final rule with the State of Pennsylvania's diesel law. MSHA provides data showing that a permissible engine equipped with a 95% filter and using the approval plate air quantity will result in a calculated ambient concentration of dpm of 142 µg/m³. In part V of this preamble, MSHA uses the ''Estimator''—a computerized spreadsheet designed to calculate dpm ambient levels from given engine emissions and mine ventilation rates and the impact of various controls on those ambient levels. Table V–3 of part V presents Estimator results using another permissible engine to show that the ambient levels would be approximately 200 µg/m³ when applying various filters and using various intake dpm concentrations.

An alternative approach to estimating exposures once the rule is implemented is to look at the factors affecting dpm production. Dpm exposure is related to the emissions from engines, ventilation, and engine duty cycle. If emissions drop from 25 and 50 gm/hr (dpm concentration range emitted from current permissible engines) to 2.5 and 5.0 gm/hr (as required under the rule), there would be a ten-fold reduction in exposure. With current ventilation required for the diesel equipment, the ambient concentrations would also be reduced accordingly. Thus, assuming that emissions will be reduced down to 200 $\mu g/m^3$ is a conservative approach in estimating benefits.

Using exposure-response relationships and assumptions described in Subsections 3.b.ii(1) and 3.b.ii(2) of this risk assessment, MSHA estimated lower bounds on the significance of risks faced by miners occupationally exposed to dpm with respect to (1) acute sensory irritations and respiratory symptoms or (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. MSHA expects the rules to significantly and substantially reduce all three kinds of risk. However, MSHA is unable, based on currently available data, to quantify with confidence the reductions expected for the first two kinds. A 24-hour exposure at 20 $\mu g/m^3$ may not have the same short-term effects as an 8-hour exposure at 60 $\mu g/m^3$. Furthermore, this concentration is only 30 percent of the maximum dpm concentration that MSHA expects once the rules are fully implemented and represents an even smaller fraction of average dpm concentrations many underground miners currently experience. It is unclear whether the same incremental effects on acute respiratory symptoms and premature mortality would apply at the much higher exposure levels found in underground mines. Additionally, as MSHA suggested in the proposed preamble and several commenters repeated, the toxicity of dpm and $PM_{2.5}$ may differ because of differences in composition. Finally, underground miners as a group may differ significantly from the populations for which the $PM_{2.5}$ exposure-response relationships were derived.

Therefore, MSHA's quantitative assessment of the rule's impact on risk is restricted to its expected impact on the third kind of risk—the risk of lung cancer. As explained in Part IV of the preamble, the rule is expected to limit dpm concentrations to which miners in underground coal mines are exposed to approximately 200 $\mu g/m^3$. Assuming that, in the absence of this rule, underground coal miners would be occupationally exposed to dpm for 45 years at a mean level of 644 $\mu g/m^3$, the following table contains the estimated reductions in lifetime risk expected to result from full implementation of the rule, based on the various exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). These estimates were obtained by calculating the difference between the corresponding estimates of excess lung cancer mortality, at 644 $\mu g/m^3$ and 200 $\mu g/m^3$, shown in Table III–7. The Regulatory Impact Analysis (RIA), presented later in this preamble, contains further quantitative discussion of the benefits anticipated from this rule.

REDUCTION IN LIFETIME RISK OF LUNG CANCER MORTALITY EXPECTED AS RESULT OF REDUCING EXPOSURE LEVEL FROM 644 $\mu G/M^3$ TO 200$\mu G/M^3$

Study and statistical model	Expected reduction in lung cancer deaths per 1000 affected miners†
Säverin et al. (1999):	
Poisson, full cohort	46
Cox, full cohort	352
Poisson, subcohort	470
Cox, subcohort	579
Johnston et al. (1997):	
15-year lag, mine-adjusted	457
15-year lag, mine-unadjusted	298

†Calculated from Table III–7.

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain even after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that, due to monetary costs and technological limitations, the underground coal mining sector as a whole cannot feasibly reduce dpm concentrations further at this time.

4. Conclusions

MSHA has carefully considered all of the evidence and public comment submitted during these proceedings to determine whether dpm exposures, at levels observed in some mines, present miners with significant health risks. This information was evaluated in light of the legal requirements governing regulatory action under the Mine Act. Particular attention was paid to issues and questions raised by the mining community in response to the Agency's ANPRM and NPRM and during workshops on dpm held in 1995. Based on its review of the record as a whole, the agency has determined that the best available evidence warrants the following conclusions:

1. Exposure to dpm can materially impair miner health or functional capacity. These material impairments include acute sensory irritations and respiratory symptoms (including allergenic responses); premature death from cardiovascular, cardiopulmonary, or respiratory causes; and lung cancer.

2. At dpm levels currently observed in underground mines, many miners are presently at significant risk of incurring these material impairments due to their occupational exposures to dpm over a working lifetime.

3. By reducing dpm concentrations in underground mines, the rule will substantially reduce the risks of material impairment faced by underground miners exposed to dpm at current levels.

In its response to MSHA's proposals, the NMA endorsed these conclusions to a certain extent, as follows:

> The members of NMA have come to recognize that it would be prudent to limit miners' exposure to the constituents of diesel exhaust in the underground environment. [NMA]

A number of commenters, however, urged MSHA to defer rulemaking for either the coal or M/NM sector, or both, until results were available from the NCI/NIOSH study currently underway. For example, referring to the M/NM proposal, one commenter stated:

> Vulcan agrees with MSHA that underground miner Dpm exposure needs to be addressed by mine operators. Vulcan agrees with MSHA that a permissible exposure level (PEL) should be established, but disagrees that adequate information is currently available to set a PEL. [Vulcan Materials]

MSHA believes that expeditious rulemaking, in both underground mining sectors, is necessary for the following reasons:

(1) The NCI/NIOSH study currently in progress will eventually provide additional information on lung cancer mortality. Non-cancer health effects, such as sensory irritations, respiratory symptoms, or premature death from cardiovascular, cardiopulmonary, or respiratory causes will not be addressed. MSHA believes that these non-cancer effects constitute material impairments.

(2) NIOSH itself has recommended that, "* * * given the length of time to complete this study and the current state of knowledge regarding dpm exposures and health effects in miners," MSHA should "proceed with rulemaking based on the evidence currently available as presented in this

FR notice.'' [NIOSH testimony by Paul Schulte, dated 5/27/99]

(3) Given the very high exposure levels measured at some underground mines, miners should not be required to serve as human guinea pigs in order to remove all doubts about the excess risks of dpm exposures in underground mines. While additional studies are in progress, miners should be protected by reducing dpm concentrations to a level more nearly commensurate with exposures in other industries.

Referring to some commenters' position that further scientific study was necessary before regulatory action could be justified, a miner at one of the dpm workshops held in 1995 said:

> * * * if I understand the Mine Act, it requires MSHA to set the rules based on the best set of available evidence, not possible evidence * * * Is it going to take us 10 more years before we kill out, or are we going to do something now * * *? (dpm Workshop; Beckley, WV, 1995).

Similar concern with the risk of waiting for additional scientific evidence was expressed by another miner, who testified:

> * * * I got the indication that the diesel studies in rats could no way be compared to humans because their lungs are not the same * * * But * * * if we don't set the limits, if you remember probably last year when these reports come out how the government used human guinea pigs for radiation, shots, and all this, and aren't we doing the same thing by using coal miners as guinea pigs to set the value? (dpm Workshop; Beckley, WV, 1995).

MSHA shares these sentiments. That is why MSHA considers it imperative to protect miners based on the weight of existing evidence, rather than to wait for the results of additional studies.

IV. Discussion of Final Rule

This part of the preamble describes each of the provisions of the final rule. As appropriate, this part references discussions in other parts of this preamble: In particular, the background discussions and controls in part II, and the feasibility discussions in part V.

Table IV–1 will be referenced throughout this discussion. The table provides information about each engine approved by MSHA for use in underground coal mines. This table reflects the emission results based on the MSHA approval data.

The top rows of the table provide information about permissible configurations, designated by the MSHA approval numbers which contain an ''A''; the remainder of the table provides information about nonpermissible configurations, designated by the MSHA approval numbers which contain a ''B''. Within each engine grouping, the permissible engines are listed in order of MSHA approval number, and the nonpermissible engines are listed in increasing ''Rated Horsepower''.

The table has ten columns. The first column gives the MSHA approval number. The second and third column lists the engine manufacturer and the engine model designation. The fourth column lists the rated horsepower of the engine as approved by MSHA. The fifth column gives the Particulate Index (PI) expressed in cubic feet per minute (cfm), the sixth column lists the DPM emissions expressed in gm/hr—weighted average over the 8 mode test cycle specified in 30 CFR 7.89, the seventh column weighted average horsepower, the eighth is the dpm expressed in grams per bhp-hr (calculated by dividing column six by column seven), the ninth column gives the filter efficiency needed to meet a 5.0 gm/hr standard, and the tenth column gives the filter efficiency needed to meet a 2.5 gm/hr standard.

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Table IV-1

MSHA Approved Diesel Engines under Part 7, subpart E

Approval No.	Manufacturer	Engine Model * Meets EPA	Rated Horse power	PI CFM	DPM gm/hr Weighted Avg.	Weighted Avg. Horsepower	DPM gr/bhp-hr	Filter Efficiency To Obtain 5.0gm/hr	Filter Efficiency To Obtain 2,5gm/hr
A001	DEUTZ	MWM 916	94	15000	25.49	51.1	0.50		90.2
A002	CATERPILLAR	3306 PCNA	150	27000	45.88	87.2	0.53		94.6
A003	CATERPILLAR	3304 PCNA	100	17500	29.74	58.1	0.51		91.6
A004	ISUZU	QD 100-306	70	50000	84.96	40.7	2.09		97.1
A004	ISUZU	QD 100-306	66	10000	16.99	34	0.50		85.3
A005	Caterpillar	3306PCTA	190	31000	52.68	95	0.55		95.3
B070	Farymann	43F	14	4000	6.80	7.00	0.97	26.4	63.2
B042	Lister Petter	LPU2 MKI	17.5	5000	8.50	9.1	0.93	41.2	70.6
B053	Kubota	V1200*	25.8	1500	2.55	13	0.20	0.0	1.9
B041	Lister Petter	LPU3 MKI	26.3	7000	11.89	13.7	0.87	58.0	79.0
B062	Deutz	F2L1011*	28.2	1000	1.70	14	0.12	0.0	0.0
B044	Lister Petter	LPU3 MKII	29	4500	7.65	15.1	0.51	34.6	67.3
B015	DEUTZ	F2L 1011F*	30	3500	5.95	15.6	0.38	15.9	58.0
B040	Lister Petter	LPU4 MKI	35	9500	16.14	18.2	0.89	69.0	84.5
B043	Lister Petter	LPU4 MKII	38.6	6000	10.20	20.1	0.51	51.0	75.5
B026	DEUTZ	F3L 912W*	40	2500	4.25	21.7	0.20	0.0	41.2
B061	Deutz	F3L1011*	41.6	1500	2.55	21	0.12	0.0	1.9
B033	PERKINS	104-19	42.5	7000	11.89	22.4	0.53	58.0	79.0
B014	DEUTZ	F3L 1011F*	44	5000	8.50	23.3	0.36	41.2	70.6
B054	Deutz	F3M1011F*	46	3500	5.95	24.2	0.25	15.9	58.0
B031	DEUTZ	F3L 912W *	47	2500	4.25	24.7	0.17	0.0	41.2
B025	DEUTZ	F4L 912W*	54	3500	5.95	28.9	0.21	15.9	58.0
B060	Deutz	F4L1011*	56.3	2000	3.40	28	0.12	0.0	26.4
B038	ISUZU	QD60 (C240)	57	5500	9.35	27.6	0.34	46.5	73.3
B027	PERKINS	704-26	58	8000	13.59	28.8	0.47	63.2	81.6
B013	DEUTZ	F4L 1011F	59	6500	11.05	31.1	0.36	54.7	77.4
B055	Deutz	F4M1011F*	61	4500	7.65	32.30	0.24	34.6	67.3
B029	DEUTZ	F4L 912W*	62	3500	5.95	32.9	0.18	15.9	58.0
B024	DEUTZ	F5L 912W*	67	4500	7.65	36.2	0.21	34.6	67.3
B019	DEUTZ	BF4L 1011F*	74	4500	7.65	40	0.19	34.6	67.3
B030	DEUTZ	F5L 912W *	76	4000	6.80	41.1	0.17	26.4	63.2
B006	ISUZU	QD 100-301	79	8500	14.44	43.5	0.33	65.4	82.7
B023	DEUTZ	F6L 912W*	80	5000	8.50	43.4	0.20	41.2	70.6
B056	Deutz	BF4M1011F*	82	5500	9.35	44.75	0.21	46.5	73.3
B028	DEUTZ	F6L 912W *	93	5000	8.50	49.3	0.17	41.2	70.6
B001	DEUTZ	MWM 916	94	11500	19.54	46.2	0.42	74.4	87.2

B004	CATERPILLAR	3304 PCNA	100	15000	25.49	52.8	0.48	80.4	90.2
B022	PERKINS	1004-40T	108	9000	15.29	55.4	0.28	67.3	83.7
B064	Caterpillar	3054DIT	108	9000	15.29	54.00	0.28	67.3	83.7
B045	ISUZU	4BG1T-MA	111	13000	22.09	57.7	0.38	77.4	88.7
B011	DEUTZ	BF4M 1012EC*	113	4000	6.80	59.1	0.12	26.4	63.2
B020	PERKINS	1004-40TW*	122	7500	12.74	62.6	0.20	60.8	80.4
B065	Caterpillar	3054DITA*	122	7500	12.74	61.00	0.21	60.8	80.4
B059	Deutz	BF4M1013*	127	4500	7.65	64	0.12	34.6	67.3
B046	ISUZU	6BG1-MA	129	16000	27.19	67.1	0.41	81.6	90.8
B039	ISUZU	QD145	135	12000	20.39	70.5	0.29	75.5	87.7
B034	DEUTZ	F6L 413FW*	137	7000	11.89	75.4	0.16	58.0	79.0
B003	CATERPILLAR	3306 PCNA	150	23000	39.08	79.2	0.49	87.2	93.6
B021	PERKINS	1006-60T	152	12000	20.39	82.8	0.25	75.5	87.7
B066	Caterpillar	3056DIT	152	12000	20.39	76.00	0.27	75.5	87.7
B008	DEUTZ	BF4M 1013EC*	158	7500	12.74	82.5	0.15	60.8	80.4
B005	GENERAL MOTORS	L57, 6.5L* - 1994	160	9500	16.14	83.5	0.19	69.0	84.5
B052	Cummins	5.9-175 w/cat* - 1994	175	3500	5.95	93.70	0.06	15.9	58.0
B052	Cummins	5.9-175 w/ocat* - 1994	175	5000	8.50	93.70	0.09	41.2	70.6
B035	DEUTZ	F8L 413FW	182	9500	16.14	100.6	0.16	69.0	84.5
B067	Navistar	A185	185	15000	25.49	93.00	0.27	80.4	90.2
B058	Deutz	BF6M1013*	194	5500	9.35	97	0.10	46.5	73.3
B016	GENERAL MOTORS	L65, 6.5L - 1998	195	24000	40.78	101.8	0.40	87.7	93.9
B068	Navistar	A225* - 1994	215	11000	18.69	108.00	0.17	73.3	86.6
B063	Caterpillar	3306PCTA	215	31000	52.68	108.00	0.49	90.5	95.3
B036	DEUTZ	F10L 413FW	228	12000	20.39	125.7	0.16	75.5	87.7
B050	Detroit Diesel	Series 40 DDEC*	230	4500	7.65	118.6	0.06	34.6	67.3
B057	Deutz	BF6M1013C*	233	8500	14.44	117.00	0.12	65.4	82.7
B051	Cummins	ISB235* - 1998	235	6000	10.20	113.6	0.09	51.0	75.5
B069	Navistar	B250* - 1994	250	6000	10.20	125.00	0.08	51.0	75.5
B007	DEUTZ	BF6M 1013ECP	261	19000	32.29	136.2	0.24	84.5	92.3
B010	CATERPILLAR	3306 DITA*	270	6000	10.20	154.5	0.07	51.0	75.5
B037	DEUTZ	F12L 413FW	274	14000	23.79	150.8	0.16	79.0	89.5
B017	CATERPILLAR	3306 ATAAC*	300	12000	20.39	172.5	0.12	75.5	87.7
B047	Detroit Diesel	Series 50 DDEC*	315	5000	8.50	166.7	0.05	41.2	70.6
B048	Detroit Diesel	Series 60 11.1 DDEC*	325	5500	9.35	179.7	0.05	46.5	73.3
B012	CATERPILLAR	3176 ATAAC	335	8000	13.59	191	0.07	63.2	81.6
B002	DEUTZ	BF6M 1015C*	402	17500	29.74	219.1	0.14	83.2	91.6
B049	Detroit Diesel	Series 60 12.7 DDEC*	475	8500	14.44	249	0.06	65.4	82.7
B018	CATERPILLAR	3406E*	500	12500	21.24	274.8	0.08	76.5	88.2
B009	DEUTZ	BF8M 1015C*	536	18000	30.59	289.7	0.11	83.7	91.8
B032	Detroit Diesel	8V-2000TA DDEC*	650	10000	16.99	364.7	0.05	70.6	85.3

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The final rule would add six new sections to 30 CFR part 72 on March 20, 2001.

Section 72.500 Emission Limits for Permissible Diesel Powered Equipment.

Organization. As with the proposed rule, this section establishes the controls applicable to permissible equipment. As proposed, 30 CFR 72.500 also had included other requirements—controls for nonpermissible heavy-duty vehicles in 30 CFR 72.500(b) and requirements for the maintenance of such controls in 72.500(c). In this final rule, MSHA has retained the requirements for dpm reduction for permissible equipment in this section but has moved the requirements for nonpermissible heavy-duty vehicles to a new 30 CFR 72.501. MSHA has also moved the maintenance requirements for emission controls to a new 30 CFR 72.503. These organizational changes were made to make it easier for the mining community to locate specific requirements in the final rule.

Summary of final rule. The final rule requires all permissible equipment to meet an emissions limit of 2.5 grams of dpm per hour. The existing fleet has 18 months to meet this limit. In addition, any permissible engine introduced into the fleet of an underground coal mine after the effective date of this rule will have to meet that standard upon being introduced into the mine. MSHA means by ''introduced'' any equipment added to the mine's diesel equipment inventory. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing. It also includes engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

Infeasibility of a concentration limit for underground coal mines. The preamble accompanying the proposed rule explained why the Agency was not proposing an ambient concentration limit for underground coal mines as it was proposing for underground metal and nonmetal mines. The Agency was not confident at the time the rule was proposed that there was a measurement method for dpm that provided 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 Agency continued to collect data and has consulted with NIOSH in an attempt to resolve questions about the measurement of dpm in underground coal mines. There were no comments received that objected to the fact that the Agency was not proposing an ambient concentration limit for underground coal mines as it was proposing for underground metal and nonmetal mines.

Why dpm emissions from permissible equipment need to be controlled. The preamble accompanying the proposed rule also explained why the agency was proposing to limit the emissions from permissible equipment in particular. Dpm concentration samples taken in the field indicate that permissible equipment used for face haulage makes the largest contribution to high dpm levels. Dpm samples taken in the intake air to working sections where diesel face haulage was used showed relatively low dpm levels. When diesel particulate filters were not used, dpm samples taken on the working section and in returns from those sections generally showed dpm levels in excess of 500 µg/m³.

Other permissible equipment can also generate significant dpm emissions because this equipment utilizes the same engines as used in face haulage equipment. Since the time of the proposal, the diesel inventory for permissible machines has not changed significantly. The same four permissible engines that were available at the time the proposal was written continue to be the power source for the current permissible fleet. Table IV–1 shows that these four engines produce higher dpm emissions on a gm/hr basis than nonpermissible engines with the same horsepower. Commenters did not present evidence that dpm concentrations in areas where permissible equipment is used have decreased since the proposed rule was published.

Why the final rule uses a machine based emission limit instead of a requirement for the addition of a filter with a specified filtration efficiency. The final rule for permissible equipment is different from that proposed. As proposed by MSHA (63 FR 17491 et.seq.), 30 CFR 72.500(a) would have required mine operators to install on permissible vehicles a system capable of removing on average, at least 95% of dpm by mass. Operators were required to complete these filter installations within 18 months from the date of publication of the final rule; no action to control emissions from permissible equipment was required before that date.

The use of an emissions limit for permissible machines in the final rule stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based rule that was proposed. In that preamble, the agency also described a number of alternative approaches considered, and asked the mining community to comment on whether there were other approaches for the control of dpm from permissible equipment that might accomplish the same task with more flexibility. 63 FR 17498, 17499, 17556, 17563. The agency also described the approach being taken by the State of Pennsylvania that combined a filter efficiency standard with a tailpipe limit.

The Agency emphasized that it was particularly interested in comment on an alternative approach it described that would establish a machine based limit on emissions in lieu of a filter efficiency requirement (see, *e.g.,* 63 FR 17556, 17563). In fact, a separate ''Question and Answer'' was included in the preamble to highlight this alternative, immediately after the description of the proposed rule. 63 FR 17501, 17653.

Based on the record, MSHA has concluded that the original proposal had deficiencies which are avoided by this alternative approach.

MSHA received many comments objecting to exclusive reliance on filters. Commenters stated that MSHA was denying operators the benefit of the full range of available dpm controls outlined in MSHA's Toolbox (the history and content of which are described in Part II of this preamble). These commenters stated that mine operators should be allowed to chose the combination of controls that best suit their operations.

On the other hand, other commenters favored requiring a filter on all underground mining equipment (including permissible equipment). Some of these commenters noted that controls are only effective if properly maintained, and some asserted that filters are easier to monitor in this regard than engines. Similarly, commenters argued that in the absence of a requirement for a filter on each piece of equipment, operators would rely primarily on increased ventilation to control dpm concentrations, and asserted that the industry had a very poor record of maintaining ventilation controls. Also, one commenter asserted that filters were the only known control that would limit the number of nanoparticles emitted as well as reducing the mass of dpm discharged, whereas newer diesel engines designed to produce less dpm mass may actually increase the number of nanoparticles emitted.

A number of commenters pointed out that even if filters were required, relying on a filter-efficiency standard would be inappropriate. These commenters noted that even if a particular efficiency (*e.g.,* 95%) is achievable with a ''dirty'' engine like those currently composing the underground coal permissible fleet, such efficiency may not be feasible on the modern, clean burning engines that will eventually take their place. That is, if the emissions from a ''cleaner'' engine are lower to begin with, the filter mounted on a machine with such an engine would have to be much more efficient than the one mounted on a machine with a dirtier engine to remove the same percentage of dpm. Commenters stated that since it might not be possible to meet the proposed requirement for a 95% efficient filter with a newer engine, MSHA's proposed rule might well inhibit the introduction of cleaner engines into underground coal mines, and thus force operators to rely on older and dirtier engines which would require more maintenance.

There was also considerable discussion at the hearings and in the written comments about the experience of Pennsylvania, which has a 95% filter efficiency standard for permissible and other diesel equipment, as well as a requirement that each piece of equipment meet an emissions standard. Commenters clarified the development of that approach, its requirements and procedures, and implementation issues to date; many noted problems in meeting the standard as currently set forth. Other commenters noted that what might be feasible for Pennsylvania, a state which heretofore has not permitted diesel equipment underground, might not be feasible for operators in other states with existing fleets.

As proposed, the rule would have ensured that the emissions from the most polluting, commonly used engine (Caterpillar 3306PCNA, 150 horsepower, 45.88 gm/hr) would be reduced by 95%, resulting in tailpipe emissions of 2.29 gm/hr (5% of 44.88 gm/hr). After carefully considering all of the discussion at the hearings and the written comments, MSHA has concluded that the alternative approach on which it initially invited comment, a dpm emissions limit for each machine, has a number of advantages over the approach initially proposed. While MSHA has evidence that there are filters readily available for the existing permissible fleet which are 95% efficient it lacks evidence of the technological feasibility of filter performance at a 95% level for the cleaner engines which will eventually replace the current fleet. Moreover, the same problem exists at any filter efficiency rating. Changing the proposed rule to require that filters on permissible equipment must only be 70% efficient, as suggested by a commenter, does not guarantee they can provide this efficiency for future engines. At the same time it sets a limit for the current fleet that is far below what can be achieved. Thus, while a requirement for a high filter efficiency could have the perverse effect of inhibiting the introduction of cleaner engine technologies or other technologies that could be forthcoming that could make substantial reductions in dpm levels, a low filter efficiency requirement fails to provide protection for miners from dpm emissions from engines in today's fleet. Accordingly, MSHA has concluded that requiring a specific filter efficiency is not a good idea, either by itself or (as is the case in Pennsylvania) as a supplement to a machine emissions limit.

The machine emission limit specified in this final rule achieves the desired goal of significantly reducing the mass of dpm emitted from the permissible machines without specifying a filter efficiency. Using the 2.5 gm/hr emission limit provides a consistent target and resolves the issue relative to lower filter efficiency or cleaner engines.

With this final rule, MSHA is allowing the mine operator a wide choice of approaches from the toolbox to control dpm such as low emission diesel engines, aftertreatment controls (catalytic converters and/or dpm filters), fuel with a very low level sulfur content, alternative fuels, and fuel additives in order to meet the machine emission limit. Other aspects of the MSHA toolbox are already a requirement in underground coal mines such as the use of approved diesel engines, fuel with a sulfur content less than 500 ppm, optional EPA approved fuel additives, regular maintenance by qualified mechanics, prohibition of unnecessary idling, and training of mechanics and equipment operators. In practice, however, MSHA expects all permissible equipment to need filtration to achieve the required limit.

The final rule does not, however, permit operators to satisfy the requirements for permissible equipment by increasing ventilation or by using enclosed cabs, although the Toolbox describes both as methods for reducing miner exposure to dpm. While MSHA encourages operators to take such steps, the Agency concluded that it would not be appropriate to make an adjustment to or an exemption from the machine emissions limit when such controls are used.

In the case of ventilation, while increasing mine ventilation does reduce dpm concentrations in the ambient air, such a change does not impact a requirement based strictly on the emissions emitted from an individual machine. One variation of the alternative proposed by MSHA would have allowed a credit for added ventilation in determining whether a machine met the required emissions limit. However, after careful consideration the agency has concluded that this approach is inappropriate. It should be noted that while the agency acknowledges the evidence offered by many commenters that reliance upon ventilation as a primary dpm control is inappropriate in light of the record of violations of ventilation standards—even though not all of the data supplied supported the general conclusion being expressed and does not reflect the implementation of the new diesel equipment rule—this is not the basis on which the agency has determined not to allow operators a credit for increasing ventilation. Rather, MSHA concluded that such an approach would not be necessary in light of its conclusion about the capabilities of paper filters alone to enable the permissible fleet to meet the requirement. Controlling engine emissions to the required levels would have called for a ventilation rate of five times the engine particulate index air quantity. This quantity would have been specified in the Approved Ventilation Plan. Such a ventilation rate is achievable in only a few mines. At the same time, once the proper filter is installed, the emissions are controlled to the required levels; allowing a credit for ventilation makes no difference in practice given the range of available filters. While providing a ventilation credit would allow operators to use a less efficient filter, this would reduce dpm emissions less in such mines; and since the use of more efficient filters is feasible, the Act requires MSHA to pick the more protective approach. Moreover, due to the mobility of the equipment, a ventilation credit for outby equipment would be difficult to monitor and enforce. The Agency has indirectly allowed for ventilation by allowing a higher outby emission rate. The higher outby emission rate for light-duty equipment was based on the duty cycle and the normally higher ventilation rates in outby areas. Additionally, allowing for a ventilation credit based on the specific air volume would have become too complicated to administer in certain cases (for example, permissible equipment in multi-entry systems, or permissible equipment used in outby areas). Ventilation regulations for single and multiple units of permissible diesel equipment are based primarily on the approval plate quantity. Depending on a ventilation quantity other than that on the approval plate would have complicated an already complex issue.

While enclosed cabs or booths can be used to lower exposures for a machine operator, cabs do not currently exist for permissible underground coal mining equipment. Even if developed for permissible equipment, these enclosures would not provide protection for other miners working in that same area. Moreover, there will be no sampling to assure that the miners are protected. Consequently, the final rule requires that even if a cab were developed for permissible equipment, dpm emission limits would have to be maintained the same as other permissible equipment.

Having made the determination that an emissions limit is preferable to a filter efficiency requirement, and not to provide credit for ventilation or an exemption for the use of cabs, MSHA turned to the question of whether filters should always be required. Some commenters noted that controls are only effective if properly maintained, and asserted that filters are easier to monitor in this regard than engines. Also, one commenter asserted that filters were the only known control that would limit the number of nanoparticles emitted as well as dpm mass, whereas newer diesel engines designed to produce less dpm mass may actually increase the number of nanoparticles emitted.

With respect to maintenance, MSHA notes that while the provisions of the recently promulgated diesel equipment regulations dealing with maintenance and the training of qualified maintenance personnel were in effect at the time of the hearing, the full effect of implementation of these provisions may not have been apparent to the commenters. These regulations when fully implemented, should address many of the concerns expressed by the commenters in this regard.

With respect to nanoparticles, section 5 of Part II of this preamble notes that there is very little information at this time about the possible risk of such particles. Moreover, the evidence on whether filters can protect against such particles is unclear. In any event, it will be some time before the newest generation of diesel engines becomes commonplace in underground mines.

Accordingly, MSHA has concluded that at this time, it is not necessary to require filters that specifically limit nanoparticles. MSHA will, however, continue to monitor the situation. If it becomes apparent that the evidence warrants further action, the agency will not hesitate to act upon that information. In practice, as noted above, current permissible equipment will have to be filtered to meet the emissions standard.

In this regard, one commenter stated that if MSHA does not require filters on all equipment underground, it would be more difficult for the individual states to require filters on all diesel equipment. MSHA does not agree with the commenter. States can impose a more stringent standard than MSHA's requirements. While MSHA recognizes that Pennsylvania and West Virginia and other States are going to take a close look at the Federal government's standard, each State faces different circumstances—*e.g.,* the number and nature of diesel powered equipment already underground, the economic situation of the state's coal industry, etc. MSHA's discussion of the risks of dpm exposure in Part III suggest that further controls would be warranted where it is technologically and economically feasible for the underground coal mining industry as a whole to implement such controls; and while MSHA has concluded this is not feasible for the US industry as a whole, an individual State might well conclude it is feasible for the situation that exists in that State.

Some commenters requested that some or all of the State of Pennsylvania approach be adopted by MSHA. The Pennsylvania law requires an MSHA approved engine, a catalytic converter, and a 95% filter. Additionally, Pennsylvania establishes a ventilating air requirement calculated to dilute the dpm emitted from the filter to 120µ/m^3. With respect to permissible equipment, MSHA's requirement for a machine dpm emission limit of 2.5 grams per hour is essentially equivalent to the emissions standard required under Pennsylvania law.

MSHA did not adopt a calculated ambient dpm concentration based on the approval plate air quantity. Instead, MSHA set the emission standard to represent the dpm emitted from the individual machine. However, since MSHA already requires an approval plate quantity based on the gaseous emissions, an ambient dpm concentration can be calculated from the engine's dpm emission data, the filter efficiency, and the approval plate air quantity. For example, as noted on Table IV–1, the Caterpillar 3306 PCNA engine produces 45.88 gm/hr of dpm from the Category A, permissible configuration. This engine has an approval plate quantity of 9500 cfm or 269m^3/minute of air. When equipped with a 95% dpm filter, the resultant calculated laboratory ambient quantity for a single machine using the Caterpillar 3306 PCNA engine would be 142µ/m^3. This is based on the following formula: (dpm,gm/hr) / 60 * ((100–95%)* 1000 / (approval plate quantity, m^3/minute)* 1000. To reduce the emissions of this engine to the level specified in the Pennsylvania law would require additional air or a higher efficiency filter.

One commenter presented data from a laboratory test conducted on different filter media. The data indicated that the highest efficiency achieved was 81% using the ISO 8178, C1 test cycle. This commenter suggested that MSHA adopt an approach similar to the Pennsylvania approach but establish a 0.5 milligram per cubic meter (mg/m^3) calculated ambient concentration instead of the 120µ/m^3 (0.120 mg/m^3). This commenter's approach included the use of a minimum 70% efficient filter and a recalculation of the approval plate air quantity to achieve the 500µ/m^3 (0.5 mg/m3) concentration.

As with the Pennsylvania approach, MSHA basically agrees with the commenter's general approach. The dpm emission limits specified in this final rule limits the machine's dpm output, requiring the mine operator to choose an engine and aftertreatment device, if necessary, to meet the standard. This approach as previously stated significantly reduces dpm emissions and is based on laboratory testing of the engine and filter. However, since MSHA currently has a requirement for the use of approval plate air quantities in underground coal, MSHA did not impose an additional calculated approval plate air quantity as suggested by the commenters. MSHA is not imposing a minimum filter efficiency as suggested by the commenters because MSHA believes that the mine operator should be able to use all the available tools to meet the standards. MSHA believes that all of the current permissible engines will require filtration to meet the standard; however with this approach taken in the final rule, MSHA is not limiting future technologies.

A commenter asked why the Agency had not chosen to utilize the particulate index established during the MSHA approval process for each engine as the basis of any dpm regulation.

As discussed in Part II of this preamble, the requirement for determining the particulate index was contained in the Agency's diesel equipment regulations. It implemented a recommendation of the Diesel Advisory Committee which called for a particulate index to be set for approved diesel engines. The particulate index specifies the quantity of air needed to dilute the particulate generated by the engine to 1 milligram of diesel particulate matter per cubic meter of air and is based on data collected under the engine approval test described in 30 CFR 7.89.

MSHA established the particulate index to be used as a guide to the mining community in making certain decisions about the control of dpm while the Agency finalized regulations that specifically addressed dpm. This information is available to the mining industry from the manufacturer and MSHA. The particulate index enables the mining community to compare the particulate levels generated by different engines in terms of a ventilating air quantity. For example, if the particulate indices for diesel engines of the same horsepower were established as 7,500 cubic feet of air per minute (cfm) and 12,000 cfm respectively, an equipment manufacturer, mine operator, and MSHA personnel can use this information, along with consideration of the type of machine the engines would power and the area of the mine in which it would be used, to make certain decisions. A mine operator can use this information when choosing an engine to roughly estimate an engine's contribution of diesel particulate to the mine's total respirable dust. MSHA would use this information when evaluating mine dust control plans. Equipment manufacturers can use the particulate index to design and install exhaust after-treatments. MSHA posts this information on its website at http://www.msha.gov/S&HINFO/DESLREG/1907b5.HTM for permissible engines and at *http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM* for nonpermissible engines.

Had the Agency decided to take an approach in this regulation similar to the approach taken by the state of Pennsylvania in its diesel law, or to establish an ambient dpm concentration limit, the particulate index could have been used directly to compute an estimated level of dpm that could be achieved with various quantities of ventilation air. Instead, as was discussed above, the Agency chose to limit the quantity of dpm emitted from the machine, and is therefore expressing the standard in that fashion.

Nevertheless, there is a relationship between the PI and the machine limits established under this rule. The determination of the quantity of dpm emitted from the machine is based on the same information from the engine approval tests in 30 CFR 7.89 as was used to establish the particulate index. Both means of expressing the dpm characteristics of the machine start with determining the permissible fleet. With the exception of the Isuzu QD100 engine which is only used in two machines in the permissible fleet, the Caterpillar 3306 PCNA meets this criteria. The Caterpillar engine emits approximately 46 grams of dpm per hour based on the MSHA approval test for part 7, Category A. Accordingly a 90% reduction would limit emissions to 5.0 grams an hour; and a 95% reduction would limit emissions to 2.5 grams an hour. If a filter could reduce the dpm emitted from the Caterpillar engine to these levels, it could reduce the emissions of any other permissible engine in the fleet to that level.

A number of commenters stated that they had been unable to substantiate the agency's contention that there are filters commercially available that meet such high efficiency requirements. Moreover they asserted that the only system which allegedly came close to this requirement, a system known as the DST®, was a system that would be economically infeasible to install on the entire current fleet of permissible equipment.

The DST® system is described in section 6 of Part II. Data was submitted for the record that the DST® system does indeed reduce the dpm emissions from an engine by more than 95% (*i.e.,* below 2.5 grams per hour) when tested on the ISO 8178,C1 test cycle. The engine tested with the DST® was a MWM916–6 diesel engine which emits 25.5 gm/hr based on the MSHA approval test for part 7, Category A. The system is composed of several components; a paper filter and a catalytic converter, with a heat exchanger used to reduce the temperature of the exhaust to the levels required by MSHA for permissible equipment. The low exhaust gas temperature enables the use of a paper filter without igniting the filter. Most permissible equipment uses water scrubbers to cool the exhaust temperature; hence, switching to the dry system would involve considerable expense.

The agency has reviewed the evidence to determine whether a commercially available paper type filter, mounted at the outlet of the water scrubber used to cool the exhaust of most permissible machines, can achieve comparable reductions in dpm emissions. Filter kits are readily available for most permissible machines, and the costs of equipping the fleet in this fashion is significantly lower than converting everything to a dry system.

MSHA had good reason to think that paper filters alone could do the job. In the early 1990's, equipment manufacturers along with the then Bureau of Mines installed paper filters to the exhaust of water scrubbers for dpm reduction. These systems proved to be very effective in dpm removal. Some mines have used these filters on permissible equipment successfully since the early 1980s. Anecdotal experience was also supportive. For example, a miner commented very favorably about improvement in emissions from a diesel equipped with a paper filter. The miner was referring to a dry system other than DST®. Moreover, based upon what it knows about the components of the DST® system discussed above, MSHA had reason to believe that based upon the extent to which the heat exchanger and catalytic convertor can themselves reduce dpm concentrations, that the main reason for the extensive dpm reduction of the system might well be the paper filter. However, although the record could support such a conclusion, the record contained no specific filter efficiency data. Moreover, some asserted that the DST® results were due to all of its components working together. Other commenters challenged the agency's assumption that a 95% reduction of emissions from the permissible engines that produce the highest dpm concentrations was feasible. Such a filter efficiency would be necessary to satisfy an emissions limit of 2.5 grams per hour.

In order to dispel any doubts about the matter and verify whether the addition of a paper filter alone could achieve such a significant reduction in dpm, MSHA had an analysis performed by an independent laboratory. MSHA has placed a full report of this verification analysis in the record. The analysis was performed on an engine that is representative of the permissible engines in the fleet that produce the most dpm.

The part 7 approval information indicates that three engines—the Caterpillar 3306 PCNA, 3304 PCNA, and the MWM 916–6—are basically of the same design. The Caterpillar 3306 PCNA used for the analysis is representative of the three engines' emissions performance. The Isuzu QD 100 is approved by MSHA and is used in a small number of permissible machines that can emit higher levels of dpm than the Caterpillar engine tested. This occurs when the Isuzu engine is adjusted to the highest horsepower rating approved by MSHA. However, this engine can be derated to an existing lower horsepower MSHA approval rating which is only 5.5% lower than maximum rating. The two machines of which MSHA is aware that are currently using this engine are operated in a two entry mine through a petition for modification. The petition for modification requires these machines to be permissible. If this was not the case, the two machines that are currently using this engine would be considered light-duty equipment. In a light-duty equipment application, the lower horsepower adjustment for this engine would not be as critical as when installed in a heavy duty machine.

MSHA contracted with Southwest Research Institute (SwRI) to determine the efficiency of a paper filter when installed on a Jeffrey dry system equipped with a Caterpillar 3306 PCNA diesel engine. Jeffrey's permissible system incorporates a heat exchanger and a synthetic type filter, but no oxidation catalytic converter. For the purpose of this verification test, a paper filter was substituted for the synthetic filter. In the setup for the verification test, as described below, the paper filter efficiency was determined.

Although most permissible equipment is cooled by a water scrubber, MSHA did not ask SwRI to verify filter performance with a water scrubber system actually in place. The agency has concluded that such verification is not feasible at this time. Laboratory testing of dpm removal efficiency with a water scrubber is very difficult due to the high moisture content of the exhaust. The high moisture content would cause interference in the measurement methods using laboratory dilution tunnels. Others have attempted this type of work on a limited basis, but in most cases, were not successful or the investigators did not repeat previous attempts. Accordingly, as noted under the next heading, MSHA will assume for compliance purposes that a paper filter whose efficiency is measured with a heat exchanger will work just as well when used with a water scrubber.

The paper filter installed on the Jeffery power package was acquired from Donaldson Filter Corporation. The filter paper was a standard primary air filter media, Donaldson Part No. EN0701026. When tested by Donaldson for use as a standard primary air filter media for many applications including diesel engine intake air filter, the paper has a particle removal efficiency of 32% for 0.5 micron particles, 60% for 1.0 micron particle, and 97% for 3.0 microns particles. This information was derived from data using neutralized KCL aerosol and on a test bench which complies with SAE J1669 requirements. The test was conducted on flatsheet media at 10.5 fpm face velocity. However, since the application of this paper filter media is unique to mining, the verification tests determined the efficiency when used in the cooled diesel exhaust stream (less than 300°F) to filter whole dpm (less than 1 micorn in size). The paper filter media used had performance specifications equivalent to the paper filter used on the DST® system. Moreover, it also is the same paper media which is used on the kits sold by Jeffrey and Wagner for installation of a paper filter on the exhaust of a water scrubber.

A standard ISO 8178, C1 eight-mode emission, test which is identical to the tests required by this final, rule was performed in three component configurations. The first configuration consisted of measuring engine-out emissions with no heat exchanger or filter attached to the engine. This was considered baseline dpm emission data. The second configuration consisted of routing the engine exhaust through the heat exchanger and filter housing with no filter installed. The third configuration consisted of installing a filter into the filter housing and routing the exhaust through the heat exchanger and then through the filter. The difference between the mass of diesel particulate measured at the outlet of the filter, and the baseline dpm emissions, enabled the collection efficiency of the filter to be determined.

The results of the verification conducted by Southwest Research Institute confirmed that a paper filter, without a catalytic converter, can reduce the dpm emissions of a Caterpillar 3306PCNA by 95%, down to a machine emissions rate of 2.3 gm/hr, thus meeting the 2.5 gm/hr standard. When the efficiency of the paper filter, as determined in the Southwest verification is applied to MSHA's approval data for these three permissible engines which make up almost all of the current permissible fleet, the 2.5 gm/hr standard is met. This is illustrated in the part of Table IV–1 dealing with permissible engines.

As can be seen in that table, machines equipped with the Isuzu QD–100 engine cannot meet the standard as currently operated. However, these engines can be derated from the highest power setting to a lower power setting and, with a paper filter, meet the emissions limit as shown by the second rating for that engine in the table. Since the paper filter used in the test has the same paper media as is generally used for dpm filters, MSHA has verified that the installation of a paper type filter alone will reduce the dpm concentration on all permissible machines currently in usage in underground coal mines.

A commenter who reviewed the report of the verification test conducted by SwRI raised two issues about relying upon the results.

One issue involves the dpm reduction from the heat exchanger. The results of the SwRI test indicated that there was a 9% reduction in dpm attributable to the heat exchanger. The commenter questioned whether the 9% attributed to the heat exchanger was also reported in the 95% reduction in dpm for the disposable paper filter. The test procedures required particulate measurements be made on bare engine emissions, with the heat exchanger in-line, and with the heat exchanger and disposable paper filter in-line. Comparing the particulate measurements made with the heat exchanger and filter installed to the measurements with only the heat exchanger installed, a 95% reduction in dpm concentration was observed.

The commenter also questioned the validity of the SwRI test because the results of two tests were different with the filter installed. MSHA is aware of the minor difference in test results. However, MSHA's interest is in the efficiency of a clean filter, not a used filter. The efficiency of a used filter is typically greater than the efficiency of a clean filter. The second test was the 8-mode test using the same filter tested in the first test. The filter was exposed to dpm for approximately four hours (time incurred in running the first test). MSHA expected this second test to perform similarly. In fact, on a percentage basis, the results were close, 94% versus 96%, as shown in figure 4 of the SwRI report. However, MSHA does agree with the commenter that the results would be expected to be closer. Although not documented on the SwRI report, the raw data did show an increase in the filter weight from the first 8 mode test. SwRI and MSHA hypothesize that a ''chunk'' of dpm may have dislodged from the filter paper during the test and biased the filter weight. As with any lab testing, further studies could have been done to investigate the difference. However, as noted in the next section, MSHA intends to use the results of this test as the basis for accepting as evidence of compliance with the standard for permissible equipment the use of a paper filter like that tested; accordingly, the agency believes it can proceed without this confirmatory data.

One commenter suggested that a standard adopted by MSHA would have to be adjusted with respect to equipment used at high altitude. This commenter stated that high altitude has an extreme effect on these types of filtration systems. This commenter's experience appeared to be related to catalytic converters. The commenter did not supply any data in supporting his position.

MSHA is aware of the effect of altitude on engine performance. Engine deration must be performed on most engines to compensate for the decrease in the density of air at increasing altitudes to maintain the proper fuel-air ratio. However, the effect on aftertreatment controls specifically claimed by the commenter is not supported by any scientific principle. MSHA has experience with the former BOM on the use of paper filters on permissible machines at a high altitude mine. These were very successful tests. MSHA is not aware of any problems with other types of filters, including ceramic filters. If a self regeneration problem is noted by a mine, then the mine could use acceptable alternative regeneration devices to clean the ceramic filters. MSHA believes that the machine's dpm emission levels specified in this final rule are feasible at high altitude mines and the mine operator has many options available to meet the standards. Moreover, as discussed in the next section, if an operator is using a paper filter that is consistent with that already tested by MSHA, the agency will find the machine in compliance. There is no requirement in the final rule for an ambient air test; the laboratory test will be used.

MSHA wishes to note that it did receive comments from some in the industry acknowledging that it was appropriate for the agency to force technology; and also received some comments from filter manufacturers to the effect that they could meet whatever requirements MSHA set. Moreover, many miners commented that the costs of controlling dpm should not factor into the human cost of overexposure to dpm.

In light of these comments, and the statute, MSHA did consider whether it would be feasible for the underground coal mining industry to meet tighter requirements than the 2.5 gm/hr standard chosen. However, as discussed in Part V concerning feasibility, MSHA recognizes that the underground coal mining community has certain other relatively new standards with which to comply and others pending; moreover, the dpm exposure generated by permissible equipment is only one dpm source in many mines that needs to be addressed. Accordingly, the agency believes that an effort to force technology on paper filters at this time would not be warranted.

How the mining community can go about implementing this requirement, and how MSHA can help. As explained above, MSHA has verified that a commercially available paper filter can reduce the emissions of any permissible piece of equipment to 2.5 grams per hour, and so has set the limit at that point. But the rule itself provides flexibility of controls, and there are many aftertreatment products on the market. Thus both MSHA and operators need a way to know whether a particular combination of controls will limit emissions to 2.5 grams per hour.

The emission rate of a machine will be determined by the engine baseline dpm concentration determined during the MSHA engine approval process. The engine baseline dpm data for each MSHA approved engine is already known to the Agency. For the convenience of the mining community, the Agency is adding this information to its approval listings currently on the agency's web site. This information for permissible engines is located at http://www.msha.gov/S&HINFO/DESLREG/1907b5.HTM.

Under the final rule, an operator can purchase any commercially available aftertreatment device and would, upon a request from MSHA, have to provide evidence that the device would reduce the emissions of the machine on which it is to be installed to the emission standard. However, in a majority of cases the mine operator will not be required to submit any data nor have any aftertreatment device tested. This is because MSHA will accept as evidence of compliance the use of any paper filter which meets or exceeds the specifications of the paper filter used in the verification described above; and, as noted in the discussion of that test, it appears that *most current paper filters designed to reduce dpm use exactly the same paper as that used in the system tested.* Thus, a mine operator can add almost any current paper filter to permissible machines without additional filter tests and be in compliance with the machine emission limit.

It should be remembered, however, that the agency has established criteria for filter media intended for use on permissible equipment that go beyond filtration efficiency. These criteria were established to ensure that the addition of the filter would not compromise the permissibility features of the machine. MSHA will continue to apply these criteria in conjunction with this rule. A list of paper filters meeting the permissibility criteria and which have the required efficiency will be posted on the MSHA web site as this information becomes available.

As noted above, MSHA's verification was conducted on a system whose exhaust was cooled by a heat exchanger, not a system whose exhaust was cooled by a water scrubber. MSHA recognizes that most permissible equipment is cooled by a water scrubber, and that MSHA has not verified filter performance with a water scrubber system actually in place. For the reasons noted, the agency has concluded that such verification is not feasible at this time. Since such verification is not feasible at this time, for purposes of implementing the rule, MSHA will assume that the results achieved with a filter tested on a dry exhaust cooling system apply equally to a system in which the exhaust is cooled by a water scrubber.

The modifications required for the addition of a paper filter to the permissible machines can be made without any additional filter efficiency tests being conducted by the mine operator or machine manufacturer. The addition of a paper filter to the exhaust of the existing permissible machines would be evidence that those machines meet the 2.5 gm/hr standard. The mine operator would simply purchase a paper filter kit from the manufacturer of the permissible machine or perform a field modification to add an equivalent paper filter to the permissible machines. Since the machines are permissible, any modifications would have to be evaluated to make sure that the permissibility aspects of the diesel power package are not affected. This would normally involve evaluation of the machine's total backpressure and the addition of a high temperature exhaust gas sensor to the safety shutdown system.

The process that mine operators may elect to follow to demonstrate compliance with the dpm standard is very similar to the process MSHA established for existing permissible machines when the 1996 diesel equipment rule was implemented. MSHA had four engines tested to determine a gaseous ventilation rate and particulate index for those engines. Mine operators only needed to update the machine approval plate to show the newly determined gaseous ventilation rate to continue to operate the existing permissible machine. The machine manufacturer normally supplied the updated plate.

To demonstrate compliance with the dpm rule, the mine operator need only add a filter kit supplied by the equipment manufacturer. Filter kits which have been evaluated for permissibility are available from machine manufacturers for approximately 222 out of the 481 permissible machines that are not already equipped with filters. In the event that a kit is not available for a particular machine, the mine operator may work with the machine manufacturer to adapt an existing kit, or fabricate a special kit. MSHA will expedite the evaluation of field modifications submitted by mine operators to add such kits.

One commenter stated that MSHA has not done enough with its knowledgeable personnel and research facility, and indicated that industry would welcome the opportunity to develop with MSHA research and development programs in the area of dpm filtration. MSHA has worked with NIOSH, labor representatives, and the industry in the past and is committed to continue to work with these groups on projects which promote a safer mining environment. The Diesel Toolbox arose out of just such an effort, as described in part II. But the Agency must also act to require the use of existing technology when it determines that miners are at significant risk of a material impairment to their health.

One concern expressed by the mining community about more extensive reliance upon paper filtration systems is the increased potential for fires if, for example, water scrubbers run dry and the exhaust gases then become hot enough to ignite the paper filters. Several commenters expressed concerns about reports of fires that occurred on permissible diesel powered equipment on which paper particulate filters had been installed. Commenters told of fires on equipment in both western and eastern mines and further stated that the fires were the result of a lack of maintenance. While MSHA is concerned about all fires in underground mines, fires on permissible equipment are of particular concern because that equipment may operate in areas of the mine where methane may be present.

Shortly after particulate filters were introduced, MSHA received reports of a filter fire in an underground mine and at a surface facility of a second mine. In the latter incident, the machine operator was unaware that a filter had been installed and continued to operate the equipment on the surface without water in the water scrubber. After looking into the incidents, MSHA issued a Program Information Bulletin informing the mining community of the importance of maintaining those components of permissible diesel power packages that limit the exhaust gas temperature below 170 degrees Fahrenheit. This PIB, P92–17, was published on October 23, 1992, and was given wide distribution throughout the country.

Until the public hearings on this rule, MSHA was not aware of any additional filter fires. MSHA has no additional information concerning incidents of fires in mines involving permissible diesel equipment with particulate filters. Maintenance personnel at one mine had related that several filters had been exposed to high exhaust gas temperatures and that the filter media had started smoldering. The smoldering had been accompanied by significant amounts of smoke which alerted the equipment operators. The equipment operators removed the filters and extinguished the smoldering material before any actual fire broke out. According to mine maintenance personnel, these incidents had occurred several years ago, and since improved maintenance procedures were established and additional training had been provided, no additional problems had been noted.

MSHA has continued to investigate this matter because of the potential consequences of a filter fire underground. MSHA is aware of a filter media used in Australia for the same application on permissible diesel equipment. The media is called Filtrete and is manufactured by 3M. The media is polypropylene and when exposed to a heat source, the media reportedly melts away rather than burns. Reportedly, the filter media is as effective at removing diesel particulate as the filters currently used on diesels with water scrubber systems. MSHA is in contact with the filter manufacturer, and with Australian mine regulatory authorities, and mine operators concerning their experience with the filters. MSHA has also reviewed the flammability characteristics of the filter media used on dry type permissible diesels. One such media is a fiberglass/polyester fabric which seems to have flammability characteristics similar to the Filtrete media.

As noted by at least one commenter, observing the recent diesel equipment maintenance requirements should minimize the already small potential for any problems. Nevertheless, MSHA will continue to look at alternative media, if for no other reason that to ascertain if they perform better than paper filters in removing dpm from the engine emissions.

Although operators can comply with this requirement by using a paper filter, MSHA would like to encourage the introduction of cleaner engines in permissible equipment. The rule does not deal directly with factors which may be discouraging operators from using engines which incorporate the latest technologies to reduce dpm emissions. In order for an engine to be used in underground coal mines in permissible equipment, the engine has to be approved by MSHA for permissible applications, and this process operates at the initiative of engine manufacturers rather than mine operators. MSHA notes that even though engine manufacturers are producing significantly cleaner diesel engines, engine manufacturers have not submitted applications to MSHA to have these newer engines approved for permissible applications prior to this final rule. There are 528 permissible diesel powered machines in underground coal mines. The majority of the permissible machines use the Caterpillar 3306 PCNA, Caterpillar 3304 PCNA, or the Deutz-MWM 916–6 diesel engines as stated previously. These engines are of older technology design and produce almost 10 times the dpm emissions as modern engines. However, due to the costs of obtaining approval of an engine for permissible applications, which are borne by the applicant, and low sales volumes in underground coal for permissible machines, engine manufacturers are understandably reluctant to submit new technology engines for approval as permissible.

MSHA is developing programs that would facilitate the availability of engines that utilize the latest technologies to reduce gaseous and particulate emissions for use in permissible equipment. Current engine designs that utilize low emissions technologies are currently approved by MSHA in nonpermissible form. Particulate emissions are currently being determined by third parties testing under 30 CFR, Part 7. MSHA is in the process of purchasing an engine particulate testing system. Once this system is installed, MSHA will be able to facilitate testing and defer some of the cost of diesel engine particulate emission testing at its Approval and Testing Center. MSHA is considering a number of other programs that could aid the industry with emission tests.

One of the programs that MSHA is considering would follow the precedent established in the recently published diesel equipment rule. To facilitate compliance with this dpm rule, MSHA is considering funding the additional emissions testing needed to gain approval as permissible, certain previously approved, non-permissible engines that utilize low emissions technology engines. Additionally, MSHA is considering waiving the normal fees that the Agency charges for the administrative and technical evaluation portion of the approval process.

Alternatively, MSHA may relax, as an interim measure, the requirement that engine approvals be issued only to engine manufacturers. This requirement, stated in part 7, is intended to ensure that the party to whom the engine approval is granted has the ability to ensure that the engine is manufactured in the approved configuration. MSHA is considering a program in which an equipment manufacturer may utilize an engine, approved by MSHA as nonpermissible, in a permissible power package. MSHA would ensure that the additional emissions tests required for permissible engines are conducted as part of the power package approval process. The use of an engine previously approved as nonpermissible is a critical element of the program. For those engines, the engine manufacturer has already made the commitment to manufacture the engine in an approved configuration. The permissible configuration would be the same as the nonpermissible configuration. Provisions of the two programs could be combined. MSHA will solicit input from the mining community as it continues to develop these program concepts.

In response to comments, MSHA also took another look at the other components added to diesel engines of permissible equipment. One such control on permissible equipment is the device used to cool the hot gases emitted by diesel engines to the temperatures required for permissible applications. Specifically, in order to use a paper filter, a means of cooling the exhaust gas must be installed upstream of the paper filter to reduce the exhaust temperature below the ignition temperature of filter media. This is accomplished on permissible machines with either a water scrubber or a heat exchanger. The water scrubber allows the water to contact the exhaust, thus cooling the exhaust to less than 170° F. The heat exchanger cools without direct contact between water and the exhaust, thus providing a dryer exhaust. Research conducted by others has shown that water scrubbers can lower dpm concentrations by 20–30%. The Southwest verification showed that a heat exchanger can remove approximately 9% of the dpm. Either cooling method would reduce dpm to some degree; however MSHA is confident, and the SwRI tests clearly showed, that the majority of the filtering comes from the paper filter.

One commenter asserted that the most important emissions control that could be placed on a piece of diesel equipment is a catalytic converter. While there is some evidence in the record suggesting that OCCs can remove up to 20% of dpm emissions, this commenter's assertions about the importance of this control appear to stem from the view that the hazards to miners from diesel emissions come primarily from diesel gases rather than the particulate emissions. As indicated in MSHA's risk assessment, the risks which MSHA is acting to prevent in this case are from particulate emissions. Catalytic converters alone could not reduce dpm emissions from permissible equipment to levels that MSHA deems necessary.

Time frames for implementation. Commenters were also concerned that the 18-month time frame established in the proposed rule to bring existing fleets into compliance would not be feasible.

In part, these concerns stemmed from technological feasibility—that controls did not yet exist which would be available by the required time. Also, these concerns related to economic feasibility. As noted above, some commenters thought they would have to replace wet systems with a dry system package in order to comply with the proposed rule; such a changeover would be expensive and, given the amount of work involved, take time. Others were concerned about the availability of filtration systems that would fit existing systems and the time necessary to develop or rig systems to fit on a variety of existing machines underground.

The evidence discussed above addresses these concerns. MSHA is not pushing technology with the proposed emissions limit; rather, the technology is already here and for many pieces of equipment already in kit form for ready installation. The costs to the industry as a whole of adding paper filter to the permissible fleet after 18 months are economically feasible as well.

Moreover, the final rule requires that a permissible piece of equipment being ''introduced'' underground for the first time 60 days after this rule is promulgated will have to be so equipped.

MSHA means by ''introduced'' any equipment added to the mine's diesel equipment inventory. That inventory, and any changes to it, must be recorded by an operator as a result of this rulemaking and be maintained pursuant to new 30 CFR 72.520. ''Introduced'' means newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

As a result of the information discussed above, MSHA has determined that this requirement is both technologically and economically feasible to require any newly introduced equipment to have the filter in place (see MSHA's REA for additional information). MSHA recognizes that in some areas, longwall moving equipment may be shared among mines, and that in one or two cases a scheduled longwall move could be impacted by this effective date; however, MSHA has concluded that by working with machine manufacturers, operators who find themselves in such a situation can avoid any disruptions.

72.501 Emission Limits for Nonpermissible Heavy Duty Diesel Powered Equipment, Generators, and Compressors

Organization. MSHA proposed limits on the dpm emitted by nonpermissible heavy-duty vehicles as part of 30 CFR 72.500, but in the final rule MSHA moved these requirements to a new 30 CFR 72.501. Also, this section now contains requirements for two types of light-duty equipment whose operating characteristics produce large quantities of dpm.

Summary of final rule. In the final rule, MSHA has adopted a machine emission limit for heavy duty diesel powered equipment, as defined by § 75.1908(a), just as it is doing with permissible equipment pursuant to § 72.500 of this final rule. It also applies this limit to generators and compressors.

Paragraph (a) specifies a machine emission limit for dpm at 5.0 gm/hr for heavy-duty equipment, generators or compressors introduced into an underground area of an underground coal mine more than 60 days after the date of publication of this final rule. ''Introduced'' means any equipment added to the mine's diesel equipment inventory.

Paragraph (b) provides that the fleet of such equipment already in a mine must reach a machine emission limit for dpm at 5.0 gm/hr within 30 months.

Paragraph (c) provides that the emission limit for all such equipment is further reduced to 2.5 gm/hr after 4 years.

Paragraph (d) exempts from the requirements of the rule any generator or compressor that discharges its exhaust directly into intake air that is coursed directly into a return air course, or discharges its exhaust directly into a return air course.

Why dpm emissions from heavy-duty equipment, generators and compressors need to be controlled.

As discussed in connection with § 72.500, MSHA determined that it could not establish a dpm concentration limit for underground coal mines, and therefore needed to focus its attention on the control of dpm emissions from specific types of equipment.

The preamble accompanying the proposed rule also explained why the agency was proposing to limit the emissions from heavy-duty equipment in particular. MSHA discussed earlier in the permissible section that engines used in permissible equipment generated large quantities of dpm. Many pieces of heavy-duty equipment utilize the same engines as permissible equipment and consequently produce similar high levels of dpm. MSHA closely examined the dpm emission rates from engines used in other heavy-duty equipment and found them to be as high as those rates found in permissible equipment. Furthermore, heavy-duty equipment is used in areas of the mine where the ventilation quantities may be less than those provided where permissible equipment is used. Equipment that moves long wall components is known to work at a high duty cycle, in close proximity to miners, and in areas of the mine where there are frequent ventilation interruptions. Numerous commenters stated that diesel emissions continue to be the cause of air quality problems during long wall moves. Even though newer engines are being added to the heavy duty fleet, additional controls are needed to further reduce the dpm levels to which miners are exposed. As shown in table IV–1, engines like the Deutz BF4M1012EC rated at 113hp and the Detroit Diesel Series 40 DDEC rated at 230 horsepower are low emission engines that have been designed to meet current EPA standards. However, the gm/hr levels are still higher than the MSHA standards and would require aftertreatment controls.

The proposed rule did not cover generators and compressors. However, the extension of the heavy duty requirements to generators and compressors stems directly from a question MSHA placed before the mining community. In reviewing alternative approaches considered by the Agency, the preamble of the proposed rule (63 FR 17564) noted that light-duty equipment does contribute to the total particulate concentration in underground coal mines, and explored the possibility of requiring light-duty equipment to be treated like permissible and heavy-duty equipment. The agency noted that it had tentatively concluded that requiring controls for the whole light duty fleet may not be feasible for the underground coal sector at this time. In this regard, it should be noted that light-duty equipment in underground coal mines makes up approximately ⅔ of the whole fleet: 2,030 engines out of the total MSHA inventory of 3121.

The Agency stated that it welcomed ''information about light-duty equipment which may be making a particularly significant contribution to dpm emissions in particular mines or particular situations, and which is likely to continue to do so after full implementation of the approval requirements of the diesel equipment rule.'' The Agency went on to say that: ''MSHA will consider including in the final rule filtration requirements that may be necessary to address any such identified problem.'' This discussion was repeated in the section by section review of the proposed rule. (63 FR 17556) The Agency reiterated its request for comments in this regard in its Questions and Answers (Q and A #10, 63 FR 17499).

As discussed below, based on the record, MSHA has concluded that generators and compressors, while considered light-duty equipment for purposes of the diesel equipment rule, in fact have operating characteristics that produce large quantities of dpm, and should be controlled in the same manner as heavy-duty equipment.

Numerous commenters spoke on the issue of whether light-duty equipment, as defined by the diesel equipment rule, should be subject to dpm emissions standards. However, the record is divided between those who asserted that this type of equipment really operates much like heavy-duty equipment—*i.e.,* works many hours during a shift at high loads—and those who asserted that the equipment is normally used at low loads and very little during the day. Very limited data was provided by proponents of either position; not enough for MSHA to make a clear determination of which position to adopt when looking at light-duty equipment as a whole.

Based on the record, MSHA believes that light-duty equipment is used in a variety of ways dependent on individual mine situations. The engine loading dependent on mine conditions can play an important role in the emissions from the diesel. Two different mining conditions with identical equipment could experience vastly different emission levels from these engines due to the engine load that must be produced to complete the work. Therefore the commenters may be correct for their individual mines where the light-duty equipment must work at higher engine loads to complete the work. However, other miners with identical equipment may not experience the same degree of engine load which could result in lower levels of exhaust emissions.

However, the situation becomes much clearer when the focus narrows to specific types of light-duty equipment. For example, one commenter noted that some light-duty equipment (such as air compressors) which was exempt from requirements in the proposed rule, emitted high levels of dpm as determined by emission analyzers. Another commenter stated that larger engines that have heavy duty loads produce more dpm per hour and should be controlled. The commenter specifically recommended an OCC, adequate ventilation, and soot (dpm) filters.

After a review of the information available, MSHA has concluded that air compressors and generators emit more dpm in the mine environment than other light-duty equipment because their engines are operated continuously under high-load conditions when they are running. Generators are designed to run under a loaded condition to produce electricity and air compressors work at full load to produce compressed air. In both cases, these engines are operating at a high load, which contributes to high dpm emissions. Based on the information provided by a commenter that the gaseous emissions levels from air compressors were high, this would correlate with high engine load and also would be related to higher dpm emissions. In addition, generators and compressors can use very large horsepower engines, *i.e.* above 200 horsepower; by comparison, permissible equipment generally does not exceed 150 horsepower. In fact, some of the highest horsepower engines in underground coal mines are in generators and compressors. For example, in Table IV–1 engines that are known to be used in generators and compressors are represented by approval numbers B018, B037, and B036 and have horsepower ratings of 500, 275, and 220, respectively. Accordingly, in the final rule MSHA requires that air compressors and the generators meet the same engine emission limits as established for heavy-duty equipment. MSHA's inventory indicates that there are 66 air compressors and generators out of a total of 3,121 pieces of diesel-powered equipment in underground coal mines—about 3% of the 2,096 light duty units.

Why the final rule uses a machine-based emission limit instead of requiring for a high-efficiency filtration system.

The proposed rule would have required mine operators by 30 months from the date of publication of the final rule to install, on nonpermissible heavy-duty vehicles, a system capable of removing, on average, at least 95% of dpm by mass.

The use of a machine emissions limit in the final rule stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based proposed rule. In that preamble, the Agency requested comment on an alternative approach that would establish a machine based limit on emissions in lieu of a filter efficiency requirement (see, *e.g.,* 63 FR 17556, 17563). In fact, a separate ''Question and Answer'' was included in the preamble to highlight this alternative, immediately after the description of the proposed rule. 63 FR 17501, 17653. Based on the record, MSHA has concluded that the original proposal had deficiencies (such as a credit for clean engines and a variety of filter efficiencies) which are avoided by the alternative approach.

As explained in connection with § 72.500, based on the record developed, the Agency concluded that a machine based emissions limit avoids a number of problems with the approach initially proposed. The explanation provided in that discussion as to (1) why MSHA moved to a machine based emissions limit for permissible equipment; (2) why it decided not to make adjustments for ventilation or permit an exemption for enclosed cabs; and (3) the flexibility in choice of controls provided to operators, is fully applicable for heavy-duty equipment, and accordingly is not repeated.

Why MSHA concluded that the emissions limit for heavy-duty equipment, generators and compressors should ultimately be 2.5 grams per hour. As with permissible equipment, the emissions limit for this type of equipment was determined with reference to technological and economic feasibility. As is evident from the final rule, the emissions limit is 2.5 grams/hour, the same as the permissible limit; and, like permissible equipment, 2.5 grams/hour represents a 95% reduction in the dpm emissions of the engine that produced the most dpm emission in this category.

MSHA wishes to emphasize that despite this fact, the limit in the final rule was not merely a determination to use the proposed rule in another form, or to have an equivalency between permissible equipment and this equipment. Rather, once MSHA decided to use an emissions limit approach, it reviewed the record to determine what could feasibly be achieved with the controls available for this type of equipment. Instead of using paper filters as with permissible equipment, this kind of equipment would generally be filtered by ceramic or other hot gas filters—or systems that lower the temperature of the emissions so that paper filters can be used. Ceramic filters cost more than paper filters, require regeneration, and have certain other associated costs. On the other hand, unlike the permissible fleet, the fleet of heavy-duty equipment, generators and compressors has many choices of approved engines available for use, many of them modern technology engines with significantly lower emission rates than the engines currently utilized in this equipment.

Table IV–1 shows the current dpm emissions from MSHA's inventory of heavy-duty equipment, generators and compressors based on engine approval data, and shows the filter efficiency required to reduce those emissions to the interim and final limits required by the final rule. Based on information about the current efficiencies of hot gas filters (discussed in the next section), MSHA believes that a significant percentage of the current fleet can immediately meet a limit of 2.5 grams/hour with such filters alone—and all of the current fleet, except equipment powered by the Caterpillar 3306PCTA, can move immediately to meet a limit of 5.0 grams/hour with filters of only that efficiency. And even in the highly unlikely case that filter efficiency does not continue to improve to meet new demands in Europe and for over the road hauling in the United States, operators can bring the remainder of the fleet into compliance with new engines and filters with present day performance capabilities. In fact, the only reason for the two-tiered approach adopted in the final rule is to ensure that implementation of the rule will be economically feasible.

Some commenters stated that the proposed rule is technology forcing and would require manufacturers to conduct approval tests to market new products, although some commenters who made this observation conceded that MSHA had the legal right to force technology. Another commenter stated that all heavy-duty equipment would require heat exchangers or equivalent means to allow for the use of paper filters since these, in the views of that commenter, appear at present to have higher filter efficiencies.

These comments have some credibility with respect to the original proposal, which would in essence have required the engines that produce the most dpm emission in this category to achieve a limit of 2.5 grams/hour with filters alone; although as noted above, there are already some hot gas filters that are approaching this result. However, the machine emission limits set forth in this section are clearly feasible with current technology, as cleaner, approved nonpermissible engines are available should a piece of equipment not be able to reduce dpm to the required limit with filter alone.

A number of commenters argued that MSHA should not establish a rule which might rely heavily on the availability of ceramic filters because such systems have not performed well from either a practical or efficiency standpoint. MSHA has been aware that in many cases the industry, especially the metal/nonmetal mining sector, has had problems with the use of ceramic filters. However, these problems were reported over 10 years ago when the ceramic filter technology was originally being developed for the on-highway truck engines. When the highway truck sector did not need ceramic traps to comply with the on-highway EPA regulations, significant work on these trap systems was abandoned for the on-highway sector.

More recently, the European directive requiring filters on diesels in confined areas, Canadian mines research with dpm filters, and the continued US efforts to reduce dpm emissions in the environment, have led filter manufacturers to improve the performance and reliability of ceramic filters. Some M/NM mines have reported favorably on the use of ceramic traps. Aftertreatment control vendors, mine operators and VERT have reported filter life of over 8000 hours. After a review of the information in the record in this regard, as was described in more detail in section 6 of Part II, MSHA has concluded that the more recent work with ceramic traps has shown they are feasible for use by the underground coal mining industry.

How the mining community can go about implementing this requirement, and how MSHA can help. While the rule provides flexibility of controls to reach the required limit (controls that reduce engine emissions, that is), most operators are going to utilize hot gas (ceramic) filters to comply. In some cases, however, installation of a cleaner engine or the DST® or similar modified dry system (one without the permissibility components) may be more cost effective, and will be permitted under this machine based rule. Therefore to determine whether a particular machine is in compliance, MSHA will generally need to know the emissions from the engine in the equipment and the filtration efficiency of the filter.

The dpm emission rate of an engine will be established by the dpm concentration determined during the engine approval process. The engine baseline dpm data for each MSHA approved non-permissible engine will be posted on the MSHA homepage at http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM.

Unlike the situation at present with permissible engines, in which none of the cleaner technology engines manufactured in recent years has been submitted for approval for permissible use, engine manufacturers have been submitting applications for approval of nonpermissible engines which meet EPA standards for both on road and nonroad applications. Thus, mine operators have the option of significantly reducing dpm emissions from heavy-duty equipment, generators and compressors by switching to cleaner approved engines. Moreover, MSHA is planning to accelerate the process of approving such engines so as to ensure that equipment of all sizes and shapes can utilize the cleanest engines available.

MSHA is developing a program which will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA approval programs for engines used in off-road applications. MSHA will continue to issue approvals for mining engines, but the application process will be abbreviated. Many of the provisions of part 7 are intended to ensure that engines continue to be manufactured in the same configuration and with the same emissions as the engine tested by MSHA. Procedures within the EPA approval programs reach the same end. Additionally, EPA has the resources and the regulatory authority to conduct an extensive quality assurance program to monitor emissions from production engines.

In addition to streamlining the application process, MSHA will establish a program under which the engine emission tests conducted for EPA approval will satisfy the part 7 testing requirements. The test cycles under which emissions are tested for both MSHA and EPA are identical, and the gaseous emission results from the EPA tests can be used to establish the ventilating air quantity that appears on the engine approval plate and is referenced in mine ventilation regulations. MSHA will announce the specifics of the program when it is finalized.

As noted in the prior section, MSHA expects that most operators will turn first to hot gas filters to reach the interim or even the final limit. Technically, an operator using a commercial filtration device would, upon a request from MSHA, have to provide evidence that the device is capable of reducing the emissions of the machine on which it is to be installed to the emission standard. The procedures by which a mine operator will demonstrate compliance with the rule are described in detail in the discussion of 30 CFR 72.503 of this part. However, the particulate removal efficiency of many commercially available hot gas filters is evaluated by VERT. VERT is a joint project of several European regulatory agencies, and private companies involved in the tunneling industry. VERT maintains facilities for the testing and evaluation of diesel engine aftertreatment devices for use on equipment used in tunneling. MSHA will accept dpm filtration efficiencies determined by VERT under the provisions of 30 CFR 72.503(c) of this rule.

VERT evaluates the filtration efficiency of candidate devices using a diesel engine with an average dpm production of 0.08 gr/hp-hr. This engine produces less dpm than the majority of engines approved by MSHA. As further discussed in section 72.503, the test must be conducted on an engine that emits no more dpm than the engine that the aftertreatment device will be used on in the machine. This is to ensure that ''dirty'' engines are not used to over estimate a filter efficiency. The VERT engine used is considered a clean engine by current production standards and clean when compared to many engines in the current underground fleet. The assigned filter efficiencies from VERT would not be considered over-rated and would be consistent with expected efficiencies when used on current underground engines. Consequently, the filter efficiency determined by VERT test can be used to establish the machine dpm level in order to comply with 72.503(b)(i).

MSHA received some comments suggesting the agency could not rely upon the most recent VERT test data (listed in Table II–4) because not enough is known about how those results were derived. MSHA agrees that more information about the test data would be useful; however, given the purposes for which the agency is relying upon the data, the agency believes the information it currently has on the test data are adequate. This information is discussed in section 6 of Part II. The VERT data is generated through procedures as stringent as those MSHA is requiring in the tests which are being established in the final rule for filters not tested by such an organization. While the results noted in Table II–4 have not been incorporated into a published article and has references that are in other sources, MSHA's review of other VERT papers shows that VERT is using the same nomenclature in all their reports and the pertinent information needed from the table is available from these other VERT papers. The table shows VERT results on filters tested ''new'' and after field test. MSHA is only concerned with the ''new'' filter efficiency data for applying a filter efficiency number to the baseline engine emission data in order to determine if the machine meets the machine emission limit specified in this final rule. The range of filter efficiencies is not critical since the operator can choose a filter system based on the need for the engine for each individual machine.

MSHA will maintain a list of dpm filtration devices and their filtration efficiencies on its website at www.msha.gov to assist the mining community. Where the particulate reduction capability of an aftertreatment device is not known, the operator would have to have the system tested at a laboratory capable of performing the tests as described in 30 CFR 72.503 of this rule to obtain the necessary data. However, in a majority of cases the mine operator will not be required to submit any data nor have the aftertreatment device tested. Since ceramic filters are used in general industry and automotive applications worldwide, extensive information on filter efficiency is available and a variety of hot gas filters are commercially available.

The two tier machine emission limits provide operators with a choice when making initial control decisions—whether to select a control that will bring the equipment into compliance with the interim limit first, or whether to go ahead and purchase controls that will be required in any event by the final emissions limit. MSHA envisions that the mine operator will in most cases make a single decision as to the options to select to bring the machine into compliance. If the machine is old and is expected to reach the end of its useful life in 4 years or less, the mine operator may choose a less costly set of options with the intention to scrap the machine when the lower emission level is effective. However, if the machine has a life expectancy beyond four years, then the mine operator may choose to install a filter system/engine combination that will meet the 2.5 gm/hr standard immediately. Moreover, MSHA has reviewed the VERT list and it identifies several filter systems that can be purchased that have sufficient efficiency ratings to meet the 2.5 gm/hr standard when matched to the majority of the MSHA approved engines in heavy-duty equipment, generators and compressors. MSHA anticipates that more such high efficiency filters will become available before the final emissions limit must be reached. Accordingly, some operators may be able to satisfy the requirements in this fashion.

Yet another alternative that can currently enable heavy-duty equipment to reach the 2.5 gm/hr final limit is the DST® system. Test data was submitted for the record showing an overall system efficiency of greater than 95%. While more costly than hot gas filters, this approach might in some cases be cheaper than a high efficiency hot gas filter and a new engine.

The final rule prohibits any piece of nonpermissible heavy duty diesel powered equipment, generator or compressor, from exceeding 5.0 grams per hour of diesel particulate emissions. MSHA believes that by working with manufacturers of aftertreatment systems, filters can be installed so that newly manufactured machines comply with this requirement. MSHA expects that new equipment, or any equipment with an expected service greater than four years will be provided with a filter capable of meeting the 2.5 gm/hr machine standard.

Section 72.502 Requirements for nonpermissible light-duty diesel powered equipment other than generators and compressors

Organization. The proposed rule did not contain specific provisions for light-duty diesel powered equipment. However, in the preamble to the rule, the agency asked the mining community if light-duty equipment should be subject to provisions that would address dpm emissions. This section is new in the final rule and is based on the large response from the mining community to that question.

Summary of final rule. Paragraph (a) of this section provides that light-duty equipment (other than generators or compressors, which are covered by 30 CFR 72.501) introduced into an underground area of an underground coal mine more than 60 days after the issuance of the final rule cannot emit more than 5.0 grams/hour of dpm. MSHA means by ''introduced'' any equipment added to the mine's diesel equipment inventory. That inventory, and any changes to it, must be recorded by an operator as a result of this rulemaking and be maintained pursuant to new 30 CFR 72.520. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another, but it does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt. MSHA will exempt newly manufactured light-duty equipment from meeting the requirements in 30 CFR 72.502, if the equipment is received after the 60 day time frame as long as a mine operator can present evidence that the equipment was ordered prior to the date of publication of this final rule.

Paragraph (b) provides that an engine will be deemed to be in compliance with this requirement if it meets or exceeds certain EPA dpm emission requirements listed in Table 72.502–1 which appears in the rule.

Paragraph (c) excludes any diesel-powered ambulance or fire fighting equipment that is being used in accordance with the mine fire fighting and evacuation plan from the requirements of this section.

Why the final rule covers newly introduced light-duty equipment. The final rule's coverage of newly introduced light-duty equipment stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based rule that was proposed.

In reviewing alternative approaches considered by the Agency, the preamble of the proposed rule (63 FR 17564) noted that light-duty equipment does contribute to the total particulate concentration in underground coal mines, and explored the possibility of requiring light-duty equipment to be treated like permissible and heavy-duty equipment. The agency noted that it had tentatively concluded that requiring controls for the whole light duty fleet may not be feasible for the underground coal sector at this time. In this regard, it should be noted that this type of equipment in underground coal mines makes up approximately ⅔ of the whole fleet: 2096 engines out of the total MSHA inventory of 3121.

The preamble further stated that the Agency welcomed ''information about light-duty equipment which may be making a particularly significant contribution to dpm emissions in particular mines or particular situations, and which is likely to continue to do so after full implementation of the approval requirements of the diesel equipment rule''. As noted in connection with 30 CFR 72.501, the record on this point led MSHA to treat light duty generators and compressors the same way as heavy duty nonpermissible equipment in the final rule.

The preamble to the proposed rule also indicated MSHA's specific interest in exploring whether it would be feasible to require controls on just the new equipment being added to the light duty fleet. ''The Agency would also welcome comment on whether it would be feasible for this sector to implement a requirement that any new light-duty equipment added to a mine's fleet be filtered.'' The Agency further noted that limiting a filtering requirement to just this portion of the light duty fleet was a different issue in terms of economic feasibility than filtering the whole fleet. ''By way of rough cost estimate, if turnover is only 10% a year, for example, the cost of such an approach would be only about a tenth of that for filtering all light-duty outby.'' 63 FR 17564. This discussion was repeated in the section by section review of the proposed rule. (63 FR 17556) The Agency reiterated its request for comments in this regard in its Questions and Answers (Q and A #10, 63 FR 17499).

As noted in the discussion of 30 CFR 72.501 of this part, MSHA received considerable comment on whether the light duty fleet as a whole should be covered. In a significant number of mines, the light duty fleet may work under heavy loads for considerable periods of time, resulting in localized intensive exposures. But it would also appear that in other mines this is not the case; moreover, many of the experiences with localized exposures may have been due to maintenance problems, as the diesel equipment rule with its requirements for maintenance had yet to go into effect.

Also, many miners commented that large numbers of light-duty equipment were in the same area of the mine on occasion and their emissions were not adequately diluted by the ventilation air provided. MSHA believes these comments were made based on experience gained before the effective date of the ventilation requirements under the diesel equipment rule.

Section 70.1900(a)(4) of the diesel equipment rule now allows the district manager to establish areas in the mine where air quality samples for gases must be collected to identify and correct problems such as those described. Even though the focus in 30 CFR 70.1900(a)(4) is on gaseous emissions, the point is that a buildup of gaseous emissions would be an indication of a build up of diesel emissions generally and thus, of the inadequate ventilation that was the concern of the commenters.

The comments about the light duty fleet as a whole were not particularly helpful in evaluating the agency's specific request for comment on whether it would be feasible for this sector to implement a requirement that the emissions from any new light-duty equipment added to a mine's fleet be limited. Nevertheless, as noted in Part III, the best available evidence is that a significant risk of adverse health effects due to dpm exposures will remain even after this rule will be implemented. Since the Agency is under a legal obligation to eliminate significant risks to the extent feasible, the Agency determined it should conduct a further analysis of the feasibility of limiting emissions from newly introduced light-duty equipment into underground coal mines. The service life of light-duty equipment (*e.g.,* pickup trucks) is roughly ten years—much shorter than other types of equipment which is often rebuilt underground. Accordingly, if the engines in the new equipment are cleaner than the ones in the old equipment, the dpm emissions in the mine can be lowered over this period of time without the need to place controls on the existing fleet.

MSHA then examined the kinds of engines that were likely to be in new light-duty equipment, as compared with the engines in the current light duty fleet. It turns out that there is likely to be a major difference. Many of the engines in the current fleet were designed and produced before the advent of EPA emission standards. Almost all of those engines likely to be available for introduction underground in the future will be subject to such standards. Accordingly, MSHA has determined that if newly introduced light duty engines or equipment are limited to more recent models, the dpm emissions from the new light duty fleet will eventually be significantly less than from the current fleet. The service life of light-duty equipment (*e.g.,* pickup trucks) is roughly ten years—much shorter than other types of equipment which is often rebuilt underground. As explained in the next section of this discussion, MSHA determined that requiring all light-duty equipment introduced underground in the future to comply with these standards is feasible; the engines required to meet the requirement are available in all types and sizes. Accordingly, the agency decided that the record warranted adoption of the alternative it had placed before the mining community, and the final rule establishes emission standards for newly introduced light-duty equipment.

How did MSHA determine the emissions limit for newly introduced light-duty equipment? MSHA examined whether it could establish the standard for newly introduced light-duty equipment at the same level as the standard it is establishing for newly introduced heavy-duty equipment, generators and compressors. In this regard, the agency looked at two sets of existing requirements to determine what types of engines used in light-duty equipment are readily available today, and then set the standard accordingly. First, the agency looked at current MSHA approval standards, and then it looked at current EPA standards.

The record indicated that equipment in the light duty fleet may be used to the extent that the dpm emissions from these vehicles could contribute to overall mine air quality in a manner similar to heavy-duty equipment. However, an equal number of commenters stated that light-duty vehicles are not used very much except for transporting miners in, out, and around the mine on a limited basis. MSHA believes that mines utilizes their light duty fleet in various ways depending on the individual mine conditions, fleet management, and standard operating practices. Also MSHA believes that many light-duty vehicles are operated in areas of the mine where the ventilation rate exceeds the approval plate quantities. Because MSHA did not receive sufficient information to establish the need to control dpm emissions from light-duty equipment to the same degree as required for heavy duty or permissible equipment, MSHA established a new approach. MSHA determined that no action needs to be taken to modify equipment in the existing light duty fleet. However, MHSA wanted to ensure that steps be taken to limit the dpm emissions from any light-duty equipment introduced into mines. The steps would include purchasing equipment that uses engines representative of the state-of-the-art in emission control that are commercially available. These engines would be the type that are being manufactured to comply with the current EPA standards for diesel engines for both on-highway and nonroad applications. MSHA also recognized that manufacturers of mine specific vehicles currently utilize engines of older design that would not meet the EPA standards. Manufacturers of this equipment could continue to use these engines with appropriate after treatment of the exhaust to limit the dpm emissions.

In its deliberations to determine the emissions standard that was required to be met by heavy-duty equipment, MSHA also determined that engines in existing light-duty equipment could be provided with commercially available aftertreatment controls to reduce the dpm emissions to 5.0 gm/hr. In fact, some light-duty equipment with relatively low horsepower engines can meet a 5.0 gm/hr standard without any aftertreatment controls.

Some existing light-duty equipment built specifically for mine use is representative of equipment that will probably continue to be introduced into the mines. This type of light-duty equipment will continue to use engines that would not meet the EPA dpm standards. Hence for any such equipment introduced into an underground coal mine after the effective date, aftertreatment will be required.

Consequently, MSHA established the 5.0 gm/hr standard for any light-duty equipment introduced into mines after the effective date of the rule.

As stated above, part of the approach established by MSHA for light-duty equipment was to ensure that introduced light-duty equipment would be provided with engines representative of the state of the art in emission control that are commercially available. These engines would be the type that are being manufactured to comply with the current EPA standards for diesel engines for both on-highway and nonroad applications.

As noted in section 5 of Part II, the EPA emission standards are established for light-duty vehicles and trucks, heavy duty highway engines, and nonroad engines. These requirements take effect for new production runs of engines at various times depending on engine type and size. MSHA recognizes that introduced equipment provided with these engines may exceed the 5.0 gm/hr standard. However, the engines being built to meet the EPA standards represent the state of the art in emission controls that are feasible to limit diesel exhaust emissions for those sizes of engines. MSHA did not intend to require aftertreatment controls on introduced light-duty equipment. MSHA believes that as long as mine operators purchase equipment with these new engines, the in-mine dpm concentrations will be reduced as the existing light-duty equipment fleet is replaced.

MSHA has established an exception in 30 CFR 72.502(b) that would allow mine operators to introduce equipment powered by engines that meet the EPA standards listed in Table 72.502–1 in lieu of meeting the 5.0 gm/hr standard given in 72.502(a). MSHA also knows that the EPA intends to tighten the emission standards for new diesel engines. As engines meeting these future requirements are produced, they will also become available for use in mining equipment, thus the overall contribution of dpm from the in-mine light-duty equipment should decrease even further.

MSHA has already approved engines produced by a variety of engine manufacturers in a wide range of horsepowers that meet the EPA standards listed in Table 72.502–1 of this part. These engines are shown on Table IV–1 by an asterisk (*).

Many pickup trucks used in underground coal mines use engines that would be classified by the EPA as ''heavy duty highway engines''. Consequently, if the engine was produced after 1994, it has met the EPA emissions standard of 0.1 g/bhp-hr shown in table 72.502–1. MSHA believes that the mining community is not likely to have any problem finding a pickup truck that meets the standard. Many pickup trucks can be moved from mine to mine and meet the standard.

This is basically the same for any on-highway engine the EPA classifies as a ''light-duty vehicle'' or ''light duty trucks''. If manufactured in or after model year 1994, the vehicle or truck must be limited to a dpm output of 0.1 gr/mile and meets the EPA requirement. However, there are no such vehicles currently in use in mines.

Mine operators frequently purchase equipment for use in underground coal mines that come with engines which are categorized by EPA as nonroad engines for use in underground coal mines. This includes both industrial equipment and mine specific equipment such as forklifts, rockdusters, tractors, pumps, manlifts, personnel carriers, and welders. EPA's requirements on nonroad engines vary by horsepower. As discussed in part II of this preamble, EPA originally regulated these engines at standards referred to as tier 1. The most recent standards that are scheduled to become effective for these engines are designated as tier 2 standards. Many of the engines used in this equipment will soon be meeting the EPA tier 2 dpm limits as a result of the 1998 rulemaking by that agency. MSHA chose the tier 2 standards in 30 CFR 72.502(b) of this part since they will represent the most advanced technologies for emission controls. As previously stated, some nonroad engines are already being produced which meet the tier 2 requirements and have been approved by MSHA. Approximately two-thirds of the nonpermissible MSHA approved engines meet the tier 2 standards. The exact EPA emission limits for each tier for each engine size category are listed in Table 72.502–1 of the final rule which is reproduced here in the preamble for reference:

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TABLE 72.502-1: EPA's Requirements on Nonroad Engines

EPA Requirement	EPA Category		PM Limit
40 CFR 86.094-8(a)(1)(I)(A)(*2*)	light-duty vehicle		0.1 g/mile
40 CFR 86.094-9(a)(1)(I)(A)(*2*)	light duty truck		0.1 g/mile
40 CFR 86.094-11(a)(1)(iv)(B)	heavy duty highway engine		0.1 g/bhp-hr
40 CFR 89.112(a)	Tier 2 nonroad		varies by power:
	kW<8	(hp<11)	0.80 g/kW-hr (0.60 g/bhp-hr)
	8≤kW<19	(11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr)
	19≤kW<37	(25≤hp<50)	0.60 g/kW-hr (0.45 g/bhp-hr)
	37≤kW<75	(50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr)
	75≤kW<130	(100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr)
	130≤kW<225	(175≤hp<300)	0.20 g/kW-hr (0.15 g/bhp-hr)
	225≤kW<450	(300≤hp<600)	0.20 g/kW-hr (0.15 g/bhp-hr)

Notes: "g" means grams "kW" means kilowatt
"hp" means horsepower "g/kW-hr" means grams/kilowatt-hour
"g/bhp-hr" means grams/brake horsepower-hour

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In this final rule, operators have the option to meet the requirements of the standard by installing filters on newly introduced light-duty equipment. For example, an operator wishing to take an existing piece of light-duty equipment whose emissions exceed 5.0 grams/hour from one mine and use it in another mine could do so if the machine is equipped with a filter or catalytic converter efficient enough to bring the emissions down to 5.0 grams/hour. MSHA anticipates that the majority of mine operators will choose to purchase equipment with MSHA approved engines meeting the EPA dpm standards. Some models of small utility equipment might be difficult to filter, so the mine operator will probably choose to introduce this type of equipment with an engine that meets EPA requirements. However in some cases where an engine which complies with the 5.0 g/hr standard or the EPA requirements is too expensive or hard to use for a specific machine application, a filter system can be designed in during the construction of the vehicle instead of a retrofit.

The Agency wishes to emphasize that it is not barring operators from introducing used equipment into an underground coal mine simply because it is used. As noted in the examples above, many of these EPA requirements have been in place for a while, so operators should have a wide choice of equipment from which to choose, and in other cases there are MSHA approved engines that will meet the standards.

MSHA will undertake other actions to further facilitate compliance with this standard. As noted above, MSHA is enabling operators to comply with this standard by selecting engines or equipment that comply with various EPA standards. However, under the diesel equipment rule, all engines used underground have to be approved by MSHA. Accordingly, MSHA is reviewing actions that could be taken to facilitate the approval process when an engine meets EPA standards.

As was described earlier in the discussion of the heavy-duty equipment requirements, MSHA is developing a program which will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA testing procedures (currently used only in the certification program for nonroad engines). MSHA will announce the specifics of the program when it is finalized. This program, when implemented, will assure mine operators and mining equipment manufacturers of the availability of low emissions engines, approved by both MSHA and EPA, in a wide range of horsepowers with which they can easily comply with the dpm requirements for light-duty equipment.

Exemption for ambulances and fire fighting equipment. Paragraph (c) of this section excludes from these requirements diesel powered ambulance and fire fighting equipment being used in accordance with the mine fire fighting and evacuation plan under 30 CFR 75.1101–23. This is done in the same manner as MSHA excluded this type of equipment in the diesel equipment rule. This exclusion ensures consistency between this rule and the diesel equipment rule.

Section 72.503 Determination of Emissions; Filter Maintenance

Organization. This section is added to the final rule to specify the means to determine and maintain compliance with the machine emission limits established in this part. The requirements of this section revise and refine provisions included in the proposal under 72.500(c) and (d). The requirements have been moved to a separate section because they are relevant to the requirements of several other sections—30 CFR 72.500, 72.501 and 72.502.

Engine emissions. Section 72.503(a) of the final rule specifies that the amount of dpm emitted by a particular engine shall be determined from the engine approval pursuant to 30 CFR 7.89(a)(9)(iii)(B) or 7.89(a)(9)(iv)(A), except for those engines in light-duty equipment deemed to be in compliance with the requirements of this rule pursuant to 30 CFR 72.502(b).

This approach using part 7 engine approval data was inherent in the requirements of proposed 30 CFR 70.500(d). The current formulation refines the requirement to make it more clear and extends coverage to the EPA approval program.

MSHA currently lists all part 7 engine approvals on the Internet. The web addresses have been previously listed in this section. To assist mine operators in complying with the provisions of this rule, MSHA will add the dpm grams per hour number for each approved engine based on the approval test data. This number is calculated from the equations in 30 CFR 7.89(a)(9)(iii)(B) or 7.89(a)(9)(iv)(A) which are direct results of tests conducted for determination of the particulate index. This value will be used as an engine's baseline dpm concentration; the efficiency of the filter will then be multiplied by this baseline dpm number to establish compliance with the machine's emission limit under the appropriate section of this rule. MSHA will use the gm/hr data obtained from the MSHA approval data and not the gm/hr data determined from other filter tests that determine the efficiency of the filter being tested. Results from different engine configurations or different laboratories could give results that could prevent the mine operator from showing compliance. The data could also be different if the tests were run differently from the approval test.

Laboratory test procedures for testing aftertreatment devices; MSHA acceptance of results of other organizations. Section 72.503(b) of this final rule provides that the efficiency of an aftertreatment device is to be established by a laboratory test with a device representative of that to be used—and not by an actual test at the mine site on a particular filter. The test of the aftertreatment device is to be on an approved engine that emits no more dpm than the engine in the machine on which the aftertreatment device is to be used. If the filter test were run on an engine with higher emissions, the filter is likely to be rated as having a higher efficiency than it does when installed on an engine that produces lower emissions. This is consistent with the views of those commenters who objected to the proposal to establish a 95% efficient filter standard on the grounds that they would not be able to maintain such an efficiency as cleaner engines are introduced. The engine is to be run on the same test cycle used for MSHA approvals. The test procedure to follow must be appropriate to the filter media being tested. Furthermore the test is to be done by a laboratory capable of testing engines in accordance with MSHA approval requirements, to ensure consistency among testing and results.

Although these requirements provide the specifications for filter efficiency tests, MSHA does not believe that many filter tests will need to be run in order for mine operators to comply with the requirements of this rule. A key reason is that 30 CFR 72.503(c) allows the Secretary to accept the results of tests conducted or certified by an organization whose testing standards are deemed by the Secretary to be as rigorous as those set forth in 30 CFR 72.503(b). Also, the Secretary may accept the results of tests for one aftertreatment device as evidencing the efficiency of another aftertreatment device which the Secretary determined to be essentially identical to the one tested.

With respect to hot gas filters, the agency has already indicated (in the discussion of 30 CFR part 72.501) its intention to accept the efficiency results of any filter tested by VERT—

notwithstanding their use of somewhat different test procedures. MSHA will provide additional information on how mine operators can easily obtain the filter efficiency data from VERT in the compliance guide for this rule.

Moreover, the record of this rulemaking contains data establishing the efficiency of both the DST® system and paper filters. Both of these were tested by SwRI in tests meeting the requirements of this section. MSHA has indicated (in the discussion of proposed section 72.500 of this part) that it will accept as having the same efficiency as the paper filter it tested, any filter using the same or equivalent media. Such filter paper appears to be used for the production of a variety of filters. Consequently, effective filters will be readily available.

The filter efficiency test procedure stated in this final rule is basically the same as that procedure specified in the proposal. This test procedure follows the test cycle specified in part 7, subpart E, for determination of the particulate index. This test is similar to the test procedure used by VERT. VERT has streamlined their test procedure to minimize testing time but retained the main dpm producing modes on the steady state test cycle. The MSHA test procedures in part 7, subpart E were originally adapted from the ISO 8178 procedures. VERT actually follows the test procedures in ISO 8178.

Several commenters questioned whether the ISO 8178 is an appropriate test for performing the filter efficiency tests, but offered no suggestions as to a cycle which should be used. Other commenters stated that the ISO 8178 is the best test at this point in time for conducting the filter efficiency test since no other cycle is available. Because ISO 8178 is an internationally accepted test cycle for evaluating diesel engine emissions, MSHA is retaining the ISO 8178 test procedure in this final rule. However the rule does allow the Secretary to accept data from tests.

MSHA will maintain a list (posted on its web site) of additional sources from which mine operators and inspectors can obtain the necessary information, including aftertreatment manufacturers who follow testing procedures MSHA deems meet its requirements. Mine operators will have to show evidence that for each particular machine, the engine baseline data multiplied by the filter efficiency will meet the appropriate standard. Any questions on acceptance of a filter manufacturer should be made prior to purchasing of the filter media. The mine operator may want to contact MSHA's approval and certification center located at Triadelphia, WVA to determine that the filter efficiency data is acceptable prior to purchasing, especially if the filter data is not from VERT or from a source listed by MSHA.

One commenter stated that industry was concerned that laboratory tests of filters may give invalid indication of filter efficiency. MSHA believes that the filter test should be appropriate to the media; that is the aftertreatment device should be tested with the contaminant that is being controlled. The aftertreatment industry has been testing filters in the laboratory for many years in development of their products. In the case of ceramic type filters, MSHA is not aware of any types of tests performed on ceramics that does not use dpm from the diesel exhaust. Aftertreatment control manufacturers that build dpm control devices test their systems for various applications worldwide, through both laboratory and field work.

Other types of filter media (*e.g.,* paper) have been developed by the mining industry for use on permissible equipment which is specific to mining. General industry does not use paper for dpm reduction due to the high exhaust gas temperatures from diesels. Paper filters are mainly produced as intake air cleaners and industry test standards for determining air cleaner efficiency are followed. Since these filters are mainly used for intake air filters, MSHA believes that industry standard intake air filter tests could be representative tests for this type of filter media when used for dpm reduction. MSHA would compare the paper specifications to determine equivalency. If the papers were equivalent, then air filter type tests would be acceptable to the Secretary for this type of media.

Aftertreatment device maintenance requirements. Section 72.503(d) of this rule states that any aftertreatment device installed on a piece of diesel equipment, upon which the operator relies to remove dpm, shall be maintained in accordance with manufacturer specifications and shall be free of observable defects. Except for the last phrase, which was added by MSHA in order to clarify the requirement for the mining community, this requirement was specified in the proposal under section 72.500(d).

One commenter requested that MSHA also require an on board engine performance and diagnostic system. MSHA is aware that some permissible machines have added electronic type shut down systems and electronic controlled fire suppression systems. On some newer nonpermissible engines, especially larger engines, engine manufacturers use electronic controls to regulate the engine's fuel injection timing and governing. Engines equipped with these electronic devices typically have complete diagnostic capability. MSHA believes as engine technologies develop, more engines will have diagnostic systems built in from the manufacturer. MSHA is not requiring in this final rule on board engine performance and diagnostic systems on equipment. However, MSHA will work with engine manufacturers under the part 7 approval process to evaluate new electronic controls, especially for permissible engines.

Other commenters stated that maintenance is part of the toolbox approach, and therefore ought not to be specifically included. MSHA has a requirement in the current diesel equipment rule to maintain diesel powered equipment in approved and safe condition or be removed from service. This final rule is extending the requirements for maintenance specifically to aftertreatment controls added to the machines to reduce dpm.

Section 72.510 Miners Health Training

Paragraph (a) of this section requires annual hazard awareness training of underground coal miners who can reasonably be expected to be exposed to dpm. Paragraph (b) includes provisions on records retention, access and transfer.

Section 72.510(a) of this rule would require any underground coal miner ''who can reasonably be expected to be exposed to diesel emissions'' be trained annually in: (1) The health risk associated with exposure to diesel particulate matter; (2) the methods used in the mine to control diesel particulate matter concentrations; (3) identification of the person responsible for maintaining those controls; and (4) actions miners must take to ensure the controls operate as intended. The final rule is the same as that proposed.

The purpose of these requirements is to promote miner awareness. Exposure to diesel particulate is associated with a number of harmful effects as discussed in Part III of this preamble, and the safe level is unknown. Miners who work in mines where they are exposed to this risk must be reminded of the dpm hazard to make them active and committed partners in implementing actions that will reduce that risk.

Several commenters expressed concern about which miners will be required to be trained. MSHA believes the rule is clear on this issue. The training need only be provided to underground miners who can reasonably be expected to be exposed to dpm at the mine. The training is to be provided by the operator; hence, it is to be without cost to the miner.

The rule places no constraints on how the operator should conduct this training. MSHA believes that the required training can be provided with minimal cost and with minimal disruption. This final rule does not require any special qualifications for instructors, nor does it specify the hours of instruction.

One-on-one discussions that cover the required topics is one approach that can be used. Alternatively, instruction could take place at safety meetings before the shift begins. Several of the training requirements can be covered by simply providing miners with a copy of MSHA's ''toolbox.'' Operators may determine how the ''toolbox'' can be used at their mine.

The Agency requested comments concerning inclusion of dpm training in the required part 48 training plan. The only comment received suggested that this training be included in the part 48 training and removed from this rule. MSHA considered whether the requirements of part 48 were adequate to ensure the training required under the final diesel particulate standard. After careful consideration, MSHA concluded that available information provided to miners under current part 48 training would be inadequate to fully convey information under the diesel particulate final rule. MSHA will, however, accept part 48 training for compliance with diesel particulate training requirements under this section, provided mine operators fully integrate the requirements of diesel particulate training into their existing program.

Section 115 of the Federal Mine Safety and Health Act of 1977 and 30 CFR part 48, ''Training and Retraining of Miners,'' requires operators to submit to MSHA and obtain its approval of training plans under which miners are provided training, primarily through initial and annual refresher training courses. Part 48, among other things, also specifies qualifications for training instructors, minimum training hours for miners and instruction on particular topics which must be covered within the specified minimum training time. Existing section 48.8(a) establishes a minimum of eight hours of annual refresher training for underground miners. Section 48.8(b), specifies that underground miners must be trained on a minimum of eleven different subjects, none of which MSHA believes would cover the specific requirements for diesel particulate training.

Nevertheless, MSHA believes compliance with this proposal can in many cases be fulfilled at the same time as scheduled part 48 training. The Agency, however, does not believe special language is required in this final rule to permit this action under part 48. If incorporated into part 48, mine operators would, however, be required to submit a revised training plan to the appropriate MSHA district office for approval. Some mine operators, however, may not be able to incorporate these topics in their part 48 plans. MSHA has endeavored to make the training requirements as simple as possible. If conducted separately from part 48 training, there are no specifications on trainer qualifications, no minimal training time, nor any training plans. If, however, the training is incorporated into part 48, then all applicable part 48 requirements will have to be met.

A commenter expressed concerns about individual MSHA inspectors determining their own set of health risks for training purposes and then trying to cite a company for not training on those health risks. They also suggested that the Agency develop a ''Question and Answer'' document to address this problem. To address the mine operators concern about the training requirements, MSHA intends to develop an instruction outline that mine operators can use as a guide for training personnel. Instruction materials will also be provided with the outline. MSHA believes this will not only provide guidance to the mining industry but also to MSHA inspectors.

The final rule does not require the mine operator to separately certify the completion of the dpm training, but some evidence that the training took place would have to be produced upon request. A serial log with the employee's signature is an acceptable practice.

Section 72.510(a)(1) of this rule requires the operator to train underground miners who can reasonably be expected to be exposed to diesel emissions in the health risk associated with dpm exposure. Several commenters disagreed with this requirement. They do not believe the health risks associated with exposures to diesel emissions have been sufficiently identified. ''If the health effects have not been identified, how can effective training be provided to the effected miners?'' MSHA disagrees with this comment. MSHA believes, as throughly discussed in Part III of this preamble, that the health effects associated with diesel emissions have been well documented. Comments received during this rulemaking further support MSHA's position concerning health effects associated with diesel emissions. Therefore, the requirements for training underground miners who can be reasonably be expected to be exposed to diesel emissions have been retained in the final rule.

Section 72.510(a)(3) of this rule requires the operator to identify personnel responsible for maintaining the methods used to control dpm in the mine. Some commenters suggested removing this provision from the rule. These commenters objected to identifying the personnel responsible for maintaining the methods used to control dpm. Because they were concerned about having the employee, ''singled out from the remaining workforce.'' Another commenter, asked how MSHA wanted the operator to identify the employee responsible for maintaining dpm controls; is the name to be posted, made available to interested persons, put in the training plan, etc? While there is no provision in this final rule for posting the information on the mine bulletin board or in any other location, this information is required to be presented to any underground miner who can reasonably be expected to be exposed to diesel emissions. The final rule requires this information to be presented at least annually but does not specify any specific method for presenting the information. The operator has the option of presenting this information orally or in written form.

The Agency believes this provision is consistent with the requirements contained in 30 CFR 75.1915(c). 30 CFR 75.1915(c) requires the operator to maintain a record of persons qualified to perform maintenance, repairs, examinations and tests on diesel-powered equipment. The operator is also required by § 75.1915(c) to include a copy of the training program used to qualify persons to perform maintenance, repairs, examinations and tests in their records. Section 75.1915(c) also requires the operator to make this record available for inspection by an authorized representative of the Secretary of Labor. All records that would need to be maintained concerning the qualification of personnel responsible for maintaining dpm controls are contained in § 75.1915(c). The individuals identified by § 75.1915(c) would also be the individuals identified in § 72.510(a)(3). The requirement to identify personnel qualified to perform specialized tasks is not a novel approach. Therefore, § 72.510(a)(3) has not been changed or deleted from the final rule.

Section 72.510(b)(1) of this rule requires that any log or record produced signifying that the training has taken place would be retained for one year. A commenter stated other records are not required to be maintained and should not be required by this rule. Numerous training records are required to be maintained for a variety of training requirements throughout 30 CFR, and MSHA believes that retention of the record for one year is important for documentation purposes. Therefore, § 72.510(b)(1) of this rule was not changed from the proposed rule and is incorporated in this final rule.

The training records need to be where an inspector can view them during the course of an inspection, as the information in the record may determine how the inspection proceeds. If the mine site has a fax machine or computer terminal, MSHA would permit the record to be maintained elsewhere so long as they are readily accessible. This approach is consistent with the Office of Management and Budget Circular A–130 and 30 CFR 75.1915(c).

Paragraph (b)(2) of section 72.510 of this rule requires mine operators to provide prompt access to the training records upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from an authorized representative of the miners. If an operator ceases to do business, all training records of employees are expected to be transferred to any successor operator. The successor operator is expected to maintain those training records for the required one year period unless the successor operator has undertaken to retrain the employees. There were no comments received concerning the maintenance of records by a successor operator. Therefore, the final rule has adopted the wording as published in the proposed rule.

Section 72.520 Diesel Equipment Inventory

Proposed § 75.371(qq) would have required, ''A list of diesel-powered units used by the mine operator together with information about any unit's emission control or filtration system.'' One commenter stated that the proposal was vague and overly burdensome. The commenter also stated that exhaustive, detailed technical specifications were not needed in the approved ventilation plan. MSHA agrees with the comments and has changed the final rule to reflect what MSHA believes is necessary information to help evaluate the effectiveness of dpm controls in underground coal mines. By specifying the information required, MSHA has provided uniform guidance to the mining community as to the information required to be submitted in the diesel equipment inventory.

Another commenter suggested the information be provided and posted at the mine and made available to a representative of the Secretary and other interested person. Another commenter was concerned with the time delay in submitting an addendum to the ventilation plan and the approval of the plan. The commenter stated that this was not required of other equipment used underground and should not be required of diesel-powered equipment. Concerns were raised by several commenters about delays in the approval of revisions to the ventilation plan.

MSHA has taken these comments into consideration and in the final rule has removed the diesel equipment inventory provision from the Approved Ventilation Plan and established it as a separate requirement § 72.520. There was no intent to require that the inventory be approved, but rather to require the information to be provided to MSHA and the representatives of the miners. The final rule requires each mine operator to prepare and submit a diesel equipment inventory to the District Manager. It also clarifies the information that must be included in the inventory. This information must be accurate so that the appropriate emission controls can be matched with an engine and to ensure that the required emission rates during the phase-in period are met. If there are modifications to the inventory, such as equipment being added or deleted, or changes to emission control systems, these modification must be submitted to the District Manager within 6 months. If no changes to the inventory are made, there is no need to update the diesel equipment inventory. The final rule also requires that mine operators provide a copy the diesel equipment inventory to the representative of the miners within 3 days.

Effective Dates

The final rule provides that unless otherwise specified, its provisions take effect 60 days after the date of promulgation. Some provisions of the final rule contain delayed effective dates that provide more time for technical assistance to the operators. Table I–1 presents the effective dates of various provisions of the final rule is reproduced below for convenience.

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Table I-1

Type of Equipment	Emissions Limit	When Applicable (from date final rule published)
Permissible		
newly introduced	2.5 grams per hour	60 days
existing fleet	2.5 grams per hour	18 months
Heavy duty nonpermissible		
newly introduced	5.0 grams per hour	60 days
existing fleet (interim)	5.0 grams per hour	30 months
existing fleet (final)	2.5 grams per hour	4 years
Generators and compressors	same as heavy duty	same as heavy duty
Other light duty nonpermissible		
newly introduced	5.0 grams per hour (or listed EPA standards)	60 days
existing fleet	no requirements	

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The final rule stipulates that any piece of diesel-powered equipment introduced into an underground coal mine 60 days after the promulgation date of this final rule is required to meet specific emission limits. For equipment that is currently used in underground coal mines, the compliance dates vary with regards to the type of diesel-powered equipment used in underground coal mines. MSHA includes in the category of equipment currently in use in underground coal mines any equipment that is ordered on or before the promulgation date of this final rule, even if the delivery date is more that 60 days from the promulgation date. By treating equipment on order as equipment already in use, the Agency is allowing the operator to use the equipment as delivered by the equipment supplier. A valid purchase order would be required of the operator as evidence that the diesel-powered equipment was ordered on or before the promulgation date of the final rule.

The time frame of 60 days after the promulgation date of the final rule also applies to newly introduced diesel-powered equipment as a result of explicit effective dates in 30 CFR 72.500, 72.501, and 72.502 of this rule. Diesel-powered equipment that is introduced in an underground coal mine 60 days after the promulgation date of the final rule must emit no more than 2.5 grams per hour of dpm. The term ''introduced'' is defined in § 72.503(e) and is explained in the appropriate Section-by-Section discussion in this preamble.

Section 72.500(b) of this rule allows the operator 18 months from the promulgation date of the final rule to meet emission limits for permissible diesel-powered equipment currently in use in underground coal mines. Several commenters stated the 18 month time frame was insufficient to comply with the proposed rule. They suggested increasing the effective date to between 2 and 4 years from the promulgation date of the final rule. The proposed rule would have required, in part, a system capable of removing, on average, at least 95% of diesel particulate matter by mass. The only system reportedly available that achieved the filtration efficiency necessary, was the DST® system. As discussed elsewhere in this preamble, the final rule sets emission limits on diesel-powered equipment and allows the operator to use whatever diesel particulate reducing technologies available to meet the limits. Information submitted during the rule making process and verification testing conducted for MSHA, has identified that readily available paper filters can achieve the emission limits set for permissible diesel-powered equipment. Therefore, MSHA has retained the 18 month effective date for diesel-powered equipment currently in use in underground coal mines.

Section 72.501 of this rule addresses emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors. There are 3 time tables associated with these pieces of diesel-powered equipment. As with permissible diesel-powered equipment, all nonpermissible heavy-duty diesel powered equipment, generators and compressors introduced into an underground coal mine 60 days from the promulgation date of the final rule would be required to meet a specific dpm emission limit. As stated the final rule differs from the proposed rule, however, the compliance date for newly introduced diesel-powered equipment has not been changed.

The final rule allows 30 months from the promulgation date for the operator to reduce the emission levels to the levels required for newly introduced diesel-powered equipment. Some commenters believe this time frame should be increased to 3 to 4 years.

Another commenter stated the time frame for complying with the standard should be shortened. Based upon information obtained during the rule making process, MSHA believes the 30 month time table is adequate and reasonable to install the necessary particulate controls to comply with the required emission limits.

Section 72.501(c) of this final rule requires all nonpermissible heavy-duty diesel-powered equipment, generators and compressors to meet a stricter emission limit within 4 years after promulgation of the final rule. The proposed rule would have allowed 6 years to achieve these stricter limits. After reviewing the record, particularly information submitted by aftertreatment device manufacturers, MSHA has concluded that these stricter standards can be met in a shorter time frame. Discussions on these emission limits are covered in greater detail elsewhere in this preamble. Therefore, the effective date for the stricter emission limits was reduced from 6 years to 4 years.

Section 72.503 of this final rule addresses nonpermissible light-duty diesel-powered equipment other than generators and compressors. The proposed rule did not address nonpermissible light-duty diesel-powered equipment. As discussed earlier in the preamble, nonpermissible light-duty diesel-powered equipment has been included in this final rule. The final rule only addresses nonpermissible light-duty diesel-powered equipment that is introduced 60 days after the promulgation date of this final rule. Equipment currently in use in underground coal mines is excluded from meeting emission limits. Based upon information gathered during the rule making process, MSHA believes 60 days after the promulgation date of the final rule is reasonable and this requirement has been added to the final rule.

V. Adequacy of Protection and Feasibility of Final Rule; Alternatives Considered

The Mine Act requires that in promulgating a standard, the Secretary, based on the best available evidence, shall attain the highest degree of health and safety protection for the miner with feasibility a consideration.

Overview. This part begins with a summary of the pertinent legal requirements, followed by a general profile of the economic health and prospects of the coal mining industry.

The discussion then turns to the main component of the rule being promulgated by the Agency for underground coal mines. MSHA is requiring that mine operators limit the emissions of dpm to defined quantities for various categories of diesel equipment underground. This part evaluates the rule to ascertain if, as required by the statute, it achieves the highest degree of protection for underground coal miners that is both technologically and economically feasible for mine operators.

About half a dozen regulatory alternatives to the final rule were also reviewed by MSHA in light of the record. After considerable study, the Agency has concluded that compliance with these alternatives either provide less protection than the feasible approach being adopted, or are not technologically or economically feasible for the underground coal mining industry as a whole at this time.

Pertinent Legal Requirements. Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) states that the Secretary of Labor (Secretary) in promulgating mandatory standards dealing with toxic materials or harmful physical agents under the Act, shall set standards when most:

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

The Mine Act also specifies that the Secretary, in promulgating these mandatory standards, must base such standards upon:

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

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration.

In relation to feasibility, the legislative history of the Mine Act states that:

> * * * This section further provides that ''other considerations'' in the setting of health standards are ''the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.'' While feasibility of the standard may be taken into consideration with respect to engineering controls, this factor should have a substantially less significant role. Thus, the Secretary may appropriately consider the state of the engineering art in industry at the time the standard is promulgated. However, as the circuit courts of appeal have recognized, occupational safety and health statutes should be viewed as ''technology-forcing'' legislation, and a proposed health standard should not be rejected as infeasible when the necessary technology looms in today's horizon. *AFL–CIO* v. *Brennan,* 530 F.2d 109 (1975); *Society of the Plastics Industry* v. *OSHA,* 509 F.2d 1301, *cert. denied,* 427 U.S. 992 (1975).

Similarly, information on the economic impact of a health standard which is provided to the Secretary of Labor at a hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of [this section], the Committee wishes to emphasize that the agency rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure. S. Rep. No. 95–181, 95th Cong., 1st Sess. 21 (1977).

Court decisions have clarified the meaning of feasibility. The Supreme Court, in *American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 101 S.Ct. 2478 (1981), defined the word ''feasible'' as ''capable of being done, executed, or effected.'' The Court stated that a standard would not be considered economically feasible if an entire industry's competitive structure was threatened. According to the Court, the appropriate inquiry into a standard's economic feasibility is whether the standard is capable of being achieved.

Courts do not expect hard and precise predictions from agencies regarding feasibility. Congress intended for the ''arbitrary and capricious standard'' to be applied in judicial review of MSHA rulemaking (S.Rep. No. 95–181, at 21.) Under this standard, MSHA need only base its predictions on reasonable inferences drawn from the existing facts. MSHA is required to produce a reasonable assessment of the likely range of costs that a new standard will have on the industry. The agency must also show that a reasonable probability exists that the typical firm in the industry will be able to develop and install controls that will meet the standard. See, *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402, 91 S.Ct. 814 (1971); *Baltimore Gas & Electric Co.* v. *NRDC,* 462 U.S. 87 103 S.Ct. 2246, (1983); *Motor Vehicle Manufacturers Assn.* v. *State Farm Mutual Automobile Insurance Co.,* 463

U.S. 29, 103 S.Ct. 2856 (1983); *International Ladies' Garment Workers' Union* v. *Donovan,* 722 F.2d 795, 232 U.S. App. D.C. 309 (1983), *cert. denied,* 469 U.S. 820 (1984); *Bowen* v. *American Hospital Assn.,* 476 U.S. 610, 106 S.Ct. 2101 (1986).

In developing a health standard, MSHA must also show that modern technology has at least conceived some industrial strategies or devices that are likely to be capable of meeting the standard, and which industry is generally capable of adopting. *United Steelworkers of America* v. *Marshall,* 647 F.2d 1189, 1272 (1980). If only the most technologically advanced companies in an industry are capable of meeting the standard, then that would be sufficient demonstration of feasibility (this would be true even if only some of the operations met the standard for some of the time). *American Iron and Steel Institute* v. *OSHA,* 577 F. 2d 825, (3d Cir. 1978); see also, *Industrial Union Department, AFL–CIO* v. *Hodgson,* 499 F. 2d 467 (1974).

Industry Profile. The industry profile provides background information describing the structure and economic characteristics of the coal mining industry. This information was considered by MSHA in reaching its conclusions about the economic feasibility of various regulatory alternatives.

MSHA divides the mining industry into two major segments based on commodity: (1) coal mines and (2) metal and nonmetal (M/NM) mines. These segments are further divided based on type of operation (*e.g.,* underground mines or surface mines). MSHA maintains its own data on mine type, size, and employment.

MSHA also collects data on the number of independent contractors and contractor employees by major industry segment.

MSHA categorizes mines by size based on employment. For the past 20 years, for rulemaking purposes, MSHA has consistently defined a small mine to be one that employs fewer than 20 workers and a large mine to be one that employs 20 or more workers. To comply with the requirements of the Small Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), however, an agency must use the Small Business Administration's (SBA's) criteria for a small entity—for mining, 500 or fewer employees—when determining a rule's economic impact.

Table V–1 presents the total number of small and large coal mines and the corresponding number of miners, excluding contractors, for the coal mining segment. This table uses three mine size categories based on the number of employees: (1) fewer than 20 employees (MSHA's traditional definition of small), (2) 20 to 500 employees (small according to SBA's definition) and (3) more than 500 employees. Table V–1 further disaggregates data by surface mines and underground mines, as well as (for employees) office workers. Table V–2 presents corresponding data on the number of independent contractors and their employees working in the coal mining segment.

Although this particular rulemaking does not apply to the surface coal sector, information about surface coal mines is provided here in order to give context for the discussions on underground mining.

TABLE V–1.—DISTRIBUTION OF COAL MINE OPERATIONS AND EMPLOYMENT (EXCLUDING CONTRACTORS) BY MINE TYPE AND SIZE [a]

Size of coal mine [b]		Mine type			
		Underground	Surface	Office workers	Total coal
Fewer Than 20 Employees	Mines	382	1,058	....	1,438
	Employees	3,751	6,491	487	10,729
20 to 500 Employees	Mines	522	492	....	1,014
	Employees	39,566	31,731	3,389	74,692
Over 500 Employees	Mines	6	1	....	7
	Employees	3,459	510	189	4,158
All Coal Mines	Mines	910	1,549	....	2,459
	Employees	46,776	38,738	4,065	89,579

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CM441/CM935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1997 Closeout Edition) Table 1, p. 5.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

TABLE V–2.—DISTRIBUTION OF CONTRACTORS AND CONTRACTOR EMPLOYMENT BY SIZE OF OPERATION [a]

Size of contractor [b]		Contractors			
		Underground	Surface	Office workers	Total
Fewer Than 20 Employees	Mines	1,077	2,403	....	3,480
	Employees	4,078	9,969	1,064	15,111
20 to 500 Employees	Mines	79	242	....	321
	Employees	4,131	11,618	1,192	16,941
Over 500 Employees	Mines	....	....	....	....
	Employees	....	....	....	....
Total Contractors	Mines	1,156	2,645	....	3,801
	Employees	8,209	32,052	2,256	30,052

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CT441/CT935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1998 Closeout Edition) Table 5, p. 20.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

Agency data (Table V–1) indicate that there were about 2,459 coal mines in 1998. When applying MSHA's definition of a small mine (fewer than 20 workers), 1,438 (about 58%) were small mines and 1,021 (about 42%) were large.[82] Using SBA's definition, only 7 coal mines (0.3 percent) were large. These data show that employment at coal mines in 1998 was about 89,600, of which (by MSHA's definition) about 10,700 (12 percent) worked at small mines and 78,900 (88 percent) worked at large mines.[83] Using SBA's definition, 95 percent of coal miners worked at small mines and 5 percent worked at large mines. Using MSHA's definition, small coal mine average 7 employees, and large coal mines average 77 employees. Using SBA's definition, there are, on average, 35 employees in each small coal mine and 594 employees in each large coal mine. MSHA classifies the U.S. coal mining segment into two major commodity groups: bituminous and anthracite. About 92 percent of total coal production is bituminous. The remaining 8 percent is the product of lignite and anthracite mines.[84]

Mines east of the Mississippi accounted for about 49% of coal production in 1998. For the period 1949 through 1998, coal production east of the Mississippi River fluctuated relatively little, from a low of 395 million tons in 1954 to a high of 630 million tons in 1990; 1998 production was estimated at 571 million tons. Coal production west of the Mississippi, by contrast, increased each year from a low of 20 million tons in 1959 to a record high of 548 million tons in 1998.[85] The growth in western coal has been due, in part, to environmental concerns that led to increased demand for low-sulfur coal, which is abundant in the West.

In addition, surface mining, with its higher average productivity, is much more prevalent in the West. Surface mining methods for coal, which include drilling and blasting, are also practiced in surface mines for other commodity types. Most surface mines use front-end loaders, bulldozers, shovels, or trucks for haulage.

The U.S. coal sector produced a record 1.12 billion short tons of coal in 1998, at an average price of $17.58 per ton. The total value of U.S. coal production in 1998 was estimated as $19.7 billion. Small mines (by MSHA's definition) produced about 4 percent (40 million tons) of domestic coal production valued at $0.7 billion, and large mines (by MSHA's definition) produced about 96 percent (1.08 billion tons) valued at $19.0 billion.[86]

The U.S. coal industry enjoys a fairly constant domestic demand. Over 90 percent of U.S. coal demand was accounted for by electric utilities in 1998.[87] Due to the high conversion costs of changing a fuel source, MSHA does not expect a substantial change in coal demand by utility power plants in the near future.[88]

Adequacy of Miner Protection Provided by the Rule for Underground Coal Mines. In evaluating the protection provided by the rule, it should be noted that MSHA has measured dpm concentrations in production areas and haulageways of underground coal mines which exceed 2500_{DPM} µg/m^3 with a mean concentration of 644_{DPM} µg/m^3. See Table III–1 and Figure III–1 in part III of this preamble. As discussed in detail in part III of this preamble, these concentrations place underground coal miners at significant risk of material impairment of their health, and the evidence supports the proposition that reducing the exposure reduces the risk.

The final rule would require operators to limit the emissions of dpm emitted by various categories of equipment in underground coal mines—permissible, heavy duty (and compressors and generators), and other light duty. Equipment added to a mine's inventory more than 60 days after the rule is promulgated (or equipment already in the inventory but equipped with a new engine after that time), would have to comply with the appropriate standard. In addition, operators would have 18 months to bring the existing fleet of permissible diesel equipment into compliance with a 2.5 gr/hr emission standard. Operators would have an additional year (30 months from date of promulgation) to bring the existing fleet of heavy duty equipment (and generators and compressors) into compliance with a 5.0 gr/hr emission standard, and up to 4 years in all to bring that fleet down to a standard of 2.5 gr/hr.

As an example of how these emission standards can reduce dpm concentration levels in a section of an underground coal mine, take the case of a single-section mine with three Ramcars (94hp, indirect injection) and a section airflow of 45,000 cfm. MSHA measured concentrations of dpm in this mine at 610_{DPM} µg/m^3. Of this amount, 25_{DPM} µg/m^3 was coming from the intake to the section, and the remaining 585 $_{DPM}$ µg/m^3 was emitted by the engines. Reducing the engine emissions by 95% through the use of commercially available paper filters would reduce the dpm emitted to 29_{DPM} µg/m^3. With an intake amount of 25_{DPM} µg/m^3, the ambient concentration would be about 54_{DPM} µg/m^3. Similarly, dramatic results can be achieved in almost any situation by adding high efficiency aftertreatment filters or by replacing current engines in the fleet with a more recent generation.

While the reductions in section concentration from the controls required by the final rule can be significant, it is important to recognize that the actual reductions in a section will vary depending upon a number of factors.

In the first place, unlike the proposed rule, the final rule does not require current dpm emissions from each machine to be reduced by 95%. While the existing permissible fleet, and much of the existing heavy duty fleet, will need to reduce engine emissions significantly to come into compliance with the final standard, this will be feasible in many cases with a less efficient filter. A detailed table illustrating by how much the emissions from each current engine in the inventory must be reduced to achieve compliance is shown in table IV–1.

Second, while aftertreatment filters currently available are capable in laboratory tests of achieving a very significant reduction in dpm mass, and this has been confirmed in some field tests, the Agency has not tested filter efficiency under a variety of actual mining conditions. Therefore, actual performance may be different in the field due to individual mining

[82] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[83] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[84] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 191.

[85] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 191.

[86] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 203, U.S. Department of Energy, Energy Information Administration, *Coal Industry Annual 1997*, December 1998, pp. ix and 154, and U.S. Department of Labor, Mine Safety and Health Administration, Division of Mining Information Systems, 1998 Final MIS data (quarter 1–quarter 4) CM441 cycle 1998/198.

[87] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 187.

[88] U.S. Department of Energy, Energy Information Administration, *Annual Energy Outlook 2000*, p. 68.

conditions (*e.g.,* ventilation changes, changes of the equipment due to maintenance, and the type of engine used).

Third, the impact on a mine section of reduced emissions from a particular machine depends upon the ventilation rate and the ambient dpm intake into the section. If ventilation levels drop below the requirements established to control gaseous emissions, or if many pieces of equipment throughout the mine create a high ambient level of dpm, implementation of the rule may not bring concentrations down as effectively as suggested in the prior example. On the other hand, if the ventilation rate is maintained at a higher level, the emissions would be better diluted and the ambient concentration could offset any decrease in control efficiency under actual mining conditions. The intake of dpm to any section depends on what emissions are upstream. In this regard, it should be noted that the final rule does not require controls on the existing fleet of light-duty equipment, except for generators and compressors; hence, mines with significant light duty equipment will have this exhaust as an ''intake'' in such calculations.

Table V–3 summarizes information from a series of simulations designed to illustrate some of these variables. The simulations were performed using MSHA's ''Estimator''—a computerized spreadsheet designed to calculate dpm ambient levels from given equipment, and the impact of various controls on those ambient levels. (The Estimator was discussed in detail in an Appendix to the preamble to the proposed rule and has since been published (Haney and Saseen, April 2000)). The example simulated here involves a mine section with a 94 horsepower engine, with a 0.3 gm/hp-hr dpm emission rate and a nameplate airflow, 5500 cfm. The engine was operated during an eight hour shift. The Estimator was used to calculate the section concentrations with a paper filter at full laboratory efficiency (95%) and two lower filter efficiencies. The same results would be obtained for multiple pieces of equipment provided that the nameplate airflow is additive for each piece of equipment.

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Table V-3: Section DPM Concentrations for Various Airflow Rates, Afterfilter Efficiencies and Intake DPM Concentrations

Airflow	Intake DPM (µg/m³)	Resulting Section DPM Concentration (µg/m³)		
		85 Percent After-filter	90 Percent After-filter	95 Percent After-filter
1.0 x Nameplate Airflow	0	452	302	151
2.0 x Nameplate Airflow	0	226	151	75
3.0 x Nameplate Airflow	0	151	101	50
4.0 x Nameplate Airflow	0	113	75	38
1.0 x Nameplate Airflow	25	477	327	176
2.0 x Nameplate Airflow	25	251	176	100
3.0 x Nameplate Airflow	25	176	126	75
4.0 x Nameplate Airflow	25	138	100	63
1.0 x Nameplate Airflow	50	502	352	201
2.0 x Nameplate Airflow	50	276	201	125
3.0 x Nameplate Airflow	50	201	151	100
4.0 x Nameplate Airflow	50	163	125	88
1.0 x Nameplate	75	527	377	226
2.0 x Nameplate Airflow	75	301	226	150
3.0 x Nameplate Airflow	75	226	176	125
4.0 x Nameplate Airflow	75	188	150	113

* Emission rate - 0.3 gm/hp-hr

Airflow - 5500 cfm

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In Table V–3, the intake dpm (second column) increases after every fourth row. Within each group of four rows, the ventilation (first column) increases from one row to the next. The last 3 columns display the ambient dpm concentration with a particular filter efficiency.

The first four rows represent a situation where there is no intake dpm. If the mine is ventilated with four times the nameplate airflow (row 4), the ambient dpm concentration using a filter operating at 95% (last column) is reduced to 38_{DPM} µg/m^3. If the filter in this situation only works in practice at 85% efficiency in removing dpm, the ambient dpm concentration is only reduced to 113_{DPM} µg/m^3. And if the ventilation is reduced to the nameplate airflow (first column) and the filter is only 85% efficient, the ambient dpm climbs to 452_{DPM} µg/m^3.

The last four rows display the parallel situation but with an ambient intake concentration to the section of 75_{DPM} µg/m^3. In this situation, depending on ventilation and filter effectiveness, the ambient dpm concentration ranges from 113_{DPM} to 527_{DPM} µg/m^3.

In the example discussed above—a single section mine with three 94 hp Ramcars—the airflow of 45,000 cfm represents three times the current nameplate requirements. Many underground coal mines may use more than the nameplate ventilation to lower methane concentrations at the face. But if this airflow were reduced to the current nameplate requirements, the ambient dpm would have been 1620_{DPM} µg/m^3, and would have been reduced by 95% effective filters to 105_{DPM} µg/m^3.

Based on its experience as to the general effects of mining conditions on the expected efficiency of equipment, and on ventilation rates, MSHA has concluded that the rule for this sector will substantially reduce the concentrations of dpm to which underground coal miners are exposed.

Alternatives considered. In order to ensure that the maximum protection that is feasible for the underground mining industry as a whole is provided, the Agency has considered some alternatives. Most are discussed elsewhere in this preamble, but are briefly repeated here and illustrate the extensive thought MSHA gave to this issue.

(1) *Establish a Concentration Limit.* MSHA considered establishing a dpm concentration limit for this sector, as it is doing for underground metal and nonmetal mines. A concentration limit provides operators with flexibility to select any combination of controls that keep ambient dpm concentrations below the limit.

The agency has concluded that it is not yet technologically feasible to establish a dpm concentration limit for underground coal mines. The problem is that significant questions remain as to whether there is a sampling and analytical system that can provide consistent and accurate measurements of dpm in areas of underground coal mines where there is a heavy concentration of coal dust. The Agency is continuing to work on the technical issues involved, and should it determine that these technological problems have been resolved, it will notify the mining community and proceed accordingly.

(2) *95% Filters on Defined Categories of Equipment.* This is what the agency initially proposed for this sector. It has the advantage of ensuring that all controlled equipment is filtered, which some assert is easier to keep in proper shape through observation, and others believe provides more protection against nanoparticles. On the other hand, such an approach may quickly become technologically infeasible as newer, cleaner engines are introduced underground; removing 95% (or any defined percentage) of the lower emissions of these engines is likely to prove much more difficult. Moreover, this approach could act as a disincentive to introduce cleaner engines underground, and thus slow the reduction of dpm that such a replacement fleet might make possible. Finally, the Agency determined that at this time, there is not enough evidence about the risks of nanoparticles to regulate on that basis. Accordingly, the agency rejected this approach in order to avoid the problems associated with its implementation over the long term.

(3) *A machine-based emissions limit with credit for extra ventilation used in the mine.* Under this approach, if the bench test of the combined engine and filter package was conducted at the approval 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. So if, for example, an engine equipped with a ceramic filter can reduce emissions to 5.0 grams/hour in a test using the approval plate ventilation, and the mine actually ventilates at twice the name plate ventilation, the system would be deemed to reach 2.5 grams/hour under that circumstance. This alternative, however, is less protective than the rule adopted by the agency, as it would not require dpm emissions to be reduced as much. Accordingly, since the more protective alternative is feasible as well, it would be inappropriate under the law for the agency to adopt this alternative.

(4) *Adjust the Time-Frame for Implementation of the Final Rule.* The final rule will not be fully implemented for several years. The existing permissible fleet is given a full 18 months to comply, even though the agency has determined that there are readily available paper filters which can bring this equipment into compliance. The implementation schedule for the existing heavy duty fleet (and compressors and generators) extends for 4 years from the date of promulgation, even though the agency has concluded that there are hot gas filters readily available which can bring most of this equipment into compliance with the final emissions limit. Accordingly, the agency has considered whether a faster implementation schedule is feasible.

Cutting the 18 month time-frame for permissible equipment does not appear to be practicable for the industry. Eighteen months to obtain and install a relatively new technology is a reasonable time. Time is needed for operators to familiarize themselves with this technology. Also, mine personnel have to be trained in how to maintain control devices in working order. Moreover, MSHA needs time to work with the mining community to develop a revised approach to approving engines for use in permissible equipment in order to accelerate the introduction of a cleaner generation of engines into the permissible fleet.

With respect to the heavy duty fleet, the four years permitted to meet the final emissions limit is actually two years faster than originally proposed by the agency when 95% filters were being proposed. As indicated in section 6 of Part II of this preamble, the development of high efficiency hot gas filters has proceeded much faster than expected, so that it is technologically feasible to comply more quickly with this requirement than originally proposed. Moreover, MSHA has determined that the cost differential to the industry of reaching the final 2.5 micrograms/hour emission limit in 4 years instead of 6 is minor (see REA). However, MSHA has concluded that moving up the timeline further would create unwarranted difficulties for operators in terms of installing the required engines and filters, and accordingly has determined that further acceleration of this schedule would be infeasible.

(5) *Require Machine Emission Limits on all Diesel Equipment in Underground Coal Mines.* The final rule would not immediately apply to more than 60% of the fleet—light-duty equipment other than generators and compressors. Over time, the final rule would have an impact on the remaining light duty fleet through controls on any new equipment introduced underground, but it will take

many years before mine workers get the benefits of this approach. By contrast, the Commonwealth of Pennsylvania has recently adopted legislation for universal high-efficiency filtration based on an agreement in the mining community of that state. The Pennsylvania law requires that all diesel-powered equipment introduced into underground coal mines in that state (essentially all equipment, given the past ban), meet an emissions limit requirement (as well as a separate filter requirement).

One reason asserted for not covering all light duty equipment is that this equipment may run only intermittently, and under light loads, hence producing less dpm than other kinds of equipment. This proposition was supported by industry representatives during the rulemaking, and disputed by miners during the rulemaking proceedings. The Agency has not been able to draw any conclusions based on the mixed evidence as to the light duty fleet as a whole; as noted previously, it has carved out the 3% of the light duty fleet that clearly works like heavy duty equipment, and is covering them in this rule (generators and compressors).

A second issue is costs. The Agency decided to consider what it would take to bring the rest of the industry up to the standard established under the Pennsylvania agreement of universal coverage. MSHA has calculated that such a requirement would cost the underground coal industry an additional $9.7 to $17.4 million a year. This would be an increase of 135–240% of the cost of the rule for the underground coal mining industry. Since drawing conclusions concerning the level of dpm actually produced by light duty equipment in underground coal mines is difficult, the Agency has decided to take the approach of phasing in emission controls for light duty outby equipment over a period of five years. This approach significantly reduces the cost of the rule. Eventually, dpm exposures will be reduced for all miners in all areas of the mine.

(6) *Requiring certain engines to meet defined particulate emission standards.* As discussed in part II of this preamble, the Mine Safety and Health Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines recommended the establishment of a particulate index (PI), and MSHA did so in its diesel equipment rule. Under that rule, the PI establishes the amount of air required to dilute the dpm produced by an engine (as determined during its approval test under subpart E of part 7) to 1000 µg/m^3.

In the preamble of the diesel equipment rule, MSHA noted that mine operators and machine manufacturers would find it useful to consider the engine PI in selecting and purchasing decisions. The agency explicitly deferred until this rulemaking the question of whether to require engines used in mining environments to meet a particular PI.

In its final rule, the Agency is, in fact, using a significant portion of the concepts embodied in the particulate index. The determination of the quantity of dpm emitted from the machine is based on the information from the engine approval tests in 30 CFR 7.89 as was used to establish the particulate index. Both means of expressing the dpm characteristics of the machine begin with determining the total amount of dpm, expressed in grams/hour, produced by the engine over the test cycle described in ISO 8178. The particulate index is determined by calculating the quantity of air required to dilute that particulate to a concentration of 1 mg/m^3. The quantity of dpm emitted from the machine is determined by multiplying the quantity of dpm emitted from the engine by the filtration efficiency of the aftertreatment device.

Had the agency been able to utilize a concentration limit in this sector, the particulate index could have been used directly to compute an estimated level of dpm that could be achieved with various quantities of ventilation air. As noted above, however, that approach was found to be infeasible.

Feasibility of final rule for underground coal mining sector. The Agency has carefully considered both the technological and economic feasibility of the rule for the underground coal mining sector as a whole.

Although some doubts were expressed about this during the rulemaking proceedings, it is clear now that the technology exists to implement the final rule's requirements. As this preamble explains in overview in section 6 of Part II, and reiterates in connection with the specific requirements of the rule in Part IV, there are available emission controls which can bring all existing and contemplated future diesel equipment into compliance with the requirements of the rule. Paper filters have now been verified to reduce emissions from the dirtiest permissible engines to the required limit of 2.5 grams per hour. Ceramic filters have been certified by VERT to have the efficiency required to reduce emissions from the dirtiest heavy duty engines to the interim limit of 5.0 grams/hour, and for all but one engine to the final limit of 2.5 grams/hour. Approved engines that meet the emissions limit for newly introduced light duty equipment are available for all categories. And as MSHA and the mining industry work together to address aspects of the approval process that may be inhibiting the introduction of the newer generations of engines into underground mines, there should be no technological nor practical barriers to further emission limit reductions.

The economic feasibility of this rule has also been carefully considered by MSHA. The total for the final rule for underground coal mines will be about $7 million per year. The costs per dieselized mine are expected to be about $48,000 a year. MSHA has calculated that the costs of the final rule amount to less than one-quarter of one percent (0.23 percent) of the annual revenues of the dieselized underground coal mining sector. (The methodology for this calculation is discussed in Chapter IV of the Agency's REA). After reviewing the economic profile of that sector, and taking into account the cost of implementing the related diesel equipment rule, MSHA has concluded that the rule is economically feasible for this sector as a whole.

Conclusion: Underground Coal Mines. Based on the best evidence available to it at this time, the Agency has concluded that the final rule for the underground coal sector meets the statutory requirement that it attain the highest degree of health and safety protection for the miners in that sector, with feasibility a consideration.

VI. Regulatory Impact Analyses

This part of the preamble reviews several impact analyses which the Agency is required to provide in connection with its final rulemaking. The full text of these analyses can be found in the Agency's Regulatory Economic Analysis (REA).

(A) Costs and Benefits: Executive Order 12866

In accordance with Executive Order 12866, MSHA has prepared a Regulatory Economic Analysis (REA) of the estimated costs and benefits associated with the final rule for the underground coal sector.

The key conclusions of the REA are summarized, together with cost tables, in part I of this preamble (see Item number 7). The complete REA is part of the record of this rulemaking, and is available from MSHA.

The Agency considers this rulemaking ''significant'' under section 3(f) of Executive Order 12866, and has so designated the rule in its semiannual regulatory agenda (RIN 1219–AA74). However, based upon the REA, MSHA has determined that the final rule does not constitute an ''economically significant'' regulatory action pursuant to section 3(f)(1) of Executive Order 12866.

(B) Regulatory Flexibility Certification.

The Regulatory Flexibility Act (RFA) requires regulatory agencies to consider a rule's economic impact on small entities. Under the RFA, MSHA must use the Small Business Administration's (SBA's) criterion for a small entity in determining a rule's economic impact unless, after consultation with the SBA Office of Advocacy, MSHA establishes an alternative definition for a small mine and publishes that definition in the **Federal Register** for notice and comment. For the mining industry, SBA defines ''small'' as a mine with 500 or fewer workers. MSHA traditionally has considered small mines to be those with fewer than 20 workers. To ensure that the final rule conforms with the RFA, MSHA has analyzed the economic impact of the final rule on mines with 500 or fewer workers (as well as on those with fewer than 20 workers).

MSHA has determined that the final rule would not have a significant economic impact on small mines, whether a small mine is defined as one with 500 or fewer workers or one with fewer than 20 workers.

Using the Agency's traditional definition of a small mine, which is one employing fewer than 20 workers, the estimated yearly cost of the final rule on small underground coal mines will be about $7,400. This estimated annualized cost for small mines compares to estimated annual revenues of approximately $9.1 million for the class of small underground coal mines.

Using SBA's definition of a small mine, which is one employing 500 or fewer workers, the estimated yearly cost of the final rule for all small underground coal mines would be about $6.1 million. This estimated cost for small mines compares to estimated annual revenues of approximately $2.95 billion for small underground coal mines, using SBA's criteria.

Based on its analysis, MSHA has determined that the final rule would not have a significant economic impact on a substantial number of small mines. MSHA has so certified these findings to the Small Business Administration. The factual basis for this certification is discussed in Chapter V of the REA for this rule.

(C) Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, the final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector of more than $100 million.

(D) Paperwork Reduction Act of 1995

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95). The final rule will impose paperwork burden hours on underground coal mine operators that use diesel powered equipment and on manufacturers of diesel powered equipment. For mine operators that use diesel powered equipment, the final rule imposes two types of burden hours. First, there are burden hours that will occur *only* in the first year the rule is in effect (hereafter known as first year burden hours). Second, there are burden hours that will occur *every* year that the rule is in effect, starting with the first year (hereafter known as ''annual'' burden hours). Manufacturers of diesel equipment that are affected by this rule, will incur only first year burden hours.

Mine Operators

First Year Burden Hours

In the first year that the rule takes effect, mine operators will incur 997 burden hours, which is composed of 349 first year burden hours (from Table VI–1) and 648 annual burden hours (from Table VI–1(a)). The related costs to mine operators will be $33,049, of which $12,627 is related to first year burden hours (from Table VI–1) and $20,422 is related to annual burden hours (from Table VI–1(a)).

Burden Hours After the First Year

Beginning in the second year the rule takes effect and continuing every year thereafter, mine operators will incur 648 burden hours and related costs of $20,422 (from Table VI–1(a)).

Manufacturers

First Year Burden Hours

In the first year that the rule is in effect, manufacturers will incur 700 burden hours and related costs of $35,000 (from Table VI–2). After the first year, manufacturers will not incur any burden hours or related costs.

TABLE VI–1.—MINE OPERATORS—FIRST YEAR BURDEN HOURS

Detail	<20 emp.		20 to 500 emp.		>500 emp.		Total	
	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs
75.1915/72.503	1.0	$28	50	$1,299	1.0	$14	52	$1,341
72.510	0.6	29	11	568	0.1	4	12	602
72.520	9.0	399	267	10,027	9.0	257	285	10,684
Total	11.0	456	329	11,895	10.0	276	349	12,627

TABLE VI–1(a).—MINE OPERATORS—ANNUAL BURDEN HOURS

Detail	<20 emp.		20 to 500 emp.		>500 emp.		Total	
	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs
72.510	5.0	$167	563	$17,971	28.0	$922	597	$19,061
72.1915/72.503	0	0	4	76	0.3	5	4	82
72.520	0.3	8	43	1,177	3.5	94	47	1,279
Total	5.0	176	610	19,225	32.0	1,021	648	20,422

TABLE VI–2.—MANUFACTURERS—ANNUAL BURDEN HOURS

Detail	Hrs.	Costs
Amended Applications	700	$35,000

The paperwork provisions for the proposed rule were approved under OMB Control Number 1219–0124. Our paperwork submission summarized above is explained in detail in the final REA. The REA includes the estimated costs and assumptions for each final paperwork requirement related to this final rule. A copy of the REA is available from us. This final rule is being submitted to OMB under the same control number. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

(E) National Environmental Protection Act

The National Environmental Policy Act (NEPA) of 1969 requires each Federal agency to consider the environmental effects of final actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the environment. MSHA has reviewed the final rule in accordance with NEPA requirements (42 U.S.C. 4321 *et seq.*), the regulations of the Council of Environmental Quality (40 CFR Part 1500), and the Department of Labor's NEPA procedures (29 CFR Part 11). As a result of this review, MSHA has determined that this rule will have no significant environmental impact.

(F) Executive Order 12360 Governmental Actions and Interference With Constitutionally Protected Property Rights

This final rule is not subject to Executive Order 12360, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

(G) Executive Order 13045 Protection of Children from Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, MSHA has evaluated the environmental health and safety effects of the final rule on children. The Agency has determined that the rule will not have an adverse impact on children.

(H) Executive Order 12988 Civil Justice Reform

The Agency has reviewed Executive Order 12988, Civil Justice Reform, and determined that the final rule will not unduly burden the Federal court system. The rule has been written so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

(I) Executive Order 13084 Consultation and Coordination with Indian Tribal Governments

MSHA certifies that the final rule will not impose substantial direct compliance costs on Indian tribal governments.

(J) Executive Order 13132 Federalism

MSHA has reviewed the final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''federalism implications.'' The final rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

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Supplementary References

Below is a list of supplemental references that MSHA reviewed and considered in the development of the proposed rule. These documents are not specifically cited in the preamble discussion, but are applicable to MSHA's findings:

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List of Subjects in 30 CFR Part 72

Coal, Health standards, Mine safety and health, Underground mines, Diesel particulate matter.

Dated: January 8, 2001.

Robert A. Elam,

Acting Assistant Secretary for Mine Safety and Health.

Chapter I of Title 30 of the Code of Federal Regulations is hereby amended as follows:

PART 72—[AMENDED]

1. The authority citation for Part 72 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957, 961.

2. Part 72 is amended by adding Subpart D to read as follows:

Subpart D—Diesel Particulate Matter—Underground Areas of Underground Coal Mines

Subpart D—Diesel Particulate Matter—Underground Areas of Underground Coal Mines

§ 72.500 Emission limits for permissible diesel-powered equipment.

(a) Each piece of permissible diesel-powered equipment introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 2.5 grams per hour of diesel particulate matter.

(b) As of July 19, 2002, each piece of permissible diesel-powered equipment operated in an underground area of an underground coal mine must not emit no more than 2.5 grams per hour of diesel particulate matter.

§ 72.501 Emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors.

(a) Each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 5.0 grams per hour of diesel particulate matter.

(b) As of July 21, 2003, each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor operated in an underground area of an underground coal mine must not emit no more than 5.0 grams per hour of diesel particulate matter.

(c) As of January 19, 2005, each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor operated in an underground area of an underground coal mine must not emit no more than 2.5 grams per hour of diesel particulate matter.

(d) Notwithstanding the other provisions of this section, a generator or compressor that discharges its exhaust directly into intake air that is coursed directly to a return air course, or discharges its exhaust directly into a return air course, is not subject to the applicable requirements of this section.

§ 72.502 Requirements for nonpermissible light-duty diesel-powered equipment other than generators and compressors.

(a) Each piece of nonpermissible light-duty diesel-powered equipment (as defined by § 75.1908(b) of this part), other than generators and compressors, introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 5.0 grams per hour of diesel particulate matter.

(b) A piece of nonpermissible light-duty diesel-powered equipment must be deemed to be in compliance with the requirements of paragraph (a) of this section if it utilizes an engine which meets or exceeds the applicable particulate matter emission requirements of the Environmental Protection Administration listed in Table 72.502–1, as follows:

TABLE 72.502–1

EPA requirement	EPA category	PM limit
40 CFR 86.094–8(a)(1)(I)(A)(2)	light duty vehicle	0.1 g/mile.
40 CFR 86.094–9(a)(1)(I)(A)(2)	light duty truck	0.1 g/mile.
40 CFR 86.094–11(a)(1)(iv)(B)	heavy duty highway engine	0.1 g/bhp-hr.
40 CFR 89.112(a)	Tier 2 nonroad	Varies by power:
	kW< (hp<11)	0.80 g/kW-hr (0.60 g/bhp-hr).
	8≤kW<19 (11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr).
	19≤kW<37 (25≤hp<50)	0.60 g/kW-hr (0.45 g/bhp-hr).
	37≤kW<75 (50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr).
	75≤kW<130 (100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr).
	130≤kW<225 (175≤hp<300)	0.20 g/kW-hr (0.15 g/bhp-hr).
	225≤kW<450 (300≤hp<600)	0.20 g/kW-hr (0.15 g/bhp-hr).

Notes: "g" means grams; "kW" means kilowatt; "hp" means horsepower; "g/kW-hr" means grams/kilowatt-hour; "g/bhp-hr" means grams/brake horsepower-hour.

(c) The requirements of this section do not apply to any diesel-powered ambulance or fire fighting equipment that is being used in accordance with the mine fire fighting and evacuation plan under § 75.1101–23.

§ 72.503 Determination of emissions; filter maintenance; definition of "introduced".

(a) MSHA will determine compliance with the emission requirements established by this part by using the amount of diesel particulate matter emitted by a particular engine determined from the engine approval pursuant to § 7.89(a)(9)(iii)(B) or § 7.89(a)(9)(iv)(A) of this title, with the exception of engines deemed to be in compliance by meeting the EPA requirements specified in Table 72.502–1 (§ 72.502(b)).

(b) Except as provided in paragraph (c) of this section, the amount by which an aftertreatment device can reduce engine emissions of diesel particulate matter as determined pursuant to paragraph (a) must be established by a laboratory test:

(1) on an approved engine which MSHA has determined, pursuant to paragraph (a) of this section, to emit no more diesel particulate matter than the engine being used in the piece of diesel-powered equipment in question;

(2) using the test cycle specified in Table E–3 of § 7.89 of this title, and following a test procedure appropriate for the filtration system, by a laboratory capable of testing engines in accordance with the requirements of Subpart E of part 7 of this title; and

(3) with an aftertreatment device representative of that being used on the piece of diesel-powered equipment in question.

(c) In lieu of the laboratory tests required by paragraph (b), the Secretary may accept the results of tests conducted or certified by an organization whose testing standards are deemed by the Secretary to be as rigorous as those set forth by paragraph (b) of this section; and further, the Secretary may accept the results of tests for one aftertreatment device as evidencing the efficiency of another aftertreatment device which the Secretary determines to be essentially identical to the one tested.

(d) Operators must maintain in accordance with manufacturer specifications and free of observable defects, any aftertreatment device installed on a piece of diesel equipment upon which the operator relies to remove diesel particulate matter from diesel emissions.

(e) For purposes of §§ 72.500(a), 72.501(a) and 72.502(a), the term "introduced" means any piece of equipment whose engine is a new addition to the underground inventory of engines of the mine in question, including newly purchased equipment, used equipment, and equipment receiving a replacement engine that has a different serial number than the engine it is replacing. "Introduced" does not include a piece of equipment whose engine was previously part of the mine inventory and rebuilt.

§ 72.510 Miner health training.

(a) Operators must provide annual training to all miners at a mine who can reasonably be expected to be exposed to diesel emissions on that property. The training must include—

(1) The health risks associated with exposure to diesel particulate matter;

(2) The methods used in the mine to control diesel particulate matter concentrations;

(3) Identification of the personnel responsible for maintaining those controls; and

(4) Actions miners must take to ensure the controls operate as intended.

(b)(1) An operator must keep a record of the training at the mine site for one year after completion of the training. An operator may keep the record elsewhere if the record is immediately accessible from the mine site by electronic transmission.

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

§ 72.520 Diesel equipment inventory.

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

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

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

[FR Doc. 01–995 Filed 1–18–01; 8:45 am]

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 57

RIN 1219–AB11

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners

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

ACTION: Final rule.

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. Overview of the Final Rule

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

(1) Summary of Key Provisions of the Final Rule

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

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

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

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

All underground metal and nonmetal mines would be given a full five years to meet this limit, which is referred to in this preamble as the ''final'' concentration limit. However, starting July 19, 2002, underground metal and nonmetal mines have to observe an ''interim'' dpm concentration limit—expressed as a restriction on the