DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 57

RIN 1219–AB29

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners

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

ACTION: Final rule.

SUMMARY: This final rule revises MSHA's existing standards addressing diesel particulate matter (DPM) exposure in underground metal and nonmetal (M/NM) mines. In this final rule, MSHA changes the interim concentration limit measured by total carbon (TC) to a comparable permissible exposure limit (PEL) measured by elemental carbon (EC), which renders a more accurate DPM exposure measurement. Also, this final rule increases flexibility of compliance for mine operators by requiring MSHA's longstanding hierarchy of controls for its other exposure-based health standards at M/NM mines, but retains the prohibition on rotation of miners for compliance. Furthermore, this final rule: Requires MSHA to consider economic as well as technological feasibility in determining if operators qualify for an extension of time in which to meet the final DPM limit; deletes the requirement for a control plan; and makes conforming changes to existing provisions concerning compliance determinations, environmental monitoring and recordkeeping.

DATES: *Effective Date:* The final rule is effective on July 6, 2005.

FOR FURTHER INFORMATION CONTACT: Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939; 202–693–9440 (telephone); or 202–693–9441 (facsimile).

You may obtain copies of this final rule and the Regulatory Economic Analysis (REA) in alternative formats by calling 202–693–9440. The alternative formats available are either a large print version of these documents or electronic files that can be sent to you either on a computer disk or as an attachment to an e-mail. The documents also are available on the Internet at *http://www.msha.gov/REGSINFO.HTM*.

SUPPLEMENTARY INFORMATION:

Outline of Preamble

This outline will assist the mining community in finding information in this preamble.

I. List of Common Terms

Listed below are the common terms used in the preamble.

Commission	Federal Mine Safety and Health Review Commission.
CV	coefficient of variation.
DE	diesel exhaust.
DOCs	diesel oxidation catalysts.
DPF	diesel particulate filter.
DPM	diesel particulate matter.
EC	elemental carbon.
ETS	environmental tobacco smoke.
Filter Selection Guide	Diesel Particulate Filter. Selection Guide for Diesel-powered Equipment in Metal and Nonmetal Mines.
First Partial Settlement Agreement	66 FR 35518 (2001) & 66 FR 35521 (2001): basis for July 5, 2001 NPRM.
HEI	Health Effects Institute.
HWE	healthy worker effect.
MARG	Methane Awareness Resource Group.
M/NM	metal/non-metal.
MSHA	Mine Safety and Health Administration.
NIOSH	National Institute for Occupational Safety and Health.
NTP	National Toxicology Program.
OC	organic carbon.
PAPR	powered air-purifying respirator.
PEL	permissible exposure limit.
PPM	parts per million.
QRA	quantitative risk assessment.
REA	Regulatory Economic Analysis.
Second Partial Settlement Agreement	67 FR 47296 (2002): basis for August 14, 2003 NPRM.
SD	standard deviation.
SKC	SKC, Inc.
TC	total carbon.
USWA	United Steelworkers of America.
$\mu g/cm^2$	micrograms per square centimeter.
$\mu g/m^3$	micrograms per cubic meter.
2001 final rule	January 19, 2001 DPM final rule.
Amended 2001 final rule	2001 final rule amended on February 27, 2002.
2002 final rule	February 27, 2002 final rule.
2002 ANPRM	Advance Notice of Proposed Rulemaking published on September 25, 2002.
2003 NPRM	Notice of Proposed Rulemaking published on August 14, 2003.

II. Rulemaking Background

On January 19, 2001, MSHA published a final rule (2001 final rule) addressing DPM exposure in underground M/NM mines (66 FR 5706), amended on February 27, 2002 at 67 FR 9180 (2002 final rule). The 2001 final rule established new health standards for underground M/NM mines that use equipment powered by diesel engines. The effective date of the 2001 final rule was listed as March 20, 2001. On January 29, 2001, AngloGold (Jerritt Canyon) Corp. and Kennecott Greens Creek Mining Company filed a petition for review of the 2001 final rule in the District of Columbia Circuit Court of Appeals. On February 7, 2001, the Georgia Mining Association, the National Mining Association (NMA), the Salt Institute, and the Methane Awareness Resource Group (MARG) Diesel Coalition filed a similar petition in the Eleventh Circuit. On March 14, 2001, Getchell Gold Corporation petitioned for review of the rule in the District of Columbia Circuit. The three petitions were consolidated, and are pending in the District of Columbia Circuit. The United Steelworkers of America (USWA) intervened in the litigation.

While these challenges were pending, the AngloGold petitioners filed with MSHA an application for reconsideration and amendment of the 2001 final rule and for postponement of the effective date of the 2001 final rule pending judicial review. The Georgia Mining Association petitioners similarly filed with MSHA a request for an administrative stay or postponement of the effective date of the 2001 final rule. On March 15, 2001, MSHA delayed the effective date of the 2001 final rule until May 21, 2001, in accordance with a January 20, 2001 memorandum from the President's Chief of Staff (66 FR 15032). The delay was necessary to give Department of Labor officials the opportunity for further review and consideration of new regulations. On May 21, 2001 (66 FR 27863), MSHA published a document in the **Federal Register** delaying the effective date of the 2001 final rule until July 5, 2001. The purpose of this delay was to allow the Department of Labor the opportunity to engage in further negotiations to settle the legal challenges to the 2001 final rule.

A. First Partial DPM Settlement Agreement

As a result of a partial settlement agreement with the litigants, MSHA published two documents in the **Federal Register** on July 5, 2001 addressing the 2001 final rule. One document (66 FR 35518) delayed the effective date of § 57.5066(b) regarding the tagging provision of the maintenance standard; clarified the effective dates of certain provisions of the 2001 final rule; and included correcting amendments.

The second document (66 FR 35521) proposed a rule to clarify § 57.5066(b)(1) and (b)(2) regarding maintenance and to add a new paragraph (b)(3) to § 57.5067 regarding the transfer of existing equipment between underground mines. MSHA published these changes as a final rule on February 27, 2002 (67 FR 9180) (2002 final rule), with an effective date of March 29, 2002.

Under the first partial settlement agreement, MSHA also conducted joint sampling with industry and labor at 31 underground M/NM mines to determine existing concentration levels of DPM; to assess the performance of the SKC, Inc., Eighty Four, PA (SKC) submicron dust sampler with the NIOSH Method 5040; to assess the feasibility of achieving compliance with the standard's concentration limits at the 31 mines; and to assess the impact of interferences on samples collected in the M/NM underground mining environment before the limits established in the final rule became effective. The final report was issued on January 6, 2003.

B. Second Partial Settlement Agreement

Settlement negotiations continued on the remaining unresolved issues in the litigation. On July 15, 2002, the parties signed an agreement (second partial settlement agreement) that formed the basis for MSHA's August 14, 2003 proposed rule (68 FR 48668) (2003 NPRM). On July 18, 2002, MSHA published a document in the **Federal Register** (67 FR 47296) announcing, among other things, that the following provisions of the 2001 final rule would become effective on July 20, 2002:

- § 57.5060(a), Addressing the interim concentration limit of 400 micrograms of TC per cubic meter of air;
- § 57.5061, Compliance determinations; and
- § 57.5071, Environmental monitoring.

The document also announced that the following provisions of the rule would continue in effect:

- § 57.5065, Fueling practices;
- § 57.5066, Maintenance standards;
- § 57.5067, Engines;
- § 57.5070, Miner training; and
- § 57.5075, Diesel particulate records, as they relate to the requirements of the rule that went into effect on July 20, 2002.

The document also stayed the effectiveness of the following provisions pending completion of this final rule:

- § 57.5060(d), Permitting miners to work in areas where the level of DPM exceeds the applicable concentration limit with advance approval from the Secretary;
- § 57.5060(e), Prohibiting the use of personal protective equipment (PPE) to comply with the concentration limits;
- § 57.5060(f) Prohibiting the use of administrative controls to comply with the concentration limits; and
- § 57.5062, DPM control plan.

Finally, the July 18, 2002, document outlined the terms of the DPM settlement agreement and announced MSHA's intent to propose specific changes to the rule, as discussed below.

On September 25, 2002, MSHA published an Advance Notice of Proposed Rulemaking (2002 ANPRM) (67 FR 60199) to amend certain provisions of the 2001 DPM rule.

The comment period closed on November 25, 2002. MSHA received comments from underground M/NM mine operators, trade associations, organized labor, public interest groups and individuals. On August 14, 2003, MSHA published the 2003 NPRM in the **Federal Register** (68 FR 48668) recommending certain revisions to the DPM rule as part of a settlement agreement reached in response to a legal challenge to the DPM standard. Public hearings were held in Salt Lake City, Utah; St. Louis, Missouri; Pittsburgh, Pennsylvania; and Arlington, Virginia in September and October 2003. The comment period closed on October 14, 2003. On February 20, 2004, MSHA published a document in the **Federal Register** announcing a limited reopening of the comment period on the 2003 NPRM. This document reopened the comment period to obtain public input on three new documents related to the August 14, 2003 rulemaking (69 FR 7881). The three documents were as follows:

(1) United States (U.S.) Department of Health and Human Services, Center for Disease Control, National Institute of Occupational Safety and Health, ''The Effectiveness of Selected Technologies in Controlling Diesel Emissions in an Underground Mine—Isolated Zone Study at Stillwater Mining Company's Nye Mine,'' January 5, 2004.

(2) U.S. Department of Labor, Bureau of Labor Statistics, and U.S. Department of Health and Human Services, Center for Disease Control, National Institute of Occupational Safety and Health, ''Respirator Usage in Private Sector Firms, 2001,'' September, 2003.

(3) Chase, Gerald, ''Characterizations of Lung Cancer in Cohort Studies and a NIOSH Study on Health Effects of Diesel Exhaust in Miners,'' undated, received January 5, 2004.

The subsequent comment period closed on April 5, 2004. MSHA received and reviewed written and oral statements on the 2003 NPRM from all segments of the mining community.

MSHA informed the mining community in both its 2002 ANPRM and its 2003 NPRM of its intentions to incorporate into the record of the current rulemaking the existing rulemaking record, including the risk assessment to the 2001 final rule. Commenters were encouraged to submit additional evidence of new scientific data related to health risks to underground M/NM miners from exposure to DPM.

This final rule for DPM exposure at M/NM mines is based on consideration of the entire rulemaking record, including all written comments and exhibits received related to the 2001 final rule as well as all related data received to the close of this rulemaking record. To serve the interest of the mining community, MSHA is revising §§ 57.5060, 57.5061, 57.5071, and 57.5075 and republishing §§ 57.5065, 57.5066, 57.5067, and 57.5070 of the DPM standards at 30 CFR part 57 in order to present all sections in their entirety in this document. What follows is a discussion of the specific revisions to the 2001 DPM standard:

- § 57.5060(a) addressing the interim limit on concentration of DPM. MSHA has changed the 2001 final rule's interim concentration limit of 400 micrograms of TC per cubic meter of air (400_{TC} µg/m^3) to a comparable permissible exposure limit of 308 micrograms of EC per cubic meter of air (308_{EC} µ/m^3);
- § 57.5060(c) addressing application and approval requirements for an extension of time in which to reduce the final DPM limit. MSHA has changed the 2001 final rule by requiring MSHA to consider economic feasibility along with technological feasibility factors in weighing whether to grant special extensions; has deleted the limit on the number of special extensions that may be granted to each mine; has limited each extension to a period of one year; has allowed for annual renewals of special extensions; and has allowed the MSHA District Manager, rather than the Secretary, to grant extensions. This final rule retains the scope of the 2001 provision for operators to apply for extensions to the final DPM limit;
- § 57.5060(d) addressing certain exceptions to the concentration limits;
- § 57.5060(e) prohibiting use of PPE to comply with the concentration limits;
- § 57.5060(f) prohibiting use of administrative controls to comply with the concentration limits. MSHA has changed the 2001 final rule by implementing the current hierarchy of controls as adopted in MSHA's other exposure-based health standards for M/NM mines. MSHA's hierarchy includes primacy of engineering and administrative controls to the extent feasible to reduce a miner's exposure to the PEL, but MSHA continues to prohibit rotation of miners for compliance purposes. If a miner's exposure cannot be reduced to the PEL with use of feasible controls, controls are infeasible, or do not produce significant reductions in DPM exposures, the new final rule requires mine operators to supplement a miner's protection with respirators and implement a respiratory protection program. This respiratory protection program must meet the requirements in existing 30 CFR 57.5005, but miners may only use the respirator filters specified by MSHA for DPM in this section. Therefore, MSHA removes the 2001 prohibition against use of respiratory protection without approval by the Secretary and clarifies that use of administrative controls other than rotation of miners is allowed;
- § 57.5062, addressing the diesel particulate control plan. This final rule removes the existing requirement for a DPM control plan; and
- conforming changes to the following existing standards that were proposed on August 14, 2003:
    - § 57.5061, addressing compliance determinations;
    - § 57.5071, addressing exposure monitoring; and,
    - § 57.5075, addressing recordkeeping requirements.

This final rule does not include provisions for written procedures for administrative controls, a written respiratory protection program, medical examination of miners before they are required to wear respiratory protection, and medical transfer of miners who are unable to wear respiratory protection for medical and psychological reasons.

III. The Final Concentration Limit

In the 2002 ANPRM, MSHA notified the mining community that this rulemaking would revise both the interim concentration limit of 400 micrograms per cubic meter of air and the final concentration limit of 160 micrograms per cubic meter of air under § 57.5060(a) and (b) of the 2001 final rule. Some commenters to the ANPRM recommended that MSHA propose separate rulemakings for revising the interim and final DPM limits to give MSHA an opportunity to gather further information to establish a final DPM limit. In the 2003 NPRM, MSHA agreed with these commenters and solicited other information from the mining community that would lead to an appropriate final DPM standard. Moreover, MSHA announced its intentions to publish a separate rulemaking to amend the existing final concentration limit in § 57.5060(b). To assist MSHA in achieving this purpose, MSHA requested comments on an appropriate final permissible exposure limit rather than a concentration limit; and asked for information on an appropriate surrogate for measuring miners' DPM exposures. MSHA concluded its request for information by clarifying that revisions to the final DPM concentration limit would not be a part of this rulemaking.

In their comments to the 2003 NPRM, organized labor requested that MSHA lower the final DPM limit below 160 micrograms based on feasibility data and the significance of the health risks from exposure to DPM. Industry trade associations and individual mine operators recommended that MSHA repeal the final limit based on issues related to health effects, inability of the mining industry to meet a lower limit than 400 micrograms per cubic meter of air, and the need for MSHA to have the results from the National Institute for Occupational Safety and Health/National Cancer Institute (NIOSH/NCI) study and exposure-response data.

MSHA believes that evidence in the current DPM rulemaking record is inadequate for MSHA to make determinations regarding revision to the final DPM limit.

IV. The 31-Mine Study

A. Summary

On January 19, 2001, MSHA published a final standard addressing exposure of underground metal and nonmetal miners to diesel particulate matter (DPM). The standard contained staggered effective dates for interim and final concentration limits. The standard was challenged by industry trade associations and several mining companies, and the United Steelworkers of America (USWA) intervened in the litigation. The parties agreed to resolve their differences through settlement negotiations with MSHA. Thereafter, MSHA delayed the effective date of certain provisions of the standard. As part of the settlement negotiations, MSHA agreed to conduct joint sampling with the litigants at 31 metal and nonmetal underground mines covered by the standard to determine existing concentration levels of DPM in operating mines and to measure DPM levels in the presence of known or suspected interferences.

The goals of the study were to use the sampling results and related information to assess:

—The validity, precision and feasibility of the sampling and analysis method specified by the diesel standard (NIOSH Method 5040);
—The magnitude of interferences that occur when conducting enforcement sampling for total carbon as a surrogate for diesel particulate matter (DPM) in mining environments; and,
—The technological and economic feasibility of the underground metal and nonmetal (MNM) mine operators to achieve compliance with the interim and final DPM concentration limits.
—The parties developed a joint MSHA/Industry study protocol to guide sampling and analysis of DPM levels in 31 mines. The parties also developed four subprotocols to guide investigations of the known or suspected interferences, which included mineral dust, drill oil mist, oil mist generated during ammonium nitrate/fuel oil (ANFO) loading operations, and environmental tobacco smoke (ETS). The parties also agreed to study other potential sampling problems, including any manufacturing defects of the DPM sampling cassette. (Executive Summary, Report on the 31-Mine Study)

MSHA requested that NIOSH peer review the draft Report on the 31-Mine Study, and NIOSH's conclusions were as follows:

1. Most mines have DPM concentrations higher than 400_{TC} µg/m^3.
2. The impactor was effective in eliminating mineral dust from collecting onto the filter analyzed for carbon by NIOSH Method 5040.
3. The ANFO data was inconclusive.
4. Oil mist from the stoper drill is a sub-micron aerosol and a potential interference. Oil mist contamination from the driller can be avoided by sampling upstream of stope or far enough downstream that the oil mist has been diluted enough to give minimal TC concentrations (if this type of sampling is possible).
5. No information about the interference of environmental tobacco smoke is present in this report.
6. The inter-laboratory comparison of the NIOSH method 5040 of paired punches from the same filter showed reasonable agreement between MSHA results and commercial laboratory results and excellent agreement between MSHA and NIOSH laboratory results. (Summary of Findings of this Report in ''NIOSH Comments and recommendations on the MSHA DRAFT report: Report on the Joint MSHA/Industry Study: Determination of DPM Levels in Underground Metal and Nonmetal Mines,'' dated June 3, 2002)

On January 6, 2003, MSHA issued its final report entitled, ''MSHA's Report on Data Collected During a Joint MSHA/Industry Study of DPM Levels in Underground Metal And Nonmetal Mines'' (Report on the 31-Mine Study). MSHA's major conclusions drawn from the study are as follows:

—The analytical method specified by the diesel standard gives an accurate measure of the TC content of a filter sample and the analytical method is appropriate for making compliance determinations of DPM exposures of underground metal and nonmetal miners.
—SKC satisfactorily addressed concerns over defects in the DPM sampling cassettes and availability of cassettes to both MSHA and mine operators.
—Compliance with both the interim and final concentration limits may be both technologically and economically feasible for metal and nonmetal underground mines in the study. MSHA, however, has limited in-mine documentation on DPM control technology. As a result, MSHA's position on feasibility does not reflect consideration of current complications with respect to implementation of controls, such as retrofitting and regeneration of filters. MSHA acknowledges that these issues may influence the extent to which controls are feasible. The Agency is continuing to consult with the National Institute of Occupational Safety and Health, industry and labor representatives on the availability of practical mine worthy filter technology.
—The submicron impactor was effective in removing the mineral dust, and therefore its potential interference, from DPM samples. Remaining interference from carbonate interference is removed by subtracting the 4th organic peak from the analysis. No reasonable method of sampling was found to eliminate interferences from oil mist or that would effectively measure DPM levels in the presence of ETS with TC as the surrogate * * * (Executive Summary, Report on the 31-Mine Study)

MSHA's complete report on the 31-Mine Study is contained in the rulemaking record.

MSHA and NIOSH have reviewed the performance characteristics of the SKC sampler, and are satisfied that it accurately measures exposures to DPM. NIOSH found in laboratory and field data that the SKC DPM cassette collected DPM efficiently. In a side protocol of the 31-Mine Study, MSHA tested the efficiency of the SKC DPM cassette to avoid mineral dust in four different mines and did not measure any mineral dust on the filter when the SKC DPM cassette was used. This was confirmed by laboratory results at NIOSH. (Noll, J. D., Timko, R. J., McWilliams, L., Hall, P., Haney, R., ''Sampling Results of the Improved SKC Diesel Particulate Matter Cassette,'' *JOEH,* 2005 Jan; 2(1):29–37.)

Results of the 31-Mine Study and the MSHA baseline compliance assistance sampling demonstrated that the SKC submicron impactor removed potential interferences from mineral dust from the collected sample.

Interference from drill oil mist was found on personal samples collected on the stoper and jackleg drillers and on area samples collected in the stope where drilling was being performed. Use of a dynamic blank did not eliminate drill oil mist interference. Tests to confirm whether oil mist from ANFO loading operations could be an interference were not conclusive. Blasting did not interfere with diesel particulate measurements. MSHA found no reasonable method of sampling to eliminate interferences from oil mist when TC is used as the surrogate.

No reliable marker was identified for confirming the presence of ETS in an atmosphere containing DPM. Use of the impactor does not remove the ETS as an interferent. No reasonable method of sampling was found that would effectively measure DPM levels in the presence of ETS with TC as the surrogate.

MSHA has found that the use of EC eliminates potential sampling interference from drill oil mist, tobacco smoke, and organic solvents, and that EC consistently represents DPM. In comparison to using TC as the DPM surrogate, using EC would impose fewer restrictions or caveats on sampling strategy (locations and durations), would produce a measurement much less subject to questions, and inherently would be more precise. Furthermore, NIOSH, the scientific literature, and the MSHA laboratory tests indicate that DPM, on average, is approximately 60 to 80% elemental carbon, firmly establishing EC as a valid surrogate for DPM.

As part of the 31-Mine Study, representatives from MSHA, NIOSH, and SKC met to address the following issues:

• The quality of manufactured SKC DPM cassettes;
• The feasibility of adding a dynamic blank filter to the SKC DPM cassette; and
• The possibility of putting a number on each SKC DPM cassette.

Also, in its October 16, 2001 letter, MSHA informed SKC about the problems that MSHA and the industry encountered using the SKC DPM sampling cassette with the submicron impactor. These problems included: dark flecks, alleged leaks, loose fitting nozzles and connectors, and difficulty in shipping the sampler. As discussed in the report on the 31-Mine Study, SKC was responsive in addressing those concerns.

B. Subsequent Activities

Some industry commenters continued to state that the sampling and analytical processes for DPM are too new for regulatory use. Other commenters questioned the availability and reliability of the SKC impactor.

MSHA moved expeditiously to help resolve the back-order and manufacturing delays for samplers reported in the 31-Mine Study. However, operators who sample alongside MSHA continued to request ample notice to have enough samplers available. MSHA purchased many of the initial production runs of these samplers to conduct its compliance assistance baseline sampling. Once the initial orders were filled, the sampler became more widely available.

Some commenters stated that SKC changed the impactor, and that NIOSH should test the new SKC sampler and evaluate its comparability to the model used in the 31-Mine Study. One of these commenters stated that the shelf life of the prior sampler affected TC measurements by adsorbing organic carbon (OC) from the polystyrene assembly onto the filter media and increasing TC measurement. These commenters questioned MSHA's changes to the SKC sampler following completion of the 31-Mine Study, and suggested that a defect to the sampler could have affected the results of the study. During the 31-Mine Study, MSHA observed that the deposit area of the SKC submicron impactor filter was not as consistent as those obtained for preliminary evaluation. This was attributed to inconsistent crimping of the aluminum foil cone on the filter capsule.

Prior to the 31-Mine Study, MSHA had determined the deposit area of the sample filter to be 9.12 square centimeters (cm^2) with a standard deviation of 3.1 percent (%). During the initial phases of the sampling analysis of the 31-Mine Study, it became apparent that the variability of the deposit area was greater than originally determined. The filter area is critical to the concentration calculation. The filter area (measured in cm^2) is multiplied by the results of the analysis (micrograms per cm^2) to get the total filter loading (micrograms). While individual filter areas could be measured, it is more practical to have a uniform deposit area for the calculations. As a result, NIOSH and MSHA consulted with SKC to develop an improved filter cassette design. With the cooperation of MSHA and the technical recommendations and extensive experimental verification by NIOSH, SKC was able to modify their cassette design to produce a consistent and regular DPM deposit area, satisfactorily resolving the problem. SKC, in cooperation with MSHA and NIOSH, then modified the DPM cassette following the 31-Mine Study.

The modification was limited to replacing the foil filter capsule with a 32 millimeter (32-mm) ring. This was done to give a more uniform deposit area (8.04 cm^2) with negligible variability, and to accommodate two 38-mm quartz fiber filters in tandem (double filters). These double filters are assembled into a single cassette along with the impactor. The 38-mm filters also eliminate cassette leakage around the filters. These modifications were completed and incorporated into units manufactured after November 1, 2002.

The results of this project were prepared into a scientific publication, ''Sampling Results of the Improved SKC Diesel Particulate Matter Cassette,'' referenced above. This paper has been peer reviewed and was published in January 2005. The following abstract was prepared for the study results:

Diesel particulate matter (DPM) samples from underground metal/non-metal mines are collected on quartz fiber filters and measured for carbon content using National Institute for Occupational Safety and Health Method 5040. If size selective samplers are not used to collect DPM in the presence of carbonaceous ore dust, both the ore dust and DPM will collect on the quartz filters, causing the carbon attributed to DPM to be artificially high. Because the DPM particle size is much smaller than that of mechanically generated mine dust aerosols, it can be separated from the larger mine dust aerosol by a single stage impactor. The SKC DPM cassette is a single stage impactor designed to collect only DPM aerosols in the presence of carbonaceous mine ore aerosols, which are commonly found in underground nonmetal mines. However, there is limited data on how efficiently the SKC DPM cassette can collect DPM in the presence of ore dust. In this study, we investigated the ability of the SKC DPM cassette to collect DPM while segregating ore dust from the sample. We found that the SKC DPM cassette accurately collected DPM. In the presence of carbon-based ore aerosols having an average concentration of 8 mg/m^3, no ore dust was detected on SKC DPM cassette filters. We did discover a problem: the surface areas of the DPM deposits on SKC DPM cassettes, manufactured prior to August 2002, were inconsistent. To correct this problem, SKC modified the cassette. The new cassette produced, with 99% confidence, a range of DPM deposit areas between 8.05 and 8.28 cm^2, a difference of less than 3%.

Because the design of the inlet cyclone, impaction nozzles, and the impaction plate and the flow rate did not change, the modifications to the filter assembly did not alter the collection or separation performance of the impactor. Throughout the compliance baseline sampling, the impactor has been a consistent and reliable sampling cassette.

Tandem filters were used in the oil mist and ANFO interference evaluations during the 31-Mine Study. The top filter collects the sample and the bottom filter is a dynamic blank. The dynamic blank provides a unique field blank for each DPM cassette. The use of EC as a surrogate would resolve the commenter's concern about shelf life and OC out-gassing on the filter. Shelf life and OC out-gassing are issues relative to OC measurements. These two issues do not apply to an EC measurement. Once the cassettes have been preheated during manufacturing, there is no source, other than sampling, to add EC to the sealed cassette filters.

MSHA discussed in the preamble to the 2003 NPRM issues related to interferences, field blanks and the error factor. Some comments on the 2003 NPRM still expressed concerns on interferences and further stated that the MSHA industrial hygiene studies, conducted to verify the magnitude of the interference problem, were not published or peer reviewed and should be removed from the rulemaking record. However, MSHA, organized labor, and the mining industry, through the negotiations process, jointly developed the protocol for conducting the 31-Mine Study. All of the parties agreed on the protocol following numerous discussions among industry, labor, and government experts, and had an opportunity to comment and make changes to the document. Thereafter, MSHA conducted the study, following the agreed upon protocol, and published its results. Before publication, the report was peer reviewed by NIOSH. Industry was given an opportunity to publish their separate results simultaneously with the government. During this rulemaking, industry submitted to MSHA through the notice and comment process their conclusions on the 31-Mine Study in a report titled, ''Technical and Economic Feasibility of DPM Regulations.'' The industry report is contained in the rulemaking record, and was considered by MSHA in reaching determinations for this final rule.

(1) Interferences

In response to the question on whether there are interferences when EC is used as the surrogate, some commenters stated that interferences were thoroughly discussed in the preamble to the 2001 final rule, and that reasonable practices to avoid them were stipulated in the rule itself. According to these commenters, this problem should not be revisited in this rulemaking.

Other commenters maintained that the 31-Mine Study did not contain the necessary protocols to address all potential interferences. Thus, in their view, MSHA does not have all the data required to answer this question. More specifically, some commenters stated that carbonaceous particulate in host rock has a smaller diameter than the impactor cut point and so, may contaminate EC samples. These commenters then concluded that MSHA should propose additional research and seek comments on the research before concluding that sampling EC with an impactor will eliminate all interference problems. However, no data were presented to support this claim or conclusion. Commenters submitted no new information relative to interferences in response to the 2003 NPRM.

(2) Field Blanks

A field blank is an unexposed control filter meant to account for background interferences and systematic contamination in the field, spurious effects due to manufacturing and storage of the filter, and systematic analytical errors. The tandem filter arrangement in the sample cassette provides a primary filter for collecting an air sample and a second filter, behind (after) the primary filter, which provides a separate control filter for each sample. This is a much more flexible method of sampling for the mining industry, since it eliminates the need to send a separate control filter to the analytical lab. MSHA informed the public of its intentions to adjust the EC result obtained for each sample by the result obtained for the corresponding media blank when MSHA measures for compliance purposes. When MSHA conducts compliance measurements, MSHA will adjust the result obtained for each corresponding sample by the field blank (tandem filter) result. No comments or information related to field blanks were submitted to MSHA in response to the 2003 NPRM.

In its comments on the 2002 ANPRM, NIOSH noted that two types of blanks, media and field, are normally used for quality assurance purposes. A media blank accounts for systematic contamination that may occur during manufacturing or storage. A field blank accounts for possible systematic contamination in the field. NIOSH does not recommend use of field blanks when EC is the surrogate. This is because EC measurements are not subject to sources of contamination in the field that would affect OC and TC results. Quartz-fiber filters are prone to OC vapor contamination in the field and to contamination by less volatile OC (such as oils) during handling. However, such contamination is irrelevant when EC is the surrogate.

(3) Error Factor

MSHA intends to cite a violation of the DPM_{EC} exposure limit only when MSHA has valid evidence that a violation actually occurred. As with all other measurement-based M/NM compliance determinations, MSHA will issue a citation only if a measurement demonstrates noncompliance with at least 95% confidence. MSHA will achieve this 95% confidence level by comparing each EC measurement to the EC exposure limit multiplied by an appropriate error factor. Generally, an error factor is used to compensate for certain known inaccuracies in the sampling and analytical process, including such things as the reliability of sampling equipment and precision of analytical instrumentation. MSHA will continue to determine that an overexposure has occurred when a sample exceeds the interim limit times the error factor.

In this rulemaking, MSHA is discussing the procedure used to obtain the error factor. This procedure is further discussed on the MSHA web site at *www.msha.gov* under, ''Single Source Page for Metal and Nonmetal Diesel Particulate Matter Regulations.'' Error factors are based on sampling and analytic errors. The manufacturers of sampling devices thoroughly investigate and quantify the error factors for their devices. While MSHA does not frequently change an error factor, it retains that latitude should significant changes to either analytical or sampling technology occur.

The formula for the error factor was based on three factors involved in making an eight-hour equivalent full-shift measurement of EC concentration using NIOSH Method 5040: (1) Variability in air volume (*i.e.*, pump performance relative to the nominal airflow of 1.7 L/min); (2) variability of the deposit area of particles on the filter (cm^2); and (3) accuracy of the laboratory analysis of EC density within the deposit ($\mu g/cm^2$). Modifications made to the sampler since the time of the 31-Mine Study have no bearing on the first and third of these factors. Variability of the filter deposit area was represented by a 3.1% coefficient of variation, based on an experiment carried out before the foil filter capsule in the sampling cassette was replaced by a 32-mm ring. Measurements subsequent to introduction of the ring show that variability of the filter deposit area is now less than 3.1% (Noll, J. D., *et al*, ''Sampling Results of the Improved SKC Diesel Particulate Matter Cassette''). This change slightly reduces the error factor stipulated for EC measurements, but not by enough to be of any practical significance.

MSHA's error factor model accounts for the joint and related variability in laboratory analysis, and combines that variability with pump flow rate, sample collection size, and other sampling and analytic variables. MSHA was then able to determine the appropriate error factor for EC samples based on a statistically strong database.

The analytical method (NIOSH 5040) relies on a punch taken from inside the deposit area on the sample filter. In effect, the punch is a sample of the dust sample. To account for uniformity in the distribution of DPM deposited on the filter, as reflected by different possible locations at which a punch might be extracted, MSHA compared two punches taken from different locations on the same filter to evaluate the accuracy of the analytical method. Therefore, variability between punch results due to their location on the filter is also included in the error factor as calculated by MSHA.

Commenters to the 2003 NPRM further questioned whether the NIOSH Method 5040 has been commercially tested. As in the preamble to the 2003 NPRM, MSHA has discussed in detail its findings regarding the NIOSH Method 5040 in this section. NIOSH's peer review of the 31-Mine Study also concludes that the analytical method specified by the diesel standard gives an accurate measure of the TC content of a filter sample. NIOSH confirmed this position by letter of February 8, 2002, in which NIOSH stated that,

> MSHA is following the procedures of NIOSH Method 5040, based on our review of MSHA P13 (MSHA's protocol for sample analysis by NIOSH Method 5040) and a visit to the MSHA laboratory.

V. Compliance Assistance

A. Baseline Sampling Summary

Under the second partial DPM settlement agreement, MSHA agreed to provide compliance assistance to the M/NM underground mining industry for a one-year period from July 20, 2002 through July 19, 2003. As part of its compliance assistance activities, MSHA agreed to conduct baseline sampling of miners' personal exposures at every underground mine covered by the 2001 final rule.

Our baseline sampling began in October 2002 and continued through October 2003. During this period a total of 1,194 valid baseline samples were collected. A total of 183 underground M/NM mines are represented by this analysis. The number of samples per mine range from one to twenty. All 874 valid baseline sampling results in the analysis published in the preamble of the 2003 NPRM are included in this updated analysis. MSHA is including 320 additional valid samples because MSHA decided to continue to conduct baseline sampling after July 19, 2003 in response to mine operators' concerns. MSHA has analyzed all baseline samples, and updated its analysis. Some of these mines were either not in operation or were implementing major changes to ventilation systems during the original baseline period. MSHA is including supplementary samples from seasonal and intermittent mines, mines that were under-represented, and mines that were not represented in the analysis published in the preamble to the 2003 NPRM. Sixty mines included in the former analysis had additional samples taken during the extended assistance period. There are 12 mines in this updated analysis that were not represented in the 2003 analysis. The results of this sampling were used by MSHA in this preamble to estimate current DPM exposure levels in underground M/NM mines using diesel equipment. These sampling results also assist mine operators in developing compliance strategies based on actual exposure levels.

This section summarizes analytical results of personal sampling for DPM collected during compliance assistance. There are a total of 1,206 samples. However, 12 samples are invalid due to abnormal sample deposits, broken cassettes or filters, contaminated backup pads, instrument failure or pump failure. Table V–1 lists the frequencies of invalid samples within each commodity.

The mines that were sampled produce clay, sand, gypsum, copper, gold, platinum, silver, gem stones, dimension marble, granite, lead-zinc, limestone, lime, potash, molybdenum, salt, trona, and other miscellaneous metal or nonmetal ores. These commodities were grouped into four general categories for calculating summary statistics: Metal, stone, trona, and other nonmetal (N/M) mines. These categories were selected to be consistent with the categories used for analysis of data for the 31-Mine Study. Most commodities are well represented in this analysis with the average number of valid samples per mine ranging from 6.0 to 8.2 (average across all mines is 6.5 samples per mine). The average number of samples per mine classified as ''Gold Ore Mining, N.E.C.'' increased from an average of 2.0 samples per mine published in the 2003 NPRM preamble to an average of 4.6 samples in this data set. Approximately 79% of all mines sampled during the assistance period have four or more results from DPM sampling in this analysis. Table V–3 lists the number of samples for each category of specific commodity. Average number of samples for more general commodity groups is listed in Table V–2.

MSHA used the same sampling strategies for collecting baseline samples as it intends to use for collecting samples for enforcement purposes. These sampling procedures are described in the *Metal and Nonmetal Health Inspection Procedures Handbook (PH90–IV–4)*, Chapter A, ''Compliance Sampling Procedures'' and Draft Chapter T, ''Diesel Particulate Matter Sampling.'' Chapter A includes detailed guidelines for selecting and obtaining personal samples for various contaminants. All personal samples were collected in the miner's breathing zone and for the miner's full shift regardless of the number of hours worked. For the 1,194 valid personal samples, 85% were collected for at least eight hours. TC and EC levels, as well as DPM levels, are reported in units of micrograms per cubic meter for an 8-hour full shift equivalent.

MSHA collected DPM samples with SKC submicron dust samplers that use Dorr-Oliver cyclones and submicron impactors. The samples were analyzed either at MSHA's Pittsburgh Safety and Health Technology Center, Dust Division Laboratory or at the Clayton Laboratory using MSHA Method P–13 (NIOSH Analytical Method 5040, *NIOSH Manual of Analytical Methods (NMAM), Fourth Edition*, September 30, 1999) for determining the TC content. Each sample was analyzed for organic, elemental, and carbonaceous carbon and calculated TC. Raw analytical results from both laboratories as well as administrative information about the sample were stored electronically in MSHA's Laboratory Information Management System.

If a raw carbon result was greater than or equal to 30 $\mu g/cm^2$ of EC or 40 $\mu g/cm^2$ of TC from the exposed filter loading, then the analysis was repeated using a separate punch of the same filter. The results of these two analyses were then averaged. The companion tandem blank was also tested for the same analyses. Otherwise, an unexposed filter from the same manufacturer's lot was used to correct for background levels. In the event the initial TC result was greater than 100_{TC} $\mu g/cm^2$, a smaller punch of the same exposed filter (in duplicate and with the corresponding blank) was taken and used in the analysis. Blank-corrected averaged results were used in the analysis when the sample was tested in duplicate.

The equation used to calculate a 480-minute (8-hour) full shift equivalent (FSE) exposure of TC is Total Carbon Concentration =

$$\frac{[EC \times 1.3] \text{ or } [OC + EC] \left(\mu g/cm^2\right) \times A \left(cm^2\right) \times 1{,}000 \left(L/m^3\right)}{\text{Flow Rate } (Lpm) \times 480 \text{ (minutes)}}$$

Where:

EC = The corrected elemental carbon concentration measured in the thermal/optical carbon analyzer, $\mu g/cm^2$,

OC = The corrected organic carbon concentration measured in the thermal/optical carbon analyzer, $\mu g/cm^2$,

A = The surface area of the deposit on the filter media used to collect the sample, cm^2,

Flow Rate = Flow rate of the air pump used to collect the sample measured in Liters per minute, and

480 minutes = Standardized eight-hour work shift.

All levels of carbon or DPM are reported in 8-hour full shift equivalent TC concentrations measured in $\mu g/m^3$.

Because personal sampling was conducted and no attempt was made to avoid interference from cigarette smoke or other OC sources, TC was also calculated using the formula prescribed in the second partial DPM settlement agreement:

Total Carbon Concentration = EC × 1.3.

MSHA agreed to use the lower of the two values (EC × 1.3 or EC + OC) for enforcement until a final rule is published reflecting EC as the surrogate.

The electronic records of the 1,194 samples available for analysis were reviewed for inconsistencies. Internally inconsistent or extreme values were questioned, researched, and verified. Although no samples were invalidated as a result of the administrative verification, 12 samples (1.0%) were removed from the data set for reasons unrelated to the values obtained. The reasons for invalidating these samples are listed in Table V–1. These samples were subjected to the same laboratory quality assessments as samples collected for compliance purposes. Accordingly, MSHA has included 1,194 samples from miners in the analyses. Table V–2 is a list of the number of valid samples by commodity group.

TABLE V–1.—REASONS FOR EXCLUDING SAMPLES.

Reason for excluding from analysis	Metal	Stone	Trona	Other N/M	Total
Abnormal Sample Deposit	0	1	0	0	1
Cassette/Filter Broken	0	2	0	1	3
Contaminated Backup Pad	1	0	0	0	1
Instrument Failure	1	1	0	0	2
Pump Failed	1	4	0	0	5
Total	3	8	0	1	12

TABLE V–2.—NUMBER OF MINES AND VALID SAMPLES, BY COMMODITY GROUP.

Commodity group	Number of mines	Number of valid samples	Average number of valid samples by mine
Metal	40	284	7.1
Stone	115	689	6.0
Trona	4	25	6.3
Other N/M	24	196	8.2
Total	183	1,194	6.5

Table V–3 lists the number of samples collected by specific commodities and sorted by average number of samples per mine. Although MSHA made efforts to sample all underground M/NM mines covered by this rulemaking within the specified time frame, several mines have few or no samples for DPM in this analysis. Some M/NM mining operations are seasonal in that they are operated intermittently or operate at less than full production during certain times. These types of variable production schedules limited efforts to collect compliance assistance samples. MSHA extended its period of baseline sampling especially to incorporate into its analysis those mines with a low sampling frequency or where no samples were collected as of March 26, 2003.

TABLE V–3.—NUMBER OF VALID SAMPLES PER MINE FOR SPECIFIC COMMODITIES

Specific commodity	No. of mines	No. of samples	Average samples per mine
Gemstones Mining, N.E.C	2	5	2.5
Dimension Marble Mining	3	9	3.0
Limestone	2	6	3.0
Talc Mining	1	3	3.0
Uranium-Vanadium Ore Mining, N.E.C	1	3	3.0
Gold Ore Mining, N.E.C	19	87	4.6
Construction Sand & Gravel Mining, N.E.C	1	5	5.0
Crushed & Broken Sandstone Mining	1	5	5.0
Hydraulic Cement	1	5	5.0
Lime, N.E.C	4	20	5.0
Copper Ore Mining, N.E.C	2	11	5.5
Dimension Limestone Mining	3	18	6.0
Crushed & Broken Limestone Mining, N.E.C	90	550	6.1
Crushed & Broken Marble Mining	4	25	6.3
Trona Mining	4	25	6.3
Crushed & Broken Stone Mining, N.E.C	4	28	7.0
Gypsum Mining	4	29	7.3
Salt Mining	14	122	8.7
Clay, Ceramic & Refractory Minerals, N.E.C	1	9	9.0
Miscellaneous Metal Ore Mining, N.E.C	1	9	9.0
Lead-Zinc Ore Mining, N.E.C	10	96	9.6
Platinum Group Ore Mining	2	20	10.0
Potash Mining	3	30	10.0
Molybdenum Ore Mining	2	22	11.0

TABLE V–3.—NUMBER OF VALID SAMPLES PER MINE FOR SPECIFIC COMMODITIES—Continued

Specific commodity	No. of mines	No. of samples	Average samples per mine
Silver Ore Mining, N.E.C	3	36	12.0
Miscellaneous Nonmetallic Minerals, N.E.C	1	16	16.0
Average of all samples	183	1,194	6.5

There are 63 different occupations in underground M/NM mines represented in this analysis. The most frequently sampled occupations are Blaster, Drill Operator, Front-end Loader Operator, Truck Driver, Scaling (Mechanical), and Mechanic. Table V–4 lists the number of valid samples by occupation and commodity group. Only occupations with 14 or more total samples are listed individually. Occupations with fewer samples were aggregated into a combined group for this table.

TABLE V–4.—VALID SAMPLES, BY OCCUPATION AND MINE CATEGORY.

Occupation	Metal	Stone	Trona	Other N/M	Total
Truck Driver	87	152	0	13	252
Front-end Loader Operator	40	149	6	19	214
Blaster, Powder Gang	12	98	0	24	134
Scaling (mechanical)	1	66	0	13	80
Drill Operator, Rotary	3	63	0	9	75
Drill Operator, Jumbo Perc.	10	19	0	9	38
Mechanic	7	15	0	12	34
Complete Load-Haul-Dump	7	2	0	23	32
Utility Man	6	4	15	4	29
Scaling (hand)	4	20	0	2	26
Mucking Mach. Operator	19	1	0	3	23
Roof Bolter, Rock	5	9	0	7	21
Drill Operator, Rotary Air	1	19	0	1	21
Miner, Drift	16	1	0	0	17
Crusher Oper/Worker	0	13	0	2	15
Miner, Stope	14	0	0	0	14
All Others Combined	52	58	4	55	169
Totals	284	689	25	196	1,194

TC levels calculated by EC × 1.3 were lower than TC levels calculated by OC + EC in 858 (72%) of the 1,194 baseline samples. Of the 336 samples where TC = OC + EC was the lower value, 68% of the TC = EC × 1.3 values were within 12% of the TC = OC + EC value. Table V–5 summarizes the results of the baseline samples when determining the TC level using either EC × 1.3 or OC + EC. Approximately 6.4% of the paired results did not concur with respect to the 400_{TC} µg/m³ standard when measuring TC by the two calculations (OC + EC vs. EC × 1.3). Approximately 19.3% of the samples were above the 400_{TC} µg/m³ interim concentration limit when using TC = EC × 1.3 and approximately 22.7% were above the concentration limit when using TC = OC + EC. There is 93.6% concurrence between the two methods of calculating TC and comparing the calculations to the 400_{TC} µg/m³ interim concentration limit.

TABLE V–5.—COMPARISON OF RESULTS WITH 400_{TC} µG/M³ CALCULATING TC BY OC + EC OR EC × 1.3

All valid samples	EC × 1.3		Total
	< 400_{TC} µg/m³	> 400_{TC} µg/m³	
OC+EC.			
< 400_{TC} µg/m³	905 (75.8%)	18 (1.5%)	923 (77.3%)
> 400_{TC} µg/m³	59 (4.9%)	212 (17.8%)	271 (22.7%)
Total	964 (80.7%)	230 (19.3%)	1,194 (100.0%)

Table V–6 lists the 26 occupations found to have at least one sample in which the level of TC was over the 400_{TC} µg/m³ interim concentration limit (TC = EC × 1.3). Table V–6 is sorted by the median (middle) TC result. The median is reported because it is a more robust measure of the middle value. Changing a single value won't change the median very much. In contrast, the value of the mean can be strongly affected by a single value that is very low or very high. The table also lists the minimum value, maximum value, and the total number of valid samples for these occupations. TC values varied widely among all miners' occupations.

TABLE V–6.—OCCUPATIONS WITH AT LEAST ONE SAMPLE GREATER THAN OR EQUAL TO 400_{TC} µG/M³ (TC = EC× 1.3)

Occupation	Total samples	TC, µg/m³		
		Minimum	Median	Maximum
Diamond Drill Operator	1	2,030	2,030	2,030
Ground Control/Timberman	2	368	545	722
Washer Operator	4	353	438	808
Engineer	1	438	438	438
Roof Bolter, Mounted	12	98	335	1,063
Mucking Mach. Operator	23	15	334	872
Miner, Stope	14	100	283	622
Cleanup Man	2	66	283	499
Scoop-Tram Operator	7	14	272	583
Drill Operator, Rotary Air	21	0	240	1,353
Miner, Drift	17	16	228	1,459
Blaster, Powder Gang	134	6	227	1,340
Belt Crew	8	26	225	502
Roof Bolter, Rock	21	63	223	1,310
Truck Driver	252	0	211	1,581
Shuttle Car Operator (diesel)	3	95	201	419
Complete Load-Haul-Dump	32	19	189	824
Drill Operator, Jumbo Perc	38	5	179	1,098
Drill Operator, Rotary	75	3	171	1,109
Motorman	8	59	168	419
Front-end Loader Operator	214	0	158	2,979
Scaling (mechanical)	80	0	139	1,246
Supervisor, Co. Official	13	1	130	856
Utility Man	29	29	94	991
Scaling (hand)	26	18	87	2,013
Mechanic	34	0	84	420

Table V–7 and Chart V–1 provide the percent of overexposures among the four commodity groups. Chart V–2 provides the number of overexposures among the four commodity groups. The metal mines have the highest percent of overexposures followed by stone, then other non-metal mines. For all samples combined, 19.3% were above 400_{TC} µg/m³.

TABLE V–7.—BASELINE SAMPLES BY COMMODITY (TC = EC × 1.3)

Commodity	Number < 400_{TC} µg/m³	Number > 400_{TC} µg/m³	Total Samples	Percent > 400_{TC} µg/m³
Metal	195	89	284	31.3
Stone	571	118	689	17.1
Other N/M	174	22	196	11.2
Trona	24	1	25	4.0
All Mines	964	230	1,194	19.3

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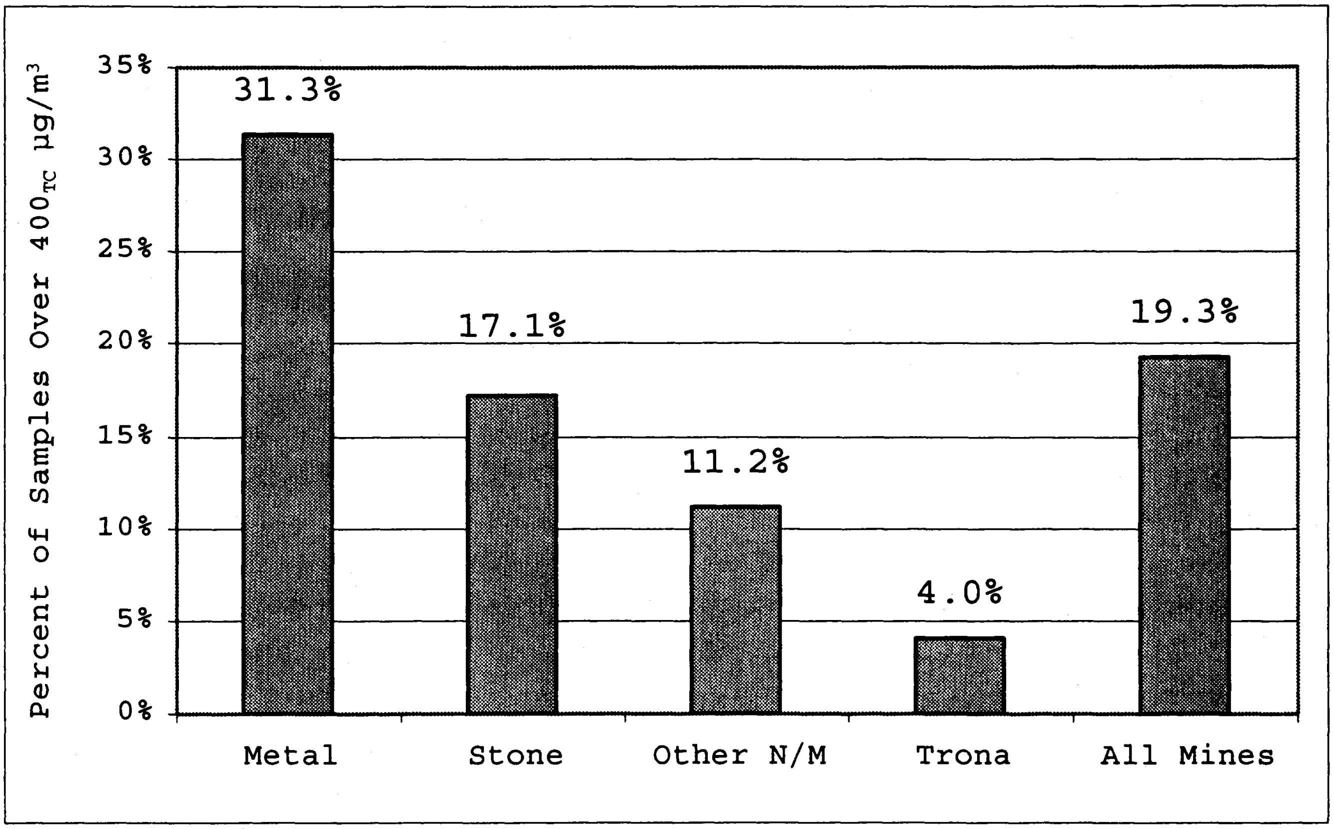

Chart V-1: Percent of Overexposures by Commodity (400_{TC} µg/m^3, TC=EC x 1.3)

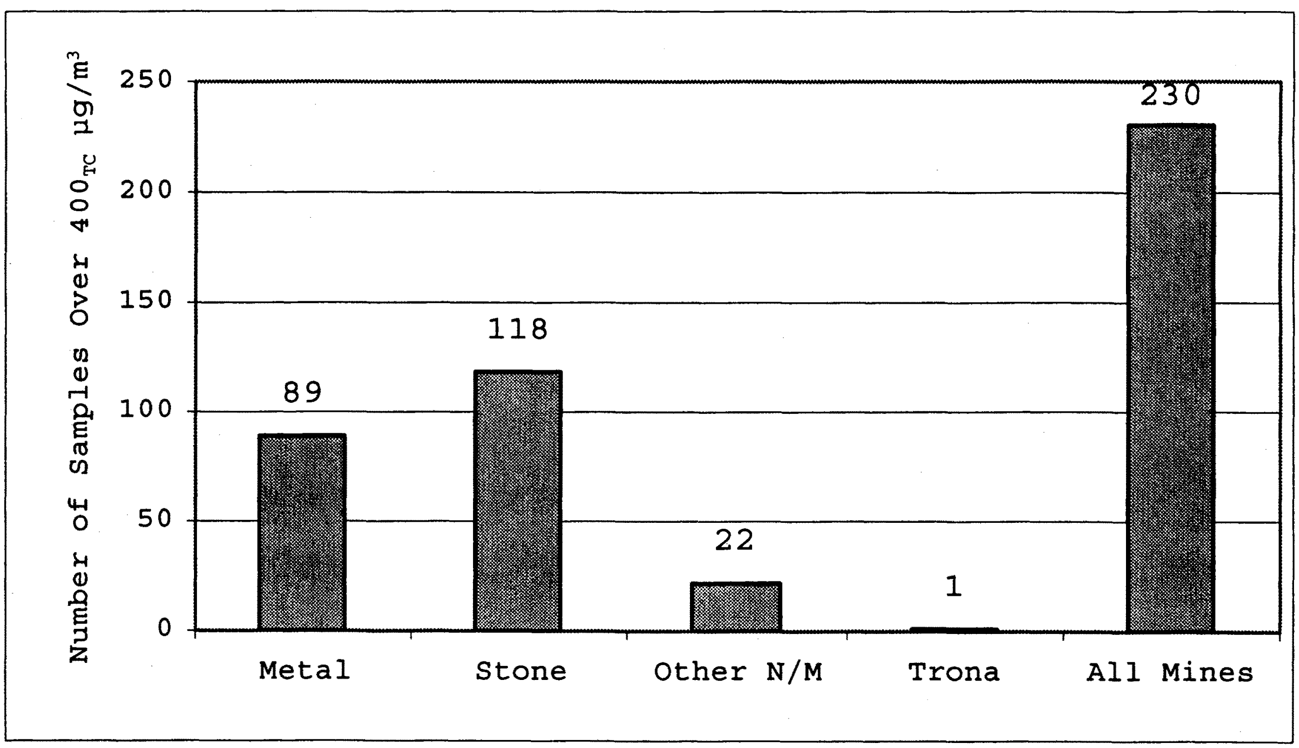

Chart V-2: Frequency of Overexposures by Commodity (400_{TC} µg/m^3, TC=EC x 1.3)

Chart V–3 shows the number of mines with a specific number of overexposures. Examination of the frequency of mines with one or more overexposures shows that 68 mines (37%) are in this category. There were no mines with more than 12 samples $>400_{TC}$ μg/m³ for that mine.

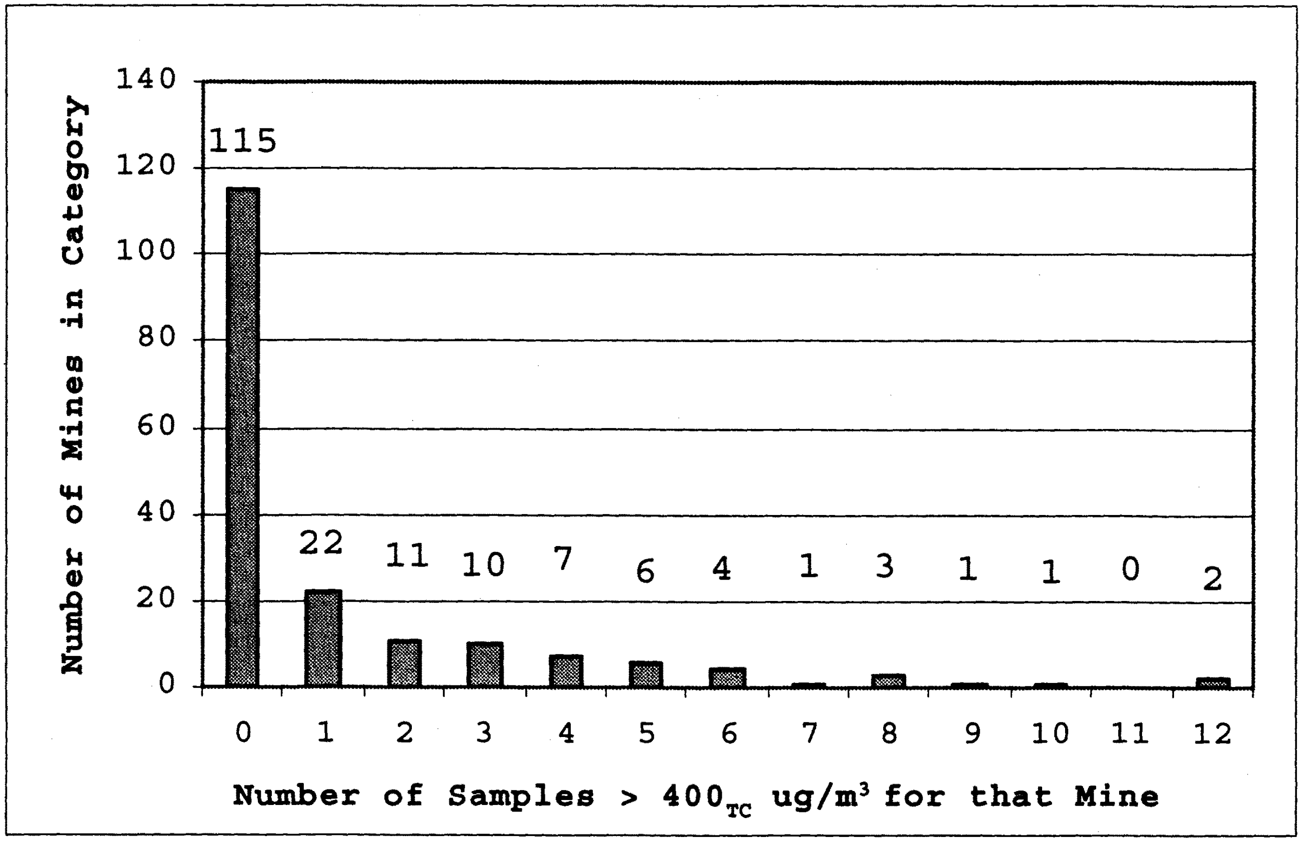

Chart V-3: Number of Mines With Specified Number of Samples > 400_{TC} μg/m³ (TC=EC x 1.3)

At four of the mines, all samples taken during the assistance period were above 400_{TC} μg/m³. Between one and ten samples were taken at each of these four mines. No overexposures were found in 115 (63%) of the mines sampled. (See Chart V–4.)

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(See Chart V-4.)

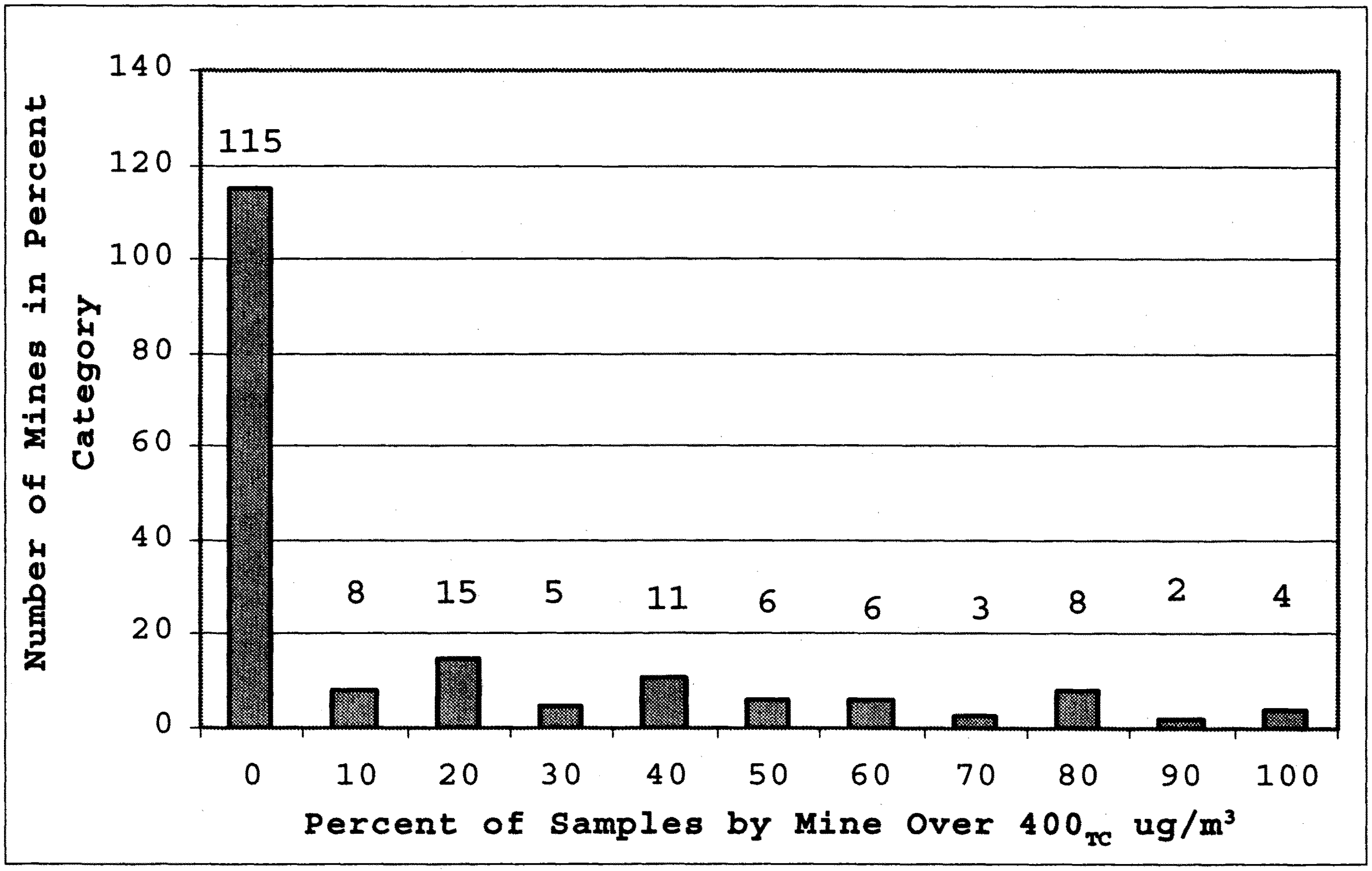

Chart V-4: Number of Mines by Percentage of Overexposures for that Mine

Tables V–8 and V–9 summarize sample statistics by commodity for TC calculated by TC = EC × 1.3 and TC = EC + OC respectively. Overall, the mean TC as calculated by EC × 1.3 is 255 μg/m³. The median level is 174 μg/m³. The mean TC level by OC + EC is 293 μg/m³ and the median level is 226 μg/m³. Individual exposure levels of TC vary widely within all commodities and most mines. The commodity groupings reported in Tables V–8 and V–9 were chosen to be consistent with those reported in the 31-Mine Study and the Quantitative Risk Assessment (QRA) for this rule.

The mean and median TC values for each group, using EC × 1.3, are lower than the interim compliance limit of 400 μg/m³. The mean (median) TC value for metal mines is 356(271) μg/m³. The mean (median) for stone mines is 236(149), other non-metal mines is 194(148), and trona mines is 105(82) μg/m³. Table V–8 lists additional statistics for TC values compiled by commodity.

TABLE V–8.—AVERAGE LEVELS OF TC BY COMMODITY MEASURED IN μG/M³ (EC × 1.3)

[Estimated 8-hour Full Shift Equivalent TC Concentration (μg/m³)]

TC = EC × 1.3	Metal	Stone	Other N/M	Trona	All Mines
No. of Samples	284	689	196	25	1,194
Maximum	2,026	2,979	960	407	2,979
Median	271	149	148	82	174
Mean	356	236	194	105	255
Std. Error	19	10	12	16	8
95% CI Upper	392	256	217	138	270
95% CI Lower	319	216	172	73	239

The mean and median TC values for each group of mines as calculated by OC + EC are also lower than the interim compliance limit of 400 μg/m³. The mean (median) TC value for metal mines is 370(313) μg/m³. The mean for stone mines is 282(209), other non-metal mines is 238(191) and for trona mines is 140(126) μg/m³. Table V–9 lists additional statistics for TC values compiled by commodity group.

TABLE V–9.—AVERAGE LEVELS OF TC BY COMMODITY GROUP MEASURED IN μG/M³ (OC + EC)

[Estimated 8-hour Full Shift Equivalent TC Concentration (μg/m³)]

TC = OC + EC	Metal	Stone	Other N/M	Trona	All Mines
No. of Samples	284	689	196	25	1,194
Maximum	2,045	2,796	1,230	344	2,796
Median	313	209	191	126	226
Mean	370	282	238	140	293
Std. Error	17	11	12	12	8
95% CI Upper	404	303	263	165	308
95% CI Lower	336	261	214	115	278

Tables V–10, V–11, and V–12 show summary statistics for whole DPM exposures for the baseline sampling and the 31-Mine Study. For baseline sampling whole DPM was calculated by EC × 1.3 × 1.25 and by (OC + EC) × 1.25. The 1.25 factor represents the assumption that TC comprises 80% of whole DPM. The other 20% includes the solid aerosols such as ash particulates, metallic abrasion particles, sulfates and silicates. The vast majority of these particulates are in the sub-micron range.

Section VI–B discusses the relationship between EC and TC. For whole DPM concentrations, the mean (median) value is 444(339) μg/m³ for metal mines, 295(186) for stone mines, 243(185) for other non-metal mines, and 132(102) μg/m³ for trona mines. The whole DPM exposures for Table V–11 were calculated as (OC + EC) × 1.25.

TABLE V–10.—BASELINE WHOLE DPM CONCENTRATIONS (EC × 1.3 × 1.25, μG/M³), BY MINE CATEGORY

[Estimated 8-hour Full Shift Equivalent Whole DPM Concentration (μg/m³)]

DPM = EC × 1.3 × 1.25	Metal	Stone	Other N/M	Trona	All Mines
Number of Samples	284	689	196	25	1,194
Maximum	2,532	3,724	1,200	509	3,724
Median	339	186	185	102	218
Mean	444	295	243	132	318
Std. Error	23	13	15	20	10
95% CI Upper	490	320	272	173	338
95% CI Lower	399	270	214	91	299

TABLE V–11.—BASELINE WHOLE DPM CONCENTRATIONS ((EC + OC) × 1.25, μG/M³), BY MINE CATEGORY

[Estimated 8-hour Full Shift Equivalent Whole DPM Concentration (μg/m³)]

DPM = (EC + OC) × 1.25	Metal	Stone	Other N/M	Trona	All Mines
Number of Samples	284	689	196	25	1,194
Maximum	2,556	3,495	1,538	430	3,495
Median	392	262	238	158	283
Mean	463	353	298	175	366
Std. Error	21	13	16	15	10
95% CI Upper	505	379	329	206	385
95% CI Lower	421	327	267	144	347

The mean whole DPM concentration for metal and stone mines (as measured by (EC + OC) × 1.25) was significantly lower during baseline compliance assistance sampling than the levels measured during the 31-Mine Study.

TABLE V–12.—31-MINE STUDY WHOLE DPM CONCENTRATIONS (μG/M³) BY MINE CATEGORY

[Estimated 8-hour Full Shift Equivalent Whole DPM Concentration (μg/m³)]

DPM = (EC + OC) × 1.25	Metal	Stone	Other N/M	Trona
Number of Samples	116	105	83	54
Maximum	2,581	1,845	1,210	331
Median	491	331	341	82
Mean	610	466	359	94
Std. Error	45	36	27	9
95% CI Upper	699	537	412	113
95% CI Lower	522	394	306	75

Chart V–5 compares the means from Tables V–10, V–11 and V–12. The mines selected in the 31-Mine Study (Table V–12) were not randomly selected, and the study is, therefore, not considered representative of the underground M/NM mining industry. Additionally, the industry has continued to change the diesel-powered fleet to low emission engines that reduce DPM exposure. Workers inside equipment cabs were not sampled during the 31-Mine Study due to possible interference from cigarette smoke. During baseline compliance assistance sampling, however, personal samples were taken on miners inside cabs.

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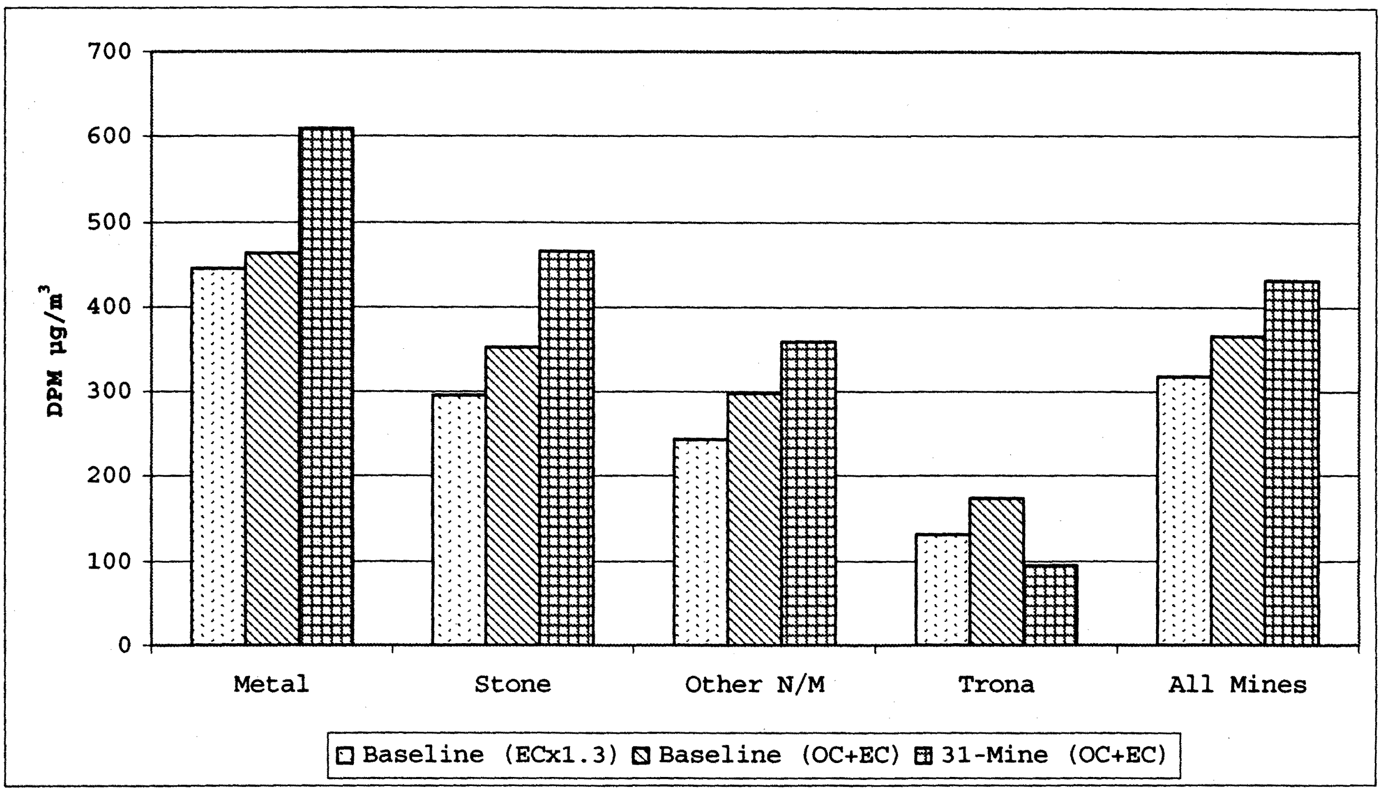

Chart V-5. Comparison of Mean DPM Levels from Baseline Sampling and the 31-Mine Study

MSHA received several comments on the baseline sampling. Some commenters stated that many mines were sampled in a manner that rendered results exceedingly low and not representative of operating conditions. Commenters also stated that the results of independent DPM sampling conducted by operators indicate MSHA's results underestimate DPM exposure. These commenters did not provide data or analyses from mine operators' sampling programs to substantiate their claim.

MSHA compliance specialists collected baseline samples in the same manner they have been instructed to use for collecting samples for enforcement purposes. It is expected that personal exposure to DPM will fluctuate due to variations in day to day operations in a mine. Reported levels of DPM are representative of the exposures of the highest risk miners identified during compliance assistance. In an ideal situation, and with unlimited resources, every potentially exposed miner would be individually sampled. It is not necessary or practical, however, to sample all miners on a mine property in order to evaluate personal exposures. Suspected and potential health hazards may be reasonably and adequately evaluated by sampling the maximum risk miner in a work area. The maximum risk miner is the one expected to have the greatest exposure of all of the miners in the area. Other miners in the same work area or area of common exposure sources may reasonably be expected to experience lesser concentrations of occupational hazards than the maximum risk miner. There may be more than one maximum risk miner when activities, operations, and exposure sources vary throughout the day. MSHA acknowledges that some samples were not taken on the highest possible risk occupation at some mines. As previously stated, we continued baseline sampling past the date of July 19, 2003 in response to this concern.

A miner experiences high risk because of the location and type of tasks performed relative to the source of the suspected hazard. The miner's predicted environment or duties may change during the course of the work shift. If the working conditions present during the exposure assessment are not typical of the regular mining operation, the sample results may not represent the typical exposure for that occupation. Compliance specialists strive to characterize the higher exposure levels during typical work shifts. The baseline samples are representative of the conditions experienced on work shifts during the defined compliance assistance period. MSHA has obtained the best available information for characterizing recent activities at the relevant M/NM mines.

B. DPM Control Technology

MSHA participated in a number of compliance assistance activities directed at improving sampling and assisting mine operators with selecting and implementing appropriate DPM control technology. Some of these activities were directed to either a segment of the mining industry, or to the entire industry, while others were conducted on a mine specific basis. In general, activities directed toward a large number of mines included outreach programs, workshops, website postings and publications, while activities directed at an individual mine included evaluation of a specific control technology, and review of the technology in use by or available to a specific mine.

Regional DPM Seminars. During September and October, 2002, MSHA conducted regional DPM seminars at the following locations: Ebensburg, PA; Knoxville, TN; Lexington, KY; Des Moines, IA; Kansas City, MO; Albuquerque, NM; Coeur d'Alene, ID; Green River, WY; and Elko, NV. MSHA offered these full-day seminars free of charge in the major underground M/NM mining regions of the country to facilitate attendance by key mining industry personnel. The seminars covered the health effects of DPM exposure, the history and specific provisions of the regulation, DPM controls, DPM sampling, and the DPM Estimator, a computerized program that calculates DPM concentration reduction.

NIOSH Diesel Emission and Control Technologies in Underground M/NM Mines Workshops. MSHA participated in these two workshops in February, 2003 in Cincinnati, OH and March, 2003, in Salt Lake City, UT. The workshops served several purposes. They provided technical presentations and a forum for discussing control technology for reducing exposure to particulate matter and gaseous emissions from the exhaust of diesel-powered vehicles in underground mines. Additionally, they intended to help mine managers, maintenance personnel, safety and health professionals, and ventilation engineers select and apply control technologies in their mines. Speakers, representing MSHA, NIOSH, and several mining companies, provided ample time for questions and in-depth technical discussion of issues raised by participants.

National Stone, Sand & Gravel Association (NSSGA)/MSHA DPM Sampling Workshop. This three day seminar, hosted by the Rogers Group, Inc.'s Jefferson County Stone and Underground in Louisville, Kentucky, was held on December 11 through 13, 2002. On the first day, MSHA reviewed DPM sampling procedures, and presented training on pump calibration, sample train assembly and note taking. On the second day, participants traveled to the Rogers Group Jefferson County Mine to conduct full shift sampling on underground miners. Our technical support staff took ventilation measurements and collected area samples to assess DPM emissions in the mine. On the third day, MSHA reviewed engine emission and ventilation measurements. Additionally, MSHA reviewed and discussed DPM outreach material. Approximately 10 industry participants attended the seminar.

Nevada Mining Association Safety Committee. In April, 2003, MSHA discussed DPM control technologies at a meeting of the Nevada Mining Association Safety Committee in Elko, NV. Discussion topics included bio-diesel fuel blends, various fuel additives and fuel pre-treatment devices, mine ventilation, environmental cabs, clean engines, and diesel particulate filter (DPF) systems. Mining company representatives discussed their experiences with and perspectives on these technologies. MSHA discussed experiences and observations that it made at various mines, and results of its laboratory and field testing.

MSHA South Central Joint Mine Safety and Health Conference. MSHA presented a DPM workshop at this conference in April 2003, in New Orleans, LA. The workshop included a detailed history and explanation of the provisions of the DPM regulation, and a technical presentation on feasible DPM engineering controls. At the April 2004 conference in Albuquerque, NM, MSHA presented a review of DPM control strategies that have generally been adopted in the underground M/NM mining industry.

National Meeting of the Joseph A. Holmes Safety Association, National Association of State Mine Inspection and Training Agencies, Mine Safety Institute of America, and Western TRAM (Training Resources Applied to Mining). MSHA presented a DPM workshop at this conference in June 2003, in Reno, NV. The workshop included a detailed history and explanation of the provisions of the regulation, and a technical presentation on DPM sampling, analytical tools for identifying and evaluating DPM sources in mines, and feasible DPM engineering controls.

DPM Sampling and Control Workshops. In March 2004, MSHA presented full one day workshops in Bloomington, IN and Des Moines, IA. In these workshops, MSHA reviewed the sampling procedures that MSHA inspectors would use for DPM, and MSHA provided hands on instruction to the participants in these procedures. MSHA also presented a review of DPM control strategies that have generally been adopted in the underground M/NM mining industry.

Equipment Manufacturers Association (EMA) DPM Workshop. In August 2003, MSHA conducted a DPM workshop for the EMA in Chicago, IL. At this workshop, MSHA reviewed the M/NM DPM regulations, discussed the need for clean engine technology, explained engine emission testing for mines, reviewed the importance of environmental cabs and discussed ventilation issues.

Web site. Our Web site, www.msha.gov, contains a single source page for DPM rules for M/NM mines. The page has links to specific topics, including:

- Draft Metal and Nonmetal Health Inspection Procedures Handbook, Chapter T—Diesel Particulate Matter Sampling.
- DRAFT Diesel Particulate Matter Sampling Field Notes.
- Metal and Nonmetal Diesel Particulate Matter Standard Error Factor for TC Analysis.
- MSHA Metal and Nonmetal DPM Standard Compliance Guide of August 5, 2003, addressing the interim DPM limit.
- NIOSH Listserver.
- MSHA-NIOSH Diesel Particulate Filter Selection Guide for Diesel-powered Equipment in Metal and Nonmetal Mines (Filter Selection Guide), last updated February 20, 2003.
- Baseline DPM Sample Results, updated October 2003.
- Presentation from Compliance Assistance Workshop, October 16, 2002.
- Summary of Requirements: MSHA Standard on Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners that are in effect as of July 20, 2002.
- Link to SKC Web site: SKC Diesel Particulate Matter Cassette with Precision-jeweled Impactor.
- Diesel Particulate Matter Control Technologies, last updated January 14, 2004.

—Table I: Paper/Synthetic Filters.
—Table II: Non-Catalyzed Particulate Filters, Base Metal Particulate Filters, Specially Catalyzed Particulate Filters, and High Temperature Disposable Filters.

—Table III: Catalyzed (Platinum Based) Diesel Particulate Filters.

• Work Place Emissions Control Estimator.

• **Federal Register** documents concerning this and prior DPM rulemakings.

• Public comments on this rulemaking.

• Economic analyses for this rule and prior DPM rules.

• MSHA News Release: MSHA Rules Will Control Miners' Exposure to Diesel Particulate, January 18, 2001.

• Program Information Bulletins:

—PIB01–10 Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners, August 28, 2001.

—PIB02–04 Potential Health Hazard Caused by Platinum-Based Catalyzed Diesel Particulate Matter Exhaust Filters, May 31, 2002.

—PIB02–08 Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners-—Summary of Settlement Agreement, August 12, 2002.

Additionally, our diesel single source page for the coal industry contains topics that may also be of interest to the M/NM mining industry, particularly for those operations at gassy mines where permissible equipment is required.

Specific control technology studies. Following the settlement agreement, MSHA was invited by various mining companies to evaluate the effectiveness of different control technologies for DPM, including ceramic filters, alternative fuels and a fuel oxygenator. Company participation was essential to the success of each test. MSHA evaluated ceramic filters in two mines, one where MSHA was the only investigator and one where NIOSH was the primary investigator. In our test, MSHA evaluated DPM on a production unit with and without ceramic filters installed on the loader and trucks. In the NIOSH study a variety of ceramic filters were tested in an isolated zone.

MSHA evaluated bio-diesel fuel in two mines. In one, MSHA evaluated a 20% and a 50% recycled bio-diesel fuel and a 50% new bio-diesel. In the other, MSHA evaluated a 35% recycled bio-diesel fuel and a 35% new bio-diesel.

MSHA evaluated the fuel catalyst system in one mine. MSHA sampled the mine exhaust with fuel catalyst systems installed on all production equipment, and also without the units installed.

MSHA evaluated water emulsion diesel fuel in four mines.

Following is a summary of the individual mine technology evaluation studies:

Kennecott Greens Creek Mining Company: MSHA participated with Kennecott Greens Creek Mining Company in a collaborative test to verify the efficiency of catalyzed ceramic DPFs for reducing diesel particulate emissions. The goal of the testing was to identify site-specific practical mine-worthy filter technology.

This series of tests was designed to determine the reduction in emissions and personal exposure that can be achieved when ceramic filters are installed on a loader and associated haulage trucks operating in a production stope. MSHA also determined relative engine gaseous and DPM emissions for the equipment under specific load conditions.

MSHA conducted the tests over a two-week period. MSHA sampled three shifts with ceramic after-filters installed; and three shifts without the after-filters. MSHA also collected personal samples to assess worker exposures, and area samples to assess engine emissions. MSHA took both gaseous and diesel particulate measurements.

Sampling results indicate significant reductions in both personal exposures and engine emissions. These results also indicated that factors such as diesel particulate contamination of intake air, stope ventilation parameters, and isolated atmospheres in vehicle cabs as well as the ceramic DPFs may have a significant impact on personal exposures. The following findings and conclusions were obtained from the test:

1. The results of the raw exhaust gas measurements conducted during the test indicate that the engines were operating properly.

2. The ceramic filters installed on the machines used in this test do not adversely affect machine operation. Even with some apparent visual cracking from the rotation of the filter media, the ceramic filters removed more than 90% of the DPM. The filters passively regenerated during machine operation.

3. The Bosch smoke test provides an indication of filter deterioration; however, the colorization method does not quantify the results.

4. Personal DPM exposures were reduced by 60% to 68% when after-filters were used.

5. CO levels decreased by up to one-half while the catalyzed filters were used. There appeared to be an increase in NO_2 (Nitrous Dioxide) while catalyzed filters were being used; however, it is unclear whether this increase was due to data variability, changes in ventilation rate, or the use of the catalyzed filters.

6. The use of cabs reduced DPM exposure by 75% when DPFs were in use and by 80% when DPFs were not in use.

7. Ventilation airflow was provided to the stopes through fans with rigid and bag tubing. Airflow was the same or greater than the Particulate Index, but typically lower than the gaseous ventilation rate.

8. The use of ceramic DPFs reduced average engine DPM emissions by 96%.

9. The reduction in personal exposure was not attributed solely to DPF performance because other factors such as ventilation, upwind equipment use, and cabs also influence personal exposure.

Carmeuse North America, Inc., Maysville Mine: MSHA entered into a collaborative effort with NIOSH, industry, and the Kentucky Department of Energy to test DPM emissions and exposures when using various blends of bio-diesel fuels in an underground stone mine. As part of our compliance assistance program, MSHA provided support to mining operations to evaluate diesel particulate control technologies. The test was initiated by the industry partner, and, along with NIOSH, MSHA provided support for test design, data collection, and sample and data analysis. The project was funded by Carmeuse and Kentucky Department of Energy, through the Kentucky Clean Fuels Coalition.

The initial test was conducted in two phases, using a 20% and a 50% bio-diesel blend of recycled vegetable oil (RVO), each mixed with low sulfur No. 2 standard diesel fuel. Baseline conditions were established using low sulfur No. 2 standard diesel fuel. In a third phase of the test, a 50% blend of new soy bio-diesel fuel was tested.

Area samples were collected at shafts to assess equipment emissions. Personal samples were collected to assess worker exposure. These samples were analyzed by NIOSH using the NIOSH 5040 method to determine TC and EC concentrations. Results indicate that significant reductions in emissions and worker exposure were obtained for all bio-diesel mixtures. These reductions were in terms of both elemental and TC. Results for the 20% and 50% RVO indicated 33% and 69% reductions in DPM emissions, respectively. Results for the tests on the 50% blend of new soy bio-diesel fuel, showed about a 37% reduction in DPM emissions.

Carmeuse North America, Inc., Black River Mine: Following the success of the bio-diesel tests at Maysville Mine, Carmeuse requested our assistance in continuing the bio-diesel optimization testing at their Black River Mine. Two bio-diesel blends were tested, and a baseline test was made. In each test personal exposures and the mine exhaust were tested for two shifts. The two bio-diesel blends included a 35% RVO and a 35% blend of new soy oil. Results for the 35% RVO showed a 32% reduction in DPM emissions. Results of the 35% blend of new soy bio-diesel fuel showed an approximate 16% reduction in DPM emissions.

Stone Creek Brick Company, Water Emulsion Fuel Tests: During the Stone Creek Brick Company compliance assistance visit, MSHA identified several control strategies that would reduce DPM emissions and exposures. These strategies included: The installation of clean engines, the use of alternative fuels, and an increase in mine ventilation. The mine chose to implement alternative fuel use followed by an engine replacement program. MSHA provided in-mine testing to evaluate the impact of using an alternative fuel. The company chose to use a water emulsion fuel. This fuel is an EPA approved fuel, consisting of a 20% blend of water with No. 2 diesel fuel. A surfactant is added to keep the water and diesel fuel from separating. MSHA sampled at the mine before (using No. 2 diesel fuel) and after the implementation of the fuel. MSHA collected personal samples to evaluate the worker exposure and area samples to evaluate emissions.

Results of the testing showed that the highest exposure was reduced from 823_{TC} µg/m^3 to 321_{TC} µg/m^3 (61% reduction). EC emissions were reduced by 49% and TC emissions were reduced by 3%. The lack of a reduction in TC emissions was attributed to the lower combustion temperature resulting from the water emulsion fuel and the older engine technology in use. The older engines have larger injector nozzles which do not provide efficient fuel burning. The mine has been using the fuel for approximately one year, and continues to be satisfied with the results.

Carmeuse North American, Inc., Maysville Mine, Water Emulsion Fuel Tests: MSHA provided assistance to Carmeuse North American, Inc., to evaluate summer and winter blends of a water emulsion fuel at their Maysville Mine. For the first test, emission reductions for a 10% blend (winter blend) of water with No. 2 diesel fuel was compared to a 35% blend of RVO. Emission reductions were compared to both a 35% blend of RVO and standard No. 2 diesel fuel. MSHA collected personal samples to evaluate the worker exposure and area samples to evaluate emissions.

Results of the testing showed that the highest average exposure (high scaler working outside a cab) was reduced from 254_{TC} µg/m^3 to 145_{TC} µg/m^3 (43% reduction) when changing from RVO to the water emulsion. EC emissions were reduced by 52% and TC emissions were reduced by 49% for the water emulsion to 35% RVO fuel comparison. EC emissions were reduced by 77% and TC emissions were reduced by 74% for the water emulsion to standard diesel fuel comparison.

For the second test, emission reductions for a 20% blend (summer blend) of water with No. 2 diesel fuel was compared to a 35% blend of RVO. Emission reductions were compared to both a 35% blend of RVO and standard No. 2 diesel fuel. The comparison to No. 2 diesel fuel was obtained by combining the water emulsion to the 35% RVO results and previously obtained 35% RVO to No. 2 diesel fuel results. MSHA collected personal samples to evaluate the worker exposure and area samples to evaluate emissions. For the summer blend, EC emissions were reduced by 60% and TC emissions were reduced by 59% for the water emulsion to 35% RVO fuel comparison. EC emissions were reduced by 81% and TC emissions were reduced by 79% for the water emulsion to standard diesel fuel comparison.

Carmeuse North American, Inc., Black River Mine, Water Emulsion Fuel Tests: MSHA provided assistance to Carmeuse North American, Inc. to evaluate summer and winter blends of a water emulsion fuel at their Black River Mine. For these tests, emission reductions for 10% and 20% blends (winter blend) of water with No. 2 diesel fuel was compared to a 35% blend of RVO. Emission reductions were compared to both a 35% blend of RVO and standard No. 2 diesel fuel. MSHA collected personal samples to evaluate the worker exposure and area samples to evaluate emissions.

For the winter blend (10%), EC emissions were reduced by 46% and TC emissions were reduced by 45% for the water emulsion to 35% RVO fuel comparison. EC emissions were reduced by 63% and TC emissions were reduced by 62%, for the water emulsion to standard No. 2 diesel fuel comparison.

For the summer blend (20%), EC emissions were reduced by 61% and TC emissions were reduced by 54% for the water emulsion to 35% RVO fuel comparison. EC emissions were reduced by 73% and TC emissions were reduced by 68% for the water emulsion to standard diesel fuel comparison.

Martin Marietta, Durham Mine, Water Emulsion Fuel Tests: MSHA provided assistance to Martin Marietta to evaluate a summer blend of water emulsion fuel at their Durham Mine. This was a multi-level mine, with a 15% ramp between levels. For this test, emissions for a 20% blend of water with No. 2 diesel fuel was compared to standard No. 2 diesel fuel. MSHA collected personal samples to evaluate the worker exposure and area samples to evaluate emissions. Even with the 15% ramps, the loss in horsepower due to the fuel did not adversely effect the mine operations.

Results of the testing showed that the highest average exposure (powder crew working outside a cab) was reduced from 372_{TC} µg/m^3 to 54_{TC} µg/m^3 (85% reduction) when changing from No. 2 diesel fuel to the water emulsion. EC emissions were reduced by approximately 80% for the water emulsion compared to standard diesel.

Rogers Group, Jefferson County Mine: MSHA was invited to this mine to evaluate a fuel catalyst system that was installed in the fuel line of the diesel equipment. The company had installed the units to increase fuel economy, and sought to determine the effects of the units on DPM. Prior to the units having been installed, MSHA had conducted baseline sampling and had collected personal samples on production workers and area samples in the mine exhaust airflow. After the units were installed on loaders and trucks and the units had accumulated 100 hours of operation, sampling was repeated. Results indicated that the use of the fuel catalyst had no measurable effect on either DPM exposure or emissions.

Summary of DPM control technology: In addition to conducting baseline sampling and providing assistance in developing DPM control strategies at specific mines, MSHA assessed the effectiveness of various DPM controls during and following the compliance assistance period. These controls included alternative fuels, fuel oxygenators, environmental cabs and ceramic DPFs. Alternative fuels evaluated included various blends of bio-diesel fuels (including both Virgin Soy Oil (VSO) and RVO), No. 1 diesel fuel, and water emulsion fuels.

The resulting reduction in DPM emissions for each of these controls is given in Chart V–6. All reductions are compared to diesel emissions with low sulfur No. 2 diesel fuel. All bio-diesel tests were conducted at mines with relatively clean engines. The first water emulsion test was conducted at a mine utilizing older engines. Subsequent water emulsion tests were conducted at mines utilizing clean engines with oxidation catalytic converters.

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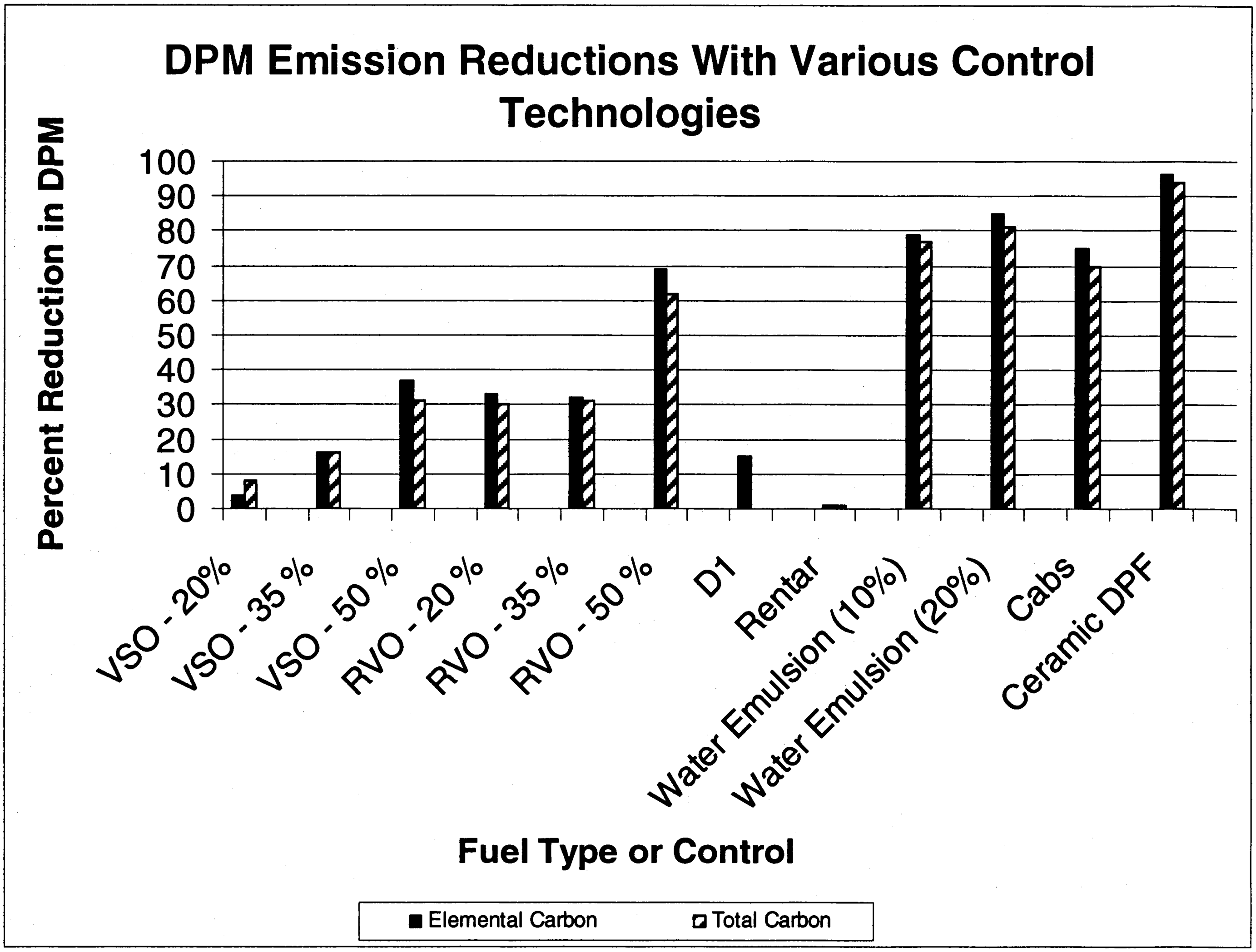

Chart V-6 Results of Field Tests on Diesel Exhaust Controls.

VSO (Virgin Soy Oil) – 20% - Columbus Junction
VSO (Virgin Soy Oil) – 35% - Black River, Carmeuse
VSO (Virgin Soy Oil) – 50% - Maysville, Carmeuse
RVO (Recycled Vegetable Oil) – 20% - Maysville, Carmeuse
RVO (Recycled Vegetable Oil) – 35% - Black River, Carmeuse
RVO (Recycled Vegetable Oil) – 50% - Maysville, Carmeuse
D1 – No. 1 Diesel Fuel – Stillwater (NIOSH, Phase I)
Rentar – Jefferson County Mine, Rogers Group,
Water Emulsion - 10% – Black River, Carmeuse
Water Emulsion - 20% – Black River, Carmeuse
Cabs – Greens Creek Mine, Kennecott Mining
Ceramic DPF– Greens Creek Mine, Kennecott Mining

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Assistance for Developing Control Strategies

Martin Marietta Aggregates: MSHA provided compliance assistance during full-day visits at the North Indianapolis Mine and the Parkville Mine in March, 2003, and at the Kaskaskia Mine and the Manheim Mine in May, 2003. MSHA reviewed each mine's DPM sampling history, current operating and equipment maintenance practices, ventilation, diesel equipment inventory, and steps taken to date and future plans to reduce DPM exposures. MSHA discussed the full range of engineering controls, demonstrated an exhaust temperature measurement and data logging system, and presented a spreadsheet for using such data to select appropriate filter systems. MSHA presented a simple approach for measuring the effectiveness of cab air filtering and pressurization systems, identified the highest DPM-emitting equipment (so future equipment-specific DPM control efforts could be appropriately focused), and discussed the likely effect of various ventilation system upgrades.

Rogers Group, Oldham County Mine: MSHA provided compliance assistance at this mine during a full-day visit in November 2002. MSHA conducted extensive DPM sampling at the mine, collecting both personal exposure samples and area samples. Further, MSHA collected DPM samples from both inside and outside of equipment cabs. No personal samples exceeded 160_{TC} µg/m³. MSHA reviewed current operating and equipment maintenance practices, ventilation, diesel equipment inventory, and steps taken to date and future plans to reduce DPM exposures. MSHA discussed the full range of engineering controls. Results from this survey indicate the environmental cabs significantly reduced the DPM exposure of equipment operators.

Rogers Group, Jefferson County Mine: MSHA provided compliance assistance at this mine during a full-day visit in December 2002. MSHA collected both personal exposure samples and area samples. The highest personal sample, collected on the loader, was 468_{TC} µg/m³. This loader was operated with the window open. MSHA reviewed current operating and equipment maintenance practices, ventilation, diesel equipment inventory, and steps taken to date and future plans to reduce DPM exposures. Mechanical ventilation was provided for the mine. MSHA discussed the full range of engineering controls, demonstrated an exhaust temperature measurement and data logging system, and presented a spreadsheet for using such data to select appropriate filter systems. MSHA presented a simple approach for measuring the effectiveness of cab air filtering and pressurization systems, identified the highest DPM-emitting equipment (so future equipment-specific control efforts could be appropriately focused), and discussed the likely effect of various ventilation system upgrades.

Nalley and Gibson, Georgetown Mine: MSHA provided compliance assistance at this mine during a full-day visit in May 2003. MSHA reviewed current operating and equipment maintenance practices, ventilation, diesel equipment inventory, and steps taken to date and future plans to reduce DPM exposures. MSHA collected DPM samples to assess improvements since the baseline sampling. At that time, mechanical ventilation provided airflow to the mine. MSHA discussed the full range of engineering controls, demonstrated an exhaust temperature measurement and data logging system, and presented a spreadsheet for using such data to select appropriate filter systems. MSHA presented a simple approach for measuring the effectiveness of cab air filtering and pressurization systems, identified the highest DPM-emitting equipment (so future equipment-specific DPM control efforts could be appropriately focused), and discussed the likely effect of various ventilation system upgrades.

Stone Creek Brick Company: MSHA provided compliance assistance at this mine during a full-day visit in May 2003. MSHA reviewed current operating and equipment maintenance practices, ventilation, diesel equipment inventory, and steps taken to date and future plans to reduce DPM exposures. MSHA collected DPM samples from underground miners. The mine was using mechanical ventilation. None of the equipment had environmental cabs. MSHA discussed the full range of engineering controls, presented a spreadsheet for using such data to select appropriate filter systems, identified the highest DPM-emitting equipment (so future equipment-specific DPM control efforts could be appropriately focused), and discussed the likely effect of various ventilation system upgrades.

Wisconsin Industrial Sand Co., Maiden Rock Mine: MSHA provided compliance assistance at this mine during a full-day visit in May 2003. MSHA reviewed the mine's current operating and equipment maintenance practices, ventilation, diesel equipment inventory, and steps taken to date and future plans to reduce DPM exposures. MSHA discussed the full range of engineering controls, presented a spreadsheet for using such data to select appropriate filter systems, and identified the highest DPM-emitting equipment so future equipment-specific DPM control efforts could be appropriately focused.

Gouverneur Talc Company, Inc., No. 4 Mine: MSHA provided compliance assistance at this mine during a full-day visit in May 2003. DPM samples were collected on underground workers. MSHA reviewed then current operating and equipment maintenance practices, ventilation, diesel equipment inventory, and steps taken to date and future plans to reduce DPM exposures. MSHA discussed the full range of engineering controls, demonstrated an exhaust temperature measurement and data logging system, and presented a spreadsheet for using such data to select appropriate filter systems. MSHA presented a simple approach for measuring the effectiveness of cab air filtering and pressurization systems, identified the highest DPM-emitting equipment (so future equipment-specific control efforts could be appropriately focused), and discussed the likely effect of various ventilation system upgrades.

Additional specific mine compliance assistance: Following the initial baseline sampling period, MSHA compiled a list of mines having at least one DPM sample which exceeded the 400_{TC} µg/m³ limit. Of the 183 mines sampled, approximately 69 mines had at least one sample over the 400_{TC} µg/m³ interim TC limit. Of the 69 mines with one or more overexposures, 44 used room and pillar mining methods. These include stone mines, salt mines and a potash mine. Of the 44 room and pillar mines, MSHA provided specific compliance assistance to 36 of these mines (two mines were closed and two mines declined assistance). Although trona mines use room and pillar mining methods, they were not visited because they were in compliance with the 400_{TC} µg/m³ limit. The remaining 15 mines with overexposures were multilevel metal mines using a variety of stoping mining methods. Industry seminars were provided to assist these mines.

Typically, the high risk workers in the mines visited were the face workers that worked outside an environmental cab. Production loader and truck operators had elevated exposures when they either did not have an environmental cab or when the cab was not being properly maintained. Additional high risk workers include the blasting crew, drillers, and roof bolters.

During each mine visit, DPM samples were collected unless the mine had been recently sampled or the mine reported no additional DPM controls had been implemented since MSHA's previous sampling was conducted. The DPM controls, including engines, ventilation, cabs, fuels and work practices, were reviewed with mine management. Specific engine emission rates, mine ventilation rates, cab pressures and work practices were determined. At some mines, a temperature trace of an engine exhaust was made. The information was entered into a computer spreadsheet model to assess the effect of control changes on DPM levels and to assist the mine in developing a DPM control strategy.

Laboratory Compliance Assistance: In addition to the compliance assistance field tests, our diesel testing laboratory has been working with manufacturers to evaluate various types of DPM control technologies. Certain of these technologies can be applied in either underground M/NM or coal mines.

Evaluating paper/synthetic media as exhaust filters: MSHA has evaluated paper/synthetic media as exhaust filters. These filters have shown DPM removal efficiencies in excess of 90% in the laboratory when tested on our test engine using the test specified in subpart E of part 7. The laboratory has tested approximately 20 different paper/synthetic media from 10 different filter manufacturers. Although much of this work is directed to underground coal mine applications for use on permissible equipment, this technology is available for use on permissible equipment that is used in underground gassy M/NM mines. In addition, some underground coal mine operators have considered adding exhaust heat exchanger systems to nonpermissible equipment in order to use the paper/synthetic filters in place of ceramic filters. The heat exchanger is needed to reduce the exhaust gas temperature to below 302° F for these types of filters. This could also be an option for equipment in M/NM mines, particularly gassy mines where permissible equipment is required.

Evaluating Ceramic Filter Systems: MSHA worked with six ceramic filter manufacturers to evaluate the effects of their catalytic wash-coats on NO_2 production. As discussed under the ''Effectiveness of the DPM Estimator'' portion of this preamble, catalytic wash-coats on the ceramic filters may cause increases in NO_2 levels. MSHA used our test engine (Caterpillar 3306 PCNA) and followed the test procedures in subpart E of 30 CFR part 7. The DPM single source webpage lists the ceramic filters that have significantly increased NO_2 levels, as well as the ceramic filters that are not known to increase NO_2 levels. MSHA tested the DPM removal efficiencies of these filters during the laboratory tests. The efficiency results agree with the efficiencies posted on our web site DPM Control Technologies with Percent Removal Efficiency page (85% for cordierite and 87% for silicon carbide). Finally, MSHA worked with NIOSH during these tests to collect DPM samples for EC analysis using the NIOSH 5040 method. The laboratory results showed that the filters removed EC at up to 99% efficiency.

Evaluation of Fuel Oxygenator System: MSHA'S laboratory completed tests on the Rentar ™ in-line fuel catalyst. The Rentar ™ unit was installed on a Caterpillar™ 3306 ATAAC, which was coupled to a generator. MSHA used an electrical load bank to load the engine under various operating conditions. To establish a baseline, MSHA tested the engine for gaseous and DPM emissions without the Rentar ™ unit. The unit was then installed, and MSHA operated the engine for a 100 hour break-in period. MSHA then repeated the gaseous and DPM emission measurements. The test results of the one laboratory evaluation for this control device to date showed no significant reductions in whole diesel particulate, however, the data did not show any adverse effects on the raw whole DPM exhaust emission. NIOSH's results were consistent with MSHA's results, and showed no significant EC reductions and no adverse effects on the engine's emissions. MSHA has discussed with Rentar ™ further laboratory tests.

Evaluation of a Magnet System: MSHA performed laboratory tests for Ecomax, a manufacturer of a magnet system installed on the fuel line, oil filter, air intake and radiator. MSHA performed a preliminary field test of this product at a surface aggregate operation. The magnetic device demonstrated a 30% reduction in CO levels. The laboratory tests were performed with the Ecomax system installed and compared to our baseline engine data. The test results of the one laboratory evaluation for this control device to date showed no significant reductions in whole diesel particulate, however, the data did not show any adverse effects on the raw DPM exhaust emissions.

Evaluation of the Fuel Preporator® System: MSHA's laboratory tested a fuel preparator system. The system is designed to remove collected air from the fuel system for better fuel combustion. The results of the system installed were compared to the baseline engine. The test results of the one laboratory evaluation for this control device to date showed no significant reductions in whole diesel particulate, however, the data did not show any adverse effects on the raw DPM exhaust emissions. NIOSH also conducted tests in our lab on the Fuel Preporator® and the results were consistent with MSHA's results. There were no significant EC reductions and no adverse effects on the engine's emissions.

VI. DPM Exposures and Risk Assessment

A. Introduction

In support of the 2001 final rule, MSHA published a comprehensive risk assessment (66 FR at 5752–5855, with corrections at 35518–35520). In the following discussion, we will refer to the risk assessment published in conjunction with the 2001 final rule as the ''2001 risk assessment.''

The 2001 risk assessment presented MSHA's evaluation of health risks associated with DPM exposure levels encountered in the mining industry. This was based on a review of the scientific literature available through March 31, 2000, along with consideration of all material submitted during the applicable public comment periods.

The 2001 risk assessment was divided into three main sections. Section 1 (66 FR at 5753–5764) contained a discussion of U.S. miner exposures based on field data collected through mid-1998. An important conclusion of this section was that, prior to the 2001 final rule,

> * * * 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 [footnote deleted] and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups. [66 FR at 5764]

Section 2 of the 2001 risk assessment (66 FR at 5764–5822) reviewed the available scientific literature on health effects associated with DPM exposures. This review covered effects of both acute and chronic exposures and also contained a discussion of potential mechanisms of toxicity. The review of acute effects included 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. The review of chronic effects included studies based specifically on exposures to diesel emissions and studies based more generally on exposures to fine particulate matter in the ambient air. As part of this discussion, MSHA evaluated 47 epidemiologic studies examining the prevalence of lung cancer within groups of workers occupationally exposed to DPM and discussed the criteria used to evaluate and rank these studies (66 FR at 5774–5810). For both acute and chronic health effects, information from genotoxicity studies and studies on laboratory animals was discussed in the separate subsection on mechanisms of toxicity. Section 2 of the 2001 risk assessment also explained MSHA's rationale for utilizing certain types of information whose relevance had been questioned during the public comment periods: health effects observed in animals, health effects that are reversible, and health effects associated with fine particulate matter in the ambient air (66 FR at 5765–55767).

In section 3 of the 2001 risk assessment (66 FR at 5822–5855), MSHA evaluated the best available evidence to ascertain whether exposure levels currently existing in mines warranted regulatory action pursuant to the Mine Act. To do this, MSHA addressed three questions: (a) Whether health effects associated with occupational DPM exposures constitute a ''material impairment'' to miner health or functional capacity; (b) whether exposed miners were at significant excess risk of incurring any of these material impairments; and (c) whether the 2001 final rule would substantially reduce such risks. After careful consideration of all the submitted public comments, the 2001 risk assessment established three main 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.

The third of these conclusions was supported primarily by a quantitative risk assessment for lung cancer (66 FR at 5848–5854).

Throughout the current rulemaking, MSHA advised the mining community of its intent to include the 2001 risk assessment in the current rulemaking record to support this final rule. In this preamble, MSHA supplements the 2001 risk assessment with new exposure data and health effects literature published after March 31, 2000. MSHA asked that public comment be focused on this supplemental information. Nevertheless, some commenters presented critiques challenging the 2001 risk assessment and disputing scientific support for any DPM exposure limit, especially by means of an EC surrogate. Other commenters endorsed the 2001 risk assessment and stated that recent scientific publications support MSHA's conclusions.

MSHA also received a number of comments from the mining industry suggesting that the risk assessment lacks an adequate scientific foundation and does not comply with present requirements under OMB and information quality guidelines to use the best available, peer reviewed science. The risk assessment sustaining this final rule uses the best available, peer-reviewed scientific studies. It supplements the risk assessment sustaining the 2001 final rule and the existing coal DPM final rule also promulgated on January 19, 2001 (66 FR 5526) (coal rule). The coal rule was unchallenged by the mining community.

Before promulgating the 2001 final rule, MSHA provided a copy of its draft risk assessment supporting the 2001 rule for peer review to two experts in the field of epidemiology and risk assessment. These experts evaluated the overall methodology used by MSHA in the draft risk assessment, the appropriateness of the studies selected by MSHA, and MSHA's conclusions. MSHA had the draft independently peer-reviewed, published the evidence and tentative conclusions for public comment, and incorporated the reviewers' recommendations in the final version. In the 2001 risk assessment, MSHA carefully laid out the best available evidence, including shortcomings inherent in that evidence.

Of particular note is that the two quantitative meta-analyses of lung cancer studies supporting the 2001 risk assessment were peer reviewed and published in scientific journals. (Bhatia, Rajiv, *et al.*, ''Diesel Exhaust Exposure and Lung Cancer,'' Journal of Epidemiology, 9:84–91, January 1998, and Lipsett M., and Campleman, Susan, ''Occupational Exposure to Diesel Exhaust and Lung Cancer: A Meta-Analysis,'' *American Journal of Public Health,* (89) 1009–1017, July 1999).

MSHA informed the public as early as September 25, 2002, in the 2002 ANPRM for this final rule, and again in the 2003 NPRM, that MSHA would incorporate the existing rulemaking record, including the 2001 risk assessment, into the record of this rulemaking. MSHA was open to considering any new scientific evidence relating to its risk assessment. Commenters were encouraged in the instant rulemaking to submit additional evidence of new scientific information related to health risks associated with exposure to DPM. After considering both the more recent scientific literature and all of the submitted comments, MSHA has concluded that no change is warranted in the 2001 risk assessment's conclusions with respect to health risks associated with DPM exposures.

Section VI.B updates Section 1 of the 2001 risk assessment by summarizing the new exposure data that became available after publication of the 2001 final rule. This summary includes a description of the relationship between EC and TC observed in these exposure measurements, and addresses public comments on possible health implications of substituting EC for TC as a surrogate measure of DPM. In Section VI.C, MSHA reviews some of the more recent scientific literature (April 2000–March 2003) pertaining to adverse health effects of DPM and fine particulates in general. In addition, this section updates the 2001 risk assessment's discussion of scientific evidence on mechanisms of DPM toxicity. Thus, Section VI.C supplements Section 2 of the 2001 risk assessment. Section VI.C also discusses a document by Dr. Gerald Chase that purports to analyze preliminary data extracted from an ongoing NIOSH/NCI study. Finally, in Section VI.D, MSHA assesses current risk to underground M/NM miners in light of the most recent exposure and health effects information. Section VI.D also responds to a critique of the 2001 risk assessment submitted by Dr. Jonathan Borak on behalf of the MARG Diesel Coalition (MARG) and the NMA.

B. DPM Exposures in Underground M/NM Mines

In Section 1 of the 2001 risk assessment, MSHA evaluated exposures based on 355 samples collected at 27 underground U.S. M/NM mines prior to promulgating the 2001 rule. Mean DPM concentrations found in the production areas and haulageways at those mines ranged from about 285 μg/m³ to about 2000 μg/m³, with some individual measurements exceeding 3500 μg/m³. The overall mean DPM concentration was 808 μg/m³. All of the samples considered in the 2001 risk assessment were collected prior to 1999, and some were collected as long ago as 1989.

Two new bodies of DPM exposure data, collected after promulgation of the 2001 final rule, have now been compiled for underground M/NM mines: (1) Data collected in 2001 and 2002 from 31 mines for purposes of the 31-Mine Study and (2) data collected between 10/30/2002 and 10/29/2003 from 183 mines to establish a baseline for future samples. Key results from these two datasets are summarized in the next two subsections below. Following these summaries, the relationship between EC and TC, including the ratio of EC to TC (EC:TC) is discussed. This discussion is based exclusively on samples taken for the 31-Mine Study, since those samples were controlled for potential TC interferences from tobacco smoking and oil mist, whereas the baseline samples were not. The subsection concludes with a response to comments on the potential health effects of substituting EC for TC as a surrogate measure of DPM.

It should be noted that the new exposure data reflect conditions at least two years, and up to five years, later than the most recent miners' exposure data considered in the 2001 risk assessment. Furthermore, all of the new exposure data were obtained after promulgation of the 2001 rule. It is, therefore, reasonable to expect that the data discussed below would show generally different exposure levels than those presented in the 2001 risk assessment—both on account of normal technological changes over time and because of DPM controls that may have been implemented in response to the 2001 rule.

(1) Data from 31-Mine Study

MSHA collected 464 DPM samples in 2001 and 2002 at 31 underground M/NM mines. (For a more detailed description, see MSHA's final report on the 31-Mine Study.) Of these 464 samples, 106 were voided—mostly because of potential interference by sources of OC other than DPM. Table VI–1 shows how the remaining 358 valid DPM samples were distributed across four broad mine categories. All samples at one of the metal mines were voided, leaving 30 mines with valid samples indicating DPM concentrations.

TABLE VI–1.—NUMBER OF DPM SAMPLES, BY MINE CATEGORY

	Number of mines with valid samples	Number of valid samples	Avg. number of valid samples per mine
Metal	11	116	10.5
Stone	9	105	11.7
Trona	3	54	18.0
Other	7	83	11.9
Total	30	358	12.5

Table VI–2 summarizes the valid DPM concentrations observed in each mine category, assuming that submicrometer TC, as measured by the SKC sampler, comprises 80% of all DPM. The mean concentration across all 358 valid samples was 432 µg/m³ (Std. error = 21.0 µg/m³). The mean concentration was greatest at metal mines, followed by stone and ''other.'' At the three trona mines sampled, both the mean and median DPM concentration were substantially lower than what was observed for the other categories. This was due to the increased ventilation used at these mines to control methane emissions.

TABLE VI–2.—DPM CONCENTRATIONS (µ/M³), BY MINE CATEGORY

[DPM Is Estimated by TC ÷ 0.8]

	Metal	Stone	Trona	Other
No. of samples	116	105	54	83
Minimum	46.	16.	20.	27.
Maximum	2581.	1845.	331.	1210.
Median	491.	331.	82.	341.
Mean	610.	465.	94.	359.
Std. Error	44.7	36.0	9.4	26.6
95% UCL	699.	537.	113.	412.
95% LCL	522.	394.	75.	306.

After adjusting for differences in sample types and in occupations sampled, DPM concentrations at the non-trona mines were estimated to be about four to five times the concentrations found at the trona mines. Although there were significant differences between individual mines, the adjusted differences between the general categories of metal, stone, and other mines were not statistically significant.[1] For the 304 valid samples taken at mines other than trona, the mean DPM concentration was 492 µg/m³ (Std. error = 23.0 µg/m³).

Again assuming that submicrometer TC as measured by the SKC sampler comprises 80% of DPM, the mean DPM concentration observed was 1019 µg/m³ at the single mine exhibiting greatest DPM levels. Four of the nine valid samples at this mine exceeded 1487 µg/m³. In contrast, DPM concentrations never exceeded 500 µg/m³ at 8 of the 30 mines with valid samples (2 of the 11 metal mines, 1 of the 3 stone, all 3 trona, and 2 of the 7 others). (Note that 500 µg/m³ is the whole particulate equivalent of the 400_{TC} µg/m³ interim limit.) Some individual measurements exceeded 200_{DPM} µg/m³ at all but one of the mines sampled.

(2) Baseline Data

MSHA s baseline sampling results are presented in Section III, Compliance Assistance. These results provide the basis for the present discussion. The baseline samples discussed here, in connection with the risk assessment, were collected and analyzed between

[1] These conclusions derive from an analysis of variance, based on TC measurements, described in the Report on the 31-Mine Study. They depend on an assumption that the ratio of DPM to TC is uncorrelated with mine category, sample type (*i.e.*, personal or area), and occupation.

October 30, 2002 and October 29, 2003. They comprise a total of 1,194 valid samples collected from 183 mines. MSHA is including 320 additional valid samples because MSHA decided to continue to conduct baseline sampling after July 19, 2003 in response to mine operator's concerns. Some of these mines were either not in operation or were implementing major changes to ventilation systems during the original baseline period. MSHA is including supplementary samples from seasonal and intermittent mines, mines that were under-represented, and mines that were not represented in the analysis published in the proposed preamble in 2003.

Table VI–3 summarizes, by general commodity, the EC levels measured during MSHA's baseline sampling through October 29, 2003. The overall mean eight-hour full shift equivalent EC concentration was 196 μg/m³, and the overall median was 134 μg/m³. Table VI–4 provides a similar summary for estimated DPM levels, using DPM ≈ TC/0.8 and TC ≈ 1.3 × EC.[2] Under these assumptions, the estimated mean DPM level was 318 μg/m³, and the median was 218 μg/m³. Since the baseline data and the 31-Mine Study both showed significantly lower levels at trona mines than at other underground M/NM mines, Tables VI–3 and VI–4 present overall results both including and excluding the three underground trona mines sampled.[3]

TABLE VI–3.—BASELINE EC CONCENTRATIONS

	8-hour Full Shift Equivalent EC Concentration (μg/m³)					
	Metal	Stone	Other N/M	Trona	Total	Total excluding Trona
No. of Samples	284	689	196	25	1,194	1,169
Maximum	1,558	2,291	738	313	2,291	2,291
Median	208	115	114	63	134	137
Mean	273	181	150	81	196	198
Std. Error	14	8	9	12	6	6
95% UCL	302	197	167	106	208	210
95% LCL	245	166	132	56	184	186

TABLE VI–4.—BASELINE DPM CONCENTRATIONS

[DPM is estimated by (1.3 × EC) ÷ 0.8]

	Estimated 8-hour Full Shift Equivalent DPM Concentration (μg/m³)					
	Metal	Stone	Other N/M	Trona	Total	Total excluding Trona
No. of Samples	284	689	196	25	1,194	1,169
Maximum	2,532	3,724	1,200	509	3,724	3,724
Median	339	186	185	102	218	223
Mean	444	295	243	132	318	322
Std. Error	23	13	15	20	10	10
95% UCL	490	320	272	173	338	342
95% LCL	399	270	214	91	299	303

Baseline EC sample results varied widely between mines within commodities and also within most mines. Table VI–5 summarizes baseline EC results for the 26 occupations found to have at least one sample where the EC level exceeded the 308 μg/m³ 8-hour full shift equivalent interim EC limit. As indicated by the table, EC levels varied widely within each occupation.

TABLE VI–5.—BASELINE EC CONCENTRATIONS FOR OCCUPATIONS WITH AT LEAST ONE VALUE EXCEEDING INTERIM EC LIMIT

Occupation	Number of valid samples	8-hour full shift equivalent EC Concentration (μg/m³)		
		Minimum	Median	Maximum
Diamond Drill Operator	1	1,561	1,561	1,561
Ground Control/Timberman	2	283	419	555
Washer Operator	4	272	337	621
Engineer	1	337	337	337
Roof Bolter, Mounted	12	76	258	818
Mucking Mach. Operator	23	12	257	671
Miner, Stope	14	77	218	479

[2] The relationship DPM ≈ TC/0.8 is the same as that assumed in the 2001 risk assessment. The relationship TC 1.3 × EC was formulated under the settlement agreement, based on TC:EC ratios observed in the joint 31-Mine Study, as described in the subsection VI.3 of this preamble.

[3] The distributions of EC values are skewed. Therefore, the standard errors and confidence intervals reported in Tables VI–3 and VI–4 should be interpreted with caution.

TABLE VI–5.—BASELINE EC CONCENTRATIONS FOR OCCUPATIONS WITH AT LEAST ONE VALUE EXCEEDING INTERIM EC LIMIT—Continued

Occupation	Number of valid samples	8-hour full shift equivalent EC Concentration (µg/m³)		
		Minimum	Median	Maximum
Cleanup Man	2	51	217	384
Scoop-Tram Operator	7	10	210	449
Drill Operator, Rotary Air	21	0	185	1,041
Miner, Drift	17	12	175	1,122
Blaster, Powder Gang	134	5	175	1,031
Belt Crew	8	20	173	386
Roof Bolter, Rock	21	48	172	1,007
Truck Driver	252	0	162	1,216
Shuttle Car Operator (diesel)	3	73	154	323
Complete Load-Haul-Dump	32	14	145	634
Drill Operator, Jumbo Perc	38	4	137	845
Drill Operator, Rotary	75	2	132	853
Motorman	8	46	129	322
Front-end Loader Operator	214	0	121	2,291
Scaling (mechanical)	80	0	107	958
Supervisor, Co. Official	13	1	100	658
Utility Man	29	22	73	762
Scaling (hand)	26	14	67	1,548
Mechanic	34	0	64	323

Figure VI–1 depicts, by mine category, the percentage of baseline samples that exceeded the interim EC limit of 308 µg/m³. Underground metal mines exhibited the highest proportion of samples exceeding this limit, followed by stone and then other nonmetal mines. In the three trona mines sampled, 24 of the 25 samples were lower than the proposed limit. Across all commodities, 19.3% of the 1,194 valid baseline samples exceeded the interim EC limit.

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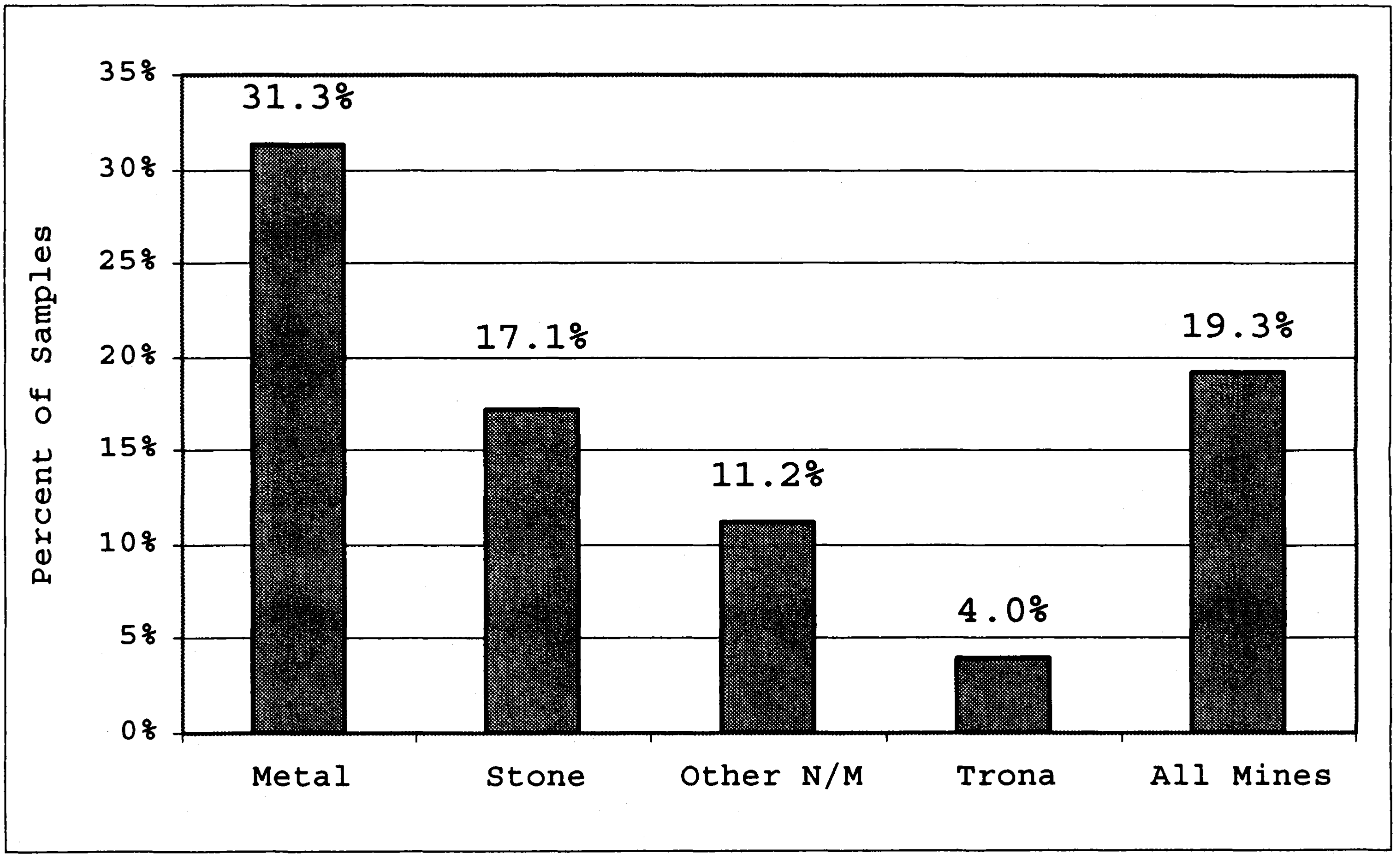

Figure VI-1. Percentage of baseline samples exceeding interim EC limit.

Figure VI–2 shows how samples exceeding the interim EC limit were distributed over individual mines. One to 20 baseline samples were taken at each mine. In 115 of the 183 mines sampled (63%), none of the baseline EC measurements exceeded 308 µg/m³. The remaining 68 mines (37%) had at least one sample for which EC exceeded 308 µg/m³. All samples taken at 4 of the mines exceeded the interim limit.

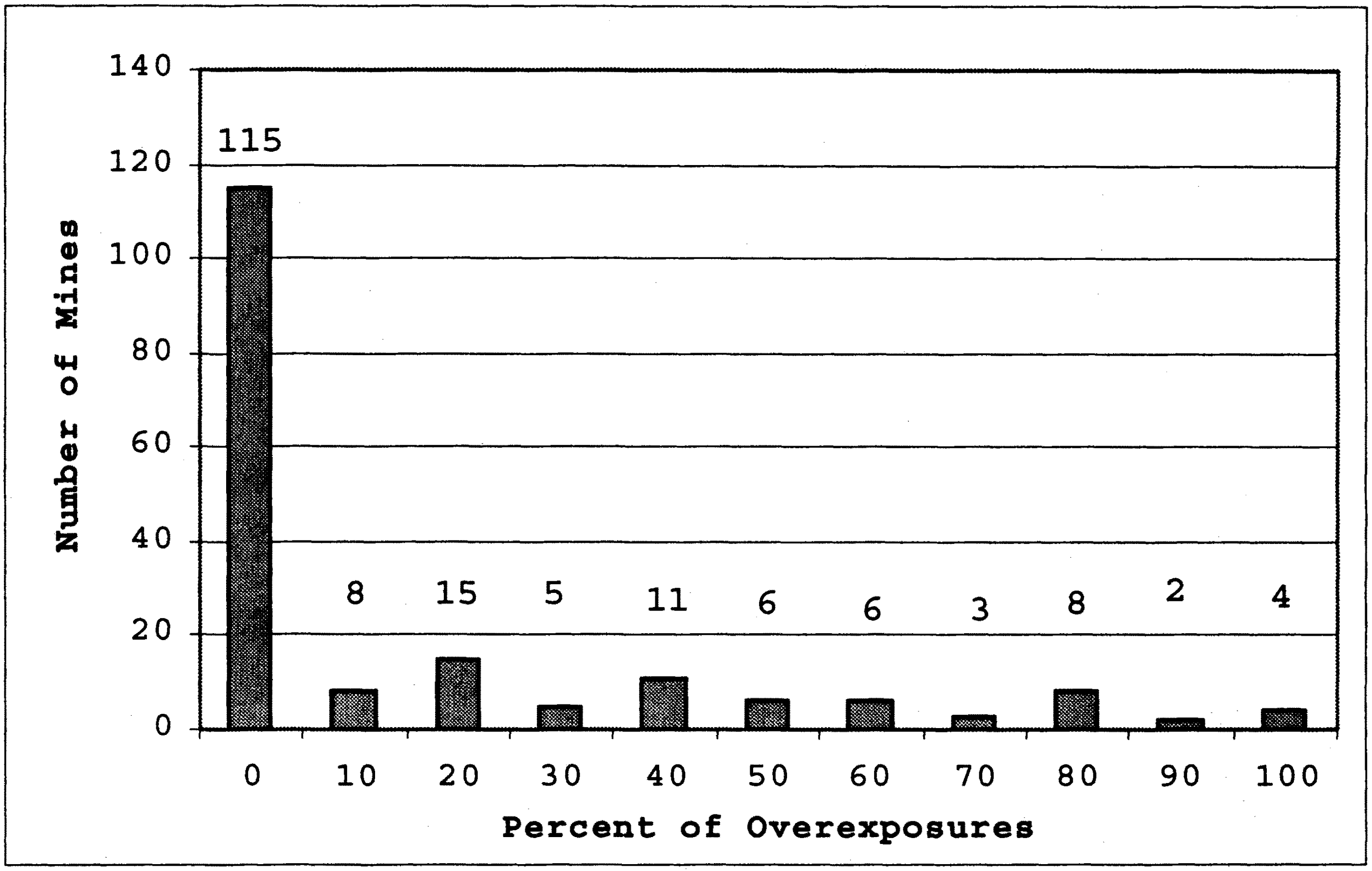

Figure VI-2. Distribution of samples exceeding interim EC limit.

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(3) Relationship Between EC and TC

The 2001 final rule stipulated that TC (*i.e.*, EC + OC) measurements would be used to monitor and limit DPM concentration levels. Although it was recognized that TC measurements were subject to various interferences from non-DPM sources, MSHA believed that, in underground metal and nonmetal mines, it could effectively eliminate such interferences by a combination of selective sampling procedures and careful analytical techniques. During the 31-Mine Study, however, MSHA found no reasonable sampling method that would adequately protect TC measurements from interference by such sources of organic carbon as oil mist and ammonium nitrate fuel oil (ANFO). Furthermore, MSHA found that it was cumbersome and impractical to restrict its TC sampling so as to avoid potential interference from environmental tobacco smoke (ETS). Indeed, as indicated earlier, nearly one fourth of the TC samples collected during the 31-Mine Study (106 out of 464) had to be voided on account of potential interferences from extraneous sources of OC. Therefore, in concert with the Second Partial Settlement Agreement, the 2003 NPRM proposed to ''[r]evise the existing diesel particulate matter (DPM) interim concentration limit measured by total carbon (TC) to a comparable permissible exposure limit (PEL) measured by elemental carbon (EC) which renders a more accurate DPM exposure measurement.'' (68 FR 48668) Using EC as the surrogate permits direct sampling of miners (such as those who smoke, operate jackleg drills, or load ANFO) for whom accurate DPM monitoring would be difficult or impossible using TC measurements.

Also in accordance with the Second Partial Settlement Agreement, the NPRM proposed to convert the existing interim exposure limit, expressed in terms of TC measurements, to a ''comparable'' EC limit by applying a specific conversion factor obtained from data gathered during the 31-Mine Study, as explained below. MSHA is adopting this proposal with the intention of providing at least the same degree of protection to miners as the existing interim limit. However, since it is unlikely that EC and OC have identical health effects, it is important to consider the extent to which the ratio of EC to OC (and hence of EC to TC) may vary in different underground mining environments.

Unlike the 31-Mine Study, no special precautions were taken during MSHA's baseline sampling to avoid ETS or other substances that could potentially interfere with using TC as a surrogate measure of DPM. Therefore, the baseline data should not be used to evaluate the OC content of DPM or the ratio of EC to TC within DPM. In the 31-Mine Study, on the other hand, great care was taken to void all samples that may have been exposed to ETS or other extraneous sources of OC.

Consequently, the analysis of the EC:TC ratio presented here relies entirely on data from the 31-Mine Study. It is important to note that nearly all of the samples in this study were taken in the absence of exhaust filters to control DPM emissions. Since exhaust filters may have different effects on EC and OC emissions, the results described here apply only to mine areas where exhaust filters are not employed.

Figure VI–3 plots the EC:TC ratios observed in the 31-Mine Study against the corresponding TC concentrations. The various symbols shown in the plot identify samples taken at the same mine. The EC:TC ratio ranged from 23% to 100%, with a mean of 75.7% and a median of 78.2%. Note that the reciprocal of 0.78, which is 1.3, equals the median of the TC:EC ratio observed in these samples.[4] The 1.3 TC:EC ratio was the value accepted, under terms of the settlement agreement, for the purpose of temporarily converting EC measurements to TC measurements.

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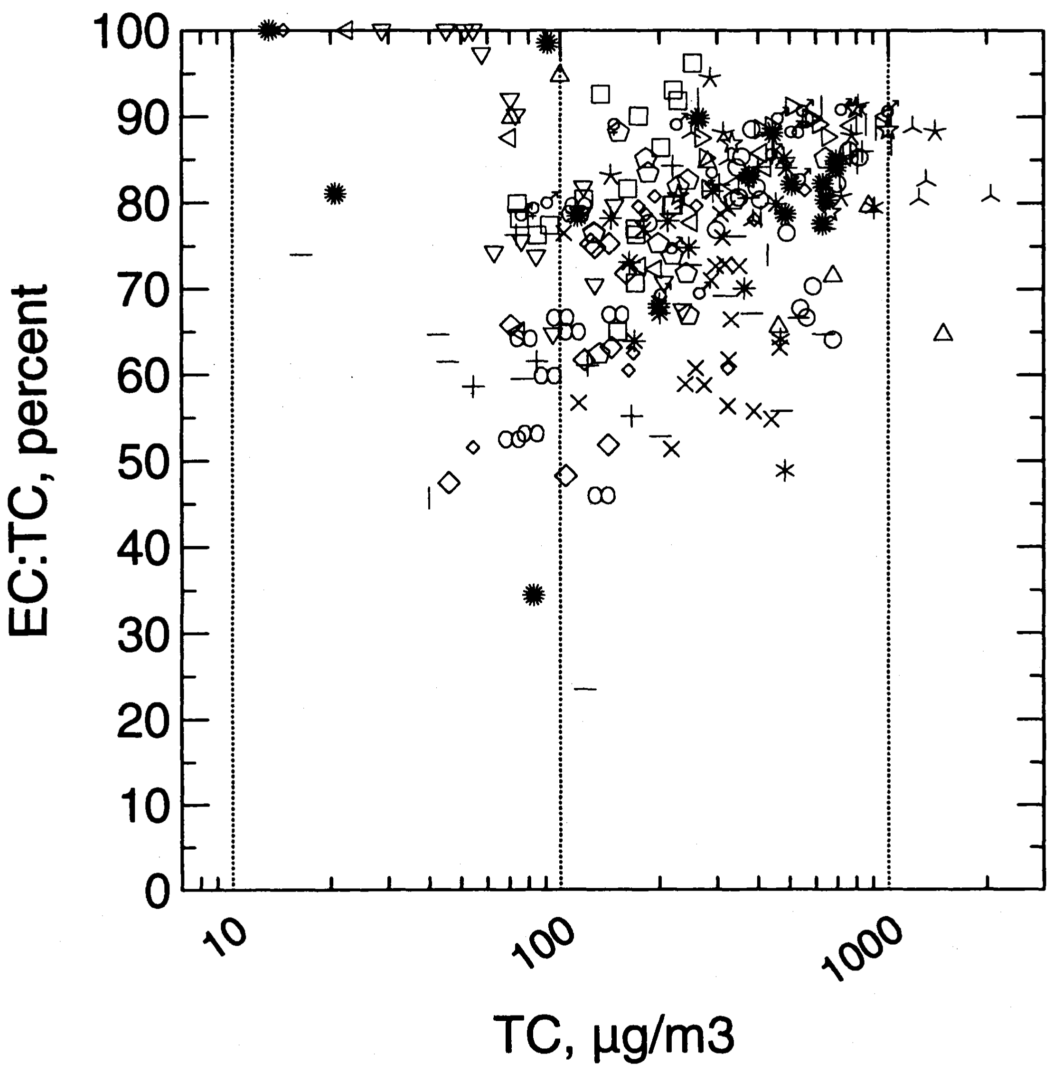

Figure VI-3. EC:TC ratios found in 358 valid samples from 31-Mine Study. Symbols identify samples from same mine.

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The 2001 rule set a TC interim concentration limit of 400 µg/m³. Under the new rule, this TC interim limit is replaced with an EC interim limit of 400/1.3 = 308 µg/m³. Table VI–6 indicates the impact of this change, based on the EC and TC data obtained from the 31-Mine Study. Both the original 400 µg/m³ TC limit and the new 308 µg/m³ EC limit were exceeded by about 31% to 32% of the samples. The difference (one sample out of 358) is not statistically significant in the aggregate. Seven samples, however, exceeded the TC limit but not the EC limit, and six samples exceeded the EC limit but not the TC limit.

[4] The median of reciprocal values is always equal to the reciprocal of the median. This relationship does not hold for the mean.

TABLE VI–6.—COMPLIANCE WITH ORIGINAL 400 µG/M³ TC LIMIT AND/OR NEW 308 µG/M³ EC LIMIT. NUMBERS IN PARENTHESES ARE PERCENTAGES

EC > 308 µg/m³	TC > 400 µg/m³		Total
	No	Yes	
No	239 (66.8)	7 (2.0)	246 (68.7)
Yes	6 (1.7)	106 (29.6)	112 (31.3)
Total	245 (68.4)	113 (31.6)	358 (100.0)

Several commenters noted that the ratio of EC to TC in DPM can vary widely. One commenter pointed out that EC appeared to make up nearly all of the TC at the mine with which he was affiliated. This commenter stated that replacing a 400 µg/m³ TC limit with a 308 µg/m³ EC limit would impose a much more stringent standard at that mine. Another commenter noted that a 308 µg/m³ EC limit would be less protective of miners than the 400 µg/m³ TC limit in cases where the ratio of EC comprised less than 78% of the TC. MARG submitted comments by a consultant, Dr. Jonathan Borak, who emphasized that the highly variable nature of the EC to OC ratio introduces ''large and important uncertainties in the exposure assessments needed to sustain QRA [*i.e.*, quantitative risk assessment].''

As indicated by Figure VI–3, the percentage of EC tended to increase with increasing TC concentration—except for cases showing a TC concentration of less than about 60 µg/m³. In many of the samples for which TC < 60 µg/m³, the recorded ratio of EC to TC was at or near 100%. Since TC concentrations less than 60 µg/m³ appear to deviate from the general pattern and are far below the interim limit, our response to commenters concerns about variability in the ratio of EC to TC will focus on those samples for which TC exceeds 60 µg/m³.

There were 319 samples with TC > 60 µg/m³. For these samples, the mean and median EC:TC ratio were 76.3% and 78.4%, respectively. In accordance with standard statistical practice, an arcsine transformation was applied to these 319 EC:TC ratios in order to normalize them for further statistical analysis (Snedecor and Cochran, *Statistical Methods,* 7th Ed., pp 290–291). The transformed EC:TC ratios are plotted against corresponding TC concentrations in Figure VI–4. Various symbols are used to identify the mineral commodity corresponding to each sample.

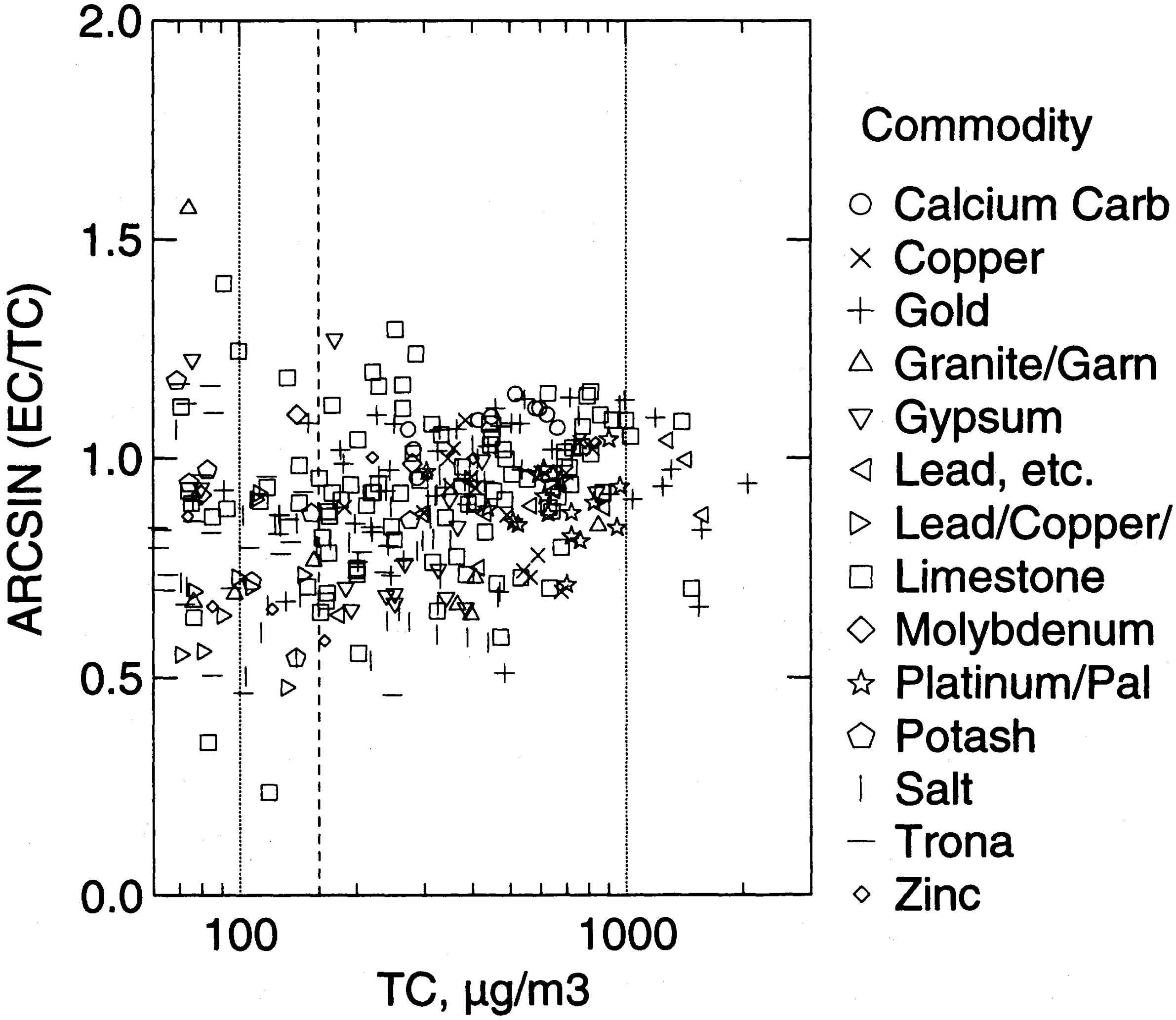

Figure VI-4. Transformed EC:TC ratios, by commodity, plotted against TC concentration. Data restricted to 319 samples for which TC > 60 µg/m³. The sine of the transformed value plotted along the verical axis (in radians) yields EC/TC. Transformed (arcsin) values of 0.5, 0.75, 1.0, and 1.6 correspond to EC/TC respectively equaling 0.48, 0.68, 0.84, and 1.00.

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It is clear from Figures VI–3 and VI–4 that individual samples in the 31-Mine Study exhibited considerable variation in their EC:TC ratios. What is not so clear from these plots, however, is whether different mines and/or working environments tended to experience different EC:TC ratios. To answer this question, an analysis of variance (ANOVA) was performed to determine whether there were statistically significant differences in the EC:TC ratios exhibited at different mines and on different days at the same mine. Table VI–7 contains the results of this ANOVA. At a confidence level exceeding 99.9%, the data show statistically significant differences in the mean EC:TC ratios between mines and between different sampling days within mines.

TABLE VI–7.—ANALYSIS OF VARIANCE FOR ARCSIN OF EC:TC RATIOS, RESTRICTED TO SAMPLES WITH TC > 60 µG/M³

Source	Sum of squares	Degrees of freedom	Mean square	F-ratio	P
MINE	3.360	29	0.116	6.960	0.000
DAY within MINE	1.643	30	0.055	3.290	0.000
Error	4.295	258	0.017		

Figure VI–5 illustrates the magnitude and extent of differences in the mean EC:TC ratio between mines. Note that values on the arcsin scale of 0.7, 0.9, and 1.1 correspond to EC:TC ratios of 64%, 78%, and 89%, respectively.

Since TC = EC + OC, variability in the EC:TC ratio corresponds to variability in the ratio of either EC or TC to OC. Dr. Borak stated that if DPM is carcinogenic, then the carcinogenic agents (for humans) are probably in the organic fraction (*i.e.*, OC). Consequently, according to Dr. Borak, neither EC nor TC provides an appropriate surrogate for assessing or limiting health risks.

MSHA believes that Dr. Borak's assumption that any carcinogenic effect of DPM is due entirely to the organic fraction is speculative. This assumption contradicts 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. Indeed, identifying the toxic components of DPM, and particulate matter in general, is an important research focus of a variety of government agencies and scientific organizations (see, for example: Health Effects Institute, 2003; Environmental Protection Agency, 2004b). The 2001 risk assessment discusses possible mechanisms of carcinogenesis for which both EC and OC would be relevant factors (66 FR at 5811–5822). 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 EC core, either alone or in combination with the organics.

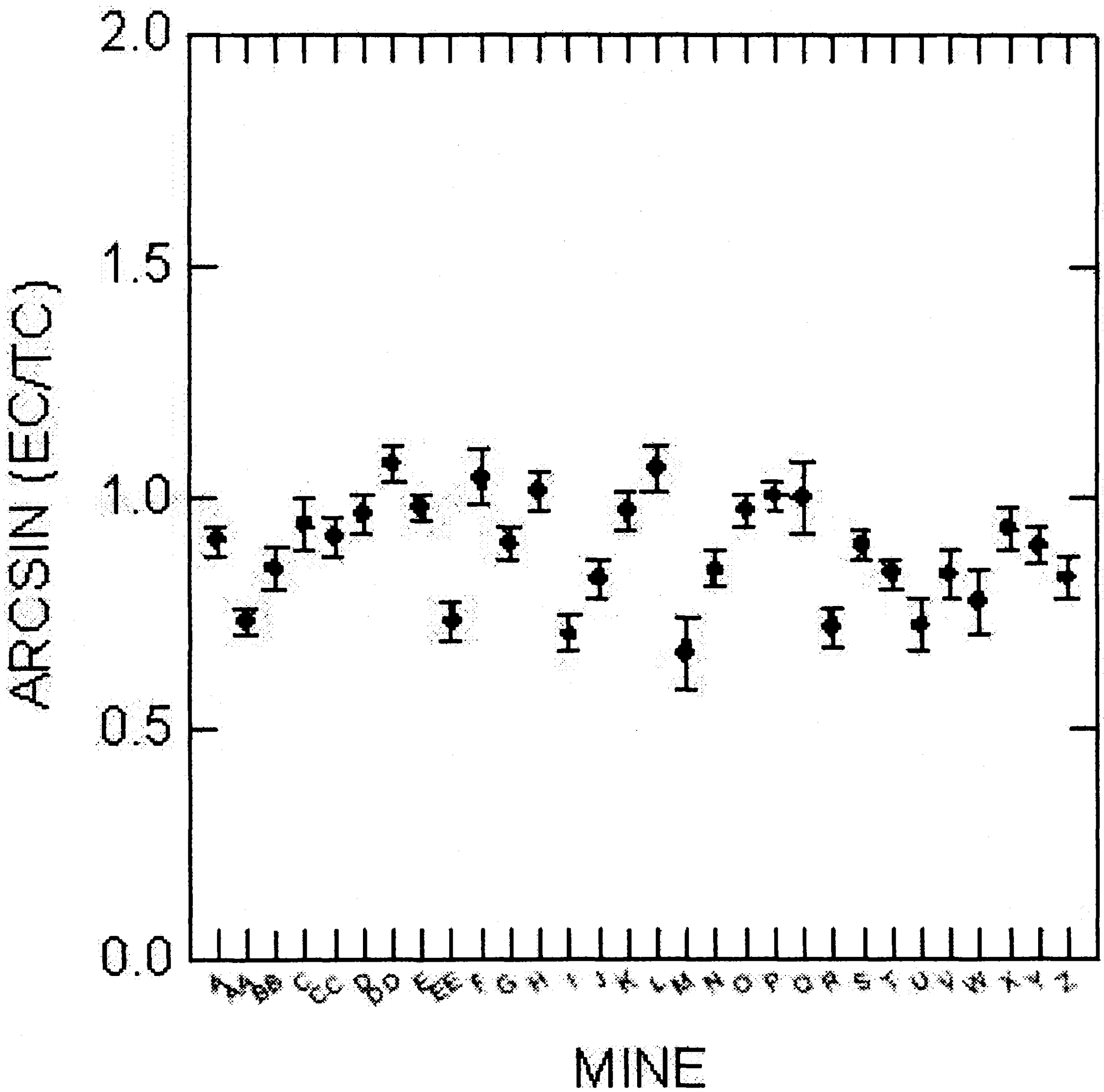

Figure VI-5. Mean EC:TC ratios (transformed values) at mines in 31-Mine Study. Vertical bar plotted for each mine represents 95% confidence interval for mean of arcsin(EC/TC). Samples with TC ≤ 60 µg/m^3 were excluded from the analysis.

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In focusing on the carcinogenic agents in OC, Dr. Borak has also ignored non-cancer health effects documented in the 2001 risk assessment—*e.g.*, immunological, inflammatory, and allergenic responses in healthy human volunteers exposed to 300_{DPM} µg/m^3 (*i.e.*, ~ 240_{TC} µg/m^3) for as little as one hour (66 FR at 5769–70, 5816–17, 5820, 5823, 5837, 5841, 5847).

The 308 µg/m^3 interim EC PEL established by this rule is intended to be commensurate with the interim TC limit of 400 µg/m^3 established under the 2001 rule—*i.e.*, to be equally protective and equally feasible. Although, as shown by Table VI–7 and Figure VI–5, the EC:TC ratio can exhibit considerable variability in specific cases, MSHA has concluded that application of the 1.3 average conversion factor, as suggested in the second partial settlement agreement, generally achieves the goal of equal protection and feasibility.

C. Health Effects

A key conclusion of the 2001 risk assessment was:

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. [66 FR at 5854–5855]

MSHA has reviewed the scientific literature pertaining to health effects of fine particulates in general and DPM in particular published later than what was considered in the 2001 risk assessment. As will be shown below, the more recent scientific evidence generally supports the conclusion above, and nothing in our review suggests that it should be altered. In fact, the U.S. Environmental Protection Agency (EPA) recently reached very similar conclusions after reviewing all of the evidence to date (EPA; 2002, 2004b).

Some commenters endorsed the 2001 risk assessment, and suggested that the latest evidence strengthens its conclusions. For example, one group of commenters jointly stated:

> The evidence presented in MSHA's 2001 risk assessment is overwhelming * * * The evidence linking exposure to particulate air pollution and/or diesel particulate matter with lung cancer, cardiovascular and cardiopulmonary and other adverse health effects continues to mount.

Similarly, another pair of commenters jointly stated that ''[t]he scientific evidence for the [adverse] health effects of DPM is overwhelming'' and that ''evidence for the carcinogenicity and non-cancer health effects of DPM has grown since 1998.''

Other commenters contended that all of the evidence to date is insufficient to support limitation of occupational DPM exposures. Several of these commenters ignored evidence presented in the 2001 risk assessment and/or mischaracterized its conclusions. For example, the NMA, MARG, and the Nevada Mining Association (NVMA) all erroneously stated that promulgation of the 2001 rule was based on only ''two principal health concerns: (1) The transitory, reversible health effects of exposure to DPM; and, (2) the long-term impacts that may result in an excess risk of lung cancer for exposed workers.'' Actually, as shown in the conclusion cited above, the 2001 risk assessment identified three different kinds of material health impairment associated with DPM exposure: (1) Acute sensory irritations and respiratory symptoms (including allergenic responses); (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (3) lung cancer. Although the cardiovascular, cardiopulmonary, and respiratory effects leading to an increased risk of premature death were associated with acute DPM exposures, commenters presented no evidence that any such effects were ''transitory'' or ''reversible.'' Nor did commenters present evidence that immunological responses associated with either short-term or long-term DPM exposure were ''transitory'' or ''reversible.''

In addition, some commenters erroneously stated that ''no [quantitative] dose/response relationship related to the PELs could be demonstrated by MSHA.'' These commenters apparently ignored the discussion of exposure-response relationships in the 2001 risk assessment (66 FR at 5847–54) and failed, specifically, to note the quantitative exposure-response relationships shown for lung cancer in the two tables provided (66 FR at 5852–53). Relevant exposure-response relationships were also demonstrated in articles by Pope *et al.* cited in the 2003 NPRM, which will be discussed further below.

Some commenters objected that the exposure-response relationships presented in the 2001 risk assessment did not justify adoption of the specific DPM exposure limits promulgated. These commenters mistakenly assumed the limits set forth in the 2001 final rule were derived from an exposure-response relationship. As explained in 66 FR at 5710–14, the choice of exposure limits, while justified by quantifiable adverse health effects, was actually driven by feasibility concerns. The exposure-response relationships provided clear evidence of adverse human health effects (both cancer and non-cancer) at levels far below those determined to be feasible for mining.

In the 2003 NPRM, MSHA identified scientific literature pertaining to health effects of fine particulates in general and DPM in particular published subsequent to the 2001 final rule. The 2003 NPRM stated MSHA's intentions to continue its reliance on the 2001 risk assessment and cited the newer literature in a neutral manner, soliciting public comment on its implications for the 2001 risk assessment.

Two commenters complained that MSHA had not described the recent scientific literature in sufficient detail to determine whether it supports the 2001 risk assessment. Most of the commenters who evaluated the recent literature found that it supported and/or strengthened the conclusions of the 2001 risk assessment. Some other commenters, however, disagreed. Accordingly MSHA will present the supplemental literature in more detail than in the 2003 NPRM and explain why MSHA believes that it continues to support the 2001 risk assessment. This discussion will include our review of an analysis by Dr. Gerald Chase of some preliminary data from an ongoing NIOSH/NCI study.

The scientific literature cited in the 2003 NPRM was meant only to update and supplement the evidence of health effects cited in the 2001 risk assessment. Although MSHA believes the 2001 risk assessment presented ample evidence to justify its conclusions, MSHA is adding this supplemental literature because it represents more recent scientific investigations related to DPM health effects. The following discussion of literature cited in the 2003 NPRM is organized into four categories, roughly corresponding to the three types of material health impairments identified in the 2001 risk assessment, followed by a category covering toxicology studies: (1) Respiratory and immunological effects, including asthma, (2) cardiovascular and cardiopulmonary effects, (3) cancer, and (4) mechanisms of toxicity. Although the discussion of cancer will focus on lung cancer, it will also take note of two recent meta-analyses of epidemiological studies investigating DPM in connection with bladder and pancreatic cancers.

(1) Respiratory and Immunological Effects, Including Allergenic Responses

In the 2001 risk assessment, acute sensory irritations with respiratory symptoms, including immunological or allergenic effects such as asthmatic responses were grouped together, and all such effects as material health impairments likely to be caused or exacerbated by excessive DPM exposures were identified. This finding was based on human experimental and epidemiological studies and was supported by experimental toxicology. (For an explanation of why MSHA considers such effects to be material impairments, regardless of whether they are ''reversible,'' See, 66 FR at 5766.)

Table VI–8 summarizes six additional studies dealing with possible respiratory and immunological effects of DPM and/or fine particulates in general. Three of these studies (Frew *et al.*, 2001; Holgate *et al.*, 2002; Salvi *et al.*, 2000) involved experiments in which human subjects inhaled specified doses of DPM. These three studies all support the view that occupational DPM exposures are likely to promote or exacerbate adverse respiratory symptoms and immunological responses. A fourth study (Svartengren *et al.*, 2000) exposed human subjects to high and low doses of an unspecified mix of diesel and gasoline engine exhausts. Although 30-minute $PM_{2.5}$ exposures greater than 100 µg/m3 were found to increase asthmatic response, the authors of this study attributed the effects they observed primarily to NO_2 exposure. The fifth study (Oliver *et al.*, 2001) attempted to relate pulmonary function test results and asthmatic conditions to estimated lifetime diesel exposure in a cohort of 359 ''heavy and highway'' (HH) construction workers. After adjustment for smoking and other potential confounders, the results indicated an elevated risk of asthma for exposed workers in enclosed spaces (tunnel workers), relative to other HH workers. The lack of additional statistically significant results may be attributable to the small cohort size. The sixth study (Fusco *et al.*, 2001) examined the relationship between various markers of engine exhaust pollution levels and daily hospital admissions for acute respiratory infections, COPD, asthma, and total respiratory conditions in Rome, Italy. No direct measurements of fine particulate concentrations were available. However, having found a significant correlation between respiratory-related admissions and CO and NO_2 levels, the authors noted that since CO and NO_2 are good indicators of combustion products in vehicular exhaust, the detected effects may be due to unmeasured fine and ultrafine particles.

TABLE VI–8.—STUDIES OF HUMAN RESPIRATORY AND IMMUNOLOGICAL EFFECTS, 2000–2002

Authors, year	Description	Key results
Frew *et al.*, 2001	25 healthy subjects and 15 subjects with mild asthma were exposed to diesel exhaust (108 μg/m^3) or filtered air for 2 hr, with intermittent exercise. Lung function was assessed using a computerized whole body plethysmograph. Airway responses were sampled by bronchial wash (BW), bronchoalveolar lavage (BAL), and mucosal biopsies 6 hr after ceasing exposures.	Both the asthmatic and healthy subjects developed increased airway resistance after exposure to diesel emissions, but airway inflammatory responses were different for the 2 groups. The healthy subjects showed statistically significant BW neutrophilia and BAL lymphocytosis 6 hr after exposure. The neutrophilic response of the healthy subjects was less intense than that seen in a previous study using a DPM concentration of 300 μg/m^3.
Fusco *et al.*, 2001	Analysis of daily hospital admissions for acute respiratory infections, COPD, asthma, and total respiratory conditions in Rome, Italy.	Respiratory admissions among adults were significantly correlated with CO and NO_2 levels, but not with suspended particles. The authors noted that since CO and NO_2 are good indicators of combustion products in vehicular exhaust, the detected effects may be due to unmeasured fine and ultrafine particles.
Holgate *et al.* 2002	25 healthy and 15 asthmatic subjects were exposed for 2 hours to 100 μg/m^3 of DPM and to filtered air on separate days. Another 30 healthy subjects were exposed for 2 hours to DPM concentrations ranging from 25 to 311 μg/m^3 and compared to 12 different healthy subjects exposed to filtered air. Exposure effects were assessed using lung function tests and biochemical tests of bronchial tissue samples.	Healthy and asthmatic subjects exhibited evidence of bronchioconstriction immediately after exposure Biochemical tests of inflammation yielded mixed results but showed small inflammatory changes in healthy subjects after DPM inhalation.
Oliver *et al.,* 2001	Pulmonary function tests and questionnaire data were obtained for 350 ''heavy and highway'' (HH) construction workers. Intensity of DPM exposure was estimated according to job classification. Duration of exposure was estimated based on length of union membership.	After adjusting for smoking and some other potential confounders, HH workers showed elevated risk of asthma. One subgroup (tunnel workers) also showed elevated risk of both undiagnosed asthma and chronic bronchitis, compared to other HH workers. Respiratory symptoms appeared to declined with exposure duration as measured length of union membership. The authors interpreted this as suggesting that HH workers tend to leave their trade when they experience adverse respiratory symptoms.
Salvi *et al.*, 2000	15 healthy nonsmoking volunteers were exposed to 300 μg/m^3 DPM and clean air for one hour at least three weeks apart. Biochemical analyses were performed on bronchial tissue and bronchial wash cells obtained six hours after each exposure.	Diesel exhaust exposure enhanced gene transcription of IL–8 in the bronchial tissue and airway cells and increased IL–8 and GRO-α protein expression in the bronchial epithelium. This was accompanied by a trend toward increased IL–5 mRNA gene transcripts in the bronchial tissue. Study showed effects on chemokine and cytokine production in the lower airways of healthy adults. These substances attract and activate leukocytes. They are associated with the pathophysiology of asthma and allergic rhintisi.
Svartengren *et al;.* 2000	Twenty nonsmoking subjects with mild allergic asthma were exposed for 30 minutes to high and low levels of engine exhaust air pollution on two separate occasions at least four weeks apart. Respiratory symptoms and pulmonary function were measured immediately before, during and after both exposure periods. Four hours after each exposure, the test subjects were challenged with a low dose of inhaled allergen. Lung function and asthmatic reactions were monitored for several hours after exposure.	Subjects with $PM_{2.5}$ exposure ≥ 100 μg/m^3 exhibited slightly increased asthmatic responses. Association with adverse outcome variables were weaker for particulates than for NO_2.

The 2003 NPRM also cited five new review articles that summarize the scientific literature pertaining to the respiratory and immunological effects of DPM and fine particulate matter in general. These review articles, published after the 2001 risk assessment, are identified and briefly described in Table VI–9. The three articles most specifically dealing with DPM effects are Pandya *et al.* (2002), Peden at al. (2002), and Sydbom *et al.* (2001). In general, these reviews indicate that while DPM is likely to contribute to asthmatic and/or other immunological responses, the role of DPM in producing these health effects is complex. As noted by Pandya *et al.* (op cit.), DPM may have a far greater impact as an adjuvant with allergens than alone. Nevertheless, all three of these review articles support the view that there is significant evidence of adverse respiratory and immunological effects to warrant regulating DPM exposures. The remaining review articles (Gavett and Koren, 2001; Patton and Lopez, 2002) offer little new support for the 2001 risk assessment, but MSHA found no studies that either refute or challenge the 2001 risk assessment.

TABLE VI–9.—REVIEW ARTICLES ON RESPIRATORY AND IMMUNOLOGICAL EFFECTS, 1999–2002

Authors, year	Description	Key results
Gavett and Koren, 2001	Summarizes results of EPA studies done to determine whether PM can enhance allergic sensitization or exacerbate existing asthma or asthma-like responses in humans and animal models.	Studies indicate that PM enhances allergic sensitization in animal models of allergy exacerbate inflammation and airway hyper-responsiveness in asthmatics and animal models of asthma.
Pandya et al. 2002	Reviews human and animal research relevant to question of whether DPM is associated with asthma.	Evidence indicates that DPM is associated with the inflammatory and immune responses involved in asthma, but DPM appears to have far greater impact as an adjuvant with allergens than alone. DPM appears to augment IgE, trigger eosinophil degranulation, and stimulate release of numerous cytokines and chemokines. DPM may also promote the cytotoxic effects of free radicals in the airways.
Patton and Lopez, 2002	Review of evidence and mechanisms for the role of air pollutants in allergic airways disease.	Evidence suggests that air pollutants (including DPM) ''affect allergic response by different mechanisms. Pollutants may increase total IgE levels and potentiate the initial sensitization to allergens and the IgE response to a subsequent allergen exposure. Pollutants also may act by increasing allergic airway inflammation and by directly stimulating airway inflammation. In addition, it is well known that pollutants can be direct irritants of the airways, increasing symptoms in patients with allergic syndromes.''
Peden, 2002	Review of ''studies that exemplify the impact of ozone, particulates, and toxic components of particulates on asthma.''.	DPM ''may play a significant role not only in asthma exacerbation but also in T_H2 inflammation via the actions of polyaromatic hydrocarbons on B lymphocytes.'' ''* * * PM in which the active agents are biologically active metal ions and organic residues * * * may have significant effects on asthma, especially modulating immune function, as demonstrated by the role of polyaromatic hydrocarbons from diesel exhaust in IgE production.''
Sydbom et al. 2001	Review of scientific literature on health effects of disease exhaust, especially the DPM components.	The epidemiological support for particle effects on asthma and respiratory health is very evident; and respiratory, immunological, and systemic effects of DPM have been documented in a wide variety of experimental studies. Acute effects of DPM exposure include irritation of the nose and eyes, lung function changes, and airway inflammation. Exposure studies in healthy humans have documented a number of profound inflammatory changes in the airways, notably, before changes in pulmonary function can be detected. Such effects may be even more detrimental in subjects with compromised pulmonary function. Ultrafine particles are currently suspected of being the most aggressive particulate component of diesel exhaust.

In its 2002 ''Health Assessment Document for Diesel Engine Exhaust,'' the Environmental Protection Agency (EPA) reached the following conclusion with respect to immunological effects of diesel exhaust:

Recent human and animal studies show that acute DE [diesel exhaust] exposure episodes can exacerbate immunological reactions to other allergens or initiate a DE-specific allergenic reaction. The effects seem to be associated with both the organic and carbon core fraction of DPM. In human subjects, intranasal administration of DPM has resulted in measurable increases of IgE antibody production and increased nasal mRNA for some proinflammatory cytokines. These types of responses also are markers typical of asthma, though for DE, evidence has not been produced in humans that DE exposure results in asthma. The ability of DPM to act as an adjuvant to other allergens also has been demonstrated in human subjects. (EPA, 2002)

(2) Cardiovascular and Cardiopulmonary Effects

In the 2001 risk assessment, the evidence presented for DPM's adverse cardiovascular and cardiopulmonary effects relied on data from air pollution studies in the ambient air. This evidence identifies premature death from cardiovascular, cardiopulmonary, or respiratory causes as an endpoint significantly associated with exposures to fine particulates. The 2001 risk assessment found that ''[t]he mortality effects of acute exposures appear to be primarily attributable to combustion-related particles in $PM_{2.5}$ [*i.e.*, fine Particulate Matter] (such as DPM) * * *.''

There are difficulties involved in utilizing the evidence from such studies in assessing risks to miners from occupational DPM exposures. As noted in the 2001 risk assessment,

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.

However,

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. [66 FR 5767]

Pope (2000) reviewed the epidemiological evidence for adverse health effects of $PM_{2.5}$ and characterized populations at increased risk due to $PM_{2.5}$ exposure. He found that ''[t]he overall epidemiologic evidence indicates a probable link between fine particulate air pollution and adverse effects on cardiopulmonary health.'' The observed endpoints include ''death from cardiac and pulmonary disease, emergency and physician office visits for asthma and other cardiorespiratory disorders, hospital admissions for cardiopulmonary disease, increased reported respiratory symptoms, and decreased measured lung function.'' Moreover, according to Pope, recent research suggests that ''those who are susceptible to increased risk of mortality from acutely elevated PM may include more than just the most old and frail who are already very near death.'' Pope went on to state that, with respect to chronic exposure, ''[t]here is no evidence that increased mortality risk is confined to any well-defined susceptible subgroup.''

Table VI–10 identifies five studies on cardiovascular and cardiopulmonary effects published since the 2001 risk assessment (Lippmann *et al.*, 2000; Magari *et al.*, 2001; Pope *et al.*, 2002; Samet *et al.*, 2000a, 2000b; Wichmann *et al.*, 2000). Three of these studies (Pope *et al.*, 2002; Samet *et al.*, 2000a, 2000b; Wichmann *et al.*, 2000) significantly strengthen MSHA's existing evidence implicating particulate exposures with premature mortality from cardiovascular and cardiopulmonary causes.[5] The Samet and Pope (2002) articles both establish statistically significant exposure-response relationships.

TABLE VI–10.—STUDIES RELATING TO CARDIOVASCULAR AND CARDIOPULMONARY EFFECTS, 2000–2002

Authors, years	Description	Key results
Lippmann *et al.* 2000	Day-to-day fluctuations in particulate air pollution in the Detroit area were compared with corresponding fluctuations in daily deaths and hospital admissions for 1985–1990 and 1992–1994.	After adjustment for the presence of other pollutants, significant associations were found between particulate levels and an increased risk of death due to circulatory causes. However, relative risks were about the same for $PM_{2.5}$ and larger particles.
Magari *et al.,* 2001	Longitudinal study of a male occupational cohort examined the relationship between $PM_{2.5}$ exposure and cardiac autonomic function.	After adjusting for potential confounding factors such as age, time of day, and urinary nicotine level, $PM_{2.5}$ exposure was significantly associated with disturbances in cardiac autonomic function.
Pope *et al.,* 2002	Prospective cohort mortality study, based on data collected for Cancer Prevention II Study, which began in 1982. Questionnaires were used to obtain individual risk factor data (age, sex, race, weight, height, smoking history, education, marital status, diet, alcohol consumption, and occupational exposures). For about 500,000 adults, these were combined with air pollution data for metropolitan areas throughout the U.S. and with vital status and cause of death data through 1998.	After adjustment for other risk factors and potential confounders, using a variety of statistical methods, fine particulate ($PM_{2.5}$) exposures were significantly associated with cardiopulmonary mortality (and also with lung cancer). Each 10-$\mu g/m^3$ increase in mean level of ambient fine particulate air pollution was associated with an increase of approximately 6% in the risk of cardiopulmonary mortality.
Samet *et al.,* 2000a, 2000b	Time series analyses were conducted on data from the 20 and 90 largest U.S. cities to investigate relationships between PM_{10} and other pollutants and daily mortality.	Results of both the 20-city and 90-city mortality analyses are consistent with an average increase in cardiovascular and cardiopulmonary deaths of more than 0.5% for every 10 $\mu g/m^3$ increase in PM_{10} measured the day before death. (Estimated effects are, in general, slightly lower using a more stringent statistical analysis. See Dominici *et al.*, 2002.)
Wichmann *et al.,* 2000	Time series analyses were conducted on data from Erfurt, Germany to investigate relationships between the number and mass concentrations of ultrafine and fine particles and daily mortality.	Higher levels of both fine and ultrafine particle concentrations were significantly associated with increased mortality rate.

[5] As discussed below, Pope *et al.* (2002) also provides strong evidence linking chronic $PM_{2.5}$ exposure with an elevated risk of lung cancer.

Pope *et al.* (2002) warrants special attention because this study addresses chronic effects of long-term $PM_{2.5}$ exposures. (Other studies on $PM_{2.5}$, described in the 2001 risk assessment, have almost all dealt with acute exposure effects.) The authors concluded that ''* * * the findings of this study provide the strongest evidence to date that long-term exposure to fine particulate air pollution * * * is an important risk factor for cardiopulmonary mortality.'' In the 2001 risk assessment, the conclusion related to cardiopulmonary effects was motivated mostly by evidence on short-term exposures from daily time series analyses. Therefore, in finding a significant increase in cardiopulmonary mortality attributable to chronic fine particulate exposures, this study provides important supplement evidence supporting this conclusion. The portion of the study related to lung cancer effects is summarized in the next section.

The EPA's 2004 Air Quality Criteria Document for particulate matter (EPA, 2004b) describes a number of additional studies related to the cardiopulmonary and cardiovascular effects of $PM_{2.5}$, including work published later than that cited in the 2003 NPRM. One of the summary conclusions presented in that document is:

> Overall, there is strong epidemiological evidence linking (a) short-term (hours, days) exposures to $PM_{2.5}$ with cardiovascular and respiratory mortality and morbidity, and (b) long-term (years, decades) $PM_{2.5}$ exposure with cardiovascular and lung cancer mortality and respiratory morbidity. The associations between $PM_{2.5}$ and these various health endpoints are positive and often statistically significant. [EPA, 2004b, Sec. 9 p. 46]

1. Cancer Effects

The 2001 risk assessment concluded that DPM exposure, at occupational levels encountered in mining, was likely to increase the risk of lung cancer. The assessment also found that there was insufficient evidence to establish a causal relationship between DPM and other forms of cancer. Both of these conclusions are supported by the most recent scientific literature. The first part of this update contains a description of three new human research studies and a literature review relating DPM and/or other fine particulate exposures to lung cancer. Since it relates specifically to lung cancer, this subsection also discusses Dr. Chase's analysis. New research on the relationship between DPM exposures and other forms of cancer are described immediately after the lung cancer discussion.

Lung Cancer

Table VI–11 presents three human studies pertaining to the association between lung cancer and exposures to DPM or fine particulates in general completed after the 2001 risk assessment was done.

TABLE VI–11.—STUDIES ON LUNG CANCER EFFECTS, 2000–2002.

Authors, year	Description	Key results
Boffetta *et al.,* 2001	Cohort consisting of entire Swedish working population other than farmers. Exposure assessment based on job title and industry, classified according to probability and intensity of diesel exhaust exposure.	Statistically significant elevations in relative risk (RR) of lung cancer among men for job categories with medium, and high exposure to diesel exhaust, compared to workers in jobs classified as having no occupational exposure
Gustavsson *et al.,* 2000	Case-control study involving all 1,042 male cases of lung cancer and 2,364 randomly selected controls (matched by age and inclusion year) in Stockholm County, Sweden from 1985 through 1990. Semi-quantitative assessment of exposure to diesel exhaust. Relative Risk (RR) estimates adjusted for age, selection year, tobacco smoking, residential radon, occupational exposures to asbestos and combustion products, and environmental exposure to NO_2.	Adjusted RR for the highest quartile of estimated lifetime exposure was 1.63, compared to the group with no exposure.
Pope *et al.,* 2002	Prospective cohort mortality study using data collected for the American Cancer Society Cancer Prevention II Study (began 1982). Questionnaires used to obtain individual risk factor data including age, sex, race, weight, height, smoking history, education, marital status, diet, alcohol consumption, and occupational exposures. This risk factor data combined with air pollution data for metropolitan areas throughout U.S. and vital status and cause of death data through 1998 for about 500,000 adults.	After adjusting for other risk factors and potential co-founders, chronic $PM_{2.5}$ exposures found to be significantly associated with elevated lung cancer mortality. Each 10-$\mu g/m^3$ increase in mean level of ambient fine particulate air pollution ($PM_{2.5}$) associated with statistically significant increase of approximately 8% in risk of lung cancer mortality.

Boffetta *et al.* (2001) investigated a Swedish cohort comprised of the whole Swedish working population not employed as farmers. Job title and industry were classified according to probability and intensity of diesel exhaust exposure in 1960 and 1970 and also according to the authors' confidence in the assessment. Cohort members were followed up for mortality for the 19-year period from 1971 through 1989. Cause of death and specific cancer type, when applicable, were obtained from national registries.

Compared to workers in jobs classified as having no occupational exposure to diesel emissions, relative risks (RR) of lung cancer among men were 0.95, 1.1, and 1.3 for job categories with low, medium, and high exposure intensity, respectively. The elevated risks for the medium and high exposure groups were statistically significant, and no similar pattern was observed for other cancer types. The authors concluded that these results ''provide evidence of a positive exposure-response relationship between exposure to diesel emissions and lung cancer among men.''

Although this study adds to the cumulative weight of evidence establishing a causal link between DPM exposure and lung cancer, it does not provide very strong evidence when viewed in isolation. One weakness of the study is that the exposure assessment was based on self-reported occupation and industry, with no information on duration of employment in various jobs. (This sort of uncertainty in the exposure assessment, however, would not normally be expected to induce a false exposure-response relationship.) Another weakness is that there was no information on potential confounders, such as tobacco smoking and lifestyle factors that may be associated with certain jobs. While recognizing this limitation, the authors considered it unlikely that confounders could account for the increasing trend in relative risk observed according to intensity of diesel exposure.

Gustavsson *et al.* (2000) performed a case-control study involving all 1,042 male cases of lung cancer and 2364 randomly selected controls (matched by age and inclusion year) in Stockholm County, Sweden from 1985 through 1990. Occupational exposure, smoking habits, and other potential risk factors were assessed based on written questionnaires mailed to the subject or next of kin. Relative Risk (RR) estimates were adjusted for age, selection year, tobacco smoking, residential radon, occupational exposures to asbestos and combustion products, and environmental exposure to NO_2. Compared to the group with no exposure, adjusted RR for the highest quartile of estimated lifetime exposure was 1.63 (95% CI = 1.14 to 2.33). The authors concluded that ''[t]he present findings add further evidence for an association between diesel exhaust and lung cancer * * * ''

Strengths of this study include a semi-quantitative exposure assessment and adjustment of the relative risk for several important potential confounders. The statistically significant result corroborates the finding of a link between DPM exposure and lung cancer in MSHA's 2001 risk assessment.

Pope *et al.* (2002) used the cohort established by the American Cancer Society Cancer Prevention II Study to examine the relationship between lung cancer and $PM_{2.5}$ air pollution. This prospective cohort mortality study, which began in 1982, used questionnaires to obtain individual risk factor data (age, sex, race, weight, height, smoking history, education, marital status, diet, alcohol consumption, and occupational exposures). For about 500,000 adults, these risk factors were combined with air pollution data for metropolitan areas throughout the U.S. and with vital status and cause of death data through 1998.

After adjusting for other risk factors and potential confounders, using a variety of statistical methods, chronic $PM_{2.5}$ exposures were found to be significantly associated with elevated lung cancer mortality.[6] Each 10 $\mu g/m^3$ increase in the mean level of ambient fine particulate air pollution was associated with a statistically significant increase of approximately 8% in the risk of lung cancer mortality. Within the range of exposures found in the study, the exposure-response relationship between $PM_{2.5}$ and lung cancer was monotonically increasing. The authors concluded that ''[e]levated fine particulate exposures were associated with significant increases in lung cancer mortality * * * even after controlling for cigarette smoking, diet, occupational exposure, other individual risk factors, and after controlling for regional and other spatial differences.''

Szadkowska-Stanczyk and Ruszkowska (2000) performed a literature review of studies relating to the carcinogenic effects of diesel emissions. The authors concluded that long-term exposure (> 20 years) was associated with a 30% to 40% increase in lung cancer risk in workers in the transport industry. This article was written in Polish, and MSHA was unable to obtain a translation of it for this update. However, based on the English abstract, it appears to add no new information to the 2001 risk assessment.

Several commenters expressed opinions on the unpublished document by Dr. Gerald Chase (2004) entitled *Characterizations of Lung Cancer in Cohort Studies and a NIOSH Study on Health Effects of Diesel Exhaust in Miners*, which was placed into the public record at MARG's request. This document presents an analysis of some preliminary data provided by NIOSH and NCI at a public stakeholder meeting held on Nov. 5, 2003. These data were taken from unpublished charts that NIOSH and NCI used to inform the public on the status and progress of their ongoing project, *A Cohort Mortality Study with a Nested Case-Control Study of Lung Cancer and Diesel Exhaust Among Nonmetal Miners* [NIOSH/NCI 1997]. Researchers involved in that project have thus far published no analyses or conclusions based on these data. Dr. Chase, however, concluded that ''based on the limited data available to date, the number and pattern of lung cancer deaths reported * * * are in agreement with lung cancer deaths from the general population for the age groups involved * * *'' and ''* * * *are possible* without attributing any excess cancers to the study subject matter: diesel exhaust'' [emphasis added]. He offered no opinion as to whether the preliminary data actually demonstrate that there were no excess lung cancers attributable to DPM exposures.

Although Dr. Chase noted that his analyses and conclusions were limited and based on incomplete information, some commenters interpreted his report as casting serious doubt on any increased risk of lung cancer associated with occupational DPM exposures. For example, one commenter said the report ''suggests lung cancer is not a problem in this worker population.'' Another commenter interpreted Dr. Chase's findings as providing ''startling evidence rebutting MSHA's PELs and risk analysis.'' Other industry commenters asserted that Dr. Chase's analysis ''eliminates the rationale upon which the final 160 microgram standard was premised.'' Another commenter claimed that Dr. Chase's analysis shows MSHA's justification for limiting DPM exposures is ''contradicted by the NIOSH/NCI data.''

Commenters representing organized labor, on the other hand, focused on the preliminary and incomplete nature of the data Dr. Chase analyzed. One such commenter pointed out that these data had not been made directly available on MSHA's website and that the status of the NIOSH/NCI study was not discussed in the re-opening announcement. Another commenter argued that the Chase analysis does not meet minimal standards of ''real epidemiological research'' and that it ''is worthless for the purpose of [MSHA's DPM] rulemaking.'' This commenter also stated that ''the record already contains ample evidence of the carcinogenicity of DPM'' and that ''the NIOSH/NCI study will not shake those findings, even if it should prove to be inconclusive.''

The Chase analysis ignores at least three factors that can reasonably be expected to heavily influence the findings of the NIOSH/NCI study: (a) Differentiation between exposed and unexposed miners within the study, (b) quantification of exposure, and (c) possible ''healthy worker effect.'' According to the 1997 NIOSH/NCI study protocol, these three factors will be taken fully into account before any conclusions are published. The remainder of this subsection will explain how ignoring them, as in the Chase report, can mask adverse health effects potentially associated with DPM exposures.

[6] As discussed earlier, Pope *et al.* (2002) also provides strong evidence that chronic $PM_{2.5}$ exposure increases the risk of premature cardiopulmonary mortality.

(a) Differentiation Between Exposed and Unexposed Miners

Approximately 50% of the miners in the NIOSH/NCI study cohort are expected to be surface workers (NIOSH/NCI, 1997, Tables A.1 and B.2). These miners are likely to have experienced far lower levels of DPM exposure than underground miners in the cohort. The NIOSH/NCI study protocol specifies that such members of the cohort—*i.e.*, those who have had little or no occupational DPM exposure ''will be used as the ''unexposed'' control group for the study. In other words, the protocol calls for statistically comparing the health of these surface workers to the health of the much more highly exposed underground workers.

Dr. Chase did not distinguish between surface and underground workers in the cohort. Consequently, his analysis may dilute the lung cancer rate for exposed miners by combining it with the rate for miners with relatively little exposure. As noted by Dr. Chase, the preliminary data presented indicate that 9.8% of the deaths in the overall cohort were from lung cancer. He also suggests that the normal or ''background'' percentage is 8.0%, based on the national lung cancer mortality rate and that the excess of 9.8% over 8.0% is not statistically significant. Suppose, however, that the overall excess of lung cancer deaths arose entirely from that half of the cohort comprising exposed, underground workers. Then, for miners in the ''exposed'' group, the percentage of deaths from lung cancer would actually be 11.6%. Since 8.0/2 + 11.6/2 = 9.8, the 8.0% rate for surface workers would have diluted the 11.6% rate for exposed underground workers to yield an average rate of 9.8%. In this case, the lung cancer rate for underground miners would be about 45% greater than the national background rate (*i.e.*, 11.6/8.0).

Dr. Chase also claims that the 8% ''background'' rate is too low, since it combines all ages and includes relatively low lung cancer death rates for ages below 55 years. Although it is true that age-specific lung cancer mortality rates increase after age 55, this should be considered only in conjunction with the age at death for members of the specific study cohort. Approximately two-thirds of the cohort members were born after 1940, with a maximum age at death of 56 years. For this age group, less than 5% of all deaths are attributed to lung cancer. Therefore, for purposes of comparison with this particular study cohort, an 8% background rate may be too high rather than too low, and the excess for underground workers may be even greater than the 45% indicated above.

(b) Quantification of Exposure

As explained in the 2001 risk assessment, quantification of exposure was an important element in MSHA's evaluation of epidemiologic studies on DPM and lung cancer (FR 66 at 5784–5785, 5795ff). Relatively little weight was placed on studies that took no account of duration and intensity of exposure. At the time of the NIOSH/NCI Joint Study Meeting to discuss information with stakeholders on the progress of the study, exposure data for individual miners still were being processed. Since such exposure data were not presented at the meeting, they could not be used in Dr. Chase's analysis.

The lack of detailed exposure data in Dr. Chase's analysis could potentially cause major distortions in interpretation of the results. The study cohort includes a number of workers with relatively short exposure duration. This is demonstrated by a 1981 NIOSH study showing that the mean tenure of underground trona miners working in 1976 was only about 3 years for ages greater than 25 years. (Attfield *et al.* 1981). The two largest trona mines included in that study were also included in the NIOSH/NCI study (identified as Numbers 6 and 8 in Table A.1 of the 1997 NIOSH/NCI study protocol). Therefore, a substantial portion of the NIOSH/NCI study cohort may have been occupationally exposed to DPM for three years or less. If such short exposures produce little or no excess in lung cancers, then this portion of the cohort could mask a significant excess among workers with longer exposures. Since Dr. Chase's analysis lumps miners together without regard to exposure duration, it provides no effective way to evaluate effects associated with long-term exposure.

(c) Internal Versus External Analysis

Another important element in MSHA's evaluation of epidemiologic studies on DPM and lung cancer was equitable composition of the groups being compared (FR 66 at 5783–5784, 5795ff). As explained in the **Federal Register**, comparison of an exposed cohort to an external control group can give rise to various forms of selection bias. For example, the ''healthy worker effect,'' which is widely recognized in the occupational health literature, tends to reduce estimates of excess risk in a group of workers when that group is compared to a general population. Several of the lung cancer cohort studies reviewed in the 2001 risk assessment cohorts showed no excess lung cancers among exposed workers compared to an external population. Nevertheless, those studies showed excess lung cancers among exposed workers compared to otherwise similar but unexposed workers.

To avoid selection biases, the 2001 risk assessment favored comparisons against internal control groups or studies that compensated for the healthy worker effect by means of an appropriate adjustment. Dr. Chase's analysis, however, focuses entirely on external comparisons with no compensating adjustment—an approach that the 2001 risk assessment generally discounted. Although the NIOSH/NCI study protocol explicitly calls for internal comparisons, the detailed exposure data necessary for such comparisons were not available to Dr. Chase since they were not presented during the November 5, 2003 public meeting.

(d) Conclusions Regarding Dr. Chase's Analysis

Dr. Chase has argued that some preliminary and incomplete data made available from the NIOSH/NCI study do not demonstrate any excess lung cancer associated with DPM exposure. Even if Dr. Chase is correct, however, this may merely reflect limitations of the preliminary and incomplete data upon which his analysis relies. Because necessary data were not yet available, the Chase analysis was unable to consider a possible healthy worker effect, occupationally unexposed workers within the cohort, or potentially important variations in exposure intensity and duration. When the NIOSH/NCI study is completed, we are confident that it will take all these factors into account in accordance with the protocol.

MSHA concludes that the data on which Dr. Chase's analysis is based are inadequate for identifying or assessing the relationship between occupational DPM exposure and excess lung cancer mortality. These incomplete data provide little insight into what a comprehensive analysis of the NIOSH/NCI study results will ultimately show, when carried out in accordance with the study protocol.

Bladder Cancer

Boffetta and Silverman (2001) performed a meta-analysis of 44 independent results from 29 distinct studies of bladder cancer in occupational groups with varying exposure to diesel exhaust. Studies were included only if there were at least five years between time of first exposure and development of bladder cancer.

Separate quantitative meta-analyses were performed for heavy equipment operators, truck drivers, bus drivers, and studies with semi-quantitative exposure assessments based on a job exposure matrix (JEM). The overall relative risk (RR) for heavy equipment operators was RR = 1.37 (95% CI: 1.05–1.81); for truck drivers, RR = 1.17 (1.06–1.29); for bus drivers, RR = 1.33 (1.22–1.45); and for JEM, RR = 1.13 (1.0–1.27).

A quantitative meta-analysis was also performed on 8 independent studies showing results for ''high'' diesel exposure. The combined results were RR = 1.23 (1.12–1.36) for ''any exposure'' and RR = 1.44 (1.18–1.76) for ''high exposure.''

The authors discovered a strong indication of publication bias for truck and bus driver studies, a tendency for studies to be published only when they showed a positive result. However, the summary RR for the seven largest truck or bus driver studies was 1.26 (1.18–1.34), which is very close to the RR based on all 27 truck or bus driver results. There was no indication of publication bias for studies with semi-quantitative exposure assessments.

The results of this meta-analysis suggest a statistically significant association between diesel exposure and an elevated risk of bladder cancer not fully explained by publication bias. Nevertheless, potential confounding by vibration, dietary factors, and infrequency of urination among drivers preclude a causal interpretation of this association.

Not included in this meta-analysis was a study by Zeegers *et al.* (2001). This was a prospective case-cohort study involving 98 cases of bladder cancer among men occupationally exposed to diesel exhaust. A cohort of 58,279 men who were 55 to 69 years old in 1986 was followed up through December 1992. Exposure was assessed by job history given on a self-administered questionnaire, combined with experts' assessment of the exposure probability for each job. A ''cumulative probability of exposure'' was determined by multiplying job duration by the corresponding exposure probability. Four categories of relative cumulative exposure probability were defined: none, lowest third, middle third, and highest third. Relative risks were adjusted for age, cigarette smoking, and exposure to other occupational risk factors.

The relative risk for the category with highest cumulative probability of exposure was RR = 1.17 (95% CI: 0.74–1.84). In light of the meta-analysis results described above, the lack of statistical significance found in this study may be due to low statistical power for detecting diesel exhaust effects, combined with nondifferential errors in the exposure assessment.

As with the epidemiological studies on diesel exposure and bladder cancer considered in the meta-analysis, no adjustment was made in this study for infrequency of urination or for dietary patterns possibly associated with occupations having diesel exposures. Therefore, this study, like the meta-analysis performed by Boffetta and Silverman, has no impact on the 2001 risk assessment.

Pancreatic Cancer

Ojajärvi *et al.* (2000) performed a meta-analysis of 161 independent results from 92 studies on the relationship between diesel exhaust exposure and pancreatic cancer. No elevated risk was associated with diesel exposure. The combined relative risk was RR = 1.0 (95% CI: 0.9–1.3). This result is consistent with the 2001 risk assessment, which identified lung cancer and bladder cancer as the only forms of cancer for which there was evidence of an association with DPM exposure.

4. Mechanisms of Toxicity

Table VI–12 describes 15 DPM toxicity studies published after the 2001 risk assessment and cited in the 2003 NPRM. Table VI–12 also describes a 16th toxicity study (Arlt *et al.*, 2002), which was cited by Dr. Jonathan Borak in comments submitted by MARG. All of these studies lend some degree of support to the conclusions of the 2001 risk assessment. In addition to briefly describing each study and its key results, the table identifies the agent(s) of toxicity investigated and indicates how the results support the risk assessment by categorizing the toxic effects and/or markers of toxicity found. The categories used to classify toxic effects are: (A) Immunological and/or allergic reactions, (B) inflammation, (C) mutagenicity and/or DNA adduct formation, (D) induction of free oxygen radicals, (E) airflow obstruction; (F) impaired clearance; (G) reduced defense mechanisms; and (H) adverse cardiovascular effects.

TABLE VI–12.—STUDIES ON TOXICOLOGICAL EFFECTS OF DPM EXPOSURE, 2000–2002

Authors, year	Description	Key results	Agent(s) of toxicity	Toxic effect(s) *	Limitations
Al-Humadi *et al.,* 2002	IT instillation in rats of 5 mg/kg saline, DPM, or carbon black.	Exposure to DPM or carbon black augments OVA sensitization; particle composition (of DPM) may not be critical for adjuvant effect.	DPM and carbon black particles.	A	
Arlt *et al.,* 2002	In Vitro and in Vivo: investigation of metabolic activation of 3-nitrobenzanthrone (3-NBA) by human enzymes.	Increased DNA adduct formation due to in the presence of human N,O acetyltransferases and sulfotransferases.	3-NBA, a constituent of the organic fraction of DPM.	C	No DPM used.

TABLE VI–12.—STUDIES ON TOXICOLOGICAL EFFECTS OF DPM EXPOSURE, 2000–2002—Continued

Authors, year	Description	Key results	Agent(s) of toxicity	Toxic effect(s) *	Limitations
Bünger *et al.,* 2000	In Vitro: assessment of content of polynuclear aromatic compounds and mutagenicity of DPM generated from four fuels, Ames assay used.	Production of black carbon and polynuclear aromatic compounds that are mutagenic; correlation with sulfur content of fuel and engine speed.	DE generated from diesel engine. DPM collected on filters and soluble organic extracts prepared.	C	
Carero *et al.,* 2001	In Vitro: assessment of DPM, carbon black, and urban particulate matter genotoxicity, human alveolar epithelial cells used.	DNA Damage produced, but no cytotoxicity produced.	DPM, urban particulate matter (UPM), and carbon black (CB). DPM, UPM purchased from NIST, CB purchased from Cabot.	C	
Castranova *et al.,* 2001.	In Vitro: assessment of DPM on alveolar macrophage functions and role of adsorbed chemicals; rat alveolar macrophages used. In Vivo: assessment of DPM on alveolar macrophage functions and role of adsorbed chemicals, use of IT instillation in rats.	DPM depresses antimicrobial potential of macrophages, thereby increasing susceptibility of lung to infections, this inhibitory effect due to adsorbed chemicals rather than carbon core of DPM.	No information on generation of DPM. (details may be found in previous publications from this lab).	D, F, G	
Fujimaki *et al.,* 2001	In Vitro: assessment of cytokine production, spleen cells used. In Vivo: assessment of cytokine production profile following IP sensitization to OA and subsequent exposure to 1.0 mg/mg^3 DE for 12 hr/day, 7 days/week over 4 weeks, mouse inhalation model used.	Adverse effects of DE on cytokine and antibody production by creating an imbalance of helper T-cell functions.	DE generated from diesel engine. DPM, CO_2, SO_2, and $NO/NO_2/NO_x$ measured.	A	Sensitization to OA via IP injection. Changes in pulmonary function not assessed.
Gilmour *et al.,* 2001	In Vivo: assessment of infectivity and allergenicity following exposure to woodsmoke, oil furnace emissions, or residual oil fly ash, mouse inhalation model used, IT instillation used in rats.	Exposure to woodsmoke increased susceptibility to and severity of streptococcal infection, exposure to residual oil fly ash increased pulmonary hypersensitivity reactions.	Woodsmoke, oil furnace emissions, and residual oil fly ash (ROFA) used.	A, B	No DPM used.
Hsiao *et al.,* 2000	In Vitro: assessment of cytotoxic effects (cell proliferation, DNA damage) of $PM_{2.5}$ (fine PM and $PM_{2.5-10}$ (coarse PM), rat embryo fibroblast cells used.	Seasonal variations in PM, in their solubility, and in their ability to produce cytotoxicity. Long-term exposure to non-killing doses of PM may lead to accumulation of DNA lesions.	PM collected Hong Kong area and solvent-extractable organic compounds used.	C	No DPM used.
Kuljukka-Rabb *et al.,* 2001.	In Vitro: assessment of adduct formation following exposure to DPM, DPM extracts, benzo[a]pyrene, or 5-methylchrysene, mammary carcinoma cells used.	Temporal and dose-dependent DNA adduct formation by PAHs. Carcinogenci PAHs from diesel extracts lead to stable DNA adduct formation.	Some DPM purchased from NIST, some DPM collected on filters from diesel vehicle, and solvent-extractable organic compounds used.	C	Use of only soluble organic fraction of DPM.

TABLE VI–12.—STUDIES ON TOXICOLOGICAL EFFECTS OF DPM EXPOSURE, 2000–2002—Continued

Authors, year	Description	Key results	Agent(s) of toxicity	Toxic effect(s) *	Limitations
Moyer *et al.*, 2002	In Vivo: 2-phase retrospective study, review of NTP data from 90-day and 2-yr exposures to particulates, use of mouse inhalation model.	Induction and/or exacerbation of arteritis following chronic exposure (beyond 90-day) to particulates.	Indium phosphide, cobalt sulfate heptahydrate, vanadium pentoxide, gallium arsenide, nickel oxide, nickel subsulfide, nickel sulfate hexahydrate, talc, molybdenum trioxide used.	B, H	Nine particulate compounds selected to represent al PM.
Saito *et al.*, 2002	In Vivo: assessment of cytokine expression following exposure to DE (100 µg/m³ or 3 mg/m³ DPM) for 7-hrs/day × 5 days/wk × 4 wks, mouse inhalation model used.	DE alters immunological responses in the lung and may increase susceptibility to pathogens, low-dose DE may induce allergic/asthmatic reactions.	DE generated from diesel engine. DPM, CO, SO_2 and NO_2 measured.	A	
Sato *et al.*, 2000	In Vivo: assessment of mutant frequency and mutation spectra in lung following 4-wk exposure to 1 or 6 mg/m³ DE, transgenic rat ihalation model used.	DE produced lesions in DNA and was mutagenic in rat lung.	DE generated from light-duty diesel engine. Concentration of suspended particulate matter (SPM) measured, 11 PAHs and nitrated PAHs identified and quantitated in SPM.	C	
Van Zijverden *et al.*, 2000.	In Vivo: assessment of immuno-modulating capacity of DPM, carbon black, and silica particles, mouse model used (sc injection into hind footpad).	DPM skew immune response toward T helper 2 (Th2) side, and may facilitate initiation of allergy.	DPM, carbon black particles (CBP) and silica particles (SIP) used. DPM donated by Nijmegen University, CBP and SIP purchased from BrunschwichChemie and Sigma.	A	Questionable relevance of exposure route (sc injection).
Vincent *et al.*, 2001	In Vivo: assessment of cardiovascular effects following 4-hr exposure to 4.2 mg/m³ diesel soot, 4.6 mg/m³ carbon black, or 48 mg/m³ ambient urban particulates, rat inhalation model used.	Increases in endothelin − 1 and − 3 (two vasoregulators) following ambient urban particulates and diesel soot exposure. Small increases in blood pressure following exposure to ambient urban particualtes.	Diesel soot, carbon black and urban air particulates used. Diesel soot purchased from NIST, carbon black donated by University of California, urban air particulates collected in Ottawa.	H	
Walters *et al.*, 2001	In Vivo: assessment of airway reactivity/responsiveness, and BAL cells and BAL cytokines following exposure to 0.5 mg/mouse aspirated DPM, ambient PM, or coal fly ash.	Dose and time-dependent changes in airway responsiveness and inflammation following exposure to PM. Increase in BAL cellularity following exposure to DPM, but airway reactivity/responsiveness unchanged.	DPM, PM, and coal fly ash used. DPM purchased from NIST, PM collected in Baltimore, and coal fly ash obtained from Baltimore power plant.	A, B	

TABLE VI–12.—STUDIES ON TOXICOLOGICAL EFFECTS OF DPM EXPOSURE, 2000–2002—Continued

Authors, year	Description	Key results	Agent(s) of toxicity	Toxic effect(s) *	Limitations
Whitekus *et al.,* 2002 ..	In Vitro: assessment of ability of six antioxidants to interfere in DPM-mediated oxidative stress, cell cultures used. In Vivo: assessment of sensitization to OA and/or DPM and possible modulation by thiol antioxidants, mouse inhalation model used.	Thiol antioxidants (given as a pretreatment) inhibit adjuvant effects of DPM in the induction of OA sensitization.	DE generated from light-duty diesel engine, DPM collected, dissolved in saline, and aerosolized.	A, D	Changes in pulmonary function associated with sensitization not assessed.

*KEY:
(A) Immunological and/or allergic reactions.
(B) Inflammation.
(C) Mutagenicity/DNA adduct formation.
(D) Induction of free oxygen radicals cardiovascular effects.
(E) Airflow obstruction.
(F) Impaired clearance.
(G) Reduced defense mechanisms.
(H) Adverse.

In addition to the new toxicity studies, four new reviews on various aspects of the scientific literature related to mechanisms of DPM toxicity were cited in the 2003 NPRM. These are listed in Table VI–13. Two of these reviews (ILSI, 2000 and Oberdoerster, 2002) focus on the applicability of the DPM rat toxicity studies to low-dose extrapolation for humans and conclude that such extrapolation is not appropriate. Since the 2001 risk assessment does not attempt to make any such extrapolation, these reviews do not affect MSHA's conclusions. As noted in the 2001 risk assessment, evidence that the carcinogenic effects of DPM in rats are due to overload of the rats' lung clearance mechanism does not rule out a mutagenic mechanism of carcinogenesis at lower exposure levels in other species. The other two review articles generally support the discussion in the 2001 risk assessment of inflammation responses due to DPM exposures.

TABLE VI–13.—REVIEW ARTICLES ON TOXICOLOGICAL EFFECTS OF DPM EXPOSURE, 2000–2002

Authors, year	Description	Conclusions	Agent(s) of toxicity	Toxic effects *
ILSI Risk Science Institute Workshop Participants, 2000.	Review of rat inhalation studies on chronic exposures to DPM and to other poorly soluble nonfibrous particles of low acute toxicity that are not directly genotoxic.	No overload of rat lungs at lower lung doses of DPM and no lung cancer hazard anticipated at lower doses.	Poorly soluble particles nonfibrous particles of low acute toxicity and not directly genotoxic (PSPs).	
Nikula, 2000	Review of animal inhalation studies on chronic exposures to DE, carbon black, titanium dioxide, talc and coal dust.	Species differences in pulmonary retention patterns and lung tissue responses following chronic exposure to DE.	DE, carbon black, titanium dioxide, talc and coal dust.	B, F
Oberdoerster, 2002	In Vivo: review of toxicokinetics and effects of fibrous and nonfibrous particles.	High-dose rat lung tumors produced by poorly soluble particles of low cytotoxicity (*e.g.*, DPM) not appropriate for low-dose extrapolation (to humans); lung overload occurs in rodents at high doses.	Fibrous particles, and nonfibrous particles that are poorly soluble and have low cytotoxicity (PSP).	
Veronesi and Oortigiesen, 2001.	In Vitro: review of nasal and pulmonary innervation (receptors) and pulmonary responses to PM, mainly BEAS cells sensory neurons used.	Pulmonary receptors stimulated/activated by PM, leading to inflammatory responses.	PM: residual oil fly ash, woodstove emissions, volcanic dust, urban ambient particulates, coal fly ash, and and oil fly ash.	A, B

*KEY:
(A) Immunological and/or allergic reactions
(B) Inflammation
(C) Mutagenicity/DNA adduct formation
(D) Induction of free oxygen radicals
(E) Airflow obstruction
(F) Impaired clearance
(G) Reduced defense mechanisms

(H) Adverse cardiovascular effects.

D. Significance of Risk

The first principal conclusion of the 2001 risk assessment was:

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.

MSHA agrees with those commenters who characterized the weight of evidence from the most recent scientific literature as supporting or even strengthening this conclusion. Furthermore, this conclusion has also been corroborated by comprehensive scientific literature reviews carried out by other institutions and government agencies.

In 2002, for example, the U.S. EPA, with the concurrence of its Clean Air Scientific Advisory Committee (CASAC), published its Health Assessment Document for Diesel Engine Exhaust (EPA, 2002). With respect to sensory irritations, respiratory symptoms, and immunological effects, this document concluded that:

At relatively high acute exposures, DE [diesel exhaust] can cause acute irritation to the eye and upper respiratory airways and symptoms of respiratory irritation which may be temporarily debilitating. Evidence also shows that DE has immunological toxicity that can induce allergic responses (some of which are also typical of asthma) and/or exacerbate existing respiratory allergies. [EPA, 2002]

In 2003, the World Health Organization (WHO) issued a review report on particulate matter air pollution and health. WHO concluded that ''fine particles (commonly measured as $PM_{2.5}$) are strongly associated with mortality and other endpoints such as hospitalization for cardiopulmonary disease, so that it is recommended that air quality guidelines for $PM_{2.5}$ be further developed.'' (WHO, 2003)

In the 10th edition of its Report on Carcinogens, the National Toxicology Program (NTP) of the National Institutes of Health formally retained its designation of diesel exhaust particulates as ''reasonably anticipated to be a human carcinogen.'' (U.S. Dept. of Health and Human Services, 2002) The report noted that:

Diesel exhaust contains identified mutagens and carcinogens both in the vapor phase and associated with respirable particles. Diesel exhaust particles are considered likely to account for the human lung cancer findings because they are almost all of a size small enough to penetrate to the alveolar region. * * * Because of their high surface area, diesel exhaust particulates are capable of adsorbing relatively large amounts of organic material * * * A variety of mutagens and carcinogens such as PAH and nitro-PAH * * * are adsorbed by the particulates. There is sufficient evidence for the carcinogenicity for 15 PAHs (a number of these PAHs are found in diesel exhaust particulate emissions) in experimental animals. The nitroarenes (five listed) meet the established criteria for listing as ''reasonably anticipated to be a human carcinogen'' based on carcinogenicity experiments with laboratory animals. [U.S. Dept. of Health and Human Services, 2002]

Similarly, EPA's 2002 Health Assessment Document for Diesel Engine Exhaust concluded that diesel exhaust (as measured by DPM) is ''likely to be a human carcinogen.'' Furthermore, the assessment concluded that ''[s]trong evidence exists for a causal relationship between risk for lung cancer and occupational exposure to D[iesel]E[xhaust] in certain occupational workers.'' (EPA, 2002, Sec. 9, p. 20)

Although most commenters agreed that the adverse health effects associated with miners' DPM exposures warranted an exposure limit, some commenters continued to challenge the scientific basis for linking DPM exposures with an increased risk of lung cancer. An industry trade group submitted a critique of the 2001 risk assessment by Dr. Jonathan Borak, and this critique was endorsed by several other commenters representing the mining industry. The following discussion addresses Dr. Borak's comments in the same order that he presented them.

1. Dr. Borak suggested that MSHA should have classified studies into 3 categories: positive, negative, and inconclusive. He indicated that MSHA's classification was asymmetric in the way that it classified studies as ''positive'' or ''negative,'' thereby distorting the results of MSHA's tabulation and nonparametric sign test, as presented in the 2001 risk assessment.

This comment was apparently based on a misunderstanding of how MSHA classified a study as ''negative'' for purposes of the sign test. In describing MSHA's criterion for classifying a study as negative, Dr. Borak quoted a passage from the 2001 risk assessment that actually pertained to a statistically significant negative study. The tabulations to which Dr. Borak referred symmetrically counted epidemiologic results as positive or negative based on whether the reported relative risk or odds ratio fell above or below 1.0.

2. Dr. Borak stated that ''MSHA approached the analysis as though any study failing to document a protective effect of diesel must perforce be evidence of a harmful effect.''

This statement is false and stems from Dr. Borak's misunderstanding of the symmetric criteria for MSHA's tabulations, as explained above. Furthermore, Dr. Borak's discussion of statistical significance and hypothesis testing in connection with this comment is applicable to evaluating the results of a single study—not to risk assessment based on combining multiple results.

To evaluate the statistical significance of the aggregated epidemiologic evidence, the 2001 risk assessment relied largely on two meta-analyses (Bhatia *et al.*, 1998; Lipsett and Campleman, 1999). MSHA applied the nonparametric sign test to its tabulation of all 47 studies in order to roughly summarize the combined evidence.

3. *Dr. Borak quoted the 2001 risk assessment as stating that ''MSHA regards a real 10% increase in the risk of lung cancer (i.e., a relative risk of 1.1) as constituting a clearly significant health hazard.'' He then stated that the concept of a ''real 10-percent increase'' is ''actually undefined and subjective.''*

Dr. Borak paraphrased language in the 2001 risk assessment, substituting a ''reported'' 10% increase for a ''real'' 10% increase (top of his p. 5). The risk assessment's distinction between ''reported'' and ''real'' relative risks is important and corresponds to the fundamental distinction between a statistical estimate and the quantity being estimated.

Contrary to Dr. Borak's characterization, the risk assessment recognized that epidemiological results are often subject to a great deal of statistical uncertainty. Such uncertainty can be expressed by means of a confidence interval for the ''real'' value being estimated by a ''reported'' result. For example, a reported relative risk (RR) of 1.5 estimates the real relative risk underlying a particular study, for which a 95% confidence interval might be 1.3 to 1.7. This interval is designed to circumscribe the real relative risk with 95% probability.

A 95% confidence interval for the real relative risk may be so broad (e.g., 0.8 to 1.4) as to overlap 1.0 and thereby render the reported result statistically non-significant. Because of the statistical uncertainty associated with a reported RR, extremely large study populations are required in order to obtain statistically significant results when the real relative risk is near 1.0. The point being made in the passage that Dr. Borak quoted and then incorrectly paraphrased is that notwithstanding this statistical uncertainty, a real (as opposed to merely reported) 10% increase in the risk of lung cancer would constitute a clearly significant health effect. Therefore, reported results whose associated confidence intervals overlap 1.1 are consistent with potential health effects that are sufficiently large to be of practical significance.

4. Dr. Borak asserted that '' * * Federal Courts have held that relative risks of less than 2.0 are not sufficient for showing causation * * * but MSHA has rejected that view.''*

MSHA has not rejected the view expressed in the court decisions to which Dr. Borak alluded. *Daubert* v. *Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993); and Hall* v. *Baxter Healthcare Corp., 947 F Supp. 1387 (1996).* As explained in the 2001 risk assessment, these decisions pertain to establishing the specific cause of disease for a particular person and not to establishing the increased risk attributable to an exposure. (FR 66 at 5787–5789) This distinction was illustrated by two analogies in the 2001 risk assessment: (1) There is low probability that a particular death was caused by lighting, but exposure to lighting is nevertheless hazardous; and (2) a specific smoker may not be able to prove that his or her lung cancer was ''more likely than not'' caused by radon exposure, yet radon exposure significantly increases the risk—especially for smokers. (FR 66 at 5787) As stated in the 2001 risk assessment, the court decisions are inapplicable because ''[t]he 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.'' (FR 66 5787)

Dr. Borak ignored MSHA's explanation of why the federal court rulings do not apply to the 2001 risk assessment. Instead, he attempted to differentiate the available epidemiologic studies on diesel exposure and lung cancer from examples, presented in the risk assessment, of studies reporting RR less than 2.0 that were nevertheless instrumental in previous clinical and public health policy decisions. For example, Dr. Borak pointed out that all ten of the results cited on the relationship between smoking and cardiovascular-related deaths achieved statistical significance. The risk assessment presented these examples, however, only to support the position that there is ''ample precedent'' for utilizing studies with RR less than 2.0 in a risk assessment. This was in response to comments urging MSHA to ignore all such results, even the many results with RR less than 2.0 that were also statistically significant. Thus, the ten results linking smoking to cardiovascular deaths, eight of which involved RR less than 2.0, adequately serve their intended illustrative purpose. Similarly, Dr. Borak's discussion of radon studies is not germane to their use as examples of studies with RR less than 2.0 that have not been generally discounted. Although the residential radon studies cited may, as Dr. Borak suggests, have been more powerful and had better exposure assessments than those available for DPM, they nevertheless demonstrate that there has been no blanket rejection of epidemiologic results whenever RR is less than 2.0.

5. Dr. Borak objected to what he termed MSHA's ''reliance on the 'healthy worker effect' [HWE] to explain the finding of small or no differences in various studies.'' He argued that ''[a]s a result, MSHA has biased its own evaluation of this literature in a manner that exaggerates the alleged human cancer risks of DPM, while diminishing studies that are not directly supportive of the MSHA perspective.''

The 2001 risk assessment expresses a clear preference for studies using internal comparisons or well-matched cases and controls—studies in which the question of whether an HWE adjustment is desirable does not even arise. In fact, internal comparisons or matched cases and controls were utilized in all eight of the epidemiological studies identified in the risk assessment as presenting ''the best currently available epidemiological evidence.'' In contrast, the risk assessment identified six negative (*i.e.*, RR or OR < 1.0) studies (out of 47) and noted that all six relied on unmatched cases and controls or on external comparisons to general populations, with no allowance for any potential HWE. However, potential bias due to HWE was not the only weakness identified in these six studies. The assessment also noted that five of the six studies had low statistical power due to a small study population, insufficient allowance for latency, or both. Furthermore, the assessment noted that all six of these negative studies contained weak DPM exposure assessments and failed to adjust for potentially different patterns of tobacco smoking in the disparate groups being compared. Dr. Borak did not dispute MSHA's exclusion of these six studies from the rank of best available epidemiologic evidence.

More specifically, Dr. Borak objected to a relatively simple method of adjusting for the HWE used in one part of a meta-analysis by Bhatia *et al.* (1998) and also in some of the individual studies cited in the risk assessment. Dr. Borak noted that ''most epidemiologists agree that the effects of selection bias are generally more important early in a person's work life and do not apply equally to all diseases and disease processes.'' Citing the adjustment formula from Bhatia *et al.* (1998), Dr. Borak claimed that it is ''implicit throughout the MSHA discussion'' that ''the effects of HWE on observed lung cancer mortality are essentially equivalent (*i.e.*, proportional) to its effects on mortality from all causes.''

Although most epidemiologists may agree selection biases do not apply equally to all diseases, this does not render consideration of HWE irrelevant to epidemiologic studies of lung cancer. Health Effects Institute (HEI) (1999) states that ''[w]orker mortality tends to be below average for all major causes of death.'' The 2001 risk assessment accepted a proportional adjustment only insofar as it was utilized in some of the published epidemiological studies. Although Dr. Borak may be correct that compensating for HWE is not really so simple, a proportional adjustment may nevertheless be better than no adjustment at all. MSHA did not itself make any such adjustments or otherwise attempt to quantify the impact of HWE in any of the studies. MSHA did, however, accept HWE adjustments as they appeared in published studies.

Although he did not explicitly say so, Dr. Borak presumably shares what he says is ''the general view that studies of cancer, particularly lung cancers, are not much affected by HWE.'' This view, however, is not universal. It is not, for example, shared by HEI (1999) or U.S. EPA (2002). Dr. Borak dwelled on pre-employment interviews and health exams as a source of HWE that would probably not apply to lung cancer studies, but pre-employment health screenings are not, after all, the only potential source of bias leading to HWE. Dr. Borak did not dispute the proposition that HWE reflects a potential bias when a working population is compared to a more general control population, or that this may be one of several factors contributing to a lack of positive results or statistical significance in some studies. As he has suggested, the potential impact of HWE in lung cancer studies may be greatest among those involving the shortest latency allowances and/or follow-up times.

6. In the study published by Säverin et al. (1999), exposure measurements were obtained in 1992, whereas ''the mines ceased production in 1991'' when ''most of the miners were dismissed and abandoned underground work and exposure.'' Based on this apparent discrepancy, Dr. Borak questioned the argument used by Säverin et al., and accepted in the risk assessment, to justify their assumption that their exposure measurements were representative of exposures from 1970 to 1991. Dr. Borak speculated that the 1992 exposure measurements were likely to have been made during a ''staged simulation'' and that these measurements may have underestimated DPM levels under conditions of routine production.

To resolve this issue, MSHA contacted Dr. Säverin directly and asked him to explain the sequence of events relating to mine closures and exposure measurements. Dr. Saverin replied as follows:

> * * * [t]he full potash production of millions of tons per year in the seventies and eighties declined in the years after 1989, the official closing date being in 1991. But until 1994, there was a lot of mining activity underground because a mine cannot be abandoned immediately. So, in 1992, we had no problems to find exposure conditions not merely similar to but exactly like the routine-production situation before. Thus, we did not have to rely on any staged simulation but made our measurements as state of the art requires. [Säverin, R. 2005]

Thus, despite any ambiguity in the published article, Dr. Säverin maintains that the 1992 measurements were obtained under normal production conditions and were fully representative of exposures from 1970 through 1991. MSHA accepts Dr. Säverin's assessment.

As stated in the 2001 risk assessment, 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.'' MSHA is not relying on any single study but, instead, is basing its evaluation on the weight of evidence from all available data.

7. Dr. Borak identified a number of weaknesses and limitations in the epidemiologic studies by Säverin et al. (1999) and Johnston et al. (1997). Despite their shortcomings, the 2001 risk assessment ranked these two studies among the eight ''that provide the best currently available epidemiologic evidence.''

As Dr. Borak indicated, all of the weaknesses and limitations he identified were recognized and discussed in the 2001 risk assessment. The risk assessment consistently and repeatedly emphasized that the strength of evidence relating DPM exposure to an increased risk of lung cancer lies not in any individual study but in the cumulative weight of the research literature taken as a whole. As stated in the risk assessment,

> * * * 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. (66 FR at 5825)

Both of the additional epidemiological studies cited in the 2003 NPRM specifically relating DPM exposures to lung cancer (Gustavsson *et al.*, 2000 and Boffetta *et al.*, 2001) found statistically significant positive results. The 2002 EPA document, which was compiled too early to consider these two newest studies, concluded that even at the far lower levels typically encountered in ambient air, ''[t]he available evidence [from toxicity studies and occupational epidemiology] indicates that chronic inhalation of DE is likely to pose a lung cancer hazard to humans.''

This conclusion has now received important additional confirmation from a large scale mortality study involving exposure to combustion-related fine particulate air pollution (Pope *et al.*, 2002). This study, which included estimates of lung cancer effects, was cited in the NPRM but not considered in either the 2001 risk assessment or the 2002 EPA document. As described earlier, a statistically significant exposure-response relationship was discovered between chronic $PM_{2.5}$ exposure in the ambient air and an increased risk of lung cancer. This finding is especially significant for confirming causality because it represents an entirely new source of evidence not subject to unknown biases that might tend to distort occupational epidemiology results in the same direction.

Dr. Borak also stated that presently available data are insufficient to establish an exposure-response relationship for lung cancer that would justify setting the PEL at any specific level. The 2001 risk assessment recognizes uncertainty in lung cancer exposure-response and presents a broad range of estimated exposure-response relationships (66 FR at 5852–53). Even the lowest estimate shows unacceptable risk at levels commonly encountered in underground mines. Lack of a definitive exposure-response relationship means MSHA cannot precisely distinguish differences in health effects—*e.g.*, between 50_{DPM} µg/m^3 and 100_{DPM} µg/m^3. Nevertheless, as explained below, MSHA can confidently say that exposures above the interim PEL are significantly more hazardous than exposures below the interim PEL.

The second principal conclusion of the 2001 risk assessment was:

> 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.

As described in Section VI.B, two new bodies of exposure data have been compiled since promulgation of the 2001 rule. Comparison of these data is not straightforward, since they employed different methods for measuring DPM. Nevertheless, the data suggest that exposure levels in many underground M/NM mines have dropped significantly, as compared to the 1989–1999 period covered by the 2001 risk assessment.

The 2001 risk assessment quantified excess lung cancer risk based on a mean DPM concentration of 808 µg/m^3. This was based on 355 MSHA area and personal samples collected in production areas and haulageways at 27 underground M/NM mines between 1989 and 1999. Nearly all of these samples were collected without an impactor and analyzed for DPM content using the RCD method. The new samples, on the other hand, were collected with an impactor and analyzed for TC or EC using NIOSH Method 5040. To see how more recent exposure levels tie into the quantitative exposure-response models used in the 2001 risk assessment, it is necessary to convert sample results from both new sources of exposure data to approximate DPM concentrations.

Samples from the 31-Mine Study were collected in 2001 using an impactor and were analyzed by NIOSH Method 5040. These samples showed a mean DPM concentration of 432 µg/m^3—assuming, as in the 2001 risk assessment, that TC comprises 80 percent of total DPM. Excluding the samples from trona mines, which were found to have significantly lower DPM levels than the other 27 underground M/NM mines with valid samples, the mean DPM concentration was approximately 492 µg/m³.[7]

The other, more recent and more extensive, body of DPM exposure data considered here consists of 1,194 baseline samples obtained at 183 mines in 2002–2003. These samples were all collected using a submicrometer impactor and analyzed by NIOSH Method 5040. Assuming that TC ≈1.3 × EC and, as before, that TC comprises about 80 percent of the DPM, the mean DPM concentration observed was approximately 320 µg/m³.[8] MSHA considers the baseline sampling results to be more broadly representative of DPM concentrations currently experienced by underground M/NM miners than the generally higher DPM concentrations reported in the 31-Mine Study. Since the baseline samples were collected later, part of the apparent reduction in mean concentration levels may be due to improved DPM controls implemented in response to the 2001 rule.

The 2001 risk assessment used the best available data on DPM exposures at underground M/NM mines to quantify excess lung cancer risk. ''Excess risk'' refers to the lifetime probability of dying from lung cancer during or after a 45-year occupational DPM exposure. This probability is expressed as the expected excess number of lung cancer deaths per thousand miners occupationally exposed to DPM at a specified mean DPM concentration. 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. Occupational exposure is assumed to begin at age 20 and to continue, for surviving miners, until retirement at age 65. The accumulation of lifetime excess risk continues after retirement through the age of 85 years.

Table VI–14, taken from the 2001 risk assessment, shows a range of excess lung cancer estimates at mean exposures equal to the interim and final DPM limits. The eight exposure-response models employed were based on studies by Saverin *et al.* (1999), Johnston *et al.* (1997), and Steenland *et al.* (1998). Assuming that TC is 80 percent of whole DPM, and that the mean ratio of TC to EC is 1.3, the interim DPM limit of 500 µg/m³ shown in Table VI–14 corresponds to the 308 µg/m³ EC surrogate limit adopted under the present rulemaking.

TABLE VI–14.—EXCESS LUNG CANCER RISK EXPECTED AT SPECIFIED DPM EXPOSURE LEVELS OVER AN OCCUPATIONAL LIFETIME

[Extracted from Table III–7 of the 2001 risk assessment]

Study and statistical model	Excess lung cancer deaths per 1,000 occupationally exposed workers †	
	Final DPM limit 200 µg/m³	Interim DPM limit 500 µg/m³
Säverin *et al.* (1999):		
Poisson, full cohort	15	44
Cox, full cohort	70	280
Poisson, subcohort	93	391
Cox, subcohort	182	677
Steenland *et al.* (1998):		
5-year lag, log of cumulative exposure	67	89
5-year lag, simple cumulative exposure	159	620
Johnston *et al.* (1997):		
15-year lag, mine-adjusted	313	724
15-year lag, mine-unadjusted	513	783

† Assumes 45-year occupational exposure at 1,920 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).

The mean DPM concentration levels estimated from both the 31-Mine Study (432–492 µg/m³, depending on whether trona mines are included) and the baseline samples (≈320 µg/m³) fall between the interim and final DPM limits shown in Table VI–14. All of the exposure-response models shown are monotonic (*i.e.*, increased exposure yields increased excess risk, though not proportionately so). Therefore, using the most current available estimates of mean exposure levels, they all predict excess lung cancer risks somewhere between those shown for the interim and final limits. Thus, despite substantial improvements apparently attained since the 1989–1999 sampling period addressed by the 2001 risk assessment, underground M/NM miners are still faced with an unacceptable risk of lung cancer due to their occupational DPM exposures.

The third principal conclusion of the 2001 risk assessment was:

By reducing DPM concentrations in underground mines, the rule will

[7] These values may be somewhat inflated due to the old ''crimped foil'' SKC sampler design used for many of the samples collected during the 31-Mine Study. As explained elsewhere in this preamble, this design resulted in lower-than-expected filter deposit areas in many cases, leading to overestimates of the corresponding TC concentrations. (The SKC sampler design was eventually modified by substituting a retainer ring for the crimped foil. However, the systematic errors in deposit area observed during the 31-Mine Study have no bearing on the ''paired punch comparison'' used in that study to evaluate analytical measurement precision.)

[8] The laboratory analysis of the baseline samples yielded two measures of TC: TC = EC + OC and TC = 1.3 × EC. However, since the intention under baseline sampling was to rely always on the lesser of these two values from each sample, no precautions were taken to avoid sampling near tobacco smoke and other substances that potentially interfere with the use of TC = EC + OC as a surrogate measure of DPM. Therefore, in the present discussion, MSHA is using only the TC = 1.3 × EC value to estimate baseline DPM levels.

substantially reduce the risks of material impairment faced by underground miners exposed to DPM at current levels.

Although DPM levels have apparently declined since 1989–1999, MSHA expects that further improvements will continue to significantly and substantially reduce the health risks identified for miners. There is clear evidence of DPM's adverse health effects, not only at pre-2001 levels but also at the generally lower levels currently observed at many underground mines. These effects are material health impairments as specified under section 101(a)(6)(A) of the Mine Act. From the baseline sampling results, 68 out of the 183 mines (37%) had at least one sample exceeding the interim exposure limit. Because the exposure-response relationships shown in Table VI–14 are monotonic, MSHA expects that industry-wide implementation of the interim limit will significantly reduce the risk of lung cancer among miners.

VII. Feasibility

A. Background

Section 101(a)(6)(A) of the Mine Act requires the Secretary of Labor in establishing health standards, to most adequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity over his or her working life. Standards promulgated under this section must be based upon research, demonstrations, experiments, and such other information as may be appropriate. MSHA, in setting health standards, is required to achieve the highest degree of health and safety protection for the miner, and must consider the latest available scientific data in the field, the feasibility of the standards, and experience gained under this or other health and safety laws.

The legislative history of the Mine Act states:

> 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 appeals 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 on today's horizon''. *AFL–CIO* v. *Brennan*, 530 F.2d 109 (3d Cir. 1975); *Society of Plastics Industry* v. *OSHA*, 509 F.2d 1301 (2d Cir. 1975), *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 [public] hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of [this section], the Committee wishes to emphasize that it rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure. Rep. No. 95–181, 95th Cong. 1st Sess. 21 (1977).

In promulgating standards, hard and precise predictions from agencies regarding feasibility are not required. The ''arbitrary and capricious test'' is usually applied to judicial review of rules issued in accordance with the Administrative Procedure Act. The legislative history of the Mine Act further indicates that Congress explicitly intended the ''arbitrary and capricious test'' be applied to judicial review of mandatory MSHA standards. ''This test would require the reviewing court to scrutinize the Secretary's action to determine whether it was rational in light of the evidence before him and reasonably related to the law's purposes.'' S. Rep. No. 95–181, 95th Cong., 1st Sess. 21 (1977). In achieving the Congressional intent of feasibility under the Mine Act, MSHA may also consider reasonable time periods of implementation. *Ibid.* at 21.

Though the Mine Act and its legislative history are not specific in defining feasibility, the Supreme Court has clarified the meaning of feasibility in the context of OSHA health standards in *American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 508–09 (1981), as ''capable of being done, executed, or effected,'' both technologically and economically.

MSHA need only base its predictions on reasonable inferences drawn from existing facts. In order to establish the economic and technological feasibility of a new rule, an agency is required to produce a reasonable assessment of the likely range of costs that a new standard will have on an industry, and an agency must show that a reasonable probability exists that the typical firm in an industry will be able to develop and install controls that will meet the standard. *United Steelworkers of America, AFL–CIO–CLC* v. *Marshall*, (OSHA Lead) 647 F.2d 1189, 1273.

B. Technological Feasibility

Courts have ruled that in order for a standard to be technologically feasible an agency must 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. *Ibid.* (citing *American Iron and Steel Institute* v. *OSHA,* (AISI–I) 577 F.2d 825 (3d Cir. 1978) at 832–35; and, *Industrial Union Dep't., AFL–CIO* v. *Hodgson,* 499 F.2d 467 (DC Cir.1974)); *American Iron and Steel Institute* v. *OSHA,* (AISI–II) 939 F.2d 975, 980 (DC Cir. 1991). The existence of general technical knowledge relating to materials and methods which may be available and adaptable to a specific situation establishes technical feasibility. A control may be technologically feasible when ''if through reasonable application of existing products, devices or work methods with human skills and abilities, a workable engineering control can be applied'' to the source of the hazard. It need not be an ''off-the-shelf'' product, but ''it must have a realistic basis in present technical capabilities.'' (*Secretary of Labor* v. *Callanan Industries, Inc.* (Noise), 5 FMSHRC 1900, 1908 (1983)).

The Secretary may also impose a standard that requires protective equipment, such as respirators, if technology does not exist to lower exposures to safe levels. See *United Steelworkers of America, AFL–CIO–CLC* v. *Marshall,* (OSHA Lead) 647 F.2d 1189, 1269 (DC Cir. 1981).

MSHA has established that it is technologically feasible to reduce underground miners' exposures to the DPM interim permissible exposure limit (PEL) of 308 micrograms of EC per cubic meter of air (308_{EC} μg/m^3) by using available engineering control technology and various administrative control methods. However, MSHA acknowledges that compliance difficulties may be encountered at some mines due to implementation issues and the cost of purchasing and installing certain types of controls. Therefore, this final rule incorporates the industrial hygiene concept of a hierarchy of controls for implementing DPM controls. To attain the interim DPM limit, mine operators are required to install, use, and maintain engineering and administrative controls to the extent feasible. When such controls do not reduce a miner's exposure to the DPM limit, controls are infeasible, or controls do not produce significant reductions in DPM exposures, operators must continue to use all feasible engineering and administrative controls and supplement them with respiratory protection. When respiratory protection is required under the final standard, mine operators must establish a respiratory protection program that meets the specified requirements. Thus, MSHA has provided a regulatory scheme that adequately accomplishes control of exposure under circumstances where a mine operator cannot reduce a miner's exposure to the interim PEL solely by use of engineering and administrative controls, including work practices.

DPM control technology is not new to the mining industry. MSHA has afforded the mining industry a significant period of time to implement DPM controls. The existing DPM standard was first promulgated on January 19, 2001 (66 FR 5706) with an effective date of July 19, 2002 for meeting the interim concentration limit of 400 micrograms of TC per cubic meter of air. The instant rulemaking provides for a comparable EC PEL of 308_{EC} µg/m^3. Under the settlement agreement, MSHA allowed mine operators an additional year in which to begin to install appropriate engineering and administrative controls to reduce DPM levels due to feasibility constraints at that time. Altogether, the mining industry has had over four years to institute controls required under this rulemaking. Any controls currently used to meet the existing concentration limit can be used to reduce miners' exposures to the interim PEL.

MSHA acknowledges that the current DPM rulemaking record lacks sufficient feasibility documentation to justify lowering the DPM limit below 308_{EC} µg/m^3 at this time. Therefore, MSHA is not lowering the limit in this rulemaking. MSHA believes that this interim limit is reasonable, and that MSHA can document feasibility across the affected sector of underground M/NM mines. MSHA is continuing to gather information on the feasibility of the mining industry to comply with a final DPM PEL of less than 308_{EC} µg/m^3

MSHA emphasizes that a DPM control may be deemed feasible, and therefore be required by MSHA even if a miner's exposure is not reduced to the DPM limit. Mine operators cited for DPM overexposures will continue to be required to implement feasible engineering and administrative controls even if these controls are not fully successful in attaining the DPM exposure limit. In the context of this rule, feasible DPM controls must be capable of achieving a significant reduction in DPM. MSHA considers a significant reduction in DPM to be at least a 25% reduction in the affected miners' exposures. Thus, for mines that are out of compliance with the DPM interim limit, controls would be required that attain compliance, or that achieve at least a 25% reduction in DPM exposure if it is not possible to attain compliance by implementing feasible controls. If feasible engineering and administrative controls are not capable of attaining compliance, or at least of achieving a DPM exposure reduction of 25%, MSHA would not require the implementation of those controls. In such cases, which MSHA believes will be very limited, MSHA would require miners to be protected using appropriate respiratory protective equipment.

Some commenters criticized the 25% threshold for a significant reduction because it lacks a scientific basis, and that controls should be evaluated individually in reference to site-specific conditions and DPM levels for significance or effectiveness. MSHA notes that the 25% threshold for DPM is lower than the 50% threshold adopted in MSHA's noise rule. However, DPM's classification as a carcinogen justifies the more protective 25% level for determining whether controls achieve a significant reduction for purposes of assessing feasibility.

MSHA also notes that most of the practical and effective controls that are currently available, such as DPM filters, enclosed cabs with filtered breathing air, and low-emission engines will achieve at least a 25% reduction. Other controls such as ventilation upgrades or alternative fuel blends may achieve a 25% reduction, depending on exposure circumstances and the specific nature of the subject control. It should also be noted that reductions of less than 25% could be due to normal day-to-day variations in mining operations as opposed to reductions due to implementing a control technology. MSHA's Compliance Guide includes the 25% significant reduction for determining feasibility.

If a particular DPM control were capable of achieving at least a 25% reduction all by itself, MSHA would evaluate the costs of that individual control to determine its economic feasibility. If a number of controls could together achieve at least a 25% reduction, but no individual control, if implemented by itself, could achieve a 25% reduction, MSHA would evaluate the total costs of all controls added together to determine their economic feasibility as a group. In determining whether a combination of controls is economically feasible, MSHA would consider whether the total cost of the combination of controls is wholly out of proportion to the expected results. MSHA will not cost the controls individually, but will combine their expected results to determine if the 25% significant reduction criteria can be satisfied.

MSHA's rulemaking record addressing feasibility includes: MSHA's final report on the 31-Mine Study; NIOSH's peer review of the 31-Mine Study; results from MSHA's baseline sampling at mines covered under the DPM standard; results of MSHA's comprehensive compliance assistance work at mining operations with implementation issues affecting feasibility; NIOSH's conclusions on the performance of the SKC sampler and the availability of technology for control of DPM; NIOSH's Diesel Emissions Workshops in 2003 in Cincinnati and Salt Lake City; the Filter Selection Guide posted on the MSHA and NIOSH Web sites; MSHA's final report on DPM filter efficiency; NIOSH's report titled, ''Review of Technology Available to the Underground Mining Industry for Control of Diesel Emissions''; and, the NIOSH Phase I Isozone study titled, ''The Effectiveness of Selected Technologies in Controlling Diesel Emissions in an Underground Mine—Isolated Zone Study at Stillwater Mining Company's Nye Mine'' all of which were developed following promulgation of the 2001 DPM final rule.

One other NIOSH document resulting from the DPM M/NM Partnership became available to MSHA in April 2004. That document is titled, ''An Evaluation of the Effects of Diesel Particulate Filter Systems on Air Quality and Personal Exposure of Miners at Stillwater Mining Case Study: Production Zone (Phase II Study).'' As stated in the final report:

> The objective of Phase II of this study was to determine the effects of those DPF systems being used on production vehicles at Stillwater Mine on workplace concentrations of EC and regulated gases in an actual mining application where multiple diesel-powered vehicles operated simultaneously during full-shift mining activities.

MSHA evaluated this evidence as it relates to feasibility and found that unlike the Phase I Isozone Study, the Phase II study does not contain any new significant information affecting the ability of the mining industry to comply with the requirements of this final rule. MSHA, therefore, finds this data to be cumulative in nature and has included it in the rulemaking record as supplemental information. MSHA discusses the Phase II study results in more detail in this section of the preamble. MSHA emphasizes that mine operators obtained access to this study on the date of publication since the study was generated by the DPM M/NM Partnership.

MSHA committed to implementing several initiatives related to enforcement and enhancing the mining industry's ability to comply with the 2001 final rule. Among other things, MSHA agreed that it would not issue citations for potential violations of the interim concentration limit promulgated in the 2001 standard until after MSHA and NIOSH were satisfied with the performance characteristics of the SKC sampler and the availability of practical mine worthy DPM filter technology. MSHA also agreed to provide DPM sampling training for its inspectors, and to provide comprehensive compliance assistance to the industry through July 19, 2003. MSHA's compliance assistance activities included:

- Conducting compliance assistance meetings throughout the country to discuss how to comply with the DPM standard;
- Providing a compliance guide answering key questions;
- Conducting an inventory of existing underground diesel-powered equipment;
- Providing information to mine operators on feasible DPM controls; and,
- Obtaining baseline sampling results at each underground mine covered under the standard solely for the purpose of compliance assistance rather than for enforcement purposes.

Additional compliance assistance activities also were conducted, and are discussed later in this section of the preamble.

During the compliance assistance period, MSHA agreed that mine operators would not be cited for potential violations of the interim limit provided they took good-faith steps to develop and implement a written compliance strategy and cooperated with MSHA. Also, MSHA would issue a noncompliance citation for exceeding the interim concentration limit only if MSHA believed that an operator was not acting in good faith, or if an operator failed to cooperate in the compliance assistance. Per the agreement, after July 19, 2003, MSHA began to issue citations for violations associated with the interim limit. During the compliance assistance period (through July 19, 2003), MSHA did not identify any mines that failed to take good faith steps toward achieving compliance or cooperate with MSHA. Consequently, no citations for violations associated with the interim limit were issued prior to July 20, 2003.

MSHA provided DPM training to its inspectors and to the extent possible, completed its compliance assistance activities in accordance with the settlement agreement. During September and October 2002, seminars covering the rule, MSHA's enforcement policy, DPM sampling, and DPM engineering control technologies were held in Ebensburg, PA, Knoxville, TN, Lexington, KY, Des Moines, IA, Kansas City, MO, Albuquerque, NM, Coeur d'Alene, ID, Elko, NV, and Green River, WY. The DPM Compliance Guide was posted on the MSHA DPM Single Source Page and also issued as an MSHA Program Policy Letter (PPL #P03–IV–1, effective August 19, 2003). Extensive information on feasible controls for DPM was included in the Compliance Guide/Program Policy Letter and listed on MSHA's DPM Single Source Page for DPM. The inventory of diesel engines was completed September 30, 2002. Baseline DPM samples were not obtained at a remaining few mines until after July 20, 2003 primarily to allow time to cover sampling at intermittent operations. However, enforcement sampling at these mines was delayed until after completion of baseline sampling to provide these mine operators with further opportunity to implement controls, if necessary.

As discussed below in this section of the preamble, both MSHA and NIOSH are satisfied with the performance of the SKC sampler and on the availability of practical DPM filter technology.

DPM Sampling Method. Though not under substantive review in this rulemaking, existing § 57.5061(b) establishes that MSHA will continue to sample miners' personal exposures by using a respirable dust sampler equipped with a submicrometer impactor and analyze samples for the amount of EC using the NIOSH Analytical Method 5040, or any other method that NIOSH determines gives equal or improved accuracy in DPM sampling. The DPM sampling method is discussed in the section-by-section portion of this preamble under § 57.5060(a) addressing the permissible exposure limit. MSHA includes a more detailed discussion of its sampling method on its DPM Single Source Web page. Based on current information in the rulemaking record, MSHA concludes that it has a technologically feasible measurement method that operators and MSHA can use to accurately determine if miners' exposures exceed the interim PEL.

Performance of the SKC Sampler. MSHA and NIOSH are satisfied with the performance of the SKC sampler. The 31-Mine Study includes a comprehensive discussion of MSHA's and NIOSH's work with SKC that improved the performance of the sampler. In MSHA's final report on the 31-Mine Study, it concluded that SKC satisfactorily addressed concerns over earlier known defects in the DPM sampling cassettes and availability of cassettes to both MSHA and mine operators. Just prior to and during the 31-Mine Study, NIOSH and MSHA observed that the perimeter of the DPM deposit on the filter was not consistently circular and varied among the SKC samplers. This resulted in a variable and unpredictable deposit area. The cause of this was found and quite successfully remedied allowing NIOSH to express its satisfaction with the performance of the SKC sampler by letter of June 25, 2003, to MSHA that states, in part:

> Concurrent with the work of the partnership were research tasks to ensure that diesel particulate matter can be accurately measured in these mines. The SKC DPM cassette is a size selective sampler designed to collect DPM samples that are characterized by an aerodynamic diameter less than 0.8μm, while avoiding contamination with mineral dust. The use of the SKC sampler could not be recommended initially because of a problem relating to irregular deposition of DPM on the cassette sample. However, this problem has been solved, and we are now satisfied with the performance of the SKC sampler. The research regarding the performance of the SKC sampler has been documented, peer-reviewed, and is currently accepted for publication by Applied Occupational and Environmental Hygiene Journal.

Baseline Sampling. For the 2001 standard, MSHA based its feasibility projections on an average DPM concentration level of over 800_{TC} μg/m³. MSHA found in the 31-Mine Study that miners' average TC exposure was 345 μg/m³. MSHA's baseline sampling revealed that miners average EC exposure was 196 μg/m³. The average TC exposure measured as EC + OC was 293 μg/m³, and as calculated by EC × 1.3 was 255 μg/m³. MSHA believes that these lower averages probably result from the introduction of DPFs, clean engines, better maintenance, and the elimination of interferences as confirmed by MSHA's compliance assistance baseline sampling. The baseline sampling results are discussed in detail in Section V.

DPM Enforcement. MSHA believes that final §57.5060(d) adequately addresses feasibility issues related to meeting the interim limit of 308_{EC} μg/m³ under § 57.5060(a). Under these sections, MSHA has amended the type of exposure that will be regulated along with the methods of compliance with the interim PEL to provide mine operators with greater flexibility in reducing DPM exposures. This final DPM rule adopts MSHA's long-standing enforcement practice established for other exposure-based standards applicable to M/NM mines. Also, MSHA underscores the fact that the enforcement scheme established in this final rule also is based on the DPM settlement agreement.

In spite of the changes in this final rule that increase flexibility, MSHA realizes that some mine operators will continue to need on-site technical assistance. MSHA is committed to assisting these operators in special mining situations that could affect the successful use of DPFs or other engineering control systems. Mine operators can request this assistance from their respective MSHA District Manager.

Additionally, MSHA concludes that the established hierarchy of controls for complying with the DPM interim limit adequately protects miners from exposure to DPM in those circumstances where MSHA found control methods to be infeasible under existing § 57.5060(d)(2) for certain activities including inspection, maintenance and repair activities. MSHA has removed from this final rule the requirement for mine operators to apply to the Secretary of Labor for relief from applying control technology to comply with the final DPM limit. Instead, MSHA's hierarchy of controls strategy will result in quicker responses to supplementing protection for miners exposed to the health risks associated with DPM.

MSHA believes that it has sufficiently accommodated the mining industry's needs with respect to complying with the DPM standard and has developed an appropriate and reasonable enforcement scheme under this rule. MSHA estimates that approximately 183 mines are covered under the standard. These mines produce commodities such as gold, limestone, trona, platinum, lead, silver, zinc, marble, gypsum, salt, and potash. Based on MSHA's baseline sampling results, over 70% of these underground mines were in compliance with the interim DPM limit.

MSHA is confident that engineering and administrative controls (including work practice controls) exist that are capable of reducing DPM exposures to the interim PEL of 308_{EC} µg/m^3 in all types of underground M/NM mines. MSHA believes that virtually all mine operators will successfully attain compliance with the interim limit by choosing from among various currently available feasible engineering and administrative DPM control options, including but not limited to DPF systems, ventilation upgrades, oxidation catalytic converters, alternative fuels, fuel additives, enclosures such as cabs and booths with filtered breathing air, improved diesel engine maintenance procedures and instrumentation, diesel engines with lower DPM emissions, various work practices and administrative controls. MSHA has given the mining industry flexibility under the final standard in selecting the individual or combination of DPM controls that best suit a mine operator's specific needs, conditions, and operating practices.

MSHA received numerous comments concerning the technological feasibility of the 2003 NPRM. Some commenters opposed any changes in the 2001 DPM standard. A few of these commenters suggested that MSHA's current rulemaking record does not support revising the 2001 final rule. They believe that in order to justify a change that in their view reduces health protection, MSHA must first make a determination that the DPM limits established in the 2001 final rule are infeasible for the mining industry as a whole to attain. These commenters note that, to the contrary, MSHA fully substantiated its conclusions regarding feasibility in the 2001 final rule.

According to these commenters, during the period from August 2001 through January 2002, MSHA stated in the final report to the 31-Mine Study that the mean concentration of DPM was 345_{TC} µg/m^3, substantially below the required concentration limit of 400_{TC} µg/m^3. These commenters pointed out that these results were obtained at a time when MSHA believes few mining operations had begun to implement DPM controls, or where the implementation of such controls was in its early stages and had not yet achieved significant reductions in DPM exposure. Other supportive evidence noted by these commenters included the results of the baseline sampling indicating that only 30% of the mines tested were out of compliance.

MSHA agrees that it should utilize data from its final report on the 31-Mine Study and the baseline sampling in assessing technological feasibility, but MSHA does not consider the mean concentration obtained in the 31-Mine Study or the number of mines with baseline samples exceeding the interim limit to be the definitive data sources in this assessment. For example, although the mean concentration of DPM reported in the final report to the 31-Mine Study was only 345_{TC} µg/m^3, the mean DPM concentration value does not reflect the wide range of sample results obtained between mines or within individual mines, some of which exceeded 1000_{TC} µg/m^3. Likewise, although only 30% of the mines had baseline sampling results exceeding the interim limit, MSHA expects some of these mines may have encountered compliance difficulties due to implementation issues relating to such factors as DPF regeneration and retrofitting DPFs to existing pieces of equipment, and due to the costs of purchasing and installing DPM controls.

Therefore, in assessing technological feasibility, MSHA believes it should also consider data obtained subsequently from other sources, including MSHA's comprehensive compliance assistance work at mining operations, current agency enforcement experience, the NIOSH Diesel Emissions Workshops in Cincinnati and Salt Lake City, and the NIOSH Phase I Isozone Study. MSHA agrees with commenters who take the position that the interim DPM limit can be attained by the industry as a whole through implementation of feasible engineering and/or administrative (including work practice) controls. However, MSHA does not agree with commenters who oppose any changes to the 2001 final rule.

Some commenters suggested that the proposed modification to the 2001 standard would reduce health protection for miners, a consequence that § 101(a)(9) of the Mine Act prohibits. MSHA disagrees. Section 101(a)(9) of the Mine Act provides that: ''No mandatory health or safety standard promulgated under this title shall reduce the protection afforded miners by an existing mandatory health or safety standard.'' MSHA interprets this provision of the Mine Act to require that all of the health or safety benefits resulting from a new standard be at least equivalent to all of the health or safety benefits resulting from the existing standard when the two sets of benefits are evaluated as a whole. *Int'l Union* v. *Federal Mine Safety and Health Admin.,* 920 F.2d 960, 962–64 (DC Cir. 1990); *Int'l Union* v. *Federal Mine Safety and Health Admin.,* 931 F.2d 908, 911 (DC Cir 1991).

In fact, MSHA believes that the interim EC limit established in this rulemaking is comparable to the existing TC limit. Correcting the surrogate for identifying miners' exposures to DPM is critical for protection of miners and will result in a valid DPM sample that MSHA can adequately substantiate. MSHA's hierarchy of controls strategy in the final rule is based on long-standing industrial hygiene practice in both the mining industry and general industry. As implemented in this final rule, the hierarchy of controls ensures that the most protective means of compliance (engineering and administrative controls) are used first, and that respiratory protection is permitted only where MSHA determines that: Engineering and administrative controls are infeasible; controls do not produce significant reductions in DPM exposures; or controls do not reduce exposures to the interim DPM limit.

The DPM litigants raised their concerns to MSHA with implementation issues related to regeneration and retrofitting exhaust after-treatment controls on existing mining equipment. These, along with various other compliance concerns, eventually led to the 31-Mine Study. At that time, only a few mine operators in the U.S. had begun to implement after-treatment control technology on their underground diesel-powered equipment. As is often the case when unfamiliar technologies are integrated into an industry sector, the process was slow, and at least initially, the results were less-than-fully satisfactory. As noted elsewhere in this section, many mine operators, for example, experimented with DPF installations on a few pieces of equipment on a trial basis, with mixed results at best. MSHA does not dispute these findings, but believes that DPF failures were the result of inappropriate DPF selection for a given application. However at the time, these operators were convinced that DPF technology was fundamentally deficient for application in underground mining. In an effort to resolve a variety of issues raised by the industry that were believed to present potential compliance problems, MSHA agreed to conduct the 31-Mine Study.

Many commenters also claimed that MSHA's determination that the rule is technologically feasible assumed the widespread utilization of DPFs, which these commenters do not believe have proven mine worthy and which may be affected by the aforementioned implementation issues. In response, MSHA notes that while it continues to highly recommend use of DPFs, its technological feasibility determination was based on the application of a variety of engineering and administrative control approaches for obtaining compliance, and was not limited to DPFs. MSHA has determined that DPF systems are available and mine worthy for controlling miners' exposures to DPM. As discussed later in this section of the preamble, both MSHA and NIOSH are satisfied that DPF systems are currently available for most mining equipment, and that these systems can be successfully applied if mine operators make informed decisions regarding filter selection, retrofitting, engine and equipment deployment, operation, and maintenance, and specifically work through issues such as in-use efficiencies, secondary emissions, engine backpressure, DPF regeneration, DPF reliability and durability.

Implementation issues, such as DPF regeneration and retrofitting DPFs to existing pieces of equipment, primarily affect a small number of mines. Mines affected are those that will need to utilize DPFs to attain compliance because other control options, such as ventilation upgrades, low-emission engines, alternative diesel fuels, and cabs with filtered breathing air are either infeasible at these particular mines, or because these mine operators have already utilized these other control options to the maximum extent feasible but have not yet attained compliance. Since a variety of feasible control options are available, and implementation issues relating to DPFs affect a relatively small number of mines, the industry as a whole will not be impeded from attaining compliance with the interim PEL.

MSHA does not dispute this early experience with DPF installations in U.S. underground mines, and in fact, acknowledged these concerns in the final report of the 31-Mine Study. One of the major conclusions of the study states:

> Compliance with both the interim and final concentration limits may be both technologically and economically feasible for metal and nonmetal underground mines in the study. MSHA, however, has limited in-mine documentation on DPM control technology. As a result, MSHA's position on feasibility does not reflect consideration of current complications with respect to implementation of controls, such as retrofitting and regeneration of filters. MSHA acknowledges that these issues may influence the extent to which controls are feasible. The Agency is continuing to consult with the National Institute of Occupational Safety and Health, industry and labor representatives on the availability of practical mine worthy filter technology.

After completing the 31-Mine Study, however, MSHA obtained additional documentation on DPM control technology that it had previously lacked. This information includes data on both implementation issues and costs, and was obtained from such sources as MSHA's comprehensive compliance assistance activities, MSHA's enforcement experience, and NIOSH's Diesel Emission Workshops in Cincinnati and Salt Lake City. Also, MSHA now has in-mine data on the filter efficiency of DPFs in U.S. mines as a result of the NIOSH Phase I Isozone study (discussed in detail in this preamble).

Effectiveness of the DPM Estimator. MSHA's DPM Estimator is a Microsoft® Excel spreadsheet computer program that calculates the reduction in DPM concentration that can be obtained by implementing individual, or combinations of engineering controls in a given production area of a mine. MSHA has repeatedly advised the mining community throughout the DPM rulemakings that the Estimator is one of many tools that can be used to assist mine operators with assessing feasibility of compliance with the DPM limits. MSHA used the estimator to support its feasibility assessment for the 2001 final rule, as well as the feasibility section of the 31-Mine Study which is used to support this final rule.

The analyses in the 31-Mine Study were based on the highest DPM sample result obtained at each mine. Using the Estimator, new DPM levels were computed for this ''worst case'' sample result based on the application of one, or a combination of the following control technologies: DPFs, low emission engines, and upgraded ventilation. To adequately protect all miners even if the mine operator changes equipment deployment schemes in the future, the methodology for the technological feasibility analysis required all major emission sources at a given mine, plus similar spare equipment, to be provided with the same DPM controls that were specified for the equipment associated with the ''worst case'' sample result.

Likewise, the economic feasibility analysis for each mine was based on costing the same controls for all major DPM emission sources, and similar spare equipment, as were required to reduce the ''worst case'' sample result to the compliance level. The rationale for this approach is that if the same controls are applied to all major DPM sources and spare equipment as are required to attain compliance for the ''worst case'' exposures, all exposures in the mine will be reduced at least to the compliance level, if not lower, regardless of future equipment usage, equipment deployment, mine production levels, etc.

In the 31-Mine Study, DPFs were assumed to be capable of achieving an 80% reduction in DPM emissions. This 80% filtration efficiency value was based on laboratory tests. Since the 2001 final rule was promulgated, MSHA has obtained the results of the NIOSH Phase I Isozone Study conducted under actual in-mine testing, and which concludes that filter efficiency is about 75% for total DPM and ranged over 88% to 90% for EC for ceramic monolith wall-flow type DPFs of either silicon carbide or cordierite composition. DPM reductions obtained by replacing older existing engines with new, low-emission engines are based on the DPM emissions of the new engine relative to the DPM emissions of the existing engine. For instance, if a new engine emits 0.10 grams per brake horsepower-hour (g/bhp-hr) of DPM and the existing engine emits 0.50 g/bhp-hr of DPM, the Estimator would compute a DPM reduction of 80% when the new engine replaces the existing engine. DPM reductions obtained through ventilation upgrades are based on the new ventilation airflow rate compared to the existing ventilation airflow rate. For example, if the new ventilation airflow rate is 80,000 cfm and the existing airflow rate is 40,000 cfm, the Estimator would compute a reduction in the DPM concentration of 50%.

The Estimator was peer-reviewed during the 2001 final rulemaking and was published both as an SME Preprint for the 1998 SME Annual Meeting (Preprint 98–146, March 1998) and in the April 2000 SME Journal. Its predictions have been compared to actual in-mine DPM measurements (before and after DPM controls were implemented) with good agreement. Indeed, one commenter who was critical of the Estimator, nonetheless, noted that, ‘‘The math which forms the basis for the Estimator's calculations cannot be challenged ‘‘total exhaust emissions from diesel equipment (in grams/hr) when diluted with mine ventilation air flows (in cubic feet per minute) yield an estimated DPM concentration (in microgram per cubic meter) if the emissions are perfectly mixed with the air flow.''

Despite its sound mathematical basis, this and other commenters stated that the Estimator was flawed, and hence, the technological and economic feasibility assessments were likewise flawed. These commenters specifically stated that the Estimator was flawed because two inputs utilized by the Estimator, DPM emissions (both raw and reduced via DPFs) and air flows, are subject to interpretation and assumptions. Furthermore, they believe that the Estimator's computations of DPM concentrations are valid only if engine emissions are perfectly mixed with the air flow, which they suggest does not occur in an actual mine.

MSHA disagrees with this conclusion. These commenters make an erroneous assumption with respect to MSHA's utilization of the Estimator. The Estimator actually incorporates two independent means of calculating DPM levels: one based on DPM sampling data for the subject mine, and one based on the absence of such sampling data. Where no sampling data exist, the Estimator calculates DPM levels based on a straightforward mathematical ratio of DPM emitted from the tailpipe (or DPF, in the case of filtered exhaust) per volume of ventilation air flow over that piece of equipment. This is referred to in the Estimator as the ‘‘Column B'' option for calculating DPM concentrations. The commenters' observation that the Estimator fails to account for imperfect mixing between DPM emissions and ventilating air flows is a valid criticism of the ‘‘Column B'' option. For this and other reasons, the Estimator's instructions urge users to utilize the ‘‘Column A'' option whenever sampling data are available.

In the ‘‘Column A'' option, the Estimator's calculations are ‘‘calibrated'' to actual sampling data. Whatever complex mixing between DPM emissions and ventilating air flows existed when DPM samples were obtained, are assumed to prevail after implementation of a DPM control. This is an entirely reasonable assumption, and in fact, there is no engineering basis to assume otherwise. Indeed, comparisons of ‘‘Column A'' Estimator calculations and actual DPM measurements taken in mines before and after implementation of DPM controls have shown good agreement, indicating that Estimator calculations do adequately incorporate consideration for complex mixing of DPM and air flows when the ‘‘Column A'' option is used.

The Estimator was originally developed with both the Column A and Column B options because at that time, the specialized equipment required for DPM sampling, such as the submicron impactor, was not widely available. Consequently, few mine operators were able to obtain the in-mine DPM sample data required for utilizing the Column A option. Now that the required sampling equipment is readily available, MSHA strongly recommends that the Column A option be used exclusively, as MSHA did in the 31-Mine Study. Since all Estimator analyses conducted during the 31-Mine Study utilized the Estimator's ‘‘Column A'' option, the comment regarding imperfect mixing is not relevant.

The Estimator utilizes raw (an unfiltered emission) tailpipe DPM emissions per se as an input data value only when a low-emission engine is specified as a DPM control. For most of the mines in the 31-Mine Study, unfiltered tailpipe DPM emissions were not factored into Estimator analysis because a change in engines was not specified. Where new engines were specified, MSHA based its estimate of unfiltered tailpipe emissions on laboratory dynamometer testing conducted according to the EPA 8-mode test duty cycle. This test is a common standard used by government and industry for diesel engine emissions analysis. Where actual test data were not available for a given engine, emissions were estimated based on the type of engine (make and model, model year, direct injection, pre-chamber, naturally aspirated, turbocharged, electronic controlled, etc.) and horsepower. Filtered emissions were assumed to be 20% of unfiltered tailpipe emissions, corresponding to 80% filter efficiency. As noted above, the 80% filter efficiency was a conservative assumption based on MSHA and other laboratory and NIOSH in-mine test data indicating DPM efficiencies of 80% to 87% for both cordierite and silicon carbide filters. Note that these efficiencies relate to DPM filtration. Higher filtration efficiencies are obtained for TC and EC. Air flows, where relevant for estimator analysis, were based on the sampler's comments, and/or the accompanying mine ventilation plans or maps.

A number of commenters suggested that MSHA's DPM sampling results in isolated sections of mines are assumed by MSHA to be representative of on-going exposure levels in those mines, despite the fact that results varied widely. In the 31-Mine Study, MSHA did not, in fact, assume a sample result from an isolated section of a mine was necessarily representative of on-going DPM exposure levels throughout that mine. The study methodology stipulated that the highest observed DPM level for a given mine would be the basis for specifying DPM controls for the entire mine. A key underlying assumption of this methodology is that DPM levels do vary, often significantly, from one part of a mine to another. However, to insure that study findings would be conservative, the study methodology required that the highest DPM level, not the average or lowest DPM level, was the basis for specifying controls.

Some commenters asserted that when analyzing sampling data for the 31-Mine Study, MSHA assumed that ventilation flows measured at the sampling location applied throughout the subject section of the mine. They also asserted that MSHA assumed effective ventilation for dilution existed throughout the mine, and that neither of these assumptions was necessarily valid. For most of the mines in the 31-Mine Study for which a DPM reduction was necessary, ventilation was not an issue, and consequently, MSHA did not specify any changes in ventilation. For these mines, DPM reductions were obtained by utilizing DPFs and/or low-emission engines, and the only assumption regarding ventilation was that it would not be changed.

In the few cases where ventilation upgrades were specified, the upgrades were limited to auxiliary systems that supplied air to the sampled area only. Initial air flows utilized by the Estimator for those areas prior to implementing the upgrades were based on the comments and/or any accompanying ventilation plans or maps accompanying the sample. Where upgraded auxiliary ventilation was specified, MSHA frequently noted deficiencies in existing auxiliary ventilation system components such as inappropriately placed fans and blast-damaged or otherwise deteriorated and compromised vent bags. In these cases, the specified ventilation changes involved simply correcting the obvious deficiencies in the existing systems and increasing fan capacity.

MSHA recognizes that there has to be a sufficient air quantity present in the main ventilation system in order for an auxiliary system to function properly (i.e. without recirculation), and that DPM levels in the main ventilation system from which the auxiliary system draws its air must be sufficiently below the DPM limit to prevent miners' overexposures in the stopes.

Some commenters stated that in the 31-Mine Study, MSHA assumed that the only equipment needing DPM controls was the equipment operating while sampling took place. As noted above, the study methodology insured a conservative result by applying the same controls required to attain compliance for the equipment associated with the ''worst case'' sample to all similar DPM sources (and spares) in the entire mine, even if the subject ''worst case'' sample concentration was substantially higher than the remaining samples for that mine, and regardless of whether a particular piece of equipment was operating during sampling or not. For most mines in the study requiring DPM reductions, controls were specified for all or most of the normal production contingent of equipment, along with an allowance for spare equipment, particularly loaders and trucks, which are typically the largest source of DPM.

Some commenters stated that in the 31-Mine Study, MSHA assumed 80% DPF filtration efficiency, and gave no consideration to potential NO_2 problems related to DPFs. As noted above, the assumption of 80% filtration efficiency is conservative, and is based on actual laboratory and in-mine test data. Regarding NO_2 generation from DPFs and the associated health concerns, MSHA acknowledges that NO_2 can be produced by passive DPFs that are wash-coated with platinum-based catalysts. However, when such filters are utilized under reasonable ventilation conditions, the NO_2 increases should be manageable and should not constitute a serious health hazard or compliance problem for the mine operator. An example of successfully using highly platinum-catalyzed DPFs without creating hazardous NO_2 concentrations is Greens Creek mine which has installed such filter systems on its large trucks and loaders. During MSHA compliance assistance sampling at this mine in January 2002, NO_2 increases of around 1 ppm were observed downstream of stopes where 1 loader and 2 or 3 trucks were operating for 2 to 3 hours.

MSHA also notes that in situations where passive DPF regeneration is desired, but where ventilation may be insufficient to adequately dilute and carry away harmful NO_2 concentrations, alternatives to highly platinum-catalyzed DPFs exist. Examples include base metal catalyzed DPFs and lightly platinum-catalyzed filters used in conjunction with a fuel-borne catalyst, which have a regeneration temperature somewhat higher than highly platinum-catalyzed filters. These passively regenerating DPFs do not increase NO_2 concentrations compared to unfiltered exhaust emissions.

Even more importantly, however, in the 31-Mine Study, all DPFs were specified as active type regeneration systems, not passive type systems. Likewise, in the corresponding economic feasibility assessment, all costs for DPFs included an assumption that mine operators would opt for active regeneration. Without detailed on-site analysis and evaluation of the subject equipment and duty cycles, MSHA could not assume a DPF system would passively regenerate. Also, active filter systems are typically more costly than an equivalent passive system, so specifying an active system would be more conservative from a costing perspective. Since actively regenerated DPFs have no platinum wash-coatings applied to the filters (and in fact, have no wash-coatings at all), they do not produce any increased NO_2 emissions compared to unfiltered engines. NO_2 emissions and associated health concerns were not addressed in the 31-Mine Study because the DPM controls specified in the study did not affect NO_2 emissions.

Some commenters also stated that MSHA failed to specify any major ventilation upgrades (new main fans, new ventilation shafts, etc.) in the 31-Mine Study, and that by avoiding major ventilation upgrades, the resulting compliance cost estimates were unrealistically low. In responding, MSHA notes that it did not specify any major ventilation upgrades in the 31-Mine Study because, based on the study methodology, the analysis did not indicate the need for major ventilation upgrades in order to attain compliance with either the interim or final DPM limits at any of the 31 mines.

This does not mean that major ventilation upgrades would have been ill-advised, ineffective, or unbeneficial for any of the mines in the study. MSHA did note in the final report that strategies other than those specified in the study could also be successful, and there may be valid reasons why a mine operator might choose a different mix of controls (such as a major ventilation upgrade) for a given mine based on mine-specific factors to which MSHA's analysts were not privy at the time of the study. It was explicitly stated in the final report that the DPM controls specified for a particular mine did not necessarily represent the only feasible control strategy, nor the optimal control strategy for that mine. The purpose of specifying controls for each mine was simply to demonstrate that feasible controls capable of attaining compliance existed, and to provide a framework for costing such controls on a mine-by-mine basis.

Indeed, since the completion of the 31-Mine Study, MSHA has observed that mine operators in the stone industry, for example, have chosen to attain compliance without utilizing DPFs. These operators instead have opted to upgrade ventilation (usually by adding or re-positioning booster fans and installing or repairing ventilation control structures such as air curtains and brattices), install low-emission engines, utilize equipment cabs with filtered breathing air, initiate a variety of work practices that contribute to reducing personal exposures to DPM, and in a few cases, use alternative diesel fuels such as bio-diesel fuel blends and diesel/water emulsions.

Some of these mine operators may have had reasons other than DPM compliance alone that helped justify their decisions. For example, ventilation upgrades can also improve gaseous emission levels, dust levels, visibility, clearance of blasting smoke and gases, and inefficient or even counterproductive deployment of booster fans. Mine operators that have opted to replace older, dirty engines with newer, low emission engines benefit from greater fuel economy and better maintenance diagnostics. Cabs with filtered breathing air improve operator comfort and productivity, as well as reducing dust and noise exposures.

DPF Systems.

DPFs suitable for any duty cycle are currently commercially available for most engine sizes and types used in underground M/NM mining. DPF options include silicon carbide and cordierite ceramic monolith type wall flow filters designed for passive regeneration, active on-board or active off-board regeneration, or passive/active regeneration. For most filters requiring active regeneration, the time required for filter regeneration varies from less than 1 hour to 8 hours, depending on system type. Another option that is suitable for smaller, light duty equipment is a high-temperature disposable pleated element filter.

Although every mine is unique, and virtually every DPF application has unique features, the variety of DPF systems available make it feasible to apply a DPF to most types of equipment or engines, and application or duty cycle. The only exception known to MSHA would be applying a DPF to a very old (pre-1970s vintage technology) engine having very high DPM emissions and a medium or light duty cycle. In theory, such an application would collect DPM, but due to rapid soot build-up on the filter media and corresponding rapid increase in engine back-pressure, such a DPF application would probably be impractical. MSHA has observed very few such engines in the underground M/NM mining industry, but in the few instances where emissions from such engines need to be controlled, mine operators are advised to choose a control option other than a DPF.

MSHA is aware of reports by mining companies and others that some DPFs have not performed satisfactorily in the field. These reports refer to problems such as short filter life (a matter of weeks in some cases), equipment that bogs down when filters are installed, and uncontrolled regenerations and similar problems resulting in damaged or destroyed filters. MSHA has determined that most DPF failures result from inappropriate filter selection due to the failure by mine operators to fully consider all filter selection criteria prior to ordering DPF systems. In a few cases, filter failures were traced to manufacturing defects that were later resolved, while in a few others, an unrelated component failure on the host equipment (such as a turbocharger failure) caused a failure in the downstream DPF.

Most problems with filter selection relate to the installation of a passively regenerating type filter on a machine that does not produce sufficient exhaust temperature for a sufficient portion of the duty cycle to initiate passive regeneration. A passive type filter that doesn't regenerate continues to trap soot until the backpressure on the engine causes the engine to ''bog down,'' or an uncontrolled regeneration occurs. The system may function satisfactorily for a while, either regenerating as expected, or at least partially regenerating. But if the machine's duty cycle lessens in severity, even for a single shift (for example, a production loader that is normally worked very hard might be used for a shift to perform road maintenance or clean-up duty), the filter may become overloaded.

MSHA's determination that DPFs are a technologically feasible DPM control option is based on two factors: Laboratory and in-mine testing which has documented their high filtration efficiency, and numerous successful applications in routine production mining situations where DPFs have been appropriately matched to machines and duty cycles. When DPFs are properly selected and maintained for an application, the result is optimal performance and maximum filter life.

In order to achieve satisfactory filter performance, filter life, and filtration efficiency, it is critical that a DPF be appropriately matched both to the diesel engine, and to the duty cycle and intended application of the subject equipment. For example, two identical machines may need different types of filter systems based on the machines' respective duty cycles. One machine that works hard due to the road grades that the machine must transverse during a shift may generate sufficient exhaust gas temperatures to support a passive regeneration DPF system. However, the second machine may run continuously on flat roads in the mine and, therefore, may not be capable of generating sufficient exhaust gas temperatures to support passive regeneration. Consequently, the second machine must use an active regenerating DPF system, or change out a disposable filter on a regular basis. Importantly, if the first machine, due for example to a breakdown of the second machine, assumes the second machine's duties, even on a temporary basis, it would be very possible if not likely, that its passive DPF system would fail to regenerate. Hence, when specifying a DPF system for a particular piece of equipment, mine operators should consider not only the intended application and duty cycle of the machine, but also other applications and duty cycles to which that machine may be occasionally assigned on a nonroutine basis.

In order to assist the mining industry in selecting an appropriate filter, the MSHA and NIOSH internet web sites include a comprehensive compliance assistance tool, the Filter Selection Guide. One of many MSHA DPM compliance assistance tools, the Filter Selection Guide provides mine operators with detailed step-by-step assistance in selecting appropriate DPF systems that are compatible with their specific equipment and duty cycles. Also, the Filter Selection Guide provides information on modifications and adjustments to diesel-powered equipment that mine operators may have to make to successfully apply DPF systems.

Prior to initiating the DPF selection process, mine operators should make certain that they are properly maintaining their engines, and that the engines are not consuming excessive amounts of crankcase oil. Operators should then obtain exhaust temperature logs or traces for several shifts, and use these traces to help select the appropriate DPF system for that machine and application. Exhaust temperature traces can be analyzed by mine personnel or DPF suppliers to assist in selecting a workable DPF system. Exhaust gas temperatures are an important factor in selecting a DPF because passive filter regeneration is possible only if sufficient exhaust gas temperatures are attained for specified minimum time periods throughout the engine's duty cycle. The exhaust temperatures that must be attained, and the corresponding DPFs, are listed in Table VII–1.

TABLE VII–1.—CERAMIC WALL-FLOW MONOLITH DPF REGENERATION OPTIONS

DPF regeneration type	Temperature that exhaust must exceed at least 30% of the time for passive regeneration to occur	DPF media	Comments
Passive	>550°C	Uncatalyzed media; can be either cordierite or silicon carbide.	Exhaust temperatures >550°C rarely if ever occur; thus, passive regeneration of uncatalyzed DPFs is not a practical option.
	>390°C	Base metal catalyzed cordierite	No increase in NO_2.
	>340°C	Lightly platinum-catalyzed cordierite or silicon carbide with fuel additive.	Special provisions must be made to ensure additive is always present in fuel and that equipment w/o DPFs cannot be fueled with additive-containing fuel. No increase in NO_2.
	>325°C	Platinum-catalyzed cordierite or silicon carbide.	Lab results indicate significant NO to NO_2 conversion; field results are mixed; successful application depends on consistently achieving required exhaust temperatures and adequate ventilation to dilute and carry away NO_2.
Active	Not applicable	Uncatalyzed cordierite or silicon carbide	DPFs manually regenerated on-board or off-board depending on system design.
	Not applicable	Uncatalyzed silicon carbide or cordierite	Active/passive[1] type system uses fuel burner to assist regeneration at any exhaust gas temperature and duty cycle; regeneration initiated automatically based on exhaust backpressure.

[1] MSHA is aware of another type of active/passive system utilizing an on-board electrical heating source to assist regeneration of sintered metal filter media, but is not aware of any underground mining applications of this system at this time.

As Table VII–1 indicates, passive DPF systems will regenerate successfully at or above the exhaust gas temperature specified by the manufacturer. However, these exhaust gas temperatures must be maintained for at least 30% of the shift to be sufficient for passive regeneration. An active regenerating system will work at any exhaust temperatures.

The tune of the engine will also be a factor for proper regeneration. If an engine goes out of tune and begins to emit higher DPM concentrations in the exhaust, the exhaust backpressure may increase too quickly. Therefore, MSHA and DPF manufacturers recommend that mine operators install backpressure monitoring devices on machines equipped with DPFs in order to properly monitor the condition and regeneration state of the filter.

In the DPM settlement agreement, MSHA agreed to a compliance assistance period of one year beginning July 20, 2002 and ending July 19, 2003. Among its many compliance assistance activities during this period, MSHA examined the mine worthiness of available DPF systems. In the preamble discussion to the 2003 NPRM, MSHA stated:

MSHA has found that most mine operators can successfully resolve their implementation issues if they make informed decisions regarding filter selection, retrofitting, engine and equipment deployment, operations, and maintenance. The Agency recognizes that practical mine-worthy DPF systems for retrofitting most existing diesel powered equipment in underground metal and nonmetal mines are commercially available and are mine worthy to effectively reduce miners' exposures to DPM. MSHA also recognizes that installation of DPF systems will require mine operators to work through technical and operational situations unique to their specific mining circumstances. In view of that, MSHA has provided comprehensive compliance assistance to the underground metal and nonmetal mining industry.

NIOSH also stated its position on the DPF systems currently available for most mining equipment during this period. By letter of June 25, 2003, to MSHA, NIOSH stated:

With regard to the availability of filters and the interim standard, the experience to date has shown that while diesel particulate filter (DPF) systems for retrofitting most existing diesel-powered equipment in underground metal and nonmetal mines are commercially available, the successful application of these systems is predicated on solving technical and operational issues associated with the circumstances unique to each mine. Operators will need to make informed decisions regarding filter selection, retrofitting, engine and equipment deployment, operation, and maintenance, and specifically work through issues such as in-use efficiencies, secondary emissions, engine backpressure, DPF regeneration, DPF reliability and durability. NIOSH is of the opinion that these issues can be solved if the informed decisions mentioned above are made. This view is supported by comments made by mine operators at the NIOSH-sponsored workshops entitled ''Diesel Emissions and Control Technologies in Underground Metal and Nonmetal Mines.'' Analysis of the recently completed Stillwater Mine experiments and related in-mine tests will also provide information regarding in-mine filter efficiency performance of these systems as compared to their performance in the laboratory.

Assuming that the results show comparable filter efficiency performance, metal/nonmetal mine operators in similar circumstances will be able to use the information with confidence to predict performance results in reducing DPM levels in particular applications.

MSHA believes that this document confirms that DPF systems are available and mine-worthy to reduce miners' exposures to DPM.

Some commenters stated that the intermittent duty cycles (bursts of heavy work, followed by idle time) common for large front-end loaders used in the stone mining industry are unlikely to produce sufficiently high exhaust temperatures for passive regenerating DPFs to be a feasible DPM control option. MSHA notes that during its 2003 compliance assistance visits, exhaust temperature monitoring conducted on a production loader indicated sufficient temperatures for a sufficient portion of the duty cycle to permit that loader to utilize a passively regenerating DPF system. Clearly, such limited testing was not definitive, and the mine operator would need to conduct additional temperature monitoring to verify these results over the complete range of work activities performed by this loader. However, there was nothing particularly unusual about this loader or its duty cycle, so the commenter's suggestion that loaders in the stone industry, in general, cannot utilize passive regenerating DPFs, is inaccurate.

Also, MSHA notes that there are feasible alternatives to passive regeneration for filtering the exhaust of any size engine used in the stone mining industry. Mine operators could choose on-board or off-board active regeneration, including an on-board fuel burner type system that actively regenerates the filter during normal production operations without any intervention by the equipment operator, without shutting down the equipment, and without any increase in NO_2 generation.

Industry commenters related the experiences of four mining companies to support the position that DPF systems are not a technologically feasible DPM control option for attaining compliance with the interim DPM limit in underground mining applications. The four companies were the Stillwater Mining Company (Stillwater mine in Montana), Newmont Gold (Carlin East and Deep Post mines in Nevada), Kennecott Minerals (Greens Creek mine in Alaska), and Cargill Salt (Avery Island mine in Louisiana).

Commenters reported that platinum wash-coated passive DPFs have proven successful at the Stillwater mine. They indicated that the equipment best suited to utilizing passive systems includes 19 primary haulage trucks, eight locomotives, and two large LHDs which together, are estimated to account for about 35% of the mine's DPM emissions. This equipment tends to work in haulageways where there is frequently a good ventilation air flow. However, as noted elsewhere in this section of this preamble, the commenters noted problems with high NO_2 emissions from equipment fitted with platinum wash-coated passive DPFs. MSHA has determined that the NO_2 problems at this mine result from inadequate ventilation, and that high NO_2 levels at this mine pre-dated the use of platinum wash-coated passive DPFs.

These commenters indicated that the remaining 321 machines at this mine do not have high enough duty cycles and exhaust temperatures to utilize passive DPFs, and that active DPF systems are not considered feasible by the mine operator. As discussed in detail below in this section, MSHA believes that the mine operator's determination of infeasibility of active filters is based on a proposed active filtration concept that is not optimal for this mine.

These same commenters also discussed the technological and economic feasibility analyses for the Stillwater mine included in the 31-Mine Study. MSHA has acknowledged that the cost estimates contained in the 31-Mine Study final report significantly underestimate the probable DPM compliance costs for this mine. At the time the 31-Mine Study was conducted, MSHA's analysts had been supplied with inaccurate information regarding this mine's diesel equipment inventory. MSHA subsequently revised its analysis based on updated equipment inventory data. The revised estimate of compliance cost for the Stillwater mine is considerably higher than the estimate included in the 31-Mine Study. However, as discussed later in this section, it is nonetheless consistent with the estimated compliance cost for a precious metals mine of this size as detailed in MSHA's REA for the 2001 final rule.

The commenters indicated that Newmont has experimented with both passive and active DPFs in the Carlin East and Deep Post mines, and that a problem exists. The commenters state that engine backpressures range from 37 to 43 inches of mercury when DPFs are in use, and one of their engine suppliers, Caterpillar, will not warrant engines when backpressure exceeds 27 inches of mercury. In response, MSHA references the NIOSH/MSHA Filter Selection Guide, which states that DPF systems must be sized so that backpressure is within the engine manufacturer's specifications.

The commenters go on to relate Newmont's successes with DPFs, including both platinum wash-coated passive filters on haulage trucks and base metal wash-coated passive/active filters on smaller LHDs and jammers. Although elevated NO_2 emissions can be associated with platinum wash-coated DPFs, the trucks equipped with these filters are used to haul ore up well ventilated ramps to the surface, so the potential for NO_2 overexposure is minimized. The smaller LHDs and jammers are typically used in production areas with lower ventilation rates, so base metal wash-coated filters are used which do not generate NO_2. Because of the limited duty cycle of these smaller machines, total filter regeneration may not occur. However, the wash-coat promotes enough regeneration that the filters are able to function properly between set service intervals that coincide with the equipment's preventive maintenance schedule, at which time the filters are changed-out, and the ''dirty'' filters actively regenerated off-board.

The commenters also related Newmont's experience with ''failed'' DPFs, including a filter that was destroyed due to excess vibration and another that was destroyed when an upstream turbocharger failed and blew oil into the DPF. However, the commenter went on to describe the steps taken by Newmont to successfully correct the vibration problem (shock absorbing filter mounts), and the other destroyed DPF was clearly caused by the failed turbocharger, not an integral failure of the DPF. MSHA has repeatedly advised the mining community that a certain amount of applications engineering will be required to insure the successful deployment of DPFs on underground mining equipment. The vibration failure example illustrates that as mine operators obtain experience with DPFs, problems will inevitably be encountered, but they can be readily solved by applying reasonably simple hardware solutions.

These commenters also questioned MSHA's assumptions regarding the feasibility of auxiliary ventilation system upgrades discussed in the 31-Mine Study, however, the upgrades specified for Carlin East in the 31-Mine Study related to achieving the final DPM limit. Compliance with the interim limit was projected without ventilation upgrades.

These commenters concluded that overall DPM compliance costs are too high for Newmont Gold. Newmont estimates that the, ''purchase and installation of DPFs, including downtime on production vehicles, will be $1.9 million for its two mines—Deep Post and Carlin East.'' No further cost breakdown is provided, so MSHA could not assess the reasonableness of this estimate. However, accepting this estimate as submitted, and assuming a two-year DPF service life, Newmont's estimate of its DPF costs implies a yearly cost of $1.05 million for the two mines ($1.9 million annualized over two years at a 7% discount rate). MSHA notes in the REA for the 2001 final DPM rule that its estimated compliance cost for a medium-sized gold mine employing 20 to 500 miners is $171,900 per year based on a diesel equipment fleet size of 24 pieces of diesel equipment. This estimate was based on analysis indicating about 78% of overall compliance costs would relate to DPFs. Adjusting MSHA's estimated annual cost to correspond to the combined 166 pieces of equipment at Newmont's two mines yields an estimated annual DPF-related compliance cost of about

$927,000, which is only 12% less than Newmont's estimate of its annual DPF-related compliance cost.

The same commenters described DPF installations on haulage trucks and loaders equipped with Detroit Diesel Series 60 engines rated at 450 horsepower and 350 horsepower, respectively, at the Kennecott Greens Creek mine in Alaska. Regarding the trucks, the same commenters reported that, ''After initial problems, mainly caused by incorrect installation and sizing of filters, the mine has successfully equipped its fleet of six Toro trucks with DPFs.'' This experience confirms two important aspects of DPF utilization that MSHA has emphasized repeatedly in its compliance assistance communications with the industry, including (1) the likely need for a certain amount of applications engineering to resolve implementation and installation issues, and (2) the need to appropriately match the DPF to the machine and duty cycle.

With respect to installations on two identical Toro 1250 loaders, it was noted that the platinum wash-coated DPF on one unit consistently passively regenerated, while the DPF on the other unit, which had a lesser duty cycle and exhaust temperatures that were 40 to 50°C lower, did not. This experience does not illustrate the failure of DPF technology. Rather, it confirms MSHA's consistent advice that the successful deployment of passively regenerating DPFs requires careful determination of exhaust temperatures to assess whether passive regeneration is feasible for that particular machine and in that application. Indeed, in this example, the filter functioned precisely as designed. The failure of the filter to passively regenerate on the second machine could have been reliably predicted based on the exhaust temperature data.

In their comments, industry also relates Greens Creek's successful application of an active DPF system on an Elphinstone R1300 3½-yd LHD with a Cat engine. This loader is used for relatively light duty clean up work, and is therefore not a suitable candidate for application of a passively regenerating DPF.

It should be noted that industry also commented that, ''Those engines in the 250–350 horsepower, and greater-than 350 horsepower ranges are considered unsuitable for DPFs with present technology. This general conclusion of unsuitability for DPF usage for these large engines comes from use of DPFs in real mine situations.'' These statements are directly contradicted by Greens Creek's successful experience filtering the exhaust from 350 horsepower and 475 horsepower engines.

Industry also presented the experience of Cargill Salt's Avery Island mine in Louisiana which installed two DCL Mine X DPF filters on a Cat 992G loader equipped with a Cat 3412 engine rated at 650 horsepower. One 15 inch diameter by 15 inch long filter was connected to each bank of the V–12 engine. This model DPF is wash-coated with a platinum catalyst to facilitate passive regeneration. The mine reported that there are no problems with elevated NO_2 levels, and visible emissions have been reduced. However, the mine also reported that the loader has lost almost all of its power, to such an extent that the loader is only used for clean-up duty.

These symptoms—no elevated NO_2 levels, visible emissions reduced, and loss of power—are all typical of a mismatch between the duty cycle of the application and the performance specifications of the DPF. In order to passively regenerate, this DPF requires exhaust temperatures of about 325°C or higher for at least 30% of its duty cycle. An insufficiently demanding duty cycle produces lower exhaust temperatures which are not sufficient to ignite and burn off accumulated DPM. Such a filter continues to collect DPM, resulting in lower visible emissions, but as the filter loads, even for a single work shift, backpressure on the engine increases, resulting in loss of power. Although these commenters report that mine mechanics worked closely with the local Caterpillar dealer in installing the system, it is very likely that this experience illustrates an inappropriate DPF application rather than a failed filter system.

Normally, the local Caterpillar dealers and any other engine manufacturer's dealers work more with issues concerning the engine installation and repairs than with DPM filter applications. Since engine manufacturers at this time do not install a DPF to the engine at the time of engine production, the local engine dealers are not usually familiar with DPF systems that are installed as retrofits on the engine.

However, even in the case of the Greens Creek experience, where the mine operator worked with the engine manufacturer, the vehicle manufacturer, and the filter manufacturer at the onset to incorporate a DPF on a new machine, the mine still initially had a failure of the DPF because of regeneration issues. As Greens Creek reported,

> the unit (DPF) was used on a waste rock backhaul route, with loads being carried down the ramp or on relatively flat hauls. Had the unit been used for ore haulage uphill routes, it would have achieved the high exhaust temperatures for the designed passive regeneration.

This mine's experience continues to emphasize that the mine must understand the duty cycle of the machine to which the DPF is being equipped to see if the duty cycle can support the regeneration needed for the DPF. In the case of Greens Creek, the waste rock backhaul vehicle did not have a sufficiently demanding duty cycle to generate the exhaust gas temperature needed for regeneration for a passive regeneration system. In such instances, the mine operator needs to go to another method of regeneration for the vehicle's DPF as discussed elsewhere in this preamble. Mine operators should also refer to the M/NM Filter Selection Guide on MSHA's Web site for assistance in choosing the appropriate DPF system for its particular circumstances.

Industry also discussed various issues relating to compliance problems for stone mines, such as feasibility of filters for large engines, biodiesel fuel, and ventilation. These issues are addressed elsewhere in this preamble in sections that deal specifically with these topics. Some commenters stated that MSHA presumed that operators would retrofit DPFs on existing diesel-powered equipment as the primary method of compliance. These commenters questioned whether implementation issues with retrofitting and regeneration would make DPFs infeasible. In response, MSHA has determined on the basis of in-mine tests conducted by NIOSH, MSHA, individual mining companies and others, and on the experiences of mining companies that have implemented DPM filtration on a routine production basis, that DPFs are a practical, mine-worthy, and effective means for reducing exposure to DPM in underground M/NM mines. Further, MSHA has determined that use of DPFs independently or in conjunction with other feasible and effective DPM engineering and administrative controls will enable most mine operators to attain compliance with the DPM interim limit. However, MSHA agrees with the commenters that implementation issues with retrofitting and regeneration may present compliance difficulties for some mines, and additional time may be required at some mines due to the cost of purchasing and installing controls.

Many commenters have cited problems with DPFs which they believe support the contention that DPFs are neither technologically nor economically feasible. As noted above, some commenters provided examples from several underground mines that experienced failed DPFs. Commenters indicated that a ceramic filter, using passive type regeneration would be the only type filter that would be acceptable to them. Commenters also stated that ceramic DPFs that require active regeneration, a fuel borne catalyst, a catalyst that could have the potential to increase NO_2 emissions, and any kind of filter for engines less than 50 horsepower or greater than 250 horsepower were infeasible for use in underground M/NM mines. Some commenters described installations that produced high exhaust backpressure on engines that could lead to voiding engine warranties or render a vehicle unusable. A commenter also stated that the number of regeneration stations that would be required to be built and maintained would make active regeneration infeasible.

Other commenters stated that when DPFs are appropriately sized and fitted to equipment, and there is a good match between the equipment application/duty cycle and the DPF regeneration method, long filter life and significant DPM reductions will result. Several commenters indicated that, after an initial trial-and-error ''learning period,'' they had experienced success with passive type DPFs and were using them on a routine production basis.

Some commenters stated that DPFs continue to be a feasible technology for significantly reducing DPM exposures. One commenter reported the successful application of an on-board active regeneration DPF. This system includes an exhaust backpressure monitor that warns the equipment operator when DPF regeneration is required. This is a feature MSHA recommends for all DPF installations.

As noted above, MSHA acknowledges the numerous documented examples of failed DPF applications in the underground M/NM mining industry. However, MSHA believes such failures are the result of inappropriate filter selection, manufacturing defects, and unrelated failures of equipment components (such as turbochargers) that have caused damage to DPFs. MSHA is confident that proper filter selection will result in satisfactory long term DPF performance, and NIOSH agrees with MSHA that DPFs are technologically feasible for most mining equipment after some technical and operational problems are solved, and that these problems can be solved in most cases.

To help mine operators avoid having to rely on costly and time consuming trial-and-error methods for DPF selection, the Filter Selection Guide was developed. It is the result of a joint effort of MSHA and the Diesel Team from the NIOSH Pittsburgh Research Laboratory. The Filter Guide provides mine operators with information on feasible and available DPFs. NIOSH will work with MSHA to maintain the Filter Guide on the internet.

MSHA continues to urge mine operators to thoroughly evaluate each application to insure that the appropriate DPF and regeneration system is chosen. Such an evaluation is well within the technical capabilities of most mine operators to perform. For the few operators that would be unable to independently perform this evaluation, technical assistance can be obtained from mining equipment manufacturers, engine manufacturers, DPF manufacturers, and MSHA.

As noted earlier, selection of an appropriate DPF for a given application requires consideration of such factors as engine type, model, and horsepower, as well as the intended usage of the equipment and related equipment duty cycles. Mine operators are fully capable of obtaining this information for every piece of equipment that is a candidate for DPF installation. In addition, the engine's DPM emission rate and exhaust temperatures must be obtained. For MSHA-approved engines, DPM emission rates are determined by MSHA and included with the engine approval. For non-approved engines, DPM emission information can be obtained from the engine manufacturer or estimated based on the characteristics of the engine (direct injection, pre-chamber, make and model, model year, naturally aspirated, turbocharged, electronically controlled, etc.). To obtain exhaust temperatures, various inexpensive (approximately $200) data logging thermocouple systems are commercially available that can be attached to the exhaust system to provide detailed exhaust temperature profiles over time periods ranging from several hours to several shifts. During its compliance assistance mine visits in the spring and summer of 2003, MSHA noted that several mine operators had acquired exhaust temperature data logging systems and were using them to systematically measure exhaust temperatures on equipment that might need to be equipped with a DPF in the future.

DPFs collect significant amounts of DPM from the engine's exhaust, thus lowering DPM exposures. This fact was not disputed by the commenters. The results from MSHA's compliance assistance work with Kennecott at their Greens Creek Mine, NIOSH's isolated zone tests conducted at the Stillwater Mine, NIOSH's production zone tests at the Stillwater mine, MSHA's laboratory data, laboratory and in-mine test results from Canadian and European studies, and various other industry applications prove that DPFs provide high efficiency reductions in both DPM and EC. For EC, the data indicate filtration efficiencies as high as 90% to 99+%.

MSHA disputes commenters' views that if passive regeneration cannot be successfully employed (due, for example, to an insufficient duty cycle and correspondingly low engine exhaust temperatures), then DPM filter technology is infeasible. Passive regeneration is only one of many regeneration schemes available to the mine operator. Clearly, not all machines or all applications are suitable for passive regeneration. One commenter stated that one of his firm's two loaders was able to use a passive regeneration DPF due to the exhaust gas temperatures reached during its duty cycle, while the other could not or was marginal. This experience demonstrates precisely what MSHA's consistent message to the industry has been—that successful application of passive regeneration DPFs depends on matching the filter to the application, and mine-worthy systems are commercially available for most any machine and any duty cycle.

It is important to note that a sufficiently heavy duty cycle does not, by itself, guarantee that a passive regeneration DPF will function properly and provide satisfactory long-term performance. It is an essential prerequisite, but the other steps in the DPF selection process must also be followed rigorously. Without the necessary exhaust temperatures for the specified amount of time, passive regeneration is impossible, regardless of how carefully the other steps in the selection process are followed. However, once the necessary exhaust temperature profile has been verified through sufficient in-mine temperature monitoring, users are urged to carefully complete the remaining steps in the selection process.

For whatever reason, if a particular machine requires a DPF, but is an unsuitable candidate for application of a passive regeneration system, the mine operator has the option of using a combination passive/active regeneration scheme or to use a purely active regeneration system. Because the option exists for utilizing either passive, active/passive, or active regeneration systems, MSHA maintains that a suitable DPF system is available for any size diesel engine and any application in the underground M/NM mining industry. The mine operator may need to address various implementation issues regarding retrofitting and regeneration, but MSHA is confident these issues can be resolved.

NIOSH's Phase I Isozone and Phase II Production Zone Studies Related to DPFs at the Stillwater Mine. NIOSH conducted a series of in-mine tests on DPF systems at the Stillwater Mining Company's underground platinum mine at Nye, MT. The tests were conducted in two phases. The Phase I tests were conducted from May 19–30, 2003, and the Phase II tests were conducted from September 8–12, 2003. The purpose of Phase I was to assess the effectiveness of DPM control technologies in an isolated zone. The purpose of Phase II was to assess the capability of DPFs to effectively control the exposure of underground miners to DPM in actual in-mine production mining scenarios.

NIOSH issued two final reports on these studies. The final report for Phase I was entitled ''Effectiveness of Selected Technologies in Controlling Diesel Emissions in an Underground Mine—Isolated Zone Study At Stillwater Mining Company's Nye Mine,'' and the report was released on January 5, 2004. NIOSH included the following in its discussion of the objective of the study:

> The objective of this study was to determine the in-situ effectiveness of the selected technologies available to the underground mining industry for reducing particulate matter and gaseous emissions from diesel-powered equipment. The protocol was established to determine the effectiveness of those technologies in an underground environment under operating conditions that closely resemble actual production scenarios.
>
> The study was designed to provide Stillwater, and the general mining community, with better insights into the performance of control technologies and enable them to identify the appropriate devices for reducing diesel emissions. The focus of the Stillwater research was on technologies that offer solutions for reducing DPM emissions. This report provides the results and assessment of the following control technologies: diesel particulate DPFs, disposable paper DPFs, diesel oxidation catalytic converter, and reformulated fuels.

The Phase II final report was entitled, ''An Evaluation of the Effects of Diesel Particulate Filter Systems on Air Quality and Personal Exposures of Miners at Stillwater Mine Case Study: Production Zone,'' and the report was released April 1, 2004. The objective of Phase II was to determine the effects of DPF systems installed on production equipment at the Stillwater Mine on workplace concentrations of EC and regulated gases in an actual production mining application where multiple diesel-powered vehicles operated simultaneously during full shift mining activities. The effects of DPF systems were examined by comparing ambient concentrations of EC, CO, CO_2, NO, and NO_2 in a production area for two different test conditions. For the baseline condition, all vehicles that operated within the ventilation split were equipped with standard exhaust systems—a diesel oxidation catalyst (DOC) and muffler—but without DPFs. For the second condition, three of the vehicles, an LHD and two haulage trucks had their DOC and muffler systems replaced with DPF systems.

The NIOSH Phase II study conducted at the Stillwater Mine is similar to the in-mine tests conducted by MSHA in January 2003 as a part of its compliance assistance program at the Kennecott Greens Creek Mine near Juneau, AK, which is discussed elsewhere in this preamble.

NIOSH Phase I study. The majority of the control devices tested were DPFs. Phase I also tested biodiesel fuel and the differences between #1 diesel fuel (D1) and #2 diesel fuel (D2). DPFs included both ceramic and high temperature disposable (synthetic media) filters. NIOSH reported that some problems did occur during the tests, mainly dealing with ventilation issues in the isolated zone and an occasional vehicle passing nearby the intake to the isolated zone. However, these problems were minor and did not compromise most tests.

As reported, NIOSH chose to normalize the data based on MSHA's nameplate gaseous ventilation rates. One commenter stated that he understood why NIOSH normalized the Phase I data to the MSHA nameplate, however, the commenter felt this was a disservice to the miners since M/NM mines do not have to comply with the ventilation rates on the approval plates. Indeed, engines in M/NM mines are not required to be MSHA approved and ventilation rates are not available for non-MSHA approved engines. MSHA agrees with the commenter that the Phase I report had the correct intent to normalize the data for reporting purposes. MSHA also agrees that the results may not be typical for operations in the M/NM sector because the ventilation schemes used by many M/NM mines do not comply with approval plate quantities for MSHA approved engines.

The Phase I report shows that the EC reduction in the isolated zone with one system was 88%, and that two other systems gave greater than 96% EC reductions when the measured concentrations were normalized by ventilation rate. NIOSH reported that several tests were discarded and not reported due to unexplainably low CO_2 concentrations found at low ventilation rates.

The filter media used in all the DPF systems during the Phase I test was either Cordierite, Silicon Carbide, or the disposable high temperature synthetic material. (An analysis conducted by an MSHA contracted laboratory indicated the synthetic material is fiberglass.) All the DPF media have very similar efficiencies for EC reductions. Even though NIOSH did not report the EC reduction efficiencies of all the DPF systems tested in Phase I, MSHA believes, based on its own evaluations, that the efficiencies for EC reductions of those DPFs not reported would have been approximately equal to the results obtained for DPF systems that were reported.

Many commenters agreed that the Phase I study accomplished its objective by showing that DPM filters are viable for reducing DPM from diesel engines and that the filter systems performed as designed. However, some of these commenters stated that the elaborate test setup in the Phase I study was only a replication of a laboratory type environment that did not represent actual mine conditions. Commenters pointed out that some of the control technologies did not perform as well as expected during the study.

MSHA agrees that the Phase I study demonstrated that DPM filters are an effective tool for reducing DPM emitted from diesel engines. The Phase I study did involve an elaborate test setup, but this test setup was primarily aimed at controlling the ventilation conditions so that extraneous DPM from upstream diesel traffic would be eliminated, thereby enabling a meaningful and accurate determination of the DPM reductions obtained by the various DPFs tested. In other respects, however, the test setup was quite realistic, in that the testing occurred underground and involved a realistic simulation of a production mining operation. For example, in testing of LHDs, the test protocol required a production LHD to repeatedly follow a proscribed duty cycle involving loading at a muckpile, tramming up a 9% grade along the main haulageway a distance of approximately 1,000 feet with a loaded bucket, various forward and reverse maneuvers over short travel distances at each end of the haulageway, and raising and lowering a loaded bucket to simulate loading a haulage truck. Other than the removal of existing exhaust system components (DOC and muffler) to accommodate installing the subject DPFs, and the installation of certain monitoring instrumentation, the equipment used in the study was unmodified and in ''as is'' condition from the mine's equipment inventory. Although this testing was based on simulated mining operations, the suggestion that it replicates a laboratory environment is an inaccurate characterization.

MSHA believes that the Phase I Isozone data is sound science, establishing with certainty that DPFs can be implemented on a broad scale in mines in the U.S. and that DPFs are capable of achieving significant reductions in miner's DPM exposures. MSHA notes that these data are consistent with the results of other similar tests, including both laboratory tests conducted by MSHA, NIOSH and others, and a Canadian in-mine isolated zone test in which NIOSH also participated. MSHA discussed the results of this Canadian test in the preamble to the 2001 final rule.

One commenter stated that the Phase I isolated zone test should have been completed long before the DPM rule was rushed to publication. MSHA does not agree with the commenter. In fact, MSHA used the results of the above mentioned Canadian isolated zone study in its original 2001 DPM rule to show the effectiveness of DPFs. The recent NIOSH isolated zone testing confirmed the results obtained by the Canadians. As noted above, the pertinent data that were derived from the Canadian study on the efficiencies of DPFs were referenced in the preamble to the 2001 final rule.

At the end of the Phase I report, NIOSH indicated that the Stillwater mine had at that time over one dozen DPFs in use for a combined total of over 22,000 operating hours. NIOSH reported that only one of these DPFs had failed (runaway regeneration), and that the other systems have been virtually maintenance free. Again, even though Stillwater's experiences with DPFs on a routine production mining basis have been with heavily platinum-catalyzed passive systems, the commercially available DPF media are the same for passive systems using other catalyst wash coats as well as for active regeneration systems that utilize uncatalyzed filter media. Moreover, all DPF media basically provide equivalent filtration efficiencies for DPM, TC, and EC.

NIOSH Phase II study. The Phase II study confirmed and expanded on the results obtained in the Phase I study. In the final report, NIOSH indicated that greater EC reductions were observed in the field than were obtained in the laboratory for whole diesel particulate:

> * * * laboratory determination of DPF efficiencies, based on reductions in total DPM mass (fairly equivalent to TPM [Total Particulate Matter]), substantially underestimates the ability of DPF systems to reduce EC emissions, the metric used by MSHA for compliance,* * *

which highlights the high EC filtration efficiency for DPFs.

MSHA believes that the Phase II study helped to confirm existing agency data that shows that it is technologically feasible to reduce miners' exposures to DPM to the 308_{EC} µg/m³ interim PEL. The Phase II study utilized three machines (1 LHD and 2 Haul Trucks) equipped for the first three days with highly platinum-catalyzed Englehard DPX® DPFs, and the last day without the DPFs, but with DOCs. The equipment engaged in normal production activities in a typical production mining area of the Stillwater mine, as opposed to the simulated mining tasks that were conducted in an isolated zone in the Phase I study. Personal sampling on equipment operators was conducted, as well as area sampling upstream and downstream from the working area where the equipment was operating. Tests were conducted with and without DPFs installed so that the capability of the DPFs to reduce personal DPM exposures and DPM levels in the ambient mine air could be quantified.

The results of the personal EC samples from the three machine operators equipped with filters were provided in the final report. NIOSH did not report Day 1 results due to inadequate sampling locations. The EC results for personal samples for Day 3 showed that the DPM exposures of all three miners were well below 308_{EC} µg/m³, and in fact, well below 160EC µg/m³. Day 2 showed exposures also below 308_{EC} µg/m³, but almost double the results of Day 3. However, it appears that the ventilation air flow through the working area on Day 2 was about half the ventilation air flow for Day 3. Thus, the differences in measured DPM levels are not contradictory, but rather, demonstrate the effectiveness of increased ventilation flow as an engineering control to reduce DPM levels in the ambient air. The EC reduction efficiencies of the DPFs based on personal exposures comparing test days with and without the filters in place were approximately 71% for the LHD operator and 78% for the haul truck drivers. These reductions are very similar to the results obtained for personal exposures in the Greens Creek study conducted by MSHA in January 2003.

NIOSH reported that some of the filters used during the Phase II testing at Stillwater may have been compromised. However, NIOSH indicated in the Phase II final report that, ''* * * even when the DPF systems are performing below expectations, they can significantly reduce the EC concentrations when compared to conditions when DPF systems were not used.'' Significantly, MSHA made a very similar observation in its report on Greens Creek. During testing at Greens Creek, there were obvious visible cracks in some of the ceramic media. But analysis of DPM concentrations in the equipment exhaust indicated that EC filtration efficiency was still quite high (>90%) despite the cracks. Clearly, even compromised DPM filters can reduce personal DPM exposures to levels below the interim PEL.

NIOSH reported increased NO_2 concentrations during the study when using DPFs, and suggested that the source of the increase was the platinum catalyst used as a wash coat for the Cordierite filter media. The platinum wash coat on the filter is used for regeneration purposes and does not affect filter efficiency for EC measurements. Therefore, the reduction observed in EC concentrations from the Phase II study should be expected when any filter is installed that has a Cordierite filter media. As discussed elsewhere in this preamble, a Silicon Carbide filter media is also used in many DPF systems and EC filtering efficiency for Silicon Carbide is very similar to Cordierite.

As noted above, NIOSH reported increases in NO_2 concentrations when highly platinum-catalyzed DPFs were used. NIOSH stated in the Phase I final report that ''* * * if the required MSHA ventilation rates were maintained during the tests, the average concentration of NO_2 over the test periods would have not exceeded 3 ppm, the long term exposure limit for NO_2.'' The greatest increase in NO_2 during the Phase I study came from the highly platinum-catalyzed DPF. When this filter was used, the ceiling limit of 5 ppm was briefly exceeded each time the equipment repeated the duty cycle. These NO_2 peaks were noted at the downstream sampling location and at about the same levels at a sampling location on the equipment near the operator's position.

NIOSH stated in the Phase II report that tests 2 and 3 (with DPF installed) were terminated when the multi-gas monitor carried by the equipment operator indicated that the 5 ppm NO_2 ceiling limit had been exceeded. NIOSH reported that they also believe the NO_2 level may have been above 5 ppm for personal exposure on test 4 when the DPFs were not installed on the machines (DOCs were installed on test 4).

Although tests 2 and 3 were terminated earlier than planned, these tests lasted between approximately 2¾ hours and 4¾ hours, respectively. MSHA believes that these tests were sufficient in duration to demonstrate the differences in EC exposures with and without DPFs. At most mines, mucking operations in an individual stope or development end are usually completed within 2–4 hours. In fact, the Greens Creek report results were based on approximately 2–3 hours of sample time, which was the total time required to muck out the subject stopes.

From the intake side to the return side of the Phase II test zone, average NO_2 increase as reported were 1.2 ppm for Day 2, and 1.1 ppm for Day 3 with DPFs. The average NO_2 increase was 1.1ppm for Day 4 with DOCs. It is significant to note that these increases are consistent with the NO_2 increases observed during the Greens Creek tests, and would not be expected to result in hazardous NO_2 exposures in mines with adequate ventilation. It should also be noted that there was no significant difference between average NO_2 increases with and without DPFs in the test area (the DPFs were replaced by DOCs on Day 4).

As stated above, NIOSH noted that Phase II tests 2 and 3 were terminated early due to excessive NO_2 levels measured in the cabs of the test equipment. Due to the layout of the area where Phase II tests were conducted, it is likely that the vehicles experiencing the highest NO_2 levels were operated for part of the duty cycle in a lower quantity of ventilation air than was available in the main haulageway. The observed personal overexposures to NO_2 occurred when the haul trucks were in this poorly ventilated area where the intake air split at an orepass and a development section. MSHA believes that if the air flows to these locations had been maintained at levels near the nameplate value, the overexposure to NO_2 would very likely not have occurred.

It should be noted that MSHA has documented very low ventilation air flows in several stopes at the mine where NIOSH's Phase II study was conducted. Ventilation measurements obtained by MSHA during a compliance assistance visit to the mine in June 2004 identified significant leakages from most of the auxiliary stope ventilation systems that were evaluated. In the six stopes for which ventilation air flow measurements could be obtained at both the auxiliary fan location and at the end of the vent bag, the average air flow at the fan location was 24,400 cfm and the average flow at the end of the vent bag was 5,100 cfm. In one stope, auxiliary ventilation system leakage was 89% and in another, leakage was 85%. Even in stopes where auxiliary system leakage was relatively low, significant recirculation was observed. With stope ventilation flow rates compromised to this extent due to auxiliary system leakage and recirculation, it is not surprising that both high gaseous emission levels and high DPM emissions have been measured at this mine.

The NIOSH Phase II data show that gaseous contaminant levels and ventilation flows had stabilized in the test area a short time after the testing was initiated (within approximately the first 30 minutes), indicating that roughly steady-state conditions had been achieved. If tests 2 and 3 had not been terminated prematurely (*i.e.*, if the poorly ventilated area had been sufficiently ventilated), it is therefore likely that the reported DPM and gaseous emission levels could have been maintained indefinitely, or at least until mining operations were completed in the test area.

As stated earlier, MSHA advised mine operators through the issuance of a PIB that the use of highly platinum-catalyzed DPFs has the potential to increase concentrations of NO_2. The increases in NO_2 observed during the Stillwater Phase I and Phase II tests demonstrate that mine operators who choose to use highly platinum-catalyzed DPFs must maintain sufficient ventilation in areas where the machines operate, and must monitor for any increases in NO_2. This advice is particularly important for mines that had experienced NO_2 problems prior to the introduction of platinum wash-coated DPFs, as was the case at the Stillwater mine. Where NO_2 levels cannot be adequately controlled by ventilation, alternatives to highly platinum-catalyzed passive filter systems are commercially available which do not increase ambient NO_2 levels. An example that is particularly well suited to heavy duty applications is the fuel burner type active regenerating DPF. A system of this type is currently installed and under evaluation at the Stillwater mine.

The results of these studies support MSHA's position that feasible control technology exists that is commercially available to effectively reduce miner exposures to DPM. As with any new mining machinery, mine operators will need to thoroughly evaluate their needs prior to ordering DPF systems to insure that each system is appropriate to the piece of equipment, engine, application, and duty cycle. Failure to appropriately consider these factors will likely result in poor filter performance, poor engine performance, possible engine and filter damage, or all of the above. Alluding to this issue, NIOSH states in the Phase II study final report that, ''Due to the nature of the study, Phase II did not address other and no less important matters relating to the application of control technologies in underground mines. These matters include selection of DPF regeneration strategies, economic, logistical, and technical feasibility of implementation of various DPF systems on mining vehicles, and the reliability and durability of the systems in mine settings.''

MSHA has consistently stated that the application of commercially available DPF systems is a task that requires mines to evaluate machine installations on a case by case and application by application basis. NIOSH agrees. Consequently, NIOSH and MSHA jointly developed an on-line Internet-based Filter Selection Guide which is discussed elsewhere in this preamble. NIOSH's written response to MSHA in this rulemaking supports the use of DPFs as a control device that can significantly reduce DPM exposures, but also states that the mine operator must evaluate each machine prior to selection and installation of DPM filter systems to insure a successful match between filter and application. When properly selected and installed for an application, DPFs are both durable and mine worthy. Almost without exception, failed DPFs that have been reported to MSHA were the result of inappropriate filter selection, manufacturer defect, or the failure of an unrelated component (usually the turbocharger) that affected the DPF.

Active Regeneration DPFs. The active regeneration systems discussed below are normally not catalyzed so they do not produce an increase in NO_2.

TABLE VII–2.—SCENARIOS FOR ACTIVE REGENERATION.

System name	Regenerating location	Regenerating controller location	Comments
On-board	On Equipment	On Equipment	Requires on-board source of electric power.
On-board	On Equipment	Designated and fixed-location.	Requires equipment to come to a specific regeneration site.
Off-board	Off equipment	Fixed-location	DPFs are exchanged and must be small enough to be handled by one person. Increases number of DPFs needed.
On-board	On-equipment	On-equipment during operation.	System is complex yet fuel burner provides advantage of regeneration during equipment use.

Scenarios for active regeneration systems are listed in Table VII–2. The second system listed in Table VII–2 is an on-board active system that requires about one to two hours of machine down time for regeneration, which might be available between shifts at some mines. To regenerate these filters, the piece of equipment must be parked at a designated location during the regeneration period so that the filter can be connected to electrical power and compressed air. MSHA recognizes that presently in some mines, production equipment is not necessarily brought to a central location at the end of each shift. At such mines, operators may need to make operational changes to accommodate such DPF regeneration designs.

Alternatively, mine operators may choose off-board active regeneration type filters, wherein, for example, the equipment operator removes the DPF at the end of the shift and brings it to a central station for regeneration. The next operator of that piece of equipment takes a regenerated DPF to the equipment at the start of the next shift. This system enables uninterrupted equipment operation, and does not require the equipment to travel to a central location for filter regeneration at the end of the shift. Where active off-board filters are used, the size and weight of the filter element is a significant factor in filter selection and overall system feasibility, as mine personnel need to be capable of removing the filter at the end of the shift and transporting it to a central regeneration station. Multiple DPFs may be installed on a machine in place of a single large filter in order to decrease the size and weight of individual DPFs.

Engine malfunctions and effects on DPF. Normally in mining, engine malfunctions are indicated by excessively smoky exhaust. That indicator will not occur when a DPF system is installed. Malfunctions such as excessive soot emissions, intake air restriction, fouled injector, and over-fueling, may result in an abnormal rise in back pressure in systems that do not spontaneously regenerate. Also, these conditions could lead to abnormal changes in back pressure in passive systems because the malfunction may raise exhaust temperatures causing the excess soot to be burned off. These malfunctions may be detected during the usual 250-hour maintenance and emissions checks conducted upstream of the DPF using carbon monoxide (CO) as an indicator. The other major filter malfunction is excessive oil consumption that is sometimes associated with blue smoke that could be masked by the performance of the DPF. However, excessive oil consumption leads to a rapid increase in baseline backpressure due to ash accumulation. Excessive oil consumption can be detected if records are kept on oil usage.

Detecting malfunctioning DPF. As noted above, the DPF can be damaged mainly by thermal events such as thermal runaway. Shock, vibration, or improper ‘‘canning’’ of the filter element in the DPF can also lead to leaks around the filter element. A Bacharach/Bosch smoke spot test can be used to verify the integrity of a DPF. Smoke spot numbers below ‘‘1’’ indicate a good filter; smoke numbers above ‘‘2’’ indicate that the DPF may be cracked or leaking. Smoke spot and CO tests during routine 250 hour preventative maintenance are good diagnostic practices. Note that although a smoke spot number above ‘‘2’’ may indicate a cracked or leaking filter, such a result does not necessarily mean the filter has ‘‘failed’’ and is not functioning adequately. In MSHA evaluations of DPF performance at the Greens Creek mine, filters that tested with smoke numbers above ‘‘2’’ of 7 were still shown to be over 90% effective in capturing EC, based on subsequent NIOSH 5040 analysis of the smoke spot filters.

Low DPM-Emitting Engines. Through its 2003 and 2004 compliance assistance mine visits and a review of its nation-wide inventory of diesel engines used in underground M/NM mines, MSHA has determined that hundreds of low DPM emission engines have been introduced into underground M/NM mines in recent years. MSHA notes that, for many mines in the stone sector, use of low emission engines has been one of the primary means of achieving compliance with the interim PEL.

EPA and European on-highway and non-road engine emission standards have forced engine manufacturers to reduce both DPM and gaseous emissions from their engines. Mine operators can purchase newer design engines with low DPM emissions in their new diesel-powered equipment as well as retrofitting such engines in their older equipment.

As noted earlier in this section of the preamble, the amount of DPM reduction that can be obtained by switching to low DPM emitting engines depends on the emission rate of the original engine compared to the emission rate of the replacement engine. For example, if the original engine emits 1.0 gram of DPM per horsepower per hour of operation, and the replacement engine emits 0.2 grams of DPM per horsepower per hour of operation, the engine replacement would achieve an 80% reduction in emitted DPM. Other benefits of newer technology engines include better fuel economy and more efficient maintenance diagnostics. The improved maintenance diagnostics associated with electronic engine monitoring systems enable lower overall equipment operating costs as well as allowing mine operators to better monitor their engines and provide the appropriate maintenance to keep exhaust emissions as low as possible.

During the compliance assistance visits to mines that had at least one baseline DPM sample result exceeding the interim DPM limit, MSHA observed numerous new or nearly new pieces of equipment powered by Original Equipment Manufacturer (OEM)-installed MSHA-Approved engines that had very high DPM emissions. The operators at these mines indicated that they were unaware of the DPM emissions of the engines that were supplied in the equipment they had just purchased. They believed that by specifying an MSHA-Approved engine, they would be in full compliance with the rule. While it is true that MSHA-Approved engines satisfy the requirements of § 57.5067, not all MSHA-Approved engines are necessarily low in DPM emissions. Non-Approved EPA Tier 1 (for engines less than 50 horsepower or 175 horsepower and greater) and Tier 2 (for engines of 50 horsepower or greater, but less than 175 horsepower) engines are also compliant with § 56.6067, but they have lower DPM emissions. During the compliance assistance visits, and in subsequent discussions with the Equipment Manufacturer's Association (EMA), MSHA emphasized the need for modern low DPM emission engines to be installed in new machines earmarked for the underground mining industry.

Ventilation Upgrades. Several commenters expressed the view that ventilation system upgrades, though potentially effective in principle, would be infeasible to implement for many mines. Specific problems that could prevent mines from increasing ventilation system capacity include inherent mine design geometry and configurations (drift size and shape), space limitations, and other external prohibitions, as well as economic considerations.

MSHA acknowledges that ventilation system upgrades may not be the most cost effective DPM control for many mines, and for others, ventilation upgrades may be entirely impractical. However, at many other mines, perhaps the majority of mines affected by this rule, ventilation improvements would be an attractive DPM control option, either implemented by itself or in combination with other controls.

Indeed, MSHA observed during its DPM compliance assistance visits that ventilation upgrades have been implemented at many mines in the stone sector for DPM control, directly contradicting the commenters' assertion that ventilation upgrades are infeasible. Nearly every stone mine visited by MSHA had completed, had begun, or was planning to implement ventilation system upgrades.

At many high-back room-and-pillar stone mines, MSHA observed ventilation systems that were characterized by (1) inadequate main fan capacity (or no main fan at all), (2) ventilation control structures (air walls, stoppings, curtains, regulators, air doors, brattices, etc.) that are poorly positioned, in poor condition, or altogether absent, (3) free standing booster fans that are too few in number, too small in capacity, and located inappropriately, and (4) no auxiliary ventilation for development ends (working faces). At some mines, the ''piston effect'' of trucks traveling along haul roads underground, along with natural ventilation pressure, provide the primary or only driving forces to move air.

In naturally ventilated mines, temperature-induced differences in air density between the surface and underground result in natural air flows through mine openings at different elevations. Warmer and lighter mine air rises up out of a mine during the colder winter months, which draws in cooler and heavier air at lower elevation mine openings. In the summer, cooler and denser mine air flows out of lower elevation openings, which draws warmer less dense air into higher elevation openings. Under the right conditions, such air flows can be significant, but they are usually inadequate by themselves to dilute and carry away DPM sufficiently to reduce miners' exposures to the interim limit.

The other principal shortcoming of natural ventilation is the inherent lack of a method of controlling air flow quantity and direction. Ventilation air flows can slow or stop when temperature differences between the surface and underground are small (common in the spring and fall), and the flow direction reverses between summer and winter, and sometimes even between morning and afternoon.

Mine operators normally supplement natural ventilation with booster fans underground. However, if overall air flow is inadequate, as is usually the case with naturally ventilated mines, and when mine elevation differences or surface and underground temperature differences are small, booster fans are largely ineffective.

The all too frequent result of these deficiencies is a ventilation system that is plagued by insufficient dilution of airborne contaminants, short circuiting, recirculation, and airflow direction and volume that are not controllable by the mine operator. These systems are barely adequate (and sometimes inadequate) for maintaining acceptable air quality with respect to gaseous pollutants (CO, CO_2, NO, NO_2, SO_2, etc.), and are totally inadequate for maintaining acceptable concentrations of DPM. Mines experiencing these problems could benefit greatly from upgrading main, booster, and/or auxiliary fans, along with the construction and maintenance of effective ventilation control structures.

MSHA believes that ventilation upgrades alone, along with the normal turnover of engines to newer, low-polluting models, may be sufficient for many stone mines to achieve compliance with the interim DPM limit. Consequently, MSHA has urged the mining industry to utilize mechanical ventilation to improve overall air flows and to enable better control of ventilating air.

Ventilation fan upgrades for the stone mining sector are usually relatively inexpensive due to the low mine resistance associated with large openings. In many of these mines, a 250,000 cfm air flow can be obtained at less than 1 inch of water gage pressure. This air flow can be provided by a 50 horsepower motor. The major cost in these applications is usually distribution of the air flow underground to insure that adequate air quantities reach the working faces rather than short-circuiting to a return or recirculating around free-standing booster fans. Good air flow distribution requires such practices as installing or repairing ventilation control structures (brattice line, air curtains, etc.) or changes in mine design to incorporate unmined pillars as air walls.

Deep multi-level metal mines have entirely different geometries and configurations from high-back room-and-pillar stone mines. They typically require highly complex ventilation systems to support mine development and production. These systems are professionally designed, they require large capital investments in shafts, raises, control structures, fans, and duct work, and they are costly to maintain and operate. At these mines, high ventilation system costs provide a major economic incentive to operators to optimize system design and performance, and therefore, there are typically few if any feasible upgrades to main ventilation system elements that these mines haven't already implemented, or would have implemented anyway, whether or not the DPM rule existed. Accordingly, and though it remains an option that might be attractive in new development, MSHA expects very few mines of this type to implement major ventilation system upgrades to achieve compliance with this rule.

Despite the built-in incentives to design and operate efficient ventilation systems, however, MSHA has observed aspects of ventilation system operation at such mines that can be improved, usually relating to auxiliary ventilation in stopes. Auxiliary fans are sometimes sized inappropriately for a given application, being either too small (not enough air flow) or too large (causing recirculation). Auxiliary fans are sometimes poorly positioned, so that they draw a mixture of fresh and recirculated air into a stope. Auxiliary fans are sometimes connected to multiple branching ventilation ducts, so that the air volume reaching a particular stope face may be considerably less than the fan is capable of delivering. Perhaps most often, the ventilation duct is in poor repair, was installed improperly, or has been damaged by blasting or passing equipment to the extent that the volume of air reaching the face is only a tiny fraction of that supplied by the fan. MSHA believes that these and similar problems exist at many mines, even if the main ventilation system is well designed and efficiently operated.

An example is the mine where NIOSH conducted its Phase II Production Zone study of DPFs. As noted earlier, several auxiliary stope ventilation systems were evaluated by MSHA during an extended compliance assistance visit to this mine in June 2004. In the six stopes for which ventilation air flow measurements could be obtained at both the auxiliary fan location and at the end of the vent bag, the average air flow at the fan location was 24,400 cfm and the average flow at the end of the vent bag was 5,100 cfm. Auxiliary ventilation system leakage was 89% in one stope and 85% in another. Even in stopes where auxiliary system leakage was relatively low, significant recirculation was observed.

Optimized auxiliary ventilation system performance alone, as one commenter noted, will not necessarily insure compliance with the DPM interim limit. Auxiliary ventilation systems simply direct air to a stope face so that the DPM generated within the stope can be diluted, transported back to, and carried away by the main ventilation air course. If this air is already heavily contaminated with DPM when it is directed into a stope, as could happen at mines employing series or cascading ventilation, its ability to dilute newly-generated DPM is diminished. In these situations, the intake to the auxiliary system must be sufficiently clean to achieve the desired amount of dilution, requiring implementation of effective DPM controls upstream of the auxiliary system intake. Such upstream controls might include a variety of approaches, such as DPM filters, low-polluting engines, alternate fuels or fuel blends, and various work practice controls, as well as main ventilation system upgrades at the few mines where they might be feasible. Toward the return end of a series or cascading ventilation system, if the DPM concentration of the auxiliary system intake is still excessive, other engineering control options would include enclosed cabs with filtered breathing air on the equipment that operates within the stope, or remote control operation of the equipment in the stope to remove the operator from the stope altogether.

Environmental Cabs With Filtered Breathing Air. Cabs on mobile equipment and control rooms or booths for stationary installations, if provided with filtered breathing air, can be highly effective for reducing personal DPM exposures. MSHA has determined that environmental cabs can reduce operator exposures to DPM by 50% to 80%. In addition, such cabs and booths can significantly reduce exposures to harmful noise and dust, and they can also improve equipment operator comfort and productivity.

The majority of equipment used in underground M/NM mining, especially in stone mines, have suitable cabs installed. However, MSHA has observed that many cabs, due to poor maintenance and operating practices, fail to provide effective control of DPM exposure. Typical problems are broken windows, ineffective door seals, inoperative AC systems and fans, plugged or missing air filters, openings into the cab where hoses or cables enter, and lack of company policies requiring doors and windows to be maintained in the closed position during operations.

Some cab ventilation and filtration systems are undersized for the volume of air they should be moving. During MSHA's compliance assistance visits in 2003, MSHA observed numerous pieces of equipment, especially face drills, that were equipped with undersized cab air filtration systems. Research has shown that cab ventilation systems should be sized to achieve approximately one-half to one air change per minute in their respective cabs. For example, a 100 cubic foot cab should be ventilated by a system having the capacity to move 50 to 100 cubic feet per minute. Cabs should also be sealed to obtain a positive pressure greater than 0.2 inches of water gage.

MSHA DPM-Related Compliance Assistance. As noted earlier, MSHA has engaged in extensive DPM-related compliance assistance since the existing rule was issued in 2001, and these activities are continuing. Compliance assistance has included seminars at various locations throughout the country, hands-on sampling training workshops, the online Filter Selection Guide, a compliance guide, a ''single source'' internet Web site devoted to underground M/NM DPM issues, DPM baseline sampling at all mines affected by the rule, online listings of MSHA-Approved diesel engines and DPF efficiencies, the Estimator, and on-site compliance assistance visits at dozens of mines, among others.

MSHA continues to consult with the M/NM Diesel Partnership (the Partnership). The Partnership is composed of NIOSH, industry trade associations, and organized labor. MSHA is not a member of the Partnership due to its ongoing DPM rulemaking activities. The primary purpose of the Partnership is to identify technically and economically feasible controls to curtail particulate matter emissions from existing and new diesel-powered vehicles in underground metal and nonmetal mines.

MSHA's diesel testing laboratory located in Triadelphia, WV has been active in evaluating many DPM control technologies. An example is the investigation to characterize NO_2 emissions from catalyzed DPFs. As a result of this work, MSHA provided information to the mining community on the effects of catalyzed DPF's on NO_2 production. MSHA's laboratory determined under steady state engine operating conditions, that a heavily platinum-catalyzed DPF would increase the NO_2 concentration measured in the raw exhaust after the exhaust gas passed through the DPF. The increase in NO_2 was compared to the required gaseous ventilation rate for the test engine without the DPF installed. The laboratory data showed that the gaseous ventilation rate would increase with a highly platinum-catalyzed DPF installed. MSHA's laboratory also tested DPFs that were either specially catalyzed with platinum (lower wash-coat platinum content) or a base metal wash-coat (no platinum used). The results of the laboratory tests showed no increase in the gaseous ventilation quantity when compared to the quantity without the DPFs installed. MSHA provided the industry with a Program Information Bulletin (PIB) P02–04, ''Potential Health Hazard Caused By Platinum-Based Catalyzed Diesel Particulate Matter Exhaust Filters,'' dated May 31, 2002. This PIB is located on MSHA's web page at the following internet address: *http://www.msha.gov/regs/complian/PIB/2002/pib02–04.htm.* The PIB states that mine operators that choose to use catalyzed DPFs that have shown an increase in NO_2 in the laboratory need to ensure that the machines installed with these filters have adequate ventilation, and recommends that personal monitoring for NO_2 should be performed.

MSHA also provides an updated list on the internet of DPFs that have been evaluated by MSHA. The internet address is: *http://www.msha.gov/01–995/Coal/DPM-FilterEfflist.pdf.* This list is divided into three tables. Table I includes paper and synthetic filters, mainly intended to be disposable. These DPFs are only used when the exhaust gas temperature is maintained to below 302°F, as is required in inby areas of gassy mines. This is normally accomplished by the use of an exhaust gas heat exchanger. Temperature sensors and backpressure sensors must be used with these filters to protect the DPF from exhaust gas temperatures that would exceed 302 °F or backpressures that would exceed the engine manufactures allowable limit. Table II lists ceramic and high temperature disposable pleated element media DPFs that do not increase the concentration of NO_2 in the exhaust. Table III lists the DPFs that are platinum-catalyzed and have been determined in the laboratory to increase NO_2 concentrations above the test engine's gaseous ventilation rate.

MSHA's laboratory has also conducted limited tests on several control technologies other than DPFs. Evaluations have been conducted on an Ecomax which consists of a series of magnets installed on the fuel system lines, Rentar, an in-line fuel catalyst installed in the machine's fuel line, and the Fuel Preporator, a system for removing collected air from the fuel system design for better fuel combustion. The test results of the laboratory evaluations were inconclusive in demonstrating significant reductions in whole diesel particulate, however the data did not show any adverse effects on the raw DPM exhaust emissions.

NIOSH also analyzed the Rentar and Fuel Preporator for their EC reduction potential. NIOSH's results were consistent with MSHA's results, and showed no significant EC reductions and no adverse effects on the engine emissions.

MSHA's laboratory evaluated the changes in engine exhaust emissions when operating at high altitudes (greater than 1000 feet in elevation). MSHA used two electronic fuel injected engines for the test, a Mercedes 904 and a Deutz BF4M 1013FC. MSHA first conducted field tests at engine laboratories located at 4000 feet and 6700 feet. Next, MSHA brought the two test engines to its laboratory. Using an altitude simulator setup, MSHA verified the accuracy of the simulator and ran various tests to evaluate the effects of altitude on the gaseous emissions and DPM. This high altitude work led to the development of guidelines that MSHA is using for approving diesel engines under 30 CFR, part 7, subpart E for engine operation above 1000 feet.

MSHA received comments suggesting that its compliance assistance visits at various mine sites support the position that the DPM rule, even at the 400_{TC} µg/m³ interim limit, is economically and technologically infeasible. MSHA did visit a number of mines that were not in compliance with the interim DPM limit to provide compliance assistance, but at each such mine, the operator was presented with recommendations for utilizing feasible engineering and work practice controls for attaining compliance. MSHA determined that these mines were out-of-compliance not because it was infeasible for them to attain compliance, but because the respective mine operators had not yet fully implemented all feasible controls that were available to them.

MSHA's compliance assistance work at the Greens Creek mine included an evaluation of DPM reductions obtained using heavily platinum-catalyzed ceramic DPFs that relied on passive regeneration. The machines were equipped with engines ranging from 300 to 475 horsepower. The results of this testing showed that personal DPM exposures for the subject equipment operators (loaders and haulage trucks) were reduced by 57% to 70% when the DPFs were installed. The use of the ceramic DPFs reduced the average engine emissions by 96%.

The Greens Creek report also showed that high DPM reductions (>90%) occurred even when a ceramic filter was compromised by cracking around the edges. This cracking was determined to be caused by a manufacturing defect related to the ''canning'' process (securing the ceramic filter in a stainless steel ''can'' for installation on the subject diesel equipment). Through discussions with the manufacturer, Greens Creek resolved the problem, and DPFs delivered since then have performed satisfactorily without any cracking. In addition, the use of environmental cabs reduced the DPM concentrations (*i.e.*, concentration inside the cab versus outside the cab) by 75% when DPFs were used and 80% when DPFs were not in use.

As expected, NO_2 increases were observed during these tests because the mine operator was using heavily platinum-catalyzed DPFs. However, the increases were so small (about 1 ppm in the downstream air flow compared to the upstream air flow in the area where a loader and two or three trucks were operating) that it was unclear whether the cause was data variability, slight changes in ventilation rate, or the use of heavily platinum-catalyzed DPFs. Greens Creek stated in its comments to this rulemaking that a 1–2 ppm increase in NO_2 is experienced when highly platinum-catalyzed DPFs are used, but that this increase has been manageable for the mine.

MSHA agrees that a highly platinum-catalyzed filter may increase NO_2 levels based on engine duty cycle and ventilation. NO_2 is formed from NO in the engine's exhaust in the presence of the catalyst. This reaction occurs at exhaust gas temperatures of approximately 325°C. This temperature is also the temperature at which the platinum catalyst will allow for passive regeneration. Manufacturers of platinum-catalyzed DPFs have normally wash-coated their filters with large amounts of platinum to make sure that the DPFs will regenerate. This large concentration of platinum, in combination with the relatively long retention time of the exhaust gas in the filter, results in the formation of NO_2.

Manufacturers have been evaluating wash-coat formulations containing less platinum loading to lower the NO_2 effects. Catalytic converters are also wash-coated with platinum; however, the loading used on catalytic converters is lower than ceramic DPFs, and due to faster movement of the exhaust gas through the catalytic converter compared to the ceramic filter, NO_2 increases are minimal. One manufacturer provides an exhaust gas recirculation system (EGR) that reduces both oxides of nitrogen (NO_X) and DPM when used in combination with a DPF.

Mine operators also have the option of using DPFs that are not heavily wash-coated with a platinum catalyst. One manufacturer offers a lightly platinum-catalyzed DPF that is used in conjunction with a platinum-cerium fuel-borne catalyst (Fuel additive). This system has a slightly higher passive regeneration temperature requirement than heavily platinum-catalyzed DPFs, but it produces no excess NO_2. Other options which do not produce excess NO_2 include base metal catalyzed passive regenerating DPFs, and various on-board and off-board active regenerating DPFs. As noted earlier, part of the DPF selection process involves an evaluation of potential NO_2 problems along with related ventilation issues. Where NO_2 exposures could be problematic, MSHA recommends that heavily platinum-catalyzed DPFs be avoided.

Table VII–1 provides information in the ''Comments'' column on the effects of DPF catalysts on NO_2 emissions. MSHA has tested in their laboratory the types of DPFs listed, and has posted on its website a list of the DPFs that can cause NO_2 increases from the engine and those catalytic formulations that do not significantly increase NO_2.

MSHA is currently not aware of problems with overexposure to NO_2 at mines using platinum-catalyzed DPFs on a routine production basis, where the overexposures are uniquely related to the DPFs. One mine operator that had been experiencing frequent overexposures to NO_2 noted that these overexposures ceased after a major ventilation upgrade, despite increased use of heavily platinum-catalyzed DPFs.

PIB #02–04 alerted mine operators that the platinum-catalyzed DPFs identified on MSHA's website could increase NO_2. MSHA continues to advise mine operators to monitor for any increases in ambient NO_2 concentrations with the addition of platinum-catalyzed DPFs to their inventory.

When NIOSH's Phase II study tests 2 and 3 were terminated prematurely due to high NO_2 levels, the overexposures were determined to be due mainly to insufficient ventilation. As discussed previously, the average increase in NO_2 from the use of platinum-catalyzed DPFs in the test area was approximately 1 ppm, but brief 3–5 ppm spikes were also observed. As stated above, mine operators are advised to sample for NO_2 when platinum wash-coated DPFs are used to ensure miners are not overexposed. Mine operators who use platinum-catalyzed DPFs should maintain ventilation systems that are able to remove or dilute the NO_2 to a non-hazardous level, and they must be aware of localized areas where NO_2 could build up more quickly and create a health hazard for exposed miners.

As discussed in the Greens Creek report, the use of catalyzed DPFs at that mine did not produce substantial increases in NO_2 levels. MSHA is continuing to work with filter manufacturers to evaluate catalytic formulations on NO_2 generation.

Stillwater mine DPM compliance. In its comments addressing the 2003 NPRM, Stillwater Mining Company (SMC) provided discussion and several tables detailing its estimated DPM-related compliance costs. In its April 2004 comments in response to the February 20, 2004 limited reopening of the public record on this rulemaking, SMC provided further discussion and another compliance cost summary table which grouped cost elements into major categories. These estimates totaled about $114 to $117 million over a 10 year period.

Using the Stillwater compliance cost estimates and other information obtained by MSHA during visits to the Stillwater mine, MSHA analyzed and evaluated Stillwater's estimated costs and developed a compliance cost estimate for this mine based on an alternative DPM control strategy. This analysis and evaluation is discussed below, and a summary is provided in Table VII–3. MSHA conducted this analysis and evaluation to demonstrate both to Stillwater and to other mines having some of the same or similar equipment, mine layouts, and operating practices that their choice of control strategy can significantly impact overall compliance costs, and therefore, the feasibility of compliance.

MSHA's estimated yearly compliance costs for this mine, which are based largely on the itemized cost estimates provided by Stillwater, are between $1.24 million and $2.09 million per year. The lower end of this range relates to estimated compliance costs not including a recent $9 million ventilation upgrade. As discussed below, although Stillwater included the cost of this upgrade in its estimated DPM compliance costs, MSHA believes this cost item should not be considered DPM-related, or is only partially attributable to DPM compliance because the ventilation system at this mine required a major upgrade anyway, independent of DPM issues. MSHA's $2.09 million yearly compliance cost estimate includes the $9 million ventilation upgrade.

Although Stillwater's DPM-related compliance costs will be significant, they are not substantially different from expectations based on MSHA's 2001 REA. In the REA for the 2001 final DPM rule, MSHA determined that annual compliance costs would be about $128,000 for an average underground M/NM mine. However, Stillwater's mining operations are not representative of an average mine. Its fleet of 350+ pieces of diesel equipment is many times larger than the average mine's. MSHA's estimated yearly DPM-related compliance costs for large precious metals mines included in the REA was $659,987, based on a fleet size of 133 diesel vehicles. Stillwater's fleet is about 2.6 times larger than the 133 vehicle basis for this estimate. Thus, yearly compliance costs of 2.6 × $659,987, or $1.72 million for Stillwater would be consistent with the 2001 REA's compliance cost estimate for a precious metals mining operation of this size.

If the cost of Stillwater's recent ventilation system upgrade is not included as a DPM compliance cost, which as noted below, is a reasonable determination based on long-standing ventilation system deficiencies at this mine, Stillwater's estimated yearly compliance cost would be $1.24 million. As noted in the preceding paragraph, by way of comparison, an estimated compliance cost of $1.72 million for a precious metals mine of this size would be consistent with the 2001 REA. If, however, the entire ventilation system upgrade is considered DPM-related, MSHA's estimated yearly compliance cost of $2.09 million for Stillwater would be about 22% higher than expected, based on the 2001 REA. If the entire ventilation system upgrade is considered DPM-related, but the annual savings resulting from the associated reduction in ventilation fan power consumption is deducted from the annualized cost of the upgrade, MSHA's estimated yearly compliance cost of $1.57 million for Stillwater would be about 9.5% less than expected, based on the 2001 REA.

For MSHA's analysis and evaluation, Stillwater's DPM compliance costs were grouped into six major cost categories. The analysis and evaluation of these six major cost categories is discussed below:

1. Ventilation. As noted above, a $9 million ventilation upgrade was recently completed at the Stillwater mine, and the cost of this upgrade was included by Stillwater in its DPM compliance cost estimate. However, MSHA believes this upgrade would have been necessary with or without a DPM rule due to ongoing air quality problems and plans for increased mine development. Thus, this expenditure should not be considered a DPM compliance cost, or at most, only partially a DPM compliance cost.

Total ventilation at the mine prior to the upgrade was about 627,000 cfm, corresponding to approximately 52 cfm/actual utilized horsepower. After the upgrade, total ventilation volume increased to 840,000 cfm, which is about 69 cfm/actual utilized horsepower.

Most of Stillwater's diesel equipment has MSHA nameplate ventilation rates between 50 and 70 cfm/horsepower. These laboratory derived values indicate the ventilation necessary to maintain compliance with MSHA exposure limits for CO, CO_2, NO, and NO_2. Taking into account such practical in-mine factors as varying equipment duty cycles, imperfect mixing, use of DOCs, etc., acceptable air quality can sometimes be attained at ventilation rates somewhat less than the nameplate values. However, other factors, including out-of-tune engines, marginal auxiliary ventilation system performance, on-shift blasting, and heavy concentrations of diesel equipment in particular sections of a mine can result in chronic localized noncompliance with gaseous emission limits.

For example, Stillwater has had a persistent problem with NO_2 overexposures for many years, indicating inadequate ventilation. Per company policy, whenever an NO_2 monitor (carried by equipment operators) exceeded 5 dpm at the operator's location, that operator was removed to the surface. The mine operator has frequently removed miners to the surface for this reason over recent years. Thus, the ventilation upgrade was overdue, even without consideration for DPM levels underground.

Other considerations also factored into the decision to carry out the ventilation upgrade, including planned production tonnage increases, the need to utilize trucks to haul ore up grade from below the level of the shaft bottom, an excessive number of booster fans (sometimes competing with each other for limited air), and the desire to increase the number of ventilation intakes into the mine (resulting in more fresh air escape routes and lower intake air velocities to improve miner comfort and dust conditions). By any number of measures, mine development had overreached the old ventilation system. The ventilation upgrade accomplished all of the above objectives, and resulted in a reduction of total fan power consumption by 1,000 horsepower.

Even if this ventilation upgrade could be entirely attributed to DPM compliance, the cost must be annualized over the expected 20+ year life of the asset, so the yearly cost (using a 7% discount rate) would be about $850,000. This yearly cost is partially offset by savings in electricity costs resulting from the 1,000 horsepower reduction in fan power consumption, so the ventilation upgrade actually resulted in a net annual cost to Stillwater of only about $197,000 (1,000 hp × 24 hours/day × 365 days/year × 0.745 kw-hr/hp-hr × 10¢/kw-hr = $652,620; $849,536 − $652,620 = $196,916).

2. Diesel Engines and Engine Upgrades. Only a portion of the expense of new diesel engines and engine upgrades should be considered a DPM compliance cost. Diesel engines have a finite life and need to be renewed and replaced periodically. Some new engines and engine upgrades would have been necessary with or without a DPM rule. Also, new, low-emission engines enable improved operating efficiencies due to lower fuel consumption and better maintenance diagnostics, resulting in significant operating cost savings that partially off-set purchase costs.

Like the ventilation upgrade, however, even if the total cost of engines and engine upgrades was attributable to DPM compliance, these costs (estimated by Stillwater at $1.2 million) must be annualized over the expected 10 year life of an engine, resulting in a yearly cost of about $171,000 (using a 7% discount rate).

3. Soot Traps, Filters, Passive DPFs. The mine currently has fewer than 30 passive regeneration DPF systems and only one passive/active regeneration DPF system (fuel burner) in use, and reports no operational problems at this time, except one filter destroyed by a failed turbo-charger.

In its comments to the 2003 NPRM, Stillwater outlined a plan for utilizing a combination of passive and active DPFs to control DPM in its mine. Passive filters would be used where equipment duty cycles and corresponding exhaust temperatures suggested the application would be successful, and active filters would be utilized on the remaining equipment. Stillwater reports $160,000 in passive filter costs to date. Assuming a filter life of two years, this results in a yearly cost of about $88,500 (using a 7% discount rate).

4. Engine Test Equipment. The engine test equipment has a 5-year life, resulting in an annualized cost of about $68,000 (using a 7% discount rate).

5. Emissions expenditure. The basis for Stillwater's ''Emissions expenditure'' line item cost of $43,000/month is unclear. As noted above, the mine currently has fewer than 30 passive regeneration DPF systems and only one active regeneration DPF system in use, and reports no operational problems at this time, except one filter destroyed by a failed turbo-charger. Engine-related emissions expenses are addressed in the diesel engines, engine upgrades, and engine test equipment line items above. However, ''emissions expenditures'' of $516,000 per year ($43,000 per month × 12 months) are included as submitted by Stillwater in MSHA's estimated compliance cost.

6. Active Regeneration Systems. Based on Stillwater's existing knowledge base relating to equipment duty cycles and exhaust temperatures, their plan for controlling DPM emissions included passive filters for only a small percentage of the mines' fleet: the large loaders and ore haulage trucks. In contrast, about 200 vehicles were expected to require active regeneration DPF systems.

For costing the active systems, Stillwater made the following assumptions:

a. Regeneration of the DPFs would be accomplished on-board the vehicles. Vehicles equipped with DPFs would travel from their normal work areas (stopes, develop ends, haulageways, etc.) to specially excavated regeneration stations provided with the necessary means of connecting the filters to power and compressed air. Upon arrival at a regeneration station, the filters would be ''plugged in'' to electrical power and compressed air utilities to accomplish regeneration.

b. In addition to including the costs of filters and associated regeneration equipment, Stillwater's active DPF cost estimates also included excavating the regeneration stations and installing the required electrical power and compressed air.

c. To insure reasonable travel distances to regeneration stations as mine workings advance over time, Stillwater's cost estimate was developed in the context of a 10-yr mine plan that included the excavation of new regeneration stations periodically over the 10 years.

Stillwater's total estimated costs for active filter systems, regeneration equipment, and regeneration stations was about $104.4 million over the 10-yr period of the mine plan. Of this total, $100.8 million (96.6%) was for excavation of the regeneration stations, and $3.6 million was for active filter systems and regeneration equipment.

Neither the number of active systems required at Stillwater, nor the estimated total cost of implementing active filters as specified in Stillwater's comments is disputed by MSHA. However, MSHA does not believe the particular plan developed by Stillwater is the optimal means of utilizing active DPM filters at this mine. Various alternative approaches for utilizing active filters exist which would be far less costly.

Since excavating regeneration stations accounted for over 96% of the total cost of implementing Stillwater's active filter plan, alternatives that do not include such excavation costs would have a significant cost advantage over Stillwater's plan. It is somewhat curious that Stillwater developed its active DPF plan on the basis of this particular on-board active regeneration system, despite the extraordinarily high cost of excavating the regeneration stations, and Stillwater's prior experience with premature failure of the on-board heating elements built into the filters.

A lower cost alternative to Stillwater's approach utilizes an on-board fuel burner system to regenerate filters. The ArvinMeritor® system has been on trial at this mine since February 2004 with excellent results. This system actively regenerates the filter media during normal equipment operations, and does not require the host vehicle to travel to a regeneration station to regenerate its filter.

Another less costly alternative would be to utilize off-board regeneration instead of on-board regeneration. In off-board regeneration, a dirty filter is removed and replaced with a clean filter at the beginning of each shift. During shift change, the dirty filters are then transported by the equipment operator or a designated filter attendant to a central regeneration station or stations.

Such stations could be a fraction of the size of the regeneration stations envisioned in Stillwater's plan, because they would only need to accommodate the filters, not the host vehicles. Since the host vehicles would not need to travel to the regeneration stations, the travel distance from normal work areas to the regeneration stations would be less important, greatly lessening the need for frequent construction of new regeneration stations as the workings advance. It is very likely that such stations could be co-located in existing underground shops, unused muck bays, unused parking areas, or other similar areas.

Off-board regeneration might not be practical on larger machines due to the size of the filters. For larger machines that are not suitable for passive regenerating filters, the fuel burner approach might be preferable. But many of the machines targeted for active filtration are quite small, having 40 to 80 horsepower engines. Active filters for these engines are correspondingly small, and could be easily and quickly removed and replaced using quick disconnect fittings.

Another lower cost option would be to utilize disposable high-temperature synthetic fabric filters, especially on smaller, light duty equipment such as pickups, boss buggies, and skid steers. Depending on equipment utilization, such filters might only need to be replaced once or twice per week.

In Table VII–3, the line for active filters shows the 10-year cost of Stillwater's plan for utilizing active filters along with MSHA's estimate of the yearly cost of alternatives to Stillwater's plan. MSHA's cost estimate for this line item is based on Stillwater's estimated cost for active filter systems, minus the cost of excavating regenerations stations, or $3.6 million over 10 years. Annualizing these active filter costs over the two-year expected life of these filters using a discount rate of 7% results in a yearly cost of about $398,000.

TABLE VII–3.—STILLWATER'S AND MSHA'S DPM COMPLIANCE COST ESTIMATES

Cost item	Stillwater's cost estimate	MSHA cost estimate	MSHA comments
Mine Ventilation Upgrade	>$9 million	$0	This upgrade necessary with or without DPM rule to address ongoing air quality problems and plans for mine development.
		$849,536/yr [1]	Even if upgrade necessary for DPM compliance, this capital cost annualized over expected 20+ year life of the asset.
		$327,440/yr [1]	Annualized cost over expected 20+ year life of the asset minus annual power cost savings.
Engine upgrades, other misc. expenses.	>$1.2 million	$170,853/yr [1]	Some engines/upgrades part of normal turnover of engines and not DPM compliance cost. Cost of engines/upgrades annualized over 10 year expected engine life.
Test Equipment	>$280,000	$68,289/yr [1]	Cost of test equipment annualized over 5 year expected equipment life.
Soot traps, filters, passive DPFs.	$160,000	$88,495/yr [1]	Cost of DPFs annualized over 2 year expected filter life.
Emissions expenditure	$43,000/month	$516,000/yr [1]	Cost element is unclear based on current filter use.
Active DPF systems, regeneration equipment, and regeneration station excavation.	$104.4 million over 10 years.	$398,226/yr [2]	Less costly approaches for implementing active regeneration were overlooked. Approaches that do not require excavation of regeneration stations save $100.8 million over 10 years. $3.6 million would still be required for filters and regeneration equipment, however, this expense would be incurred over 10 years.
Grand Total	$104.4 million over 10 years for active DPFs, plus $10–$13 million for other costs over 10 years. Total cost $114–$117 million over 10 years.	Annual cost of $1.24 to $2.09 million. $1.24 million if cost of ventilation upgrade is not included;. $2.09 million if cost of ventilation upgrade is included;. $1.57 million if cost of ventilation upgrade is included minus power cost savings.	Certain cost elements should not be considered DPM compliance costs. However, even including *ALL* listed costs for ventilation, passive and active DPFs, engines/engine upgrades, test equip, and emissions expenditures, MSHA estimates total yearly cost for DPM compliance will not exceed $2.09 million. Excluding ventilation, estimated total yearly cost is $1.24 million. Including ventilation but considering power cost savings, estimated total yearly cost is $1.57 million. Estimated yearly compliance cost of $1.72 million for a precious metals mine of this size would be consistent with 2001 REA.

Notes:

[1] Cost estimate based on commenter's estimated cost, annualized over the expected life of the item using a 7% discount rate. The annualization factor for a capital expenditure is 9.4% for 20 years, 14.2% for 10 years, 24.4% for 5 years, and 55.3% for 2 years.

[2] Cost estimate based on commenter's estimated cost for active systems minus the cost of excavating regeneration stations, annualized over the expected life of the active systems.

Kerford Limestone DPM compliance. Kerford Limestone reported the results of a consultant's study that indicated compliance with the DPM limit for that mine would cost $348,000 for engine improvements, $1.15 million for ventilation upgrades, and $25,500 to $38,500 per year for DPFs. They reported investing $975,000 to date toward DPM compliance.

Kerford's engine costs of $348,000, when annualized over 10 years at a discount rate of 7%, results in a yearly cost of about $49,500. The $1.15 million ventilation cost, when annualized at the same discount over the expected 20+ year life of this asset, results in a yearly cost of about $108,600. When these two yearly costs are added to the maximum estimated annual DPF cost of $38,500, the total yearly cost for Kerford is about $196,600.

Without commenting specifically on the reasonableness of Kerford's itemized cost estimates or whether the overall DPM control strategy proposed by its consultant was optimized for this mine, MSHA notes that Kerford's self-reported total yearly compliance cost of about $196,000 is not excessive for an underground stone mine in its size category. By way of comparison, a yearly compliance cost of over $300,000 for a stone mine of this size would be consistent with MSHA's REA for the existing 2001 final rule.

MSHA's REA for the existing 2001 final rule estimated compliance costs for a medium sized (20 to 500 employees) stone mine to be $150,738. However, this estimate was based on a fleet size of 9.5 pieces of production equipment for this industry sector and mine size category. Kerford operates 19 pieces of production equipment. Adjusting the REA estimate of $150,738 for the larger fleet size at Kerford results in an estimated yearly compliance cost of $301,476. Thus, Kerford's estimated $196,600 yearly compliance cost is only about 65% of the level that would be expected for an underground stone mine of this size, based on the 2001 REA. The cost is virtually unchanged in the REA supporting this final rule.

It was suggested by a commenter that MSHA underestimated Kerford Limestone's compliance costs by over $1 million, and it was further suggested that this underestimate, if extrapolated to the entire underground stone mining industry, resulted in industry-wide compliance costs exceeding $100 million. However, Kerford Limestone's yearly compliance costs, using its own cost estimates, are substantially less than expected, based on the 2001 REA for a medium sized underground stone mine.

Bio-Diesel tests at Carmeuse Black River and Maysville mines. Commenters stated that in-mine tests with bio-diesel fuel produced measurable reductions in ambient DPM concentrations, but did not bring the subject mine into compliance. These comments refer to MSHA's compliance assistance work at the Carmeuse Black River and Maysville stone mines in Kentucky. At both mines, the use of bio-diesel fuel produced reductions in DPM. The recycled vegetable oil (RVO) with a 50% blend of bio-diesel to standard diesel fuel showed a 69% reduction in DPM, based on TC, for the area samples at the Maysville mine. Personal samples collected at the Black River Mine showed a 44% reduction in DPM with RVO at a 35% blend of bio-diesel to standard diesel fuel. The Virgin Soy Oil (VSO) mixtures showed reductions, but they were not as effective as the RVO at similar blends.

The Maysville mine was in compliance with the interim limit based on the baseline samples and the samples taken with bio-diesel. In contrast, the Black River Mine was not in compliance with the interim limit based on the samples taken, even with the reduction in DPM using bio-diesel. One main difference between the two mines was that the Maysville mine had significantly more ventilation than Black River. This result indicates that the Black River mine will have to implement additional DPM controls to come into compliance, such as ventilation upgrades, cleaner engines, or DPFs.

These commenters did not dispute the DPM reductions obtained. However, they indicated the following: That Deutz Corporation's Technical Circular does not approve the use of bio-diesel blends above 20%; that a 50% bio-diesel fuel presented insurmountable equipment problems; and that the cost of bio-diesel has increased significantly, adversely impacting the feasibility potential of the 20% mixture.

MSHA reviewed Deutz's Technical Circular (0199–3005en), and discussed this issue with Deutz. The Technical Circular provides a general statement that bio-diesel fuel is approved for Deutz brand engines. The Technical Circular does not mention any limitation on the use of bio-diesel above a certain percentage blend. Deutz requires that all fuels used in their engines meet Deutsches Institute für Normung e.V. (DIN) specifications (German National Standards). The Deutz Technical Circular provides the DIN specifications for bio-diesel fuel.

Comments regarding equipment problems relate to reports of bio-diesel fuel causing clogging of fuel filters, resulting in excessive equipment downtime. One commenter expressed concern that Tier 2 engines used fuel filtering systems that would not be compatible with bio-diesel. MSHA understands that engine manufacturers are working with the filter manufacturers to provide the best filtration for all engines. MSHA is not aware of any unique changes for EPA Tier 2 engines as related to fuel filtering systems or for utilizing bio-diesel fuel. As the engine technology continues to improve, especially in the area of the fuel system components, better fuel filtration systems will be utilized by the engine manufacturers.

There are frequent references in the technical literature to bio-diesel fuels initially cleaning old sediments out of fuel lines, thereby causing fuel filters to clog. It follows that fuel filters should be changed more frequently when bio-diesel is first used in a fuel system. However, the commenter suggests an entirely different type of incompatibility that is not limited to the transition period when bio-diesel is first used. This may or may not be a unique situation that may take additional work to resolve. The mine may have to install an additional by-pass filtering system on the machine to allow the operator to switch to another set of fuel filters instead of shutting down production if a fuel filter clogs.

MSHA is not aware of long term filter clogging with the use of bio-diesel fuel. However, through the NIOSH List-Server, mine operators have the opportunity to share experiences like the filter clogging problem with the mining community, and possibly receive a solution. A mine operator may use the List-Server to ask others in the mining community if their problem has been observed in other situations. Interested parties can respond, thus sharing experiences and solutions in a timely manner. The List-Server was established by the diesel team at NIOSH, Pittsburgh in response to the expressed and obvious need for a means to disseminate and share information and experiences concerning the application of available technologies for the reduction of miner exposures to DPM and gaseous emissions in underground mines.

Regarding the cost of bio-diesel, MSHA acknowledges that users pay a premium for bio-diesel over standard diesel fuel. The cost for bio-diesel can vary based on such factors as market price swings in the cost of feed-stocks, state tax incentives, proximity to production facilities, etc., but normally, where bio-diesel is available, the premium is about one cent per gallon per percent bio-diesel in the fuel blend. At higher percentage bio-diesel blends, this premium can result in significantly higher overall fuel costs for the end-user. Depending on mine-specific factors, however, use of bio-diesel may be a cost-effective DPM control option, either used by itself or in conjunction with other controls. Since the rule is performance oriented, the mine operator is free to choose the means of compliance.

Based on these results and other data, MSHA's believes that bio-diesel is a feasible DPM control. In the case of the Black River mine, bio-diesel would have to be used in combination with other controls for the mine to achieve compliance, or the mine operator may choose to abandon bio-diesel altogether and rely entirely on other controls for attaining compliance. MSHA disagrees with the commenters' assertion that a 50% bio-diesel blend presents ''insurmountable equipment problems.'' Bio-diesel is recognized by the EPA as an alternative clean fuel, engine manufacturers do not recommend against its use, and clogging can be prevented by the use of by-pass filtering systems.

Water Emulsion Fuel: As discussed under the MSHA compliance assistance activities, we conducted tests at four mines to evaluate water emulsion fuel. These tests included a test at a small clay mine that used older technology engines, two single level limestone mines that used clean burning engines, and one multilevel limestone mine that used clean burning engines. Summer (20% water) and winter (10% water) blends of fuel were tested at two mines. Only summer blends of fuel were tested at the other two mines. MSHA evaluated the reduction in total mine DPM emissions by taking measurements at the mine exhaust openings, with and without the water emulsion fuel in use, and comparing these to similarly made measurements when standard No. 2 diesel fuel was used. Table VII–4 summarizes the reductions in emissions measured for the tests.

For clean burning engines the reduction in DPM emissions (as EC) ranged from 63 to 81 percent. For older engines the reduction in DPM emissions (as EC) was approximately 49 percent. Personal exposures were also reduced, however, this reduction was more variable than the reduction in engine emissions. This variability was attributed to the use of cabs, location in the mine and the specific ventilation rates at the work area in the mine.

TABLE VII–4.—EMISSION REDUCTIONS FOR WATER EMULSION FUEL TESTS

Mine	Percent reduction in EC (winter blend)	Percent reduction in EC (summer blend)
Clay		49
Limestone	77	81
Limestone	63	73
Multilevel Limestone		80

For each mine test, equipment operators reported a noticeable loss of horsepower. However, this horsepower loss, even in the multilevel limestone mine, did not adversely effect production. In fact, during several of the mine tests, production was significantly above normal. The water emulsion fuel was favorably received by the employees. Workers reported that visibility improved. The water emulsion fuel has the same per gallon cost as No. 2 diesel fuel. Several operators reported as much as a 20 percent increase in fuel usage to compensate for the power loss.

During the water emulsion fuel tests, a potential operating problem was observed when the fuel was used in Deutz engines. Simply put, some engines would not run. The source of this problem was traced by the engine and fuel manufacturers to a high efficiency water separator in the engine fuel line. The engine and fuel manufacturers have indicated that the problem can be corrected by replacing the standard high efficiency water separator with a less efficient unit.

We believe that the use of water emulsion fuels provides a significant reduction in diesel engine emissions over a broad range of applications. Currently the biggest impediment to the use of the emulsified fuel is distribution. The manufacturer is making efforts to make the fuel more widely available.

MSHA has not tested the fuel at high altitude mines (above 5000 feet). At these elevations there are potential problems due to additional horsepower loss, steep grades and low winter temperatures. MSHA is working with the fuel manufacturer and mining industry to evaluate these concerns.

Combining DPM Controls Into An Overall Strategy. The DPM rule allows mine operators flexibility in choosing engineering and administrative controls that are appropriate for site-specific conditions and operating practices. During its compliance assistance visits, MSHA urged mine operators to combine various engineering and administrative controls, including work practices, into an integrated DPM control strategy for their mines. For example, in stone mines where haulage trucks transport broken stone out of the mine to a surface crusher, and where the truck drivers are protected by effective environmental cabs with filtered breathing air, MSHA recommends that the main ramp used by the haulage trucks to travel out of the mine be maintained as an exhaust air course. Typically, the combined horsepower of the production loader and haulage trucks at a stone mine exceeds the horsepower of all other equipment combined. When haulage trucks travel loaded upgrade out of the mine, they generate significant amounts of DPM. If the ramp used by these trucks is maintained as an intake air course, the fresh air supply for the entire mine can become contaminated. Maintaining this ramp as an exhaust air course and requiring the loaded trucks to haul up this ramp as an administrative control enables the mine operator to provide better ventilation air quality along the face line. Depending on mine layout and ventilation, it may be possible to maintain all ramps traveled by the haulage trucks as exhaust air courses. It is especially important, however, that the ramps used for upgrade loaded haulage be maintained as exhaust air courses. This combination of engineering (cabs and ventilation) and administrative controls (loaded trucks haul up the ramps used as exhaust air course) particularly benefits powder crew workers who are required to work most of their shift outside of a protective cab.

Some commenters stated that the industry has exhausted the ''easy'' methods of DPM control, and reducing DPM to lower limits would be prohibitively expensive. MSHA is not entirely certain what is meant by ''easy'' methods, but suspects the commenter was referring to DPM controls other than major ventilation upgrades (new main fans, new ventilation shafts, etc.) and DPFs, which are either more costly than other options, or are perceived as more costly. At some mines, ''easy'' could also mean ''familiar,'' indicating the methods and strategies with which these mine operators have had actual first-hand experience. Based on this meaning, easy upgrades appear to be: Ventilation fans (main or booster), airflow distribution systems, environmental cabs, modern engines and alternate fuels.

By either definition, MSHA believes that only a small portion of the industry has exhausted these control methods. For example, based on compliance assistance mine visits, baseline sampling results, and other data, MSHA has observed that many mines have not yet implemented relatively low cost ventilation upgrades, and that at most mines that have initiated such programs, not all necessary upgrades have been completed.

Another example involves environmental cabs with filtered breathing air. As noted above, even though most major pieces of production equipment in stone mines are provided with cabs, the corresponding health benefits are seldom fully realized due to open or broken windows, company policies that permit equipment to be operated with its doors open, inoperative or poorly maintained AC systems and cab pressurizing fans, damaged door seal gaskets, etc.

A final example relates to the failure to employ effective work practices such as utilizing return air courses as truck haulage roads when the truck drivers are protected by environmental cabs with filtered breathing air.

MSHA determined that compliance costs were economically feasible for the M/NM mining industry. In the REA for the 2001 final DPM rule, MSHA determined that annual compliance costs would be about $128,000 for an average underground M/NM mine. Some mines, in particular mine size and commodity groups, because of mining methods used, equipment deployments, etc., would be expected to incur higher than average compliance costs. For example, the REA estimated yearly compliance costs for large precious metals mines to be $660,000. Based on its compliance assistance mine visits, baseline sampling results, and other data, MSHA believes that most mines have expended far less than the expected $128,000 yearly for DPM compliance. Though expenditures will undoubtedly need to rise in the future as the familiar and less costly DPM control methods are exhausted, they are not expected to exceed levels previously determined by MSHA to be economically feasible.

C. Economic Feasibility

MSHA has determined that a PEL of 308 micrograms per cubic meter of air (308_{EC} µg/m^3) is economically feasible for the M/NM mining industry. Economic feasibility does not guarantee the continued viability of individual employers, but instead, considers the industry in its entirety. It would not be inconsistent with the Mine Act to have a company which turned a profit by lagging behind the rest of an industry in providing for the health and safety of its workers to consequently find itself financially unable to comply with a new standard; *See United Steelworkers of America* v. *Marshall,* 647 F.2d 1189, 1265 (1980). Although it was not Congress' intent to protect workers by putting their employers out of business, the increase in production costs or the decrease in profits would not be sufficient to strike down a standard. *See Industrial Union Dep't.,* 499 F.2d at 477. On the contrary, a standard would not be considered economically feasible if an entire industry's competitive structure were threatened. *Id.* at 478; *See also, AISI–II,* 939 F.2d 975, 980 (DC Cir. 1991); *United Steelworkers,* 647 F.2d at 1264–65; *AISI–I,* 577 F.2d 825, 835–36 (1978). This would be of particular concern in the case of foreign competition, if American companies were unable to compete with imports or substitute products. The cost to government and the public, adequacy of supply, questions of employment, and utilization of energy may all be considered when analyzing feasibility.

MSHA has also determined that there will be a small cost savings in economic impact on the mining industry under this final rule, because the requirements for meeting the PEL are similar to those in the existing DPM enforcement policy for the 2001 DPM standard. Specifically, MSHA will continue to require mine operators to establish, use and maintain all feasible engineering and administrative control methods to reduce a miner's exposure to the PEL. The final rule affords mine operators the flexibility to choose either engineering or administrative controls, or a combination of controls to reduce a miner's exposure. In the event that controls do not reduce a miner's exposure to the PEL, are not feasible, or do not produce significant reductions in DPM exposures, the operator must use and maintain controls to reduce the miner's exposure to as low as feasible and supplement controls with respiratory protection. Mine operators must establish a respiratory protection program when controls are infeasible. If MSHA confirms that mine operators have met all of the abovementioned requirements for addressing a miner's overexposure, and the miner's exposure continues to exceed the PEL (not counting respirators), MSHA will not issue a citation for an overexposure. Instead, MSHA will continue to monitor the circumstances leading to the miner's overexposure, and as controls become feasible, MSHA will require the mine operator to install and maintain them to reduce the miner's exposure to the PEL.

MSHA believes that it has established in this final rulemaking that the new interim PEL is comparable to the TC interim concentration limit. Therefore, in determining the economic feasibility of engineering and administrative controls that the M/NM underground industry will have to use under this final rule, MSHA evaluated the cost of controls that are used to comply with the existing DPM TC interim concentration limit to that of the newly promulgated EC interim PEL. These controls include DPFs, ventilation upgrades, oxidation catalytic converters, alternative fuels, fuel additives, enclosures such as cabs and booths, improved maintenance procedures, newer engines, various work practices and administrative controls. MSHA's evaluation includes costs of retrofitting existing diesel-powered equipment and regeneration of DPFs.

On the basis of evidence in the rulemaking record, including MSHA's current enforcement experience, MSHA has determined that this final rule results in a cost savings of $3,634 per year, primarily due to MSHA's determination to delete the DPM control plan.

In highly unusual circumstances where the use of further controls may not be economically viable, the standard provides for a hierarchy of control strategy that allows specifically for the cost impact to be considered on a case-by-case basis. MSHA's DPM enforcement policy, therefore, takes into account the financial hardship on an individualized basis which MSHA believes effectively accommodates mine operator's economic concerns, particularly those of small mine operators.

Whether controls are feasible for individual mine operators is based in part upon legal guidance from decisions of the independent Federal Mine Safety and Health Review Commission (Commission) involving enforcement of MSHA's noise standards for M/NM mines, 30 CFR 56.5–50 (revised and recodified at 30 CFR 62.130). According to the Commission, a control is feasible when it: (1) Reduces exposure; (2) is economically achievable; and (3) is technologically achievable. *See Secretary of Labor* v. *A. H. Smith,* 6 FMSHRC 199, 201–02 (1984); *Secretary of Labor* v. *Callanan Industries, Inc.,* 5 FMSHRC 1900, 1907–09 (1983).

In determining the economic feasibility of an engineering control, the Commission has ruled that MSHA must assess whether the costs of the control are disproportionate to the ''expected benefits,'' and whether the costs are so great that it is irrational to require implementation of the control to achieve those results. The Commission has expressly stated that cost-benefit analysis is unnecessary to determine whether a control is required.

Consistent with Commission case law, MSHA considers three factors in determining whether engineering controls are feasible at a particular mine: (1) The nature and extent of the overexposure; (2) the demonstrated effectiveness of available technology; and (3) whether the committed resources are wholly out of proportion to the expected results. A violation under the final standard will entail an agency determination that a miner was overexposed, that controls are feasible, and that the mine operator failed to install or maintain such controls. According to the Commission, an engineering control may be feasible even though it fails to reduce exposure to permissible levels contained in the standard, as long as there is a significant reduction in a miner's exposure. *Todilto Exploration and Development Corporation* v. *Secretary of Labor,* 5 FMSHRC 1894, 1897 (1983).

MSHA will consistently utilize its longstanding enforcement procedures under its other exposure-based standards at M/NM mines. As a result, MSHA will consider the total cost of the control or combination of controls relative to the expected benefits from implementation of the control or combination of controls when determining whether the costs are wholly out of proportion to results. If controls are capable of achieving a 25% reduction, MSHA will evaluate the cost of controls and determine whether their costs would be a rational expenditure to achieve the expected results.

MSHA emphasizes that the concept of ''a combination of controls'' is not new to the mining industry. It is MSHA's consistent practice not to cost controls individually, but rather, combine their expected results to determine if the 25% significant reduction criteria, as discussed earlier in this section, can be satisfied.

MSHA heavily weighs the potential benefits to miners' health when considering economic feasibility and does not conclude economic infeasibility merely because controls are expensive. Mine operators have the responsibility for demonstrating to MSHA that technologically feasible controls are so costly as to result in a significant economic hardship.

In situations where MSHA finds that the mine operator has not installed all feasible controls, MSHA will issue a citation and establish a reasonable abatement date. Based on a mine's technological or economic circumstances, the standard gives MSHA the flexibility to extend the period within which a violation must be corrected. If a particular mine operator is cited for violating the DPM PEL, but that operator believes that the standard is technologically or economically infeasible for that operation, the operator ultimately can challenge the citation in an enforcement proceeding before the independent Commission.

MSHA found that most of the practical and effective DPM controls that are available, such as DPFs, enclosed cabs with filtered breathing air, alternative diesel fuels, and low-emission engines, will achieve at least a 25% reduction in DPM exposure. Though this final rule affords each mine operator the flexibility to select the DPM control or combination of controls that are appropriate to their site-specific conditions, MSHA believes that the most cost effective DPM controls are DPF systems. MSHA believes that there are a number of available DPFs that do not increase production of NO_2.

MSHA estimates that DPFs for the M/NM underground mining industry range in cost from $5,000 to $12,000 per filter. This range of cost is consistent with the reported DPF costs from the NIOSH Phase I Study. A typical example is a 15″ x 15″ Engelhard DPX platinum-catalyzed DPF used on 475 horsepower haulage trucks at a multilevel metal mine in Alaska that costs $8,700.

The average life expectancy of a DPF is approximately 8,000 hours. Some commenters, however, have reported life expectancies of between 2,000 and 4,000 hours, while some other commenters have reported life expectancies for longer than 8,000 hours. However, in most of these cases the shortened DPF life was due to a malfunction of another piece of equipment, installation problems or a manufacturer's defect, depending on the type of DPF selected by an operator. MSHA's 8,000 hour estimate is based on an operation and maintenance guide prepared by DCL Incorporated and two technical papers given at the Mining Diesel Emission Conference in Toronto, Canada, November 1999. (*See* MSHA's REA for 2001 final rule.) Support for this estimate is provided by NIOSH in its publication titled ''Review Technology Available to the Underground Mining Industry for Control of Diesel Emissions'' (George H. Schnakenberg, PhD, Information Circular 9462, 2002) which reports that average ceramic DPF service life at Agrium's Canadian potash mines is 5 years. This publication also references reports of a few Engelhard DPFs that have been in service 10 years.

MSHA believes that the requirements for engineering and administrative controls clearly meet the feasibility requirements of the Mine Act, its legislative history and related case law.

The trends in DPM control technology development to date, especially DPFs, indicate that manufacturers are creating more innovative designs. MSHA believes that more cost effective control methods are on the horizon. This reasoning is supported by a recently published EPA final rule for the control of emissions from nonroad diesel engines. The ''Clean Air Nonroad Diesel—Final Rule'' (Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel, 69 FR 38958 (2004)) sets emission standards for airborne contaminants, including DPM, for all diesel engine horsepower ranges. For engines up to 750 horsepower, the requirements will be phased in from 2008 through 2014. For engines above 750 horsepower, the final compliance date is extended to 2015. EPA's Clean Air Nonroad Diesel Rule is a comprehensive national program to reduce emissions from future non-road diesel engines used in industries such as construction, agriculture and mining. To meet these emission standards, engine manufacturers will produce new engines with advanced emission-control technologies similar to catalytic technologies used in passenger cars. Exhaust emissions from these engines will decrease by more than 90%. Because the emission-control devices can be damaged by sulfur, the EPA is also adopting a limit to decrease the allowable level of sulfur in nonroad diesel fuel by more than 99% from current levels (from approximately 3,000 parts per million [ppm] now to 15 ppm in 2010). This will be consistent with the on-highway fuel sulfur requirements. New engine standards take effect, based on engine horsepower, starting in 2008. Both the EPA and the diesel engine manufacturers agree that clean engine technology alone cannot achieve EPA's newly mandated emission limits; manufacturers will also have to use advanced technology options such as DPFs.

MSHA believes DPFs are currently commercially available for any engine, application, or duty cycle used in underground M/NM mining. These new EPA rules, however, will undoubtedly be technology forcing and result in an increase in the variety, features, and capabilities of DPFs from which mine operators may choose, as well as lower the cost of DPFs and promote other technological innovation in this field.

In spite of these trends in new technology, MSHA recognizes that, in a few cases, individual mine operators, particularly small operators, may have economic difficulty in achieving full compliance with the interim limit immediately because of a lack of financial resources to purchase and install engineering controls. MSHA's revised enforcement strategy is designed to accommodate this problem. Under this enforcement strategy, MSHA allows mine operators with feasibility issues the necessary time to reduce exposures to the interim PEL.

MSHA also has demonstrated that the effective date for this final rule does not pose an economic burden for underground M/NM mine operators. As stated earlier, the EC surrogate standard is comparable to the existing TC surrogate standard which has been in effect since July 2002, and has been enforced by MSHA since July 20, 2003. Consequently, MSHA cannot justify affording mine operators additional time to comply with an exposure limit currently enforced. MSHA believes that the startup date is justified by the rulemaking record and the mining industry's present capability of complying with the existing interim limit.

Moreover, MSHA has afforded the underground M/NM mining industry additional consideration in relieving the financial impact of this final rule by delaying the period of time that was allowed for compliance with the 2001 comparable TC concentration limit. In response to concerns raised by the mining industry and the terms of the DPM settlement agreement, MSHA allowed as much as 2½ years for a DPM compliance phase-in strategy.

Specifically, on March 15, 2001, MSHA published a notice delaying the effective date of the final DPM rule of January 19, 2001, (66 FR 5706) until May 21, 2001 (66 FR 15032). By notice of May 21, 2001, (66 FR 27863), MSHA delayed the final rule another 45 days, until July 5, 2001. Furthermore, by notice of July 5, 2001, (67 FR 9180), MSHA delayed § 57.5066(b), Maintenance standards, relating to ''tagging'' requirements. MSHA also clarified that the interim concentration limit at § 57.5060(a) and its related provisions in the final rule would not apply until after July 19, 2002, pursuant to its original effective date. By notice of July 18, 2002, MSHA stayed the effectiveness of: § 57.5060(d), permitting miners to work in areas where DPM exceeds the applicable concentration limit with advance approval from the Secretary; § 57.5060(e), prohibiting the use of PPE to comply with the concentration limits; § 57.5060(f), prohibiting the use of administrative controls to comply with the concentration limits; and, § 57.5062, addressing the DPM control plan. These provisions were stayed pending completion of this final rule.

Finally, in the DPM settlement agreement, MSHA agreed to enforce: § 57.5060(a), addressing the interim concentration of 400 micrograms of TC per cubic meter of air; § 57.5061, addressing compliance determinations; § 57.5070, addressing miner training; and § 57.5071, addressing environmental monitoring. However, to further assist the mining industry in instituting engineering controls, MSHA gave the mining industry an additional year, from July 20, 2002, until July 20, 2003, to begin to develop a written strategy of how they intended to comply with the interim DPM concentration limit. Operators with DPM levels above the concentration limit were to begin to order and install controls to reduce miners' exposures by July 20, 2003. Concurrently, MSHA provided comprehensive compliance assistance to M/NM underground operators. MSHA retained the discretion to take appropriate enforcement actions against operators who refuse either to cooperate in good faith with MSHA's compliance assistance, or to take good-faith steps to develop and implement a written compliance strategy for their mines. Mine operators had the obligation to develop a strategy to control DPM emissions and order engineering controls. MSHA began enforcing the interim limit at M/NM underground mines on July 20, 2003, under the terms of the settlement agreement.

MSHA received a number of comments in response to its proposed economic feasibility discussion. Several commenters wanted MSHA to define ''economic feasibility.'' They believe that controls should be considered economically feasible if implementation would not bankrupt the company or force the mine to close. They also believe that MSHA's 2003 NPRM did not indicate how MSHA will enforce the new language and wanted access to records of feasibility determinations made by MSHA. MSHA has chosen not to define ''economic feasibility'' nor ''technological feasibility'' since the Supreme Court has done so in the OSHA *Cotton Dust* decision. As stated earlier in this part, the Supreme Court defined ''feasibility'' as ''capable of being done'' (*American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 508–509 (1981)). This preamble also discusses how the independent Commission explains the Secretary's burden of proof in establishing technological and economic feasibility of controls.

Commenters criticized the high costs of DPM controls associated with attempts to achieve a significant reduction. These commenters stated that mine ventilation systems cost more than $100 million and provide a benefit only of a 3% to 4% DPM reduction, whereas a less-than $100 million administrative control could achieve a 21% to 22% reduction.

First, MSHA disputes the assertion that a ventilation system costs $100 million. MSHA assumes mines already have some form of ventilation, since ventilation is needed whether or not DPM is a consideration. The existing system may be minimal, and rely partly or largely on natural ventilation, but a basic ventilation network must be present per existing MSHA ventilation regulations (§ 57.8518 through § 57.8535) and air quality standards (§ 57.5001 through § 57.5039) to support normal mining operations. Thus, in the context of the final rule, the question is not whether a ventilation system needs to be provided for compliance, but rather, whether an upgrade to an existing ventilation system is needed. If so, mine operators must examine whether major additions (new shaft, new main fan, etc.) are required, versus relatively minor improvements such as booster fans, auxiliary ventilation system upgrades, or repair or extensions to existing ventilation control structures. Even in an extreme case where a new ventilation shaft and main fan installation could be justified solely on the basis of DPM compliance, such upgrades cost far less than $100 million. Costs in the range of $5 million to as much as $20 million would be more accurate.

MSHA also notes that the level of DPM reduction obtained through a ventilation upgrade is proportional to the ratio of new ventilation air flow to the existing ventilation air flow. If overall air flow is doubled, DPM levels would be roughly cut in half. Of course factors such as imperfect mixing and effective distribution of air flow underground would ultimately determine the actual DPM reduction achieved. Major ventilation upgrades costing $5 to $20 million would typically result in DPM reductions of at least 20% to 30% or more, which is far greater than the 3% to 4% reduction that commenters estimated for a ventilation upgrade costing $100 million.

It is also significant to note that some DPM controls that may be easier fixes for controlling DPM exposures may actually be quite high in overall life-cycle costs compared to other approaches that mine operators perceive to be higher cost options. For example, if the operator of a stone mine determined that compliance could be achieved by installing a 150 horsepower fan costing $25,000, this control option might appear to be advantageous compared to installing DPFs with an expected filter life of two years on the mine's production loader and three haulage trucks at a cost of $60,000 (4 filters × $15,000 per filter = $60,000). However, if the total cost of the ventilation upgrade is considered, including power costs to operate the fan 12 hours per day 6 days per week, the annual cost for ventilation surpasses the cost for filters. The $60,000 cost for DPFs, annualized over the two-year filter life is $33,186 (using a 7% discount rate). The fan power cost alone would be over $40,000 annually at $0.10 per kilowatt-hour (150hp × 12 hours/day × 6 days/week × 52 weeks/year × 0.745 kw-hr/hp-hr × .10 $/kw-hr).

One commenter suggested that MSHA's failure to specify major ventilation upgrades for any mine in its 31-Mine Study results in a serious underestimate of compliance costs for those mines and the industry as a whole. This commenter states that the trona mines have already attained compliance with the final limit because of their high ventilation air flow rates, and that similarly high flows will be required at many other mines to attain compliance.

MSHA notes that the final rule is performance oriented, and allows mine operators great latitude to choose the DPM control or controls that are most efficient and cost effective for a given mine. The trona mines are required to ventilate at very high rates for reasons other than DPM compliance to address methane issues, for instance. For them, ventilation is the logical DPM control because the control is already in place. Other type mines have more and varied choices, and selecting the optimum DPM control strategy involves evaluation of a broad range of factors such as current DPM levels, equipment and engines used, equipment deployments, mine layout, existing ventilation system, availability of alternate diesel fuels, and many more.

For reasons of financial self-interest, mine operators would be unwise to implement high cost controls that achieve very little DPM reduction, such as a $100 million ventilation system that reduces DPM levels by only 3% to 4%. Such a choice would preclude less costly and more effective options available, such as DPFs, low emission engines, alternative diesel fuels, and cabs with filtered breathing air.

As stated earlier, the final rule incorporates economic feasibility in its hierarchy of controls enforcement scheme. MSHA, likewise, could not require a mine operator to implement a control or combination of controls where the costs are wholly out of proportion to the expected results. MSHA would judge a ventilation upgrade costing $100 million, or even $5 to $20 million that achieves a DPM reduction of 3% to 4% as infeasible because the cost is wholly out of proportion to the expected results, and it is likely a mine operator would consider it a poor DPM compliance strategy for the same reason. The commenter suggests a lower cost administrative control that achieves a 21% to 22% reduction would be a better choice. MSHA agrees, if this control in combination with other controls would result in at least a 25% reduction.

As noted previously, with some DPFs, filter efficiency is as high as 99+% for EC. MSHA, however, believes that both economic and technological feasibility must be considered. Whereas filter efficiency is a major component of technological feasibility, MSHA must consider all aspects of feasibility including implementation issues and cost of compliance to the mining industry. As stated earlier in this preamble, MSHA believes that some mine operators would need more time to meet a lower DPM limit presently based on economic feasibility and implementation issues with DPFs.

Establishing a lower interim limit in this final rule would present complications with respect to economic feasibility, particularly where ventilation upgrades would be needed to meet a lower limit. Moreover, MSHA envisions that mine operators would have to filter larger numbers of diesel-powered equipment in order to meet a lower limit. Such a requirement could impose higher costs for the mining industry before experience is gained at the current level and the mining industry is given adequate time to meet a lower standard.

Some commenters objected to MSHA's assessment of the number of mining operations that will need costly ventilation upgrades. These operators believe that a large number of mines will have to make ventilation improvements, provide cab improvements, add other engineering controls, implement other administrative controls, replace engines, and utilize DPFs. In response, the DPM rulemaking record does not sustain this position. MSHA found in its baseline sampling that only 37% of the mining operations covered by this DPM rule had miners overexposed to DPM. Consequently, at 63% of the mines sampled, MSHA found no overexposures to DPM. MSHA conducted this sampling in the same manner as it does its enforcement of the 2001 interim limit DPM rule. MSHA collected roughly 1,194 samples at 183 mines. Additionally, MSHA responded to each mine operator's request for compliance assistance and technical support for resolving engineering control implementation issues. The results of MSHA's work are included in the rulemaking record. Overall, the mining industry has been successful in reducing average DPM levels as demonstrated in the comparison of baseline sampling and 31-Mine Study data shown in Chart V–5.

Also, in the 31-Mine Study, MSHA established that most mining operations would not need major ventilation changes, but rather, could implement less costly ventilation upgrades and DPFs. In most instances, the ventilation upgrades require no more than adding booster fans or auxiliary ventilation, and repairs or extensions to ventilation control structures such as brattice lines or air walls.

A commenter suggested that ventilation costs for complying with the DPM rule for the Kerford Limestone mine were projected to be $1.15 million, plus $348,450 for engine replacements, plus an additional $25,500 to $38,500 for DPF maintenance. According to the commenter, this mine has invested $975,000 since October 2001, primarily for ventilation improvements including sinking a shaft, consultant costs, a new blasting truck, and a new engine for a bolter. The commenter points out that in the 31-Mine Study, MSHA projected that first-year compliance costs for this same mine would be only $77,600, and suggests the discrepancy is an example of MSHA's underestimate of DPM compliance costs.

MSHA notes that 13 DPM samples were taken during the 31-Mine Study at the Kerford mine. Sample results ranged from 143_{TC} µg/m³ to 490_{TC} µg/m³. Per the 31-Mine Study methodology, DPM controls were specified based on the highest sample result. However, since the highest sample result only exceeded the interim DPM limit by about 23% (490_{TC} µg/m³ versus the interim DPM limit of 400_{TC} µg/m³), the controls necessary to attain compliance at this mine were not very extensive. Indeed, MSHA's analysis indicated that controlling DPM emissions from the mine's three loaders (two loaders used in normal operations plus one spare) using active DPF systems with filter efficiencies of 80% would enable the mine to attain compliance with the interim limit. MSHA estimated the first year cost of three filter systems for the subject loaders plus an oven for regenerating the filters (active off-board regeneration) to be $77,600.

MSHA has not seen the consultant's report that indicates new engines, DPFs, and a major ventilation upgrade would be required for the Kerford mine to comply with the interim DPM limit. However, these recommendations appear excessive based on MSHA's analysis in the 31-Mine Study and also on the fact that compliance for this mine requires only a relatively small reduction in DPM levels from 490_{TC} µg/m³ to 400_{TC} µg/m³.

As noted in the 31-Mine Study final report, MSHA is not suggesting that its findings represent the optimum compliance strategy for this or any mine. Rather, MSHA maintained merely that the controls specified in the final report are feasible and would be expected to attain compliance. MSHA suspects that the combination of controls recommended by Kerford's consultant, though capable of attaining compliance, is not the optimum and most cost effective approach available.

As discussed in the Technological Feasibility section of this preamble, MSHA also notes that the total yearly cost represented by the consultant's recommended engine, ventilation system, and DPF expenditures is roughly in line with MSHA's 2001 REA estimate for an average mine, even though Kerford Limestone is substantially larger than average. The engine costs of $348,000, when annualized over 10 years at a discount rate of 7%, results in a yearly cost of $49,500. The $1.15 million ventilation cost, when annualized over the expected 20+ year life of this asset, results in a yearly cost of $108,600. When these two yearly costs are added to the maximum estimated annual DPF cost of $38,500, the total yearly cost for Kerford is about $196,600. When compared to the MSHA REA's estimated compliance cost of over $300,000 for a stone mine of this size, Kerford's costs are significantly less.

Some mines, in particular mine size and commodity groups, because of their mining methods used, equipment deployments, etc., would be expected to incur higher than average compliance costs of $128,000 per year. For example, the REA estimated yearly compliance costs for large precious metals mines to be $660,000. Based on its compliance assistance mine visits, baseline sampling results, and other data, MSHA believes that most mines have expended far less than the expected $128,000 yearly for DPM compliance. Though expenditures will undoubtedly need to rise in the future as the easy DPM control methods are exhausted, they are not expected to exceed levels previously determined by MSHA to be economically feasible.

Another mine that disputed MSHA's estimated DPM compliance cost estimates is the Stillwater Mine. MSHA estimated in the 31-Mine Study that DPM filters would be required on all LHDs and haulage trucks at this mine in order to attain compliance with the interim limit. Accordingly, MSHA estimated Stillwater's first year costs to be $470,100 and annual costs to be $108,163 for three loaders and twelve trucks used in normal mining production operations plus three more spare loaders and four more spare trucks. In its comments on the 2003 NPRM, Stillwater indicated that its total diesel equipment inventory consists of over 350 pieces of diesel equipment, including over 90 loaders and 40 haulage trucks, plus miscellaneous production equipment and spares. MSHA has since acknowledged that it had an inaccurate inventory of diesel equipment for the Stillwater mine when the 31-Mine Study was conducted. On the basis of the newly obtained inventory data, MSHA raised its compliance cost estimate for this mine to $935,000 to cover DPFs for the total production fleet.

In its comments on the 2003 NPRM, Stillwater submitted its own compliance cost estimates. This estimate included a $9 million ventilation upgrade, $160,000 for passive DPFs, $1.2 million for engine upgrades, $280,000 for engine test equipment, $43,000 per month in emissions expenditures, over $100 million over ten years for active DPFs, plus various miscellaneous costs. Combining these items resulted in an estimated annual compliance cost for Stillwater of $11 to $12 million.

Clearly, the most significant cost item listed by Stillwater is active DPF systems. However, almost 97% of Stillwater's estimated active DPF systems costs are for excavation of parking areas. Stillwater's active DPF system implementation plan specified on-board active filter regeneration, wherein a vehicle would travel to a regeneration station and its DPF would be connected to electrical power and compressed air for regeneration. To insure reasonable travel distances between normal working areas and regeneration stations, Stillwater's active filter cost estimate was developed in the context of a ten-year mine plan, wherein new regeneration stations would be excavated periodically with the advance of the mine workings.

As discussed in detail in the Technological Feasibility section of this preamble, MSHA analyzed and evaluated the Stillwater compliance cost estimate, and determined that compliance could be attained at a much lower cost. Since the cost of excavating regeneration stations was such a significant component of Stillwater's overall cost estimate, MSHA focused on eliminating this cost element. As explained in the Technological Feasibility section, MSHA described three feasible alternative approaches for utilizing active filtration that do not require excavation of regeneration station parking areas. Although MSHA disputed several of the remaining cost items, MSHA nonetheless accepted these costs as submitted by Stillwater in developing an alternate compliance cost estimate for this mine. The inclusion of these disputed items accounts for MSHA's estimated compliance cost of $1.57 million for the Stillwater mine being somewhat higher than the revised 31-Mine Study cost estimate of $935,000.

As noted in the Technological Feasibility section of this preamble, MSHA's estimate of $1.57 million in annual DPM compliance cost is significant. However, it is less than MSHA estimated in the REA for the 2001 final DPM rule for a large precious metals mine. The REA estimated annual compliance costs of $660,000 based on a fleet size of 133 vehicles. Adjustment for Stillwater's fleet size of 350+ vehicles results in an estimated compliance cost of $1.7 million.

Several other commenters suggested that MSHA's compliance cost estimates, in general, were unrealistically low. However, without specific examples to evaluate and analyze, such comments are difficult to refute. MSHA has supported its cost estimating methodologies in general, and where specific examples have been provided by commenters, MSHA has fully supported its compliance cost estimates, such as the above discussions of the Kerford and Stillwater mines.

Except for general comments regarding the DPM Estimator, MSHA did not receive information to dispute the technological and economic feasibility for mines using room and pillar mining methods to meet the 308_{EC} µg/m³ limit. These mines include stone, salt, trona and potash mines. When additional controls were necessary to attain DPM compliance, these mines have typically elected to meet the interim limit by upgrading ventilation, using cabs with filtered breathing air, use of alternative fuels, and using equipment with clean engines. The comments received from mines in these sectors of industry focused on the difficulties of installing after-filters on large, high horsepower equipment and the increasing cost of bio-diesel fuel. These issues, along with the DPM Estimator, are discussed in detail in the Technological Feasibility section of this preamble.

VIII. Summary of Costs and Benefits

The provisions in this final rule will increase compliance flexibility with the existing final rule, and continue to reduce significant health risks to underground miners. These risks include lung cancer and death from cardiovascular, cardiopulmonary, or respiratory causes, as well as sensory irritations and respiratory symptoms. In Chapter III of the REA in support of the 2001 final rule, MSHA demonstrated that the rule will reduce a significant health risk to underground miners. This risk included the potential for illnesses and premature death, as well as the attendant costs to the miners' families, to the miners' employers, and to society at large. Benefits of the January 19, 2001 final rule include reductions in lung cancers. MSHA estimated that in the long run, as the mining population turns over, a minimum of 8.5 lung cancer deaths per year will be avoided. MSHA noted that this estimate was a lower bound figure that could significantly underestimate the magnitude of the health benefits. For example, the estimate based on the mean value of all the studies examined in the 2001 final rule was 49 lung cancer deaths avoided per year. MSHA uses the 2001 risk assessment for support of this rule.

This final rule results in net cost savings of approximately $3,634 annually, primarily due to reduced recordkeeping requirements. All MSHA cost estimates are presented in 2002 dollars. This represents an average annual savings of $20 per mine for the 177 underground metal/non-metal mines that would be affected by this 2003 NPRM. Of these 177 mines, 66 have fewer than 20 workers, 107 have 20 to 500 workers; and 4 have more than 500 workers. The cost savings per mine for mines with fewer than 20 workers will be $74. The cost increase per mine for mines having 20 to 500 workers and more than 500 workers will be $10 and $10, respectively. In the 2001 REA, MSHA estimated that the costs per underground dieselized metal or nonmetal mine for the existing rule to be about $128,000 annually, and the total cost to the mining sector to be about $25.1 million a year, even with the extended phase-in time. Nearly all of those anticipated costs would be investments in equipment to meet the interim and final concentration limits.

IX. Section-By-Section Discussion of the Final Rule

A. Section 57.5060(a) Interim DPM Limit

MSHA's existing interim DPM limit at § 57.5060(a), which became applicable July 20, 2002, restricts TC concentrations in underground mines to 400_{TC} μ/m³. The concentration limit applies to areas where miners normally work or travel. In the 2001 final rule, MSHA chose TC as the surrogate for measuring DPM concentrations.

Consistent with the 2003 NPRM, final § 57.5060(a) changes the surrogate from TC to EC, which renders a more accurate measurement. In addition, MSHA is basing the interim limit on a miner's personal exposure rather than on an environmental concentration, which results in a PEL. The new interim limit restricts a miner's personal exposure for a full shift to 308_{EC} μg/m³. MSHA believes that this new interim limit is comparable to the existing TC limit.

Because EC comprises only a fraction of TC, MSHA used a conversion factor to adapt the former interim concentration limit of TC to a new EC PEL. MSHA proposed to use a factor of 1.3, to be divided into 400_{TC} μg/m³, which produces a reasonable estimate of TC without interferences. The final EC limit is based on the median TC to EC (TC/EC) ratio of 1.3 that was observed for valid samples in the 31-Mine Study and the DPM settlement agreement. The 1.3 factor also is supported by information provided by NIOSH indicating that the ratio of TC to EC in the 31-Mine Study is 1.25 to 1.67. Most commenters to MSHA's 2003 NPRM supported an interim EC PEL of 400_{TC} μg/m³ divided by 1.3 = 308_{EC} μg/m³.

Also in the 31-Mine Study, MSHA concluded that the submicron impactor that MSHA used for DPM sampling was effective in removing carbonaceous mineral dust from the DPM sampler, and therefore, its potential for interfering with the MSHA sampling analysis. The remaining carbonate interference is removed from the sample analysis by subtracting the 4th organic peak. No reasonable method of sampling was found in the 31-Mine Study that would eliminate interferences from sources of oil mist and ammonium nitrate fuel oil (ANFO). Moreover, MSHA could not determine DPM levels in the presence of ETS with TC as the surrogate. Using EC as the surrogate will enable MSHA to directly sample miners, such as those who smoke, operate jackleg drills or load ANFO, for whom valid personal samples would be difficult to obtain with TC as the surrogate for DPM.

MSHA has found that EC consistently represents DPM. Compared to using TC as the DPM surrogate, using EC accomplishes the following: Imposes fewer restrictions or caveats on sampling strategy (locations and durations); produces a more accurate measurement; and inherently will be more precise than TC. Furthermore, NIOSH, the scientific literature, and the MSHA laboratory tests (see NIOSH letter dated April 3, 2002 and July 31, 2000 comment to the proposed rule for the 2001 rule) indicate that DPM, on average, is approximately 60% to 80% EC, firmly establishing EC as a valid surrogate for DPM.

Under the new standard, MSHA is not reducing the protection from that afforded miners under the former interim TC concentration limit, since the old TC and new EC limits are comparable in exposure reduction. Establishing a standard that focuses control efforts on diminishing the DPM level in air breathed by a miner is supported by some commenters in labor. Some commenters stated, ''We agree that personal sampling gives a better representation of real exposure, and we support the change.''

MSHA has determined that this new interim limit is both technologically and economically feasible for the M/NM mining industry to achieve. Although the risk assessment indicates that a lower DPM limit would enhance miner protection, it would be infeasible at this time for the underground M/NM mining industry to reach a lower interim limit. MSHA will continue to monitor the feasibility of the affected mining industry to comply with a lower EC exposure limit. MSHA believes that it is critical to gain compliance experience, both from the standpoint of DPF efficiency and implementation issues raised by the mining industry during this rulemaking, in order to address a final DPM limit.

Most commenters supported the value of 308_{EC} μg/m³ for the interim PEL. Some commenters suggested a limit of 320_{EC} μg/m³ as the preferred PEL. Some of these commenters cited research by Cohen, Borak and Hall in support of their position. The evidence in the rulemaking record, however, overwhelmingly supports MSHA's decisions on the appropriate interim DPM limit of 308_{EC} μg/m³. MSHA's review of the cited publication by these authors demonstrated no reference to a value of 320_{EC} μg/m³. A 320_{EC} μg/m³ limit value would have resulted from using a conversion factor of 1.25, and represents the high end of the range reported by NIOSH. MSHA disagrees with using a limit of 320_{EC} µg/m^3 and believes that the limit of 308_{EC} µg/m^3 is the appropriate limit based on the evidence contained in the rulemaking record.

Another commenter stated that mine data gathered since the current final rule was promulgated requires MSHA to lower the 2001 interim limit. This commenter believes that all of industry could reach compliance with the interim concentration limit without significant economic investment and that the control technology is available to reduce DPM to below the 2001 interim limit for feasible costs.

MSHA agrees that most of the M/NM mining industry has the capability of reaching the new interim PEL. MSHA, however, does not agree that compliance with the new PEL can be accomplished in every instance and circumstance due to implementation issues that vary from mine to mine.

During MSHA's compliance assistance visits, on many occasions it was observed that mines had purchased new equipment or installed modern engines in existing equipment. Several mines were using or testing alternative fuels and many mines had made upgrades to their ventilation systems by improving airflow distribution systems. MSHA mostly observed that mines had not begun to install DPM filters to reduce miners' exposures, as recommended by MSHA as the most cost-effective method of compliance. The DPM standard does not specify that mine operators must use a specific type of control, but MSHA recommended DPFs as a very effective method for controlling DPM. MSHA chose to leave that decision to the individual mine operator's judgment.

Most commenters from industry and labor continued to strongly support the change in the surrogate from TC to EC. These commenters stated that given the interferences known to be present in underground mining environments, using EC as the surrogate would improve the accuracy of MSHA samples. Some commenters criticized MSHA for not realizing earlier that EC was a more appropriate surrogate than TC and that use of EC would lower sampling costs of the mining industry. At the time that the 2001 final rule was promulgated, MSHA's rulemaking record supported TC as the more appropriate surrogate. Following completion of the 31-Mine Study, MSHA obtained sufficient data to change the surrogate.

Some other commenters opposed changing the surrogate. One commenter stated that the change is without foundation because the record does not support MSHA's claim that the amount of EC is an accurate surrogate for the amounts of DPM that need to be measured under actual mining conditions. MSHA disagrees. MSHA supports using EC as the most suitable surrogate for measuring DPM. Moreover, this commenter believes that the record does not support MSHA's claim that there is no solution to interference issues that arise when TC is used as the surrogate for DPM. MSHA disagrees with this comment, as well. Data in the rulemaking record from the 31-Mine Study demonstrates that there is no ''reasonable'' solution to interference issues when using TC as the surrogate.

Another commenter stated that MSHA should consider using a better surrogate than EC, since most DPM studies were conducted on whole DPM which would measure exposure to the most relevant substance. In addition, this commenter believes that a substance other than EC could be the ultimate carcinogenic agent in DPM. Many organic compounds in DPM are known carcinogens, and there is no stable EC:TC ratio. This commenter also believes that interferences from ETS introduce less variability than EC. Furthermore, the commenter states that the interference problem could be solved another way since Harvard investigators have successfully adjusted DPM measurements for ETS. Since the commenter did not provide a specific reference cite for the Harvard investigation, MSHA was unable to verify this claim. MSHA based its decisions in this final rule on the best data available to MSHA. That data demonstrates that measuring EC for determining DPM exposures will allow MSHA to sample miners' exposures in the presence of ETS without interference issues. No adjustment has to be made in the sample analysis because ETS does not affect the measurement of EC. During the 31-Mine Study, NIOSH found that there was no reliable marker for cigarette smoke in the presence of DPM.

Some commenters suggested that MSHA establish an ''action level * * * at which additional sampling and some controls kick in.'' These commenters recognized that it would be difficult for MSHA to enforce an action level below the PEL. MSHA believes that the best method of protecting miners from exposure to DPM is through the primary use of reliable controls. In Section VII of its feasibility analysis, MSHA determined that the rulemaking record has little evidence at this time to lower the PEL due to implementation and cost issues for the mining industry. Also, MSHA's air quality standards for M/NM mines do not include requirements for regulating action levels for other airborne contaminants. Furthermore, pursuant to § 57.5071 of the DPM rule, mine operators are required to monitor as often as necessary to effectively determine whether the concentration of DPM in any area of the mine where miners normally work or travel exceeds the applicable limit. In MSHA's experience at M/NM mines, this approach to worker protection is more effective and practical than establishing an ''action level'' that the commenters recognize may be unenforceable.

Several comments were received on the use and development of the error factor for DPM sampling. One commenter stated that error factors give the benefit of doubt to mine operators and exposes miners to DPM above an already inadequate exposure limit. This commenter also stated that miners' health should be given precedence over mine operators' property rights. MSHA believes that it has the burden of proving that a sample is above the PEL for enforcement purposes. Establishment of an error factor assists MSHA and reviewing courts in knowing when that burden has been met. Mine operators should review their sample results and make decisions on the level of controls required or when improvements to controls might be necessary. However, MSHA's practice has been to cite only when an exposure sample exceeds the standard times the error factor.

MARG submitted data and a consultant's comments on the sampling and analytical variability of EC measurements. These comments will be referred to below as the ''Borak/Sirianni analysis.'' The Borak/Sirianni analysis examined three bodies of EC sampling data. The first of these consisted of 25 groups of four or five simultaneous EC concentration measurements collected by MARG and summarized in Table 1 of the appendix submitted with the Borak/Sirianni analysis. This dataset, identified below as the ''MARG basket data,'' is a portion of the data obtained in the MARG study which was conducted in seven underground nonmetal mines (Cohen HJ, Borak J, Hall T, *et al.:* Exposure of miners to diesel exhaust particulates in underground nonmetal mines, *Am Ind Hyg Assoc J* 63:651–658, 2002). The second body of data, identified below as the ''baseline paired punches,'' consisted of two analytical EC results on each of 223 samples from MSHA's compliance assistance database. The third body of data examined in the Borak/Sirianni analysis was a relatively small subset (63 samples out of over 800) of the paired-punch EC data available from the 31-Mine Study. This dataset will be identified below as the ''31-Mine Study Subset.''

Based on the Borak/Siriani analysis, MARG concluded that ''* * * the [measurement] system is not accurate and not feasible.'' MSHA disagrees. Our analysis of the same data shows variability of the EC measurements presented to be well within acceptable limits. As will be shown below, the Borak/Sirianni analysis is mathematically invalid.

Each of the datasets is discussed below, first with respect to deficiencies in the Borak/Sirianni analysis and then with respect to what the submitted data actually reveal about sampling and analytical variability.

MARG Basket Data

The submitted MARG basket data consisted of 25 groups of four or five samples in which at least one EC measurement fell within the range of 75 μg/m^3 to 200 μg/m^3. Neither MARG nor the Borak/Sirianni analysis explained whether MARG collected additional basket data falling outside of this range. Additionally, no explanation was provided as to why the submitted data were restricted in this way, if more data were collected.

Unfortunately, the samples were collected without the submicron impactor. The sample results are, therefore, not appropriate to use in this rulemaking. The study reference does not indicate the type of filter holder and cyclone attachment configuration or if the mineral-dust-related carbonate that occurs in the organic portion of the analysis was subtracted off the OC determination.

When using a filter holder with an internal cyclone connection, the cyclone nozzle acts as an impactor jet and mineral dust is deposited in the center of the filter. This gives a high level of mineral dust in the center of the filter, and a non-uniform deposit of material on the filter surface. A non-uniform deposit precludes any analysis of duplicate sample punch repeatability. Additionally, three of the seven mines produced either limestone or trona. Both of these minerals contain carbonates which are evolved in the organic portion of the analysis. Failure to remove this mineral dust by use of an impactor may affect the split point between OC and EC. The referenced study indicates that up to 15 mg/m^3 of total mineral dust was present at one of the mines.

MARG did not provide individual sample results for this dataset. Nor did MARG provide any information on sampling times or filter loadings (μg/cm^2), both of which affect expected analytical variability. Only summary data, consisting of the EC measurement range, mean, standard deviation (SD), and coefficient of variation (CV), were provided for each group of ''four or five'' samples. There was no indication of which groups contained four and which groups contained five samples. Despite the statistical instability of estimated SDs, CVs, and means based on as few as four or five measurements, no confidence intervals or other measures of statistical uncertainty were provided for the summary statistics.

The Borak/Sirianni analysis consisted of tabulating ''the number and proportion of baskets corresponding to CV ranges of 0–4.99, 5–9.99, >10 and >12.5%. More specifically, Borak/Sirianni observed that ''32% of baskets containing at least one sample in the 75–200 μg/m$_3$ range had a CV ≥ 12.5%.'' Although they presented no mathematical evaluation of this finding s statistical significance, Borak/Sirianni concluded that it was ''inconsistent with the NIOSH criteria for appropriateness of analytical methods and does not meet guidelines presented in the proposed Final Rule.'' [9]

The Borak/Sirianni analysis of these data appears to be founded on an elementary misconception: That a high percentage of individual baskets with CV > 12.5% (based on four or five measurements per basket) provides evidence of a high sampling and analytical CV. Actually, as demonstrated below, the Borak/Sirianni finding reflects statistical instability (i.e., lack of reliability) in CV estimates calculated using only four or five measurements. CV estimates based on a limited number of measurements display random variability around the true CV value underlying the measurement process. It should, therefore, be expected that many of the CV estimates based on individual baskets will fall below, many will fall above, and none or few will fall exactly on the true CV. More specifically, the Borak/Sirianni finding is entirely consistent with a measurement process satisfying the NIOSH accuracy criterion.

To illustrate this point, MSHA generated a dataset of 10,000 simulated measurements randomly drawn from a log normal distribution having mean = 126 and CV = 12%.[10] More than 96% of these measurements fell within ±25% of the 126 mean or ''reference value,'' thereby showing that the simulated measurement process satisfied the NIOSH Accuracy Criterion. The 10,000 ''measurements'' were then grouped into simulated ''baskets'' of four or five measurements each,[11] and a separate unbiased estimate of the CV was calculated from the data within each basket. This resulted in 2,250 separate CV estimates of the same underlying CV, with each calculation based on four or five measurements. Figure IX–1 displays the cumulative distribution of the individual CV estimates. Despite the fact that the underlying CV was 12% for all these data, 808 (35.9%) of the CV estimates based on individual baskets exceeded 12%. This demonstrates that the corresponding Borak/Sirianni finding (32%) is consistent with meeting the NIOSH Accuracy Criterion.

As mentioned earlier, MARG did not provide filter loadings (μg/cm^2) or sampling times for the basket data. Figure IX–2, which is derived from the paired-punch comparison of EC results from the 31-Mine Study,[12] shows how NIOSH Method 5040 analytical uncertainty is expected to vary with different filter loadings. In the range of EC concentrations exhibited by MARG's basket data, sampling times substantially less than 480 minutes could substantially increase variability in the analytical results due to relatively low filter loadings. Even if we assume, however, that MARG's basket samples were all taken for at least 480 minutes, the submitted data do not show excessive sampling and analytical variability. A crude estimate of the

[9] The proposed rule does not, in fact, present any such guidelines.

[10] The simulated data were generated and analyzed using SYSTAT Statistical Software, Version 10. A computer file containing this dataset, along with a number indicating the ''basket'' to which each ''measurement'' was randomly assigned, is being placed into the public record under the name SYMBASKETS.txt. The mean value of 126 was chosen to coincide with the overall mean concentration for the MARG basket data, but this choice has no substantive bearing on the results. The CV value of 12% was chosen in order to exemplify an unbiased measurement process that satisfies the NIOSH accuracy criterion.

[11] Since the Borak/Sirianni analysis did not reveal how many of MARG's baskets contained four and how many contained five samples, the 10,000 simulated measurements were divided equally into baskets of four and five. This resulted in 1250 simulated ''baskets'' of four measurements each and 1000 ''baskets'' of five measurements each.

[12] Analytical imprecision of EC measurements is quantified, based on paired-punch results from the 31-Mine Study, in the technical document on MSHA's Web site cited as Reference #4 in the Borak/Sirianni Analysis. In the notation of that document, the quantity plotted in Figure IX–2 is CVμ [X] calculated using $\sigma\tau = 0.256$. $\sigma\tau$ incorporates both intra- and inter-laboratory analytical variability.

overall CV can be obtained by pooling results from all 25 baskets. The average of the 25 CV values given is 10.8% at a mean EC concentration of 126 μg/m³. For a dpm sample, collected with the submicron impactor (filter area 8.04 cm²), for 480 minutes at a flow rate of 1.7 Lpm, the concentration in μg/m³ is approximately 10 times the filter loading in μg/cm² (8.04 × 1000/480/1.7 = 9.85). As a result, the 126 μg/m³ corresponds to a mean EC filter loading of 12.8 μg/cm². Figure IX–2 shows that, at this loading, the CV expected for analytical variability alone is approximately 10%. Since variability within baskets reflects not only analytical variability but also variability in the volume of air pumped and in location within each basket, an overall CV of 10.8% is neither surprising nor excessive.

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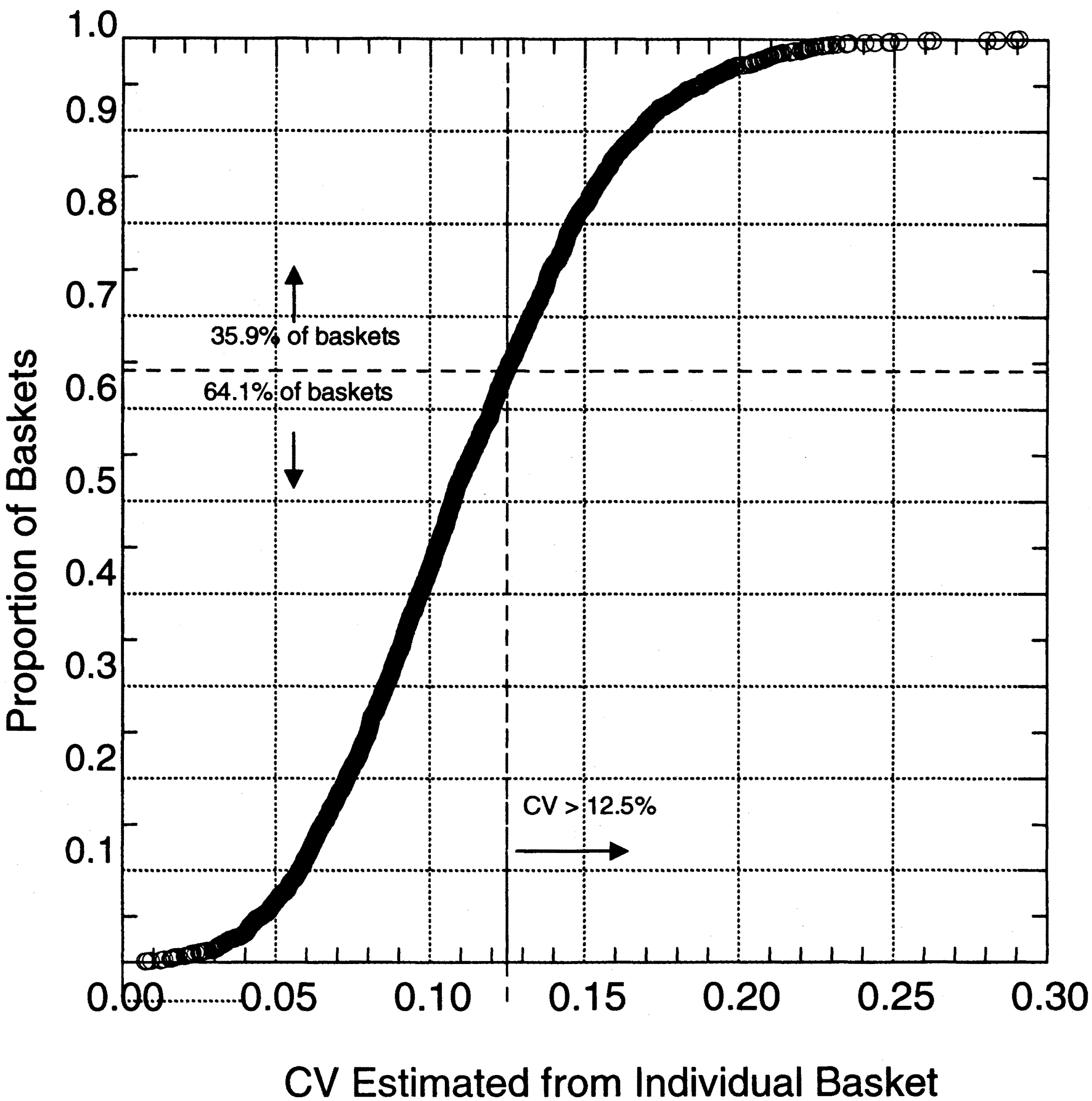

Figure IX-1. Distribution of individual CV estimates, calculated from simulated basket data satisfying NIOSH Accuracy Criterion. Dataset consists of 10,000 simulated measurements randomly drawn from lognormal distribution (mean = 126, CV = 12%) and grouped into "baskets" of 4 or 5 measurements. NIOSH Accuracy Criterion is met because 96.25% of the 10,000 measurements fall within the range 126±25%.

MARG provided no indication that any of the analytical results for its basket data were averaged over two punches, as per MSHA's procedure for samples used to cite noncompliance with the DPM standard (2003 NPRM, 68 FR 48672). It should, therefore, be noted that the analytical component of variability observed in these data would have been reduced by a factor equal to if such averaging had been performed √2. For example, if the analytical portion of variability amounted to a CV of 10%, then this would have been reduced to 7.1% if two punches had been averaged for every measurement.

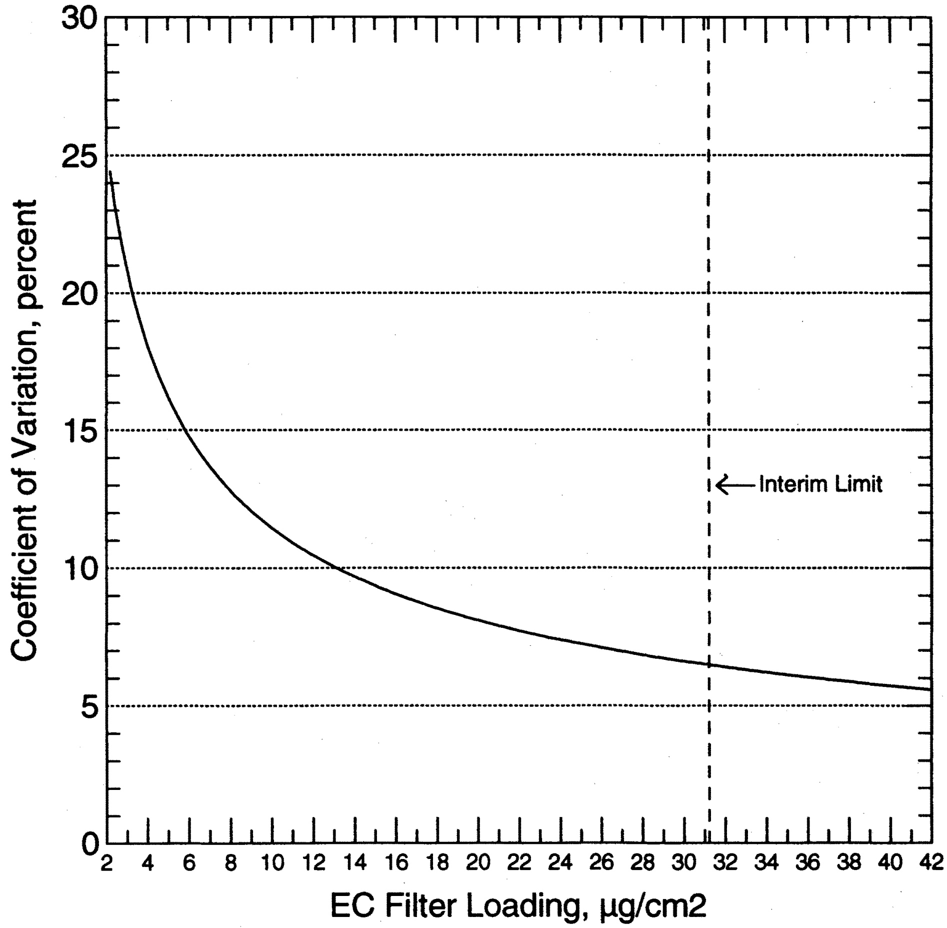

Figure IX-2. Analytical imprecision of a single EC measurement (µg/cm^2), based on paired-punch comparison in 31-Mine Study. Vertical line marked "Interim Limit" refers to EC loading corresponding to a concentration of 308 EC µg/m^3 sampled for 480 minutes at a pump airflow rate of 1.7 Lpm. CV represents analytical imprecision for result from a single punch and would be reduced by a factor of $\sqrt{2}$ if results from two punches are averaged. Plotted CV incorporates both intra- and inter-laboratory variability. Because CV is based on comparing punches taken from two locations on each filter, it combines purely analytical imprecision with heterogeneity of the deposit on the filter (a form of sampling variability). CV does not, however, reflect other sources of sampling imprecision such as variability in deposit area or pump performance. Effects of any adjustment based on a control filter are also not included.

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Baseline Paired Punches

The baseline paired-punch data examined in the Borak/Sirianni analysis consisted of laboratory results from 223 samples, collected during MSHA's baseline compliance assistance program, that were analyzed twice for EC content.[13] In accordance with MSHA's interim policy for DPM noncompliance determinations, a second punch was analyzed from each of these samples because the first punch showed EC ≥ 30

[13] The Borak/Sirianni analysis erroneously states that all 223 of these samples were "collected using an older version of the SKC impactor that differs from the impactor proscribed [sic] in the proposed final rule." We assume that the intended word was "prescribed." As explained in the 2003 NPRM at 68 FR 48679–80 and 48706, there has been no change to the impactor in the SKC sampler. For reasons explained elsewhere in this preamble, an improvement was made in the SKC filter capsule, but this change has no bearing on the comparison of paired punches taken from within the area of deposit on the filter. The older design, employing a crimped foil capsule, was used for 93 of the 223 samples. The remaining 130 samples utilized the newer design, in which a retaining ring replaced the crimped foil.

μg/cm² or TC ≥ 40 μg/cm² (see 2003 NPRM, 68 FR 48672). Results from the two punches were then averaged for purposes of determining compliance or noncompliance with the interim exposure limit.

The Borak/Sirianni analysis of these 223 paired-punch results consisted of calculating, for each pair, the ''percentage difference'' between the two punch results and tabulating the frequency of cases in which that quantity fell into three categories: 0–4.99%, 5–9.99%, and ≥10%. The ''percentage difference'' was apparently calculated as $100_X|X_1 - X_2| \div X_1$, where X_1 is the first measurement recorded within each pair. No explanation was given of the statistical properties of this quantity, and no discussion was presented of its mathematical relationship to a CV, which is defined quite differently. In particular, Borak/Sirianni made no attempt to relate the ''percentage difference'' mathematically to CV_A, which refers to the coefficient of variation for the average (not difference!) of two punch results. Nevertheless, the authors concluded (without explanation) that the frequency of cases in which the ''percentage difference'' exceeded MSHA's estimate of CV_A indicates that MSHA's estimate is too low. They also asserted that ''it is almost certain'' that these data ''document failure to meet the NIOSH and MSHA acceptability criteria.''

The Borak/Sirianni analysis of these data commits the following five errors. The first three of these distort their analysis sufficiently to render its conclusions entirely without merit.

1. Our best estimate of the true carbon loading on a filter is given by the average of the two available punch results from that filter. Therefore, individual measurement errors are best estimated as the distance of each result from the midpoint between them. In contrast, the ''percentage difference,'' as defined by the Borak/Sirianni formula, is twice the size of the percentage deviation of either punch result from the midpoint between them. This serves to exaggerate the deviation of each result from the true value. Mathematically, the relative standard deviation (RSD) of the difference exceeds the RSD of an individual punch result by a factor of √2 (prior to any blank adjustment).

2. Borak/Sirianni fail to account for the fact that MSHA's estimate of CV_A applies to the average of two punch results, rather than to an individual analytical measurement. The RSD of an individual punch result exceeds the RSD of the two-punch average by another factor of √2 (again, prior to any blank adjustment).

3. The combined effect of (1) and (2) is that, when blank adjustments are negligible, variability in the ''percentage difference,'' as expressed by an appropriate CV within pairs, would be expected to exceed analytical imprecision in a 2-punch average by a factor of 2. However, Borak/Sirianni made no attempt to calculate such a CV or make any other meaningful comparison. Instead, they simply tabulated instances in which the ''percentage difference'' exceeded CV_A. CV_A, like any coefficient of variation, does not represent an upper bound on individual deviations or differences. Indeed, approximately one-third of individual errors (without regard to direction) would normally be expected to exceed the corresponding CV. (This is why MSHA multiplies the appropriate CV by a ''confidence coefficient'' when establishing a 1-tailed 95% confidence error factor for noncompliance determinations.) Combining the factor of 2 explained above with a 95% 2-tailed confidence coefficient (1.96), ''percentage differences,'' as defined by Borak/Sirianni, are expected to exceed 2×1.96×CV more than 5% of the time. (The reason such excesses would be expected more than 5% of the time is given below, under point 4.)

4. The Borak/Sirianni method of calculating ''percentage difference'' causes such differences to take on more extreme values than they would if they were calculated relative to the average of the two punch results (*i.e.,* if the denominator of the calculation were the average of X_1 and X_2 rather than just the X_1 result). For example, using the Borak/Sirianni formula, a sample with two punch results of 192 and 212 would yield a ''percentage difference'' of either 10.4% or 9.4%, depending on which one of the two measurements is recorded as X_1. If, instead, the average of X_1 and X_2 were used as the denominator, then the percentage difference would be calculated as 9.9%.[14] So long as the smaller result is equally likely to be X_1 as X_2, the Borak/Sirianni formula for ''percentage difference'' increases some percentage differences and decreases others. Nevertheless, as shown in this example, the Borak/Sirianni formula artificially increases the count of differences exceeding 10% (or any other specified value). Furthermore, as will be explained later, the Borak/Sirianni formula for ''percentage difference'' induces an even greater systematic bias in their analysis of the 31-Mine Study subset.

5. The Borak/Sirianni analysis ignores heterogeneity of the analytical CV within the range of EC loadings considered. As indicated by Figure IX–2, the frequency of relatively large percentage differences would be expected to increase at low EC loadings. The method shown in ''Metal and Nonmetal Diesel Particulate Matter (Dpm) Standard Error Factor for TC Analysis,'' published on MSHA's Web site at *http://www.msha.gov/01–995/dieselerrorfactor.pdf,* provides one way of properly estimating analytical variability from the baseline paired punches while accounting for such heterogeneity. This method was also published as Appendix II of the 31-Mine Study (BKG–54–2) and as Appendix 2 of MSHA's web document on the error factor (AB29–BKG–61, cited as Ref. #4 by Borak/Sirianni).

To properly analyze the baseline paired punch data by the method of MSHA's web document on the error factor, the square root of each punch result (μg/cm²) is first calculated. Next, we calculate the difference between square roots within each pair and compute the standard deviation of these differences. The result for these data is an estimated SD of σ = 0.175. Contrary to the Borak/Sirianni conclusions, this is substantially less than the corresponding value, σ_τ=0.256, derived from EC analyses on 621 pairs of punches obtained during the 31-Mine Study and published in MSHA's web document on the error factor (Borak/Sirianni Ref. #4). Although Borak/Sirianni stated that ''MSHA has not evaluated its proposed method by means of systematic determinations of the CV for samples obtained under real mining settings,'' their Ref. #4 contains such an evaluation based on real mine data (621 pairs of punches) obtained during the 31-Mine Study. The lower analytical variability exhibited in these baseline paired punch data, as compared to the 31-Mine Study, is not surprising, since, for the baseline samples, both punches within each pair were analyzed by the same laboratory. For the 31-Mine Study, this was not generally the case, so both intra- and inter-laboratory variability are included in σ_τ.

As shown in MSHA's web document on the error factor, the analytical CV for an individual punch result (*X*) at a specified loading (μ) is given by

[14] Note that, in this example, the relative deviation of either X_1 or X_2 from the midpoint between them is actually 10/202 = 4.95%. This would be the appropriate value for comparison to a CV or RSD quantifying measurement imprecision.

$$CV_{\mu}[X] = \sigma\sqrt{\frac{2}{\mu}}\,.$$

This quantity, which is plotted in Figure IX–2 using σ = 0.256, must be further divided by √2 to specify analytical imprecision for a 2-punch average, as in the value of CV_A cited by Borak/Sirianni. Therefore, at an EC loading of μ = 10 μg/cm², the estimated analytical error CV for a 2-punch average is 8.1% using σ = 0.256 (as in MSHA's web document on the error factor) or 5.5% using σ = 0.175 (based on the baseline paired-punch data). For simplicity, the effect of applying a blank adjustment (by means of a control filter) has been left out of these calculations. However, the formula for CV_A provided in MSHA's web document (AB29–BKG–61) does account for the effect of a blank adjustment on analytical variability.

31-Mine Study Subset

The third body of data examined in the Borak/Sirianni analysis consisted of 63 pairs of EC results extracted from the 31-Mine Study. As in the baseline paired punches, each pair consisted of the results for two punches taken from the same sample filter. Each analytical EC punch result was converted to a blank-adjusted EC concentration (μg/m³) and multiplied by 1.3.

No explanation was provided as to why these particular 63 pairs were included in the Borak/Sirianni analysis while about 750 other paired punch results available from the 31-Mine Study were excluded. However, by examining the identification numbers of the 63 samples included, MSHA determined that they included 52 samples collected from the three trona mines involved in the 31-Mine Study, along with 11 samples collected from one of the lead/zinc mines. All 63 of these samples had one of the punches acidified so that the effects of such acidification could be evaluated. But this was apparently not the only inclusion criterion, since the Borak/Sirianni analysis excluded approximately 150 other paired-punch samples in which one of the punches was acidified. Acidification is the process by which carbonates ($CaCO_3$) are chemically removed from a DPM sample prior to the Method 5040 analysis. The collected DPM filter is exposed to hydrochloric (HCl) acid vapors. The chlorine combines with the calcium; carbon dioxide and water are evolved from the sample. Results from the 31-Mine Study showed that the submicron impactor successfully removed the carbonate minerals from the sample, and that acidification was not required prior to the analysis.

MSHA based its statistical analysis of EC analytical precision (AB29–BKG–61) on all 621 paired-punch samples from the 31-Mine Study for which (1) valid analytical results were available on both punches and (2) both punches had received identical treatment with respect to acidification. Since all 63 samples included in the Borak/Sirianni analysis had one punch acidified and the other not acidified, they, along with approximately 150 other such samples were excluded from MSHA's statistical analysis of analytical precision.

The Borak/Sirianni method of analyzing these data was, with one notable exception, identical to the method they used for the baseline paired punches. As in their statistical analysis of the baseline paired punches, they tabulated, for these 63 samples, the frequency of cases in which the ''percentage difference'' fell into three categories: 0–4.99%, 5–9.99%, and ≥10%. The only methodological difference was that, for these data, the percentage difference was always calculated relative to the lower of the two punch results within each pair. Borak/Sirianni provided no explanation or justification for why they rearranged the data within each pair so that the lower value always appears as ''Punch A'' and thus forms the denominator in their calculation of percentage difference.

The Borak/Sirianni analysis reached the same conclusion with respect to this dataset as with the baseline paired punches: that ''it is almost certain'' that these data ''document failure to meet the NIOSH and MSHA acceptability criteria.'' Likewise, since they used essentially the same statistical method, the authors reproduced the same five fallacies described earlier in connection with the baseline paired punches. There are, however, at least three more reasons why the Borak/Sirianni analysis of this particular dataset is invalid, in addition to points 1–5 above:

6. One of the punches in each pair was acidified, and the other was not. Therefore, differences in the analytical results within pairs confound analytical variability with the potential effects of acidification and differential handling. For this reason, these 63 samples (along with all others that were similarly treated) were excluded from MSHA's paired-punch analysis of analytical variability (AB29–BKG–61).

7. Fifty of the 63 Punch A results (79%) fell below 10 μg/cm² and 33 of them (52%) fell below 5 μg/cm². As shown in Figure 2, EC loadings below 5 μg/cm² exhibit substantially greater analytical variability than loadings corresponding to EC concentration limits anticipated in the second partial settlement agreement. Indeed, results for the three samples showing the greatest ''percentage difference'' all fell below the minimum value (2 μg/cm²) normally reported by a laboratory EC analysis.

8. In addition to the bias explained under point 4 above, the Borak/Sirianni calculation of ''percentage difference'' was further biased by rearranging the data within each pair so that the ''Punch A'' result (X_1) is always less than ''Punch B'' (X_2). If the Punch A and B designations (as provided in the original 31-Mine Study spreadsheet) had been left unchanged, then the ''percentage difference'' would sometimes have been calculated relative to the lower value and sometimes relative to the higher, as in the Borak/Sirianni analysis of the baseline paired punches. In their analysis of the 31-Mine Study subset, however, the lower of the two values always forms the denominator for the ''percentage difference.'' This yields systematically higher percentages than a denominator equal to the average of the two punches.

The sample identified as SKC–1D–166 illustrates the impact of points 7 and 8 on the Borak/Sirianni analysis and conclusions. In the original spreadsheet, the EC results for Punch A and B, prior to any blank adjustment, were 0.92 μg/cm² and 0.76 μg/cm². Under normal procedures, EC values this low would not even be reported by the laboratory. However, the percentage difference, relative to the average of these two values, is 9.5%. A percentage difference of this magnitude is inconsequential, given that the mean EC loading is only 0.84 μg/cm². In the Borak/Sirianni analysis, however, a blank adjustment of 0.58 μg/cm² was applied to both punch results, yielding adjusted values of 0.34 and 0.18 μg/cm². The punch A and B designations were then switched, and the percentage difference was calculated relative to the lower value, yielding a reported 89% difference. (If the punch A and punch B designations had not been switched, then Borak/Sirianni would presumably have reported the ''percentage difference'' as 47%.) Thus, the reported percentage difference is mostly an artifact of applying the blank adjustment to such small EC loadings and of calculating the percentage relative to the lower value.

Despite the additional potential variability attributable to differential handling of the punches, punch-to-punch variability in this dataset appears to be well within acceptable limits when the EC loadings are taken into account. The estimated value of σ calculated for these 63 data pairs by the method of MSHA's web document on the error factor is 0.090. This is substantially lower than the corresponding value ($\sigma\tau$ = 0.256) used in the calculation of CV_A for the average of two blank-adjusted punches as described in MSHA's web document (AB29–BKG–61). Therefore, contrary to the Borak/Sirianni assessment, this dataset exhibits less variability than what MSHA has assumed in determining an appropriate error factor. MSHA believes that this data, when analyzed correctly, verifies that the sampling and analytical method meet the NIOSH criteria.

B. Section 57.5060(c)

Section 57.5060(c) of the 2001 final rule allows mine operators to apply to the Secretary for additional time to meet the final concentration limit of 160_{TC} $\mu g/m^3$ of air. Operators are allowed only one special extension per mine, which cannot exceed a period of two years. The rule also contains certification and posting requirements and requires operators to provide a copy of the approved application to the authorized representative of miners. The rule, however, does not apply to the interim concentration limit.

In the DPM settlement agreement, MSHA agreed to adapt this provision to apply it to the interim EC limit, include consideration of economic feasibility, and allow for annual renewals of special extensions. MSHA proposed to revise the standard pursuant to the terms of the settlement agreement.

Unlike the 2003 NPRM, final § 57.5060(c)(1) does not expand the scope of the provision to the interim PEL. Instead, MSHA has decided to retain the scope of the 2001 final rule so that a special extension applies solely to the final concentration limit. MSHA believes that the feasibility data in the rulemaking record does not justify providing for an extension of time in which to comply with the interim PEL. MSHA found that the baseline sampling results project that 63% of miners sampled were not overexposed to the interim DPM limit. In the 2001 final rule, MSHA intended that this provision apply to mine operators who needed more time to implement technological solutions to control DPM in their individual mines. Also, MSHA wanted to give mine operators some flexibility where the regulatory scheme prohibited administrative controls and respiratory protection. Under this final rule, MSHA has included its traditional hierarchy of controls. The test for determining if an individual operator has implemented all feasible controls is very similar to that for qualifying for a special extension absent burdensome paperwork requirements.

MSHA believes that by incorporating the hierarchy of controls approach, this final rule addresses the primary concern expressed by industry commenters who supported special extensions: that compliance with the interim DPM limit using engineering and administrative controls alone is not feasible for each individual operator's circumstances. MSHA, however, has decided to retain the 2001 requirement, as revised, for the final concentration limit. At this time, the DPM rulemaking record does not contain sufficient information to delete the requirement as it applies to the final limit.

In final § 57.5060(c)(1), MSHA will consider both economic and technological feasibility when determining whether operators qualify for a special extension for the final concentration limit. MSHA believes that both technological and economic feasibility must be assessed on a case-by-case basis. Therefore, mine operators will have an opportunity to demonstrate to MSHA that there is no cost-effective solution to reducing a miner's exposure to DPM.

Section 57.5060(c)(1) also authorizes the MSHA District Manager, rather than the Secretary, to approve special extensions to the final concentration limit. MSHA believes that the district managers have extensive knowledge of the specific conditions and circumstances that exist at mines within their regions. Consequently, MSHA has determined that they are the appropriate entity to assess technical and economic feasibility issues at mines. In unusual or particularly complex circumstances, district staff may be assisted by personnel from MSHA's Directorate of Technical Support.

When determining whether to grant a special extension for complying with the final concentration limit, MSHA will apply the criteria of the standard. MSHA will conduct an analysis of the circumstances at a mining operation to determine whether the mine operator has exhausted all feasible engineering and administrative controls before using respiratory protection to supplement controls. A mine operator's application for an extension must include information that explains why the operator believes engineering and administrative controls sufficient to achieve compliance with the applicable limit are economically and/or technologically infeasible. The application also must include the most recent DPM monitoring results, and specify the actions the operator intends to take during the extension period to minimize miners' exposures to DPM, such as monitoring, ordering controls, adjusting ventilation, respiratory protection, and other good faith actions of the mine operator. The circumstances under which MSHA requires respiratory protection are in this final § 57.5060(d). In order for MSHA to approve an application for a special extension, MSHA will evaluate whether the mine operator has utilized all feasible controls. Such an evaluation will involve consideration of numerous factors including the specific mining conditions, type of mining equipment used, nature of the overexposure, controls used by the mine operator, and MSHA policy and case law governing the economic and technological feasibility of controls. Comprehensive discussion regarding economic and technological feasibility, and enforcement of feasible controls is included elsewhere in this preamble.

Where an extension is granted, overexposed miners will be required to wear respiratory protection under a respiratory protection program as specified in § 57.5060(d). As MSHA stated in the preamble to the 2003 NPRM, it does not intend for PPE to be permitted during an extension period as a substitute for feasible engineering and administrative controls. Rather, MSHA will require mine operators to implement all feasible engineering and administrative controls to reduce exposures to the applicable limit, or if that is not possible, to the lowest level feasible. Once these controls are implemented, MSHA will consider whether to grant the extension. During the period of the extension, the mine operator will be required to maintain these engineering and administrative controls, along with implementation of a respiratory protection program fully compliant with ANSI Z88.2–1969 for all miners whose exposure to DPM continues to exceed the applicable DPM limit.

Like the 2003 NPRM, § 57.5060(c)(2) of the final rule retains the requirement for the mine operator to certify that one copy of the application was posted at the mine site for at least 30 days prior to the date of application, and another copy was provided to the authorized representative of miners. It is the agency's position that such advance notification provides miners with the opportunity to provide comments to the District Manager regarding the information provided by the mine operator in the application. This record also is subject to access to records requirements under § 57.5075 of the 2001 final rule.

One commenter questioned the need for the requirement under § 57.5060(c)(2) to provide advance notification to a miners' representative when a mine operator is going to submit an application for a special extension. This commenter suggested instead that it is sufficient to give a copy to the miner's representative at the time the application is submitted. MSHA disagrees for the above reasons.

Final § 57.5060(c)(3) limits each special extension to a period of one year from the date of approval, and removes the limit on the number of special extensions that may be granted to each mine. MSHA's determination is based on limited data in the rulemaking record at this time to conclude that mine operators feasibly can meet the final DPM limit.

MSHA also considered longer durations for special extensions. MSHA acknowledges that durations longer than one year would reduce the paperwork burden on mine operators. However, MSHA rejected the concept, since MSHA has observed rapid progress in the development of improved DPM control technology since 2001. Moreover, introduction of new mining equipment models increasingly include features aimed at better reducing DPM exposures, such as cleaner engines and better environmental cabs. It is not MSHA's intent to allow mine operators to use respiratory protection for extended periods of time where controls are feasible.

Other commenters who supported the proposed changes to § 57.5060(c) wanted the criteria used for granting or denying a special extension to be communicated clearly and unambiguously to the mining industry in the body of the standard. Moreover, these commenters wanted MSHA to give a mine operator an extension if the operator meets the criteria under this standard.

Given that each mine has unique circumstances affecting economic or technological feasibility to comply with the DPM standard, MSHA chose to include generic criteria in the standard for mine operators to develop and for MSHA to consider in granting extensions.

Final § 57.5060(c)(4) requires mine operators to comply with the terms of an approved application for a special extension. This provision also requires mine operators to post a copy of the approved application at the mine site for the duration of the extension, and provide a copy to the authorized representative of the miners.

One commenter stated that posting a copy of the application on the mine bulletin board for the duration of the extension is excessive. As an alternative, this commenter suggested posting the application for a sufficient time for miners to view it. MSHA believes that miners and their representatives should have the right to review the approved special extension at the mine site for the duration of its effectiveness. Consequently, MSHA has retained the posting requirement in this final rule.

MSHA requested comments on whether proposed § 57.5060(c) would be necessary in light of MSHA's recommendations to prescribe use of feasible engineering and administrative controls supplemented by respiratory protection. MSHA also requested that the public give examples of how this requirement would benefit mine operators if it were included in the final regulatory framework. MSHA stated in the preamble to the 2003 NPRM that it was interested in avoiding duplication and increased paperwork for the mining industry to resolve feasibility issues at individual mining operations. Therefore, MSHA was seeking further input from the public on the need for proposed § 57.5060(c) and how this provision fits within the comprehensive structure of the current rulemaking.

With respect to the interim limit, MSHA agrees with the commenter who observed that MSHA routinely handles compliance problems that are due to circumstances beyond the control of the mine operator without special extensions, and that therefore, if these same procedures are followed with respect to DPM, special extensions of the interim DPM limit are not justified. The commenter's other suggestion that remaining issues regarding special extensions be deferred until rulemaking begins on the final DPM limit will be considered by MSHA at that time. Until then, provisions relating to special extensions to the final DPM limit have been retained in this final rule.

MSHA apprised the mining community in the proposed preamble of its concerns over whether a special extension is necessary given the changes to the methods of compliance in the new final rule. MSHA believes that these revisions accomplish the same objective as a special extension, but without the associated paperwork and recordkeeping. MSHA explained that it believed special extensions were appropriate in the context of the original 2001 final rule, because it prohibited respiratory protection and administrative controls as means of compliance. The 2001 final rule would have required mine operators to comply with the applicable DPM limit using only engineering and work practice controls. Respiratory protection and administrative controls (defined uniquely as job rotation) were expressly prohibited as means of compliance.

Numerous comments to the 2003 NPRM were received concerning this provision. Several commenters supported the proposed changes to § 57.5060(c). Some other commenters supported the proposed changes, but suggested that an appeals process should be specified so a mine that is denied a special extension by the District Manager could appeal that decision to a higher authority. Several commenters who supported the addition of an appeals process suggested that a time limit of 30 days be imposed on the District Manager to determine whether to grant a special extension. In addition, they suggested that an additional 60 days be provided for an appeal if the District Manager does not grant the special extension. MSHA believes that the Mine Act currently affords mine operators adequate due process rights to a hearing on the merits before an administrative law judge (ALJ) of the independent Commission. If an operator disagrees with the ALJ's decision, the operator may request an appeal before the Commission, which is composed of five independent commissioners. Any person adversely affected by a determination of the Commission may obtain review from a U.S. court of appeals for the applicable circuit. For the foregoing reasons, MSHA sees no reasonable basis for creating parallel procedures to accomplish the same objective as existing procedures.

One of the commenters suggested that MSHA grant extensions prior to issuance of a citation for an overexposure to DPM, rather than using the citation as the triggering event that initiates the special extension process. Under the final provision, a citation does not need to be issued before MSHA can grant an extension. MSHA, however, must assess feasibility of compliance before granting an extension or denying an application for an extension. If MSHA finds a miner overexposed to DPM and the mine operator does not comply with all aspects of § 57.5060(d), MSHA will cite the operator for noncompliance.

Several comments were received that were opposed to any form of special extension or any mechanism by which mine operators could delay compliance with the applicable DPM limits using exclusively engineering or work practice controls. Commenters who opposed special extensions stated that MSHA lacks evidence to substantiate the need for expanding the scope of the special extension provision to include the interim limit. These commenters believe that the rulemaking record adequately documents feasibility of the mining industry, as a whole, to comply with the DPM limits. Commenters noted that MSHA requested examples that substantiate this need, but none were submitted by the mining industry. One commenter suggested that just because some operators require technical help doesn't mean the rule is infeasible for the industry as a whole. This commenter also noted that the proposed changes to the special extension provision address both the interim and final DPM limits, despite the fact that the preamble to the 2003 NPRM stated that MSHA, ''is only now seeking information about whether the final limit needs to be changed.''

MSHA wishes to clarify that it proposed making changes to § 57.5060(c) that would have applied special extensions to both the interim and final DPM limits. MSHA strongly agrees that the mining industry, as a whole, can comply with the interim PEL. Also, the 31-Mine Study, baseline sampling results, compliance assistance visits, and MSHA's current experience with enforcing a comparable interim limit all sustain MSHA's determination regarding the interim PEL. MSHA, however, does not have adequate evidence at this time to delete the special extension requirement for the final concentration limit.

Commenters opposed to special extensions also expressed that the proposed changes to the special extension provision are less protective than the existing provision because respirators could be substituted for more protective engineering and work practice controls. These commenters stated further that such action violates the Mine Act requirement in Section 101(a)(6)(a) that such rules attain the highest degree of protection for miners, with feasibility as a consideration. Since these commenters believe feasible engineering and work practice controls exist for the industry as a whole to comply with the applicable DPM limits, they reasoned that a provision permitting compliance by respirators would constitute a diminution of protection to miners. MSHA disagrees. Nowhere does this final rule allow respiratory protection in lieu of feasible engineering and administrative controls. If anything, MSHA has provided greater protection for miners by allowing prompt usage of supplemental protection for miners when feasible controls have been exhausted.

C. Sections 57.5060(d) and 57.5060(e)

Section 57.5060(d) of the 2001 final rule permits miners engaged in specific activities involving inspection, maintenance, or repair activities to work in concentrations of DPM that exceed the interim and final limits, with advance approval from the Secretary. MSHA specifies in the standard that advance approval is limited to activities conducted as follows:

(i) For inspection, maintenance or repair activities to be conducted:

(A) In areas where miners work or travel infrequently or for brief periods of time;

(B) In areas where miners otherwise work exclusively inside of enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; or

(C) In shafts, inclines, slopes, adits, tunnels and similar workings that the operator designates as return or exhaust air courses and that miners use for access into the mine or egress from the mine;

Operators must meet the conditions set forth in the standard for protecting miners when they engage in the specified activities in order to qualify for approval of the Secretary to use respiratory protection and work practices. MSHA considers work practices a component of administrative controls.

In tandem with this requirement is § 57.5060(e) of the 2001 final rule which prohibits use of respiratory protection to comply with the concentration limits, except as specified in an approved extension under § 57.5060(c), and then, only for activities related to inspection, repair, or maintenance activities. Additionally, Section 57.5060(f) of the 2001 final rule prohibits use of administrative controls to comply with the concentration limits. On July 18, 2002, MSHA stayed §§ 57.5060(d), (e) and (f) of the 2001 final rule (67 FR 47296) pending completion of their revisions in this final rulemaking.

Pursuant to the DPM settlement agreement, MSHA proposed to adopt the same hierarchy of controls as required in MSHA's other exposure-based health standards for M/NM mines, and considered requiring application to the Secretary before respirators could be used to comply with the DPM standard. MSHA further specified that employee rotation would not be allowed as an administrative control for compliance with this standard.

As proposed, the new final rule on the interim limit requires that when a miner's exposure exceeds the PEL, operators must reduce the miner's exposure by installing, using and maintaining feasible engineering and administrative controls; except operators are prohibited from rotating a miner to meet the DPM limits. When controls do not reduce a miner's exposure to the DPM limits, controls are infeasible, or controls do not produce significant reductions in DPM exposures, operators must continue to use all feasible controls and supplement them with a respiratory protection program, the details of which are discussed below in this preamble. The new final rule does not include requirements for written administrative control procedures, written respiratory protection programs, medical examinations of respirator wearers or transfer of miners unable to wear respirators. Additionally, the new final rule deletes § 57.5060(e), prohibiting respiratory protection as a method of compliance with the DPM rule, and § 57.5060(f), prohibiting the use of administrative controls for compliance with the 2001 final rule.

The new final rule does not give preference to engineering controls over administrative controls. MSHA will require all feasible controls, of both types if necessary, to be implemented to reduce a miner's exposure to DPM. Employee rotation, however, is not permitted as an administrative control under this standard. Under the new final rule, mine operators have a choice of which control method they will use first. MSHA intended for mine operators to have the flexibility to choose to start with engineering or administrative controls, or a combination of both, for the control method that best suits their circumstances.

MSHA, however, believes that engineering controls should be included in the first tier of any control method for protecting miners against exposure to airborne contaminants. Engineering controls provide a permanent method of modifying the exposure source, or they modify the environment of the exposed miner. As a result, they decrease the miner's exposure to hazardous levels of DPM. Moreover, engineering controls are more consistent and reliable protection for miners. The effectiveness of engineering controls can be readily determined and assessed. Routine maintenance of engineering controls provides greater effectiveness.

In the 2001 final rule, MSHA uniquely defined administrative controls as ''worker rotation.'' MSHA historically has considered other types of controls, besides worker rotation, to be administrative controls, including work practice controls which MSHA permits under this new final rule.

Work practice controls are changes in the manner work tasks are performed in order to reduce or eliminate a hazard. MSHA strongly believes that these types of administrative controls do not compromise miners' health and safety and do not reduce the level of protection provided miners under the existing final rule. Moreover, mine operators should be given the flexibility to choose to start with either engineering or administrative controls, or a combination of both, for the control method best suited for their mines. Some examples of work practice controls include: Minimizing engine idling; limiting number of diesel-powered equipment operating in an area; reducing or limiting engine horsepower; hauling upgrade in exhaust drifts rather than in intake; and limiting the number of persons working in high exposure areas.

MSHA's regulatory scheme for its hierarchy of controls is based on its current enforcement policy for its airborne contaminants which are included in MSHA's M/NM air quality standards (30 CFR 56/57.5001–.5006). Under these standards, MSHA requires mine operators to abate a citation for an overexposure to airborne contaminants by using feasible engineering and administrative controls to reduce the miner's exposure to the contaminant's exposure limit. Respiratory protection is required to supplement feasible controls that do not reduce a miner's exposure to the permissible level. The air quality standards do not contain a requirement for mine operators to develop written administrative control procedures, nor does MSHA's enforcement policy require a written respiratory protection program. (See *MSHA Program Policy Manual, Volume IV, Parts 56 and 57, Subpart D, §§ .5001 and .5005, August 30, 1990*).

Some commenters opposed changing the control method from that of the 2001 final rule, while others supported removing the prohibition on administrative controls and respirators in order to have greater compliance flexibility. MSHA agrees that operators should be afforded greater flexibility of compliance where such modifications to the DPM standard do not compromise or lower miners' health protection from that provided under the 2001 final rule. Additionally, miners should be afforded the added protection of respirators when engineering and administrative controls are not feasible, cannot reduce DPM exposures to within permissible limits, or cannot achieve significant reduction in DPM levels.

MSHA evaluated the potential consequences of relying on the hierarchy of controls in the final rule. MSHA also examined different control methods but abandoned them since they were less protective than those in the 2001 final rule. These approaches included allowing rotation of miners, and respiratory protection upon application to the Secretary of Labor. MSHA also examined giving preference for engineering controls as a first resort with a lesser role for administrative controls, including work practices. Though some of these approaches would save money for the mining industry, MSHA found that they either could be less protective or, in some cases, too restrictive for the mining industry in complying with the DPM rule. There is also insufficient scientific evidence in the rulemaking record to justify some of these changes for controlling exposure to a potential human carcinogen. For example, allowing worker rotation would increase the number of persons exposed to a potential carcinogen and thereby increase the number of individuals at risk.

Commenters suggested that MSHA lacks legal justification for its hierarchy of controls and reliance on other MSHA rules does not justify this approach. Many commenters believe that MSHA should allow mine operators to use respiratory protection on an equal footing with engineering and administrative controls. In fact, some commenters believe that respiratory protection is an engineering control. MSHA disagrees. MSHA believes that it has adopted an approach that is supported by the best available evidence and sustains the standard industrial hygiene practice to rely first upon engineering and administrative controls to reduce a person's exposure to hazardous airborne contaminants.

Throughout this rulemaking, MSHA has asked the mining community for their views on the appropriate role for administrative controls, and whether it would be necessary for MSHA to require written administrative procedures. In response to the 2003 NPRM, the mining industry strongly objected to written administrative procedures. Commenters stated that such a requirement would increase compliance costs and reduce efficiency and personnel availability. Organized labor recommended that MSHA require operators to have written administrative control strategies and post them on the mine's bulletin board.

MSHA's M/NM air quality standards do not require that administrative controls be in writing. However, written administrative controls are required under MSHA's more recently promulgated noise standard at 30 CFR part 62. Although the 2001 final rule specifically prohibits the use of administrative controls, it does not prohibit other types of work practices which MSHA considers to be administrative controls. The 2001 final rule does not include a requirement that mine operators develop a written work practice control strategy when using such controls to achieve compliance with the PEL, however, MSHA recommends it as a good industrial hygiene practice. MSHA is relying upon its current experience under the air quality standards that do not include written administrative control procedures. Thus far, the lack of these written procedures has not hindered MSHA's effective enforcement of its air quality standards. Where possible, MSHA is avoiding additional paperwork burdens under the final DPM rule.

MSHA also proposed to prohibit rotation of miners as an administrative control to comply with the final DPM rule. Most commenters requested that job rotation be allowed because it is a low cost control method and it increases management flexibility to achieve compliance. These commenters, however, offered no scientific evidence in support of their position. Organized labor and some other commenters opposed allowing worker rotation. They stated that rotation may reduce the risk to an individual miner, but it will not necessarily reduce the overall risk to the population of miners; also, depending on the shape of the dose response curve, it may actually increase the population risk, resulting in more cancer overall.

As stated earlier, the 2001 risk assessment upon which this rule is based classifies DPM as a probable human carcinogen. The majority of scientific data for regulating exposures to carcinogens supports that job rotation is an unacceptable method for controlling exposure to both known and probable human carcinogens because it increases the number of persons exposed. Recent OSHA chemical-specific regulations for both known human carcinogens and probable human carcinogens prohibit job rotation as a means of compliance. Examples include the OSHA standards for asbestos, butadiene, and ethylene oxide, which are known human carcinogens (based on the CDC National Toxicology Program (NTP) Report on Carcinogens for 2002 (*Report on Carcinogens, Tenth Edition; U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, December 2002.*)), and OSHA standards for methylenedianiline at 29 CFR § 1910.1050 and methylene chloride, (29 CFR § 1910.1052), which are reasonably anticipated to be human carcinogens (based on the same NTP report). DPM also appears on the NTP listing of chemicals that are reasonably anticipated to be human carcinogens. Therefore, based on the scientific data in the DPM rulemaking record, final § 57.5060(e) retains the prohibition on the rotation of miners as an administrative control used for compliance with this the DPM rule.

Engineering controls are intended to refer to controls that remove the DPM hazard by applying such methods as modification, substitution, isolation, enclosure, and ventilation. MSHA would consider a control to be effective in reducing DPM exposure if credible scientific or engineering studies conclude that a control will achieve a significant reduction in exposure. Additionally, MSHA will consider a control to be effective if MSHA finds that similar diesel equipment operating under similar conditions has demonstrated that the equipment is capable of significantly reducing exposures. These significant reductions may be achieved either by a single control, or in combination with other controls, and in either laboratory or field trials. MSHA believes that a 25% or greater reduction in DPM exposure is significant. MSHA discusses this issue in more detail in the Feasibility section of this preamble.

MSHA considers certain traditional methods for control of exposure to airborne contaminants to be technologically feasible for controlling exposures to DPM, such as improved ventilation (main and/or auxiliary) and enclosed cabs with filtered breathing air. Improving ventilation may involve upgrading main fans, use of booster fans, and use of auxiliary fans that may or may not be connected to flexible or rigid ventilation duct, as well as installation of ventilation control structures such as air walls, stoppings, brattices, doors, and regulators. At most mines, cabs with filtered breathing air are technologically feasible for many newer model trucks, loaders, scalers, drills, and other similar equipment. However, use of enclosed cabs with filtered breathing air may not be feasible as a retrofit to certain older equipment or where the function performed by miners using a particular piece of equipment is inconsistent with any type of cab (*e.g.*, loading blastholes from a powder truck, installing utilities from a scissors-lift truck) or where the height of the mine roof is insufficient for cab clearance. Other examples of effective DPM engineering controls that MSHA would consider to be technologically feasible include: DPM exhaust filters; certain alternative fuels; fuel blends; fuel additives; fuel pre-treatment devices; and replacement of older, high-emission engines with modern, low-emission engines.

MSHA asked for comments on the appropriate role for respiratory protection in controlling DPM exposure. Although commenters disagree on the types of restrictions that MSHA should place on their use, most commenters indicated that respirators with some restriction on their use should be permitted as a means of compliance with the DPM limits. Some commenters believe MSHA DPM regulations should conform verbatim to the current respirator requirements in MSHA's air quality standards at 30 CFR 57.5005. Other commenters felt that the only change MSHA should make to the existing requirements for respirator use in 30 CFR 57.5005, would be to add requirements for filters. Comments were received from those who believe that PPE such as respiratory protection may be far more effective in protecting miners from suspected DPM health effects than any available and feasible engineering control technology.

Other commenters suggested MSHA model its respirator program after OSHA's generic standard for respiratory protection at 29 CFR 1910.134. One commenter said that routine use of respirators for any normal production job or activity should be allowed only under a special extension and only for the final exposure limit, or where controls are in the process of being installed. They and other commenters also said that respirators are hard to tolerate under the best of conditions, and that a 10-minute break should be allowed every two hours, so the miner can remove the respirator in clean air. Another commenter requested that respirators not be used for the purpose of determining compliance. Some of the objections to the use of respirators that were given by commenters are: Respirators leak, interfere with communication, increase the work of breathing, and are stressful; instead of creating one system to protect all workers, use of respirators creates one system per worker, each of which needs maintenance; some workers cannot wear respirators for a variety of reasons; and routine use of respirators breeds carelessness.

MSHA agrees that respiratory protection does not provide comparable protection to that of engineering and administrative controls. Therefore, the new final rule only requires respiratory protection as a supplement to feasible engineering and administrative controls. When controls do not reduce a miner's DPM exposure to the limit, controls are infeasible, or controls do not produce significant reductions in DPM exposures, then controls must be used to reduce the miner's exposure to as low a level as feasible and be supplemented with respiratory protection in accordance with 30 CFR 57.5005(a), (b), and 30 CFR 57.5060(d)(1) and (d)(2).

Based on observations and experience in underground M/NM mines, MSHA continues to believe that feasible engineering and administrative controls exist to adequately address most overexposures to the interim DPM limit. However, MSHA is not persuaded that all DPM overexposures can be eliminated through implementation of feasible engineering and administrative controls alone. Extra protective measures such as those afforded by respiratory protection must be taken to protect miners in such circumstances. Therefore, MSHA's final § 57.5060(d) conforms to the current respirator requirements in MSHA's air quality standards in § 57.5005, with the addition that the types of filters appropriate for protection from DPM are specified.

Type of Respiratory Protection

In the 2003 NPRM, MSHA proposed that filters for air purifying respirators, used to comply with the DPM limits, be certified in accordance with 30 CFR part 11 as a high efficiency particulate air (HEPA) filter; certified per 42 CFR part 84 as 99.97% efficient; or, certified by NIOSH for DPM. Additionally, the 2003 NPRM would have required that non-powered, negative-pressure, air purifying, particulate-filter respirators use an R-or P-series filter or any filter certified by NIOSH for DPM. It also specified that R-series filters not be used for longer than one work shift.

MSHA requested comments on the type of respirators that would be suitable for protection against DPM. Some commenters suggested that various commercially available respirators, including those with filtering facepieces, were suitable for protection against particles smaller than DPM, and would therefore be suitable for DPM as well. NIOSH recommended that respirators used for protection against DPM have an R–100 or P–100 certification per 42 CFR part 84. NIOSH also recommended against using N-rated respirators since diesel exhaust contains oil, and aerosols containing oil can degrade the performance of N-rated filters.

As some commenters suggested, MSHA is adhering to the provisions for respiratory protection afforded in accordance with § 57.5005(a) and (b). However, § 57.5005(a) requires that respirators approved by NIOSH under

42 CFR part 84 which are applicable and suitable for the purpose intended be furnished and miners use the protective equipment in accordance with training and instruction. Currently, there is no non-powered, negative-pressure, air purifying, particulate-filter respirator certified by NIOSH as appropriate for protection from DPM. In order to protect miners from DPM exposure, MSHA is adopting the NIOSH recommendation that respirators be NIOSH certified per 42 CFR part 84 as a high-efficiency particulate air (HEPA) filter, certified per 30 CFR part 11 as 99.97% efficient, or certified by NIOSH for DPM. MSHA is technology-forcing in its rulemaking, and therefore, addressed the likelihood that a respirator may be approved in the future by NIOSH for DPM. MSHA is also adopting the NIOSH recommendation that filters used in non-powered, negative-pressure, air purifying respirators be either R- or P-series.

In MSHA PPL No. P03–IV–1, effective August 8, 2003, MSHA addressed the question of whether a powered air-purifying respirator (PAPR) could provide suitable respiratory protection from DPM. MSHA stated, ''Yes, if the PAPR is equipped with filters that meet one of the following criteria:

- Certified by NIOSH under 30 CFR part 11 as high efficiency particulate air (HEPA) filter;
- Certified by NIOSH under 42 CFR part 84 as 99.97% efficient; or
- Certified by NIOSH for DPM.''

This holds true for compliance with final § 57.5060, and MSHA's position will be reiterated in MSHA's compliance guide for the new final rule. MSHA believes that most workers who are medically unable to use a negative pressure respirator will be able to use a PAPR, which offers considerably less breathing resistance than a negative pressure respirator. Employees who cannot use a negative pressure respirator could be provided with a less physiologically burdensome respirator that will enable them to continue in their jobs protected against DPM exposure.

NIOSH also recommended that combination filters capable of removing both particulates and organic vapor be specified, since organic vapors and gases can be adsorbed onto DPM. MSHA, however, does not have data substantiating that a DPM overexposure would necessarily indicate an associated overexposure to organic vapors. Therefore, the final rule does not require respirators to be certified for organic vapor. If simultaneous sampling for DPM and organic vapors indicate overexposure to both contaminants, any subsequent citation(s) relating to the overexposures would require that respirators be used and equipped with a filter or combination of filters rated for both DPM and organic vapors.

Based on the above comments and discussion, MSHA's final rule on the interim limit requires that when respirators are used for compliance with the DPM limits, that air purifying respirators be equipped with either:

(i) Filters certified by NIOSH under 30 CFR part 11 as a high efficiency particulate air (HEPA) filter;

(ii) Filters certified by NIOSH under 42 CFR part 84 as 99.97% efficient; or

(iii) Filters certified by NIOSH for DPM.

Additionally, when non-powered, negative-pressure, air purifying, particulate-filter respirators are used for compliance, the final rule requires the use of an R- or P-series filter, or any filter certified by NIOSH for DPM, and that an R-series filter not be used for longer than one work shift.

Written Respiratory Protection Program. The 2003 NPRM recommended that when respirators were used for compliance with the DPM limits, their use be in accordance with MSHA Air Quality Standard, § 57.5005(a), (b), and § 57.5060(d)(1) and (d)(2). Section 57.5005(b) incorporates by reference, ANSI Z88.2–1969, ''American National Standards Practices for Respiratory Protection.'' ANSI 1969 contains numerous recommended practices for the appropriate selection, use, and maintenance of respirators. Included among these is a recommendation that written standard operating procedures governing the selection and use of respirators be established. MSHA's enforcement policy on its air quality standards has focused on several of the key recommendations in ANSI 1969, including fit testing, maintenance, and cleaning of respirators. MSHA's policy, however, is silent regarding the ANSI recommendation on written standard operating procedures. Accordingly, under the 2003 NPRM, a written respirator program would not have been required.

In MSHA's 2003 NPRM, it asked the mining community to submit further information for justifying a written respiratory protection program, including cost data, benefits to miners' health, and projected paperwork burden.

One commenter stated that it was wrong to create a respiratory protection requirement that treats exposure to DPM differently than other gaseous substances requiring the use of such protective means. Another commenter stated that proposing changes to MSHA's respirator standard creates multiple technical, scientific, medical, and economic issues that must be closely examined from the perspective of MSHA's statutory mandates. This commenter suggested that given the vast number of issues involved, it would be inappropriate to consider respirator standard changes in an ''expedited'' rulemaking limited to the DPM standard. Other commenters also suggested that MSHA address any additional respiratory protection requirements in a separate, generic rulemaking applicable to all contaminants. Some commenters opposed a written program because they believe the rule already carries too heavy a paperwork burden.

Commenters supporting a requirement for a written respirator program suggested that it is an essential element of a respiratory protection plan and that MSHA's requirements for respiratory protection should be modeled after OSHA's requirements in 29 CFR 1910.134.

MSHA agrees with commenters who believe that the final respiratory protection provisions should be consistent with the current air quality requirements. Therefore, MSHA has decided not to require that respiratory protection programs be in writing in this final rule.

Medical Evaluation and Miner Transfer. The 2003 NPRM did not include provisions addressing the medical evaluation of respirator wearers or the transfer of miners unable to wear respirators due to medical and psychological conditions. MSHA, however, asked for further information from the public as to whether the final rule should include requirements for medical examination and transfer. Commenters were asked to submit cost implications of such a program.

In MSHA's 2003 NPRM, it discussed this issue at length and asked commenters to provide their views for consideration in the final rule. Moreover, MSHA included in this discussion its statutory authority to promulgate, where appropriate, medical surveillance and transfer of miner requirements to prevent miners from being exposed to health hazards. The Mine Act provision addressing this issue is Section 101(a)(7) which states, in pertinent part:

> Where appropriate, such mandatory standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring miner exposure at such locations and intervals, and in such manner so as to assure the maximum

protection of miners. In addition, where appropriate, any such mandatory standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the operator at his cost, to miners exposed to such hazards in order to most effectively determine whether the health of such miners is adversely affected by such exposure. Where appropriate, the mandatory standard shall provide that where a determination is made that a miner may suffer material impairment of health or functional capacity by reason of exposure to the hazard covered by such mandatory standard, that miner shall be removed from such exposure and reassigned. Any miner transferred as a result of such exposure shall continue to receive compensation for such work at no less than the regular rate of pay for miners in the classification such miner held immediately prior to his transfer. In the event of the transfer of a miner pursuant to the preceding sentence, increases in wages of the transferred miner shall be based upon the new work classification.

Currently, MSHA standards do not require medical transfer of M/NM miners. Existing standards at 30 CFR 56/57.5005(b) for control of miners' exposures to airborne contaminants require that mine operators establish a respiratory protection program consistent with the ANSI Z88.2–1969 ''American National Standard for Respiratory Protection'' which includes medical determinations for potential respirator wearers. However, MSHA's air quality enforcement policy for M/NM mines is silent regarding this recommendation. ANSI Z88.2–1969 also does not include any recommendations regarding the transfer of persons unable to wear a respirator.

OSHA acknowledges within its current standards addressing respiratory protection at 29 CFR 1910.134(e) that use of a respirator may place a physiological burden on workers while using them. OSHA requires employers to provide medical evaluations before an employee is fit tested or required to use respiratory protection. Employers are required to have a physician or other licensed health care professional have the worker complete a questionnaire, or in the alternative, conduct an initial medical examination in order to make the determination. If the worker has a positive response to certain specified questions, the employer must provide a follow-up medical examination. The questionnaire is contained in the body of the OSHA rule. The preamble to the OSHA final rule states:

> Specific medical conditions can compromise an employee's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the employee at increased risk of illness, injury, and even death (Exs. 64–363, 64–427). These medical conditions include cardiovascular and respiratory diseases (e.g., a history of high blood pressure, angina, heart attack, cardiac arrhythmias, stroke, asthma, chronic bronchitis, emphysema), reduced pulmonary function caused by other factors (e.g., smoking or prior exposure to respiratory hazards), neurological or musculoskeletal disorders (e.g., ringing in the ears, epilepsy, lower back pain), and impaired sensory function (e.g., a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, can also impair the effective use of respirators by employees and may also cause, independent of physiological burdens, significant elevations in heart rate, blood pressure, and respiratory rate that can jeopardize the health of employees who are at high risk for cardiopulmonary disease (Ex. 22–14). One commenter (Ex. 54–429) emphasized the importance of evaluating claustrophobia and severe anxiety, noting that these conditions are often detected during respirator training. (See 63 FR 1152, at 330, 01/08/1998)

NIOSH, in its response to MSHA's proposed DPM rule, recommended that ''mine operators be required to have a written respiratory protection program, analogous to that required by OSHA for general industry in 29 CFR 1910.134 Respiratory Protection, that is work-site specific and includes administration by a trained program administrator, respirator selection criteria, worker training, a program to determine that the workers are medically able to use respiratory protective equipment, and provisions for regular evaluation of the program's effectiveness.''

Organized labor and industry were divided on this issue. In general, industry commenters oppose any additions to the respiratory protection requirements for compliance with the current air quality standards. Some commenters also suggested that MSHA address any additional respiratory protection requirements in a separate rulemaking applicable to all airborne contaminants. Organized labor strongly emphasized in their comments that to protect miners' jobs, the final rule must contain requirements for an effective respiratory protection program, including a written program, medical evaluation of respirator wearers, and transfer of miners unable to wear respirators. Some commenters stated that their respiratory protection programs already provide for medical examination of miners before they are required to wear respiratory protection. One commenter stated that in an underground mine, transfer of employees to areas free of diesel exhaust would be extremely difficult.

MSHA believes that it is feasible for mine operators to achieve compliance with the interim limit by using effective engineering and administrative controls in most circumstances. As a result, MSHA projects that there will be very few instances where miners will be required to wear respirators for long-term compliance. Further, mine operators have several alternatives in respirator selection. They can choose either positive- or negative-pressure respirators, or powered or non-powered air purifying respirators. Those few miners who have a medical condition that would prevent them from wearing a negative-pressure respirator could be provided with and could normally wear a powered air purifying respirator. MSHA believes that it would be a rare occurrence to encounter a miner who could not wear any type of respirator due to a medical condition.

Whereas MSHA agrees that there is sound evidence establishing that some persons may have difficulty wearing respirators and should be prohibited from wearing these devices, MSHA finds that many mine operators have voluntarily established programs to medically evaluate miners' ability to wear respirators. One document in the rulemaking record that supports this position was developed by the Bureau of Labor Statistics of the Department of Labor and the National Institute for Occupational Safety and Health. These two agencies issued a recent joint survey report entitled ''Respirator Usage in Private Sector Firms, 2001.'' This publication summarizes the results of a questionnaire mailed to over 40,000 general industry and mining companies. The survey found that 64% (2,246) of the estimated 3,493 mining companies that used respirators during the 12 months prior to the survey assess employees' medical fitness to wear respirators. The survey also found that 61% (2,138) of these mining companies have written procedures and schedules for maintaining respirators. The 3,493 mining companies, however, included establishments that extract oil and gas.

Although the Mine Act requires, where appropriate, that MSHA standards prescribe the type and frequency of medical examinations to determine whether the health of miners is adversely affected by exposure to hazards, it does not mandate medical examinations to determine a miner's ability to wear PPE for protection from those hazards.

Based on the above, MSHA believes a requirement for medical evaluation of respirator wearers, and transfer of miners unable to wear respirators is inappropriate for this rulemaking. Such requirements would have minimal application, particularly considering the extent to which mine operators are voluntarily implementing such provisions and the limited long term use of respirators envisioned under the interim rule.

Application To Use Respirators

Section 57.5060(d) of the 2001 final rule permits miners engaged in specific activities involving inspection, maintenance, or repair activities to work in concentrations of DPM that exceed the interim and final limits, to use respiratory protection with advance approval from the Secretary. In MSHA's 2003 NPRM, it proposed several changes to its requirements on respiratory protection, including deleting the requirement that mine operators apply in writing to the Secretary for approval to use respiratory protection.

Although some commenters recommended requiring approval by the Secretary before respiratory protection should be permitted as a means of compliance with the applicable DPM limit, MSHA was not persuaded that such a step would be necessary, and the final § 57.5060(d) does not include this recommendation. Respiratory protection functions as a supplemental control. Operators must have ready access to respirators when they must be used to supplement protection provided by controls. When a mine operator is issued a citation under § 57.5060(d) for a miner's exposure exceeding the applicable DPM limit, and the mine operator intends to use respiratory protection as an interim control measure, MSHA will make certain that a respiratory protection program is established and appropriate respirators are used in accordance with § 57.5005(a), (b) and § 57.5060(d)(1) and (d)(2) concerning filter selection for air-purifying respirators. Accordingly, the requirement to apply in writing to the Secretary for approval to use respiratory protection can be deleted from the existing rule without reducing protection to the miners.

D. Section 57.5061 Compliance Determination

(1) Section 57.5061(a)

Under existing 57.5061(a), the Secretary determines compliance with ''an applicable limit on the concentration of [DPM] pursuant to § 57.5060.'' MSHA only proposed conforming changes to § 57.5061(a). As proposed, final § 57.5061(a) deletes the term ''concentration limit'' and replaces it with the term ''DPM limit'' to reflect a permissible exposure limit in § 57.5060(a) and a concentration limit in existing § 57.5060(b). MSHA did not receive comments specific to this conforming change. MSHA did not propose changes to the single sample compliance determination but received comments from industry on this issue. Those comments are beyond the scope of this rulemaking and not included in this preamble discussion.

(2) Section 57.5061(b)

Compliance determinations under existing § 57.5061(b) are based on TC measurements. As in the 2003 NPRM, final § 57.5061(b) reflects that compliance determinations will be based on EC measurements instead of TC. This change conforms to the proposed change in the interim limit in § 57.5060(a). Copies of the NIOSH 5040 Analytical Method can be obtained at *www.cdc.gov/niosh* or it can be obtained by contacting MSHA's Pittsburgh Safety and the Health Technology Center, P.O. Box 18233, Cochrans Mill Road, Pittsburgh, PA 15236. As a result, the address in the existing rule is removed from the regulatory language.

MSHA did not receive comments on this conforming change.

(3) Section 57.5061(c)

Under existing § 57.5061(c), the Secretary determined the appropriate sampling strategy for conducting compliance sampling utilizing personal sampling, occupational sampling, or area sampling, based on the circumstances of a particular exposure. MSHA proposed that § 57.5061(c) specify that only personal sampling would be utilized for compliance determinations. The final rule adopts this change which does not alter compliance requirements for mine operators.

MSHA believes that, since it has adopted EC as the surrogate for DPM, personal sampling alone will result in an accurate determination of miner exposure to DPM. Section 57.5060(a) establishes a DPM limit that specifically relates to the exposure of miners to DPM. Since the limit relates to the exposure of miners, the appropriate sampling method to determine compliance is personal sampling. In this respect, the sampling method for compliance determination with this rule is consistent with MSHA's longstanding practice of utilizing personal sampling to determine compliance with exposure limits for other airborne contaminants in the M/NM sector.

MSHA anticipates several benefits of standardizing personal sampling as the compliance sampling method. MSHA expects that mine operators and miners are already familiar with personal sampling, since MSHA utilizes it routinely when compliance sampling for noise, dust, and other airborne contaminants. Utilizing personal sampling eliminates possible disputes that could have arisen over whether an area sample was obtained ''where miners normally work or travel.'' Mine operators who choose to conduct environmental monitoring for DPM under § 57.5071 using MSHA's compliance sampling method will not need to anticipate which sampling method MSHA would most likely have selected (personal, area, or occupational) based on the circumstances of a particular exposure. Personal sampling avoids situations where area sampling is intended to capture the exposure of a particular miner for the full work shift even if that miner moves to a new location during the shift. Personal sampling for EC avoids the problem of determining compliance for an equipment operator who is a smoker and who works inside an enclosed cab. The measurement of DPM using EC as the surrogate is not affected by ETS. Under the existing rule, this miner could not be sampled inside the cab due to interference from tobacco smoke, and area sampling outside the cab would not indicate that miner's DPM exposure or the impact of the environmental cab.

Most industry and labor commenters supported personal sampling. A few commenters, however, were opposed to the elimination of area and occupational sampling for compliance determination. Two commenters suggested that relying on personal sampling alone would enable a mine operator to influence the sampling result to the mine operator's advantage by re-assigning a miner being sampled to an area with lower DPM levels. MSHA believes that although a mine operator may attempt to defeat compliance sampling by re-assigning the miner being sampled, MSHA's existing enforcement authority is adequate to ensure a valid and representative sample can nonetheless be obtained. If the miner being sampled for DPM is re-assigned to a different workplace with lower DPM levels, or the miner's DPM exposure is deliberately manipulated by some other means, such as by withdrawing a ''dirty'' piece of equipment from the area where the miner is working, the inspector has the authority to investigate the circumstances, and invalidate the sample if the inspector determines that the miner's workday was not representative.

Other commenters supported the retention of area and occupational sampling to give inspectors flexibility and to avoid sample tampering. While MSHA is sensitive to these issues, it believes it has the authority to address them in existing enforcement procedures.

One commenter suggested that exposure be defined for this regulation as ''the exposure that would occur if the employee were not using respiratory protective equipment.'' MSHA agrees with this position but believes that it is unnecessary to be this specific in the regulation. MSHA's longstanding practice for assessing exposure to an airborne contaminant is to not give credit for respiratory protection in determining a worker's exposure. MSHA, however, does encourage workers to use respiratory protection.

MSHA believes that the use of EC as the DPM surrogate allows the exclusive use of personal sampling to establish compliance with the DPM limit. MSHA believes that this consistency in sampling strategy outweighs concerns of commenters.

E. Section 57.5062 DPM Control Plan

Existing § 57.5062 requires mine operators to establish a DPM control plan, or modify the plan, upon receiving a citation for an overexposure to the concentration limit in § 57.5060. A single citation triggers the plan. A violation of the plan is citable without consideration of the current DPM concentration level. The operator must demonstrate that the new or modified plan will be effective in controlling the DPM concentration to the limit. The existing rule also sets forth a number of other specific details about the plan, including a description of controls that the operator will use to maintain the DPM concentration; a list of diesel-powered units maintained by the mine operator; information about each unit's emission control device; demonstration of the plan's effectiveness; verification sampling; retention of a copy of the control plan at the mine site for the duration of the plan plus one year; and a plan duration of three years from the date of the violation requiring establishment of the plan. By notice of July 18, 2002, MSHA stayed the effectiveness of this standard pending completion of this rulemaking (67 FR 47296).

In accordance with the DPM settlement agreement, MSHA agreed to publish a notice of proposed rulemaking to revise current § 57.5062. The settlement agreement, however, did not specify how MSHA should revise this section. In its 2003 NPRM, MSHA proposed provisions to modify and simplify the plan requirements, including deleting the requirement for operators to demonstrate plan effectiveness by monitoring.

MSHA's rationale for requiring a DPM control plan was derived from the rule's initial approach to setting control requirements. MSHA recognized that every mine covered by this rule had unique conditions and circumstances that affect DPM exposures such as the number and sizes of diesel-powered engines, idling duration and frequency, emission controls, diesel maintenance practices, and ventilation. MSHA was also interested in developing uniform DPM control requirements that would be effective in protecting miners' health and practical for the mining industry to implement. MSHA acknowledges that there are numerous approaches in accomplishing this objective.

In the existing rule, the control plan would only have to include a description of the controls the operator would use to maintain the concentration of DPM to the applicable limit, a list of diesel-powered units maintained by the mine operator, information about any units emission control device, and the parameters of any other methods used to control the concentration of DPM. Operators could also consolidate the DPM control plan with ventilation plan.

In proposed § 57.5062, MSHA would require an operator to establish a written control plan, or modify an existing control plan, if it will take the mine operator more than 90 calendar days from the date of a citation to achieve compliance. A single violation of the PEL would continue to be the basis for triggering the requirement for a control plan. The control plan would remain in effect for a one-year period following termination of the citation. Mine operators would also be required to include in the plan a description of the controls that will be used to reduce the miners' exposures to the PEL.

Although MSHA proposed to retain the control plan, MSHA clearly alerted the mining community of the possibility that it would delete the control plan in the final rule. MSHA raised concerns with justifying the need for a control plan requirement in light of the other proposed revisions to the DPM rule, including MSHA's traditional hierarchy of controls for exposure-based standards. MSHA also currently maintains an inventory of the diesel-powered equipment in each mine. Consequently, MSHA asked the mining community for its views on this alternative approach in light of the other proposed changes to the DPM standard. MSHA received a number of comments on this issue.

Some commenters were in favor of retaining the control plan provisions and stated that MSHA had provided no evidence indicating that control plans are infeasible. Several other commenters who oppose deleting the control plan requirement stated that planning is essential for any complex activity, and that mine operators have spent a great deal of time and money in this rulemaking, arguing that the control of DPM is exceedingly complex. They felt it was hard to understand how mine operators could simultaneously argue that control plans are unnecessary.

Other commenters favored deleting existing § 57.5062 because the hierarchy of controls would ensure that operators employ all reasonable means to maintain allowable levels of DPM. Some of these commenters stated that if compliance cannot be achieved through engineering and administrative controls, they were required to use respiratory protection, and the end result would be that miners are protected from overexposure. They stated that a mine operator would get a citation if miners are not protected, and during the abatement period the operator must comply with DPM requirements addressing maintenance, after-treatment controls, low sulfur fuel, proper idling practices and tagging requirements.

Commenters opposed to retention of the control plan provisions felt that a control plan would add nothing to miner health, and create a paperwork burden. They stated the enforcement process provides all the documentation necessary for compliance. They also believe that the requirement for a control plan is a disproportionate response to a single overexposure. MSHA initially intended to apply a concentration limit that would result in controlling DPM in the underground mine environment. Since MSHA has changed the compliance approach from a concentration limit to a personal exposure limit, the control plan would have to address each miner's overexposure, rather than reducing mine-wide concentrations.

MSHA agrees with commenters who believe that the control plan is unjustifiable in the final rule. Moreover, the DPM rulemaking record contains little, if any, rationalization in support of retaining this provision. The hierarchy of controls in the final rule ensures that operators employ all means to maintain allowable exposure levels of DPM. MSHA is, therefore, deleting existing § 57.5062, DPM control plan. MSHA can monitor an operator's good faith efforts and obtain supporting documentation during regular inspections. Operators may choose to control DPM emissions by filtering the diesel-powered equipment; installing cleaner-burning engines; increasing ventilation; improving fleet management; utilizing administrative controls; or using a variety of other readily available controls, all without consulting with, or seeking approval from MSHA.

MSHA also agrees with those commenters that expressed concerns about the increase in paperwork requirements. In promulgating standards for the mining industry, MSHA takes considerable initiative to avoid placing an unreasonable burden upon mine operators, especially small mine operators. It was never MSHA's intent to have unnecessary duplication of effort in obtaining compliance under the DPM rule.

The existing rule also contained a requirement in § 57.5062(c) that the operator must demonstrate plan effectiveness by monitoring. Although MSHA has deleted the control plan requirements in this final rule, MSHA believes that monitoring to verify the effectiveness of DPM controls is adequately addressed under § 57.5071, which requires mine operators to monitor in order to determine, under conditions that can be reasonably anticipated in the mine, whether DPM exposures exceed the applicable limits specified in § 57.5060. These requirements provide an effective alternative to the existing requirement in § 57.5062(c) for operators to demonstrate plan effectiveness by monitoring. Further, MSHA will conduct additional compliance sampling whenever MSHA suspects that miners' exposures to DPM are not being maintained to the PEL.

Although a control plan might serve to deter repeat overexposures, MSHA can utilize existing enforcement tools to accomplish this purpose. For example, MSHA often asks operators to provide a control strategy to justify extending citations. MSHA also documents action taken by the operator to comply when terminating a citation. Further, repeat overexposures can be cited with a higher degree of negligence that typically require a higher penalty assessment. Failure to correct overexposure conditions in a timely manner could also be addressed through existing mechanisms such as Section 104(b) of the Mine Act that includes sanctions currently employed for failure to abate violations.

F. Section 57.5075 Diesel Particulate Records

Existing § 57.5075(a) summarizes the recordkeeping requirements of the DPM standards contained in §§ 57.5060 through 57.5071. As proposed, MSHA has renumbered the Diesel Particulate Recordkeeping Requirements table and added the recordkeeping requirement established in existing § 57.5071(c) for records of corrective actions taken. This notation was inadvertently omitted from the table in the 2001 final rule.

MSHA also proposed that the record of corrective action be retained ''until the citation is terminated.'' MSHA has changed this retention period in the final rule to ''Until the corrective action is completed.''

As proposed, MSHA also has deleted the table entry for existing § 57.5060(d), ''approved plan for miners to perform inspection, maintenance or repair activities in areas exceeding the concentration limit,'' as the corresponding provision of the rule was deleted.

MSHA also deleted, as proposed, records relating to § 57.5062(c), ''compliance plan verification sample results.''

Finally, the final rule eliminates the additional recordkeeping requirements relating to control plans pursuant to § 57.5062 since this final rule deletes the existing requirements for such plans.

Of the comments received on the general subject of recordkeeping, only two were directed at the proposed changes to the recordkeeping requirements. Of the comments that were relevant to the scope of this rulemaking, most of the comments expressed concern about the recordkeeping burden required by § 57.5062(a) as related to control plans. As noted above, the control plan requirement has been removed from the final rule.

One of the two comments that addressed proposed changes to the recordkeeping requirements identified possible errors in the Diesel Particulate Recordkeeping Requirements table in § 57.5075(a) (Recordkeeping Requirements table). The commenter noted that the existing rule requires that a record of applications approved for extensions of time to comply with the exposure limits must be retained one year beyond the duration of the extension. The commenter stated that this requirement did not reflect MSHA's intent as stated in the preamble to the existing rule to retain this record for the duration of the extension. MSHA agrees that the recordkeeping requirement listed in the existing rule was in error. MSHA proposed to correct this error in the 2003 NPRM and has adopted the change in this rule. The final rule clarifies that the required retention time for this record is for the duration of the extension.

This commenter also noted that the retention time for evidence of corrective action taken as a result of a mine operator's environmental monitoring per § 57.5071(c) was listed in Table 57.5075(a) in the 2003 NPRM as, ''Until the citation is terminated.'' MSHA agrees that this table entry is in error, as a citation would not be issued on the basis of an operator's environmental monitoring. MSHA has corrected the table entry in the final rule to read ''Until the corrective action is completed.''

The other comment relating to proposed changes in recordkeeping requirements expressed the general concern that the information collection provisions of the rule are not necessary for MSHA to perform its functions. The commenter suggested reducing the paperwork burden by relying on current testing for gaseous emissions and deleting the final DPM limit from the rule.

MSHA believes that each record specified in § 57.5075 relates to information that MSHA must have access to in order to determine that the mine operator is complying with the corresponding provisions of the rule.

X. Distribution Table

Old section	New section
57.5060(a)	57.5060(a)
57.5060(b)	57.5060(b)
57.5060(c)	57.5060(c)
57.5060(d)	57.5060(d)
57.5060(e)	57.5060(d)
57.5060(f)	57.5060(d) and (e)
57.5061	57.5061
57.5062	Removed
57.5065	57.5065
57.5066	57.5066
57.5067	57.5067
57.5070	57.5070
57.5071	57.5071
57.5075	57.5075

XI. Regulatory Impact Analysis

This part of the preamble reviews several impact analyses which MSHA is required to provide in connection with its final rulemakings. The full text of these analyses can be found at MSHA's Regulatory Economic Analysis (REA) Web page which is available from MSHA at *http://www.msha.gov/REGSINFO.HTM*.

A. Costs and Benefits: Executive Order 12866 Regulatory Planning and Review and Regulatory Flexibility Act

Executive Order 12866, as amended by Executive Order 13258, requires that regulatory agencies assess both the costs and benefits of regulations. The final rule will result in estimated net cost savings (negative costs) for underground M/NM mine operators of $3,634 per year. This represents an average yearly savings of $20 per mine for the 177 underground metal/non-metal mines that will be affected by this final rule. Of these 177 mines, 66 have fewer than 20 workers; 107 have 20 to 500 workers; and 4 have more than 500 workers. For a complete breakdown of the compliance costs and savings of the final rule, see Chapter IV of the REA associated with this rulemaking.

The amended provisions in this final rule will increase flexibility of compliance with the existing final rule, but continue to reduce significant health risks to underground miners. Benefits of the existing final rule are those discussed by MSHA in the REA for the January 19, 2001 final rule and include reductions in lung cancers. In the long run, as the mining population turns over, MSHA estimates that a minimum of 8.5 lung cancer deaths will be avoided per year. Other benefits noted in the 2001 REA were reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes and reductions in the risk of sensory irritation and respiratory symptoms.

B. Regulatory Flexibility Act (RFA) and Small Business Regulatory Enforcement Fairness Act (SBREFA)

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 operator and publishes that definition in the **Federal Register** for notice and comment. For the mining industry, SBA defines ''small'' as a mine operator with 500 or fewer employees. Traditionally, MSHA has also looked at the impacts of its final rules on a subset of mines with 500 or fewer employees—those with fewer than 20 employees, which the mining community refers to as ''small mines.'' These small mines differ from larger mines not only in the number of employees, but also, among other things, in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. Therefore, their costs of complying with MSHA rules and the impact of MSHA rules on them would also tend to be different. It is for this reason that ''small mines,'' as traditionally defined by the mining community, are of special concern to MSHA.

Therefore, MSHA's analysis complies with the legal requirements of the RFA for an analysis of the impacts on ''small entities'' while continuing MSHA's traditional look at ''small mines.'' Using SBA's definition of a small mine operator, the estimated yearly net compliance cost savings of this final rule on small underground M/NM mine operators is approximately $3,675. These estimated yearly net compliance cost savings compare with estimated annual revenues of approximately $2.35 billion for small underground M/NM mine operators with 500 or fewer employees. Using MSHA's definition of a small mine operator, the estimated yearly net compliance cost savings of this final rule on small underground M/NM mine operators is approximately $4,795. These estimated yearly net compliance cost savings compare with estimated annual revenues of approximately $0.14 billion for small underground M/NM mine operators with 20 or fewer employees.

MSHA concludes that the final DPM rule would not have a significant economic impact on a substantial number of small entities that are covered by this rulemaking. MSHA has determined that this is the case both for mines affected by this rulemaking with fewer than 20 employees and for mines affected by this rulemaking with 500 or fewer employees. MSHA has certified these findings to the SBA. The factual basis for this certification is discussed in Chapter V of the REA associated with this rulemaking.

C. Paperwork Reduction Act (PRA)

This final rule contains changes to information collection requirements in various provisions. Most of these paperwork requirements were previously approved by OMB as part of OMB Control Number 1219–0135. The information collection requirements are summarized below and explained in detail in the REA that accompanies the rule. The REA includes the estimated costs and assumptions for the paperwork requirements related to this final rule. A copy of the REA is available on our Web site at *http://www.msha.gov/regsinfo.htm* and can also be obtained in hard copy from MSHA. These information collection requirements have been submitted to OMB for review under 44 U.S.C. 3504(h) of the Paperwork Reduction Act of 1995, as amended. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

As a result of this rule, mine operators will obtain burden hour and cost savings for the first two years that the rule is in effect. In the third year that the rule is in effect, mine operators will incur a net increase in burden hours and costs. For every year thereafter, burden hours and costs will be the same as in the third year.

In the first year of the rule, mine operators will incur burden hour savings of approximately 274 hours. These savings will result from mine operators (1) not having to apply for approval from the Secretary to work in concentrations of DPM exceeding the applicable limit under § 57.5060(d) of the 2001 final rule and maintaining the conditions of the approval during the period that the interim concentration limit is in effect; and (2) not having to write a DPM Control Plan under § 57.5062.

In the second year of the rule, mine operators' burden savings increase to about 961 hours. These savings will result from mine operators (1) not having to apply for approval from the Secretary to work in concentrations of DPM exceeding the applicable limit under § 57.5060(d) of the 2001 final rule and maintaining the conditions of the approval during the period that the final concentration limit is in effect; and (2) not having to write a DPM Control Plan under § 57.5062.

In the third year of the rule, mine operators will incur a net increase of about 368 burden hours. This increased burden occurs because mine operators will no longer experience the savings from not having to apply for approval from the Secretary to work in concentrations of DPM exceeding the applicable limit under § 57.5060(d) of the 2001 final rule and maintaining the conditions of the approval during the period that the final concentration limit would be in effect; and will incur an increase in burden associated with requesting special extensions of the final concentration limit under § 57.5060(c).

Mine operators incur a net increase in paperwork burden costs of $12,250 per year. This net increase is composed of an annualized cost increase of $24,181 per year from changes to § 57.5060(c); an annualized cost decrease of $6,394 per year from changes to § 57.5060(d); and an annualized cost decrease of $5,537 per year from changes to § 57.5062.

In comparison with the 2003 NPRM, this final rule revises two provisions (§§ 57.5060(c) and 57.5062) in a manner that reduces the burden hours and associated costs. These reductions in burden hours and associated cost savings relative to the 2003 NPRM are incorporated into the calculations of the previous paragraphs, which compare the final rule with the existing rule.

Sections 57.5071 and 57.5075 both involve information collection activities. Section 57.5071 triggers notice requirements when environmental monitoring indicates that the DPM limit has been exceeded. The paperwork burden for this provision has not changed from the former requirements. Section 57.5075 summarizes in chart form the recordkeeping requirements of the rule. The paperwork burden has only changed for three of the provisions listed, §§ 57.5060(c), 57.5060(d), and 57.5062. These provisions are discussed more fully above and in the REA.

MSHA received several comments regarding information collection. Some commenters stated that the paperwork requirements for developing a control plan were too burdensome, and others stated that they were justified. MSHA has removed the requirement for control plans due to the establishment of the hierarchy of controls for meeting the interim PEL. Removal of the control plan requirement is discussed at length under the section-by-section discussion for § 57.5062.

Some commenters stated that all information collection activities associated with the rule including DPM sampling and analysis mandates, the plan provisions, the posting requirements, and all of the required records are unnecessary because MSHA can perform its job without such requirements as demonstrated by the existence of standards that control other diesel exhaust components. MSHA disagrees. Although MSHA has deleted certain information collection requirements in this final rule, it considers those included to be necessary to determine whether mine operators are in compliance with the rule.

D. The Unfunded Mandates Reform Act of 1995

This final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments; nor does it increase private sector expenditures by more than $100 million annually; nor does it significantly or uniquely affect small governments. Accordingly, the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) requires no further agency action or analysis.

E. National Environmental Policy Act

MSHA has reviewed this final rule in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 U.S.C. 1500), and the Department of Labor's NEPA procedures (29 CFR part 11).

This final rule has no significant impact on air, water, or soil quality; plant or animal life; the use of land; or other aspects on the human environment. MSHA solicited public comment concerning the accuracy and completeness of this environmental assessment when this rule was first proposed, and received no comments relevant to this environmental assessment. MSHA finds, therefore, that the final rule has no significant impact on the human environment. Accordingly, MSHA has not provided an environmental impact statement.

F. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

This final rule has no affect on family well-being or stability, marital commitment, parental rights or authority, or income or poverty of families and children. Accordingly, Section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires no further agency action, analysis, or assessment.

G. Executive Order 12630: Government Actions and Interference With Constitutionally Protected Property Rights

This final rule does not implement a policy with takings implications. Accordingly, Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, requires no further agency action or analysis.

H. Executive Order 12988: Civil Justice Reform

This final rule was written to provide a clear legal standard for affected conduct, and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. Accordingly, this final rule meets the applicable standards provided in Section 3 of Executive Order 12988, Civil Justice Reform.

I. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This final rule has no adverse impact on children. Accordingly, Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, as amended by Executive Orders 13229 and 13296, requires no further agency action or analysis.

J. Executive Order 13132: Federalism

This final rule does not have "federalism implications," because it 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." Accordingly, Executive Order 13132, Federalism, requires no further agency action or analysis.

K. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This final rule does not have "tribal implications," because it does not "have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes." Accordingly, Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, requires no further agency action or analysis.

L. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Regulation of the M/NM sector of the mining industry has no significant impact on the supply, distribution, or use of energy. This final rule is not a "significant energy action," because it is not "likely to have a significant adverse effect on the supply, distribution or use of energy" * * * (including a shortfall in supply, price increases, and increased use of foreign supplies)." Accordingly, Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, requires no further agency action or analysis.

M. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

MSHA has thoroughly reviewed this final rule to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. As discussed in Chapter V of the REA, MSHA has determined and certified that this final rule will not have a significant economic impact on a substantial number of small entities. MSHA solicited public comment concerning the accuracy and completeness of this potential impact when the rule was first proposed. The agency took appropriate account of comments received relevant to the rule's potential impact on small entities. Accordingly, Executive Order

13272, Proper Consideration of Small Entities in Agency Rulemaking, requires no further agency action or analysis.

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List of Subjects in 30 CFR Part 57

Diesel particulate matter, Metal and Nonmetal, Mine Safety and Health, Underground mines.

■ Accordingly, chapter I of title 30 of the Code of Federal Regulations is amended as follows:

PART 57—SAFETY AND HEALTH STANDARDS—UNDERGROUND METAL AND NONMETAL MINES

■ 1. The authority citation for part 57 continues to read as follows:

Authority: 30 U.S.C. 811 and 813.

§ 57.5062 [Removed]

■ 2. Section 57.5062 is removed.

■ 3. Also, in part 57:

■ A. Sections 57.5060, 57.5061, 57.5071, and 57.5075 are revised; and

■ B. Sections 57.5065, 57.5066, 57.5067, and 57.5070 are republished without change.

The text reads as follows:

§ 57.5060 Limit on exposure to diesel particulate matter.

(a) A miner's personal exposure to diesel particulate matter (DPM) in an underground mine must not exceed an average eight-hour equivalent full shift airborne concentration of 308 micrograms of elemental carbon per cubic meter of air (308_{EC} g/m³). [This interim permissible exposure limit (PEL) remains in effect until the final DPM exposure limit becomes effective. When the final DPM exposure limit becomes effective, MSHA will publish a document in the **Federal Register**.]

(b) After January 19, 2006, any mine operator covered by this part must limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 160 micrograms per cubic meter of air (160TC µg/m³). (c)(1) If a mine requires additional time to come into compliance with the final DPM limit established in § 57.5060 (b) due to technological or economic constraints, the operator of the mine may file an application with the District Manager for a special extension.

(2) The mine operator must certify on the application that the operator has posted one copy of the application at the mine site for at least 30 days prior to the date of application, and has provided another copy to the authorized representative of miners.

(3) No approval of a special extension shall exceed a period of one year from the date of approval. Mine operators may file for additional special extensions provided each extension does not exceed a period of one year. An application must include the following information:

(i) A statement that diesel-powered equipment was used in the mine prior to October 29, 1998;

(ii) Documentation supporting that controls are technologically or economically infeasible at this time to reduce the miner's exposure to the final DPM limit.

(iii) The most recent DPM monitoring results.

(iv) The actions the operator will take during the extension to minimize exposure of miners to DPM.

(4) A mine operator must comply with the terms of any approved application for a special extension, post a copy of the approved application for a special extension at the mine site for the duration of the special extension period, and provide a copy of the approved application to the authorized representative of miners.

(d) The mine operator must install, use, and maintain feasible engineering and administrative controls to reduce a miner's exposure to or below the DPM limit established in this section. When controls do not reduce a miner's DPM exposure to the limit, controls are infeasible, or controls do not produce significant reductions in DPM exposures, controls must be used to reduce the miner's exposure to as low a level as feasible and must be supplemented with respiratory protection in accordance with § 57.5005(a), (b), and paragraphs (d)(1) and (d)(2) of this section.

(1) Air purifying respirators must be equipped with the following:

(i) Filters certified by NIOSH under 30 CFR part 11 (appearing in the July 1, 1994 edition of 30 CFR, parts 1 to 199) as a high efficiency particulate air (HEPA) filter;

(ii) Filters certified by NIOSH under 42 CFR part 84 as 99.97% efficient; or

(iii) Filters certified by NIOSH for DPM.

(2) Non-powered, negative-pressure, air purifying, particulate-filter respirators shall use an R- or P-series filter or any filter certified by NIOSH for DPM. An R-series filter shall not be used for longer than one work shift.

(e) Rotation of miners shall not be considered an acceptable administrative control used for compliance with the DPM standard.

§ 57.5061 Compliance determinations.

(a) MSHA will use a single sample collected and analyzed by the Secretary in accordance with the requirements of this section as an adequate basis for a determination of noncompliance with the DPM limit.

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

(c) The Secretary will use full-shift personal sampling for compliance determinations.

§ 57.5065 Fueling practices.

(a) Diesel fuel used to power equipment in underground areas must not have a sulfur content greater than 0.05 percent. The operator must retain purchase records that demonstrate compliance with this requirement for one year after the date of purchase.

(b) The operator must only use fuel additives registered by the U.S. Environmental Protection Agency in diesel powered equipment operated in underground areas.

§ 57.5066 Maintenance standards.

(a) Any diesel powered equipment operated at any time in underground areas must meet the following maintenance standards:

(1) The operator must maintain any approved engine in approved condition;

(2) The operator must maintain the emission related components of any non-approved engine to manufacturer specifications; and

(3) The operator must maintain any emission or particulate control device installed on the equipment in effective operating condition.

(b)(1) A mine operator must authorize each miner operating diesel-powered equipment underground to affix a visible and dated tag to the equipment when the miner notes evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section. The term evidence means visible smoke or odor that is unusual for that piece of equipment under normal operating procedures, or obvious or visible defects in the exhaust emissions control system or in the engine affecting emissions.

(2) A mine operator must ensure that any equipment tagged pursuant to this section is promptly examined by a person authorized to maintain diesel equipment, and that the affixed tag not be removed until the examination has been completed. The term promptly means before the end of the next shift during which a qualified mechanic is scheduled to work.

(3) A mine operator must retain a log of any equipment tagged pursuant to this section. The log must include the date the equipment is tagged, the date the equipment is examined, the name of the person examining the equipment, and any action taken as a result of the examination. The operator must retain the information in the log for one year after the date the tagged equipment was examined.

(c) Persons authorized by a mine operator to maintain diesel equipment covered by paragraph (a) of this section must be qualified, by virtue of training or experience, to ensure that the maintenance standards of paragraph (a) of this section are observed. An operator must retain appropriate evidence of the competence of any person to perform specific maintenance tasks in compliance with those standards for one year after the date of any maintenance, and upon request must provide the documentation to the authorized representative of the Secretary.

§ 57.5067 Engines.

(a) Any diesel engine introduced into an underground area of a mine covered by this part after July 5, 2001, other than an engine in an ambulance or fire fighting equipment which is utilized in accordance with mine fire fighting and evacuation plans, must either:

(1) Have affixed a plate evidencing approval of the engine pursuant to subpart E of part 7 of this title or pursuant to part 36 of this title; or

(2) Meet or exceed the applicable particulate matter emission requirements of the Environmental Protection Administration listed in Table 57.5067–1, as follows:

TABLE 57.5067–1

EPA requirement	EPA category	PM limit
40 CFR 86.094–8(a)(1)(i)(A)(2)	light duty vehicle	0.1 g/mile.
40 CFR 86.094–9(a)(1)(i)(A)(2)	light duty truck	0.1 g/mile.
40 CFR 86.094–11(a)(1)(iv)(B)	heavy duty highway engine	0.1 g/bhp-hr.
40 CFR 89.112(a)	nonroad (tier, power range)	varies by power range:
	tier 1 kW<8 (hp<11)	1.0 g/kW-hr (0.75 g/bhp-hr).
	tier 1 8≤kW<19 (11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 1 19≤kW<37(25≤hp<50)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 2 37≤kW<75(50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr).
	tier 2 75≤kW<130(100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr).
	tier 1 130≤kW<225(175≤hp<300)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 225≤kW<450(300≤hp<600)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 450≤kW<560(600≤hp<750)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 kW≥560(hp≥750)	0.54 g/kW-hr (0.40 g/bhp-hr).

Notes:
"g" means grams.
"hp" means horsepower.
"g/bhp-hr" means grams/brake horsepower-hour.
"kW" means kilowatt.
"g/kW-hr" means grams/kilowatt-hour.

(b) For purposes of paragraph (a):

(1) The term ''introduced'' means any engine added to the underground inventory of engines of the mine in question, including:

(i) An engine in newly purchased equipment;

(ii) An engine in used equipment brought into the mine; and

(iii) A replacement engine that has a different serial number than the engine it is replacing; but

(2) The term ''introduced'' does not include engines that were previously part of the mine inventory and rebuilt.

(3) The term ''introduced'' does not include the transfer of engines or equipment from the inventory of one underground mine to another underground mine operated by the same mine operator.

§ 57.5070 Miner training.

(a) Mine operators must provide annual training to all miners at a mine covered by this part who can reasonably be expected to be exposed to diesel emissions on that property. The training must include—

(1) The health risks associated with exposure to diesel particulate matter;

(2) The methods used in the mine to control diesel particulate matter concentrations;

(3) Identification of the personnel responsible for maintaining those controls; and

(4) Actions miners must take to ensure the controls operate as intended.

(b) An operator must retain a record at the mine site of the training required by this section for one year after completion of the training.

§ 57.5071 Exposure monitoring.

(a) Mine operators must monitor as often as necessary to effectively determine, under conditions that can be reasonably anticipated in the mine, whether the average personal full-shift airborne exposure to DPM exceeds the DPM limit specified in § 57.5060.

(b) The mine operator must provide affected miners and their representatives with an opportunity to observe exposure monitoring required by this section. Mine operators must give prior notice to affected miners and their representatives of the date and time of intended monitoring.

(c) If any monitoring performed under this section indicates that a miner's exposure to diesel particulate matter exceeds the DPM limit specified in § 57.5060, the operator must promptly post notice of the corrective action being taken on the mine bulletin board, initiate corrective action by the next work shift, and promptly complete such corrective action.

(d)(1) The results of monitoring for diesel particulate matter, including any results received by a mine operator from sampling performed by the Secretary, must be posted on the mine bulletin board within 15 days of receipt and must remain posted for 30 days. The operator must provide a copy of the results to the authorized representative of miners.

(2) The mine operator must retain for five years (from the date of sampling), the results of any samples the operator collected as a result of monitoring under this section, and information about the sampling method used for obtaining the samples.

§ 57.5075(a) Diesel particulate records.

(a) Table 57.5075(a), ''Diesel Particulate Recordkeeping Requirements,'' lists the records the operator must retain pursuant to §§ 57.5060 through 57.5071, and the duration for which particular records must be retained.

TABLE 57.5075(A).—DIESEL PARTICULATE RECORDKEEPING REQUIREMENTS

Record	Section reference	Retention time
1. Approved application for extension of time to comply with exposure limits.	§ 57.5060(c)	Duration of extension.
2. Purchase records noting sulfur content of diesel fuel	§ 57.5065(a)	1 year beyond date of purchase.
3. Maintenance log	§ 57.5066(b)	1 year after date any equipment is tagged.
4. Evidence of competence to perform maintenance	§ 57.5066(c)	1 year after date maintenance performed.
5. Annual training provided to potentially exposed miners	§ 57.5070(b)	1 year beyond date training completed.
6. Record of corrective action	§ 57.5071(c)	Until the corrective action is completed.
7. Sampling method used to effectively evaluate a miner's personal exposure, and sample results.	§ 57.5071(d)	5 years from sample date.

(b)(1) Any record listed in this section which is required to be retained at the mine site may, notwithstanding such requirement, be retained elsewhere if the mine operator can immediately access the record from the mine site by electronic transmission.

(2) Upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators must promptly provide access to any record listed in the table in this section.

(3) An operator must provide access to a miner, former miner, or, with the miner's or former miner's written consent, a personal representative of a miner, to any record required to be maintained pursuant to § 57.5071 to the extent the information pertains to the miner or former miner. The operator must provide the first copy of a requested record at no cost, and any additional copies at reasonable cost.

(4) Whenever an operator ceases to do business, that operator must transfer all records required to be maintained by this part, or a copy thereof, to any successor operator who must maintain them for the required period.

Dated: May 23, 2005.

David G. Dye,

Acting Assistant Secretary for Mine Safety and Health.

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