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30 CFR Part 72

Determination of Concentration of Respirable Coal Mine Dust; Proposed Rule

30 CFR Parts 70, 75 and 90

Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust; Proposed Rule

DEPARTMENT OF LABOR

Mine Safety and Health Administration

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30 CFR Part 72

RIN 1219–AB18

Determination of Concentration of Respirable Coal Mine Dust

AGENCIES: Mine Safety and Health Administration (MSHA), Labor, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services (DHHS).

ACTION: Proposed rule; notice of hearings.

SUMMARY: This proposal announces that the Secretary of Labor and the Secretary of Health and Human Services (the Secretaries) would find in accordance with sections 101 (30 U.S.C. 811) and 202(f)(2) (30 U.S.C. 842(f)(2)) of the Federal Mine Safety and Health Act of 1977 (Mine Act) that the average concentration of respirable dust to which each miner in the active workings of a coal mine is exposed can be accurately measured over a single shift. The Secretaries are proposing to rescind a previous 1972 finding, by the Secretary of the Interior and the Secretary of Health, Education, and Welfare, on the validity of such single-shift sampling. Today's proposal addresses the final decision and order in *NMA* v. *Secretary of Labor,* issued by the United States Court of Appeals for the 11th Circuit on September 4, 1998 (153 F. 3d 1264). That case vacated a 1997 Joint Finding and MSHA's proposed policy concerning the use of single, full-shift respirable dust measurements to determine noncompliance when the applicable respirable dust standard was exceeded.

The Agencies are also announcing that they will hold public hearings on the joint proposed rule within 45 to 60 days of its publication. The hearings will be held in the following locations: Prestonsburg, Kentucky (Jenny Wiley State Park); Morgantown, West Virginia; and Salt Lake City, Utah.

DATES: Comments concerning this proposed rule should be submitted on or before August 7, 2000.

The hearing dates, times and specific locations will be announced by a separate document in the **Federal Register**. The rulemaking record will remain open 7 days after the last public hearing.

ADDRESSES: You may use mail, facsimile (fax), or electronic mail to send your comments to MSHA. Clearly identify comments as such and send them—(1) By mail to Carol J. Jones, Director, Office of Standards, Regulations, and Variances, MSHA, 4015 Wilson Boulevard, Room 631, Arlington, VA 22203;

(2) By fax to MSHA, Office of Standards, Regulations, and Variances, 703–235–5551; or

(3) By electronic mail to comments@msha.gov.

FOR FURTHER INFORMATION CONTACT: Carol J. Jones, Director, Office of Standards, Regulations and Variances; MSHA; 703–235–1910. Copies of this proposed rule in alternative formats may be obtained by calling (703) 235–1910. The alternative formats available are large print, electronic file on computer disk, and audiotape. The proposed rule is also available on the Internet at http://www.msha.gov.

SUPPLEMENTARY INFORMATION: In accordance with sections 101 and 202(f) of the Mine Act (30 U.S.C. 811 and 842(f)), this proposed mandatory standard is published jointly by the Secretaries of the Departments of Labor, and Health and Human Services.

I. Table of Contents

The preamble to this proposed rule on the accuracy of single shift exposure measurements discusses events leading to the proposed rule, health effects of exposure to respirable coal mine dust, degree and significance of the reduction in the number of shifts during which there are overexposures, an analysis of the technological and economical feasibility of this proposed rule, and regulatory impact and regulatory flexibility analyses.

The preamble discussion follows this outline:

II. Introduction

For as long as miners have taken coal from the ground, many have suffered respiratory problems due to their occupational exposures to respirable coal mine dust. These respiratory problems, range from mild impairment of respiratory function to more severe diseases, such as silicosis and progressive massive fibrosis (PMF). For some miners, the impairment of their respiratory systems is so severe, they die prematurely. There is a clear dose-response relationship between miners' cumulative exposures (*i.e.,* dose multiplied by the time exposed to the coal mine dust) to respirable coal mine dust and the severity of resulting respiratory conditions. On each and every workshift, it is essential to prevent miners from being exposed to respirable coal mine dust concentrations that exceed the mandated exposure limits.

The Federal Coal Mine Health and Safety Act of 1969 (Coal Act) established the first comprehensive dust standard for underground U.S. coal mines by setting a limit of 2.0 milligrams of respirable coal mine dust per cubic meter of air (mg/m³). The 2.0 mg/m³ standard limits the concentration of respirable coal mine dust permitted in the mine atmosphere during each shift to which each miner in the active workings of a mine is exposed. Congress was convinced that the only way each miner could be protected from black lung disease or other occupational dust diseases was by limiting the amount of respirable coal mine dust allowed in the air that miners breathe.

The Coal Act was subsequently amended by the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 801 *et seq.* The standard limiting respirable dust in the mine atmosphere to 2.0 mg/m³ was retained in the Mine Act, which also required that ''each operator shall continuously maintain the average concentration of respirable dust in the mine atmosphere during each shift to which each miner in the active workings of such mine is exposed at or below 2.0 milligrams of respirable dust per cubic meter of air,'' Section 202(b)(2) (30 U.S.C.842(b)). (Other provisions in the Mine Act, Sections 205 and 203(b)(2) (30 U.S.C. 845 and 843(b)(2)), provide for lowering the applicable standard when quartz is present and when miners with evidence of the development of pneumoconiosis have elected to work in a low-dust work environment).

Today, dust levels in underground U.S. coal mines are significantly lower than they were when the Coal Act was passed. Federal mine inspector sampling results during 1968–1969 showed that the average dust concentration in the environment of a continuous miner operator was 7.7 mg/m³. Current sampling (FY 1998) indicates that the average dust level for a continuous miner operator has been reduced by 86 percent to 1.1 mg/m³. Despite this progress, the Secretaries believe that respirable coal mine dust continues to present a serious health risk to coal miners. In November 1995, the National Institute for Occupational Safety and Health (NIOSH) issued a comprehensive review of the literature concerning occupational exposure to respirable coal mine dust in its Criteria Document (NIOSH Criteria Document, 1995). NIOSH concluded, among other things, that coal miners in our country continue to be at increased risk for developing respiratory disease as a result of their exposure to respirable coal mine dust. Although it is beyond the scope of this rulemaking, in its 1995 Criteria Document, NIOSH recommended a time weighted average exposure limit to respirable coal mine dust of 1.0 mg/m³, up to ten hours per day for a 40-hour work week.

The Secretary of Labor and the Secretary of Health and Human Services believe that miners' health can be further protected from the debilitating effects of occupational respiratory disease by limiting their exposures to respirable coal mine dust exceeding the applicable standards. MSHA's improved program to eliminate overexposures on each and every shift includes multiple rulemakings. Through this proposal, MSHA would be able to use single, full-shift respirable coal mine dust samples to more effectively identify overexposures and address them. Other overexposures to respirable coal mine dust would be prevented through finalizing a proposed rule that would require each underground coal mine operator to have a verified mine ventilation plan. MSHA would verify the effectiveness of the mine ventilation plan for each mechanized mining unit (MMU) to controlling respirable dust under typical mining conditions. Furthermore, that proposal would revoke underground operator compliance and abatement sampling. Consequently in underground coal mines, MSHA intends to increase the number of compliance inspections per year, and MSHA would conduct abatement sampling for non-compliance determinations. The notice of proposed rulemaking to promulgate new regulations to require operators to have a verified ventilation plan in underground coal mines is published elsewhere in today's **Federal Register**.

III. General Discussion

The issues related to this notice of proposed rulemaking are complex and highly technical. The Agencies have organized this proposal to allow interested persons to first consider pertinent introductory material on the Agencies' 1972 notice and its 1999 recission, and a short overview of the NIOSH mission and assessment of this proposal, as well as those aspects of MSHA's coal mine respirable dust program relevant to this proposal. Following this introductory material is a discussion of the ''measurement objective,'' or what the Secretaries intend to measure with a single, full-shift measurement, and the use of the NIOSH Accuracy Criterion for determining whether a single, full-shift measurement will ''accurately represent'' the full-shift atmospheric dust concentration. Next, the validity of the sampling process is addressed, including the performance of the approved sampler unit, sample collection procedures, and sample processing. The concept of measurement uncertainty is then addressed, and why sources of dust concentration variability and various other factors are not relevant to the proposal. In addition, the proposal summarizes the health effects of occupational exposure to respirable coal mine dust and presents MSHA's quantitative risk assessment (QRA). Finally, the proposal explains how the total measurement uncertainty is quantified, and how the accuracy of a single, full-shift measurement meets the NIOSH Accuracy Criterion. Several Appendices, which contain relevant technical information, are attached and incorporated in this notice. Appendix E contains the references used throughout this notice of proposed rulemaking.

The proposed rule is consistent with Executive Order 12866, the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act (SBREFA), the National Environmental Policy Act (NEPA), the Paperwork Reduction Act, the Unfunded Mandates Reform Act, and the Mine Act.

A. The 1971/1972 Joint Notice of Finding

In 1971, the Secretary of the Interior and the Secretary of Health, Education, and Welfare proposed, and in 1972 issued, a joint finding under the Coal Act. The finding concluded that a single, full-shift measurement of respirable dust would not, after applying valid statistical techniques, accurately represent the atmospheric conditions to which the miner is continuously exposed. For the reasons that follow, the Secretaries believe that the 1972 joint finding was incorrect.

Section 202(b)(2) of the Coal Act provided that ''each operator shall continuously maintain the average concentration of respirable dust in the mine atmosphere during each shift to which each miner in the active workings of such mine is exposed at or below the applicable respirable dust standard.'' In addition, the term ''average concentration'' was defined in section 202(f) of the Coal Act as follows:

> * * * the term ''average concentration'' means a determination which accurately represents the atmospheric conditions with regard to respirable dust to which each miner in the active workings of a mine is exposed (1) as measured during an 18 month period following the date of enactment of this Act, over a number of continuous production shifts to be determined by the Secretary of the Interior and the Secretary of Health, Education and Welfare, and (2) as measured thereafter, over a single shift only, unless the Secretary of the Interior and the Secretary of Health, Education and Welfare find, in accordance with the provisions of section 101 of this Act, that such single shift measurements will not, after applying valid statistical techniques to such measurement, accurately represent such atmospheric conditions during such shift.

Therefore, 18 months after the statute was enacted, the ''average concentration'' of respirable dust in coal mines was to be measured over a single shift only, unless the Secretaries found that doing so would not accurately represent mine atmospheric conditions during such shift. If the Secretaries found that a single shift measurement would not, after applying valid statistical techniques, accurately represent mine atmospheric conditions during such shift, then the interim practice of averaging measurements ''over a number of continuous production shifts'' was to continue.

On December 16, 1969, the U.S. Congress published a Conference Report in support of the new Coal Act. The Report refers to section 202(f) by noting that:

> At the end of this 18 month period, it requires that the measurements be over one production shift only, unless the Secretar[ies] * * * find, in accordance with the standard setting procedures of section 101, that single shift measurements will not accurately represent the atmospheric conditions during the measured shift to which the miner is continuously exposed (Conference Report, page 75).

This Report is inconsistent with the wording of the section 202(f), which seeks to apply a single, full-shift measurement to ''accurately represent such atmospheric conditions during such shift.'' Section 202(f) does not mention continuous exposure. The Secretaries believe that the use of this phrase, ''continuously exposed'', is confusing, and to the extent that any weight of interpretation can be given to the legislative history, that the Senate's Report of its bill provides a clearer interpretation of section 202(f) when read together with the statutory language. The Senate Committee noted in part that:

> The committee * * * intends that the dust level not exceed the specified standard during any shift. It is the committee's intention that the average dust level at any job, for any miner in any active working place during each and every shift, shall be no greater than the standard. [Standard = 2 mg/m³]

Following passage of the Coal Act, the Bureau of Mines (MSHA's predecessor Agency within the Department of the Interior) expressed a preference for multi-shift sampling. Correspondence exchanged during that time period of 1969 to 1971 reflected concern over the technological feasibility of controlling dust levels to the limits established, and the potentially disruptive effects of mine closure orders because of noncompliance with the respirable dust limits. Both industry and government officials feared that basing noncompliance determinations on single, full-shift measurements would increase those problems. In June 1971, the then-Associate Solicitor for Mine Safety and Health at the Department of the Interior issued a legal interpretation of section 202(f), concluding that the average dust concentration was to be determined by measurements that accurately represent respirable dust in the mine atmosphere over time rather than during a shift. On July 17, 1971, the Secretaries of the Interior and of Health, Education, and Welfare issued a proposed notice of finding under section 202(f) of the Coal Act. The finding concluded that, ''a single shift measurement of respirable dust will not, after applying valid statistical techniques to such measurement, accurately represent the atmospheric conditions to which the miner is continuously exposed'' (36 FR 13286).

In February, 1972, the final finding was issued (37 FR 3833). It concluded that:

> After careful consideration of all comments, suggestions, and objections, it is the conclusion of the Secretary of the Interior and the Secretary of Health, Education, and Welfare that a valid statistical technique was employed in the computer analysis of the data referred to in the proposed notice [footnote omitted] and that the data utilized was accurate and supported the proposed finding. Both Departments also intend periodically to review this finding as new technology develops and as new dust sampling data becomes available.
>
> The Departments intend to revise part 70 of title 30, Code of Federal Regulations, to improve dust measuring techniques in order to ascertain more precisely the dust exposure of miners. To complement the present system of averaging dust measurements, it is anticipated that the proposed revision would use a measurement over a single shift to determine compliance with respirable dust standards taking into account (1) The variation of dust and instrument conditions inherent in coal mining operations, (2) the quality control tolerance allowed in the manufacture of personal sampler capsules, and (3) the variation in weighing precision allowed in the Bureau of Mines laboratory in Pittsburgh.
>
> The proposed finding, as set forth at 36 FR 13286, that a measurement of respirable dust over a single shift only, will not, after applying valid statistical techniques to such measurement, accurately represent the

atmospheric conditions *to which the miner under consideration is continuously exposed,* is hereby adopted without change (emphasis added).

As explained in the 1971 proposed finding, the average concentration of all ten full-shift samples (from one occupation) submitted from each working section under the regulations in effect at the time (these were the ''basic samples'' referred to in the proposed notice of finding) was compared with the average concentration of the two most recently submitted samples, then to the three most recently submitted samples, then to the four most recently submitted samples, etc. In discussing the results of these comparisons, the Secretaries stated that ''* * * the average of the two most recently submitted samples of respirable dust was statistically equivalent to the average concentration of the current basic samples for each working section in only 9.6 percent of the comparisons.''

The title of the 1971/1972 notice and the conclusion it reaches are clearly inconsistent. The title states that it is a ''Notice of Finding That Single Shift Measurements of Respirable Dust Will Not Accurately Represent Atmospheric Conditions During Such Shift.'' However, the conclusion states that, ''* * * a single shift measurement * * * will not, after applying valid statistical techniques * * * accurately represent the atmospheric conditions to which the miner is *continuously* exposed'' (emphasis added).

The Secretaries have determined that section 202(f) would require a determination of accuracy with respect to ''atmospheric conditions during such shift,'' not ''atmospheric conditions *to which the miner is continuously exposed''* (37 FR 3833) (emphasis added). The Secretaries believe that the 1972 Finding does not apply the Mine Act's requirement at Section 202(f), 30 U.S.C. 842. The statistical analysis referenced in the 1971/1972 proposed and final findings simply did not address the accuracy of a single, full-shift measurement in representing atmospheric conditions during the shift on which it was taken. For this and other reasons, such as advancements in sampling technology, set forth in the notice, the Secretaries hereby propose to rescind the 1972 joint final finding.

IV. NIOSH Mission Statement and Assessment of the Joint Finding

The National Institute for Occupational Safety and Health (NIOSH) was created by Congress in the Occupational Safety and Health Act in 1970. The Act established NIOSH as part of the Department of Health, Education, and Welfare (currently NIOSH is a part of the Department of Health and Human Services) to identify the causes of work-related diseases and injuries, evaluate the hazards of new technologies, create new ways to control hazards to protect workers, and make recommendations for new occupational safety and health standards. Under section 501 of the Mine Act (30 U.S.C. 951), Congress gave specific research responsibilities to NIOSH in the field of coal and other mine health. These responsibilities include the authority to conduct studies, research, experiments and demonstrations, in order ''to develop new or improved means and methods of reducing concentrations of respirable dust in the mine atmosphere of active workings of the coal or other mine,'' and also ''to develop techniques for the prevention and control of occupational diseases of miners * * *''

When the initial finding, issued under section 202(f) of the Coal Act, was published in 1972, both the Secretary of the Interior and the Secretary of Health, Education, and Welfare (the predecessor to the Department of Health and Human Services) indicated that the finding would be reassessed as new technology was developed, or new data became available. The Secretary of Health and Human Services, through delegated authority to NIOSH, has reconsidered the provisions of section 202(f) of the Mine Act (30 U.S.C. 842(f)), reviewed the current state of technology and other scientific advances since 1972, and has determined that the following innovations and technological advancements are important factors in the reassessment of the 1971/1972 joint finding.

In 1977, NIOSH published its ''Sampling Strategies Manual,'' which provided a framework for the statistical treatment of occupational exposure data (DHEW (NIOSH) Publication No. 77–173; Sec. 4.2.1). Additionally, that year, NIOSH first published the NIOSH Accuracy Criterion, which was developed as a goal for methods to be used by OSHA for compliance determinations (DHEW (NIOSH) Publication No. 77–185; pp. 1–5). In 1980, new mine health standards issued by the Secretary of Labor (30 CFR parts 70, 71, and 90) improved the quality of the sampling process by revising sampling, maintenance, and calibration procedures. Through the mid-nineteen-eighties, MSHA continued to refine and improve its sampling process. In 1984, a fully-automated, robotic weighing system was introduced along with state-of-the-art electronic microbalances. Prior to 1984, filter capsules used in sampling were manually weighed by MSHA personnel using semi-micro balances, making precision weights to the nearest 0.1 mg (100 micrograms). In 1994, the balances were further upgraded, and in 1995 the weighing system was again improved, increasing weighing sensitivity to the microgram level. Also, in 1987, electronic flow-control sampling pump technology was introduced in the coal mine dust sampling program with the use of Mine Safety Appliances FlowLite™ pumps.[1] These new pumps compensate for the changing filter flow-resistance that occurs due to dust deposited during the sampling period. The second generation of constant-flow sampling pumps was introduced in 1994, with the introduction of the Mine Safety Appliances Escort ELF® pump. The automatic correction provided by these new pumps improves the stability of the sampler air flow rates and reduces the inaccuracies that were inherent in the 1970–1980s vintage sampling pumps. One further improvement was made in 1992 with the introduction of the new tamper-resistant filter cassettes. Because of these evolving improvements to the sampling process, a better understanding of statistical methods applied to method accuracy, and a reconsideration of the requirements of section 202(f) of the Mine Act (30 U.S.C. 842(f)), the Secretary of Health and Human Services has determined that the previous joint finding should be reevaluated.

V. MSHA Mission Statement and Overview of the Respirable Dust Program

With the enactment of the Mine Act, Congress recognized that ''the first priority and concern of all in the coal or other mining industry must be the health and safety of its most precious resource—the miner.'' Congress further realized that there ''is an urgent need to provide more effective means and measures for improving the working conditions and practices in the Nation's coal or other mines in order to prevent death and serious physical harm, and in order to prevent occupational diseases originating in such mines.'' With these goals in mind, MSHA is given the responsibility to protect the health and safety of the Nation's coal and other miners by enforcing the provisions of the Mine Act.

[1] Reference to specific equipment, trade names or manufacturers does not imply endorsement by NIOSH or MSHA.

A. The Coal Mine Respirable Dust Program

In 1970, federal regulations were issued by MSHA's predecessor agency that established a comprehensive coal mine operator dust sampling program for underground mines. The program required the environment of the occupation on a working section exposed to the highest respirable dust concentration to be sampled—the ''high risk occupation'' concept. All other occupations on the section were assumed to be protected if the high risk occupation was in compliance. Under this program, each operator was required to initially collect and submit ten valid respirable dust samples to determine the average dust concentration across ten production shifts. If the analysis showed the average dust concentration to be within the applicable dust standard, the operator was required to submit only five valid samples a month. If compliance continued to be demonstrated, the operator was required to take only five valid samples every other month. The initial, monthly, and bimonthly sampling cycles were referred to as the ''original,'' ''standard,'' and ''alternative sampling'' cycles, respectively. When the average dust concentration exceeded the applicable standard, the operator reverted back to the standard monthly sampling cycle.

In addition to sampling the high risk occupation at specified frequencies, each miner was sampled individually at different intervals. However, these early individual sample results were not used for enforcement but were provided to NIOSH for medical research purposes. Also required to be sampled every 90 days in underground mines, beginning in 1971, and in surface mines, beginning in 1974, were individuals who had evidence of the development of pneumoconiosis and exercised their option to transfer to a low dust area.

Federal regulations establishing a comprehensive operator dust sampling program for surface coal mines were issued in 1972. Under this program, each miner was sampled initially prior to July 1, 1972, and then either semiannually, if the initial sample exceeded 1.0 mg/m^3 but was less than 2.0 mg/m^3, or annually if the initial sample was 1.0 mg/m^3 or less.

MSHA revised these regulations in April 1980 (45 FR 23990) to reduce the operator sampling burden, to simplify the sampling process, and to enhance the overall quality of the sampling program. The result was to replace the various sampling cycles in effect in underground and surface coal mines with a bimonthly sampling cycle and to eliminate the requirement that each miner be sampled. Unlike the underground sampling requirements, operators of surface coal mines were required to sample bimonthly only after a ''designated work position'' (DWP) was established by MSHA. Once established, only one sample is required to be collected each bimonthly period. Under the revised regulations, MSHA could also withdraw the designation of work positions for sampling if samples taken by the operator and by MSHA demonstrated continuing compliance with the applicable dust standard. These are the regulations that currently govern the mine operator dust sampling program at both underground and surface coal mines, and which, in the case of underground mines, continue to be based on the high risk occupation concept, now referred to as the ''designated occupation'' or ''D.O.'' sampling concept.

It should be noted that the April 1980 preamble to the final rule, amending the regulations for underground coal mines, explicitly refers to the use of single versus multiple samples as it applies to the operator respirable dust sampling program (45 FR 23997):

> Compliance determinations will generally be based on the average concentration of respirable dust measured by five valid respirable dust samples taken by the operator during five consecutive shifts, or five shifts worked on consecutive days. Therefore, the sampling results upon which compliance determinations are made will more accurately represent the dust in the mine atmosphere than would the results of only a single sample taken on a single shift. In addition, MSHA believes the revised sampling and maintenance and calibration procedures prescribed by the final rule will significantly improve the accuracy of sampling results.

At the time of these amendments, MSHA examined section 202(b)(2) of the Coal Act, which was retained unchanged in the 1977 Mine Act. The Agency stated in the preamble to the final rule that:

> Although single-[full] shift respirable dust sampling would be most compatible with this single-shift standard, Congress recognized that variability in sampling results could render single-shift samples insufficient for compliance determinations. Consequently, Congress defined ''average concentration'' in section 202(f) of the 1969 Coal Act which is also retained in the 1977 Act.

MSHA believes that this interpretation merely recognized the two ways of measurement authorized in section 202(f), and expressed the preference on the part of MSHA in 1980 to retain multi-shift sampling in the operator sampling program. The phrase used in the preamble to the final rule reflects that MSHA understood that the 2.0 mg/m^3 limit was a single-shift standard, meaning that it was not to be exceeded on a shift. The preamble referenced the continuous multi-shift sampling and single-shift sampling conducted by the Secretary of the Interior and the Secretary of Health, Education, and Welfare, and noted that in the 1971/1972 proposed and final findings:

> ''It had been determined after applying valid statistical techniques, * * * that a single shift sample should not be relied upon for compliance determinations when the respirable dust concentration being measured was near 2.0 mg/m^3. Accordingly, the [Secretaries] prescribed consecutive multi-shift samples to enforce the respirable dust standard.''

The preamble provides no further explanation for the statement that single-shift samples should not be relied on when the respirable dust concentration being measured was near 2.0 mg/m^3. Thus, the 1980 final rule, which reduced the number of samples that operators were required to take for compliance determinations, merely reiterated the rationale behind the 1971/1972 proposed and final findings concerning single-shift samples, and did not address the accuracy of a single, full-shift measurement.

MSHA continues to take an active role in sampling for respirable dust and has recently expanded its sampling to more than once annually at each surface and underground coal mine. During these inspections, MSHA inspectors collect samples on multiple occupations to determine whether miners are being overexposed to respirable coal mine dust; to assess the effectiveness of the operator's dust control program; to quantify the level of respirable crystalline silica (quartz) in the work environment and whether there is a need to adjust the applicable dust standard; and to identify occupations in underground mines, other than the ''D.O.'', and occupations in surface mines, that are at risk of being overexposed and should be routinely monitored by the mine operator.

Depending on the concentration of respirable coal mine dust measured, an MSHA inspector may terminate sampling after the first day if levels are very low, or continue for up to five shifts or days before making a compliance or noncompliance determination. For example, MSHA inspection procedures require inspectors to sample at least five occupations, if available, on each mechanized mining unit (MMU) on the first day of sampling. Based on the first shift of sampling, the operator is cited if the average of those measurements exceeds the applicable standard. However, if the average falls below the standard, but one or more of the measurements exceed the applicable standard, additional samples are collected on the subsequent production shift or day. The results of the first and second shift of sampling on all occupations are then averaged to determine if the applicable standard is exceeded. Additionally, when an inspector continues sampling after the first shift because a previous measurement exceeds the standard, MSHA's procedures call for all measurements taken on a given occupation to be averaged within that occupation, across all sampling shifts. If the average of measurements taken over more than one shift on all occupations is equal to or less than the applicable standard, but the average of measurements taken on any one occupation exceeds the value in a decision table developed by MSHA, the operator is cited for violation of the applicable standard.

B. The Spot Inspection Program (SIP)

In response to concerns about possible tampering with dust samples in 1991, MSHA convened the Coal Mine Respirable Dust Task Group (Task Group) to review the Agency's respirable dust program. The Task Group was directed to consider all aspects of the current program in its review, including the role of the individual miner in the sampling program; the feasibility of MSHA conducting all sampling; and the development of new and improved monitoring technology, including technology to continuously monitor the mine environment. Among the issues addressed by the Task Group was the actual dust concentration to which miners are exposed. As part of the Task Group review, MSHA developed a special respirable dust ''spot inspection program'' (SIP).

This program was designed to provide the Agency with information on the dust levels to which underground miners are typically exposed. Because of the large number of mines and MMUs (mechanized mining units) involved and the need to obtain data within a short time frame, respirable dust sampling during the SIP was limited to a single shift or day, a departure from MSHA's normal sampling procedures. The term ''MMU'' is defined in 30 CFR 70.2(h) to mean a unit of mining equipment, including hand loading equipment, used for the production of material. As a result, MSHA decided that if the average of multiple occupation measurements taken on an MMU during any one-day inspection did not exceed the applicable standard, the inspector would review the result of each individual full-shift sample. If any individual full-shift measurement exceeded the applicable standard by an amount specified by MSHA, a citation would be issued for noncompliance, requiring the mine operator to take immediate corrective action to lower the average dust concentration in the mine atmosphere in order to protect miners.

During the SIP inspections, MSHA inspectors cited violations of the 2.0 mg/m^3 standard if either the average of the five measurements taken on a single shift was equal to or greater than 2.1 mg/m^3, or any single, full-shift measurement was equal to or exceeded 2.5 mg/m^3. Similar adjustments were made when the 2.0 mg/m^3 standard was reduced due to the presence of quartz dust in the mine atmosphere.[2]

The procedures issued by MSHA's Coal Mine Safety and Health Division during the SIP were similar to those used by the MSHA Metal/Nonmetal Mine Safety and Health Division and the Occupational Safety and Health Administration (OSHA) when determining whether to cite based on a single, full-shift measurement. That practice provides for a margin of error reflecting an adjustment for uncertainty in the measurement process (*i.e.*, sampling and analytical error, ''SAE''). The margin of error thus allows citations to be issued only where there is a high level of confidence that the applicable standard has been exceeded.

Based on the data from the SIP inspections, the Task Group concluded that MSHA's practice of making noncompliance determinations solely on the average of multiple-sample results did not always result in citations in situations where miners were known to be overexposed to respirable coal mine dust. For example, if measurements obtained for five different occupations within the same MMU were 4.1, 1.0, 1.0, 2.5, and 1.4 mg/m^3, the average concentration would be 2.0 mg/m^3. Although the dust concentrations for two occupations exceed the applicable standard, under MSHA procedures, no citation would have been issued nor any corrective action required to reduce dust levels to protect miners' health. Instead, MSHA policy required the inspector to return to the mine the next day that coal was being produced and resume sampling in order to decide if the mine was in compliance or not in compliance.

Thus, the SIP inspections revealed instances of overexposure that were masked by the averaging of results across different occupations. This showed that miners would not be adequately protected if noncompliance determinations were based solely on the average of multiple measurements. The process of averaging dilutes a high measurement made at one location with lower measurements made elsewhere.

The Task Group also recognized that the results of the first full-shift samples taken by an inspector during a respirable dust inspection are likely to reflect higher dust concentrations than samples collected on subsequent shifts or days during the same inspection. MSHA's comparison of the average dust concentration of inspector samples taken on the same occupation on both the first and second day of a multiple-day sampling inspection showed that the average concentration of all samples taken on the first day of an inspection was almost twice as high as the average concentration of samples taken on the second day. MSHA recognized that sampling on successive days does not always result in measurements that are representative of everyday respirable dust exposures in the mine because mine operators can anticipate the continuation of inspector sampling and make adjustments in dust control parameters or production rates to lower dust levels during the subsequent sampling.

In response to these findings, in November 1991, MSHA decided to permanently adopt the single, full-shift inspection policy initiated during the SIP for all mining types.

C. The Keystone Decision

In 1991, three citations based on single, full-shift measurements were issued under the SIP to the Keystone Coal Mining Corporation. The violations were contested, and an administrative law judge from the Federal Mine Safety and Health Review Commission (Commission) vacated the citations. The decision was appealed by the Secretary of Labor to the Commission because the Secretary believed that the administrative law judge was in error in

[2] Quartz may be present in the coal seam and therefore may become airborne during coal production. MSHA regulates coal miners' work-shift exposure to quartz since it may be deposited in the lungs of miners and cause silicosis. MSHA's current standard for respirable coal mine dust, 2.0 mg/m^3, also requires quartz levels to be 5% or lower. Otherwise, if the percent of quartz is higher than 5%, the respirable coal mine dust exposure limit must be adjusted downward based on this formula: Respirable dust standard (mg/m^3)= {(10 mg/m^3)/(%Quartz)} For example, if the respirable dust contains 15 percentage of quartz the respirable coal mine dust standard would be 0.67 mg/m^3 since 10 mg/m^3 divided by 15 equals 0.67 mg/m^3.

finding that rulemaking was required under section 202(f) of the Mine Act (30 U.S.C. 842(f)) for the Secretary to use single, full-shift measurements for noncompliance determinations. In addition, the Secretary contended that the 1971/1972 finding pertained to operator sampling and that the SIP at issue involved only MSHA sampling. The Commission, which affirmed the decision of the administrative law judge, found that:

Title II [of the Mine Act] applies to both operator sampling and to MSHA actions to ensure compliance, including sampling by MSHA. Section 202(g) specifically provides for MSHA spot inspections. Nothing in § 202(f) or § 202(g) suggests that § 202(f) applies differently to MSHA sampling. Thus, the 1971 finding, issued for purposes of title II, applies broadly to both MSHA and operator sampling of the mine atmosphere.

The Commission also held that the revised MSHA policy was in contravention of the 1971/1972 finding and could only be altered if the requirements of the Mine Act and the Administrative Procedure Act, 5 U.S.C. 550, were met. Through this proposed notice of rulemaking, MSHA is now attempting to meet those requirements.

D. The Interim Single-Sample Enforcement Policy (ISSEP)

On February 3, 1998, MSHA published a corrected notice in the **Federal Register** (63 FR 5687) announcing its final policy on the use of single, full-shift measurements to determine noncompliance and issue citations, based on samples collected by MSHA inspectors, when the applicable respirable dust standard is exceeded. The enforcement policy, thereafter referred to as ISSEP, which took effect on May 7, 1998, provides better protection to miners' health because it enabled MSHA to more effectively identify overexposures that were previously masked by the averaging of results across different occupations. Again, through the proposed single, full-shift sample approach, citations for noncompliance with the respirable coal mine dust standard would be able to be made for overexposures which would not be identified through the current procedure of averaging multiple-sample results. For example, if measurements obtained for five different occupations within the same MMU were 4.1, 1.0, 1.0, 2.6, and 0.8 mg/m^3, the average concentration would be 1.9 mg/m^3. Although the dust concentrations for two occupations statistically exceeded the applicable standard, under the current practice, of averaging results, no citation would be issued nor any corrective action required to reduce dust levels to protect miners' health. The ISSEP was in place until September 9, 1998, when MSHA reinstituted its previous procedure of averaging sample results for noncompliance determinations after the 11th Circuit Court of Appeals vacated the Agencies' 1998 Finding and MSHA's final policy.

Under the ISSEP, MSHA followed its existing dust sampling procedures in regard to where and how many samples an inspector collects during a sampling shift at underground and surface coal mines. While the Agency continued its practice of collecting multiple occupational samples at each MMU, the minimum number of occupations monitored was reduced from five to three, focusing only on those occupations at high risk of being overexposed. As part of the ISSEP, inspectors carried with them a control filter when conducting respirable dust sampling. This control filter, which was unexposed, was used to adjust the weight gain obtained on each of the exposed filters. Any change in weight of the unexposed control filter was subtracted from the change in weight of each exposed filter. For the exposed filter to be valid, the control and exposed filter must have been both pre- and post-weighed on the same days. If the control filter was either missing or invalid, the measurement(s) were not used for enforcement purposes and the entity type (*i.e.*, mining section) was to be resampled. An operator was found to be in violation of the applicable dust standard when a single, full-shift measurement met or exceeded the Citation Threshold Value (CTV) corresponding to the dust standard in effect. Each CTV listed in *Chapter 1 of the Coal Mine Health Inspection Procedures Handbook* (PH89–V–1(10)) was calculated to ensure that citations would be issued only when a measurement demonstrated, with at least 95-percent confidence, that the applicable standard had been exceeded.[3] No more than one citation was to be issued based on single, full-shift measurements from the same MMU, if the sampled occupations were exposed to the same dust generating sources. Issuance of separate citations were to be considered only after determining that the affected occupations were exposed to different dust generating sources.

When a single, full-shift measurement exceeded the applicable standard but was less than the CTV, a citation was not to be issued since noncompliance was not demonstrated at a sufficiently high confidence level. Instead, the MMU or other entity type sampled was to be targeted for additional sampling to verify the adequacy of the operator's dust control measures to maintain compliance, with special emphasis directed toward working environments with applicable standards below 2.0 mg/m^3. If subsequent sampling exceeded the applicable standard but not the CTV, the MSHA district responsible for inspecting the mine would thoroughly review the dust control parameters stipulated in the operator's approved ventilation or respirable dust control plan (applicable to surface mines and Part 90 miners) to determine if the parameters should be upgraded.

The process by which a violation of the applicable standard was to be abated by a mine operator remained unchanged. That is, an operator must first take corrective action to reduce the average dust concentration to within the permissible level, and then sample each production or normal work shift until five valid respirable dust samples are taken. MSHA considers a violation to be abated when the average dust concentration measured by these five valid samples was at or below the applicable standard. Under the ISSEP, MSHA inspectors sampled 1,662 MMUs and other entity types, such as roof bolter DAs and Part 90 miners, in underground mines; and some 860 DWPs and over 3,700 nondesignated work positions at surface mining operations. The Agency issued a total of 309 excessive dust citations based on the results of single, full-shift samples, involving 182 MMUs and 113 other underground entity types, and 14 surface work positions. Of the 1,662 MMUs sampled, 182 or 11 percent were cited, compared to the 27 percent MSHA had projected based on inspector sampling results for 1995. Also, it is important to point out that only 14 of the over 4,500 surface entities sampled were found to be out of compliance. These sampling inspections, which showed a significant decline in the number of cited instances of noncompliance compared to previous experience under the SIP and the earlier projections documented in the 1998 notices, reveal that mine operators are capable of maintaining dust concentrations at or below the applicable standard on every shift.

VI. Procedural and Litigation History of This Proposal

On February 18, 1994, the Secretary of Labor and the Secretary of Health and Human Services published a proposed

[3] MSHA plans to issue a revised Coal Mine Health Inspection Procedures Handbook after publication of this proposed standard as a final rule. The Handbook would list the CTVs.

Joint Notice of Finding in the **Federal Register** (59 FR 8357). The Joint Notice proposed to rescind the 1972 finding by the Secretaries of the Interior and Health, Education and Welfare, and instead, find that a single, full-shift measurement will accurately represent the atmospheric conditions with regard to the respirable dust concentration during the shift on which it was taken. Concurrently, MSHA published a separate notice in the **Federal Register** announcing its intention to use both single, full-shift measurements and the average of multiple, full-shift measurements for noncompliance determinations under the MSHA respirable coal mine dust program (59 FR 8356). That notice was published to inform the mining public of how the Agency intended to implement its new enforcement procedure utilizing single, full-shift samples, and to solicit public comment on the procedure.

After a notice and comment procedure extending over some three and one-half years, which also included three public hearings, the Agencies published a final corrected notice of finding in the **Federal Register** (63 FR 5664) on February 3, 1998.

The National Mining Association (NMA) along with the Alabama Coal Association petitioned the United States Court of Appeals for the 11th Circuit to review the 1998 Notice of Finding (Joint Finding) issued by the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH), and additionally asked for an emergency motion for stay of the Joint Finding pending review. The motion for an emergency stay was denied by the Court.

On appeal NMA argued, among other things, that the agency had not met the requirements of section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) (30 U.S.C. 811(a)(6)(A)) because it failed to address material impairment of health and economic and technological feasibility. MSHA and the Department of Labor responded that the agencies addressed the positive effect of the notice on miner health, and also concluded in the course of performing the analysis required under the Regulatory Flexibility Act that the economic impact of the Joint Finding was not significant. On September 4, 1998, the United States Court of Appeals for the 11th Circuit issued a decision in the case of *National Mining Association* v. *Secretary of Labor*, (153 F.3d 1264). The Court of Appeals vacated the Joint Finding and concluded that the agency was required to ''satisfy the requirements of Section 811(a)(6)'' by ''demonstrat[ing] that the new standard (a) adequately assures that no miner will suffer a material impairment of health, on the basis of the best available evidence; (b) uses the latest available scientific data in the field; (c) is feasible [in both an economic and technological sense]; and (d) is based on experience gained under the Mine Act and other health and safety laws,'' supra, at 1268–1269. The Court then concluded that ''the record contains no finding of economic feasibility,'' and that MSHA therefore ''failed to comply with Section 811(a)(6) of the Mine Act.'' MSHA asked the Court for a clarification of its decision by filing a Motion for Clarification. The Court, without opinion, denied the Secretary's motion on November 11, 1998.

MSHA and NIOSH understand the Court's ruling as requiring the Agencies to comply with all requirements under section 101(a)(6)(A) of the Mine Act (30 U.S.C. 811(a)(6)(A)). Therefore, in response to the Court's ruling, the Secretaries are proposing today to add a new mandatory health standard to 30 CFR part 72. Pursuant to section 202(f) of the Mine Act (30 U.S.C. 842(f)), the 1972 joint notice of finding would be rescinded and a new finding would be made that a single, full-shift measurement will accurately represent atmospheric conditions to which a miner is exposed during such shift. This finding is the basis for the new proposed mandatory health standard.

The Secretaries believe that single, full-shift measurements must be implemented into the MSHA coal mine respirable dust program as quickly as possible in order to better protect miners' health. Therefore, in order to speed the process of reproposing this critical measurement technique, the Secretaries are incorporating the record of the previous 1998 Joint Finding into the record for this proposal and adding appropriate new data and information to support this rulemaking under section 101(a)(6)(A) of the Mine Act (30 U.S.C. 811(a)(6)(A)). The Secretaries have used as much of the original wording as possible from the vacated final finding in this notice of proposed rulemaking. References to previous comments and commenters in the body of this proposal are meant to apply to previous comments received in response to the earlier proposed Joint Finding that was ultimately vacated by the U.S. Court of Appeals for the 11th Circuit.

VII. Health Effects

A. Introduction

Since the 1800s, occupational respiratory disease associated with working in a coal mine has been commonly referred to as ''Black Lung.'' As coal is mined, respirable-sized dust is generated. Depending upon the mine location and its geologic features, silica may also be present in the mine atmosphere. Dust in air that is breathed by miners has the potential to be deposited in their lungs. Some of this dust may be retained. Coal mine dust remaining in the lungs of miners for prolonged periods of time has the potential to result in respiratory diseases, sometimes even after occupational exposure to respirable coal mine dust has stopped. There is a clear and direct relationship between miners' cumulative exposures (*i.e.,* dose multiplied by the time exposed to the coal mine dust) to respirable coal mine dust and the severity of resulting respiratory conditions (as discussed more extensively, later in this section).

Diseases resulting from long-term retention of coal mine dust in the lung include chronic coal workers' pneumoconiosis (simple CWP), progressive massive fibrosis (PMF), silicosis, and chronic obstructive pulmonary disease (COPD) (*e.g.,* asthma, chronic bronchitis, emphysema). Historically, the medical term, ''pneumoconiosis'', has included simple CWP and PMF and their sub-categories. Chronic, or simple, CWP is partitioned into three levels of severity, proceeding from lowest to highest: Category 1, category 2, and category 3. Progressive Massive Fibrosis is similarly divided into three categories of increasing levels of severity: A, B and C.

Miners with simple CWP have a substantially increased risk of developing PMF. In the advanced stages of pneumoconiosis (*i.e.,* PMF), a significant loss of lung function may occur and respiratory symptoms (*e.g.,* breathlessness, wheezing) may persist. Miners are at risk of increased morbidity and premature mortality due to simple CWP, PMF and various other respiratory diseases.

Factors that are important in the development of simple CWP, PMF and COPD include the type of dust (*e.g.,* coal and/or silica), dust concentration (to which the miner was exposed), number of years of exposure, age of the miner (often measured as age at time of medical examination), and rank of the coal (the higher the rank the greater the risk).

In 1998, MSHA estimated that approximately 45,000 miners and

39,000 miners were employed at underground and surface coal mines, respectively (Mattos, 1999). A small percentage of the mining involved anthracite coal, the highest rank coal, while most involved bituminous coal which is a medium rank coal.

There are complementary data sources, described below, which provide estimates of the prevalence of occupational respiratory disease among coal miners. Together these data demonstrate the progress over the last thirty years in the reduction of occupational respiratory disease among coal miners, as well as the need for further action to reduce occupational lung disease among today's coal miners.

Estimates of the prevalence of simple CWP and PMF among the underground coal miners are gathered from the x-ray program, through which operators are required to provide miners the opportunity to be evaluated periodically for the presence of occupational lung disease, mandated pursuant to Section 203(a) of the Mine Act (30 U.S.C. 843(a)). However, miners are not required to participate. From 1970 to 1995,the prevalence of simple CWP and PMF among miners participating in the mandated x-ray program has dropped from 11 percent to 3 percent (MSHA, Internal Chart, 1998).

In accordance with 30 CFR part 50, those cases of occupational illnesses which both surface and underground coal mine operators learn of must be reported to MSHA. Under this requirement, mine operators reported 224 cases of pneumoconiosis (simple CWP and PMF, combined) in 1998 (Mattos, 1999). Of these, 138 cases occurred among coal miners who worked underground, while the remaining 86 cases occurred among surface coal miners (Mattos, 1999). There were also 14 cases of silicosis, eight in underground mines, reported to MSHA in 1998 in accordance with 30 CFR part 50 (Mattos, 1999). Since miners participate in both these programs at their own discretion, these data do not include the occupational health experience of all coal miners. The prevalence of occupational lung disease among participating miners may significantly differ from the prevalence among non-participants. Thus, the data from these programs may not be representative of the true magnitude of the prevalence of simple CWP and PMF among today's coal miners.

In the 1990s, MSHA conducted a series of one-time medical surveillance programs, in various regions of the country, to develop a more accurate estimate of the prevalence of simple CWP and PMF. Through these special programs, MSHA tried to minimize obstacles which may prevent some miners from either participating in or reporting to operators the results of respiratory diagnostic procedures. Nine geographical cohorts of miners, from around the country, were encouraged to participate in an independent x-ray program (MSHA, Internal Chart, 1999). These cohorts included eight active surface coal mining communities in the states of Pennsylvania, Kentucky and West Virginia, as well as the towns of Poteau, Oklahoma and Gillette, Wyoming. A ninth cohort included underground miners in Kentucky. The process was designed to encourage miner participation by providing for a greater degree of anonymity than may be available under the program provided by Section 203(a) of the Mine Act (30 U.S.C. 843(a)). Across the eight surface cohorts surveyed, the prevalence rate of simple CWP and PMF combined, among participants was 4.8%. The prevalence rate among the participating underground Kentucky miners was 9.2%.

Also, as part of its ongoing effort to ''end black lung now and forever,'' beginning in October 1999, MSHA implemented a pilot program to provide miners at both surface and underground mines with confidential health screening. Referred to as the ''Miners' Choice Health Screening'', the program addresses the key recommendations of the Secretary's Advisory Committee by (1) increasing participation toward the 85-percent level and (2) expanding the scope of the eligibility to include surface coal miners and surface coal mine independent contractors. The pilot program will operate separately from the existing Coal Workers' X-ray Surveillance Program administered by NIOSH. Since the Miners' Choice Health Screenings' inception, over 7,000 miners have been screened, with the participation rate in most areas exceeding 50 percent. With half of the x-rays taken during the first six months having been processed by NIOSH, preliminary results indicate a prevalence rate of approximately 2.25 percent.

The National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Administration (MSHA) are concerned about the prevalence of occupational lung disease among today's miners. Epidemiological studies from the U.S. and abroad have consistently shown that underground and surface coal miners are at risk of developing simple CWP, PMF, silicosis, and chronic obstructive pulmonary disease (NIOSH Criteria Document, 1995).

B. Hazard Identification

1. Agent: Coal

Coal is a fossil fuel derived from partial degradation of vegetation. Through its combustion, energy is produced which makes coal a valuable global commodity. It has been estimated that over one-third of the world uses energy provided by coal (Manahan, 1994). Approximately 1,800 underground and surface coal mines are in operation in the United States annually producing slightly over a billion short tons of coal (Mattos, 1999).

Coal may be classified on the basis of its type, grade, and rank. The type of coal is based upon the plant material (*e.g.*, lignin, cellulose) from which it originated. The grade of coal refers to its chemical purity. Although coal is largely carbon, it may also contain other elements such as hydrogen, oxygen, nitrogen, and sulfur. ''Hard'' coal refers to coal with a higher carbon content (*i.e.*, 90–95%) than ''soft'' coal (*i.e.*, 65–75%). Coal rank relates to geologic age, indexed by its fixed carbon content, down to 65%, and then by its heating value. Volatile matter varies inversely with the fixed carbon value. The most commonly described coal ranks include lignite (low rank), bituminous coal (medium rank), and anthracite (high rank) (Manahan, 1994).

2. Physical State: Coal Mine Dust

Aerosols are a suspension of solid or liquid particles in air (Mercer, 1973); they may be dusts which are solid particles suspended in the air. Coal dust may be freshly generated or may be re-suspended from surfaces on which it is deposited in mines. As discussed below, coal mine dust may be inhaled by miners, depending upon the particle size.

Coal mine dust is a heterogenous mixture, signifying that all coal particles do not have the same chemical composition. The particles are influenced by the type, grade, and rank of coal from which they were generated (Manahan, 1994). Irrespective of differences in coal characteristics, these dusts are water-insoluble, which is important biologically and physiologically. Unlike soluble dusts which may readily pass into the respiratory system and be cleared via the circulatory system, insoluble dusts may remain in the lungs for prolonged periods of time. Thus, a variety of cellular responses may result that could eventually lead to lung disease.

3. Biological Action: Respirable Coal Mine Dust

The principal route of occupational exposure to respirable coal mine dust occurs via inhalation. As a miner breathes, coal mine dust enters the nose and/or mouth and may pass into the mid airways (*e.g.*, bronchi, terminal bronchioles) and lower airways (*e.g.*, respiratory bronchioles, alveolar ducts).

Coal mine dust has a size distribution that is estimated to range between 1 and 100 micrometer (μm) (1 μm = 10^{-6} m) (Silverman, *et al.*, 1971). The size of coal particles is critical in determining the level of the respiratory tract at which deposition and retention occur (American Conference of Governmental Industrial Hygienists, 1999; American Industrial Hygiene Association, 1997).

Particles that are above 10 μm are largely filtered in the nasal passages, although some of these particles may reach the thoracic (or tracheal-bronchial) region of the lung (*e.g.*, 6% of 20 μm) (American Conference of Governmental Industrial Hygienists, 1999). Thus, there is evidence that ''oversized'' particles (*i.e.*, >10 μm) can move beyond the nose, deeper into the respiratory tract. Particles below 10 μm may easily move throughout the respiratory tract. As particle size decreases from 10 to 5 μm, however, there is greater penetration into the mid and lower regions of the lung. Particles that are approximately 1–2 μm are the most likely to be deposited in the lung (American Conference of Governmental Industrial Hygienists, 1999; Mercer, 1973). During mouth breathing, there may be a slight upward shift in the particle deposition curve such that 2–3 μm-sized particles are the most likely to be deposited in the respiratory tract (Heyder, *et al.*, 1986). Irrespective of nasal or mouth breathing, the potential respiratory tract penetration of particles whose size is approximately 10 μm or less is important because particles in the respirable size range deposit in the deep lung where clearance is much slower.

For the purposes of this rule, ''respirable dust'' is defined as dust collected with a sampling device approved by the Secretary of Labor and the Secretary of the Department of Health and Human Services (DHHS) in accordance with 30 CFR Part 74 (Coal Mine Dust Personal Sampler Units). In practice, the coal mine dust personal sampler unit has been used in the U.S. The particles collected with an approved sampler approximate that portion of the dust which may be deposited in the lung (West, 1990; 1992). It does not, however, indicate pulmonary retention (*i.e.*, those particles remaining in the lung). For those particles that are deposited in the lung, clearance mechanisms normally operate to assist in their removal. For example, within the thoracic (tracheal-bronchial) region of the lung, cilia (*i.e.*, hairlike projections) line the airways and are covered by a thin layer of mucus. They assist in particle clearance by beating rhythmically to project particles toward the throat where they may be swallowed, coughed, sneezed, or expectorated. This rhythmic beating action is effective in removing particles fairly quickly (*i.e.*, hours or days). Within the alveolar region of the lung, particles may be engulfed by pulmonary macrophages. These large ''wandering cells'' may remove particles via the blood or lymphatics. This process, unlike the movement of the cilia is much slower (*i.e.*, months or years). Thus, some particles, particularly those that are insoluble, may remain in the alveolar region for long periods of time, despite the fact that pulmonary clearance is not impaired. It is the pulmonary retention of coal mine dust which may be the impetus for respiratory disease.

It is also important to note that silica may be present in the coal seam, within dirt bands in the coal seam, and in rock above and below coal seams. Of the silica found in coal mines, quartz is the form which is found. Thus, quartz may become airborne during coal removal operations (Manahan, 1994). Miners may inhale dust that is a mixture of quartz and coal. MSHA is concerned with the inhalation of quartz since it may be deposited in the lungs of miners and produce silicosis. This is a restrictive lung disease which is characterized by a stiffening of the lungs (West, 1990; 1992). Silicosis has been seen in coal miners (*e.g.*, surface miners, drillers, roofbolters) (Balaan, *et al.*, 1993). Silicosis may develop acutely (*i.e.*, 6 months to 2 years) following intense exposure to high levels of respirable crystalline quartz. Silicosis has also been observed in coal miners following chronic exposure (*i.e.*, 15 years or more), but may be accelerated (*i.e.*, 7–10 years) in some cases (Balaan, *et al.*, 1993). Silicosis is irreversible and may lead to other illnesses and premature mortality. People with silicosis have increased risk of pulmonary tuberculosis infection and an increased risk of lung cancer (Althouse, *et al.*, 1995; International Agency for Research on Cancer, 1997). MSHA's current standard of 2.0 mg/m^3 for respirable coal dust requires that quartz levels be 5% or lower. Otherwise, the 2.0 mg/m^3 respirable coal dust exposure limit does not apply and must be adjusted downward for percentage of quartz. If coal dust contains more than 5% quartz, then the following formula is applied (30 CFR 70.101; 30 CFR 71.101).

Respirable dust standard (mg/m^3)= {(10 mg/m^3)/(%Quartz)}

The intent of this formula is to maintain miner exposures to quartz below 0.1 mg/m^3 (100 μg/m^3).

C. Health-Related Effects of Respirable Coal Mine Dust

1. Description of Major Health Effects

Consistently, epidemiological studies have demonstrated miners to be at risk of developing respiratory symptoms, a loss of lung function, and lung disease as a consequence of occupational exposure to respirable coal mine dust. As noted previously, risk factors include type(s) of dust, dust concentration, duration of exposure, age of the miner (often measured as age at time of medical examination), and coal rank.

a. Simple Coal Workers' Pneumoconiosis (Simple CWP) and Progressive Massive Fibrosis (PMF)

In earlier stages of pneumoconiosis the term, ''simple coal workers' pneumoconiosis'' (simple CWP), has been used, while in more advanced stages, the terms ''complicated CWP'' and PMF have been used interchangeably. Simple CWP and PMF involve the lung parenchyma and are produced by deposition and retention of respirable coal dust in the lung.

To determine if a miner has simple CWP or PMF, chest x-rays are taken and classified by a certified radiologist or reader. Opacities are identified on chest films and then classified using a scale of 0–3 (*e.g.*, simple CWP category 1), where higher category values indicate increasing concentration of opacities. In some instances, two category values may be given. For example, simple CWP category 2/3 signifies that the reader decided the film was category 2, but suspected that it might have been category 3. The International Labour Office (ILO) has provided a full description of the criteria for these classifications (ILO, 1980).

Simple CWP can be associated with a loss of lung function and with premature mortality (Morgan, *et al.*, 1974; Jacobsen, 1976; Cochrane, *et al.*, 1979; Parkes, 1982). MSHA recognizes that simple CWP increases the risk of developing PMF substantially (Cochrane, 1962; Jacobsen, *et al.*, 1971; McLintock, *et al.*, 1971; Balaan, *et al.*, 1993).

Progressive massive fibrosis (PMF) is associated with decreased lung function and increased premature mortality (Rasmussen, *et al.*, 1968; Atuhaire, *et al.*, 1985; Miller and Jacobsen, 1985; Attfield and Wagner, 1992). Progressive massive fibrosis is also associated with increases in respiratory symptoms such as chest tightness, cough, and shortness of breath. Miners with PMF also have an increased risk of acquiring infections and pulmonary tuberculosis (Petsonk and Attfield, 1994; Yi and Zhang, 1996). Finally, miners with PMF have an increased risk of right-side heart failure (*i.e.*, cor pulmonale) (Cotes and Steel, 1987).

b. Other Health Effects

During a medical examination, a miner may be questioned by his physician about symptoms such as cough, phlegm production, chest tightness, shortness of breath, and wheezing. Occupational physicians may also conduct pulmonary function tests using spirometry or plethysmography. Pulmonary performance may be assessed via repeated measurements of lung volumes and capacities, such as the forced expiratory volume in one second (FEV_1), vital capacity (VC), forced vital capacity (FVC), residual volume (RV), and total lung capacity (TLC) (West, 1990; 1992). Changes in lung volumes and capacities may indicate a loss of the integrity of the lung (*i.e.*, respiratory system). More importantly, they can provide information for diagnosis of diseases affecting the airways and/or elasticity of the lung (*i.e.*, obstructive vs. restrictive lung disease) (West, 1990; 1992).

The term, chronic obstructive pulmonary disease (COPD), refers to three disease processes that are often difficult to properly diagnose and differentiate: chronic bronchitis, emphysema, and asthma (Coggon and Taylor, 1998; Garshick, *et al.*, 1996; West, 1990; 1992). As indicated by several studies, the exposure of miners to respirable coal mine dust place them at increased risk of developing COPD. Furthermore, COPD may occur in miners with or without the presence of simple CWP or PMF.

Chronic Obstructive Pulmonary Disease (COPD) is characterized by airflow limitations, and thus there is a loss of pulmonary function. As in simple CWP or PMF, a miner with COPD may have a variety of respiratory symptoms (*e.g.*, shortness of breath, cough, sputum production, and wheezing) and may be at increased risk of acquiring infections. Chronic Obstructive Pulmonary Disease is associated with increased premature mortality (Hansen, *et al.*, 1999; Meijers, *et al.*, 1997).

Briefly, in chronic bronchitis and in asthma, there is excess mucous secretion in the mid-lower airways (West, 1990; 1992). In contrast, emphysema is characterized by dilatation (enlargement) of alveoli that are distal to the terminal bronchioles, which leads to poor gas exchange (*i.e.,* poor transfer of oxygen and carbon dioxide). Additionally, there is a breakdown of the interstitium between the alveoli. These pathological changes may be confirmed upon autopsy. With asthma, the airflow limitations may be partially or completely reversible, while they are only partially reversible with chronic bronchitis and emphysema.

The Mine Safety and Health Administration (MSHA) and the NIOSH recognize that respiratory symptoms, loss of lung function, and COPD may impair the ability of a miner to perform his job and may diminish his quality of life. Additionally, miners having such health effects are at increased risk of morbidity (*e.g.,* from cardio-pulmonary disease, infections) and premature mortality.

2. Toxicological Literature

To better understand the human health effects of exposure to respirable coal mine dust and to more fully characterize the associated risks, it is important to consider data that have been obtained in animal based toxicological studies. To date, sub-acute studies (a study with a duration of 30 days, or less, in which multiple exposures of the same agent are given) and chronic studies (a study with a duration of more than 3-months, in which multiple exposures of the same agent are given) attempted to mimic miners' exposures. Inhalation was generally the route of exposure, although several studies have also employed instillation techniques (*i.e.,* a method which places a known quantity of dust into the trachea or bronchi).

Most recent toxicological studies have been short-term studies, largely focusing on ''lung overload'' (Snipes, 1996; Oberdorster, 1995; Morrow, 1988, 1992; Witschi, 1990), species-dependent lung responses (Nikula, *et al.,* 1997a,b; Mauderly, 1996; Lewis, *et al.,* 1989; Moorman, *et al.,* 1975), and particle size-dependent lung inflammation (Soutar, *et al.,* 1997). The data have shown that pulmonary clearance of particles may become impaired, potentially leading to inflammatory and other cellular responses in the lung. Although overloading has not been demonstrated in humans, the finding of reduced lung clearance among retired U.S. coal miners (Freedman and Robinson, 1988) is consistent with this possibility.

The data from Moorman, *et al.* (1975), Lewis, *et al.* (1989), and Nikula, *et al.* (1997a,b) are noteworthy for several reasons. First, these groups of investigators conducted chronic inhalation toxicity studies (*i.e.,* chronic bioassays). This is important since miners' exposures also occur via inhalation, and over a working lifetime. Secondly, the investigators used an exposure concentration of 2.0 mg/m³ in their bioassays. As noted above, this is the current MSHA standard for respirable coal mine dust. Thirdly, the exposures involved nonhuman primates, whose responses are thought to closely mimic those of man. Some of the key findings of these studies included: deposition of coal dust in the animals' lungs, retention of coal dust in alveolar tissue, altered lung defense mechanisms, reduced pulmonary airflows, and hyperinflation of the lungs. One of the shortcomings of these studies is that complete dose-response relationships were not developed. However, at higher exposure concentrations, greater effects may be expected which is a basic tenet of toxicology. Thus, at exposure concentrations above 2.0 mg/m³, MSHA and NIOSH believe that more severe obstructive lung disease may occur.

3. Epidemiological Literature

Epidemiology studies have consistently demonstrated the serious health effects of exposure to high levels of respirable coal mine dust (*i.e.,* above 2.0 mg/m³) over a working lifetime. Table VII–1 lists epidemiology studies since 1986 whose results will be discussed on the basis of the type of observed health effect. Studies completed even earlier including the early work of Cochrane (1962), McLintock, *et al.* (1971), and Jacobsen, *et al.* (1971) demonstrated the adverse health effects (*e.g.,* simple CWP, PMF) of respirable coal mine dust in British coal miners.

Both early and recent studies have shown that the lung is the major target organ (*i.e.,* organ in which toxic effects occur) when exposure to respirable coal mine dust occurs. As seen in Table VII–1, numerous studies of miners have been conducted. Recent U.S. studies were conducted using data from one or more of the first four rounds of the National Study of Coal Workers' Pneumoconiosis (NSCWP), and have provided extensive data on miners' health. Many of these studies demonstrated that miners are at increased risk of multiple, concurrent respiratory ailments (Attfield and

Seixas, 1995; Kuempel, *et al.,* 1997; Meijers, *et al.,* 1997; Seixas, *et al.,* 1992).

TABLE VII–1.—RESPIRABLE COAL MINE DUST EPIDEMIOLOGICAL STUDIES, BY REPORTED OUTCOMES FROM 1986 TO PRESENT

Studies	Reported outcomes
Meijers, *et al.,* 1997	PMF, CWP, COPD, LLF.
Maclaren, *et al.,* 1989	PMF, CWP, LLF, RS.
Kuempel*, *et al.,* 1995	PMF, CWP, COPD.
Bourgkard *et al.,* 1998	PMF, CWP, LLF.
Kuempel*, *et al.,* 1997	
Love, *et al.,* 1997	
Love, *et al.,* 1992	
Attfield and Morring*,1992b	PMF, CWP.
Attfield and Seixas*, 1995	
Hodous and Attfield*, 1990	
Hurley and Jacobsen, 1986	
Hurley and Maclaren, 1987	
Hurley, *et al.,* 1987	
Starzynski, *et al.,* 1996	
Yi and Zhang, 1996	
Wang, *et al.,* 1997	CWP, LLF.
Goodwin and Attfield*, 1998.	CWP.
Morfeld, *et al.,* 1997	
Marine, *et al.,* 1988	COPD, LLF, RS.
Seixas*, *et al.,* 1993	
Soutar and Hurley, 1986	
Carta, *et al.,* 1996	LLF, RS.
Henneberger and Attfield*,1997	
Henneberger and Attfield*,1996	
Seixas*, *et al.,* 1992	
Attfield and Hodous*, 1992	LLF.
Lewis, *et al.,* 1996	

COPD: Chronic obstructive pulmonary disease.
CWP: Simple coal workers' pneumoconiosis.
LLF: Loss of lung function.
PMF: Progressive massive fibrosis.
RS: Respiratory symptoms.
* Studies of U.S. Miners Who Participated in the National Study of Coal Workers' Pneumoconiosis (NSCWP).

a. Simple Coal Workers' Pneumoconiosis (Simple CWP) and Progressive Massive Fibrosis (PMF)

Studies following Cochrane (1962) and McLintock *et al.,* (1971) have confirmed that the risk of PMF increases with increasing category of simple CWP (Hurley and Jacobsen, 1986; Hurley, *et al.,* 1987; Hurley and Maclaren, 1988; Hodous and Attfield, 1990). However, the risk of PMF was greater than previously predicted among miners with simple CWP category 1 or without simple CWP (*i.e.,* category 0) (Hurley, *et al.,* 1987). The risk of PMF increased with increasing cumulative exposure, regardless of the initial category of simple CWP (Hurley, *et al.,* 1987), indicating that reducing dust exposures is a more effective means of reducing the risk of PMF than reliance on detection of simple CWP.

Attfield and Seixas (1995) have demonstrated a relationship between cumulative exposure to respirable coal mine dust and predicted prevalence of pneumoconiosis (*i.e.,* simple CWP, PMF). They studied a group of approximately 3,200 men who worked in underground bituminous coal mines. The U.S. miners and ex-miners had participated in Round 1 (1970–1972) or Round 2 (1972–1975) of the NSCWP and were examined again between 1985 and 1988. Chest x-rays were read to determine the number of cases of simple CWP and PMF. Dust exposure estimates were generated from measurements of dust concentrations as well as from work history. A logistic (or logit) regression model was used to estimate prevalence of simple CWP and PMF. In this statistical analysis, proportions are transformed to natural logarithmic values, *i.e.,* $y = 1n\,[p/(1-p)]$, before a linear model is fit to the data (Armitage, 1977). The logistic model assumes that the data have a binomial distribution (*e.g.,* presence or absence of PMF) for a given set of covariate values (*e.g.,* age, coal rank, dust exposure, pack-years of smoking). Using logistic modeling, relationships were developed between cumulative dust exposure and prevalence of simple CWP (category 1+, category 2+) and PMF. These relationships were the key strengths of the Attfield and Seixas study and serve as the basis for the Quantitative Risk Assessment of this rule.

The recent paper of Kuempel, *et al.,* (1997) has provided a detailed discussion and quantitative presentation of excess risks associated with respirable coal dust exposures. Their study was based upon results from previous studies of some 9,000 underground coal miners who participated in the NSCWP (Attfield and Morring, 1992b; Attfield and Seixas, 1995). Kuempel, *et al.,* estimated excess (exposure-attributable) prevalence of simple CWP and PMF (*i.e.,* number of cases of disease present in a population at a specified time, divided by the number of persons in the population at that specified time). Point estimates of excess risk of PMF ranged from 1/1000 to 167/1000 among miners exposed at the current MSHA standard for respirable coal mine dust. These estimates were based upon dust exposure that occurred over a miner's working lifetime (*e.g.,* 8 hours per day, 5 days a week, 50 weeks per year, over a period of 45 years). Actual occupational lifetime exposure may be more, due to extended work shifts and work weeks. The point estimates of PMF presented by Kuempel, *et al.,* (1997) were related to coal rank, where higher estimates (*e.g.,* 167/1000) were obtained for high-rank coal (anthracite coal) and somewhat lower estimates were obtained for medium/low rank bituminous coal (*e.g.,* 21/1000). Within each coal rank, the estimates of simple CWP cases were at least twice as high as those for PMF (*e.g.,* 167/1000 PMF vs. 380/1000 simple CWP$\geq$1).

The data of Attfield and Seixas (1995) and Kuempel, *et al.,* (1995; 1997) were consistent with previous data of Attfield and Morring (1992b) who reported relationships between estimated dust exposure and predicted prevalence of simple CWP or PMF. They also noted that exposure-response relationships were steeper for higher ranks of coal such as anthracite, and concluded that the risks for anthracite miners appeared to be greater than for miners exposed to lower rank coal dust. Attfield and Morring (1992b) used similar methods as described above (*i.e.,* logistic modeling), but included miners from Round 1 of the NSCWP (1969–1971); thus representing an earlier time point in the NSCWP when the respirable coal mine dust concentrations were much higher than they are today.

Recently, Goodwin and Attfield (1998) reported that there were concerns regarding methodological inconsistencies across surveys given during the four rounds of the NSCWP. In particular, they noted the discordance in classification of simple CWP and PMF among readers of chest films. Despite potential discordance, Goodwin and Attfield (1998) have confirmed previous findings of a decline in simple CWP prevalence from 1969 to 1988. Yet, these analyses also demonstrated that simple CWP has not been eliminated. The Round 4 prevalence rates were 3.9 percent for simple CWP category 1 and higher, and 0.9 percent for category 2 and higher. This illustrates the need for continued efforts to reduce dust exposures.

Given the current system for monitoring exposures and identifying overexposures in the U.S., miners are at increased risk of developing simple CWP and PMF from a working lifetime exposure to respirable coal mine dust (Kuempel, *et al.,* 1997, 1995; Attfield and Seixas, 1995; Goodwin and Attfield, 1998; Attfield and Morring, 1992b). Whenever overexposures (*i.e.,* excursions above the applicable standard) occur, the long-term mean exposure of miners may be increased, thereby causing an upward shift on the exposure-response curve. Such a shift then places these overexposed coal miners at increased risk of developing and dying prematurely from simple CWP and PMF.

The Attfield and Seixas epidemiological study (1995) is the most appropriate to use in estimating the benefit of reduction of overexposures. The authors applied scientific rigor to the collection, categorization, and analyses of the radiographic evidence for the group of 3,194 underground bituminous coal miners who participated in Round 4, 1985–1988, of the National Study of Coal Workers' Pneumoconiosis (NSCWP); this study population excludes 86 miners for whom there was missing exposure data or unreadable x-rays. Radiologic evidence was carefully collected and analyzed by multiple independent, NIOSH certified B readers to identify stages of simple CWP and PMF. In the targeted population of 5,557 miners, the participating miners (3,280) were similar to the non-participants (2,277) with regard to age at the first medical examination and prevalence of simple CWP category 1 or greater. The non-participants had worked slightly longer, yet had lower prevalence of simple CWP category 2 or greater, than the participants. This study describes the differences among current miners and ex-miners (health-related or job-related) in the relationships between the estimated cumulative exposure to respirable coal mine dust and prevalence of simple CWP category 1 or greater. Such data and relationships were not available in other U.S. studies and non-U.S. studies.

A potential limitation in the U.S. studies is the possible bias in the exposure data, which has been the subject of several studies (Boden and Gold, 1984; Seixas *et al.,* 1991; Attfield and Hearl, 1996). An advantage of the Attfield and Seixas 1995 study (and the earlier studies based on the same data set) is that the larger mines included in these epidemiological studies were shown to have exposure data with relatively small bias (Attfield and Hearl, 1996). Another limitation in exposure data used in the U.S. studies is that the airborne dust concentrations used to estimate individual miners' cumulative exposures to respirable coal mine dust were based on average concentrations within job category (these average values were combined with data of each individual miner's duration employed in a given job). The earlier U.S. exposure-response studies of miners participating in the first medical survey of the NSCWP (Attfield and Morring, 1992b; Attfield and Hodous, 1992; Kuempel, *et al.,* 1995) relied primarily on exposure measurements from a dust sampling survey during 1968–1969 to estimate miners' exposures before 1970 (Attfield and Morring, 1992a). An advantage of the Attfield and Seixas 1995 study is that, in addition to the pre-1970 exposure estimates, more detailed exposure data were available to estimate miners' exposures from 1970 to 1987, during which the mean airborne concentrations were stratified by mine, job, and year (Seixas, *et al.,* 1991).

The most complete exposure data available are those for coal miners in the United Kingdom (Hurley, *et al.,* 1987; Hurley and Maclaren, 1987; Soutar and Hurley, 1986; Marine, *et al.,* 1988; Maclaren, *et al.,* 1989). These studies include medical examinations and individual estimates of exposure for more than 50,000 miners for up to 30 years. The U.S. studies are consistent with these U.K. studies in demonstrating the risks of developing occupational respiratory diseases from exposure to respirable coal mine dust. These risks increase with increasing exposure concentration and duration, and with exposure to dust of higher ranked coal. The quantitative assessment of risk and associated benefits were based on the Attfield and Seixas (1995) study because, in addition to the advantages described above, it best represents the recent conditions experienced by miners in the U.S. This quantitative assessment follows in Section VIII. The international studies provide an important basis for comparison with the U.S. findings, and several of the recent international studies are described in detail here.

Bourgkard, *et al.,* (1998) conducted a 4-year study of a group of French coal miners who were employed in underground and surface mines. The investigators examined the prognostic role of cumulative dust exposure, smoking patterns, respiratory symptoms, lung CT scans, and lung function indices for chest x-ray worsening and evolution to simple CWP and PMF. Bourgkard, *et al.,* (1998), through selection of a younger worker population (*i.e.,* 35–48 years old at start of study), attempted to focus on the early stages of simple CWP. In essence, they hoped to identify those miners who needed to be relocated to less dusty workplaces or who needed to be clinically monitored. Bourgkard, *et al.,* (1998) concluded that there was an association between cumulative dust exposure and what was termed chest x-ray "worsening" (*i.e.,* increase in reader-designated category signifying progression of simple CWP). Their conclusion, however, was based on pooling of the data (*i.e.,* three combined groups of miners) who had different cumulative exposures (*i.e.,* 20, 66 and 85 mg-yr/m^3).

Love, *et al.,* (1997, 1992) reported on occupational exposures and the health of British opencast (*i.e.,* surface or strip) coal miners. They studied a group of approximately 1,200 miners who were employed at sites in England, Scotland, and Wales. The mean age of the men was 41; many had worked in the mining industry since the 1970s. To determine dust exposure levels, full-shift personal samples were collected. Most were respirable dust samples which were collected using Casella cyclones according to the procedures described by the British Health and Safety Executive (HSE). Thus exposure determinations would be comparable to exposure determinations obtained in U.S. surface coal mines since both measure respirable dust according to the BMRC criteria.

These investigators found a doubling in the relative risk of developing profusion of simple CWP category 0/1 for every 10 years of work in the dustiest jobs in surface mines. These respirable coal dust exposures were under 1 mg/m^3. Love, *et al.,* (1992, 1997), like other investigators, emphasized the need for monitoring and controlling exposures to respirable coal mine dust, particularly in high risk operations (*e.g.,* drillers, drivers of bulldozers).

Meijers, *et al.,* (1997) studied Dutch coal miners who were examined between 1952 and 1963, and who were followed until the end of 1991. They reported an increased risk of mortality from simple CWP and PMF among miners who had generally worked underground for 20 or more years. Their conclusions were based upon dramatic increases in standardized mortality ratios (SMRs). There were several limitations in this study, however.

Morfeld, *et al.,* (1997) published a recent paper that investigated the risk of developing simple CWP in German miners and addressed the occupational exposure limit for respirable coal dust in Germany. Their study included approximately 5,800 miners who worked underground from the late 1970s to mid-1980s. Morfeld, *et al.,* observed increases in relative risks (RRs) of developing early x-ray changes, category 0/1, that were exposure-dependent. Relative risks (RRs) increased with higher dust concentrations.

Starzynski, *et al.,* (1996) conducted a mortality study on a group of 11,224 Polish males diagnosed with silicosis, simple CWP, or PMF between 1970 and 1985. This cohort was subdivided by occupation into four subcohorts: Coal miners (63%); employees of underground work enterprises (8%) (*i.e.,* drift cutting and shaft construction jobs); metallurgical industry and iron, and nonferrous foundry workers (16%); and refractory materials, china, ceramics and quarry workers. The investigators found that coal miners had a slight, statistically significant excess overall mortality (*i.e.,* all causes) as indicated by a Standardized Mortality Ratio (SMR) of 105 (with a 95% Confidence Interval (C.I.) of 100–110). Also, excess of deaths from diseases of the respiratory system among coal miners was nearly four times that of the referent population (SMR of 383 with a 95% C.I. of 345–424). The study of Starzynski, *et al.,* (1996) agrees with others that there is premature mortality among coal miners from simple CWP and PMF. Unfortunately, there is little or no information presented on miner work history, exposure assessment (*e.g.,* respirable coal mine dust, silica), and mine environment (*e.g.,* coal rank(s), underground vs. surface mining).

Yi and Zhang (1996) conducted a study to measure the progression from simple CWP to PMF or death among a cohort of 2,738 miners with simple CWP who were employed at the Huai-Bei coal mine in China. Relative risks (*i.e.,* RRs) were calculated for progression from simple CWP category 1 to simple CWP category 3 and for progression from simple CWP category 3 to death. Their results demonstrated that miners with simple CWP category 1 are at risk of developing simple CWP category 2 and simple CWP category 3 (*e.g.,* RRs of 1.101 and 2.360, respectively). They also found that miners with PMF had a decreased life expectancy. Other risk factors for development of PMF included long-term work underground, and drilling. This study was limited by a lack of exposure assessment, estimation of miner smoking histories, and use of a radiological classification system that differs from that of the ILO.

Hurley and Maclaren (1987) studied British coal miners who were examined between 1953 and 1978, over 5-year intervals. They have shown that exposure to respirable coal dust increases the risks of developing simple CWP and of progressing to PMF. As seen in their data analysis, these responses were dependent upon dust concentration and coal rank. That is, greater responses were seen at higher dust concentrations and with higher rank coal (*i.e.,* increasing per cent carbon). The investigators also noted that estimated risks were unaffected by changes in the proportion of miners with simple CWP who transferred jobs. The authors concluded that ''limiting exposure to respirable coal dust is the only reliable way of limiting the risks of radiological changes to miners.''

b. Other Health Effects

As noted in Table VII–1, there were 16 studies in which the loss of lung function (LLF) was examined in coal miners. Six of these studies also included an evaluation of respiratory symptoms (RS) in the miners. There were five studies describing chronic obstructive pulmonary disease (COPD) in miners.

Henneberger and Attfield (1997; 1996), Kuempel, *et al.* (1997), Seixas, *et al.,* (1993), Attfield and Hodous (1992), and Seixas, *et al.,* (1992) evaluated data from pulmonary function tests and standardized questionnaires to miners in the NSCWP. A common finding in their studies was an increase in respiratory symptoms such as cough, shortness of breath, and wheezing. The symptoms were dependent upon the dust concentration to which the miners had been exposed, with more pronounced symptoms occurring after long-term exposures to higher exposure levels. These studies also demonstrated that a loss of lung function occurred among miners.

Attfield and Hodous (1992) studied U.S. miners who had spent 18 years underground (on average) and who participated in Round 1 (1969–1971) of the NSCWP. They observed that greater reductions in pulmonary function were associated with exposure to higher ranks of coal (*i.e.,* anthracite vs. bituminous vs. lignite). Using linear regression models, Kuempel *et al.,* (1997) predicted the excess (exposure attributable) prevalence of lung function decrements among miners with cumulative exposures to respirable coal mine dust of 2 mg/m^3 for 45 years (*i.e.,* 90 mg-yr/m^3). The excess prevalence estimates were 315 and 139 cases per thousand for forced expiratory volume in one second (FEV_1) of <80% and <65% of predicted normal values, respectively, among never-smoking miners (a sub-group of 977 NSCWP participants studied in Seixas *et al.,* 1993). Such reductions in FEV_1 are clinically significant; FEV_1 <80% (of predicted normal values) is a measure that is used to determine ventilatory defects (American Thoracic Society, 1991). Three recent studies found impaired FEV_1 to be a predictor of increased pre-mature mortality (Weiss, *et al.,* 1995; Meijers, *et al.,* 1997; Hansen *et al.,* 1999).

Seixas, *et al.* (1993) conducted an analyses of 977 underground coal miners who began working in or after 1970 and were participants of both NSCWP Round 2 (1972–1975) and Round 4 (1985–1988). They found a rapid loss of lung function in miners and further declines in lung function with continuing exposure to coal mine dust. Collectively these studies have shown that the prevalence of decreased lung function was proportional to cumulative exposure. That is, with exposure to higher coal dust levels over a working lifetime, there were more miners who experienced a loss of lung function. Also, the types of respiratory symptoms and patterns of pulmonary function decrements observed by both Attfield and Hodous (1992) Seixas, *et al.* (1992;1993) are characteristic of COPD.

The U.S. findings on respiratory symptoms and loss of lung function in miners have agreed with those of previous British studies by Marine, *et al.,* (1988) and Soutar and Hurley (1986). Marine, *et al.*, (1988) analyzed data from British coal miners and focused their attention on respiratory conditions other than simple CWP and PMF. In particular, they examined the Forced Expiratory Volume in one second (FEV_1) among smoking and nonsmoking miners and, on the basis of reported respiratory symptoms, identified those miners with bronchitis. Using these data, logistic regression models were used to estimate the prevalence of chronic bronchitis and loss of lung function. Marine, *et al.,* concluded that both exposure to respirable coal mine dust and smoking independently cause decrements in lung function; their contributions to COPD appeared to be additive in coal miners.

Soutar and Hurley (1986) examined the relationship between dust exposure and lung function in British coal miners and ex-miners. The men who were studied were employed in coal mines in the 1950s and were followed up and examined 22 years later. These miners and ex-miners were categorized as smokers, ex-smokers, or nonsmokers. The Forced Expiratory Volume in one second (FEV_1), the Forced Vital Capacity (FVC), and the FEV_1/FVC ratios decreased in all study groups and these reductions in lung function were inversely proportional to dust exposure. Thus, Soutar and Hurley concluded that exposure to respirable coal mine dust can cause severe respiratory impairment, even without the presence of simple CWP or PMF. They speculated that the pathology of coal dust-induced lung disease differs from that induced by smoking.

Recent studies from China (Wang, *et al.,* 1997) and the European community (Bourgkard, *et al.,* 1998; Carta, *et al.,* 1996; Lewis, S., *et al.,* 1996) have also supported the British and U.S. findings which demonstrated the correlation between occupational exposure to coal dust and respiratory symptoms and loss of lung function in miners.

Wang, *et al.,* (1997) examined lung function in underground coal miners and other workers from several other factories in Chongqing, China. For their study, information was obtained on exposure duration, results of radiographic tests, and smoking history. Pulmonary function tests were performed, providing the Forced Expiratory Volume in one second (FEV_1), the Forced Vital Capacity (FVC), and FEV_1/FVC data. Additionally, the diffusing capacity for carbon monoxide (DL_{CO}) was measured. This is an indicator of diffusion impairment at the ''blood-gas barrier'' which may occur, for example, when this barrier becomes thickened (West, 1990; 1992). Wang, *et al.,* (1997) found that there was impairment of pulmonary function among the coal miners and they had evidence of obstructive disease. Like other studies, such effects were observed among coal miners even in the absence of simple CWP. Pulmonary function was further decreased when simple CWP was present. This study did not provide exposure measurements and there was no consideration of exposure-response relationships. Also, silica exposures and their potential effects were not examined in the underground coal miners.

As noted above, Bourgkard, *et al.,* (1998) was interested in the earlier stages of simple CWP (*i.e.,* Categories 0/1 and 1/0) and the prognostic role of cumulative dust exposure, smoking patterns, respiratory symptoms, lung CT scans, and lung function indices for chest x-ray worsening and evolution to simple CWP category 1/1 or higher. Over a 4-year period, they studied French coal miners who were employed in underground and surface mines. Bourgkard, *et al.,* (1998) found that, at the first medical examination, the ratio of the Forced Expiratory Volume in one second (FEV_1) to the Forced Vital Capacity (FVC) (*i.e.,* FEV_1/FVC) and other airflows determined from a forced expiration (West, 1990; 1992) were lower among miners who later developed simple CWP category 1/1 or higher. These miners also experienced more wheezing at the first medical examination. Thus, the results of their study suggested that lung function changes may serve as an early indicator of miners who are at increased risk of developing simple CWP and PMF and who should be monitored more closely.

Carta, *et al.,* (1996) have examined the role of dust exposure on the prevalence of respiratory symptoms and loss of lung function in a group of young Italian coal miners (*i.e.,* mean age at hire 28.9 years, mean age at first survey 31.2 years). These miners worked underground and were exposed to lignite (*i.e.,* low rank coal) which had a 5–7% sulfur content. They were followed for a period of 11 years, from 1983 and 1993. Carta, *et al.,* (1996) found few abnormalities on miner chest x-rays taken throughout the 11-year study. However, there was an increased prevalence of respiratory symptoms and loss of lung function. This was particularly noteworthy since dust exposures were often below 1.0 mg/m³; the cumulative dust exposure for the whole cohort was 6.7 mg-yr/m³ after the first survey. Thus, Carta, *et al.,* (1996) demonstrated that miners experience respiratory effects of exposure to dust generated from a lower rank coal and at lower concentrations. They have recommended yearly measurements of lung function for miners.

Lewis, *et al.,* (1996) studied a group of British miners, many of whom entered the coal industry in the 1970s. Based upon chest x-rays, the miners had no evidence of simple CWP or PMF. The objective of this study was to determine whether coal mining (*i.e.,* exposure to respirable coal mine dust) is an independent risk factor for impairment of lung function. Lewis, *et al.* (1996) found that there was a loss of lung function in miners (smokers and nonsmokers), particularly among miners who were under approximately 55 years of age. For miners who smoked, there was a greater loss of lung function than in nonsmoking miners with the same level of exposure to respirable coal mine dust. Above age 55, the loss of lung function was similar for miners and their controls, although all smokers continued to exhibit a greater loss of lung function than nonsmokers. Lewis, *et al.,* (1996) concluded that the deficits in lung function may occur in the absence of simple CWP and PMF, and independent from the effects of smoking.

There have been two recent mortality studies that have demonstrated a relationship between exposure to respirable coal mine dust and development of COPD. This association was reported by Kuempel, *et al.,* (1995) in the U.S., and by Meijers, *et al.* (1997) in the Netherlands. These two groups of investigators have reported that occupationally-induced COPD (*e.g.,* chronic bronchitis, emphysema) can occur in miners, with or without the presence of simple CWP or PMF. They also found that the risk of premature mortality from COPD was elevated among miners and could be separated from the effects of smoking and age.

Kuempel, *et al.* (1995) found an increase in relative risk (RR) of premature mortality from COPD among U.S. coal miners who participated in the NSCWP from 1969 through 1971. In their data analysis, the exposure-response relationship was evaluated using the Cox proportional hazards model. This model assumes that the hazard ratio between nonexposed and exposed groups does not significantly change with time. When fitting a curve to the data (*e.g.,* log-linear), cumulative exposure was expressed as a categorical or continuous variable. Due to model limitations (*e.g.,* less statistical power, influence of category scheme, use of lowest exposure group for comparisons vs. use of non-exposed group), Kuempel, *et al.* (1995) believed that the exposure data should be expressed as a continuous variable. If, for example, the cumulative exposure was 90 mg-yr/m³ (*i.e.,* 2 mg/m³ for 45 years), then the relative risk of mortality from chronic bronchitis or emphysema was 7.67. Kuempel, *et al.* (1995) also showed that relative risk decreased with lower cumulative exposures (*i.e.,* below 90 mg-yr/m³) and increased with higher cumulative exposures (*i.e.,* above 90 mg-yr/m³. Thus, these investigators demonstrated a statistically significant exposure-response relationship for COPD.

Meijers, *et al.* (1997) have shown, among Dutch miners, reductions in lung volumes and capacities are good predictors of the increased risk of premature mortality from COPD. For example, a diminished forced expiratory volume in one second (FEV_1) or a diminished ratio of the FEV_1 to the forced vital capacity [4] (FVC) (*i.e.,* FEV_1/FVC) upon medical examination was associated with a significantly increased standardized mortality ratio (SMR) for COPD (322 and 212, respectively). In other words, miners with diminished lung capacity based on FEV_1 were two to three times more likely to die prematurely due to COPD than miners who had normal lung function. In contrast, SMRs for COPD were not significantly increased in miners with normal lung volumes and capacities.

[4] Forced vital capacity (FVC) is the total volume of gas that can be exhaled with a forced expiration after a full inspiration; The vital capacity measured with a FVC may be less than that measured with a slower exhalation (West, 1992).

These data support prior conclusions of Seixas, *et al.* (1992, 1993) and Attfield and Hodous (1992) based on morbidity studies.

VIII. Quantitative Risk Assessment

As mentioned previously, in addition to this proposed notice of rulemaking, today's **Federal Register** contains another NPRM, Verification of Dust Control Plan (RIN 1219–AB18), ''plan verification.'' In combination, these rules present MSHA's strengthened plan to meet the Mine Act's requirement that a miner's exposure to respirable coal mine dust be at or below the applicable standard on each and every shift. MSHA's improved program to eliminate overexposures on each and every shift includes the simultaneous implementation of an improved tool to identify overexposures (*i.e.,* inspectors use of single, full-shift samples for noncompliance determinations) and a new regulation requiring operators implement verified ventilation plans in underground coal mines.

Having reviewed the reported health effects associated with exposure to coal mine dust, MSHA and NIOSH have evaluated the evidence to determine whether the current regulatory strategy can be improved. The criteria for this evaluation is established by the Mine Act under section 101(a)(6)(A) [30 U.S.C. 811(a)(6)(A)] which provides that:

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

Based on Court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that must be addressed: (1) Whether health effects associated with the current pattern of overexposures on individual shifts constitute a material impairment to miner health or functional capacity; (2) whether the current pattern of overexposures on individual shifts places miners at a significant risk of incurring any of these material impairments; and (3) whether the proposed rules would substantially reduce those risks.

The criteria for evaluating the health effects evidence do not require scientific certainty. The need to evaluate risk does not mean that an agency is placed into a ''mathematical straightjacket.'' *See Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 100 S.Ct 2844 (1980), otherwise known as the ''Benzene'' decision. When regulating on the edge of scientific knowledge, certainty may not be possible and,

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

The statutory criteria for evaluating the health evidence do not require MSHA and NIOSH to wait for absolute certainty and precision. MSHA and NIOSH are required to use the ''best available evidence'' (section 101(a)(6)(A) of the Mine Act (30 U.S.C. 811(a)(6)(A)).

As explained earlier, MSHA's objective in strengthening the requirements for verifying the effectiveness of dust control plans, and in enforcing effective plans through the new enforcement policy proposed in this notice, is to ensure that no miner is exposed to an excessive concentration (*i.e.*, a concentration in excess of the applicable standard) of respirable dust on any individual shift. Annual inspector samples have demonstrated overexposures on individual shifts in many mines. Data compiled from the far more frequent, bimonthly, operator sampling program show that in many mines, the applicable dust standard is exceeded on a substantial percentage of the production shifts. This pattern has persisted for many years, and, since individual shift excursions above the applicable standard are permitted under the existing program, the same pattern can be expected to continue over the working lifetime of affected miners—unless an effort is made to eliminate excess exposures on individual shifts. In this quantitative risk assessment (QRA), MSHA will demonstrate that reducing coal mine dust concentrations, over a 45-year occupational lifetime, to no more than the applicable standard on just that percentage of shifts currently showing an excess, thereby lowering the cumulative exposure to respirable coal mine dust than would otherwise occur, would significantly reduce the risk of both simple CWP and PMF among miners. We have estimated the health benefits of the two rules arising from the elimination of overexposures on all shifts at only those MMUs exhibiting a pattern of recurrent overexposures on individual shifts.[5]

Based on 1999 operator data, there were 704 MMUs (out of 1,251 total) at which dust concentrations for the designated occupation (D.O.) samples exceeded the applicable standard on at least two of the sampling shifts (MSHA, Data file:Operator.ZIP).[6] MSHA considers these 704 MMUs, representing more than half of all underground coal miners working in production areas, to have exhibited a pattern of recurrent overexposures.[7] Valid operator D.O. samples were collected on a total of 18,569 shifts at these 704 MMUs, and the applicable standard was exceeded on 3,977 of these shifts, or about 21.4 percent. For this 21.4 percent, the mean excess above the standard, as measured for the D.O. only, was 1.04 mg/m^3.

These results are based on a large number of shifts (an average of more than 26 at each of the 704 MMUs). Therefore, assuming representative operating conditions on these shifts, the results can be extrapolated to all production shifts, including those that were not sampled, at these same 704 MMUs. With 95-percent confidence, the overall percentage of production shifts on which the D.O. sample exceeded the standard was between 20.6 percent and 22.2 percent for 1999. At the same confidence level, again assuming representative operating conditions, the overall mean excess on noncompliant shifts at these MMUs was between 0.96 mg/m^3 and 1.12 mg/m^3. If operators tend to reduce production and/or increase dust controls on sampled shifts, as some commenters to the previous single, full-shift sample rulemaking and the Dust Committee have alleged, then the true values could be higher than even the upper endpoints of these 99-percent confidence intervals.

In 1998, MSHA attempted to enforce compliance on individual shifts. Therefore, to compare the 1999 pattern

[5] By ''exhibiting a pattern of recurrent overexposures,'' MSHA means that, at a 95-percent confidence level, the applicable standard is exceeded on at least six shifts per year.

[6] If a different definition of ''exhibiting a recurrent pattern of overexposures'' were used in these analyses the estimate of the reduction in risk and associated benefits would be different. For example, if the criterion were that four or more D.O. bimonthly exposure measurements exceeded the applicable standard then, with 95% confidence, at least 20 shifts would be overexposures in a year of 384 shifts. Using the four as the criterion, this would reduce the population for whom we are estimating benefits, and the estimated number of prevented cases would decrease by 19%.

[7] MSHA estimates an MMU average of 384 production shifts per year. Since mine operators are required to submit five valid designated operator (D.O.) samples to MSHA every two months, there would typically be 30 valid D.O. samples—representing 30 of the 384 production shifts—for each MMU that was in operation for the full year. If dust concentrations on two or more of the sampled shifts exceeded the standard, then it follows, at a 95-percent confidence level, that the standard was exceeded on at least six shifts over the full year.

of excess exposures on individual shifts to that of previous years under the current enforcement policy, MSHA examined the regular bimonthly D.O. sample data submitted to MSHA by mine operators in the eight years from 1990 through 1997. The same three parameters were considered as discussed above for 1999: (1) The percentage of MMUs exhibiting a pattern of recurrent overexposures, as indicated by at least two of the valid measurements above the applicable standard in a given year; (2) for those and only those MMUs exhibiting recurrent overexposures, the overall percentage of production shifts on which the D.O. was overexposed, as estimated by the percentage of valid measurements above the applicable standard; and (3) for the MMUs identified as exhibiting recurrent overexposures, the mean excess above the applicable standard, as calculated for just those valid measurements that exceeded the applicable standard in a given year.

Although MSHA found minor differences between individual years, there was no statistically significant upward or downward trend in any of these three parameters over the 1990–1997 time period (see Table VIII–1). In 1999, the percentage of MMUs exhibiting a pattern of recurrent overexposures (Parameter #1) was approximately 56 percent. Also in 1999, for those MMUs exhibiting a pattern of recurrent overexposures, the overall percentage of production shifts on which the D.O. was overexposed (Parameter #2) was approximately 21 percent. In 1999, the average excess above the applicable standard (Parameter #3) for MMUs exhibiting recurrent overexposures was 1.0 mg/m^3, a significant decrease from prior years. MSHA attributes this decrease to two important changes in the Agency's inspection program, beginning near the end of 1998. These changes, which both resulted in increased inspector presence, were: (1) An increase in the frequency of MSHA dust sampling at underground coal mines; and (2) initiation of monthly spot inspections at mines experiencing difficulty in maintaining consistent compliance with the applicable dust standard.

TABLE VIII–1.—1990–1997, DISTRIBUTION OF PARAMETERS OF ANNUAL OVEREXPOSURE TO RESPIRABLE COAL MINE DUST

1990–1997	Parameter #1 (Percent)	Parameter #2 (Percent)	Parameter #3 (mg/m^3)
Number of Years	8	8	8
Median	52.6	20.5	1.23
Mean (Standard Error)	50.9 (1.62)	20.6 (0.32)	1.25 (0.020)

Parameter #1: percentage of MMUs exhibiting a pattern of recurrent overexposures.

Parameter #2: for those MMUs exhibiting a pattern of recurrent overexposures, the percentage of production shifts on which the D.O. was overexposed.

Parameter #3: for those MMUs exhibiting a pattern of recurrent overexposures, the mean excess above the applicable standard among valid D.O. measurements that exceeded the applicable standard.

The available data suggest that unless changes are made to enforce the dust standard on every shift, the same average pattern of overexposures observed in 1999 will persist into the future. Therefore, we conclude that without the proposed changes:

- More than one-half of all MMUs would continue to have a pattern of recurrent overexposures on individual shifts;
- At those MMUs with recurrent overexposures, full-shift average respirable dust concentrations for the D.O. would continue to exceed the applicable standards on about 21 percent of all production shifts;
- Among those shifts on which D.O. exposure exceeds the applicable standards, the mean excess for the D.O. would continue to be approximately 1.0 mg/m^3.

We invite public comment on whether these three parameters, based on operators' regular 1999 bimonthly samples, under-represent or over-represent the frequency and/or magnitude of excessive dust concentrations on all individual shifts—including those that are not sampled.

If all overexposures on individual shifts are eliminated, the reduction in total respirable coal mine dust inhaled by a miner over a working lifetime will depend on the following factors: The average volume of air inhaled on each shift that would otherwise have exceeded the applicable standard, the degree of reduction in respirable dust concentration in the air inhaled on such shifts, and the number of such shifts per working lifetime. If a miner inhales ten cubic meters of air on a shift (U.S. EPA, 1980), reducing the respirable dust concentration in that air by 1.0 mg/m^3 would result in 10 mg less dust inhaled on that shift alone. Assuming the miner works 240 shifts per year, then reducing inhaled respirable dust by an average of 10 mg on 21 percent of the shifts would reduce the total dust inhaled by 504 mg per year, or nearly 22,700 mg over a 45-year working lifetime:

1.0 mg per m^3 of inhaled air
× 10 m^3 inhaled air per shift
× 50.4 affected shifts (*i.e.,* 21% of 240) per work year
× 45 work years per working lifetime
= 22,680 mg less dust inhaled per working lifetime.

The Secretaries invite comments on the health benefits expected from reducing the total coal mine dust inhaled over a working lifetime by this amount.

In Section VII, the strengths and weaknesses of various epidemiological studies were presented, supporting the selection of Attfield and Seixas (1995) as the study that provides the best available estimate of material health impairment with respect to CWP and PMF. Two of the distinguishing qualities of this study are the dose-response relationship over a miners' lifetime and the fact that these data best represent the recent conditions experienced by miners in the U.S. Using this relationship, it is possible to evaluate the impact on risk of both simple CWP and PMF expected from bringing dust concentrations down to or below the applicable standard on every shift. This is the only contemporary epidemiological study of simple CWP and PMF providing such a relationship.

Attfield and Seixas used two or three B readers to identify the profusion of opacities using the ILO classification scheme. If three readings were available, the median value was used. If two readings were available, the higher of the two ILO categories was recorded. Eighty radiographs were eliminated because only one reading was available. The most inclusive category of CWP 1+ includes simple CWP, categories 1, 2, 3, as well as PMF. Category CWP 2+ does not include simple CWP, category 1, but does include the more severe simple CWP categories, 2 and 3, as well as PMF. The third category used in their report was PMF, denoting any category of large opacities.

Attfield and Seixas (1995) provided logistic regression models for the prevalence for CWP 1+, CWP 2+ and PMF as a function of cumulative dust exposure, expressed as the product of dust concentration measured in the mine atmosphere and duration of exposure at that concentration. These models can be used to estimate the impact on miners' risk of both simple CWP and PMF of reducing lifetime accumulated exposure by eliminating excessive exposures on a given percentage of individual shifts.

At the MMUs being considered (those exhibiting a pattern of recurrent overexposures), bringing dust concentrations down to no more than the applicable standard on each and every production shift would reduce D.O. exposures on the affected shifts by an average of 1.04 mg/m^3. Assuming this average reduction applies to only 21 percent of the shifts, the effect would be to reduce cumulative exposure, for each miner exposed at or above the D.O. level, by 0.22 mg-yr/m^3 over the course of a working year (*i.e.,* 21 percent of shifts in one year, times 1.04 mg/m^3 per shift). Therefore, over a 45-year working lifetime, the benefit to each affected miner would, on average, amount to a reduction in accumulated exposure of approximately 10 mg-yr/m^3 (*i.e.,* 45 years times 0.22 mg-yr/m^3 per year). If, as some miners have testified, operator dust samples currently submitted to MSHA tend to under-represent either the frequency or magnitude (or both) of individual full-shift excursions above the applicable standard, then eliminating such excursions would provide a lifetime reduction of even more than 10 mg-yr/m^3 for each exposed miner.

The Attfield and Seixas models predict the prevalence of CWP 1+, CWP 2+, and PMF for miners who have accumulated a given amount of exposure, expressed in units of mg-yr/m^3, by the time they attain a specified age. Benefits of reducing cumulative exposure can be estimated by calculating the difference between predictions with and without the reduction. For example, suppose a miner begins work at age 20 and retires at age 65. By the year of retirement, that miner is expected to accumulate nearly 10 mg-yr/m^3 less exposure if individual shift excursions are eliminated. For 65-year-old miners, reducing accumulated dust exposure by a total of 10 mg-yr/m^3 reduces the predicted prevalence of CWP 1+ by at least 11 per thousand (See Table VIII–2).

This 11 per thousand, however, applies only to miners of age 65. The Attfield and Seixas models provide different predictions for each year of age that a miner attains. The predicted benefit turns out to be smaller for younger miners and larger for older miners. This is partly because younger miners will have accumulated less exposure reduction from the proposed changes, and partly because the Attfield and Seixas models depend directly on age as well as on cumulative exposure. The health effects of recurrent overexposures can occur long after the overexposures occurred. Even after a miner retires and is no longer exposed to respirable coal mine dust, the extra risk attributable to an extra 10 mg-year/m^3, accumulated earlier, continues to increase with age. Consequently, the benefit to be gained from eliminating individual shift excursions also continues to increase after a miner is no longer exposed. For example, assuming no additional exposure after age 65, the predicted reduction in average prevalence of CWP1+ increases from 12 per thousand at age 65 to 17 per thousand at age 70. Presumably, the increasingly greater predicted reduction in risk of disease after age 65 is due to the latent effects of the reduction in earlier exposure.

To project the benefits of the two rules expected from eliminating overexposures on individual shifts, MSHA applied the Attfield and Seixas models to a hypothetical population of miners who, on average, begin working at age 20 and retire at age 65, assuming different lifetimes. The risks for three different ages have been presented to show a range of risk depending on the lifetime: 65, 73, and 80 years. During the 45 ''working years'' between 20 and 65, the lifetime benefit accumulates at a rate of 0.22 mg-yr/m^3 of reduced exposure per year, reaching a maximum of about 10 mg-yr/m^3 at age 65. Between ages 65 and 80, the accumulated reduction in dust exposure remains at an estimated average of 10 mg-yr/m^3, but the benefit in terms of both simple CWP and PMF risk continues to increase, as explained previously.

The expected lifetime for all American males conditional on their having reached 20 years of age, is 73 years (calculated from: U.S. Census March 1997, Table 18; U.S. Census March 1997, Table 119).[8] On average, the best estimate of the lifetime benefit to exposed miners is expressed by the reduction in prevalence of disease at age 73. Carrying out the calculation at a 73-year average lifetime, MSHA expects that, at the MMUs under consideration, bringing dust concentrations down to no more than the applicable standard on each shift will:

- Reduce the combined risk of simple CWP and PMF by at least 18.0 cases per 1000 affected D.O. miners;[9]
- Reduce the combined risk of simple CWP (category 2 and 3) and PMF by at least 9.8 cases per 1000 affected D.O. miners;
- Reduce the risk of PMF by at least 5.1 cases per 1000 affected D.O. miners.

Presented in the first row of Table VIII–2 are the average reductions in risk for simple CWP and PMF combined, and PMF alone, over an occupational lifetime, among affected D.O. miners who live to ages 65, 73, and 80, who have worked at an MMU exhibiting a pattern of recurrent overexposures. Across health outcomes, the benefit due to the predicted reduction in cumulative exposure to respirable coal mine dust, through limiting miners' exposure to no more than the applicable standard on each and every shift, increases with age.

When the dust concentration measured for the D.O. exceeds the applicable standard, measurements for at least some of the other miners may also exceed the standard on the same shift, though usually by a lesser amount. Furthermore, although the D.O. represents the occupation most likely to receive the highest exposure, other miners working in the same MMU may be exposed to even higher concentrations than the D.O. on some shifts. Therefore, in addition to the affected D.O. miners, there is a population of other affected miners who are also expected to experience a significant reduction in risk as a result of eliminating overexposures on their individual shifts.

To estimate how many miners other than the D.O. would be substantially affected, MSHA examined the results from all valid dust samples collected by MSHA inspectors in underground MMUs during 1999 (MSHA, Data file:Inspctor.zip). Within each MMU, the inspector typically takes one full-shift sample on the D.O. and, on the same shift, four or more additional samples representing other occupations.

[8] Since females have a greater life expectancy than males, expected benefits would increase if the proportion of female miners increases substantially in the future.

[9] ''affected D.O. miners'' include all miners who work at the 56-percent of MMUs under consideration and who are exposed to dust concentrations similar to the D.O. over a 45-year working lifetime.

On 896 shifts, at a total of 450 distinct MMUs, the D.O. measurement exceeded the applicable standard and there were at least three valid measurements for other occupations available for comparison. There was an average of 1.2 non-D.O. measurements in excess of the standard on shifts for which the D.O. measurement exceeded the standard.[10] For non-D.O. measurements that exceeded the standard on the same shift as a D.O. measurement, the mean excess above the standard was approximately (0.8 mg/m^3).[11]

Combining these results with the 21-percent rate of excessive exposures observed for the D.O. on individual shifts, it is reasonable to infer that, at the MMUs under consideration, an average of 1.2 other miners, in addition to the one classified as D.O., is currently overexposed on at least 21 percent of all production shifts. Over the course of a working year, the reduction in exposure expected for these other miners is 0.17 mg-yr/m^3 (*i.e.,* 21 percent of one year, times 0.8 mg/m^3).

To assess the reduction in risk expected from eliminating all single-shift exposures for faceworkers experiencing lower exposures than the D.O., MSHA again applied the Attfield and Seixas models to miners who begin working at age 20, retire at age 65, assuming various lifetimes: 65, 73, and 80 years. This time, however, the resulting decrease in predicted prevalence was multiplied by 1.2/7 = 0.171, to reflect the fact that the assumed rate of overexposure applies, on average, to about 17 percent of the faceworkers not classified as the D.O.[12]

In the second row of Table VIII–2, we see that over an occupational lifetime, the beneficial average reduction in risk for simple CWP and PMF combined, and for PMF alone, increases with age. However, the magnitude of the risk reduction is smaller for the affected non-D.O.s than the affected D.O.s. This is expected because the estimated probability that a non-D.O. will be overexposed on a given shift is only 17 percent of the corresponding probability for the D.O. Based on this calculation for the MMUs under consideration, the predicted reduction in risk for faceworkers other than the D.O. who live an expected lifetime of 73 years is at least: 2.3 fewer cases of PMF or simple CWP, per thousand affected miners; 1.3 fewer cases of PMF or simple CWP, categories 2 or 3, per thousand affected miners; and 0.7 fewer cases of PMF per thousand affected miners.

Various data, assumptions and caveats were used to conduct the quantitative risk assessment. Therefore, we request any information which would enable us to conduct more accurate analyses of the estimated health benefits of the single, full-shift sample rule and plan verification rule, both individually, and in combination.

TABLE VIII–2.—BY AGE, AVERAGE REDUCTION IN RISK FOR OCCUPATIONAL RESPIRATORY DISEASE PER 1,000 AFFECTED UNDERGROUND COAL MINERS EXPECTED TO RESULT FROM IMPLEMENTATION OF SINGLE, FULL-SHIFT SAMPLING AND PLAN VERIFICATION RULES

Type of miner	Reduction in risk for occupational respiratory disease per 1,000 affected miners								
	Simple CWP[a] (categories 1, 2 or 3) or PMF[b]			Simple CWP (categories 2 or 3) or PMF			PMF		
	Age			Age			Age		
	65	73	80	65	73	80	65	73	80
Affected Designated Occupation Miners[c]	11.0	18.0	25.0	3.7	9.8	21.0	1.8	5.1	12.0
Affected Non-Designated Occupation Miners[d]	1.4	2.3	3.3	0.5	1.3	2.7	0.2	0.7	1.5

[a] Simple CWP: simple coal workers' pneumoconiosis.
[b] PMF: progressive massive fibrosis.
[c] Affected Designated Occupation (D.O.) Miners: includes all miners who work at the 56-percent of the Mechanized Mining Units under consideration and who are exposed to dust concentrations similar to the D.O., over a 45-year occupational lifetime.
[d] Affected Non-Designated Occupation (Non-D.O.) Miners: includes all underground faceworkers under consideration who are not classified as the D.O.

IX. Significance of Risk

The criteria for evaluating the evidence to determine whether these proposed standards improve the regulatory strategy for controlling exposures to respirable coal mine dust are established by the Mine Act pursuant to section 101(a)(6)(A) (30 U.S.C. 811(a)(6)(A))which provides that:

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

Based on Court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that must be addressed: (1) Whether health effects associated with the current pattern of overexposures on individual shifts constitute a material impairment to miner health or functional capacity; (2) whether the current pattern of overexposures on individual shifts places miners at a significant risk of incurring any of these material impairments; and (3) whether the proposed rules would substantially reduce those risks.

The statutory criteria for evaluating the health evidence do not require MSHA and NIOSH to wait for absolute certainty and precision. MSHA and NIOSH are required to use the ‘‘best available evidence’’ (section 101(a)(6)(A) of the Mine Act (30 U.S.C. 811(a)(6)(A)). The need to evaluate risk does not mean that an agency is placed

[10] With 95-percent confidence, on shifts for which the D.O. measurement exceeds the standard, the mean number of other occupational measurements also exceeding the standard is at least 1.11.

[11] With 95-percent confidence, the mean excess is at least 0.72 mg/m^3.

[12] There are an estimated 7 non-D.O. miners for each D.O. miner, and an average of 1.2 of these 7 miners are overexposed.

into a ''mathematical straightjacket.'' *See Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607, 100 S.Ct 2844 (1980), otherwise known as the ''Benzene'' decision. When regulating on the edge of scientific knowledge, certainty may not be possible and,

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

We have taken steps in our quantitative risk assessment to conduct a balanced analysis using available data. Some of our assumptions were conservative, while others were not.[13]

In identifying the number and percentage of MMUs exhibiting a pattern of recurrent overexposures on individual shifts we choose to include only those MMUs with two or more 1999-operator bimonthly samples in excess of the applicable standard, rather than the population of MMUs with any overexposures.[14] Also, the quantitative risk assessment estimates of reduction in risk are averages across MMUs exhibiting a pattern of recurrent overexposures. For those miners who work at mines exhibiting a pattern of recurrent overexposures which differs from the one applied in the Quantitative Risk Assessment, their reduction in risk would be more than or less than the expected average, depending on whether or not their overexposures are at a higher or lower than average rate and intensity.

Another important decision impacting choice in this risk assessment involves the use of the traditional coal miner work schedule of 8-hours per day, 5-days per week, 48-weeks per year. Many of today's miners work longer hours per day, month, and year than the traditional work schedule. These longer work hours increase miners' cumulative exposure to respirable coal mine dust beyond the parameters of exposure used in our estimates of risk. Even so, to the extent that a proportion of miners may have a more limited work schedule (and occupational exposure), either in number of years, weeks per year, or hours per week, their expected health benefit would have to be adjusted downward, all other variables being constant.

Also, because of heavy, physical work, some miners may work at ventilatory rates in excess of the above-cited 10 cubic meters per 8-hour shift; an estimate of this ventilatory rate is 13.5 cubic meters per 8-hour shift (ICRP, 1994). The sub-population of miners with higher breathing rates would inhale more respirable coal mine dust than would otherwise occur given the same environmental exposures, thereby increasing their risks for the development of simple CWP and PMF.

In the Quantitative Risk Assessment, to estimate average reduction in exposure, we chose the best available data sets: 1999 operator bimonthly samples for D.O.s and N.D.O.s., respectively. Currently, both operator bimonthly and inspector samples[15] may be taken on production shifts that may not reflect typical production levels.[16] Although other factors may mediate the amount of airborne respirable dust such as, ventilation and water sprays, on average, higher production is correlated with increased quantities of airborne respirable coal mine dust (Webster, *et al.,* 1990; Haney, *et al.,* 1993; Green, *et al.,* 1994). Some previous commenters and the Dust Advisory Committee have alleged that operators tend to reduce production and/or increase dust controls on sampled shifts. Based on MSHA's and NIOSH's experience and expertise, and previous comments, we believe the production levels observed on sampling shifts are indeed lower than typical (See discussion in Benefits section). We also believe at some MMUs, more engineering controls at higher levels of efficacy are used during sampling shifts than on the majority of shifts (See discussion in Benefits section). Thus, it is reasonable to conclude that the number of MMUs exhibiting a pattern of recurrent overexposures is greater than the 704 captured in this Quantitative Risk Assessment. Furthermore, the severity and rate of overexposures to respirable coal mine dust among the 704 MMUs exhibiting a pattern of recurrent overexposures are probably also greater than we have estimated. We have derived our best estimate of the risk reduction using the best available data. Yet due to limitations in these data, we believe that we have underestimated the magnitude and frequency of typical respirable coal mine exposures. To the extent that our values underestimate the true reduction in respirable coal mine dust exposures, we have underestimated the benefits of these rules.

Other aspects of our risk assessment methodology reflect more conservative choices including the selection of an occupational lifetime of 45-years. Various factors may affect the consistency of the type and duration of jobs miners hold and hence their associated cumulative exposure levels. For example, some miners who lose their jobs upon mine closure are employed by other mines, sometimes in less-exposed jobs. Some miners may chose to move from job to job over their careers at underground coal mines, sometimes preferring positions away from the mining face. Moreover, if the trend of increasing mechanization continues, there will be fewer miners, and for some of them, their occupational lifetimes will be shorter.

For reasons already explained, we believe these choices are appropriate for this risk assessment. We also recognize that use of the most conservative approach at every step of the risk assessment analysis could produce mathematical risk estimates which, because of the additive effect of multiple conservative assumptions, may overstate the likely risk. We believe this QRA for simple CWP and PMF strikes a reasonable balance based on available data. To the extent that we may have underestimated the magnitude of overexposures which would be prevented, we believe the actual benefits to be greater than we have estimated.

It should be noted that reductions in the prevalence of simple CWP and PMF attributable to eliminating individual shift overexposures are not expected to materialize immediately after the overexposures have been substantially reduced or eliminated. Because these diseases typically arise after many years of cumulative exposure, allowing for a period of latency, the beneficial effects of reducing exposures are expected to become evident only after a sufficient time has passed that the reduction in cumulative exposure could have its effect. The total realized benefits would not be fully evident until after the youngest of today's underground coal miners retire.

Finally, even standing alone without simultaneously requiring that mine

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[13] In the context of the field of risk assessment, a ''conservative'' assumption is one that results in an estimate of more protection for workers than a less conservative assumption would. Therefore, estimated benefits are greater under assumptions that are ''conservative'' in this sense.

[14] By ''exhibiting a pattern of recurrent overexposures,'' means that, at a 95-percent confidence level, the applicable standard is exceeded on at least six shifts per year.

[15] Valid MSHA inspector samples require production to be at least 60-percent of the average production for the last 30-days. Valid operator bimonthly samples must be taken on a normal production shift (*i.e.,* a production shift during which the amount of material produced in a MMU is at least 50 percent of the average production reported for the last set of five valid samples) (30 CFR 70.101).

[16] Therefore assuming representative operating conditions on these shifts, in our QRA the results were extrapolated to all production shifts, including those that were not sampled, at those same 704 MMUs.

operators verify the effectiveness of their mine ventilation plans, the proposed standard allowing MSHA to use single, full-shift samples to identify overexposures requiring corrective action would provide miners with health benefits (See detailed discussion in Quantitative Risk Assessment). Both the prospect of being cited for overexposures and actual issuance of additional citations due to this rule would serve to compel mine operators to be more attentive to the level of respirable dust in their mines. Therefore, it is reasonable to expect, over time, a further decline in the number of shifts during which the concentration of respirable coal mine dust is at or above the applicable standard. Thus, the use of full-shift single samples will in and of itself, on average, lower miners' cumulative exposure to respirable coal mine dust. Since cumulative exposure to respirable coal mine dust is the main determinant in the development of both simple CWP and PMF, the Agencies are confident that the use of single, full-shift samples, by itself, and even without the impact of a verified dust control plan, would result in better health protection to miners (Jacobsen, *et al.,* 1977; Hurley, *et al.,* 1987; Kuempel, *et al.,* 1995; Attfield and Morring, 1992; Attfield and Seixas, 1995).

While there may be some concern from mine operators that the use of single, full-shift samples could dramatically increase the number of MSHA citations for overexposure to respirable coal mine dust, MSHA's 1998 Interim Single-Sample Enforcement Policy (ISSEP) has demonstrated that mine operators can maintain coal mine dust concentrations at or below the applicable standard.

As discussed in greater detail later in this notice, under ISSEP (May 7, 1998–September 9, 1998), of the 1,662 MMUs sampled, 182 or 11 percent were cited and only 14 of the 4,600 surface entities sampled were found to be out of compliance.

The anticipated increase in MSHA citations due to the use of single full-shift sampling would be the result of identifying overexposures which the current method of sampling masks due to the averaging of samples. Such overexposures and their prospective medical impact on the health of miners has been the subject of a Federal Mine Safety and Health Review Commission case which was affirmed by the Court of Appeals. *Consolidation Coal Co.* v. *Secretary of Labor,* 5 FMSHRC 378 (March 1983), *aff'd,* 8 FMSHRC 890 (June 1986), 824 F.2d 1071 (D.C. Cir. 1987).

In affirming an MSHA citation designated as ''significant and substantial'' under Section 104(a) of the Mine Act based on a mine operator's bimonthly dust samples which had an average concentration of respirable dust of 4.1 milligrams per cubic meter of air, the Commissioner quoted the administrative law judge who explained in detail the potentially damaging health effects of respirable coal mine dust:

> It is clear that the exposure covered by the dust samples which resulted in the citation herein *in itself* would neither cause nor significantly contribute to chronic bronchitis or coal workers pneumoconiosis. It is also clear that longer exposure to the same dust levels can in a significant number of instances cause or significantly contribute to chronic bronchitis or to coal workers pneumoconiosis. There is no question that chronic bronchitis and coal workers' pneumoconiosis are illnesses ''of a reasonably serious nature.'' There is no question that each unit of exposure time is important in contributing to the disease. I think it would be illogical and unrealistic to hold that a serious disease results from a long series of insignificant and unsubstantial exposures. Dr. Hodous testified that the disease results from ''an aggressive accumulation of dust and every drop in the bucket hurts.'' How much the drop will hurt may depend in part on the status of the bucket when the drop falls. If the bucket is full or nearly full, the drop may cause it to overflow. If a miner has worked 20 or 30 years in an underground coal mine, a 2 month exposure to excessive dust may be enough to cause the first signs of coal workers' pneumoconiosis, or to transform simple pneumoconiosis to a complicated form of the disease and possibly lead to progressive massive fibrosis. If the bucket is empty when the drop falls, in itself it won't mean much. If the miner exposed to excessive dust for a 2-month period is a new miner with healthy lungs, he probably will not be adversely affected, if his exposure stops. But if the exposure continues for 20 years (six 2-month periods each year), that miner too will be at risk to contract black lung.
>
> I conclude that *every drop in the bucket,* every two month sampling period where excessive dust is present, significantly and substantially contributes to a health hazard—the hazard of contracting chronic bronchitis or coal workers' pneumoconiosis. (emphasis added)

Consolidation Coal, 5 FMSHRC at 389–90 (citations omitted) (footnotes omitted). *See also Consolidation Coal,* 8 FMSHRC at 897 (''There is no dispute, however, that overexposure to respirable dust can result in chronic bronchitis and pneumoconiosis.'') and *Consolidation Coal,* 824 F.2d at 1086 (using the legislative history of the Mine Act and the administrative law judge's ''drop in the bucket'' analogy to strike down the mine operator's argument that ''no single violation of the respirable dust standard could ever be designated as significant and substantial.'').

While *Consolidation Coal, supra,* dealt with overexposures identified under the operator sampling program, it is obvious that overexposures identified from the MSHA inspector sampling program similarly affect a miner's cumulative exposure to respirable coal mine dust.

Thus, the same analogy would apply to overexposures identified through single, full-shift exposures. MSHA and NIOSH firmly believe that noncompliance determinations based on single, full-shift measurement will improve working conditions for miners because mine operators will be compelled either to implement and maintain more effective dust controls to minimize the chances of being found in noncompliance by an MSHA inspector, or to take corrective actions to lower those dust concentrations that are shown to be in excess of the applicable standard.

To the extent that the use of single, full-shift samples reduce a miner's cumulative exposure to respirable coal mine dust, as compared to the current method of dust sampling, it reduces a miner's risk of developing occupational respiratory disease. The proposed mandatory standard would provide for fewer drops in each miner's exposure bucket. The health benefit that each miner receives from this rule will vary depending on ''how full their bucket is'' when the rule is implemented as well as other mediating factors, such as the percentage of quartz and rank of the coal.

Yet, all miners, irrespective of their cumulative exposure to respirable coal mine dust, would benefit by having fewer drops (*i.e.,* shifts with overexposures to respirable coal mine dust) placed in their buckets over the course of each miner's working life because this reduction would reduce their occupational hazard—the risk of developing simple CWP or PMF. Therefore, the Agencies reiterate that health benefits would accrue to miners due to single, full-shift sample rule alone even in the absence of a regulatory requirement for a verified dust control plan at each underground coal mine.

X. Issues Regarding Accuracy of a Single, Full-shift Measurement

Some previous commenters questioned the accuracy of single, full-shift measurements, and challenged the Secretaries' assessment of measurement accuracy. Some commenters questioned the Secretaries' interpretation of section 202(b) of the Mine Act (30 U.S.C.

842(b)), while others agreed with the interpretation. The following issues were generally raised: The measurement objective as defined by the Mine Act; the definition of the term ''accurately represent'', as used in section 202(f) (30 U.S.C. 842(f)); the validity of the sampling process; measurement uncertainty and dust concentration variability; and the accuracy of a single, full-shift measurement.

A. Measurement Objective

Some previous comments reflected a general misunderstanding of what the Secretaries intend to measure with a single, full-shift measurement, *i.e.,* the measurement objective. For example, some previous commenters asserted that the dust concentration that should be measured is dust concentration averaged over a period greater than a single shift. Some previous commenters noted that dust concentrations can vary during a shift and that dust concentrations are not uniform throughout a miner's work area. In order to clarify the intent of the Secretaries, the explanation that follows describes the elements of the measurement objective and how the measurement objective relates to the requirements of section 202(f).

To evaluate the accuracy of a dust sampling method, it is necessary to specify the airborne dust to be measured, the time period to which the measurement applies, and the area represented by the measurement. Once specified, these items can be combined into a measurement objective. The measurement objective represents the goal of the sampling and analytical method to be utilized.

1. The Airborne Dust to be Measured

Section 202(f) of the Mine Act (30 U.S.C. 842(f)) states that ''average concentration'' means

> * * * a determination [*i.e.,* measurement] which accurately represents the atmospheric conditions with regard to respirable dust to which each miner in the active workings of a mine is exposed * * *

The phrase ''atmospheric conditions'' is used to refer to the concentration of respirable dust. Therefore, the airborne dust to be measured is respirable dust. Section 202(e) defines the concentration of respirable dust as the dust measured by an approved device.

2. Time Period to Which the Measurement Applies

Section 202(b)(2) provides that each mine operator ''* * * shall continuously maintain the average concentra tion of respirable dust in the mine atmosphere during each shift to which each miner *; * * is exposed'' at or below the applicable standard. In section 202(f) ''average concentration'' is defined as an atmospheric condition measured ''over a single shift only, unless * * * such single shift measurement will not, after applying valid statistical techniques, accurately represent such atmospheric conditions during such shift.''

Some previous commenters argued that Congress intended that the measurement objective be a long-term average. Specifically, some of these commenters stated that because coal dust exposure is related to chronic health effects, the exposure limit should be applied to dust concentrations averaged over a miner's lifetime. These commenters identified the measurement objective as being the dust concentration averaged over a long, but unspecified, term and argued that a single, full-shift measurement cannot accurately estimate this long-term average.

If the objective of section 202(b) were to estimate dust concentration averaged over a lifetime of exposure, then the Secretaries would agree that a single, full-shift sample, or even multiple samples collected during a single inspection, would not provide the basis for an accurate measurement. Section 202(b) of the Mine Act (30 U.S.C. 842(b)), however, does not mention long-term averaging, rather it explicitly requires that the average dust concentration be continuously maintained at or below the applicable standard during *each shift* (emphasis added). Furthermore, in *Consolidation Coal Company* v. *Secretary of Labor* 8 FMSHRC 890, (1986), aff'd 824 F.2d 1071, (D.C. Cir. 1987), the Commission found that each episode of a miner's overexposure to respirable dust significantly and substantially contributes to the health hazard of contracting chronic bronchitis or coal workers' pneumoconiosis, diseases of a fairly serious nature.

If exposure is limited on each shift, then this will ensure that a miner's total lifetime exposure will not be excessive. In the context of the proposed finding, the Secretaries have determined that ''atmospheric conditions'' means the fluctuating concentration of respirable coal mine dust during a single shift. These are the atmospheric conditions to which a miner at the sampling location would be exposed. Therefore, the proposed finding pertains only to the accuracy in representing the average of the fluctuating dust concentration over a single shift.

3. Area Represented by the Measurement

The Mine Act gives the Secretary of Labor the discretion to determine the area to be represented by respirable dust measurements collected over a single shift. Section 202(a) of the Mine Act (30 U.S.C. 842(a)) refers to ''the amount of respirable dust in the mine atmosphere to which each miner in the active workings of such mine is exposed'' measured ''* * * at such locations * * *'' as prescribed by the Secretary of Labor. It is sufficient for the purposes of the Mine Act that the sampler unit accurately represent the amount of respirable dust at such locations only. As articulated by the United States Court of Appeals for the 10th Circuit in *American Mining Congress (AMC)* v. *Marshall*, 671 F.2d 1251 (1982), the Secretary of Labor may place the sampler unit in any area or location ''* * * reasonably calculated to prevent excessive exposure to respirable dust.''

Some previous commenters submitted evidence that dust concentrations can vary significantly near the mining face, and that these variations may extend into areas where miners are located. That is, the average dust concentration over a full shift is not identical at every point within a miner's work area. These commenters submitted several bodies of data purporting to show significant discrepancies between simultaneous dust concentration measurements collected within a relatively small distance of one another. Several previous commenters maintained that the measurement objective is, or should be, to accurately measure the average concentration within some arbitrary sphere about the head of the miner, and that multiple measurements within this sphere are necessary to obtain an accurate measurement.

The Secretaries recognize that dust concentrations in the mine environment can vary from location to location, even within a small area near a miner. As mentioned earlier, the Mine Act does not specify the area that the measurement is supposed to represent, and the sampler unit may therefore be placed in any location, reasonably calculated to determine excessive exposure to respirable dust.

Because the Secretary of Labor intends to prevent excessive exposures by limiting dust concentrations at every location in the active workings, it is sufficient that each measurement accurately represent the respirable dust concentration at the corresponding sampling location only. Limiting the dust concentration at every such location ensures that no miner in the active workings will be exposed to excessive respirable dust.

Several previous commenters suggested that the measurement objective should be a miner's ''true exposure'' or what the miner actually inhales. The Secretaries do not intend to use a single, full-shift measurement to estimate any miner's ''true exposure,'' because no sampling device can exactly duplicate the particle inhalation and deposition characteristics of a miner at any work rate (these characteristics change with work rate), let alone at the various work rates occurring over the course of a shift. Limiting the respirable dust concentration at every location in the active workings to which miners are exposed ensures that the respirable dust concentration actually inhaled by any miner is limited.

4. Justification for the Proposed Measurement Objective

A number of previous commenters identified the dust concentration to be estimated as either the mean dust concentration over some period greater than an individual shift, the mean dust concentration over some spatially distributed region of the mine, or a ''grand mean'' consisting of some combination of the above. These comments were based on the premise that the measurement objective should be something other than the average atmospheric conditions during a single shift at the sampling location. It is true that the mean quantities described by some commenters cannot accurately be estimated using a single, full-shift measurement, but the Secretaries make no claim of doing so, nor do they believe that a broader measurement objective would be desirable for enforcement purposes.

The Secretaries believe that MSHA's proposed use of single, full-shift samples for enforcement purposes would eliminate an important source of sampling bias due to averaging, as explained in Appendix A. Under MSHA's existing enforcement procedures, measurements made at the dustiest occupational locations or during the dustiest shifts sampled are diluted by averaging them with measurements made under less dusty conditions. This practice has frequently caused failures to cite clear cases of excessive dust concentration. Therefore, the Secretaries believe that enforcement based on averaging does not provide miners with the greatest level of protection possible under the current exposure limit for respirable coal mine dust.

Some previous commenters proposed that MSHA continue to average at least five separate measurements prior to making a noncompliance determination. They stated that abandoning this practice would reduce the accuracy of noncompliance determinations. Several of these commenters maintained that the average of dust measurements obtained at the same occupational location on different shifts more accurately represents dust exposure to a miner than a single, full-shift measurement. These commenters argued that not averaging measurements would reduce accuracy to unacceptable levels.

Other previous commenters agreed with MSHA and NIOSH that the averaging of multiple samples can dilute and mask specific instances of overexposure. Some of these commenters stated that averaging not only distorts the estimate of dust concentration applicable to individual shifts, but also biases the estimate of exposure levels over a longer term. According to these commenters, this is because dust control measures and work practices affecting dust concentrations are frequently modified in response to the presence of an MSHA inspector over more than a single shift. These commenters argued that the presence of the MSHA inspector causes the mine operator to be more attentive to dust control than normal.

Section 202(b) of the Mine Act currently requires each mine operator to ''continuously maintain the average concentration of respirable dust in the mine atmosphere during each shift to which each miner is exposed'' at or below the applicable standard. The greater the variation in mining conditions from shift to shift, the less likely it is that a multi-shift average will reflect the average dust concentration to which a miner is exposed on any individual shift. Appendix A contains further discussion of this issue.

Accordingly, the Secretaries would define the measurement objective to be the accurate determination of the average concentration of respirable dust at a sampling location over a single shift.

B. Accuracy Criterion

A ''single shift measurement'' means the calculated dust concentration resulting from a valid single, full-shift sample of respirable coal mine dust. In reviewing the various issues raised by previous commenters, the Agencies found that the term ''accurately represent,'' as used in section 202(f) (30 U.S.C. 842(f)) in connection with a single shift measurement, was not defined in the Mine Act. Therefore, on March 12, 1996, (61 FR 10012), the Secretaries proposed to apply an accuracy criterion developed and adopted by NIOSH in judging whether a single, full-shift measurement will ''accurately represent'' the full-shift atmospheric dust concentration. The NIOSH Accuracy Criterion requires that measurements come within 25 percent of the corresponding true dust concentration at least 95 percent of the time (Kennedy, *et al.,* 1995). MSHA and NIOSH again are proposing to use the NIOSH Accuracy Criterion.

One previous commenter opposed the application of the NIOSH Accuracy Criterion since it ignores environmental variability. For reasons explained above, the Secretaries have restricted the measurement objective to an individual shift and sampling location. Therefore, environmental variability beyond what occurs at the sampling location on a single shift would not be relevant to assessing measurement accuracy.

For over 20 years, the NIOSH Accuracy Criterion has been used by NIOSH and others in the occupational health professions to validate sampling and analytical methods. This accuracy criterion was devised as a goal for the development and acceptance of sampling and analytical methods capable of generating reliable exposure data for contaminants at or near the Occupational Safety and Health Administration's (OSHA) permissible exposure limits.

OSHA has frequently employed a version of the NIOSH Accuracy Criterion when issuing new or revised single substance standards. For example, OSHA's benzene standard provides: ''[m]onitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of benzene'' (29 CFR 1910.1028(e)(6)). Similar wording can be found in the OSHA standards for vinyl chloride (29 CFR 1917), arsenic (29 CFR 1918), lead (29 CFR 1925), 1,2-dibromo-3-chloropropane (29 CFR 1044), acrylonitrile (29 CFR 1045), ethylene oxide (29 CFR 1047), and formaldehyde (29 CFR 1048). Note that for vinyl chloride and acrylonitrile, the accuracy criterion for the method is ±35 percent at 95 percent confidence at the permissible exposure limit.

Some previous commenters contended that the NIOSH Accuracy Criterion does not conform with international standards recently adopted by the European Committee for Standardization (CEN) (European Standard No. EN 482, 1994). Contrary to these assertions, the NIOSH Accuracy Criterion not only conforms to the CEN criterion but is, in fact, more stringent.

The CEN criterion requires that 95 percent of the measurements fall within ±30 percent of the true concentration, compared to ±25 percent under the NIOSH criterion. Consequently, any sampling and analytical method that meets the NIOSH Accuracy Criterion will also meet the CEN criterion. Furthermore, EN 482 imposes no control over inaccuracy in the measurement of sampling and analytical accuracy itself.

The NIOSH Accuracy Criterion is relevant and widely recognized and accepted in the occupational health professions. Further, previous commenters proposed no alternative criteria for accuracy. Accordingly, for purposes of section 202(f) of the Mine Act (30 U.S.C.842(f)), the Secretaries would consider a single, full-shift measurement to ''accurately represent'' atmospheric conditions at the sampling location, if the sampling and analytical method used meets the NIOSH Accuracy Criterion.

Several commenters suggested that method accuracy should be determined under actual mining conditions rather than in a laboratory or in a controlled environment. Although the NIOSH Accuracy Criterion does not require field testing, it recognizes that field testing ''does provide further test of the method.'' However, in order to avoid confusing real differences in dust concentration with measurement errors when testing is done in the field, ''precautions may have to be taken to ensure that all samplers are exposed to the same concentrations'' (Kennedy, *et al.*, 1995). Similarly, the CEN criterion for method accuracy specifies that ''testing of a procedure shall be carried out under laboratory conditions.'' (European Standard No. EN 482, 1994)

To determine, so far as possible, the accuracy of its sampling and analytical method under actual mining conditions, MSHA conducted 22 field tests in an underground coal mine. To provide a valid basis for assessing accuracy, 16 sampler units were exposed to the same dust concentration during each field test using a specially designed portable chamber. The data from these field experiments were used by NIOSH in its ''direct approach'' to determining whether or not MSHA's method meets the long-established NIOSH Accuracy Criterion. (See section X.E.2. of this notice).

In response to the March 12, 1996 notice, a commenter claimed that the supplementary information and analyses introduced into the public record by that notice addressed the precision of a single, full-shift measurement rather than its accuracy. According to this commenter, by focusing on precision, important sources of systematic error had been overlooked. The Secretaries agree with the comment that precision is not the same thing as accuracy. The accuracy of a measurement depends on both precision and bias (Kennedy, *et al.*, 1995). Precision refers to consistency or repeatability of results, while bias refers to a systematic error that is present in every measurement. Since the NIOSH Accuracy Criterion requires that measurements consistently fall within a specified percentage of the true concentration, the criterion covers both precision and uncorrectable bias.

Since the amount of dust present on a filter capsule used by an MSHA inspector is measured by subtracting the pre-exposure weight from the post-exposure weight, any bias present in both weight measurements is mathematically canceled out by subtraction. Furthermore, as will be discussed later, a control (*i.e.*, unexposed) filter capsule has been and would continue to be pre- and post-weighed along with the exposed filter capsules. The weight gain of the exposed capsule would be adjusted by the weight gain or loss of the control filter capsule. Therefore, any bias that may be associated with differences in pre-and post-exposure laboratory conditions, or with changes introduced during storage and handling of the filter capsules would also be mathematically canceled out. Moreover, the concentration of respirable dust is effectively defined by section 202(e) of the Mine Act (30 U.S.C. 842(e)) and the implementing regulations in 30 CFR parts 70, 71, and 90 to be whatever is measured with an approved sampler unit after multiplication by the MRE-equivalent conversion factor prescribed by the Secretary of Labor. Therefore, the Secretaries would conclude that the improved sampling and analytical method is statistically unbiased. This means that such measurements contain no systematic error. It should also be noted that since any systematic error would be present in all measurements, measurement bias would not be reduced by making multiple measurements. Other comments regarding measurement bias are addressed in Appendix B.

For unbiased sampling and analytical methods, a standard statistic—called the coefficient of variation (CV)—is used to determine if the method meets the NIOSH Accuracy Criterion. The CV, which is expressed as either a fraction (*e.g.*, 0.05) or a percentage (*e.g.*, 5 percent), quantifies measurement accuracy for an unbiased method. An unbiased method meets the NIOSH Accuracy Criterion if the ''true'' CV is no more than 0.128 (12.8 percent). However, since it is not possible to determine the true CV with 100-percent confidence, the NIOSH Accuracy Criterion contains the additional requirement that there be 95-percent confidence that measurements by the method will come within 25 percent of the true concentration 95 percent of the time. Stated in mathematically equivalent terms, an unbiased method meets the NIOSH Accuracy Criterion if there is 95-percent confidence that the true CV is less than or equal to 0.128 (12.8 percent).

C. Validity of Sampling Process

A single, full-shift measurement of respirable coal mine dust is obtained with an approved sampler unit, which is either worn or carried by the miner directly to and from the sampling location and remains operational during the entire shift or for eight hours, whichever time is less. A portable, battery-powered pump draws dust-laden mine air at a flow rate of 2 liters per minute (L/min) through a 10-mm nylon cyclone, a particle-size selector that removes non-respirable particles from the airstream. Non-respirable particles tend to be removed from the airstream by the nose and upper respiratory airways. Such particles fall to the bottom of the cyclone body called the ''grit pot,'' while smaller, respirable particles (of the size that would normally enter into the lungs) pass through the cyclone, directly into the inlet of the filter cassette. This airstream is directed through the pre-weighed filter leaving the particles deposited on the filter surface. This collection filter is enclosed in an aluminum capsule to prevent leakage of sample air around the filter and the loss of any dust dislodged due to impact. The filter capsule is sealed in a protective plastic enclosure, called a cassette, to prevent contamination. After completion of sampling, the filter cassette is sent to MSHA's Respirable Dust Processing Laboratory in Pittsburgh, Pennsylvania, where it is weighed to determine the weight gain in milligrams or the amount of dust collected on the filter surface. The concentration of respirable dust, expressed as milligrams per cubic meter (mg/m3) of air, is determined by dividing the observed weight gain by the volume of mine air passing through the filter and then multiplying this quantity by a conversion factor (discussed in Appendix B) prescribed by the Secretaries.

Some previous comments generally addressed the quality and reliability of the equipment used for sampling.

Specific concerns were expressed about the quality of filter cassettes and the reliability of sampling pumps used by MSHA inspectors, due to their age and condition. Other commenters questioned the effect of sampling and work practices on the validity of a sample.

The validity of the sampling process is an important aspect of maintaining accurate measurements. Since passage of the Coal Act, there has been an ongoing effort by MSHA and NIOSH to improve the accuracy and reliability of the entire sampling process. In 1980, MSHA issued new regulations revising sampling, maintenance and calibration procedures in 30 CFR parts 70, 71, and 90. These regulatory provisions were designed to minimize human and mechanical errors and ensure that samples collected with approved sampler units in the prescribed manner would accurately represent the full-shift, average atmospheric dust concen tration at the location of the sampler unit. These provisions require: (1) Certification of competence of all individuals involved in the sampling process and in maintaining the sampling equipment; (2) calibration of each sampler unit at least every 200 hours; (3) examination, testing, and maintenance of units before each sampling shift to ensure that the units are in proper working order; and (4) checking of sampler units during sampling to ensure that they are operating properly and at the proper flow rate. In addition, significant changes, such as robotic weighing and the use of electronic balances were made in 1984, 1994, and 1995 that improved the reliability of sample weighings at MSHA's Respirable Dust Processing Laboratory. These changes are discussed below in section X.C.3.

All of these efforts improved the accuracy and reliability of the sampling process since the time of the 1971/1972 proposed and final findings. A discussion follows concerning the three elements which constitute the sampling process: sampler unit performance, collection procedures, and sample processing.

1. Sampler Unit Performance

In accordance with the provisions of section 202(e) of the Mine Act (30 U.S.C. 842(e)), NIOSH administers a comprehensive certification process under 30 CFR part 74 to approve dust sampler units for use in coal mines. To be approved for use, a sampler unit must meet stringent technical and performance requirements governing the quantity of respirable dust collected and flow rate consistency over an 8-hour period when operated at the prescribed flow rate. As necessary, NIOSH also conducts performance audits of approved sampler units purchased on the open market to determine if the units are being manufactured in accordance with the specifications upon which the approval was issued.

The system of technical and quality assurance checks currently in place is designed to prevent a defective sampler unit from being manufactured and made commercially available to the mining industry or to MSHA. In the event that these checks identify a potential problem with the manufacturing process, established procedures require immediate action to correct the problem.

In 1992, NIOSH approved the use of new tamper-resistant filter cassettes with features that enhanced the integrity of the sample collected. A backflush valve was incorporated into the outlet of the cassette, preventing reverse airflow through the filter cassette, and an internal flow diverter was added to the filter capsule, reducing the possibility of dust dislodged from the filter surface from falling out of the capsule inlet.

Also, in 1999, based on recent MSHA studies, Kogut, *et al.* (1999), involving the weighing stability of the current filter design and in an effort to standardize the manufacturing process, the filter cassette manufacturer submitted for NIOSH approval a modification to the current design. The change involves replacing the Tyvek'' support pad with a stainless steel wheel, similar to the one located on the inlet side of the collection filter. A similar modification was incorporated in sampling filters employed by OSHA over the past several years. Upon NIOSH approval, the new cassette would be used in MSHA inspector sampling, thereby improving the stability of sample weights.

Several previous commenters questioned the quality of the filter cassettes used in the sampling program, expressing concern as to whether the cassettes always meet MSHA specifications. These concerns primarily involve filter-to-foil distance and floppiness of the filters, which are manufacturing characteristics specific to filters and filter capsules, not related to part 74 performance requirements. The Secretaries believe that such characteristics would have no effect on the accuracy of a single, full-shift measurement because, unlike the part 74 requirements, they would not affect the amount of dust deposition.

Previous commenters also questioned the condition of sampling pumps used by MSHA inspectors, stating that many of the pumps are 10 to 20 years old and are not maintained as well as they could be. They claimed that the age and condition of these pumps call into question not only whether the sampling equipment could meet part 74 requirements if tested, but also the accuracy of the measurement.

MSHA believes that this concern is unwarranted, since in 1995, MSHA replaced all pumps in use by inspectors with new constant-flow pumps that incorporate the latest technology in pump design. These pumps provide more consistent flow throughout the sampling period. In addition to using new pumps, inspection procedures require MSHA inspectors to make a minimum of two flow rate checks to ensure that the sampler unit is operating properly. A sample is voided if the proper flow rate was not maintained during the final check at the conclusion of the sampling shift. In fiscal year 1998, only 151 samples or 0.4 percent of the 37,042 inspector samples processed were voided because the sampling pump either failed to operate throughout the entire sampling period or failed to maintain the proper flow rate during the final check. Units found not meeting the requirements of part 74 are immediately repaired, adjusted, or removed from service. Nevertheless, MSHA recognizes that as these pumps age, deterioration of the performance of older pumps could become a concern. However, there is no evidence that the age of the equipment affects its operational performance if the equipment is maintained as prescribed by 30 CFR parts 70, 71, and 90.

Some previous commenters suggested that the accuracy of a dust sample may be compromised when a miner is operating equipment, due to vibration from the machinery. The potential effect of vibration on the accuracy of a respirable dust measurement was recognized by NIOSH in 1981. An investigation, supported by NIOSH, was conducted by the Los Alamos National Laboratory which found that vibration has an insignificant effect on sampler performance (Gray and Tillery, 1981).

2. Sample Collection Procedures

MSHA regulations at 30 CFR parts 70, 71, and 90 prescribe the manner in which mine operators are to take respirable dust samples. The collection procedures are designed to ensure that the samples accurately represent the amount of respirable dust in the mine atmosphere to which miners are exposed on the shift sampled. Samples taken in accordance with these procedures are considered to be valid.

Several previous commenters questioned the effects of sampling and work practices on the validity of a sample. Instances were cited where the sampling unit was accidentally dropped, with the potential for the sample to become contaminated. Previous commenters also pointed out that work activities requiring crawling, duck walking, bending, or kneeling could cause the sampling hose to snag. Such activities could also cause the sampling head assembly to be impacted or torn off a person's garment, possibly contaminating the sample. These commenters stated that sampler units are sometimes treated harshly while being worn by miners, mishandled when being transferred from one miner to another, or handled casually at the end of a work shift.

These commenters also maintained that it is impossible for MSHA inspectors or mine operators to continuously observe collection of a sample in order to ensure its validity, and that, for this reason, the reliability and accuracy of the sampling equipment, when used under actual mining conditions, is not the same as when tested and certified in a laboratory. Averaging multiple samples would, according to these commenters, provide some ''leeway'' in the system, by reducing the impact of an aberrant sample.

While MSHA and NIOSH would agree that it is not possible to continuously observe the collection of each sample, MSHA inspectors are normally in the general vicinity of the sampling location, and therefore would have knowledge of the specific conditions under which samples are taken. In addition, MSHA inspectors are instructed to ask miners wearing the sampler units whether anything that could have affected the validity of the sample occurred during the shift. If so, the inspector would note this on the data card and request that the sample be examined to determine its validity.

Other previous commenters expressed concern that, if special dust control measures are in effect during sampling, a single, full-shift measurement may fail to represent atmospheric conditions during shifts when samples are not collected. The Secretaries believe that this concern is beyond the scope of this new proposal, which, as described in the discussion of measurement objective, deals solely with the accuracy of a measurement in representing atmospheric conditions on the shift being sampled. One previous commenter recommended that MSHA, NIOSH, or the Bureau of Mines (now a part of NIOSH) should evaluate the need for standardizing the MSHA respirable dust sampling procedures. In fact, the procedures for respirable dust sampling have already been standardized under the revised 1980 MSHA regulations codified at 30 CFR parts 70, 71 and 90.

As previously mentioned, as part of the ISSEP discussion, MSHA inspectors are also using unexposed control filters to eliminate any bias that may be associated with day-to-day changes in laboratory conditions or introduced during storage and handling of the filter capsules. A control filter is an unexposed filter that was pre-weighed on the same day as the filter used for sampling. This control filter is used to adjust the weight gain obtained on each exposed filter. Any change in weight of the control filter is subtracted from the change in weight of each exposed filter. MSHA began using control filters on May 7, 1998, with the implementation of the ISSEP, and has continued this practice, even after reverting back to basing noncompliance determinations on an average of multiple samples following the ruling of the 11th Circuit Court of Appeals discussed earlier. The control filter, which is carried by the inspector in a shirt or coverall pocket during the sampling inspection, is plugged to prevent exposure to the mine environment. The experience gained from the use of control filters under ISSEP is discussed in section V.D.

Also, once NIOSH approves the modified design mentioned earlier, MSHA inspectors would use only filters incorporating a stainless steel support wheel. These filters, according to MSHA studies, demonstrated better weighing stability as compared to filters employing Tyvek® material for the support pad.

3. Sample Processing

Sample processing consists of weighing the exposed and control (unexposed) filters, recording the weight changes, and examining certain samples in order to verify their validity. Sample processing also includes electronic transmission of the results to MSHA's MIS center where dust concentrations are computed. The results are then transmitted to MSHA enforcement personnel and to mine operators.

(a) Weighing and Recording Procedures

The procedures and analytical equipment, as well as the facility used by MSHA to process respirable coal mine dust samples have been continuously improved since 1970 to maintain a state-of-the-art laboratory. From 1970 to 1984, samples were manually weighed using semimicro balances. This process was automated in 1994 with the installation of a state-of-the-art robotic system and electronic balances, which increased the precision of sample-weight determinations. Weighing precision was further improved in 1994, when both the robotic system and balances were upgraded. Also, beginning in early 1998, all respirable coal mine dust samples were being processed in a new, specially designed clean room facility that maintains the temperature and humidity of the environment at 72 ±2°F and 50 ±5%, respectively. Using a modified HEPA filtration system, the environment is maintained at a clean room classification of 1000 (near optimum for clean room cleanliness).

The full benefit of the 1994 improvements of the weighing system for inspector samples was, however, not attained until mid-1995, when MSHA implemented two modifications to its procedures for processing inspector samples. One modification involved pre- and post-weighing filter capsules to the nearest microgram (0.001 mg) within MSHA's laboratory. Prior to mid-1995, filters had been weighed in the manufacturer's (Mine Safety and Appliances Co.) laboratory before sampling, and then in MSHA's laboratory after sampling. MSHA is currently pre-weighing all such filters in its own laboratory. To maintain the integrity of the weighing process, eight percent of all filters are systematically weighed a second time. If a significant deviation is found, the balance is recalibrated and all filters with questionable weights are reweighed.

The other modification was to discontinue the practice of truncating (to 0.1 mg) the recorded weights used in calculating dust concentrations. This means that MSHA is now using all significant digits associated with the weighing capability of the balance (0.001mg) when processing inspector samples. These modifications improved the overall accuracy of the measurement process.

To eliminate the potential for any bias that may be associated with day-to-day changes in laboratory conditions or introduced during storage and handling of the filters, MSHA is also using control filters in its enforcement program. Any change in the weight of the control filter is subtracted from the measured change in weight of the exposed filter.[17]

Since MSHA began pre- and post-weighing filters to the nearest µg, coal

[17] If a control filter either shows a weight gain greater than 100 micrograms (µg) or a weight loss greater than 30 µg, the control filter is voided and the concentration measurement(s) are not used for enforcement purposes.

mine operators have asked to use filters pre-weighed to a µg to collect optional samples that they submit to MSHA for quartz analysis. The use of these pre-weighed filters would eliminate the need to sample multiple shifts in order to obtain sufficient dust mass on the collection filter for quartz analysis. Currently, filters used by coal mine operators to sample in accordance with 30 CFR parts 70, 71, and 90 are pre-weighed by the filter manufacturer, Mine Safety Appliances Co., to the nearest 10 µg. Therefore, only samples taken with filters preweighed to the nearest 10 µg, with a net weight gain of at least 450 µg, contain sufficient dust mass to permit the percentage of quartz to be determined.

In 1996, Mine Safety Appliances Company upgraded their equipment used to pre-weigh filter capsules and now uses the same balance as MSHA's Coal Dust Processing Laboratory, thereby permitting weight determinations to be made to the nearest µg.

The requirement that inspector samples be pre- and post-weighed in the same laboratory was developed prior to adopting control filters and was based on the assumption that no control filters were being used. Since use of the control filters adjusts for differences that may exist in laboratory conditions on the days of pre- and post-weighing, it is no longer necessary to pre- and post-weigh the filters in the same laboratory.

To determine the viability of using exposed filters pre-weighed by Mine Safety Appliances Co. and post-weighed by MSHA in establishing the percentage of quartz, the Agency conducted a study to quantify weighing variability between the Mine Safety Appliances Co. and MSHA laboratories (Parobeck, *et al.*, 1997). Based on this study, the overall imprecision of an interlaboratory weight-gain measurement was estimated to be 11.5 for capsules with a stainless steel filter support pad. This estimate closely matches the 11.6 result reported for capsules with stainless steel support pads in a more recent study (Kogut, *et al.*, 1999). In this more recent study, unexposed capsules were pre-weighed by MSHA, assembled into cassettes by Mine Safety Appliances Co., sent out to the field and carried during an inspection, and then post-weighed by MSHA.''

Using the higher of these two estimates, NIOSH has reassessed the accuracy of MSHA's improved sampling and analytical method, which incorporates a control filter adjustment and employs filter capsules with a stainless steel support pad. NIOSH has concluded that the control filter adjustment will correct for any potential biases due to differences in laboratory conditions, so that it is no longer necessary to pre- and post-weigh filter capsules in the same laboratory (Grayson, 1999b). Therefore, in accordance with NIOSH, MSHA is proposing to change the existing processing procedures for inspector samples from pre- and post-weighing in the same laboratory (with adjustment by a control filter) to pre- and post-weighing of samples to the nearest µ in different laboratories (with continued adjustment by a control filter). The Agencies would welcome comments on this proposed change.

To insure the precision and accuracy of the pre-weight of filters used by inspectors, MSHA plans to institute a program to monitor the daily production of filters weighed to the nearest µg by the manufacturer. The program will conform to MIL–STD–105D, which defines the criteria currently used to monitor the quality of pre-weighed filters used in MSHA's operator sampling program.

(b) Sample Validity Checks

All respirable dust samples collected and submitted as required by 30 CFR parts 70, 71, and 90 are considered valid unless the dust deposition pattern on the collection filter appears to be abnormal or other special circumstances are noted that would cause MSHA to examine the sample further. Several previous commenters expressed concern about the potential contamination of samples with ''oversized particles.'' Such contamination, according to one commenter, can result in aberrational weight gains. These commenters noted that current procedures do not systematically ensure that samples collected by MSHA contain no oversized particles. It was recommended that MSHA analyze, for the presence of oversized particles, any dust sample that exceeds the applicable dust standard. Also suggested for such an analysis was any sample with a weight gain significantly different from other samples taken in the same area.

Standard laboratory procedures, involving visual, and microscopic examination as necessary, are used to verify the validity of samples. Samples with a weight gain of 1.4 milligrams (µg) or more are examined visually for abnormalities such as the presence of large dust particles (which can occur from agglomeration of smaller particles), abnormal discoloration, abnormal dust deposition pattern on the filter, or any apparent contamination by materials other than respirable coal mine dust. Also examined are samples weighing 0.1 mg or less for insufficient dust particle count. Similar checks are also performed in direct response to specific inspector or operator concerns noted on the dust data card to which each sample is attached.

The previous commenters' concerns about the contamination of samples with oversized particles are based on the assumption that all oversized particles, defined as dust particles greater than 10 micrometers (µm) in size, are not respirable and therefore should be totally excluded from any sample taken with an approved sampler unit. However, it has long been known that some particles greater than 10 µ *can* be inhaled, and that some of these particles *can* reach the alveoli of the lungs (Lippman and Albert, 1969). According to the British National Coal Board, ''particles as large as 20 microns (*i.e.* micrometers) mean diameter may be deposited, although most ''lung dust'' lies in the range below 10 microns diameter'' (Goddard, *et al.*, 1973). Furthermore, it is known that, due to the irregular shapes of dust particles, the respirable dust collected by the MRE instrument (the dust sampler used by the British Medical Research Establishment in the epidemiological studies on which the U.S. coal dust standard was based) may include some dust particles as large as 20 micrometers (Goddard, *et al.*, 1973). Moreover, MSHA studies have shown that nearly all samples taken with approved sampler units, even when operated in the prescribed manner, contain some oversized particles (Tomb, August 31, 1981). Since section 202(e) of the Mine Act (30 U.S.C. 842(e)) defines concentration of respirable dust to be that measured by an approved sampler unit, and because the approved sampler unit will collect some oversized particles, the Secretaries do not consider a sample to be ''contaminated'' because it contains some oversized particles.

The Secretaries recognize that there are occasions when oversized particles can properly be considered a contaminant. For example, an excessive number of such particles could enter the filter capsule if the sampling head assembly is accidentally or deliberately turned upside down or ''dumped'' (possibly causing some of the contents of the cyclone grit pot to be deposited on the collection filter), if the pump malfunctions, or if the entire sampler unit is dropped. When MSHA has reason to believe that such contamination has occurred, the suspect sample is examined to verify its validity.

Contrary to the assertions of some previous commenters, checking for oversized particles is not standard industrial hygiene practice. Nevertheless, MSHA checks any dust sample suspected of containing an excessive number of oversized particles. MSHA's laboratory procedures require any sample exhibiting an excessive weight gain (over 6 mg) or showing evidence of being "dumped" to be examined for the presence of an excessive number of oversized particles (MSHA Method P–4, August 1989). Samples identified by an inspector or mine operator as possibly contaminated are also examined. If this examination indicates that the sample contains an excessive number of oversized particles according to MSHA's established criteria, then that sample is considered to be invalid, is voided and not used. In fiscal year 1998, only one sample of the 37,042 inspector samples processed was found to contain an excessive number of oversize particles and thus was not used.

While rough handling of the sampler unit or an accidental mishap could conceivably cause a sample with a weight gain less than 6 mg to become contaminated, as claimed by some previous commenters, studies show that short-term accidental inclinations of the cyclone will not affect respirable mass measurements made with currently approved sampler units (Treaftis and Tomb, 1974). Sampler units currently used are built to withstand the rigors of the mine environment, and are therefore less susceptible to contamination than suggested by some previous commenters. In any event, the Secretaries believe that the validity checks currently in place, as discussed above, would detect such samples.

D. Measurement Uncertainty and Dust Concentration Variability

Overall variability in measurements collected on different shifts and sampling locations comes from two sources: (1) Environmental variability in the true dust concentration and (2) errors in measuring the dust concentration in a specific environment. The major portion of overall measurement variability reflects real variability in dust concentration on different shifts or at different sampling locations (Nicas, *et al.*, 1991).[18]

Variability in the dust concentration is under the control of the mine operator and does not depend on the degree to which the dust concentration can be accurately measured. Measurement uncertainty, on the other hand, stems from the differing measurement results that could arise, at a given sampling location on a given shift, because of potential sampling and analytical errors. Therefore, unlike variability in dust concentration, measurement uncertainty depends directly on the accuracy of the measurement system. Measurement errors generally contribute only a small portion of the overall variability observed in datasets consisting of dust concentration measurements.

Numerous previous commenters identified sources of measurement uncertainty and dust concentration variability that they believed should be considered when determining whether or not a measurement accurately represents such atmospheric conditions. Because the measurement objective is to accurately represent the average dust concentration at the sampling location over a single shift, it does not take into consideration dust concentration variability between shifts or locations. Sources of dust concentration variability would not be considered by the Secretaries in determining whether a measurement is accurate. Consequently, the Secretaries have concluded that the only sources of variability relevant to establishing accuracy of a single, full-shift measurement for purposes of section 202(f) of the Mine Act (30 U.S.C. 842(f)) would be those related to sampling and analytical error.

1. Sources of measurement uncertainty

Filter capsules are weighed prior to sampling. After a single, full-shift sample is collected, the filter capsule is weighed a second time, and the weight gain (g) is obtained by subtracting the pre-exposure weight from the post-exposure weight, which will then be adjusted for the weight gain or loss observed in the control filter capsule. A measurement (x) of the atmospheric condition sampled is then calculated by Equation 1:

$$x = \frac{1.38 \cdot g}{v} \qquad (1)$$

where:

x is the single, full-shift dust concentration measurement (mg/m³);

1.38 is a constant MRE-equivalent conversion factor; g is the observed weight gain (mg) after adjustment for the control filter capsule; and

v is the estimated total volume of air pumped through the filter during a typical full shift.

The Secretaries recognize that random variability, inherent in any measurement process, may cause *x* to deviate either above or below the true dust concentration. The difference between x and the true dust concentration is the measurement error, which may be either positive or negative. Measurement uncertainty arises from a combination of potential errors in the process of collecting a sample and potential errors in the process of analyzing the sample. These potential errors introduce a degree of uncertainty when *x* is used to represent the true dust concentration.

The statistical measure used by the Secretaries to quantify uncertainty in a single, full-shift measurement is the total sampling and analytical coefficient of variation, or CV_{total}. The CV_{total} quantifies the magnitude of probable sampling and analytical errors and is expressed as either a fraction (*e.g.*, 0.05) or as a percent (*e.g.*, 5 percent) of the true concentration. For example, if a single, full-shift measurement *(x)* is collected in a mine atmosphere with true dust concentration equal to 1.5 mg/m³, and the standard deviation of potential sampling and analytical errors associated with *x* is equal to 0.075 mg/m³, the uncertainty associated with *x* would be expressed by the ratio of the standard deviation to the true dust concentration: $CV_{total} = 0.075/1.5 = 0.05$, or 5 percent.

Based on a review of the scientific literature, the Secretaries in their March 12, 1996 notice concerning the NIOSH Accuracy Criterion identified three sources of uncertainty in a single, full-shift measurement, which together make up CV_{total}:

(a) CV_{weight}—variability attributable to weighing errors or handling associated with exposed and control filter capsules. This covers any variability in the process of weighing the exposed or control filter capsules prior to sampling (pre-weighing), assembling the exposed and control filter cassettes, transporting

[18] Although MSHA and NIOSH accept the finding presented by Nicas, *et al.* (1991) that environmental variability generally exceeds analytical variability, the Agencies do not accept the authors' conclusions with regard to how this finding should affect enforcement policy.

the filter cassettes to and from the mine, and weighing the exposed and control filter capsules after sampling (post-weighing).

(b) CV_{pump}—variability in the total volume of air pumped through the filter capsule. This covers variability associated with calibration of the pump rotameter,[19] variability in adjustment of the flow rate at the beginning of the shift, and variation in the flow rate during sampling. It should be noted that variation in flow rate during sampling was identified as a separate component of variability in MSHA's February 18, 1994, notice. Here, it is included within CV_{pump}.

(c) $CV_{sampler}$—variability in the fraction of dust trapped on the filter. This is attributable to physical differences among cyclones. This component was introduced in the material submitted into the record in September 1994.

These three components of measurement uncertainty can be combined to form an indirect estimate of CV_{total} by means of the standard propagation of errors formula:

$$CV_{total} = \sqrt{CV_{weight}^2 + CV_{pump}^2 + CV_{sampler}^2} \qquad (2)$$

These three components are discussed in greater detail, along with responses to specific previous comments, in Appendix B.

2. Sources of Dust Concentration Variability

Previous commenters also raised issues related to sources of dust concentration variability. Some of these commenters maintain that the Secretaries should include in CV_{total} additional components representing the effects of shift-to-shift variability and variability related to location (spatial variability). These comments reflect a misunderstanding of the measurement objective as intended by the Mine Act (see Section X.A. of this notice).

Exposure variability due to job, location, shift, production level, effectiveness of engineering controls, and work practices will be different from mine to mine. This type of variability has nothing to do with measurement accuracy and depends on factors under the control of the mine operator. The sampler unit is not intended to account for these factors.

(a) Spatial Variability

Previous commenters stated that CV_{total} should account for spatial variability, or the differences in concentration related to location. The Secretaries agree that dust concentrations vary between locations in a coal mine, even within a relatively small area. However, real variations in concentration between locations, while sometimes substantial, do not contribute to measurement error. As stated earlier, the measurement objective would be to accurately measure average atmospheric conditions, or concentration of respirable dust, at a sampling location over a single shift.

(b) Shift-to-shift Variability

Previous commenters stated that CV_{total} should take into account the differences or variations in dust concentration that occur shift to shift. Although the Secretaries would agree that dust concentrations vary from shift to shift, the measurement objective is to measure average atmospheric conditions on the specific shift sampled. This result would be consistent with the Mine Act, which requires that concentrations of respirable mine dust be maintained at or below the applicable standard during each shift.

3. Other Factors Considered

(a) Proportion of Oversized Particles

Previous commenters expressed concern that respirable dust cyclones are handled in a rough manner in normal use and occasionally turned upside down. According to one commenter, this type of handling would cause more large particles to be deposited on the filter in the mine environment than when used in the laboratory. This commenter knew of no data that could be used to evaluate the error associated with such occurrences and recommended that a study be commissioned to measure the proportion of non-respirable particles on the filters after they are weighed to MSHA standards.

After considering this recommendation, the Secretaries would conclude that the available evidence shows that short-term inclinations of the cyclone, as might frequently occur during sampling, will not affect respirable dust measurements made with approved sampler units (Treaftis and Tomb, 1974). The weight of the sampler head assembly makes it extremely unlikely that a sampler unit could be turned upside down in normal use. Furthermore, with a field study of the type recommended, variability in the field measurements due to normal handling would be confounded with variability due to real differences in atmospheric conditions. Therefore, the Secretaries believe that such a study would not be useful in establishing variability in measurements due to differences in handling of the sampler unit.

(b) Anomalous Events

Previous commenters asserted that unpredictable, infrequent events, such as a ''face blowout'' on a longwall (a violent expulsion of coal together with large quantities of coal dust and/or methane gas) or high winds at a surface mine, can cause rapid loading of a filter capsule and thereby distort a measurement to show an excessive dust concentration based on a single, full-shift sample when, they argue, the dust standard had not been exceeded. In fact, if such an occurrence were to cause a measurement above the applicable standard, the dust standard would be violated. No evidence was previously presented to demonstrate that short-term high exposures can overload a dust sampling filter or cause the sampling device to malfunction. Nor was evidence presented to demonstrate that miners are not also exposed to the same high dust concentrations as the sampler unit when such events occur. The Secretaries would conclude that such events are results of the dynamic and ever-changing mine environment—an environment to which the miner is exposed. The sampler unit is designed to measure the atmospheric condition at a specific sampling location over a full shift. If such events occur, the sampler unit will accurately record the atmospheric condition to which it is exposed.

[19] The rotameter consists of a weight or ''float'' which is free to move up and down within a vertical tapered tube which is larger at the top than the bottom. Air being drawn through the filter cassette passes through the rotameter, suspending the ''float'' within the tube. The pump is ''calibrated'' by drawing air through a calibration device (usually what is known as a bubble meter) at the desired flow rate and marking the position of the float on the tube. The processes of marking the position on the tube (laboratory calibration) and adjusting the pump speed in the field so that the float is positioned at the mark are both subject to error.

(c) MRE Conversion Factor Used in the Dust Concentration Calculation

Several previous commenters questioned the 1.38 MRE-conversion factor used in Equation 1. This factor is used to convert a measurement obtained with the type of dust sampler unit currently approved for use in coal mines to an equivalent concentration as measured with an MRE gravimetric dust sampler. The term ''MRE instrument'' is defined in 30 CFR § 70.2 (i). The conversion factor is necessary because the coal mine dust standard was derived from British data collected with an MRE instrument, which collects a larger fraction of coal mine dust than does the approved dust sampling unit (Tomb, *et al.*, 1973). The 1.38 constant has been established by the Secretaries as applying to the currently approved dust sampler unit described in 30 CFR part 74.

Some previous commenters contended that variability involved in the data analysis used in establishing the conversion factor should be taken into account in determining CV^{total}. This suggestion demonstrates a misunderstanding of the difference between measurement imprecision and measurement bias. The 1.38 factor applies to every sampler unit currently approved under part 74. Since the same conversion factor is applied to every measurement, any error in the value used would cause a measurement bias but would have no effect on measurement imprecision. Since Congress defined respirable dust in section 202(e) of the Mine Act (30 U.S.C. 842(e)) as whatever is collected by a currently approved sampler unit, a measurement incorporating the 1.38 factor is unbiased by definition. Further discussion is provided in Appendix B on why use of the 1.38 factor does not introduce a bias. Appendix B also addresses comments relating to other aspects of the 1.38 conversion factor; comments regarding the fact that MSHA's sampler unit does not conform to other definitions of respirable dust; and questions concerning the effect of static charge on sampler unit performance.

(d) Reduced Dust Standards

One commenter pointed out that in estimating CVtotal, MSHA and NIOSH did not take into account any potential errors associated with silica analysis. The commenter argued that since silica analysis is used to establish reduced dust standards, MSHA and NIOSH had failed to demonstrate ''* * * accuracy for all samples 'across the range of possible reduced dust standards.'' '

This commenter confuses the accuracy of a respirable dust concentration measurement with the accuracy of the procedure used to establish a reduced dust standard. MSHA has a separate program in which silica analysis is used to set the applicable respirable coal mine dust standard, in accordance with section 205 of the Mine Act (30 U.S.C. 845), when the respirable dust in the mine atmosphere of the active workings contains more than 5 percent quartz. As shown by Equation 1, no silica analysis is used in a single, full-shift measurement of the respirable dust concentration. Therefore, the Secretaries would not agree with the comment that CV_{total} should include a component representing potential errors in silica analysis.

(e) Dusty Clothing

Several previous commenters pointed out that local factors such as dusty clothing could cause concentrations in the immediate vicinity of the sampler unit to be unrepresentative of a larger area. Dust from a miner's clothing nevertheless represents a potential hazard to the miner. No evidence was previously presented to demonstrate that miners are not also exposed to dust originating from dusty clothing.

E. Accuracy of a Single, Full-shift Measurement

1. Quantification of Measurement Uncertainty

Several previous commenters argued that MSHA underestimated CV_{total} in its February 18, 1994 proposed notice of Joint Finding and suggested alternative estimates ranging from 16 to 50 percent. These commenters cited several published studies and submitted five sets of data in support of these higher estimates. Statistical analyses of the data were also submitted.

MSHA and NIOSH reviewed all of the studies referenced by the previous commenters. The review showed that all of the estimates of measurement variability were from studies carried out prior to improvements mandated by the 1980 MSHA revisions to dust sampling regulations, discussed earlier in ''Validity of the Sampling Process'' (see Section X.C.). For example, the General Accounting Office (GAO) [20] and the National Bureau of Standards (NBS, now the National Institute of Standards and Technology) studies were conducted in 1975. The National Academy of Sciences report, which analyzed the same data as the NBS and GAO reports, was issued in 1980. The review further showed that the measurement variability quantified in these studies included effects of spatial variability—a component of variability the Secretaries deliberately exclude when determining the accuracy of a sampling and analytical method as discussed in section X.D.2.(a). Additionally, since past studies frequently relied on combining estimates of variability components obtained from different bodies of data, some of them also suffered from methodological problems related to combining individual sources of uncertainty. For example, in 1984, a NIOSH study identified several conceptual errors in earlier studies that had led to double-or even triple-counting of some variability components (Bowman, *et al.*, 1984). Although all the data and analyses submitted by previous commenters included effects of spatial variability, one of these data sets, consisting of paired sample results, contained sufficient information to indicate that weighing imprecision was less than what MSHA had assumed in its February 18, 1994 notice. However, without an independent estimate of spatial variability applicable to these samples, it is not mathematically possible to utilize this data set to estimate variability attributable to the sampler unit or the volume of air sampled. A second data set consisted only of differences in dust concentration between paired samples, making it impossible to use it even for evaluating weighing imprecision. The remaining three data sets included effects of shift-to-shift variability, which, like spatial variability, would not be relevant to the measurement objective. Therefore, none of these data could be used to estimate overall measurement imprecision. Further details are provided in Appendix C.

One of the previous commenters particularly questioned the value MSHA used in its February 18, 1994 proposed notice of Joint Finding to represent variability in initially setting the pump flow rate. In response to this commenter's suggestion, MSHA conducted a study to verify the magnitude of this variability component. This study simulated flow rate adjustment under realistic operating conditions by including a number of persons checking and adjusting initial flow rate under various working situations (Tomb, September 1, 1994). Results showed the coefficient of variation associated with the initial flow

[20] Many of the recommendations in the GAO report were later adopted and implemented by MSHA.

rate adjustment to be 3 ± 0.5 percent, which is less than the 5-percent value used by MSHA in the February 1994 notice. In addition, based on a review of published results, the Secretaries would conclude that the component of uncertainty associated with the combined effects of variability in flow rate during sampling and potential errors in calibration is actually less than 3 percent. As explained in Appendix B, these two sources of uncertainty can be combined to estimate CV_{pump}. After reviewing the available data and the comments submitted, the Secretaries would conclude that the best estimate of CV_{pump} is 4.2 percent. Additional details regarding CV_{pump}, along with the Secretaries' responses to comments, are presented in Appendix B.

Intersampler variability, represented by $CV_{sampler}$, accounts for uncertainty due to physical differences from sampler to sampler. Most of the previous commenters ignored this source of uncertainty. As explained in Appendix B, the Secretaries would adopt a 5-percent estimate of $CV_{sampler}$.

To address previous commenters' concerns that the Agencies had underestimated CV_{total}, MSHA conducted a field study to directly estimate the overall measurement precision attainable when dust samples are collected with currently approved sampler units and analyzed using state-of-the-art analytical techniques. The study involved simultaneous field measurements of the same coal mine dust cloud using sampling pumps incorporating constant flow technology. Using a specially designed portable dust chamber, 22 tests were conducted at various locations in an underground coal mine. Each test consisted of collecting 16 dust samples simultaneously and at the same location. No adjustments in the flow rate were made beyond what would routinely have been done by an MSHA inspector.

Prior to the field study, two modifications to MSHA's sampling and analytical method had been considered by MSHA and NIOSH: (1) Measuring both the pre-and post-exposure weights to the nearest microgram (µg) on a balance calibrated using the established procedure within MSHA's Respirable Dust Processing Laboratory; and (2) discontinuing the practice of truncating the recorded weights used in calculating the dust concentration. These modifications were incorporated into the design of the field study.

One previous commenter characterized the field study as being ''woefully incomplete'' because it was conducted ''in a tightly controlled environment * * * not subject to normal environmental variation.'' While it is true that the samples within each test were not subject to normal environmental variability, this was because the experiment was deliberately designed to avoid confusing spatial variability in dust concentration with measurement error. However, pumps were handled and flow rates were checked in the same manner as during routine sampling. Furthermore, the sampler units were disassembled and reassembled in the normal manner to remove and replace dust cassettes.

Previous commenters also questioned the value that MSHA used in the February 1994 proposed notice of Joint Finding to represent uncertainty due to potential weighing errors. In September 1994, MSHA submitted into the record an analysis based on replicated weighings for 300 unexposed filter capsules, each of which was weighed once by the cassette manufacturer and twice in MSHA's laboratory (Kogut, May 12, 1994). An estimate of weighing imprecision derived from this analysis was used by NIOSH in its September 20, 1995 assessment of MSHA's sampling and analytical procedure (discussed in more detail later in section X.E.)

In the March 12, 1996 notice concerning the NIOSH Accuracy Criterion, MSHA described the results of an investigation into repeated weighings of the same capsules made over a 218-day period using MSHA's automatic weighing system. It was noted that after approximately 30 days, filter capsules left exposed and unprotected gained a small amount of weight—an average of 0.8 µg (micrograms) per day. Neither NIOSH nor MSHA considered this a problem, since all dust samples are analyzed within 24 hours of receipt and are not left exposed and unprotected. However, more recent data collected to quantify weighing variability between the Mine Safety Appliances Co. and MSHA laboratories showed that filter capsules tend to gain a small amount of weight even when stored in plastic cassettes (Parobeck, *et al.*, 1997). To check this result, 75 unexposed filter cassettes that had been distributed to MSHA's district offices were recalled and the filter capsules were reweighed. On average, the weight gain was about 40 µg over a time period of roughly 150 days. Statistical analyses of these data performed by MSHA and NIOSH confirmed the previous result (Parobeck, *et al.*, 1997; Wagner, May 28, 1997). While the cause has not been established, it is hypothesized that at least some of the observed weight gain may be the result of outgassing from the plastic cassette onto the filter capsule. If uncorrected, any systematic change in weight not due to coal mine dust would introduce a bias in dust concentration measurements.

One commenter had previously stated that the Secretaries were addressing only precision, thereby implying that potential biases were being ignored. To eliminate the potential for any bias due to a spurious gain or loss of filter capsule weight, MSHA has used control filter capsules in its enforcement program since April 30, 1998. Any change in weight observed for the control filter capsule will be subtracted from the measured change in weight of the exposed filter capsule. Each control filter capsule will be pre-weighed with the other filter capsules, will be stored and transported with the other capsules, and will be on the inspector's person during the day of sampling. This 1998 modification to MSHA's inspector sampling and analytical procedure will ensure an unbiased estimate of the true weight gain (Wagner, May 28, 1997).

(a) Experience Gained From Use of Control Filters

As explained above under the headings of ''Sample Processing'' and ''Quantification of Measurement Uncertainty'', evidence of relatively small weight gains in unexposed filter capsules led MSHA, in 1998, to begin using unexposed control filters to adjust the weight gains measured for exposed filters. Under the new system, respirable coal mine dust samples taken by MSHA inspectors are matched with unexposed control filter capsules. For an inspector sample to be valid, the matching, unexposed control filter capsule must have been weighed on the same two days as the exposed capsule—initially before exposure and then, for a second time, afterwards.

From April 30, 1998 through December 31, 1998, a total of 5,578 such control filter capsules were weighed for the second time in MSHA's laboratory after having been sent out to the field. Although MSHA's new processing system was not fully implemented before April 30, 1998, many of these control filter capsules which were constructed with Tyvek®, along with the corresponding exposed capsules, were initially weighed prior to 1998. The time intervals between first and second weighings ranged from 32 to 608 days. Excluding six filter capsules that were broken, misidentified, improperly labeled, or contaminated, weight gains measured for the remaining 5,572 unexposed filter capsules ranged from a maximum of 420 µg down to a negative 317 µg (*i.e.*, a weight loss of 317 µg). Approximately 50% of the unexposed filter capsules showed a weight gain of 15 µg or more. The mean weight gain measurement (counting losses as negative gains) was 14.0 µg, and the standard deviation was 24.6 µg. The initial and second weight measurements for each of these control filter capsules which were constructed with Tyvek® support pads, along with the measurement dates, are being placed into the public record for analysis and comment by interested parties.

As explained earlier, if an unexposed control filter either shows a weight gain greater than 100 µg or a weight loss greater than 30 µg, then, instead of using it to make any adjustment, MSHA simply voids the corresponding coal mine respirable dust sample. This occurred in 126 cases, leaving 5,446 cases in which the control filter was actually used to adjust a dust sample. For these 5,446 control filters, the mean weight gain measurement was 14.8 µg, and the standard deviation was 19.2 µg. Consequently, weight gains observed in exposed filters were reduced by about 15 µg, on average, through the end of 1998. This corresponds to an average reduction in measured dust concentration of about 0.02 mg/m^3 for a 480-minute dust sample. Individual dust concentration measurements, however, were reduced by up to 0.14 mg/m^3 (corresponding to a 100-µg weight gain measured for the control filter) or increased by up to 0.04 mg/m^3 (corresponding to a 30-µg weight loss for the control filter).

Variability in unexposed filter weight gain measurements, as expressed by the standard deviation of 24.6 µg, consists of three components: (1) random weighing errors; (2) spurious but real changes in weight, such as might be due to contamination or outgassing from the plastic filter cassette onto the filter capsule; and (3) effects of any changes in laboratory conditions between the first and second weighings. Each of these three effects also contributes to uncertainty in the amount of coal mine dust accumulated on an exposed filter.

MSHA's purpose in using unexposed control filters to adjust weight gains measured for exposed filters is to eliminate the second and third of these components as sources of measurement uncertainty for the exposed filters. Unfortunately, the control filter adjustment cannot eliminate the first component, comprised of random weighing errors. To the contrary, making the adjustment based on a single control filter doubles the number of weighings required to establish weight gain for an exposed filter. This increases (by a factor of √2) uncertainty due to the random error potentially associated with each weighing. Therefore, there is a tradeoff in applying the control filter adjustment: the adjustment improves accuracy only if it succeeds in reducing uncertainty due to changes in laboratory conditions and spurious changes in filter weight by an amount greater than the increase in uncertainty resulting from the additional weighings required.

Estimates representing the first component (*i.e.,* the standard deviation of random errors in measuring the change in weight of a filter capsule) are presented in Appendix C and range from 8.2 µg to 11.3 µg for Tyvek®-supported filters under MSHA's current procedures. Even if the true value were so high as 11.3 µg, then applying the control filter adjustment increased this source of uncertainty to no more than $11.3 \cdot \sqrt{2} = 16.0$ µg. This is still substantially less than the 24.6 µg standard deviation observed in CNTRL_98, which includes, in addition to random weighing errors, the effects of variability in laboratory conditions and spurious but real changes in filter weight (MSHA, Data file: CNTRL_98, 1999). Therefore, so long as the control filter adjustment successfully eliminated these latter sources of variability, its net effect was to reduce uncertainty in the amount of respirable coal mine dust deposited on an exposed filter.

Control filters, however, fully eliminate the effects of day-to-day variation in laboratory conditions and spurious changes in filter weight only if these effects are consistent for all filters weighed on the same days and sent out to the same field location for the same length of time between weighings. In the absence of evidence to the contrary, MSHA and NIOSH consider this to be a reasonable assumption in the case of laboratory effects: any systematic differences in laboratory conditions between the dates of initial and final weighing should have essentially the same effect on weights recorded for unexposed filter capsules as for exposed filter capsules.

The remaining component of uncertainty, resulting from spurious but real weight changes such as might be caused by outgassing or contamination, is eliminated by the control filter adjustment only to the extent that such effects are consistent for all filters pre-weighed on the same day, sent out to the same field location, and then post-weighed on the same day. MSHA checked this assumption for currently approved filter capsules—*i.e.,* those employing Tyvek® support pads—using a body of control filter data being placed into the public record (MSHA, Data file: NHSCP_99, 1999).

The NHSCP_99 dataset consists of 108 ''batches'' in which several control filter capsules were first weighed on the same day, taken to the same mine site (but left unexposed), and then all weighed again on the same day in 1999. For example, a batch of six capsules may have been initially weighed on December 19, 1997, left unexposed during a mine visit on February 23, 1999, and then weighed for the second time on March 2, 1999. The NHSCP_99 data set contains information on a total of 564 filter capsules, divided into 108 such batches so that, on average, there were about five unexposed filter capsules per batch. The time interval between initial and final weighings averaged 335 days and ranged from 136 to 694 days. Closely matching results from CNTRL_98, the overall mean weight gain recorded for these unexposed filter capsules was about 14 µg, and the overall standard deviation was about 25 µg.

If changes in weight are indeed consistent for control filters subjected to similar handling and aging effects, then variability in weight gains within batches should not significantly exceed variability attributable to random weighing errors alone. MSHA's statistical analysis of NHSCP_99, however, indicated that variability in weight gains within batches was significantly greater than what can be attributed to random weighing errors under current processing procedures (Kogut, *et al.,* 1999). MSHA's estimate of the standard deviation of weight gains measured for unexposed filters within batches was 19.8 µg. This suggests that, for filter capsules employing Tyvek® support pads, the effects on weight gain of handling, aging, and/or environment may not be uniform—even when the filter capsules are treated similarly.

MSHA then performed a field experiment to determine if modifying the filter capsule would reduce variability due to spurious changes in weight (Kogut, *et al.,* 1999). In this experiment, 300 unexposed filter capsules employing the standard Tyvek® support pad were compared with a matched set of 300 unexposed modified capsules employing a stainless steel support pad (MSHA, Data file: MFSC.xls, 1999). Ninety-nine different MSHA inspectors used three of each type of filter capsule as controls during coal mine dust inspections at 100 different MMUs in 100 different mines. All six unexposed capsules used in an inspection were carried and handled by the inspector in the same way as during routine dust inspections. Also in accordance with MSHA's normal practice, all filter capsules in the batch used for an inspection were pre- and post-weighed on the same pair of days at MSHA's Respirable Dust Weighing Laboratory.

MSHA's statistical analysis of the MFCS data indicated that substituting a stainless steel support pad for the Tyvek® support pad currently in use, in both exposed and unexposed filter capsules, could significantly improve measurement accuracy. This modification reduced the standard deviation of weight gains measured for unexposed filters within batches to 11.6 μg.

MSHA and NIOSH would welcome further statistical analysis of the datasets being placed into the public record with this notice. The Agencies would also welcome suggestions on how MSHA might further modify its analytical procedures to reduce uncertainty in the amount of dust deposited on an individual filter.

2. Verification of Method Accuracy

NIOSH's first independent analysis of MSHA's sampling and analytical method involved MSHA's 1995 field study data.[21] These data incorporated certain improvements that NIOSH had proposed for MSHA's sampling and analytical method. As described elsewhere in this notice, these improvements were later adopted for all MSHA inspector samples. From these data, NIOSH determined, with 95-percent confidence, that the true CV_{total} for MSHA's proposed sampling and analytical method was less than the target maximum value of 12.8 percent for dust concentrations of 0.2 mg/m³ or greater (Wagner, 1995). This demonstrated that MSHA's sampling and analytical method for collecting and processing single full-shift samples would meet the NIOSH Accuracy Criterion whenever the true dust concentration was at least 0.2 mg/m³.

In the same report NIOSH also applied an indirect approach for assessing the accuracy of MSHA's sampling and analytical method. The indirect approach involved combining separate estimates of weighing imprecision, pump-related variability, and variability associated with physical differences between individual sampler units. This indirect approach also indicated that MSHA's sampling and analytical method would meet the NIOSH Accuracy Criterion at concentrations greater than or equal to 0.2 mg/m³, thereby corroborating the analysis of MSHA's field data.

As discussed above, MSHA later obtained data suggesting that filter capsules containing Tyvek® backup pads sometimes exhibit spurious changes in weight. Although the changes observed were relatively small, compared to weight gains required for MSHA's noncompliance determinations, this led MSHA to begin using unexposed control filters in its enforcement program. As explained in Appendices A and B, the use of a control filter adjustment eliminates systematic errors due to such effects, but also affects the precision of a single, full-shift measurement. Consequently, NIOSH reassessed the accuracy of MSHA's sampling and analytical method, taking into account the effects of using a control filter capsule (Wagner, May 28, 1997). After accounting for the effects of control filter capsules on both bias and precision, NIOSH concluded, based on both its direct and indirect approaches, that a single, full-shift measurement will meet the NIOSH Accuracy Criterion at true dust concentrations greater than or equal to 0.3 mg/m³.

As part of its ongoing commitment to improving the sampling and analytical method, MSHA recently compiled data showing that weight stability of the filter capsule would be improved by substituting stainless steel support grids for the Tyvek® support pads currently in use (Kogut *et al.,* 1999). Therefore, NIOSH again reassessed the accuracy of MSHA's method, this time taking into account the proposal to switch to stainless steel support grids (Grayson, 1999a; 1999b). After accounting for the effects of switching to stainless steel support grids, and of using unexposed control filters to adjust for any potential systematic errors that might remain, NIOSH once again concluded that a single, full-shift measurement will meet the NIOSH Accuracy Criterion at true dust concentrations greater than or equal to 0.3 mg/m³.

One previous commenter stated that the Secretaries ''have not addressed the 'accuracy' of a single sample collected from an environment where the concentration is unknown.'' The purpose of any measurement process is to produce an estimate of an unknown quantity. The Secretaries have concluded that MSHA's sampling and analytical method for inspectors meets the NIOSH Accuracy Criterion for true concentrations at or above 0.3 mg/m³, but it is also possible to calculate the range of measurements for which the Accuracy Criterion is fulfilled. Since CV_{total} increases at the lower concentrations, all that is necessary is to determine the lowest measurement at which the NIOSH Accuracy Criterion is met. This is done as follows. If the true concentration exactly equaled the lowest concentration at which MSHA's sampling and analytical method meets the Accuracy Criterion (i.e., 0.3 mg/m³), then no more than 5% of single, full-shift measurements would be expected to exceed 0.36 mg/m³ (Wagner, May 28, 1997). Conversely, if a measurement equals or exceeds 0.36 mg/m³, it can be inferred, with at least 95% confidence, that the true dust concentration equals or exceeds 0.3 mg/m³ (Wagner, May 28, 1997). Consequently, the Secretaries conclude that MSHA's improved sampling and analytical method satisfies the NIOSH Accuracy Criterion whenever a single, full-shift measurement is at or above 0.36 mg/m³.

The Secretaries recognize that future technological improvements in MSHA's sampling and analytical method may reduce CV_{total} below its current value. Also, as additional data are accumulated, updated estimates of CV_{total} may become available. However, so long as the method remains unbiased and CV_{total} remains below 12.8 percent, at a 95-percent confidence level, the sampling and analytical method will continue to meet the NIOSH Accuracy Criterion, and the present finding will continue to be valid.

XI. Proposed New Finding and Proposed Rescission of the 1972 Joint Finding

The Secretaries have concluded that sufficient data exist for determining the uncertainty associated with a single, full-shift measurement; rigorous requirements are in place, as specified by 30 CFR parts 70, 71, and 90, to ensure the validity of a respirable coal mine dust sample; and valid statistical techniques were used to determine that MSHA's improved dust sampling and analytical method meets the NIOSH Accuracy Criterion. For these reasons the Secretaries would find that a single, full-shift measurement at or above 0.36 mg/m³ will accurately represent atmospheric conditions to which a miner is exposed during such shift. Therefore, pursuant to section 202(f) (30 U.S.C. 842(f)) and in accordance with section 101 (30 U.S.C. 811) of the Mine Act, the 1972 joint notice of finding would be rescinded.

XII. Feasibility Issues

Section 101(a)(6)(A) of the Mine Act (30 U.S.C. 811(a)(6)(A)) requires the Secretary of Labor to set standards which most adequately assure, on the basis of the best available evidence, that

[21] With its field study, MSHA exceeded the usual requirements for determining the accuracy of a sampling and analytical method, as described by NIOSH (Kennedy, *et al.,* 1995) and the European Community (European Standard No. EN 482, 1994). Both of these require only a laboratory determination of method accuracy.

no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to such hazards dealt with by such standard over his or her working lifetime. 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 and other health and safety laws.

In relation to promulgating health standards, the legislative history of the Mine Act states that:

> * * * This section further provides that ''other considerations'' in the setting of health standards are ''the latest available scientific data in this 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.
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> * * * * *
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> Similarly, information on the economic impact of a health standard which is provided to the Secretary of Labor at a hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of section 102(a)(5)(A), the Committee wishes to emphasize that it rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure.

S. Rep. No. 95–181, at 21–22 (1977), reprinted in 1977 U.S.C.C.A.N. 3421–22.

In *American Textile Manufacturers' Institute* v. *Donovan,* 452 U.S. 490, 508–509 (1981), the Supreme Court defined the word ''feasible'' as ''capable of being done, executed, or effected.'' The Court further stated, however, that a standard would not be considered economically feasible if an entire industry's competitive structure were threatened. In promulgating standards, hard and precise predictions from agencies regarding feasibility are not required.

A. Technological Feasibility

MSHA, in consultation with NIOSH, believes that compliance determination based on an inspector, single, full-shift exposure measurement would be technologically feasible for the mining industry. 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. *American Iron and Steel Institute* v. *OSHA,* (AISI–II) 939 F.2d 975, 980 (D.C. Cir. 1991); *American Iron and Steel Institute* v. *OSHA,* (AISI–I) 577 F.2d 825 (3d Cir. 1978) at 832–835; and *Industrial Union Dep't., AFL–CIO* v. *Hodgson,* 499 F.2d 467, 478 (D.C. Cir. 1974).

This NPRM would not be a technology-forcing standard. The single, full-shift sample rule when promulgated predominantly affects MSHA's procedures since MSHA alone conducts inspector sampling. After the promulgation of single, full-shift sample rule, coal mine operators would continue to comply with the existing respirable dust concentration limit of 2.0 mg/m³. Such compliance with the applicable standard has proven feasible over the years. Furthermore, single, full-shift samples were found to be technologically feasible during the prior effective Interim Single-Sample Enforcement Policy (ISSEP), March 2, 1998 through September 4, 1998 (see section V.D. of the preamble detailing the ISSEP).

B. Economic Feasibility

MSHA, in consultation with NIOSH, believes that the single full shift sample (SFSS) rule would be economically feasible for the coal mining industry. The coal mining industry would incur costs of approximately $1.8 million yearly to comply with the proposed SFSS rule. Coal mine operators would also incur approximately an additional $0.2 million yearly in penalty costs associated with the additional citations arising from the proposed SFSS rule. That the total $2.0 million borne yearly by the coal mining industry as a result of the proposed SFSS rule is well less than 1 percent (about 0.01 percent) of the industry's yearly revenues of $19.8 billion provides convincing evidence that the proposed rule is economically feasible.

Economic feasibility does not guarantee the continued existence of individual employers—''A standard is not infeasible simply because it is financially burdensome, * * * or even because it threatens the survival of some companies within an industry:'' *United Steelworkers of America* v. *Marshall,* 647 F.22d 1189, 1265 (D.C. Cir. 1981).

This rule would not threaten the industry's competitive structure. After the promulgation of single, full-shift sample rule the Agencies expect that coal mine operators would continue to comply with the existing respirable dust concentration limit of 2.0 mg/m³. Single, full-shift samples were found to be economically feasible during two prior effective periods—July 15, 1991 through December 31, 1993, and March 2, 1998 through September 4, 1998—when noncompliance determinations were based on the results of MSHA inspector single samples. No disruption in mining activity was attributed to MSHA's single-sample enforcement policy during either of these periods.

XIII. Regulatory Impact Analysis

MSHA's improved program to eliminate overexposures on each and every shift includes (1) the simultaneous implementation of the use of inspector single, full-shift respirable coal mine dust samples to identify overexposures more effectively in both underground and surface coal mines (single, full-shift sample), and (2) in underground coal mines, verified ventilation plans to maintain miners' respirable dust exposure at or below the applicable standard on each and every shift (plan verification). The plan verification NPRM is published elsewhere in today's **Federal Register**. This part of the preamble reviews several impact analyses which the Agencies are required to provide in connection with the single, full-shift sample proposed rulemaking. Since single, full-shift sample and plan verification are complementary NPRMs intended to be promulgated at the same time, the detailed presentation of assumptions and estimates for each are available in the same Preliminary Regulatory Economic Analysis (PREA)(MSHA, December 1999).

Assumptions for single, full-shift sample requirements are based upon information provided by MSHA technical personnel. We encourage the mining community to provide detailed comments in this regard to ensure that single, full-shift sample cost assumptions and estimates are as accurate as possible.

A. Costs and Benefits: Executive Order 12866

In accordance with Executive Order 12866, the Agencies have prepared a detailed PREA of the estimated costs and benefits associated with the proposed rule for the underground and surface coal mining sectors. We have fulfilled this requirement for the proposed rule and determined that this rulemaking is not a significant regulatory action. The key findings of the PREA are summarized below.

1. Compliance Costs

The Agencies estimate that the cost of this NPRM would be approximately $1.8 million annually, of which all but about $5,200 would be borne by underground coal mine operators (the residual $5,200 to be borne by surface coal mine operators). Table XIII–1 summarizes the estimated compliance costs by provision, for underground and surface coal mines, for the following three mine size categories: (1) those employing fewer than 20 workers; (2) those employing between 20 and 500 workers; and (3) those employing more than 500 workers.

The compliance costs arising from the single, full-shift sample NPRM would occur as a result of a slight increase in the number of MSHA inspector citations issued to underground and surface coal mine operators due to the determination of noncompliance with the respirable coal mine dust standard being based on inspector single, full-shift samples rather than the average of multiple inspector exposure measurements. The additional citations due to single, full-shift sample would require mine operators to undertake the following actions and to incur associated compliance costs: take corrective action(s) in order to get back into compliance with the applicable respirable coal mine dust standard; perform abatement sampling; complete dust data cards; send abatement samples to MSHA; post abatement sample results; write respirable dust plans; and post or give a copy of dust plans.

In addition to these estimated compliance costs, mine operators would incur yearly penalty cost increases of about $0.2 million. Penalty costs conventionally are not considered to be a cost of a rule (and, in fact, are clearly not a compliance cost) but merely a transfer payment from a party violating a rule to the government. Therefore, the penalty costs are not included as part of the compliance costs of the proposed SFSS rule noted above. These penalty costs are relevant, however, in determining the economic feasibility of the proposed SFSS rule.

The derivation of the above cost figures are presented in Chapter IV of the PREA that accompanies this rule.

TABLE XIII–1.—SUMMARY OF COMPLIANCE COSTS FOR SINGLE, FULL-SHIFT SAMPLE PROPOSED RULE

Estimated costs by category	< 20 emp.	> 20 emp. < 500	> 500 emp.	Total
UNDERGROUND COAL MINES				
Corrective Actions	$328,488	$1,266,767	$19,527	$1,614,782
Abatement Sampling	38,658	128,264	1,129	168,051
Dust Data Cards	717	2,588	37	3,343
Send Sample to MSHA	1,200	4,331	62	5,593
Post Sample Results	241	865	12	1,117
Write Dust Plan	151	302	0	453
Post or Give Dust Plan	3	5	0	8
Total Underground	369,457	1,403,122	20,769	1,793,348
SURFACE COAL MINES				
Corrective Actions	366	2,194	0	2,560
Abatement Sampling	594	1,394	0	1,989
Dust Data Cards	3	13	0	17
Send Sample to MSHA	6	22	0	28
Post Sample Results	4	8	0	12
Write Dust Plan	151	453	0	604
Post or Give Dust Plan	3	8	0	10
Total Underground	1,127	4,094	0	5,220
UNDERGROUND AND SURFACE COAL MINES				
Corrective Actions	328,854	1,268,961	19,527	1,617,342
Abatement Sampling	39,252	129,658	1,129	170,040
Dust Data Cards	720	2,602	37	1,282
Send Sample to MSHA	1,205	4,353	62	5,621
Post Sample Results	245	873	12	1,129
Write Dust Plan	302	756	0	1,058
Post or Give Dust Plan	5	13	0	18
Grand Total	370,584	1,407,215	20,769	1,798,568

* Totals may vary due to rounding.

2. Benefits

Occupational exposure to excessive levels of respirable coal mine dust imposes significant health risks. These include the following adverse health outcomes: simple coal workers' pneumoconiosis (simple CWP), progressive massive fibrosis (PMF), silicosis, and chronic obstructive pulmonary disease (COPD) (e.g., asthma, chronic bronchitis, emphysema) (see the Health Effects section for details). Cumulative exposure to respirable coal mine dust is the main determinant in the development of both simple CWP and PMF although other factors such as the percentage of quartz in the respirable dust and the type of coal also affect the risk of miners developing simple CWP and PMF (Jacobsen, *et al.,* 1977; Hurley, *et al.,* 1987; Kuempel, *et al.,* 1995; Attfield and Morring, 1992; Attfield and Seixas, 1995). The true magnitude of occupationally induced simple CWP and PMF among today's coal miners is unknown, although prevalence estimates are available from various surveillance systems. For example, from 1970 to 1995, the prevalence of simple CWP and PMF among miners, based on the operator sponsored x-ray program, dropped from 11 percent to 3 percent (MSHA, Internal Chart, 1998). Also, later rounds of the National Study for Coal Worker's Pneumoconiosis consistently demonstrated, through prevalence rates in the range of 2.9–3.9 percent, that simple CWP and PMF have not been eliminated.

Through the joint promulgation of single, full-shift sample and plan verification rules, miners would be further protected from the debilitating effects of occupational respiratory disease by limiting their exposures to respirable coal mine dust to no more than the applicable standard on each and every shift.[22] Reducing respirable coal mine dust concentrations over a 45-year occupational lifetime to no more than the applicable standard on just that percentage of shifts currently showing an excess would lower the cumulative exposure, thereby significantly reducing the risk of both simple CWP and PMF among miners. We have estimated the health benefits of the two rules arising from the elimination of overexposures on all shifts at only those MMUs exhibiting a pattern of recurrent overexposures on individual shifts.

Based on 1999 operator data, there were 704 MMUs (out of 1,251) at which regular (not abatement) designated occupational (D.O.) samples exceeded the applicable standard on at least two of the sampling shifts reported in 1999 (MSHA, Data file: Operator.ZIP).[23] MSHA considers these 704 MMUs, representing more than one-half of all underground coal miners working in production areas, to have exhibited a pattern of recurrent overexposures. Based on valid D.O. operator samples collected on a total of 18,569 shifts at these 704 MMUs, the applicable standard was exceeded on about on 3,977 of these shifts or 21.4 percent.

At the MMUs being considered (those exhibiting a pattern of recurrent overexposures),[24] bringing dust concentrations down to no more than the applicable standard on each and every production shift would reduce D.O. exposures on the affected shifts by an average of 1.04 mg/m^3. Assuming this average reduction applies to only 21 percent of the shifts, the effect would be to reduce cumulative exposure, for each miner exposed at or above the D.O. level, by 0.22 mg-yr/m^3 over the course of a working year (i.e., 21 percent of shifts in one year times 1.04 mg/m^3 per shift). Therefore, over a 45-year working lifetime, the benefit to each affected D.O. miner would, on average, amount to a reduction in accumulated exposure of approximately 10 mg-yr/m^3 (i.e., 45 years times 0.22 mg-yr/m^3 per year). If, as some miners have testified, operator dust samples currently submitted to MSHA tend to under-represent either the frequency or magnitude (or both) of individual full-shift excursions above the applicable standard, then eliminating such excursions would provide a lifetime reduction of even more than 10 mg-yr/m^3 for each exposed miner.

When the dust concentration measured for the D.O. exceeds the applicable standard, measurements for at least some of the other miners working in the same MMU may also exceed the standard on the same shift, though usually by a smaller amount. Furthermore, although the D.O. represents the occupation most likely to receive the highest exposure, other miners working in the same MMU may be exposed to even higher concentrations than the D.O. on some shifts. Therefore, in addition to the affected D.O. miners, there is a population of other affected miners who are also expected to experience a significant reduction in risk as a result of eliminating overexposures on their individual shifts.

To estimate how many miners other than the D.O. would be substantially affected, MSHA examined the results from all valid dust samples collected by MSHA inspectors in underground MMUs during 1999 (MSHA, Data file: Inspctor.zip). Within each MMU, the inspector typically takes one full-shift sample on the D.O. and, on the same shift, four or more additional samples representing other occupations. On 896 shifts, at a total of 450 distinct MMUs, the D.O. measurement exceeded the applicable standard, and there were at least three valid measurements for other occupations available for comparison. There was an average of 1.2 non-D.O. measurements in excess of the standard on shifts for which the D.O. measurement exceeded the standard.[25] For non-D.O. measurements that exceeded the standard on the same shift as a D.O. measurement, the mean excess above the standard was approximately (0.8 mg/m^3).[26]

Combining these results with the 21-percent rate of excessive exposures observed for the D.O. on individual shifts, it is reasonable to infer that, at the MMUs under consideration, an average of 1.2 other miners, in addition to the one classified as D.O., is currently overexposed on at least 21 percent of all production shifts. Over the course of a working year, the reduction in exposure expected for these affected non-designated occupational (N.D.O.) miners, is 0.17 mg-yr/m^3 (i.e., 21 percent of one year, times 0.8 mg/m^3).

The expected lifetime for all American males, conditional on their having reached 20 years of age, is 73 years (U.S. Census March 1997, Table 18; U.S. Census March 1997, Table 119).[27] On average, the best estimate of the lifetime benefit to exposed miners is expressed by the reduction in prevalence of disease at age 73. To project the reduction in risk of simple CWP and PMF among affected D.O.s and N.D.O.s, MSHA applied its best estimate of dose response to a hypothetical cohort of underground coal miners who work on an MMU exhibiting a pattern of recurrent overexposure, and who, on average, begin working at age 20, retire at age 65, and live to age 73. Strengths and weaknesses of various epidemiological studies were presented in the Health Effects section supporting the selection of Attfield and Seixas (1995) as the study that provides the best available estimate of material impairment with respect to simple CWP and PMF. Two of the distinguishing qualities of Attfield and Seixas (1995) are the dose-response relationship over a miner's lifetime and the fact that these data best represent the recent conditions experienced by miners in the U.S. Using this relationship, it is possible to evaluate the impact on risk of both simple CWP and PMF expected from

[22] For details, see the Quantitative Risk Assessment and Significance of Risk sections.

[23] If a different definition of "exhibiting a recurrent pattern of overexposures" were used in these analyses the estimate of the reduction in risk and associated benefits would be different. For example, if the criterion were that four or more D.O. bimonthly exposure measurements exceeded the applicable standard then, with 95% confidence, at least 20 shifts would be overexposures in a year of 384 shifts. Using the four as the criterion, this would reduce the population for whom we are estimating benefits, and the estimated number of prevented cases would decrease by 19%.

[24] MSHA estimates an MMU average of 384 production shifts per year. Since miner operators are required to submit five valid designated operator (D.O.) samples to MSHA every two months, there would typically be 30 valid D.O. samples–for each MMU that was in operation for the full year. If dust concentrations on two or more of the sampled shifts exceed the standard, then it follows, at a 95-percent confidence level, that the standard was exceeded on at least six shifts over the full year.

[25] With 95-percent confidence, on shifts for which the D.O. measurement exceeds the standard, the mean number of other occupational measurements also exceeding the standard is at least 1.11.

[26] With 95-percent confidence, the mean excess is at least 0.72 mg/m^3

[27] Since females have a greater life expectancy than males, the expected benefits would increase if the proportion of female miners increases substantially in the future.

bringing respirable coal mine dust concentrations down to or below the applicable standard on every shift. This is the only contemporary epidemiological study of simple CWP and PMF providing such a relationship.

To estimate the benefits (i.e., number of cases of simple CWP and PMF prevented) of single, full-shift sample and plan verification rules combined, we applied these estimates of risk reduction to the estimated sub-populations of affected miners. As of February 12, 1999, there were 984 producing MMUs;[28] applying the pattern of recurrent overexposures among MMUs as identified in the Quantitative Risk Assessment, 56 percent, by mine size, we estimate there to be 552 affected MMUs (MSHA Table, November 18, 1999; MSHA Table, February 12, 1999). Based on MSHA's experience, we would expect one D.O. and seven N.D.O.s for each shift of production at each MMU. Therefore, among underground coal miners working on an MMU, we estimate 12.5% to be designated occupational miners and 87.5% to be non-designated occupational miners.

The benefits that would accrue to coal miners exposed to respirable coal mine dust and to mine operators, and ultimately to society at large, are substantial and take a number of forms. These proposed rules would reduce a significant health risk to underground coal miners, reducing the potential for illnesses and premature death and their attendant costs to miners, their employers, their families, and society.

The joint promulgation of these rules should realize a positive economic impact on the Department of Labor's (DOL's) Black Lung Program and relatedly on mine operators. The Black Lung Program compensates eligible miners and their survivors under the Black Lung Benefits Act. This program provides monthly payments and medical benefits (diagnostic and treatment) to miners who are found to be totally disabled by black lung disease, including cases of PMF and simple CWP. In 1986, DOL's Employment Standards Administration reported that 12% of approved cases of Black Lung Program were identified as cases of PMF based on chest radiographs, while sixty-four percent had simple CWP based on chest radiographs (ESA, 1986). For miners who stopped working in coal mines after 1969 and for whom the DOL can establish that the miner worked for the same operator for at least one calendar year, and that miner had at least 125 working days in that year, that operator is financially responsible for the miner's Black Lung benefit payment. If a responsible operator cannot be identified for an eligible miner, benefit payments are made by the Black Lung Disability Trust Fund. To the extent that these rules reduce overexposures to respirable coal mine dust, there should be fewer Black Lung Program cases. Therefore, over time, the associated financial outlay by responsible operators through either insurance premiums or direct payments of Black Lung benefits should be lower than would otherwise occur. The financial impact could be substantial (see discussion in Chapter IV, of the PREA). In 1980, the Black Lung Program estimated average lifetime payouts for responsible operators for married miners of about $248,700 dollars, assuming a 7-percent annual increase (ESA, 1980). In fiscal year 1999, 443 claims for Black Lung Benefits were accepted as new cases; sixty-six percent (293) are the financial responsibility of coal mine operators (Peed, 2000).

The most tangible benefit of these rules is the number of cases of simple CWP and PMF which would be prevented. Table XIII–2 presents the estimated number of cases of simple CWP and PMF that would be prevented among the 56 percent of MMUs currently exhibiting a pattern of recurrent overexposures. For all categories of simple CWP and PMF combined, we estimate 37 fewer of these cases among affected miners, than would otherwise occur without the promulgation of single, full-shift sample and plan verification rules. Eleven of these cases would be the most severe form of coal miners pneumoconiosis, PMF, and as such these cases could be interpreted as prevented premature deaths due to occupational exposure to respirable coal mine dust. Since simple CWP predisposes the development of PMF, it is important that it also be prevented (Balaan, *et al.,* 1993).

As discussed in the Significance of Risk sections, MSHA believes this QRA for simple CWP and PMF strikes a reasonable balance based on available data. Yet, our estimates likely understate the true impact of these rules since our analyses are restricted to a sub-population of affected miners, those working at MMUs exhibiting a pattern of recurrent overexposures, not the broader population of coal miners who would benefit from these rules. Furthermore, to estimate the average overexposure which would be prevented, MSHA had to use data collected for compliance purposes, which may not represent typical environmental conditions and the associated respirable coal mine dust exposure in underground coal mines.

The degree to which the exposure level of respirable coal mine dust on sampling shifts may not be representative of typical exposure levels is affected by the following factors:

(1) There exists a positive relationship between coal production and generation of respirable coal mine dust;

(2) Current sampling procedures permit sampling measurements to be taken at the mid-range of the distribution of the level of production—sampling measurements must be taken on shifts with production at least 60% of the average production during the last 30 days and at least 50% of average production for the last valid set of bimonthly samples for inspector and operator samples, respectively;

(3) Miners have reported and MSHA data have demonstrated lower levels of production on sampling shifts versus non-sampling shifts (MSHA, September 1993);

(4) On some sampling shifts, miners have reported that more engineering controls may be used than on other shifts, thus reducing the measured amount of respirable coal mine dust;

(5) MSHA analyses have demonstrated, even when controlling for production, in mines with fewer than 125 employees, on continuous mining MMUs, respirable coal mine dust exposures were much higher during the unannounced Spot Inspection Program (SIP) sampling shifts than on shifts operators sampled—this is consistent with the effect of increasing engineering controls on shifts during which bimonthly samples are conducted compared to the level of use of engineering controls used on shifts for which the operator does not expect sampling to be conducted given the same production level (Denk, 1993);

(6) Across mine size, designated area samples have been found to be larger for shifts on which unannounced compliance sampling occurred compared to operator sampling shifts—in one study they differed by at least a factor of 40 percent in large mines and 100 percent in the smallest mines (Ibid., pp. 211–212); and

(7) Existing MSHA technical information indicates that some reduction in production levels occurs during some sampling periods on longwalls (Denk, 1990).

Therefore, at a bare minimum, over an occupational lifetime (45-years) for miners who live to age 73 who worked

[28] Nine hundred and eighty-four refers to the number of MMUs operating on February 12, 1999. The 1,443 number mentioned previously refers to all MMUs in operation at any time in 1999.

at MMUs exhibiting a pattern of recurrent overexposures, we estimate at least 37 fewer cases of pneumoconiosis (simple CWP and PMF) than would otherwise occur without the promulgation of these rules.

Our current quantitative estimate of benefits demonstrates and qualitative discussions punctuate that these rules would have a significant positive impact on the health of our nation's coal miners when promulgated. Yet, due to the limitations in these data, we believe our benefit estimate may understate the number of cases of simple CWP and PMF which would be prevented over an occupational lifetime.

MSHA believes that cases of simple CWP and PMF would also be prevented among other types of underground miners, such as roofbolters working in designated areas (D.A.). Based on MSHA experience it is reasonable to expect roofbolter D.A.'s pattern of overexposures for respirable coal mine dust to be similar to that for miners with the highest exposure on a MMU. If so, we would expect 13 additional cases of simple CWP and PMF to be prevented. Affected D.A.s include D.A.s who work at the 56 percent of the MMUs under consideration who are exposed to dust concentrations similar to the D.O., over a 45-year occupational lifetime (MSHA Table, November 1999; MSHA Table, February 1999).

Also, it is reasonable to expect surface miners' health to be further protected by the promulgation of the SFSS rule alone since it would identify and require resolution of overexposures not previously identified and may thereby lower some miners' cumulative exposure to respirable coal mine dust. Furthermore, to the extent that cumulative exposure to respirable coal mine dust affects other adverse health outcomes, such as silicosis and chronic obstructive pulmonary disease, it is reasonable to expect a reduction in the number of cases and/or in the severity of cases for these diseases among surface and underground coal miners.

Although the effect cannot readily be quantified, to the extent that these rules would also reduce the cumulative exposure to respirable coal mine dust among some miners working in those MMUs currently not exhibiting overexposures, it is reasonable to expect that we would observe an incremental benefit among that sub-population of coal miners. Moreover, to the extent that the cumulative dust exposure is reduced for miners working in the ''outby'' areas, away from the mining face (i.e., MMU) where coal is extracted from the coal seam, they too may realize occupational health benefits due to the simultaneous promulgation of these proposals. Therefore, our best estimate of 37 prevented cases of simple CWP and PMF, combined, among all affected miners likely underestimates the true benefit realized by the coal mining workforce through the reduction of overexposures to no more than the applicable standard on each shift.

Clearly, PMF is associated with premature death. Since simple CWP may evolve to PMF, even after occupational exposure has ceased, it has the propensity to become a life-threatening illness. By reducing the total number of simple CWP and PMF cases among affected miners from 259 to 222, over 45 years,[29] these standards are projected to prevent an average of four cases of simple CWP and PMF for each 5-year interval.

For all those reasons previously identified, MSHA believes that its estimate of 37 prevented cases of simple CWP and PMF over a 45 year working life understates the true number of cases of simple CWP and PMF which would be prevented. This belief is further supported by the fact that during the past few years, the Black Lung Benefits Program has been approving roughly 400 claims each year. These claims come from individuals whose exposure for the most part came after the current standard of 2.0 was established in 1972. Thus, we believe the consistent identification, from year to year, of hundreds of new cases of simple CWP and PMF per year into the Black Lung Benefits Program supports our belief that the true lifetime occupational health benefits of the proposed rules are higher than we have estimated. Even assuming that the number of new claims would decline in future years simply due to the continuing decline in the number of coal miners, MSHA expects that assuring that future exposures are maintained below the 2.0 exposure limit will reduce the number of new cases of simple CWP and PMF by considerably more than 1 per year.

In addition to the prevention of simple CWP and PMF, each of the 8,640 affected miners at MMUs exhibiting a pattern of recurrent overexposures will realize some health benefit by limiting his or her cumulative exposure to respirable coal mine dust to no more than the applicable standard on each and every shift.

The expected number of prevented cases of simple CWP and PMF would not be realized for some time even after the pattern of overexposures has been minimized or eliminated. This is due, in part, to the latency (that is, the disease does not develop immediately after exposure) of the development of simple CWP and PMF and the pre-existing occupational exposure histories of members of the current coal mining workforce. Our estimated benefit is based on the estimated number of underground coal miners working at the mine face, 17,280. If the size of this workforce significantly changed in the future and the projected pattern of prevented overexposures remained the same, the number of cases of prevented simple CWP and PMF would need to be adjusted to account for the change.

Finally, even standing alone, without simultaneously requiring that the effectiveness of underground mine ventilation plans be verified (i.e., the Plan Verification NPRM), the proposed standard allowing MSHA to use single, full-shift samples to identify overexposures requiring corrective action would provide miners with health benefits.[30] Both the prospect of being cited for overexposure and the actual issuance of additional citations due to this rule would compel mine operators to be more attentive to the level of respirable dust in their mines. Therefore, it is reasonable to expect, over time, a further decline in the number of shifts during which the concentration of respirable coal mine dust is at or above the applicable standard. Thus, implementation of the single, full-shift sample strategy will, in and of itself, on average, lower miners' cumulative exposure to respirable coal mine dust. Since cumulative exposure to respirable coal mine dust is the main determinant in the development of both simple CWP and PMF, the Agencies are confident that the use of single, full-shift samples, by themselves, even without the help of a verified dust control plan, would result in better health protection to miners.

Various data, assumptions and caveats were used to conduct the quantitative risk assessment, significance of risk discussion, and benefits analyses. Therefore, we request any information which would enable us to conduct more accurate analyses of the estimated health benefits of the single, full-shift sample rule and plan verification rule, both individually, and in combination.

[29] Applying the estimated prevalence rate of 3.0 percent to the estimated population of affected miners (8,640) results in an estimate of 259 cases of simple CWP and PMF.

[30] See detailed discussion in the Significance of Risk section.

TABLE XIII–2.—OVER A WORKING LIFETIME AMONG AFFECTED MINERS, ESTIMATED NUMBER OF CASES OF CWP [A] AND PMF [B] PREVENTED DUE TO THE IMPLEMENTATION OF SINGLE-SAMPLE AND PLAN VERIFICATION

Type of miner	Affected miners, n=	Simple CWP categories 1, 2, 3 or PMF		Simple CWP categories 2 or 3 or PMF		PMF	
		Reduction in risk [c]	Prevented cases, n=	Reduction in risk [c]	Prevented cases, n=	Reduction in risk [c]	Prevented cases, n=
Affected Designated Occupational Miners [d]	1,080	18.0/1,000	19.4	9.8/1,000	10.6	5/1,000	5.5
Affected Non-Designated Occupational Miners [e]	7,560	2.3/1,000	17.4	1.3/1,000	9.8	1/1,000	5.3
Total ..	8,640	na	37	na	20	na	11

[a] Simple CWP: simple coal workers' pneumoconiosis.
[b] PMF: progressive massive fibrosis.
[c] Reduction in risk per 1,000 affected miners, over a 45-year working lifetime.
[d] Affected Designated Occupation (D.O.) Miners: includes all miners who work at the 56-percent of the Mechanized Mining Units under consideration and who are exposed to dust concentrations similar to the D.O., over a 45-year occupational lifetime.
[e] Affected Non-Designated Occupation (Non-D.O.) Miners: includes all underground faceworkers under consideration who are not classified as the D.O.

B. Regulatory Flexibility Certification and Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires MSHA and NIOSH to conduct an analysis of the effects of the single, full-shift sample rule on small entities. That analysis is summarized here; a copy of the full analysis is included in Chapter V of the Agencies' PREA in support of the proposed rule. The Agencies encourage the mining community to provide comments on this analysis.

The Small Business Administration generally considers a small entity in the mining industry to be one with 500 or fewer workers. MSHA has traditionally defined a small mine to be one with fewer than 20 workers, and has focused special attention on the problems experienced by such mines in implementing safety and health rules. Accordingly, the Agencies have separately analyzed the impact of the joint notice proposed rule both on mines with 500 or fewer workers and on those with fewer than 20 workers.

Pursuant to the Regulatory Flexibility Act, MSHA must determine whether the costs of the joint notice proposed rule constitute a ''significant impact on a substantial number of small entities.'' Pursuant to the Regulatory Flexibility Act, if an Agency determines that a proposed rule would not have such an impact, it must publish a ''certification'' to that effect. In such a case, no additional analysis is required (5 U.S.C. § 605). In evaluating whether certification is appropriate, MSHA utilized a ''screening test,'' comparing the costs of the joint notice proposed rule to the revenues of the affected coal sector. If the estimated costs are less than 1 percent of revenues for the affected entities, then the rule is assumed not to have a significant impact on small mine operators.

Table XIII–3 compares, for small underground and surface coal mines (using both MSHA's and SBA's definition), MSHA's estimated total annual compliance costs of the joint notice proposed rule to estimated annual revenues.

TABLE XIII–3.—ESTIMATED YEARLY REVENUES AND COSTS FOR SINGLE, FULL-SHIFT SAMPLE PROPOSED RULE FOR UNDERGROUND AND SURFACE COAL MINES

[dollars in thousands]

Mine size	Estimated yearly costs [a]	Estimated revenues [b]	Costs as percentage of revenues
Underground Coal Mines			
<20	$369.0	$249,418	0.1
≤500 [c]	1,770.5	6,883,339	0.03
Surface Coal Mines			
<20	1.1	498,935	<0.01
≤500	5.2	10,864,156	<0.01

[a] Estimated yearly costs are composed of only annual costs. There are no first year costs or annualized costs in the proposed rule.

[b] Data for revenues derived from: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations and Variances, based on 1997 Final MIS data (Quarter 1—Quarter 4), CM441, Cycle 1997/84; and U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998,* DOE/EIA–0384(98), July 1999, p. 203.
[c] Includes mines with fewer than 20 employees.

Table XIII–3 shows that under either MSHA's or SBA's definition of a small mine, for underground and/or surface coal mines, the estimated costs would be significantly less than one percent of revenues. As a result, MSHA is certifying that the single, full-shift sample rule for underground and surface coal mines would not have a ‘‘significant impact on a substantial number of small entities,'' and has performed no further analyses.

XIV. Other Statutory Requirements

A. Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, this rule does not include any Federal mandate that may result in increased expenditures by State, local, and tribal governments, or increased expenditures by the private sector of more than $100 million.

B. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95). The proposed SFSS rule has annual burden hours beginning in the first year and recurring every year thereafter. Both underground and surface coal mines have paperwork provisions under the proposed SFSS rule. Underground coal mine operators would incur 2,985 annual burden hours and associated costs of $70,822. Surface coal mine operators would incur 29 annual burden hours and associated costs of about $1,009. These burden hours relate to operators performing abatement sampling, completing dust data cards, mailing samples to MSHA for analysis, writing respirable dust plans, and posting respirable dust plans. Table XIV–1 shows the burden hours and associated costs for each SFSS paperwork provision by mine size for underground and surface mines.

TABLE XIV–1.—SUMMARY OF MINE OPERATORS' ANNUAL PAPERWORK BURDEN HOURS AND COSTS ARISING FROM THE SINGLE, FULL-SHIFT SAMPLE PROPOSED RULE *

Detail	<20 emp.		≥20 emp. ≤500		> 500 emp.		Total	
	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs
UNDERGROUND COAL MINES								
Abatement Sampling	575	$13,872	2,080	$50,181	30	$724	2,685	$64,776
Dust Data Cards	14	716	52	2,589	1	37	67	3,342
Send Samples to MSHA	48	910	173	3,292	2	47	224	4,250
Write Dust Plan	3	149	6	299	0	0	9	448
Post or Give Dust Plan	0.1	2	0.2	4	0	0	0	6
Total Underground	640	15,649	2,311	54,364	33	809	2,985	70,822
SURFACE COAL MINES								
Abatement Sampling	5	$121	10	$241	0	$0	15	$362
Dust Data Cards	0.1	6	0.3	12	0	0	0.4	19
Send Samples to MSHA	0.4	8	0.8	16	0	0	1.2	24
Write Dust Plan	3	149	9	448	0	0	12	597
Post or Give Dust Plan	0.1	2	0.3	6	0	0	0.4	7
Total Surface	9	286	20	723	0	0	29	1,009
UNDERGROUND AND SURFACE COAL MINES								
Abatement Sampling	580	$13,993	2,090	$50,422	30	$724	2,700	$65,138
Dust Data Cards	15	722	52	2,602	1	37	68	3,361
Send Samples to MSHA	48	918	174	3,308	2	47	225	4,273
Write Dust Plan	6	299	15	747	0	0	21	1,046
Post or Give Dust Plan	0	4	1	9	0	0	1	13
Grand Total	649	15,935	2,332	57,087	33	809	3,014	73,831

* Totals may vary due to rounding.

MSHA invites public comments and is particularly interested in comments which:

1. Evaluate whether the proposed collection of information (presented here and in MSHA's PREA) is necessary for the proper performance of the functions of MSHA, including whether the information will have practical utility;

2. Evaluate the accuracy of MSHA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, *e.g.*, permitting electronic submissions of responses.

Submission

MSHA and NIOSH have submitted a copy of this proposed rule to OMB for its review and approval of these information collections. Interested persons are requested to send comments regarding this information collection, including suggestions for reducing this burden, to the Office of Information and Regulatory Affairs, OMB New Executive Office Building, 725 17th St., NW, Rm. 10235, Washington, DC 20503, Attn: Desk Officer for MSHA. Submit written comments on the information collection not later than September 5, 2000.

MSHA's paperwork submission summarized above is explained in detail in the PREA. The PREA includes the estimated costs and assumptions for each proposed paperwork requirement related to this proposed rule. A copy of the PREA is available from MSHA. These paperwork requirements have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1995. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

C. National Environmental Protection Act

The National Environmental Policy Act (NEPA) of 1969 requires each Federal agency to consider the environmental effects of proposed actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the human environment. MSHA has reviewed the proposed standard in accordance with the requirements of the NEPA (42 U.S.C. 4321 *et seq.*), the regulation of the Council on Environmental Quality (40 CFR Part 1500), and the Department of Labor's NEPA procedures (29 CFR Part 11). As a result of this review, MSHA has preliminarily determined that this proposed standard will have no significant environmental impact.

Commenters are encouraged to submit their comments on this determination.

D. Executive Order 12630: Government Actions and Interference with Constitutionally Protected Property Rights

This proposed rule is not subject to Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

E. Executive Order 12988: Civil Justice Reform

The Agency has reviewed Executive Order 12988, Civil Justice Reform, and determined that this rulemaking will not unduly burden the Federal court system. The regulation has been written so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

F. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, protection of children from environmental health risks and safety risks, MSHA has evaluated the environmental health or safety effects of the proposed rule on children. The Agency has determined that this proposal would not have an adverse impact on children.

G. Executive Order 13084 Consultation and Coordination with Indian Tribal Governments

MSHA certifies that this proposed rule does not impose substantial direct compliance costs on Indian tribal governments.

H. Executive Order 13132 (Federalism)

We have reviewed this rule in accordance with Executive Order 13132 regarding federalism, and have determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

XV. Public Hearings

The Agencies will hold public hearings on the proposed rule. The hearings will be held in Prestonsburg, Kentucky, (Jenny Wiley State Resort Park); Morgantown, West Virginia; and Salt Lake City, Utah. The hearing dates, times, and specific locations will be announced by a separate document in the **Federal Register**. The hearings will be held under Section 101 of the Federal Mine Safety and Health Act of 1977.

Appendix A—The Effects of Averaging Dust Concentration Measurements

MSHA's measurement objective in collecting a dust sample is to determine the average dust concentration at the sampling location on the shift sampled. As discussed in the main text, MSHA and NIOSH find that a single, full-shift measurement can accurately represent the average full-shift dust concentration being measured. Nevertheless, because of sampling and analytical errors inherent in even the most accurate measurement process, the true value of the average dust concentration on the sampled shift can never be known with complete certainty. However accurate the representation, a measurement can provide only an estimate of the true dust concentration.

Throughout this appendix, some public comments made to February 18 and June 6, 1994 notices relevant to issues regarding single, full-shift sampling will be cited and addressed to emphasize key findings on accuracy and the effects of averaging dust concentration measurements. Some previous commenters contended that MSHA should not rely on single samples for making noncompliance determinations, because an average of results from multiple samples would estimate the true dust concentration more accurately than any single measurement.

Contrary to the views expressed by these commenters, averaging a number of measurements does not necessarily improve the accuracy of an estimation procedure. Consider, for example, an archer aiming at targets mounted at random and possibly overlapping positions on a long partition. Each arrow might be aimed at a different target. Suppose that an observer, on the opposite side of the partition from the archer, cannot see the targets but must estimate the position of each bull's eye by locating protruding arrowheads.

Each protruding arrowhead provides a measurement of where some bull's eye is located. If two arrowheads are found on opposite ends of the partition, averaging the positions of these two arrowheads would not be a good way of determining where any real target is located. To estimate the location of an actual target, it would generally be preferable to use the position of a single arrow. The average would represent nothing more than a "phantom" target somewhere near the center, where the archer probably did not aim on either shot and where no target may even exist.

The archery example can be extended to illustrate conditions under which averaging dust concentration measurements does or does not improve accuracy. If each arrowhead is taken to represent a full-shift dust sample, then the true average dust concentration at the sampling location on a given shift can be identified with the location of the bull's eye at which the corresponding arrow was aimed. The accuracy of a measurement refers to how closely the measurement can be expected to come to the quantity being measured. Statistically, accuracy is the combination of two distinct concepts: precision, which pertains to the consistency or variability of replicated measurements of exactly the same quantity; and bias, which pertains to the average amount by which these replicated measurements deviate from the quantity being measured. Bias and precision are equally important components of measurement accuracy.

To illustrate, arrows aimed at the same target might consistently hit a sector on the lower right side of the bull's eye. The protruding arrowheads would provide more or less precise measurements of where the bull's eye was located, depending on how tightly they were clustered; but they would all be biased to the lower right. On the other hand, the arrows might be distributed randomly around the center of the bull's eye, and hence unbiased, but spread far out all over the target. The protruding arrowheads would then provide unbiased but relatively imprecise measurements.

More complicated situations can easily be envisioned. Arrows aimed at a second target would provide biased measurements relative to the first target. Alternatively, if the archer always aims at the same target, the first shot in a given session might tend to hit near the center, with successive shots tending to fall off further and further to the lower right as the archer's arm tires; or shots might progressively improve, as the archer adjusts aim in response to prior results.

Averaging reduces the effects of random errors in the archer's aim, thereby increasing precision in the estimation procedure. If the archer always aims at the same target and is equally adept on every shot (i.e., if the arrowheads are all randomly and identically distributed around a fixed point), then averaging improves the estimate's precision without introducing any bias. Averaging in such cases provides a more accurate method of estimating the bull's eye location than reliance on any single arrowhead. If, however, the archer intentionally or unintentionally switches targets, or if the archer's aim progressively deteriorates, then averaging can introduce or increase bias in the estimate. If the gain in precision outweighs this increase in bias, then averaging several independent measurements may still improve accuracy. However, averaging can also introduce a bias large enough to offset or even surpass the improvement in precision. In such cases, the average position of several arrowheads can be expected to locate the bull's eye less accurately than the position of a single arrowhead.

I. Multi-Locational Averaging

Some previous commenters opposed MSHA's use of a single, full-shift measurement for enforcement purposes, claiming that determinations based on such measurements would be less accurate than those made under MSHA's existing enforcement policy of averaging multiple measurements taken on an MMU. There are two distinctly different types of multi-locational measurement averages that could theoretically be compiled on a given shift: (1) the average might combine measurements taken for different occupational locations and (2) the average might combine measurements all taken for the same occupational location. For MMUs, the averages used in MSHA's sampling program usually involve measurements taken for different occupational locations on the same shift. These are averages of the first type. MSHA's sampling program has never utilized averages of the second type. Therefore, those commenters who claimed that reliance on a single, full-shift measurement would reduce the accuracy of noncompliance determinations, as compared to MSHA's existing enforcement policy, are implicitly claiming that accuracy is increased by averaging across different occupational locations.

Averaging measurements obtained from different occupational locations on an MMU is like averaging together the positions of arrows aimed at different targets. The average of such measurements is an artificial, mathematical construct that does not correspond to the dust concentration for any actual occupational location. Therefore, this type of averaging introduces a bias proportional to the degree of variability in actual dust concentration at the various locations averaged.

The gain in precision that results from averaging measurements taken at different locations outweighs this bias only if variability from location to location is smaller than variability in measurement error. However, commenters opposed to MSHA's use of single, full-shift measurements for enforcement purposes argued that this is not generally the case and even submitted data and statistical analyses in support of this position. Commenters in favor of noncompliance determinations based on a single, full-shift measurement agreed that variability in dust concentration is extensive for different occupational locations and argued that MSHA's existing policy of measurement averaging is not sufficiently protective of miners working at the dustiest locations.

Since an average of the first type combines measurement from the dustiest location with measurements from less dusty locations, it must always fall below the best available estimate of dust concentration at the dustiest location. In effect, averaging across different occupational locations dilutes the dust concentration observed for the most highly exposed occupations or dustiest work positions. Therefore, such averaging results in a systematic bias against detecting excessive dust concentrations for those miners at greatest risk of overexposure.

A somewhat better case can be made for the second type of multi-locational averaging, which combines measurements obtained on the same shift from a single occupational location. As some previous commenters pointed out, however, there is ample evidence that spatial variability in dust concentration, even within relatively small areas, is frequently much larger than variability due to measurement error. Therefore, the same kind of bias introduced by averaging across occupational locations would also arise, but on a lesser scale, if the average measurement within a relatively small radius were used to represent dust concentration at every point in the atmosphere to which a miner is exposed. A miner is potentially exposed to the atmospheric conditions at any valid sampling location. Consistent with the Mine Act and implementing regulations, MSHA's enforcement strategy is to limit atmospheric dust concentration wherever miners normally work or travel. Therefore, the more spatial variability in dust concentration there is within the work environment, the less appropriate it is to use measurement averaging to enforce the applicable standard by averaging measurements obtained at different sampling locations.

Some of the previous comments implied that instead of measuring average dust concentration at a specific sampling location, MSHA's objective should be to estimate the average dust concentration throughout a miner's ''breathing zone'' or other area near a miner. If estimating average dust concentration throughout some zone were really the objective of MSHA's enforcement strategy, then averaging measurements made at random points within the zone would improve precision of the estimate without introducing a bias. This type of averaging, however, has never been employed in either the MSHA or operator dust sampling programs. MSHA's current policy of averaging measurements obtained from different zones does not address spatial variability in the area immediately surrounding a sampler unit. Therefore, even if averaging measurements from within a zone were somehow beneficial, this would not demonstrate that MSHA's existing enforcement policy is more reliable than basing noncompliance on a single, full-shift measurement.

Furthermore, if the objective were really to estimate average dust concentration throughout some specified zone on a given shift, then it would often be necessary to obtain far more than five simultaneous measurements within the zone. This is not only because of potentially large local differences in dust concentration. In order to use such measurements for enforcement purposes, variability in dust concentration within the sampled area would have to be estimated along with the average dust concentration itself. As some previous commenters correctly pointed out, doing this in a statistically valid way would generally require at least twenty to thirty measurements. One of these commenters also pointed out that such an estimate, based on even this many measurements in the same zone, could be regarded as accurate only under certain questionable assumptions about the distribution of dust concentrations. This commenter calculated that hundreds of measurements would be required in order to avoid these tenuous assumptions. Clearly, this shows that the objective of estimating average dust concentration throughout a zone is not consistent with any viable enforcement strategy to limit dust concentration on each shift in the highly heterogeneous and dynamic mining environment. The large number of measurements required to accurately characterize dust concentration over even a small area merely demonstrates why it is not feasible to base enforcement decisions on estimated atmospheric conditions beyond the sampling location.

MSHA and NIOSH recognize that a single, full-shift measurement will not provide an accurate estimate of average dust concentration anywhere beyond the sampling location. The Mine Act, however, does not require MSHA to estimate average dust concentration at locations that are not sampled or to estimate dust concentration averaged over any zone or region of the mine.

Instead, the Mine Act requires that a miner will not be exposed to excessive dust wherever he/she normally works or travels. This can be accomplished by maintaining the average dust concentration at each valid sampling location at or below the applicable standard during each shift.

II. Multi-Shift Averaging

Some previous commenters maintained that in order to reduce the risk of erroneous noncompliance determinations, MSHA should average measurements obtained from the same occupation on different shifts. These commenters contended that the average of measurements from several shifts represents the average dust concentration to which a miner is exposed more accurately than a single, full-shift measurement. Other commenters, who favored noncompliance determinations based on single, full-shift measurements, claimed that conditions are sometimes manipulated so as to produce unusually low dust concentrations on some of the sampled shifts. These commenters suggested that, due to these unrepresentative shifts, multi-shift averaging can yield unrealistically low estimates of the dust concentration to which a miner is typically exposed. Some of these commenters also argued that the Mine Act requires the dust concentration to be regulated on each shift, and that multi-shift averaging is inherently misleading in detecting excessive dust concentration on an individual shift.

Those advocating multi-shift averaging generally assumed that the measurement objective is to estimate a miner's average dust exposure over a period longer than an individual shift. This assumption is flawed, as shown by the fact that section 202(b) of the Mine Act specifies that each operator will continuously maintain the average concentration of respirable dust in the mine atmosphere during each shift at or below the applicable standard. Some of those advocating multi-shift averaging, however, suggested that MSHA should average measurements obtained on different shifts even if the quantity of interest is dust concentration on an individual shift. These commenters argued that averaging smooths out the effects of measurement errors, and that therefore the average over several shifts would represent dust concentration on each shift more accurately than the corresponding individual, full-shift measurement.

The Secretaries recognize that there are circumstances, not experienced in mining environments, under which averaging across shifts could improve the accuracy of an estimate for an individual shift. Just as averaging the positions of arrows aimed at nearly coinciding targets might better locate the bull's eye than the position of any individual arrow, the gain in precision obtained by averaging dust concentrations observed on different shifts could, under analogous circumstances, outweigh the bias introduced by using the average to estimate dust concentration for an individual shift. This would be the case, however, only if variability in dust concentration among shifts were small compared to variability due to measurement imprecision. It would do no good to average the location of arrows aimed at different targets unless the targets were at nearly identical locations.

To the contrary, several previous commenters pointed out that variability in dust concentration from shift to shift tends to be much larger than variability due to measurement error and introduced evidence in support of this observation. Measurements on different shifts are like arrows aimed at widely divergent targets. The more that conditions vary, for any reason, from shift to shift, the more bias is introduced by using a multi-shift average to represent dust concentration for any individual shift. Under these circumstances, any improvement in precision to be gained by simply averaging results is small compared to the bias introduced by such averaging. Therefore, the Secretaries have concluded that MSHA's existing practice of averaging measurements collected on different shifts does not improve accuracy in estimating dust concentration to which a miner is exposed on any individual shift. To paraphrase one previous commenter, averaging Monday's exposure measurement with Tuesday's does not improve the estimate of Monday's average dust concentration.

Some previous commenters argued that since the risk of pneumoconiosis depends on cumulative exposure, the measurement objective should be to estimate the dust concentration to which a miner is typically exposed and to identify cases of excessive dust concentration over a longer term than a single shift. Other previous commenters claimed that a multi-shift average does not provide a good estimate of either typical dust concentrations or exposures over the longer term. These commenters claimed that different shifts are not equally representative of the usual atmospheric conditions to which miners are exposed, implying that the average of measurements made on different shifts of a multi-day MSHA inspection tends to systematically underestimate typical dust concentrations.

The Secretaries interpret the Mine Act as requiring that dust concentrations be kept at or below the applicable standard on each and every shift. Nevertheless, the Secretaries recognize that, under certain conditions, the average of measurements from multiple shifts can be a better estimate of ''typical'' atmospheric conditions than a single measurement. This applies, however, only if the sampled shifts comprise a random or representative selection of shifts from whatever longer term may be under consideration. As shown below, evidence to the contrary exists, supporting those commenters who maintained that measurements collected over several days of a multi-day MSHA inspection do not meet this requirement. Therefore, the Secretaries have concluded that averaging such measurements is likely to be misleading even for the purpose of estimating dust concentrations to which miners are typically exposed.

Whether the objective is to measure average dust concentration on an individual shift or to estimate dust concentration typical of a longer term, the arguments presented for averaging across shifts all depend on the assumption that every shift sampled during an MSHA inspection provides an unbiased representation of dust exposure over the time period of interest.[31] To check this assumption, MSHA performed a statistical analysis of multi-shift MSHA inspections carried out prior to the SIP. This analysis, placed into the record in September 1994, examined the pattern of dust concentrations measured over the course of these multi-shift inspections and compared results from the final shift with results from a subsequent single-shift sampling inspection (Kogut, September 6, 1994b).

The analysis found that dust concentrations measured on different shifts of the same MSHA inspection were not randomly distributed. The later samples tended to show significantly lower results than earlier samples, indicating that dust concentrations on later shifts of a single inspection may decline in response to the presence of an inspector. Furthermore, the analysis provided evidence that the reduction in dust concentration tends to be reversed after the inspection is terminated. These two results led to the conclusion that averaging dust concentrations measured on different shifts of a multi-day MSHA inspection introduces a bias toward unrealistically low dust concentrations.

One previous commenter questioned the validity of this analysis, stating that ''there is absolutely no basis in the * * * report for the assertion that the trend is reversed after the inspection is terminated.'' This commenter apparently overlooked Table 3 of the report. That table shows a statistically significant reversal at those mine entities included in the analysis that were subsequently inspected under MSHA's SIP. Dust concentrations measured at these mine entities had declined significantly between the first and last days of the multi-shift inspection. It was primarily to address the commenter's implication that these reductions reflected permanent ''adjustments in dust control measures'' that the analysis included a comparison with the subsequent SIP inspection. An increase, representing a reversal of the previous trend, was observed on the single shift of the subsequent inspection, relative to the dust concentration measured on the final shift of the previous multi-shift inspection. This reversal was found to be ''statistically significant at a confidence level of more than 99.99 percent.''

The same commenter also stated that MSHA ''* * * fails to address the systematic [selection] bias of the study. MSHA only does multiple day sampling when the initial results are higher, but not out of compliance.'' It is true that in order to be selected for revisitation, a mine entity must have shown relatively high concentrations on the first shift—though not, in the case of an MMU, so high as to warrant a citation on first shift. Since no experimental data were available on mine entities randomly selected to receive multi-shift inspections, the only cases in which patterns over the course of a multi-shift inspection could be examined

[31] Technically, the assumption is that dust concentrations on all shifts sampled are independently and identically distributed around the quantity being estimated.

were cases selected for multi-shift inspection under these criteria.

Although the impact of the selection criteria was not explicitly addressed, it was recognized that entities selected for multi-day inspections do not constitute a random selection of mine entities. This recognition motivated, in part, the report's comparison of the final shift measurement to the dust concentration measured during a subsequent single-shift inspection. The magnitude of the average reversal indicates that most of the reduction observed over the course of the multi-shift inspection cannot be attributed to the selection criteria. Furthermore, it was not only mine entities with relatively low dust concentration measurements that were left out of the study group. Mine entities with the highest dust concentration measurements were immediately cited based on the average of measurements taken and excluded from the group subjected to multi-shift dust inspections. Therefore, the effect on the analysis of selecting mine entities with relatively high initial dust concentration measurements was largely offset by the effect of excluding those entities with even higher initial measurements. In any event, the magnitude of the average reduction between first and last shifts of a multi-shift inspection was significantly greater than what can be explained by selection for revisitation due to measurement error on the first shift sampled.

The assumption that multiple shifts sampled during a single MSHA inspection are equally representative is clearly violated if, as some commenters alleged, operating conditions are deliberately altered after the first shift in response to the continued presence of an MSHA inspector and then changed back after the inspector leaves. However, if samples are collected on successive or otherwise systematically determined shifts or days, the assumption can also be violated by changes arising as part of the normal mining cycle. As one commenter pointed out, multi-shift averaging within a single MSHA inspection potentially introduces biases typical of "campaign sampling," in which observations of a dynamic process are clustered together over a relatively narrow time span. In order to construct an unbiased, multi-shift average for each phase of mining activity, it would be necessary to collect samples from several shifts operating under essentially the same conditions. Alternatively, to construct an unbiased, multi-shift estimate of dust concentration over a longer term, it would be necessary to collect samples from randomly selected shifts over a period great enough to reflect the full range of changing conditions. Neither requirement is met by multi-shift MSHA inspections because (1) the mine environment is dynamic and no two shifts are alike and (2) MSHA inspectors are not there long enough to observe every condition in their inspection.

Based on the analysis presented by Kogut (September 6, 1994b) and also on public comments received in response to the February 18 and June 6, 1994, notices, the Secretaries have concluded that it should not be assumed that multiple shifts sampled during a single MSHA inspection are equally representative of atmospheric conditions to which a miner is typically exposed. This conclusion undercuts the rationale for multi-shift averaging within a single MSHA inspection, regardless of whether the objective is to estimate dust concentration for the individual shifts sampled as it is for MSHA inspector sampling or for typical shifts over a longer term as implied by some commenters. Measurements collected by MSHA on consecutive days or shifts of the same inspection do not comprise a random or otherwise representative sample from any larger population of shifts that would properly represent a long-term exposure or a particular phase of the mining cycle. Therefore, there is no basis for assuming that multi-shift averaging improves accuracy or reduces the risk of an erroneous enforcement determination.

Appendix B—Why Individual Measurements are Unbiased

The accuracy of a measurement depends on both precision and bias (Kennedy, *et al.*, 1995). Precision refers to consistency or repeatability of results, and bias refers to an error that is equally present in every measurement. Since the amount of dust present on a filter capsule is measured by subtracting the pre-exposure weight from the post-exposure weight, any bias present in both weight measurements is mathematically canceled out by subtraction. A control filter capsule is pre- and post-weighed along with the exposed filter capsules. The weight gain of each exposed capsule is adjusted by subtracting the weight gain or loss of the control filter capsule. Consequently, any bias due to differences in pre- and post-exposure laboratory conditions, or to changes introduced during storage and handling of the filter capsules, is also mathematically canceled out. Therefore, since respirable dust is defined by section 202(e) of the Mine Act (30 U.S.C. 842(e)) to be whatever is measured by an approved sampler unit, the Secretaries have concluded that a single, full-shift measurement made with an approved sampler unit provides an unbiased representation of average dust concentration for the shift and sampling location sampled. Some previous commenters, however, suggested that MSHA's sampling and analytical method is subject to systematic errors that would have the same effect on all measurements. These comments are addressed in this appendix.

I. The Value of the MRE Conversion Factor

The current U.S. coal mine dust standard is based on studies of British coal miners. In these studies, full-shift dust measurements were made using a sampler employing four horizontal plates which removed the large-sized particles by gravitational settlement (simulating the action of the nose and throat) and collecting on a pre-weighed filter those particles which are normally deposited in the lungs (Goddard, *et al.*, 1973). This instrument, known as the Mining Research Establishment (MRE) sampler, was designed to collect airborne dust according to a collection efficiency curve, developed by the British Medical Research Council (BMRC) to approximate the deposition of inhaled particles in the lung. Because the MRE instrument was large and cumbersome, other samplers using a 10-mm nylon cyclone were developed for taking samples of respirable dust in U.S. coal mines. However, these cyclone-based samplers collected less dust than the MRE instrument. Therefore, a factor was derived (1.38) to convert measurements obtained with the cyclone-based samplers to measurements obtained with the MRE instrument.

Two previous commenters noted that the 1.38 conversion factor was derived from a comparison of MRE measurements to measurements obtained using pumps made by two manufacturers: Mine Safety Appliances Co. and Unico. These commenters noted that there was some variability in these comparisons that MSHA and NIOSH did not consider in estimating CV_{total}, and stated that MSHA and NIOSH should therefore make allowances for any error or uncertainty in the conversion factor. It was also noted that the report deriving the conversion factor showed that Mine Safety Appliances Co. pumps more closely approximated MRE concentrations than Unico pumps, indicating that the 1.38 conversion factor (derived empirically using both types of pumps) may systematically overestimate the MRE-equivalent dust concentration for Mine Safety Appliances Co. samplers specifically. This commenter argued that such potential bias in the conversion factor should be addressed in order to account for the possibility of a systematic error in the conversion.

The study referred to these previous commenters involved collecting side-by-side samples using MRE and cyclone-based samplers (Tomb, *et al.*, 1973). The data showed that multiplying the cyclone sample concentrations by a constant factor of 1.38 gave values in reasonable agreement with MRE measurements. Consequently, a conversion factor of 1.38 was adopted for use with approved sampler units equipped with the 10-mm nylon cyclone.

Variability in the operating characteristics of individual sampler units is expressed by $CV_{sampler}$. In response to the comment on potential bias, MSHA and NIOSH reviewed the original report recommending the 1.38 MRE conversion factor. This report contained both an empirical determination, using side-by-side comparison data collected in underground coal mines, and a theoretical determination of the conversion factor. Two sets of field data were collected: one set was collected by mine inspectors who visited 200 coal mines across the U.S.; the other set was collected by investigators from MSHA's Pittsburgh laboratory at 24 coal mines. Linear regression was used to analyze both sets of data, with the slope of the regression line representing the conversion factor. The theoretical determination suggested that the conversion factor should be close to a value of 1.35. Analysis of the district mine inspector data resulted in a conversion factor of 1.38, while analysis of the laboratory investigator data suggested a greater conversion factor of 1.45.

Because the conversion factor derived from the inspector data came closer to the theoretical value, the former U.S. Bureau of Mines' Pittsburgh Technical Support Center (in the Department of Interior) recommended that 1.38 be the value adopted for any approved sampler unit operating at 2.0 L/min and equipped with a 10-mm nylon cyclone. This recommendation was subsequently accepted. The 1.38 conversion factor was not, as implied by the commenters, meant to represent the average value to be used with two different types of sampler unit, one of which is no longer in use. Instead, based largely on the theoretical value, it was meant to represent the appropriate value to be used with any approved sampler unit operating at 2.0 L/min and equipped with a 10-mm nylon cyclone. No data or analyses were submitted to suggest that this conversion factor, which has been accepted and used for over twenty years, should be any other value.

II. Conforming to the ACGIH and ISO Standard

One commenter implied that the respirable dust cyclone specifications used by MSHA result in a different particle collection efficiency curve than that specified by the American Conference of Governmental Industrial Hygienists (ACGIH) and the International Organization for Standardization (ISO) for a respirable dust sampler. Other previous commenters questioned whether the 2.0 L/min flow rate used by MSHA was appropriate, since a NIOSH study recommended using a 1.7 L/min flow rate when conforming to the recently adopted ACGIH/ISO specifications for collecting respirable particulate mass.

It is true that MSHA's respirable dust cyclone specifications result in a different particle size distribution than that specified by ACGIH and ISO. However, this fact has no bearing on the conversion to a respirable dust concentration as measured by an MRE sampler, which is the basis of the respirable dust standard. The 1.38 factor used to obtain an MRE-equivalent concentration was derived for a cyclone flow rate of 2.0 L/min. If a flow rate of 1.7 L/min were used, then this would correspond to some other factor for converting to an MRE-equivalent dust concentration. Therefore, the particle size distribution obtained at 2.0 L/min governs the relationship derived between an approved respirable coal mine dust sampler and an MRE sampler. The appropriate dust fraction (*i.e.*, the fraction corresponding to the 1.38 conversion factor) is sampled so long as the specified 2.0 L/min flow rate is maintained.

III. Effects of Other Variables

The effects of any other variables on the sampled dust fraction are covered by the 1.38 conversion factor, so long as these effects were present in the data from which the conversion factor was obtained. For example, one commenter expressed concern that nylon cyclones are subject to performance variations due to static charging phenomena. Any systematic effect of static charging on the performance characteristics of the nylon cyclone is implicitly accounted for in the conversion factor, because the same static charging effect would have been present when the comparative measurements were obtained for deriving the relationship between an approved sampler unit and an MRE instrument. Random effects of static charging, *i.e.*, effects that vary from sample to sample, are included in CV_{total}.

Appendix C—Components of CV_{total}

I. Weighing Uncertainty

(a) Derivation of CV_{weight}

The weight of a dust sample is determined by weighing each filter capsule before and after exposure and then determining the weight gain by subtraction. This weight gain is adjusted by subtracting any change in weight observed for the unexposed, control filter capsule. This practice eliminates potential biases due to any possible outgassing of the plastic cassette or other time-related factors but introduces two additional weighings. The weighing process is designed to control potential effects of temperature, humidity, and contamination. However, because the initial and final weighings of both the exposed and the control filter capsules are each still subject to random error, there is some degree of uncertainty in the computed weight of dust collected on the filter.

For both the control and the exposed filter capsule, the error in the weight-gain measurement results from combining two independent weighing errors. For example, suppose that the true pre- and post-exposure weights of a filter capsule are $W_1 = 392.275$ mg and $W_2 = 392.684$ mg, respectively. The true weight gain (G) would then be:

$$G = W_2 - W_1 = 0.409 \text{ mg.}$$

If, due to weighing errors, pre- and post-exposure weights were measured at $w_1 = 392.282$ mg and $w_2 = 392.679$ mg, respectively, then the measured weight gain (g) would be:

$$g = w_2 - w_1 = 0.397 \text{ mg.}$$

The error (e) in this particular weight-gain measurement, resulting from the combination of a 7 µg error in w_1 and a5 µg error in w_2, would then be:

$$\begin{aligned} e &= g - G \\ &= (w_2 - w_1) - (W_2 - W_1) \\ &= (w_2 - W_2) - (w_1 - W_1) \\ &= -5 - 7 = -12 \ \mu g^{32} \end{aligned}$$

Imprecision in the true weight gain is expressed by Qe, the standard deviation of e. When a weight-gain measurement (g) is converted to an MRE-equivalent concentration (in units of mg/m^3) based on a 480-minute sample at 2.0 L/min, both the actual weight gain (G) and the weight-gain error (e) are multiplied by the same factor:

$$\frac{1.38}{480 \text{ min} \cdot \frac{2 \text{ liters}}{\text{min}} \cdot \frac{1 \text{ m}^3}{1000 \text{ liters}}} = \frac{1.438}{\text{m}^3}$$

[32] Prior to mid-1995 there were two additional sources of uncertainty in the weight gain recorded for MSHA inspector samples. First, filter capsules were routinely weighed in different laboratories before and after exposure, without use of blank filters or control filters, thus subjecting them to interlaboratory variability. Second, the pre- and post-exposure weights were both truncated down to the nearest exact multiple of 0.1 mg, below the weight actually measured, prior to recording weight gain and calculating dust concentration.

Therefore, the standard deviation of the propagated weighing error component in a single, full-shift measurement ($x = g \cdot 1.438/m^3$) is $1.438\sigma_e$ mg/m³, assuming no adjustment for weight change in the control filter capsule.

Since a control filter capsule will is used to eliminate potential bias, the weight gain measured for the exposed filter (g) is adjusted by subtracting the change in weight (which may be positive or negative) observed for the control filter capsule (g′). Therefore, the adjusted measurement of dust concentration is

$$x' = (g - g') \cdot 1.438 / m^3.$$

Any change in weight observed for the control filter capsule is subject to the same measurement imprecision due to random weighing errors, represented by σ_e, as the weight gain measurement for an exposed filter. In addition to the weight-gain error for the exposed filter whose measured weight gain is g, x′ will also contain a weight-gain error contributed by the measured change in weight of the control filter capsule (g′). Using a standard propagation-of-errors formula, the imprecision is represented by

$$\sqrt{\sigma_e^2 + \sigma_e^2} = \sqrt{2\sigma_e^2} = \sigma_e\sqrt{2}\,\cdot$$

Therefore, the standard deviation of the propagated weighing error component in the adjusted measurement is $1.438\sigma_e\sqrt{2}$ mg/m³.

To form an estimate of CV_{weight} when control filter capsules are used, the estimated value of $1.438\sigma_e$ is multiplied by $\sqrt{2}$ and expressed as a percentage of the true dust concentration being measured (*X*):

$$CV_{weight} = \frac{1.438 \cdot \sigma_e \sqrt{2}}{X} \cdot 100\% \qquad (3)$$

Since σ_e is essentially constant with respect to dust concentration, CV_{weight} decreases as the dust concentration increases.

(b) Values Expressing Uncertainty Due to Random Errors in Weight-Gain Measurements

Table C–1 summarizes 13 different estimated values for σ_e. Six of these values were mentioned during earlier proceedings related to this notice, and two additional values for σ_e are derived in this appendix from data introduced during these earlier proceedings. Three other values for σ_e are derived from data and statistical analyses placed into the record along with the **Federal Register** notices published by MSHA and NIOSH on February 3, 1998 (Parobeck, *et al.,* 1997; Wagner, May 28, 1997). The remaining two values of σ_e are derived in an analysis being placed into the record in connection with the present **Federal Register** notice (Kogut, *et al.,* 1999). The 13 values listed in Table C–1 are not inconsistent, but as explained below, represent estimates of weight-gain imprecision during different historical periods or under different sample processing procedures. Eleven of these values are based on weight gains measured for capsules employing a Tyvek; filter support pad. Two are based on capsules with stainless steel support pads.

TABLE C–1.—STANDARD DEVIATION OF ERROR IN WEIGHT GAIN (σ_e)

Description	Reference	σ_e (µg)
MSHA's historical estimate of upper bound	59 FR 8356; Kogut, September 6, 1994a	97.4
1981 measurement assurance estimate;† older technology, truncation of weights	Parobeck, *et al.,* 1981; Bartley, September 7, 1994.	81
300 unexposed tamper-resistant capsules pre- and post-weighed in different labs;† no truncation.	Kogut, May 12, 1994	29
Inspector samples processed between late 1992 and mid 1995;† capsules pre- and post-weighed in different labs with truncation; estimate adjusted for differences between labs.	Appendix C	51.7
NMA data obtained from samples collected by Skyline Coal, Inc.†	Appendix D	76
Value used in NIOSH "indirect approach" based on repeated measurements on same day and in same lab;† derived from Kogut.	61 FR 10012; Kogut, May 12, 1994	5.8
1995 MSHA field study;† capsules pre-weighed, assembled, and post-weighed by MSHA.	Kogut, *et al.,* 1997; Wagner, 1995	9.1
1996 measurement assurance estimate †	61 FR 10012; Tomb, February 16, 1996	6.5
75 unexposed capsules recalled from MSHA field offices †	Wagner, May 28, 1997	8.2
50 replicate weighings of 16 unexposed filter capsules †	Parobeck, *et al.,* 1997	10.3
50 replicate weighings of 16 unexposed filter capsules †	Parobeck, *et al.,* 1997	11.2
2,640 unexposed "quality control" capsules pre-weighed by MSHA, assembled by MSA, and subsequently post-weighed by MSHA †.	Kogut, *et al.,* 1999	11.3
300 unexposed capsules pre-weighed by MSHA, assembled by MSA, carried during MSHA inspection, and subsequently post-weighed by MSHA‡.	Kogut, *et al.,* 1999	11.6

† Tyvek support pad.
‡ stainless steel support pad.
MSA Mine Safety Appliances Co.

In MSHA's February 1994 notice, $1.438\sigma_e$ (identified as "variability associated with the pre- and post-weighing of the filter capsule") was presented as 0.14 mg/m³, or 7 percent of 2.0 mg/m³, as described in Kogut (September 6, 1994a). It follows that the value of σ_e

implicitly assumed in MSHA's February 1994 notice (obtained by dividing 0.14 by 1.438) was 0.0974 mg (97.4 µg). Seven percent of 2.0 mg/m³ had been used by MSHA from the inception of its dust enforcement program to represent an upper bound on weighing imprecision in a dust concentration measurement.

After publication of the February 1994 notice, several other candidate values for σ_e were placed into the public record. In 1981, based on data collected to implement a measurement assurance program in MSHA's weighing laboratory, σ_e was estimated using a method developed by the NBS to be 0.0807 mg (80.7 µg) (Parobeck, *et al.,* 1981). The published NBS estimate reflected weighing technology in place at the time the article was published (1981), as well as the practice (no longer in effect for MSHA inspector samples) of truncating both the pre- and post-exposure weights down to an exact multiple of 0.1 mg. This estimate was used to calculate CV_{weight} by Bartley (September, 1994).

Some previous commenters misread or misunderstood the published NBS estimate. One of these previous commenters claimed that ''the only published report of the weighing error in MSHA's laboratory * * * was 0.16 mg of variation, which would convert to a concentration of 0.20 mg/m³ compared to the 0.14 mg/m³ * * * MSHA and NIOSH used.'' This is incorrect, since the standard deviation of weight-gain errors (including the effect of truncation) is actually identified as 0.0807 mg in the Appendix to Parobeck, *et al.,* (1981). The 0.16-mg figure quoted by the commenter is presented in that paper as defining a 2-tailed 95-percent confidence limit, for use in establishing process control limits. It is derived by multiplying σ_e by 2.0. As explained above, the published value of σ_e = 0.0807 mg is multiplied by 1.438 m^{-3} to propagate an MRE-equivalent concentration error of 0.116 mg/m³. Contrary to the commenters' assertion, this is less—not more—than the quantity (0.14 mg/m³) assumed in the February 1994 notice.

In September 1994, a more recent analysis was placed into the public record, based on repeated weighings of 300 unexposed filter capsules, each of which was weighed once in the Mine Safety Appliances Co. laboratory and twice in MSHA's laboratory using current equipment (Kogut, May 12, 1994). Based on this analysis, σ_e was estimated to be 29 µg for pre- and post-weighings on different days at different laboratories, or 5.8 µg for pre- and post-weighings on the same day within MSHA's laboratory. The 5.8-µg value was used as part of the NIOSH ''indirect approach'' in its 1995 accuracy assessment (Wagner, 1995). Neither of these two estimates, however, reflects the effects of truncation or of a mean difference of about 12 µg discovered between weighings in the two laboratories. Combining these two additional effects with the 29-µg estimate results in an adjusted estimate of σ_e = 51.7 µg for weighings made in different laboratories and truncated to a multiple of 0.1 mg. MSHA and NIOSH regard this 51.7-µg value to be the best available estimate of σ_e for inspector samples processed between late 1992, when the current style of (tamper-resistant) cassette was introduced, and mid-1995, changes in inspector sample processing were implemented.

Some previous commenters suggested that the estimates of σ_e, placed into the record in September 1994, did not adequately account for potential errors in the weighing process as it existed at that time. One of these previous commenters asserted that truncation error was an additional source of uncertainty that had not been accounted for. As explained above, however, σ_e accounts for uncertainty deriving from both the pre- and post-exposure weighings. Both the 80.7-µg NBS estimate and the 97.4-µg value assumed in the February 1994 notice included the effects of truncating weight measurements to 0.1 mg. Truncation effects are also included in the 51.7-µg estimate.

Some previous commenters expressed special concern over the accuracy of pre-exposure filter capsule weights as measured by Mine Safety Appliances Co. One commenter expressed ''grave concern'' with regard to the 12-µg systematic difference in weights found between Mine Safety Appliances Co. and MSHA weighings of the same unexposed capsules, as described in MSHA's 1994 analysis (Kogut, May 12, 1994). These concerns became moot, at least with respect to MSHA's inspector sampling program, when MSHA began pre- and post-weighing all inspector samples at MSHA's laboratory. Furthermore, any potential bias resulting from differences in laboratory conditions on the days of pre- and post-exposure weighings should now be eliminated by the use of control filter capsules. However, contrary to this commenter's interpretation, the analysis submitted to the record in September 1994 resulted in a substantially lower estimate of σ_e than that assumed in the February 1994 notice—even after adjustment for the 12-µg systematic difference observed between weighing laboratories. The 51.7-µg estimate discussed above includes this adjustment.

MSHA and NIOSH also analyzed data submitted by the NMA in connection with these proceedings. An important result of that analysis, described in Appendix D, was an estimate of σ_e equal to 76 µg ± 15 µg.[33] This estimate is not significantly different, statistically, from either the 97.4-µg value assumed in the February 1994 notice, the 80.7-µg NBS estimate, or the 51.7-µg value estimated for samples collected between late 1992 and mid-1995. Since the NMA data were obtained from samples collected by Skyline Coal, Inc. prior to 1995, the Secretaries believe these data confirm the 51.7-µg value of σ_e applicable to the Skyline samples. The estimate of σ_e obtained from the Skyline data is, however, significantly greater than the value estimated for weight-gain measurements under MSHA's current inspection program. This is explained by the fact that when the Skyline samples were collected, all samples were weighed in different laboratories before and after sampling, and the weights were truncated to 0.1 mg. before calculating the weight gain.

Both truncation of weights and the practice of pre- and post-weighing samples in different laboratories were discontinued for inspector samples in mid-1995. Under MSHA's revised procedures for processing inspector samples, filter capsules were weighed both before and after sampling in MSHA's laboratory. Furthermore, MSHA began to use weights recorded to the nearest µg in calculating dust concentrations. Therefore, the 5.8-µg estimate of σ_e described above, applying to pre- and post-exposure weighings in the same laboratory using current equipment and no truncation, was used by NIOSH to calculate CV_{weight} as part of the NIOSH ''indirect'' evaluation of CV_{total}, placed into the public record on March 12, 1996.

Based on the results of MSHA's 1995 field study, σ_e was estimated to be 9.12 µg (Kogut, *et al.,* 1997). The filter capsules involved in this study were used to collect respirable coal mine dust samples in an underground mine between pre- and post-exposure weighings in MSHA's laboratory, potentially subjecting them to unknown sources of variability in weight gain not covered by the laboratory estimates. Substituting the estimated value of σ_e = 9.12 µg into Equation 3 results in a corresponding estimate of CV_{weight} that declines as the sampled dust concentration increases—ranging from 9.3 percent at dust concentrations of 0.2 mg/m³ to less than one percent at concentrations greater than 2.0 mg/m³. This estimate of CV_{weight} applies to the procedure utilizing control filter capsules.

An updated estimate of σ_e = 6.5 µg was also calculated using the published NBS procedure for filter capsules processed with the current equipment and procedures for inspector samples. This estimate, derived from weighing the same group of 55 unexposed filter capsules 139 times over a 218-day period, was described in material placed into the public record on March 12, 1996 (Tomb, February 16, 1996). The 6.5 µg estimate applies to filter capsules pre- and post-weighed robotically on different days within MSHA's laboratory, but it does not reflect any potential effects of removing the capsule from the laboratory and exposing it in the field between weighings.

The estimate of imprecision in measured weight gain derived from MSHA's 1995 field study discussed earlier (9.1 µg), falls only slightly above the 6.5-µg laboratory estimate. This suggested that the process of handling and actually exposing the filter capsule in a mine environment does not add appreciably to the imprecision in measured weight gain.

In February 1997, 75 unexposed filter capsules that had been pre-weighed in MSHA's laboratory and distributed to MSHA district offices were recalled and reweighed. After adjusting for variability attributable to the date of initial weighing (*i.e.,* variability that would be eliminated by use of a control filter capsule), these data provided an estimate of σ_e equal to 8.2 µg (Wagner, May 28, 1997). This estimate, based on weighings separated by a span of about four to five months, corroborated the 9.1-µg estimate obtained from MSHA's 1995 field study.

[33] To construct a 90-percent confidence interval for σ_e, based on the Skyline data, the 15-µg ''standard error of the estimate'' must be multiplied by a confidence coefficient of 1.64.

An MSHA report placed into the public record with the December 31, 1997 **Federal Register** notices described results from an experiment in which 32 filter capsules were each weighed on 50 different days, alternating between the MSHA and Mine Safety Appliances Co. laboratories. Sixteen of these capsules employed a Tyvek® filter support pad of the type approved under 30 CFR part 74. The remaining sixteen were of the modified type, in which the Tyvek® support pad was replaced by a stainless steel support pad. The residual variance associated with an individual weight measurement was found to be 53.5 μg^2 for filter capsules employing a Tyvek® support pad and 62.9 μg^2 for capsules employing a stainless steel support pad (Parobeck, *et al.,* 1997, Table 3.) These figures represent the squared residual variability not ''explained'' by repeated handling, elapsed time, changes in laboratory conditions, or other terms of the model used in the report. The other sources of variability reported (*i.e.*, those ''explained'' by the model) are all eliminated by the use of a control filter. Therefore, since measurement of a weight gain requires two measurements of weight, the corresponding estimates of σ_e are $(2 \cdot 53.5)^{1/2} = 10.3$ µg for Tyvek®-supported filters and $(2 \cdot 62.9)^{1/2} =$ 11.2 µg for stainless steel.

The final two values for σ_e presented in Table C–1 of this appendix are based on filter capsules pre-weighed in MSHA's laboratory, sent to Mine Safety Appliances Co. for assembly into standard plastic cassettes, and then later weighed a second time in MSHA's laboratory. This is currently the normal practice for filter capsules used by MSHA inspectors. Both of these values, summarized below, are derived in a statistical analysis being placed into the public record along with this notice (Kogut, *et al.,* 1999, Table A–2). In that analysis, ''σ_n'' represents the portion of uncertainty in a weight gain measurement that a control filter correction cannot be expected to eliminate. This includes both weighing imprecision and spurious but unsystematic changes in weight, such as might be due to random contamination. Therefore, in the present context, σ_e can conservatively be identified with σ_n.

In 1998, to maintain quality control for the production of filter capsules used in MSHA's enforcement program, 2,640 unexposed filter capsules were weighed at MSHA's laboratory before and after assembly by Mine Safety Appliances Co. All of these capsules employed a Tyvek® filter support pad. The estimated value for σ_n (here identified with σ_e) associated with these capsules was 11.3 µg.

In 1999, MSHA performed a special Modified Filter Capsule Study (MFCS) in which the Tyvek® filter support pad was replaced by a stainless steel support pad. The purpose of the MFCS was to quantify the impact of such a substitution on the accuracy of respirable coal mine dust measurements. Based on an analysis of weight gains measured for 300 modified filter capsules, σ_n (here identified with σ_e) was estimated to be 11.6 µg. All of these capsules were initially weighed in MSHA's laboratory, assembled into cassettes by Mine Safety Appliances Co., distributed to MSHA inspectors, carried but not exposed during a mine inspection, and then weighed for a second time in MSHA's laboratory. The 11.6 µg value represents the combined effects of weighing imprecision and random contamination during assembly, distribution, and field use. It therefore provides a conservative estimate of σ_e for filter capsules employing stainless steel support pads.

(c) Negative Weight-Gain Measurements

Some previous commenters pointed out that MSHA routinely voids samples when the measured pre-exposure weight of a filter capsule is greater than the measured post-exposure weight. According to these commenters, such occurrences reflect an unacceptable degree of inaccuracy in weight-gain measurements. One commenter asserted that such cases are ''of particular significance when only one sample is relied upon.'' This commenter attributed such occurrences solely to errors in the capsule pre-weight and implied that they should not be expected to occur under MSHA's quality assurance program. It was, therefore, implied that negative weight-gain measurements are not consistent with the degree of uncertainty being attributed to weighing error.

Prior to implementation of the 1995 processing modifications, a significant fraction of samples with less than 0.1 mg of true weight gain (*i.e.,* $G < 0.10$ mg) could be expected to exhibit negative weight gains (*i.e.,* $g \leq -0.1$ mg). Contrary to the commenter's implication, however, negative weight-gain measurements do not arise exclusively from positive pre-exposure weighing errors (*i.e.,* $w_1 > W_1$). They can also arise, with equal likelihood, from negative post-exposure weighing errors (*i.e.,* $w_2 < W_2$).

What is required for a negative weight gain ($w_2 < w_1$) is that $e < -G$. Since the true weight gain (G) is always greater than or equal to zero, this means that a negative weight gain is observed when e is sufficiently negative. Under standard assumptions of normally distributed errors, σ_e fully accounts for the probability of such occurrences. Naturally, this probability becomes smaller as G increases and also as σ_e decreases.

The occasional negative weight-gain measurements that have been observed are consistent with values of σ_e estimated for previous processing procedures. Table C–2 contains the probability of a negative weight-gain measurement for true weight gains (G) ranging from 0.0 mg to 0.08 mg, assuming σ_e = 51.7 µg and the previous practice of truncation, which has now been discontinued for inspector samples. Since the purpose here is to evaluate the probability of negative weight gains under MSHA's previous processing procedures, it is also assumed that no control filter capsules are used to adjust weight gains.

TABLE C–2.—PROBABILITY OF NEGATIVE WEIGHT-GAIN MEASUREMENT, ASSUMING TRUNCATION AND σ_e = 51.7 µG

True weight gain G = $W_2 - W_1$ (mg)	Estimated probability of negative measurement, %
0.00	12.9
0.01	8.4
0.02	5.1
0.03	2.8
0.04	1.5
0.05	0.7
0.06	0.4
0.07	0.2
0.08	0.1

Note: Tabled probabilities (in percent) were obtained from a simulation of 35,000 weight-gain measurements at each value of G, assuming normally distributed weighing errors and the now discontinued practice of measurement truncation.

One commenter suggested the use of a test based on the frequency of negative weight-gain measurements to check the magnitude of the MSHA/NIOSH estimate of CV_{total}. As proposed by the commenter, the test of CV_{total} would consist of comparing the observed proportion of samples voided due to a negative recorded weight gain to the proportion expected, given CV_{total} equal to the MSHA/NIOSH estimate. If the observed proportion were to exceed the expected proportion, then this would constitute evidence that CV_{total} was being underestimated.

The commenter miscalculated the expected proportion, because he mischaracterized the MSHA/NIOSH estimate of CV_{total} as constant over the continuum of dust concentrations. The MSHA/NIOSH estimate of CV_{total} increases as dust concentrations decrease. This would cause a higher proportion of negative results than what the commenter projected under the MSHA/NIOSH estimate, regardless of what statistical distribution of dust concentrations is assumed. The commenter's projection also neglected to take into account the effects of truncating pre- and post-exposure weights to multiples of 0.1 mg. Although this practice has now been discontinued for MSHA inspector samples, it is a factor in the available historical data.

In principle, if the statistical distribution of true dust concentrations were known, the expected proportion of samples voided for negative weight gain could be recalculated to reflect both a variable CV_{total} and, when applicable, truncation of recorded weights. However, under the commenter's proposal, deriving the expected proportion of negative measurements would involve not only CV_{total}, but also an estimate of the distribution of true dust concentrations. Such an estimate would rely on the tenuous assumption that a mixture of dust concentrations in different environments is closely approximated by a lognormal distribution far into the lower tail—*i.e.*, even at concentrations extremely near zero. Furthermore, valid estimation of the lognormal parameters, applicable to dust concentrations near zero, would be complicated by measurement errors, especially those resulting in negative or zero values. Depending on the data used, truncation effects could also confound the analysis.

Before truncation was discontinued, negative weight-gain measurements were caused by various combinations of pre- and post-exposure weighing and truncation error. Before MSHA began adjusting weight gains using an unexposed control filter, differences in laboratory conditions on the two weighing days and/or unexplained but real systematic weight losses over time may also have contributed to the observed frequency of negative weight gains. Now that truncation has been removed as a source of error in weight-gain measurements for inspector samples, and control filters are used to correct for systematic changes, the frequency of negative weight gains observed historically is largely irrelevant. Significant negative weight-gain measurements—*i.e.*, those that cannot be explained by normal weighing imprecision—are expected to occur less frequently than in the past.

(d) Comparing Weight Gains Obtained From Paired Samples

Some previous commenters maintained that ''although there may be slight differences between how the samples are dried * * *'' differences between the weight gain observed in MSHA samples and simultaneous samples collected nearby (and processed at an independent laboratory) indicated a greater degree of weighing uncertainty than what was being assumed. In response to the Secretaries' request for any available data supporting this position, results from paired dust samples were provided by two coal companies.

In comparing measurements obtained from paired samples, there are several important considerations that some previous commenters did not take into account. First, if two different sampler units are exposed to identical atmospheres for the same period of time, the difference between weight-gain measurements g_1 and g_2 arises, in part, from two independent weight-gain measurement errors, e_1 and e_2. If uncertainty due to each of these errors is represented by σ_e, then the difference between g_1 and g_2 has uncertainty due to weighing error equal to $\sigma_e\sqrt{2}$. Consequently, weight gains measured in the same laboratory, on the same day, for different filter capsules exposed to identical atmospheres can be expected to differ by an amount whose standard deviation is $1.41\sigma_e$.

Furthermore, if the two exposed capsules are processed at different laboratories, the difference in weight gains contains an additional error term arising from differences between laboratories. Evidence was presented that this term (in the notation of Kogut, May 12, 1994) is far more significant than the intra-lab, intra-day weighing error in MSHA's laboratory. Moreover, the additional uncertainty introduced by use of a third laboratory also depends on unknown weighing imprecision within that laboratory, which may differ from that maintained by MSHA's measurement assurance process. (See Appendix D for analysis of paired sample data submitted by NMA).

However, the most important consideration in comparing weight gains from two different samples is that under real mining conditions, the atmospheres sampled may not be identical—even if the sampler units are located near one another. Differences in atmospheric dust concentrations over relatively small distances have been documented (Kissell, *et al.*, 1993). Such differences would be expected to produce corresponding differences in weight gain that are unrelated to the accuracy of a single, full-shift measurement as defined by the measurement objective explained earlier in this notice.

II. Pump Variability

The component of uncertainty due to variability in the pump, represented by CV_{pump}, consists of potential errors associated with calibration of the pump rotameter, variation in flow rate during sampling, and (for those pumps with rotameters) variability in the initial adjustment of flow rate when sampling is begun. The Secretaries believe that CV_{pump} adequately accounts for all uncertainty identified by previous commenters as being associated with the volume of air sampled.

In deriving the Values Table published in MSHA's February 1994 notice, MSHA used a value of 5 percent to represent uncertainty associated with initial adjustment of flow rate at the beginning of the shift and another value of 5 percent to represent flow rate variability. The 5-percent value for variability in initial flow rate adjustment was estimated from a laboratory experiment conducted by MSHA in the early 1970s, while the value for flow rate variability was based on the allowable flow rate tolerance specified in 30 CFR part 74. This part requires that the flow rate of all sampling systems not vary by more than ±5 percent over a full shift with no more than two adjustments. MSHA did not include a separate component of variability for pump rotameter calibration because it was already included in the 5-percent value used to represent flow rate variability.

Based on a review of published results by Bowman *et al.* (1984), the Secretaries concluded that the component of uncertainty associated with the combined effects of variability in flow rate during sampling and potential errors in calibration is less than 3 percent. Therefore, as proposed in the March 12, 1996 notice, the Secretaries are now estimating uncertainty due to variability in flow rate to be 3 percent.

Because MSHA could not provide the experimental data supporting the 5-percent value used to represent uncertainty associated with the initial adjustment of flow rate, one commenter recommended that MSHA conduct a new experiment. In response to that request, MSHA conducted a study to establish the variability associated with the initial flow rate adjustment. The study, placed into the public record on September 9, 1994, attempted to emulate realistic operating conditions by including a variety of sampling personnel making adjustments under various conditions. Results showed the coefficient of variation associated with the initial adjustment to be 3 ± 0.5 percent (Tomb, September 1, 1994). The Secretaries consider this study to provide the best available estimate for uncertainty associated with the initial adjustment of a sampler unit's flow rate. Therefore, as proposed in the March 12, 1996 notice, the Secretaries are now estimating uncertainty due to variability in the initial adjustment to be 3 percent.

One previous commenter expressed concern regarding how representative MSHA's study on initial flow rate adjustment was of actual sampling conditions. The Secretaries consider the conditions under which the study was conducted to have adequately mimicked conditions under which the flow rate of a coal mine dust sampling system is adjusted. This was more rigorous than the original study, from which MSHA estimated the 5-percent value assumed in the February 12, 1994 notice. The tests were conducted in an underground mine, using both experienced and inexperienced persons to make the adjustments. Also, the only illumination was supplied by cap lamps worn by the person making the adjustments. Tests were conducted for adjustments made in three different physical positions: standing, kneeling and prone. Inspection personnel participating in the study provided guidance as to the methods typically used by inspection personnel in adjusting pumps. In fact, environmental conditions under which the test was conducted were generally more severe than those normally encountered by inspection personnel, since initial adjustment of the pumps normally occurs on the surface just before the work shift begins.

The same commenter also questioned why only the variability associated with initial adjustment of the flow rate was estimated and not the variability associated with subsequent adjustments during the shift. This is because the variability associated with the subsequent flow rate adjustments of an approved sampler unit is already included in the 3-percent value estimated for variability in flow rate over the duration of the shift.

Since variability in the initial flow rate adjustment is independent of calibration of the pump rotameter and variability in flow rate during sampling, these two sources of uncertainty can be combined through the standard propagation of errors formula:

$$CV_{pump} = \sqrt{(3\%)^2 + (3\%)^2} = 4.2\%$$

This estimate accords well with a more recent finding based on 186 measurements in an underground mine, using constant flow-control pumps (Kogut *et al.,* 1997). That study estimated CV_{pump} = 4.0 percent and concluded that CV_{pump} was unlikely to exceed 4.4 percent.

Three previous commenters stated that there are reports of sampling pumps being calibrated and used at altitudes differing by as much as 3,000 feet and that, for many pumps, this could result in more than a 3-percent change in flow rate per 1,000 feet of altitude. MSHA recognized this as a potential problem as early as 1975. As a result, MSHA conducted a study to ascertain the effect of altitude on coal mine dust sampler calibration (Treaftis, *et al.,* 1976). The study showed that both pump performance and rotameter calibration were affected by changes in altitude but that an approved Mine Safety Appliances Co. sampling system, calibrated and adjusted at an altitude of 800 feet to a flow rate of 2.0 L/min, would meet the requirement of 30 CFR 74.3(11) when sampling at an altitude of 10,000 feet, even if no adjustment were made to the pump. The study also provided equations for adjusting the calibration mark on the pump rotameter so that, when sampling at an altitude different from the one at which the rotameter was calibrated, the appropriate flow rate would be obtained. These procedures are used by MSHA inspectors in instances where the sampling altitude is significantly different from the altitude where the sampling system is calibrated.

Some previous commenters questioned the ability of the older Mine Safety Appliances Co. Model G pumps to meet the same flow rate specifications as new pumps. MSHA has discontinued the use of these older pumps in its sampling program and will be using only flow-control pumps. More recent MSHA studies show that these pumps continue to meet the flow rate requirement of 30 CFR 74.3(11) at altitudes up to 10,000 feet (Gero, *et al.,* 1995). As a result, the flow-control pumps currently used by inspectors can be calibrated at one altitude and used at another altitude with no additional adjustments made to the pumps. Furthermore, all sampler units used to measure respirable dust concentrations in coal mine environments are required to be approved in accordance with the regulatory requirements of 30 CFR part 74, which require flow rate consistency to be within $\pm$ 0.1 L/min of the 2.0 L/min flow rate.[34] MSHA's experience over the past 20 years has demonstrated that flow rate consistency of older sampling systems will continue to meet the requirements specified in part 74, provided the systems are regularly calibrated and maintained in approved condi tion. To ensure that sampling systems continue to meet the specification of part 74, MSHA's policy requires calibration and maintenance by specially trained personnel in accordance with MSHA Informational Report No. 1121 (revised).

[34] Section 74.3(13) requires that flow rate in an approved sampler unit deviate from 2.0 L/min by no more than 5 percent over an 8-hour period, with no more than 2 readjustments after the initial setting. However, this is a maximum deviation, and the uncertainty associated with pump flow rate, as quantified by its coefficient of variation, is 3 percent.

III. Intersampler Variability

Intersampler variability, represented by $CV_{sampler}$, accounts for uncertainty due to physical variations from sampler to sampler. Most of the previous commenters ignored this source of uncertainty. One commenter, however, stated that 10-mm nylon cyclones are subject to performance variations due to static charging phenomena (discussed in Appendix B).

Intersampler variability was investigated by Bowman, *et al.,* (1984), Bartley, *et al.* (1994), and Kogut, *et al.* (1997). Bowman, *et al.* designed a precision experiment to determine the contribution to CV_{total} from differences between individual coal mine dust sampler units. Based on their experiment, they reported $CV_{sampler}$ = 1.6 percent, which included variation in both the 10-mm nylon cyclone and the Mine Safety Appliances Co. Model G pump. They concluded that this low degree of component variability indicates there is excellent uniformity in the mechanical components of dust sampler units. Bartley, from his experimental investigation of eight 10-mm nylon cyclones, estimated $CV_{sampler}$ to be no more than 5 percent for aerosols with a size distribution typical of those found in coal mine environments. Based on an analysis involving 32 different sampler units, Kogut, J., *et al.,* (1997) found that $CV_{sampler}$ was unlikely to exceed 3.1 percent. Unlike Bartley's study, however, this analysis relied on new cyclones, which might be expected to exhibit less variability than older, heavily used cyclones. Therefore, NIOSH used the more conservative estimate of 5 percent, with an upper 95-percent confidence limit of 9 percent, in its ''indirect approach'' for estimating CV_{total} and evaluating method accuracy (Wagner, 1995).

Appendix D—Data Submitted by Previous Commenters

During the public hearings, several previous commenters indicated they had data showing that MSHA and NIOSH had underestimated the overall magnitude of uncertainty associated with a single, full-shift measurement. These data and accompanying analyses were submitted to the record and evaluated by MSHA and NIOSH. Some of the data sets consisted of paired samples, where two approved sampler units were placed nearby one another and operated for a full shift. One of the resulting samples was analyzed in MSHA's laboratory and the other by an independent laboratory. These data were represented as showing that single, full-shift measurements cannot be used to accurately estimate dust concentrations. Other data sets submitted consisted of unpaired measurements collected from miners at intervals over varying spans of time. These data sets were represented as showing that exposures vary widely between shifts and between occupations.

I. Paired Sample Data Submitted by the NMA

The American Mining Congress and National Coal Association [AMC and NCA have since merged into the National Mining Association, (NMA)] submitted at the request of MSHA and NIOSH a data set consisting of 381 pairs of exposure measurements. These measurements had been obtained from the ''designated occupations'' on two longwall and six continuous mining sections belonging to Skyline Coal, Inc. Two sampling units were placed on each participating miner and operated for the full shift. After sampling, one sample cassette was sent to MSHA for analysis while the other was analyzed at a private laboratory. All samples were reported to be ''portal to portal'' samples as required by MSHA regulations. Using these data, the NMA estimated an overall CV of 16 percent. Based on this 16-percent estimate, the NMA suggested that MSHA had underestimated measurement uncertainty in its February 1994 notice by 60 percent at dust concentrations of 2.0 mg/m^3.

The NMA estimate of 16 percent for overall CV includes not only sampling and analytical error, but also variability arising from two additional sources: (1) Spatial variability between the locations where the two samples were collected; and (2) interlaboratory variability introduced by the fact that a third laboratory was involved in weighing exposed filter capsules.

Since the two dust samples within each pair submitted were not collected at precisely the same location, differences observed between paired samples in the Skyline data are partly due to spatial variability. The Secretaries fully recognize and acknowledge that, as suggested by the Skyline data, spatial variability in mine dust concentrations can exist, even within a relatively small area such as the so-called breathing zone of a miner. Consistent with general industrial hygiene practice, however, the Secretaries do not consider such variability relevant to the accuracy of an individual dust concentration measurement.

The NMA expressed sampling and analytical error as a single percentage relative to the average of all dust concentrations that happened to be observed in the data analyzed. Contrary to the NMA analysis, sampling and analytical error cannot be expressed as a constant percentage of the true dust concentration. Because σ_e is constant with respect to dust concentration, CV_{weight} declines with increasing dust concentration, as explained in Appendix C. The value of CV_{total} assumed by MSHA and NIOSH for the period when the Skyline samples were collected (*i.e.,* prior to 1995) is approximately 7.5 percent when the true dust concentration (μ) is 2.0 mg/m^3 and approximately 16.2 percent when μ=0.5 mg/m^3. This is based on applying Equations 2 and 3 to σ_e=51.7 μg, CV_{pump}=4.2 percent, and $CV_{sampler}$=5 percent.

Even if the effects of spatial variability and the third laboratory are ignored, and the overall CV is interpreted as an average over the range of concentrations encountered, the 16-percent value reported by the NMA makes no allowance for the paired covariance structure of the data. Therefore, MSHA and NIOSH consider the 16-percent value to be erroneous, even under NMA's assumptions.

MSHA and NIOSH re-analyzed the Skyline data in order to check whether these data were consistent with the value of σ_e (*i.e.,* 51.7

μg) estimated for the time when the Skyline samples were collected. To distinguish the NMA interpretation of sampling and analytical error (including spatial variability) from the Secretaries' interpretation (excluding spatial variability), SAE will denote sampling and analytical error according to the Secretaries' interpretation, and SAE* will denote sampling and analytical error according to the NMA interpretation. If $CV_{spatial}$ denotes the component of SAE* attributable to spatial variability for each measurement, it follows that

$$SAE^{*} = \left(CV_{total}^{2} + CV_{spatial}^{2}\right)^{1/2}.$$

To estimate SAE* as a function of dust concentration from the data provided, a least-squares regression analysis was performed on the square of the difference between natural logarithms of dust concentrations x_1 and x_2 observed within each pair. Let μ* denote the true mean dust concentration, not only over the full shift sampled, but also over the two locations sampled. The expected value (E{·}) of each squared difference forms the ordinate of the regression line at each value of the abscissa $(1/\mu^*)^2$:

$$\begin{aligned} E\left\{\left(Ln(X_1) - Ln(X_2)\right)^2\right\} &\approx 2\left(SAE^*\right)^2 \\ &= 2\left(CV_{total}^2 + CV_{spatial}^2\right) \\ &= 2\left[CV_{pump}^2 + CV_{sampler}^2 + CV_{weight}^2 + CV_{spatial}^2\right] \\ &= 2\left(CV_{pump}^2 + CV_{sampler}^2 + CV_{spatial}^2\right) + 2\left(1.438\sigma_e / \mu^*\right)^2 \\ &= a_0 + a_1\left(1/\mu^*\right)^2 \end{aligned}$$

Since no control filter capsules were used in processing the Skyline dust samples, CV_{weight} does not, in this analysis, contain the $\sqrt{2}$ factor shown in Equation 3 of Appendix C. The intercept of the regression line is: $a_0=2(CV^2_{pump}+CV^2_{sampler}+CV^2_{spatial})$, and the slope is $a_1=2(1.438\sigma_e)^2$. To carry out the regression analysis, μ* was approximated by $(x_1+x_2)/2$. Regression estimates of the parameters a_0 and a_1 were used to generate corresponding estimates of $_e$ and $CV^2_{spatial}$.

The least squares estimate of σ_e obtained from this analysis is 76.0 μg, with standard error of ±15 μg. This is not significantly different, statistically, from the 51.7-μg value estimated for the time period when the Skyline samples were collected. Assuming CV_{pump} = 4.2 percent and $CV_{sampler}$ = 5 percent, the value of $CV_{spatial}$ obtained from the least squares estimate of a_0 is 19.7 percent, with standard error of ± 2.9 percent.

II. Paired Sample Data Submitted by Mountain Coal Company

Mountain Coal Company submitted a data set consisting of the difference (expressed in mg/m³) between paired samples collected from miners over roughly a one-year period. Two sampler units were placed on each participating miner (presumably one on each collar or shoulder) and operated for roughly a full shift. One sample cassette was sent to MSHA for analysis (post-weighing) while the other was analyzed at a private laboratory.

Mountain Coal Company provided only the differences between measurements within each pair and not the concentration measurements themselves. Since CV_{total} varies with dust concentration, and the dust concentrations were not provided, it was impossible to form a valid estimate of measurement variability from these data, or to determine what part of the observed differences could be attributed to weighing error and what part to spatial variability or variability attributable to operation of the pump and physical differences between sampler units.

III. Exposure Data Submitted by Jim Walter Resources, Inc.

Jim Walter Resources, Inc. submitted a data set consisting of exposure measurements collected from all miners working on two longwall sections. Measurements were collected from each miner on five consecutive days. This procedure was repeated during five sampling cycles over a two-year period. During each sample cycle the five measurements for each miner were averaged and compared to the respirable dust standard. According to Jim Walter Resources, Inc., the sampling plan ''eliminates the effect of the variability of the environment and minimizes the error due to the coefficient of variation of the pump because *all miners* [original emphasis] are sampled for five shifts,'' and these data ''show the variability of the sample pump and of the worker's exposure to respirable dust.''

In its submission, Jim Walter Resources, Inc. apparently assumed that the quantity being measured is average dust concentration across a number of shifts, rather than dust concentration averaged over a single shift at the sampling location. The Secretaries agree that dust concentrations do vary from shift to shift and from job to job, as these data illustrate. This variability, however, is largely under the control of the mine operator and should not be considered when evaluating the accuracy of a single, full-shift measurement.

IV. Exposure Data Submitted by the NMA

The NMA submitted data consisting of recently collected and historical measurements collected from the designated occupations (continuous miner operator for continuous mining sections and either the headgate or tailgate shearer operator for longwall mining sections) for three continuous mining sections and five longwall mining sections. According to the NMA analysis, there is a 17-percent probability that these mines would be cited, even though the long-term average is less than the respirable dust standard.

The NMA failed to recognize that the quantity being measured is dust concentration averaged over a single shift at the sampling location. The Secretaries agree that exposures do vary from shift to shift, as these data illustrate. This variability, however, is largely under the control of the mine operator and should not be considered when evaluating the accuracy of a single, full-shift measurement.

V. Sequential Exposure Data Submitted by Jim Walter Resources, Inc.

Jim Walter Resources, Inc. submitted data collected from several longwall faces. For each longwall, seven dust samples were collected, using sampler units placed on the longwall face at least 48″ from the tailgate at the MSHA 061 designated location. Pumps were successively turned off in one hour increments, resulting in samples covering progressively longer time periods over the course of the shift, from one to eight hours. This was repeated on a number of days at each longwall.

Many of the samples showed either the same or less weight gain than the previous sample (collected over a shorter time period) within a sequence. In the cover letter and written comments accompanying these data, it was claimed that the weight gains observed for samples within each sequence should progressively increase, irrespective of variations in air flow and production levels, and that the patterns observed exemplify ''the variability of sample results with today's equipment and weighing techniques.''

MSHA and NIOSH have concluded that these data cannot be used to estimate or otherwise evaluate measurement accuracy for the following reasons: First, a highly sensitive and accurate sampling device would be expected to produce variable results when exposed to even slightly different environments. Since the samples within each sequence of seven were not collected at exactly the same point, they are subject to spatial variability in dust concentration. It is well known that dust concentrations can vary even within small areas along a longwall face. Therefore, variability in sample results is attributable not only to measurement errors but also to variations in dust concentration due to spatial variability.

Second, even on a production shift, variations in air flow and production levels over the course of the shift can result in periods within the shift during which the true dust concentration to which a sampler is exposed is low or near zero. If a sampler unit is exposed to a relatively low dust concentration during the final hour in which it is exposed, any difference between that sample and the previous sample will tend to be dominated by spatial variability. In such cases the increase in weight accumulated during the final hour would be statistically insignificant as compared to variability in dust concentration at different locations. Without detailed knowledge of the airflow and production levels as they varied over each shift, it is impossible to determine how many cases of this type would be expected. However, approximately one-half of such samples would be expected to exhibit less weight gain than the previous sample.

Further, because sample weights were truncated to 0.1 mg at the time these data were collected, and because expected weight gains of less than 0.1 mg are not uncommon over a one-hour period, there would be no apparent increase in recorded weight gain in many cases where the two sample results actually differed by a positive amount. Therefore, some unknown number of cases showing no difference in successive weight gains are attributable to truncation effects. Truncation has now been discontinued for samples collected under MSHA's inspection program.

Finally, as has been shown in Appendix C, a certain percentage of negative weight-gain measurements at low dust concentrations is consistent with the weighing imprecision experienced at the time these samples were collected. However, since these data were not collected in a controlled environment, it is impossible to determine what that percentage should be. Because the weight gain for each sample is determined as the difference between two weighings, comparison of weight gains between two samples involves a total of four independent weighing errors. Therefore, variability attributable purely to weighing error in the difference between weight gains in two successive samples is greater (by a factor equal to ''2) than variability due to weighing error in a single sample. Furthermore samples collected over less than a full shift are subject to more variability due to random fluctuations in pump air flow and cyclone performance than samples collected over a full shift. Both of these considerations increase the likelihood that a sample will exhibit less weight gain than its predecessor, as compared to the likelihood of recording a negative weight gain for a single, full-shift sample.

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XVI. Regulatory Text

List of Subjects in 30 CFR Part 72

Coal, Health standards, Mine safety and health, Underground mines, Miscellaneous.

Dated: May 31, 2000.

Alexis M. Herman,

Secretary, Department of Labor.

Dated: May 31, 2000.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

Accordingly, it is proposed by the Department of Labor, Mine Safety and Health Administration, to amend chapter I of title 30 of the Code of Federal Regulations as follows:

PART 72—[AMENDED]

1. The authority citation for part 72 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957, 961.

2. Section 72. 500 is added to subpart E of part 72 to read as follows:

§ 72.500 Single, full-shift measurement of respirable coal mine dust.

The Secretary may use a single, full-shift measurement of respirable coal mine dust to determine average concentration on a shift if that measurement accurately represents atmospheric conditions to which a miner is exposed during such shift.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 70, 75 and 90

RIN 1219–AB14

Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust

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

ACTION: Proposed rule; notice of hearings.

SUMMARY: MSHA is proposing to revoke existing operator respirable dust sampling procedures under parts 70 and 90, and to implement new regulations that would require each underground coal mine operator to have a verified mine ventilation plan. Under this proposal, MSHA would verify the effectiveness of the mine ventilation plan for each mechanized mining unit (MMU) in controlling respirable dust under typical mining conditions. MSHA would collect full-shift respirable dust samples, called ''verification samples,'' to demonstrate the adequacy of the dust control parameters specified in the mine ventilation plan in maintaining the concentration of respirable coal mine and quartz dust at or below 2.0 mg/m^3 and 100 μg/m^3, respectively. The adequacy of these parameters would be demonstrated on shifts during which the amount of the material produced is at or above the ''verification production level'' (VPL) or the tenth highest production level recorded in the most recent 30 production shifts.