DEPARTMENT OF LABOR

Mine Safety and Health Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

RIN 1219–AA82

Mine Shift Atmospheric Conditions; Respirable Dust Sample

AGENCIES: Mine Safety and Health Administration, Labor, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, HHS.

ACTION: Final notice of joint finding.

SUMMARY: This notice announces that the Secretary of Labor and the Secretary of Health and Human Services (the Secretaries) find, in accordance with sections 101 and 202(f)(2) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 811 and 842(f) respectively, 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. This notice should be read in conjunction with the notice published separately by the Mine Safety and Health Administration (MSHA) elsewhere in today's **Federal Register**. The Secretaries are rescinding the previous finding, which was proposed on July 17, 1971 and issued on February 23, 1972, by the Secretary of the Interior and the Secretary of Health, Education and Welfare.

EFFECTIVE DATE: This notice will be effective on March 2, 1998.

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

SUPPLEMENTARY INFORMATION: In accordance with section 202(f)(2) and section 101 of the Mine Act, this notice is published jointly by the Secretaries of the Departments of Labor, and Health and Human Services.

I. Introduction

For as long as miners have taken coal from the ground, the presence of respirable dust in coal mines has been a source of health problems for miners. Coal workers' pneumoconiosis, one of the most insidious of occupational diseases, is caused by deposits of coal mine dust in the lung and is known as "black lung disease." The disability that may result from these deposits can range from slightly impaired lung function to significant decreases in lung function resulting in breathlessness, recurrent chest illness, and even heart failure. In addition, the disease may progress even after the miner is no longer exposed to coal mine dust.

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/m^3). The 2.0 mg/m^3 standard sets a limit on 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 disease was by limiting the amount of respirable 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/m^3 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). (Other provisions in the Mine Act, sections 205 and 203(b)(2), provide for lowering the applicable standard when quartz is present and when miners with evidence 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 show that the average dust concentration in the environment of a continuous miner operator was 7.7 mg/m^3. Current sampling indicates that the average dust level for that occupation has been reduced by 83 percent to 1.3 mg/m^3. Despite this progress, the Secretaries believe that occupational lung disease continues to present a serious health risk to coal miners. In November 1995, the National Institute for Occupational Safety and Health (NIOSH) issued a criteria document which concluded that coal miners in our country continue to be at risk for developing black lung disease.

The Secretary of Labor believes that miners' health can be further protected from the debilitating effects of black lung disease by improving their workplace conditions through more effective assessment of respirable dust concentrations during individual, full shifts. On February 18, 1994, the Secretary of Labor and the Secretary of Health and Human Services published a notice in the **Federal Register** proposing to find 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 in accordance with section 202(f)(2) of the Mine Act (56 FR 8357). Additionally, the Secretaries proposed to rescind the previous finding, which was proposed on July 17, 1971 (36 FR 13286) and issued on February 23, 1972 (37 FR 3833), by the Secretary of the Interior and the Secretary of Health, Education and Welfare.

II. General Discussion

The issues related to this finding are complex and highly technical. The Agencies have organized this final notice to allow interested persons to first consider pertinent introductory material on the Agencies' 1972 notice and its recision, and a short overview of the NIOSH mission and assessment of this finding, as well as those aspects of MSHA's coal mine respirable dust program relevant to this finding. 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 finding. Finally, the notice explains how the total measurement uncertainty was quantified, and how the accuracy of a single, full-shift measurement was shown to meet the NIOSH Accuracy Criterion. Several Appendices, which contain relevant technical information, are attached and incorporated with this notice. The Agencies have additionally included references to the Appendices throughout this notice.

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 shift measurement 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 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.

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.
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> 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.
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> The proposed finding, as set forth at 36 F.R. 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.

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) requires 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). 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 set forth in the notice, the Secretaries hereby rescind the 1972 joint final finding.

III. 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 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, Congress gave specific research responsibilities to NIOSH in the field of coal or 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 the National Institute for Occupational Safety and Health, has reconsidered the provisions of section 202(f) of the Mine Act, 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. 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 1984, a fully-automated, robotic weighing system was introduced along with state-of-the-art electronic microbalances. 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 MSA 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 MSA 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, the Secretary of Health and Human Services has determined that the previous joint finding should be reevaluated.

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

IV. 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.

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, which 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 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 standard, the operator reverted back to the standard 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.

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 with a bimonthly sampling cycle and to eliminate the requirement that each miner be sampled. These are the regulations that currently govern the mine operator dust sampling program, and which 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 preamble to the final rule amending the regulations in April 1980 (45 FR 23997), explicitly refers to the use of single versus multiple samples as it applies to the operator respirable dust sampling program.

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-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, which 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 by conducting inspections annually at each surface and underground coal mine. During these inspections, MSHA inspectors collect samples on multiple occupations to determine compliance with the applicable standard, assess the effectiveness of the operator's dust control program, quantify the level of crystalline silica (quartz) in the work environment, and identify occupations other than the ''D.O.'' which may be at risk and should be monitored by the mine operator.

Depending on the concentration of 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. 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. 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 it, additional samples are collected on the subsequent production shift or day. The results of the first and second day 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 day because a previous measurement exceeds the standard, MSHA's procedures call for all measurements taken on a given occupation to be averaged individually for that occupation. If the average of measurements taken over more than one day 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 (based on the cumulative concentration for two or more samples exceeding 10.4 mg/m^3, which is equivalent to a 5-measurement average exceeding 2.0 mg/m^3), the operator is cited for exceeding 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. As part of that 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 greater than or equal to 2.1 mg/m^3, or any single, full-shift measurement exceeded or equaled 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.

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). 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 concentration for two occupations exceeds 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.

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 shift inspection policy initiated during the SIP.

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 finding that rulemaking was required under section 202(f) of the Mine Act 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.

V. Executive Order 12866 and Regulatory Impact Analysis

MSHA has designated this joint finding as a significant action; it has been reviewed by OMB under E.O. 12866. MSHA estimates that the total annual costs associated with the implementation of this finding will be $707,950, of which $446,125 will be incurred by underground coal mines and $261,825, incurred by surface coal operations. MSHA projects that this finding will result in reductions of future cases of occupational lung disease and attendant cost savings. MSHA has prepared a separate regulatory impact analysis which is available to the public upon request.

VI. Procedural History of the Current Notices

As a result of the innovations and technological advancements described earlier, and the decision in *Keystone Coal* v. *Secretary of Labor*, 16 FMSHRC 6 (January 4, 1994), the Secretary of Labor and the Secretary of Health and Human Services published a proposed joint notice in the **Federal Register** on February 18, 1994 (59 FR 8357), pursuant to sections 101 and 202(f)(2) of the Mine Act. The notice proposed to rescind the 1971/1972 proposed and final findings by the Secretaries of the Interior and Health, Education and Welfare, and 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 respirable dust measurements and the average of multiple, full-shift respirable dust measurements for noncompliance determinations (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 new procedure.

The comment period on the proposed joint finding was scheduled to close on April 19, 1994, but was extended to May 20, 1994, in response to requests from the mining community (59 FR 16958). Subsequently, public comments were received, including comments from both labor and industry.

On July 6, 1994, in response to requests from the mining community, a public hearing was held on both notices in Morgantown, West Virginia (59 FR 29348). Also, in response to additional requests from the mining community, a second hearing was held on July 19, 1994, in Salt Lake City, Utah. To allow for the submission of post-hearing comments, the record was held open until August 5, 1994.

The hearings on the proposed joint notice were conducted by a joint MSHA/NIOSH panel. Presenters at the Morgantown hearing included international and local representatives of the United Mine Workers of America (UMWA), several mine operators, and a panel presentation from the American Mining Congress (AMC) and the National Coal Association (NCA). Presenters at the Salt Lake City hearing included the Utah Mining Association, several mine operators, and another joint AMC/NCA panel. The joint MSHA/NIOSH panel received prepared remarks from the presenters and asked questions as well. The joint agency panel also responded to questions from the presenters.

To ensure that all issues raised were fully considered, MSHA and NIOSH conducted a thorough review of existing data, engaged in an extensive literature search, sought an independent analysis of the scientific validity of single, full-shift measurements, and conducted additional testing. These efforts resulted in the collection of a significant amount of information, which was made a part of the public record on September 9, 1994 (59 FR 50007). To allow interested parties the opportunity to review and comment on the supplemental material, the Agencies extended the comment period from September 30 to November 30, 1994.

After the close of the comment period, the Agencies reviewed all of the comments, data and other information submitted into the record. Some of the commenters raised questions regarding the accuracy of single, full-shift measurements and challenged the Agencies' estimate of measurement imprecision inherent in sample collection and analysis. While reviewing these issues, the Agencies concluded that the term ''accurately represent'' as used in section 202(f) needed to be defined because of the issues which commenters raised. In response, the Agencies reopened the record on March 12, 1996, to provide a criterion for ''accuracy'', to supply new data and statistical analytical analyses on the precision of coal mine respirable dust measurements obtained using approved sampling equipment, and to allow the public to review and submit comments on the supplemental information (61 FR 10012). In addition, the March 12 notice identified certain refinements in MSHA's measurement process as applied to inspector samples. These modifications, currently in place, involve the measurement of both pre- and post-exposure filter weights to the nearest microgram on a scale calibrated using the established procedure in MSHA's laboratory, and discontinuing the practice of truncating the recorded weights used in calculating the dust concentration (that is, MSHA no longer ignores digits representing hundredths and thousandths of a milligram).

The new comment period was scheduled to close on April 11, 1996, but was extended until June 10, 1996, in response to requests from the mining community. Additionally, on April 11, 1996, the Agencies announced their intention to conduct a second public hearing on the content of the March 12 notice (61 FR 16123). On May 10, 1996, a public hearing conducted by a joint MSHA/NIOSH panel was held in Washington, DC. One scheduled presenter, representing the UMWA, appeared at this hearing.

Some commenters expressed concern for the procedures used by the Agencies in making a new finding, asserting that MSHA and NIOSH were not complying with the rulemaking provisions of the Mine Act. These commenters contended that the recision of the final finding and implementation by MSHA of single, full-shift sampling can only be effectuated through notice and comment rulemaking. These commenters argue that because MSHA failed to appeal the *Keystone* case, MSHA was bound by the Commission decision in that case which mandated notice and comment rulemaking to rescind the prior finding and authorize use of single samples by the Agency.

MSHA and NIOSH have considered these comments, but believe that the process they have chosen to follow is consistent with the requirement of section 202(f) of the Mine Act, which provides that a finding shall be made ''in accordance with the provisions of section 101'' of the Mine Act. Section 101 contains the procedural requirements for promulgation of mandatory health and safety standards, including provision for notice and comment. All interested parties were given ample opportunity for notice and comment at every stage of consideration of the proposed joint finding. The Agencies are not developing, promulgating, or revising a mandatory health standard in this notice, nor is the 2.0 mg/m^3 respirable dust standard being revised. Moreover, the Agencies have made a finding that the average concentration of respirable dust in the mine atmosphere to which each miner in the active workings of a coal mine is exposed during a shift can be accurately measured with a single, full-shift sample. This is a scientific finding contemplated by section 202(f) of the Mine Act. While one commenter asserted that the Secretaries were not following proper notice and comment procedures in section 101 [e.g., sections 101(a)(1) through (9)], the only example given by the commenter is the fact that the notice was published in the ''Notice'' section, rather than the ''Proposed Rules'' or ''Rules and Regulations'' section of the **Federal Register**. Because this is not a mandatory safety and health standard, there is no need for the Secretaries to publish the finding as a proposed rule, or to address feasibility, for example, which would be required under section 101(a)(6)(A) when a mandatory safety or health standard is promulgated. The Secretaries have properly complied with all the procedural elements of section 101 which apply to this notice.

Some commenters referenced section 101(a)(9) of the Mine Act, 30 U.S.C. 811(a)(9), which provides that no mandatory standard shall reduce the protection afforded miners by an existing standard under the Mine Act. As stated previously, this scientific finding does not constitute rulemaking and is not a promulgation of a mandatory health standard. Rather, it is a ''finding'' under the Mine Act, established in the same manner as the initial finding, in 1972, the effect of which is to increase health protection for miners by allowing single, full-shift measurements to be used to determine average concentrations during a single work shift instead of continuing to rely solely on averaging the results of several days of sampling or sampling across various occupations on the same shift.

In MSHA's notice published on February 18, 1994 (59 FR 8356), the Agency specifically noted that any change to the substantive procedure for mine operator respirable dust sampling governed by MSHA regulations would require rulemaking by MSHA.

VII. Issues Regarding Accuracy of a Single, Full-Shift Measurement

Some 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, 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); 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 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 commenters asserted that the dust concentration that should be measured is dust concentration averaged over a period greater than a single shift. Some commenters noted that dust concentrations can vary during a shift and that dust concentration is 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 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.'' Later in section 202(f), 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 respirable dust as the dust measured by an approved sampler unit.

2. Time Period to Which the Measurement Applies

Section 202(b)(2) provides that each mine operator ''* * * shall 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. 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.'' For the purpose of this notice, the Secretaries have determined that ''atmospheric conditions'' mean the fluctuating concentration of respirable coal mine dust during a single shift. These are the atmospheric conditions to which a sampler unit is exposed. Therefore, the present 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. As articulated by the United States Court of Appeals for the 10th Circuit in *American Mining Congress (AMC)* versus *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.'' Because the Secretary of Labor intends to prevent excessive exposure by limiting dust concentration at every location in the active workings, the area represented by any respirable dust measurement must be the sampling location.

Some 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 false premise that the measurement objective in section 202(f) is something other than the average atmospheric conditions during a single shift at the sampling location. It is true that these mean quantities described by some commenters cannot be accurately estimated using a single, full-shift measurement, but the Secretaries make no claim of doing so, nor are they required to make such considerations.

Some commenters argued that Congress intended that the measurement objective be a long-term average. Specifically, some 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, 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* versus *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.

Some 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 commenters maintained that the measurement objective is 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 prevent excessive exposure to respirable dust.

Several 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. Section 202(a) of the Mine Act, however, 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.

Accordingly, the Secretaries define the measurement objective to be the accurate determination of the average atmospheric conditions, or 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 commenters, the Agencies found that the term ''accurately represent,'' as used in section 202(f) in connection with a single shift measurement, was not defined in the Mine Act. Therefore, in their March 12, 1996 notice, 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. This criterion requires that measurements come within 25 percent of the corresponding true dust concentration at least 95 percent of the time [1].

One 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 is not 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 criteria for the method is ±35 percent at 95 percent confidence at the permissible exposure limit.

Some commenters contended that the NIOSH Accuracy Criterion does not conform with international standards recently adopted by the European Committee for Standardization (CEN) [2]. 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.

The NIOSH Accuracy Criterion is relevant and widely recognized and accepted in the occupational health professions. Further, commenters proposed no alternative criteria for accuracy. Accordingly, for purposes of section 202(f) of the Mine Act, the Secretaries 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'' [1]. Similarly, the CEN criterion for method accuracy specifies that ''testing of a procedure shall be carried out under laboratory conditions.'' 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 VII.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 [1,3]. 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 determined in the same laboratory, any bias in the weighing process attributable to the laboratory is mathematically canceled out by subtraction. Furthermore, as will be discussed later, a control (i.e., unexposed) filter capsule will be pre- and post-weighed along with the exposed filter capsules. The weight gain of the exposed capsule will be adjusted by the weight gain or loss of the control filter capsule. Therefore, any bias that may be associated with day-to-day changes in laboratory conditions or introduced during storage and handling of the filter capsules is also mathematically canceled out. Moreover, the concentration of respirable dust is effectively defined by section 202(e) of the Mine Act 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 have concluded 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 cannot be reduced by making multiple measurements. Other comments regarding measurement bias are addressed in Appendix A.

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 the 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 is operated portal to portal. The unit 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 are particles that tend to be removed from the airstream by the nose and upper respiratory airways. These 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. The 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 again to determine the weight gain in milligrams, which is the amount of dust collected on the filter. The concentration of respirable dust, expressed as milligrams per cubic meter (mg/m^3) of air, is determined by dividing the weight gain by the volume of mine air passing through the filter and then multiplying this quantity by a conversion factor (discussed below in Appendix A) prescribed by the Secretary.

Some 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, due to their age and condition, of sampling pumps used by MSHA inspectors. 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 error and ensure that samples collected with approved sampler units in the prescribed manner would accurately represent the full-shift, average atmospheric dust concentration 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 using 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 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, 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. NIOSH also conducts annual 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 these checks identify a potential problem with the manufacturing process, the system requires immediate action to identify and 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 falling out of the capsule inlet.

Several commenters questioned the quality of the filter cassettes used in the sampling program, expressing concern about whether the cassettes always meet MSHA specifications. These concerns primarily involve filter-to-foil distance and floppiness of the filters, which are manufacturing characteristics not related to part 74 performance requirements. The Secretaries believe that such characteristics 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.

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.

This concern is unwarranted. 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, MSHA inspectors are required to make a minimum of two flow rate checks to ensure that the sampler unit is operating properly. The sample is voided if the proper flow rate was not being maintained during the final check at the conclusion of the sampling shift. 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 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 [4].

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 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. 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 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 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 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 affect the validity of the sample had occurred during the shift.

Other 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 notice, 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 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 are already standardized under the revised 1980 MSHA regulations codified at 30 CFR parts 70, 71 and 90.

MSHA inspectors will also begin using control filter capsules 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 capsule is an unexposed filter capsule that was pre-weighed on the same day as the filter capsules used during a sampling inspection. These control filter capsules will be carried by the inspector, but will remain plugged and not be exposed to the mine environment.

3. Sample Processing

Sample processing consists of weighing the filter capsules, recording the weight gains, and examining certain samples in order to verify their validity. Sample processing also includes electronic transmission of the results to MSHA's computer center where dust concentrations are computed. The results are then distributed to MSHA enforcement personnel and to mine operators.

(a) *Weighing and recording procedures.* One commenter cited a personal experience in which anomalies were noted in the pre-exposed weights recorded by the dust cassette manufacturer. The commenter was concerned that such anomalies indicated poor quality control in the manufacturer's weighing process, implying that this would cause a significant number of single, full-shift measurements to be inaccurate.

The procedures and analytical equipment used by MSHA to process respirable coal mine dust samples have improved since 1970. From 1970 to 1984, samples were manually weighed using semimicro balances. In 1984, the process was automated with 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 balance were upgraded.

The full benefit of the 1994 improvements of the weighing system for inspector samples was, however, not fully attained until mid-1995, when MSHA implemented two modifications to its procedures for processing inspector samples. One modification involved measuring both the pre- and post-exposed weights to the nearest microgram (0.001 mg) on a balance calibrated using the established procedure within MSHA's laboratory. Prior to mid-1995, filter capsules had been weighed in the manufacturer's laboratory before sampling, and then in MSHA's laboratory after sampling. MSHA is now pre-weighing all such filter capsules in its own laboratory, which will significantly reduce the potential for anomalous pre-exposed weights of filter capsules used by inspectors. To maintain the integrity of these pre-exposed weights, eight percent of all capsules are systematically weighed a second time. If a significant deviation is found, the balance is recalibrated and all filter capsules with questionable weights are reweighed.

The other modification was to discontinue the practice of truncating the recorded weights used in calculating dust concentration. This means that MSHA no longer ignores digits representing hundredths and thousandths of a milligram 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 filter capsules, MSHA will use control filter capsules in its enforcement program. Any change in weight of the control filter capsule will be subtracted from the change in weight of the exposed filter capsule.

(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 a questionable appearance of the filter capsule or other special circumstances are noted that would cause MSHA to examine the sample further. Several commenters expressed concern about the potential contamination of samples with ''oversize 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 oversize particles. It was recommended that MSHA analyze, for the presence of oversize 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 weighing 1.4 milligrams (mg) or more are examined visually and microscopically, as necessary, 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 commenters' concerns about the contamination of samples with oversize particles are based on the assumption that all oversize particles, defined as dust particles greater than 10 micrometers in size, are not respirable and therefore should be totally excluded from any sample taken with an approved sampler unit. In fact, it has long been known that particles greater then 10 micrometers in size can be inhaled, and that some of these particles can reach the alveoli of the lungs [5]. 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'' [6]. 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 [6]. Moreover, MSHA studies have shown that nearly all samples taken with approved sampler units, even when operated in the prescribed manner, contain some oversize particles [7]. Since section 202(e) of the Mine Act defines concentration of respirable dust to be that measured by an approved sampler unit, and because the approved sampler unit will collect some oversize particles, the Secretaries do not consider a sample to be ''contaminated'' because it contains some oversize particles.

The Secretaries recognize that there are occasions when oversize particles can properly be considered a contaminant. For example, an excessive number of such particles could be introduced into 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 drawn into the filter capsule), 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 commenters, checking for oversize particles is not standard industrial hygiene practice. Nevertheless, MSHA checks any dust sample suspected of containing an excessive number of oversize 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 oversize particles. 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 oversize particles according to MSHA's established criteria, then that sample is considered to be invalid, and is voided and not used. In fiscal year 1996, only 83 samples or 0.4 percent of the 20,331 inspector samples processed were found to contain an excessive number of oversize particles and thus were not used.

While rough handling of the sampler unit or an accidental mishap could conceivably cause a sample weighing less than 6 mg to become contaminated, as claimed by some commenters, studies show that short-term accidental inclinations of the cyclone will not affect respirable mass measurements made with currently approved sampler units [8]. 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 commenters. In any event, the Secretaries believe that the validity checks currently in place, as discussed above, will detect such samples.

D. Measurement Uncertainty and Dust Concentration Variability

Overall variability in measurements collected on different shifts and sampling locations results from the combination of errors associated with the measurement of a particular dust concentration and variability in dust concentration. Variability in dust concentration refers to the differing atmospheric conditions experienced on different shifts or at different sampling locations. Measurement uncertainty, on the other hand, refers to the differing measurement results that could arise, at a given sampling location on a given shift, because of potential sampling and analytical errors.

Numerous 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 will 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 are 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/m ^{3});

1.38 is a constant MRE-equivalent conversion factor;

g is the observed weight gain (mg) after adjustment for the control filter capsule;

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}. 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 percentage (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/m ^{3}, and the standard deviation of potential sampling and analytical errors associated with x is equal to 0.075 mg/m ^{3}, the uncertainty associated with x would be expressed by the ratio of the standard deviation to the true dust concentration: $CV_{total} = 0.075/1.5 = 5$ percent.

Based on a review of the scientific literature, the Secretaries in their March 12, 1996 notice, identified three sources of uncertainty in a single, full-shift measurement, which together make up CV:

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

(2) CV_{pump}—variability in the total volume of air pumped through the filter capsule. This covers variability associated with calibration of the pump rotameter,[2] 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}.

(3) $CV_{sampler}$—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 comments, in Appendix B.

2. Sources of Dust Concentration Variability

Numerous 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 VII.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, and is under the control of the mine operator. The sampler unit is not intended to account for these factors.

(a) *Spatial variability.* Several 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 is to accurately measure average atmospheric conditions, or concentration of respirable dust, at a sampling location over a single shift.

(b) *Shift-to-shift variability.* Several commenters stated that CV_{total} should take into account the differences or variations in dust concentration that occur shift to shift. Although the Secretaries 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 is 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 oversize particles.* Several 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 have concluded 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 [8]. The weight of the sampler head assembly makes it extremely unlikely that a

[2] 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.

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.* Several 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 in fact be violated. No evidence was 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 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.

(c) *Conversion factor used in the dust concentration calculation.* Several 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 [9]. 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 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 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 A on why use of the 1.38 factor does not introduce a bias. Appendix A 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 CV_{total}, 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, 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 do not agree with the comment that CV_{total} should include a component representing potential errors in silica analysis.

(e) *Dusty clothing.* Several 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 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 commenters argued that MSHA underestimated CV_{total} in its February 18, 1994 notice 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 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.'' For example, the General Accounting Office (GAO)[3] 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 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 [10].

Although all the data and analyses submitted by commenters included effects of spatial variability, one of these data sets, consisting of paired sample results, contained sufficient information to indicate that weighing imprecision

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

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, is not 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 commenters particularly questioned the value MSHA used in its February 18, 1994 notice 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 [11]. Results showed the coefficient of variation associated with the initial flow 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 have concluded 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 have concluded 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 commenters ignored this source of uncertainty. As explained in Appendix B, the Secretaries have adopted a 5-percent estimate of $CV_{sampler}$.

To address 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 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.

Commenters also questioned the value that MSHA used in the February 1994 notice 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 [12]. 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 the March 12, 1996 joint notice, 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 MSA and MSHA laboratories showed that filter capsules tend to gain a small amount of weight even when stored in plastic cassettes [13]. 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 [13,14]. 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 will use control filter capsules in its enforcement program. 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 modification to MSHA's inspector sampling and analytical procedure will assure an unbiased estimate of the true weight gain [14].

2. Verification of Method Accuracy

With its field study, MSHA exceeded the usual requirements for determining the accuracy of a sampling and analytical method, as described by NIOSH [1] and the European Community [2]. Both of these require only a laboratory determination of method accuracy. NIOSH's independent analysis of the study data determined, with 95-percent confidence, that the true CV_{total} for MSHA's sampling and analytical method is less than the target maximum value of 12.8 percent for concentrations ranging from 0.2 mg/m^3 to greater than 2 mg/m^3 [3]. In other words, NIOSH demonstrated that, with two recommended modifications, MSHA's sampling and analytical method for collecting and processing single, full-shift samples would meet the NIOSH Accuracy Criterion at dust concentrations greater than or equal to 0.2 mg/m^3.

NIOSH also applied an indirect approach for assessing the accuracy of MSHA's sampling and analytical method. The indirect approach involved combining independently derived estimates, previously placed into the public record, of intra-laboratory 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 meets the NIOSH Accuracy Criterion at concentrations greater than or equal to 0.2 mg/m^3, thereby corroborating the analysis of MSHA's field data.

These NIOSH analyses predate MSHA's more recent data indicating a correctable weight gain bias (discussed above). As explained in Appendices A and B, the use of control filter capsules will eliminate this bias but also affect the precision of a single, full-shift measurement. Consequently, NIOSH reassessed the accuracy of MSHA's sampling and analytical method, taking into account the effect of using a control filter capsule on the measurement process [14]. 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 dust concentrations greater than or equal to 0.3 mg/m^3.

One commenter claimed 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. Since the Secretaries have concluded that MSHA's sampling and analytical method for inspectors meets the NIOSH Accuracy Criterion for true concentrations ranging from 0.3 mg/m^3 to greater than 2 mg/m^3, it is possible to calculate the range of measurements for which the Accuracy Criterion applies. Since CV_{total} increases at the lower concentrations, it is important to determine the lowest measurement at which the NIOSH Accuracy Criterion is met. 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/m^3), no more than 5% of single, full-shift measurements would be expected to exceed 0.36 mg/m^3 [14]. Conversely, if a measurement equals or exceeds 0.36 mg/m^3, it can be inferred, with at least 95% confidence, that the true dust concentration equals or exceeds 0.3 mg/m^3 [14]. 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/m^3.

As a result of the prior analyses, MSHA's existing inspector sample processing procedures were changed to reflect the modifications that were incorporated into MSHA's field study. MSHA is now pre- and post-weighing inspector samples in the same laboratory, and reporting the pre- and post-exposure weights of inspector samples to the nearest microgram (μg). As a result of NIOSH's latest analysis, MSHA will now require its inspectors to use control filter capsules during sampling. In addition, MSHA is now using only constant-flow control pumps in the inspector sampling program. MSHA believes that exclusive use of constant-flow pumps, as in the field study, further enhances the quality of the Agency's sampling program.

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.

VIII. 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 find that a single, full-shift measurement at or above 0.36 mg/m^3 will accurately represent atmospheric conditions to which a miner is exposed during such shift. Therefore, pursuant to section 202(f) and in accordance with section 101 of the Mine Act, the 1972 joint notice of finding is hereby rescinded.

Appendix A—Why Individual Measurements are Unbiased

The accuracy of a measurement depends on both precision and bias [1,3]. 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, for MSHA inspector samples, by subtracting the pre-exposure weight from the post-exposure weight observed in the same laboratory, any bias in the weighing process attributable to the laboratory is mathematically canceled out by subtraction. A control filter capsule will be pre- and post-weighted along with the exposed filter capsules. The weight gain of each exposed capsule will be adjusted by subtracting the weight gain or loss of the control filter capsule. Consequently, any bias 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 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 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 [6]. 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 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. (MSA) 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 noted 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 MSA 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 MSA 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 by these commenters involved collecting side-by-side samples using MRE and cyclone-based samplers [9]. 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 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 B—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:

$G=W_2-W_1=0.409$ 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:
$g=w_2-w_1=0.397$ mg.

The error (e) in this particular weight-gain measurement, resulting from the combination of a 7 μg error in w_1 and a −5 μg error in w_2, would then be:

$$e=g-G=(w_2-w_1)-(W_2-W_1)=(w_2-W_2)-(w_1-W_1)=-5-7=-12\ \mu g.$$[4]

Imprecision in the true weight gain is expressed by σ_e, the standard deviation of e. When a weight-gain measurement (g) is converted to an MRE-equivalent concentration (in units of mg/m³) 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:

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

Therefore, the standard deviation of the propagated weighing error component in a single, full-shift measurement ($x=g1.438/m^3$) is $1.438\sigma_e$ mg/m³, assuming no adjustment for weight change in the control filter capsule.

Since a control filter capsule will be used to eliminate potential bias, the weight gain measured for the exposed filter (g) will be 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 in g-g′ is represented by

$$\sqrt{\sigma_e^2+\sigma_e^2}=\sqrt{2\sigma_e^2}=\sigma_e\sqrt{2}.$$

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 Weight-Gain Uncertainty

Table 1 summarizes six different values of σ_e that have been mentioned during the proceedings related to this notice and two additional values for σ_e derived in this appendix from data introduced during these proceedings. A ninth value for σ_e is derived from newly acquired data being placed into the record along with this notice [14]. The nine values listed in Table 1 are not inconsistent, but as explained below, represent estimates of weight-gain imprecision during different historical periods or under different sample processing procedures.

TABLE 1.—STANDARD DEVIATION OF ERROR IN WEIGHT GAIN

DESCRIPTION	Reference	σ_e (μg)
MSHA's historical estimate of upper bound	59 FR 8356, [15]	97.4
1981 Measurement Assurance Estimate (older technology, truncation of weights)	[16,17]	81
Experiment on 300 unexposed, tamper-resistant filter capsules (pre- and post-weighing in different labs; no truncation).	[12]	29
Inspector samples processed between late 1992 and mid 1995 (truncation of weights; pre- and post-exposure weighing in different labs; adjusted for differences between labs).	Appendix B	51.7
NMA Data (obtained from samples collected by Skyline Coal, Inc.)	Appendix C	76
Value used in NIOSH ''indirect approach'' (pre- and post-exposure weighing on same day and in the same lab; derived from Kogut [12]).	61 FR 10012, [12]	5.8
MSHA Field Study	[18,3]	9.1
1996 Measurement Assurance Estimate	61 FR 10012, [19]	6.5
1997 field data (75 unexposed capsules)	[14]	8.2

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 [15]. 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) [16]. 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

[4] 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, 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.

down to an exact multiple of 0.1 mg. This estimate was used to calculate CV_{weight} by Bartley [17], in September 1994.

Some commenters misread or misunderstood the published NBS estimate. One of these 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/m^3 compared to the 0.14 mg/m^3 * * * 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.* [16]. 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 to propagate an MRE-equivalent concentration error of 0.116 mg/m^3. Contrary to the commenters' assertion, this is less—not more—than the quantity (0.14 mg/m^3) 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 MSA laboratory and twice in MSHA's laboratory using current equipment [12]. 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 [3]. 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, when the most recent changes in inspector sample processing were implemented.

Some 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 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 commenters expressed special concern over the accuracy of pre-exposure filter capsule weights as measured by MSA. One commenter expressed ''grave concern'' with regard to the 12-µg systematic difference in weights found between MSA and MSHA weighings of the same unexposed capsules, as described in MSHA's 1994 analysis [12]. These concerns are moot, at least with respect to MSHA's inspector sampling program, since all inspector samples are now pre- and post-weighed at MSHA's laboratory. Furthermore, any potential bias resulting from differences in laboratory conditions on the days of pre- and post-exposure weighings should 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 C, was an estimate of σ_e equal to 76 µg ± 15 µg.[5] 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.

Truncation of weights, and also 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 are weighed both before and after sampling in MSHA's laboratory. Furthermore, the results recorded and used in calculating dust concentrations are expressed to the nearest µg. 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 [18]. In this study, the filter capsules 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/m^3 to less than one percent at concentrations greater than 2.0 mg/m^3. 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 [19]. 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 the

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

MSHA's 1995 field study discussed earlier (9.1 μg), falls only slightly above the 6.5 μg laboratory estimate. This suggests 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 [13]. 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 provide an estimate of σ_e equal to 8.2 μ*g* [14]. This estimate, which is based on weighings separated by a span of about four to five months, corroborates the 9.1 μ*g* estimate obtained from MSHA's 1995 field study.

(c) Negative Weight-Gain Measurements

Some 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 ≤–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 estimated for previous processing procedures. Table 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 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
.01	8.4
.02	5.1
.03	2.8
.04	1.5
.05	0.7
.06	.4
.07	.2
.08	.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. Since truncation, and especially interlaboratory variability, have now been removed as sources of error in weight-gain measurements for inspector samples, negative weight-gain measurements are expected to occur less frequently than in the past.

(d) Comparing weight gains obtained from paired samples

Some 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 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 $1.41 \bullet \sigma_e$.

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 (σ_σ in the notation of [12]) 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 C 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 [20]. 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 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 [10], 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 [11]. 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 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 [18]. That study estimated $CV_{pump} = 4.0$ percent and concluded that CV_{pump} was unlikely to exceed 4.4 percent.

Three commenters stated that there are reports of sampling pumps being calibrated and used at altitudes differing by as much as 3000 feet and that, for many pumps, this could result in more than a 3-percent change in flow rate per 1000 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 [21]. The study showed that both pump performance and rotameter calibration were affected by changes in altitude but that an approved MSA 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 commenters questioned the ability of the older MSA 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 [22]. 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 ± 0.1 L/min of the 2.0 L/min flow rate.[6] 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 condition. 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).

III. Intersampler Variability

Intersampler variability, represented by $CV_{sampler}$, accounts for uncertainty due to physical variations from sampler to sampler. Most of the 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 A).

Intersampler variability was investigated by Bowman *et al.* [10], Bartley *et al.* [17], and Kogut *et al.* [18]. 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 MSA 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 *et al.* 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 [3].

Appendix C—Data Submitted by Commenters

During the public hearings, several 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 accurately be used to 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

[6] 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.

Appendix B. The value of CV_{total} assumed by MSHA and NIOSH for the period when the Skyline samples were collected 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

$SAE^* = (CV^2{}_{total} + CV)^2{}_{spatial})^{1/2}$.

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 $(1/\mu^*)^2$:

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

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 B. 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 σ_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/m ^{3}) 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 average 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.

VII. 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.

VIII. 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 then 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 B, 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 $\sqrt{2}$) 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.

References

1. Kennedy, E.R., T.J. Fischbach, R. Song, P.M. Eller, and S.A. Shulman. *Guidelines for Air Sampling and Analytical Method Development and Evaluation*. U.S. Department of Health and Human Services, Public Health Service, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 95-117.

2. European Standard No. EN 482: *Workplace atmospheres—General requirements for the performance of procedures for the measurement of chemical agents*. European Committee for Standardization (CEN), 1994.

3. Wagner, G.R. Letter of October 13, 1995, from Gregory R. Wagner, M.D., National Institute for Occupational Safety and Health, to Ronald J. Schell, Chief, Division of Health, Coal Mine Safety and Health, Mine Safety and Health Administration.

4. Gray, D.C. and M.I. Tillery. *Cyclone vibration effects.* Am Ind Hyg Assoc J, 42(9):685–688, 1981.

5. Lippmann, M. and R.E. Albert. *The Effect of Particle Size on the Regional Deposition of Inhaled Aerosols in the Human Respiratory Tract.* Am Ind Hyg Assoc J, 30:257–275, 1969.

6. Goddard, B., K. Bower, and D. Mitchell. *Control of Harmful Dust in Coal Mines.* National Coal Board, 6–12, 1973.

7. Tomb, T.F. Memorandum of August 31, 1981, from Thomas F. Tomb, Chief, Dust Division, Pittsburgh Health Technology Center, MSHA, to William Sutherland, Chief, Division of Health, Coal Mine Safety and Health, MSHA, Subject: *Evaluation of Criterion Used to Select Respirable Coal Mine Dust Samples for Examination for Oversize Particles.*

8. Treaftis, H.N. and T.F. Tomb. *Effect of Orientation on Cyclone Penetration Characteristics*. Am Ind Hyg Assoc J, 35(10):598–602, 1974.

9. Tomb, T.F., H.N. Treaftis, R.L. Mundell, and P.S. Parobeck. *Comparison of Respirable Dust Concentrations Measured With MRE and Modified Personal Gravimetric Sampling Equipment*. BuMines RI 7772, 1973.

10. Bowman, J.D., G.M. Breuer, S.A. Shulman, and D.L. Bartley. *Precision of Coal Mine Dust Sampling.* U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, NTIS No. PB–85–220–721, 1984.

11. Tomb, T.F. Memorandum of September 1, 1994, from Thomas F. Tomb, Chief, Dust Division, Pittsburgh Safety and Health Technology Center, MSHA, to Ronald J. Schell, Chief, Division of Health, Coal Mine Safety and Health, MSHA, Subject: *Determination of the Precision of Setting the Rotameter Ball to a Calibration Mark on Personal Respirable Dust Sampling Pumps.*

12. Kogut, J. Letter of May 12, 1994, from Jon Kogut, MSHA, to David Bartley, Division of Physical Sciences and Engineering, NIOSH.

13. Parobeck, P., J. Kogut, T. Tomb, and L. Raymond. *Investigation of Weighing Variability Between MSHA and MSA Laboratories*. Internal MSHA Report 1997.

14. Wagner, G.R. Letter of May 28, 1997, from Gregory R. Wagner, M.D., Acting Associate Director for Mining, National Institute for Occupational Safety and Health, to Ronald J. Schell, Chief, Division of Health, Coal Mine Safety and Health, MSHA.

15. Kogut, J. Memorandum of September 6, 1994, from Jon Kogut, Mathematical Statistician, Denver Safety and Health Technology Center, MSHA, to Ronald J. Schell, Chief, Division of Health, Coal Mine Safety and Health, MSHA, Subject: *Coal Mine Respirable Dust Standard Noncompliance Determinations.*

16. Parobeck, P., T. Tomb, H. Ku, and J. Cameron. *Measurement Assurance Program for Weighings of Respirable Coal Mine Dust Samples.* J Qual Tech, 13(3):157–165, 1981.

17. Barley, D.L. Letter of September 7, 1994, from David L. Bartley, Research Physicist, Division of Physical Sciences and Engineering, NIOSH, to Ronald J. Schell, Chief, Division of Health, Coal Mine Safety and Health, MSHA.

18. Kogut, J., T.F. Tomb, P.S. Parobeck, A.J. Gero, and K.L. Suppers. *Measurement Precision With the Coal Mine Dust Personal Sampler.* Internal MSHA Report, 1995.

19. Tomb, T.F. Memorandum of February 16, 1996, from Thomas F. Tomb, Chief, Dust Division, Pittsburgh Safety and Health Technology Center, MSHA, to Ronald J. Schell, Chief, Division of Health, Coal Mine Safety and Health, MSHA, Subject: *Investigation to Determine the Precision of MSHA's Automatic Weighing System for Weighing Respirable Coal Mine Dust Samples.*

20. Kissell, F.N. and R.A. Jankowski. *Fixed-Point and Personal Sampling of Respirable Dust for Coal Mine Face Workers.* Paper in

Proceedings of the 6th US Mine Ventilation Symposium. Society of Mining, Metallurgy, and Exploration, Inc (SME), Littleton, CO, 281–186, 1993.

21. Treaftis, H.N., T.F. Tomb, and H.F. Carden. *Effect of altitude on personal respirable dust sampler calibration.* Am Ind Hyg Assoc J, 37(3):133–138, 1976.

22. Gero, A.J., P.S. Parobeck, K.L. Suppers, B.P. Apel, and J.D. Jolson. *The Effect of Altitude, Sample Port Inlet Loading, and Temperature on the Volumetric Flow Rate of the MSA Escort Elf® Constant Flow Rate Pump.* Pres. at Second International Conference on the Health of Miners, Pittsburgh, PA, November 11–13, 1995.

Dated: December 19, 1997.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

Dated: December 19, 1997.

Linda A. Rosentock,

Director, National Institute for Occupational Safety and Health.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

Coal Mine Respirable Dust Standard Noncompliance Determinations

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice; final policy.

SUMMARY: This notice announces the Mine Safety and Health Administration's (MSHA) final policy concerning the use of single, full-shift respirable dust measurements to determine noncompliance and issue citations, based on samples collected by MSHA, when the applicable respirable dust standard is exceeded. This notice should be read in conjunction with the notice published elsewhere in today's **Federal Register** jointly by the Department of Labor and the Department of Health and Human Services.

EFFECTIVE DATE: This policy is effective March 2, 1998.

FOR FURTHER INFORMATION CONTACT: Ronald Schell, Chief, Division of Health, Coal Mine Safety and Health; MSHA; 703–235–1358.

SUPPLEMENTARY INFORMATION:

I. About This Notice

This notice provides information about MSHA's new enforcement policy for the use of single, full-shift respirable dust measurements obtained by inspectors to determine noncompliance with the respirable dust standard (applicable standard) under the MSHA coal mine respirable dust program. A question and answer format has been used to explain the background for the enforcement policy, the reasons for the policy change, and the specific elements of the new policy. In addition, several appendices are attached to and incorporated with this final notice which address technical issues concerning the new enforcement policy.

II. Background Information

A. How Has MSHA Sampled Coal Mines for Noncompliance in the Past?

Prior to October 1975, noncompliance determinations were based on the average of full-shift measurements collected from individual occupations on multiple shifts. MSHA interprets a full shift for underground coal mines to mean the entire shift worked or 8 hours in duration or whichever time period is less (30 CFR 70.201(b)). The need to reduce the Agency's administrative burden attributable to inspector sampling prompted MSHA to revise its underground health inspection procedures and redirect the Agency's enforcement resources away from sampling and toward assessing the effectiveness of mine operators' respirable dust control programs.

Since October 1975, MSHA has determined noncompliance with the applicable standard based on the average of measurements obtained for different occupations during the same shift of a mechanized mining unit (MMU), or on the average of measurements obtained for the same occupation on successive days. 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. MSHA inspectors routinely sample multiple occupations to determine compliance with the applicable standard, assess the effectiveness of mine operators' dust control programs, determine whether excessive levels of quartz dust are present, and verify the designation of the "high risk occupation" (now referred to as the "designated occupation" or "D.O."—the occupation on a working section exposed to the highest respirable dust concentration) to be sampled by mine operators.

Under the sampling procedures in place between 1975 and 1991, MSHA inspectors would collect full-shift measurements from the working environment of the "D.O." and four other occupations, if available, on the first day of sampling each MMU. The mine operator was cited if the average of all measurements obtained during the same shift exceeded the applicable standard by at least 0.1 milligram of respirable dust per cubic meter of air (mg/m^3). If one or more measurements exceeded the applicable standard but the average did not, the Agency's practice was to continue sampling for up to four additional production shifts or days. If the inspector continued sampling after the first day because a previous measurement exceeded the applicable standard, noncompliance determinations were based on either the average of all measurements taken or on the average of measurements taken on any one occupation. Thus, if the average of measurements taken over more than one day on all occupations was less than or equal to the applicable standard, but the average of measurements taken on any one occupation exceeded the value set by MSHA (based on the cumulative concentration for two or more measurements exceeding 10.4 mg/m^3, which is equivalent to a 5-measurement average exceeding 2.0 mg/m^3), the operator was cited for exceeding the applicable standard.

In some instances, MSHA inspectors sampled for a maximum of five production shifts or days before making a noncompliance determination. However, most citations issued prior to 1991 were based on the average of multiple measurements on different occupations collected during a single shift. To illustrate, MSHA conducted a computer simulation using data from 3,600 MMU inspections conducted between October 1989 and June 1991. This simulation showed that a total of 293 MMUs would have met the criteria to be found in noncompliance with the applicable standard based solely on the average of multiple measurements. Two hundred forty-two of those noncompliance determinations, or 83 percent, met the citation criteria based on sampling results from the first day of MSHA sampling, rather than from multi-day sampling. Only 51 MMUs, or 17 percent, were citable based on the average of measurements collected over multiple shifts or days. These statistics clearly show that the citation criteria were met based not only on the average of measurements taken during several shifts, but also on the average of multiple measurements obtained during the same shift.

B. Why Did MSHA Establish the Coal Mine Respirable Dust Task Group and Initiate the Spot Inspection Program?

In 1991 concerns were raised about the adequacy of MSHA's program to control respirable coal mine dust in underground coal mines. In response to these issues, MSHA established the Coal