0.96, we amend 28 CFR part 548 as follows.

Subchapter C—Institutional Management

PART 548—RELIGIOUS PROGRAMS

1. The authority citation for 28 CFR part 548 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; 42 U.S.C. 1996; 28 CFR 0.95–0.99.

2. Add a new § 548.21 to read as follows:

§ 548.21 Chapel library materials.

(a) The Bureau maintains chapel library materials for inmates to pursue religious beliefs and practices while in Bureau custody consistent with ensuring that such materials do not jeopardize the safety, security, or orderly operation of Bureau facilities, or protection of the public.

(b) Material may be excluded from the chapel library if it is determined that such material could incite, promote, or otherwise suggest the commission of violence or criminal activity.

(c) For purposes of this subpart, inciting, promoting, or otherwise suggesting the commission of violence or criminal activity may include, but is not limited to:

(1) Advocating or fostering violence, vengeance, or hatred toward particular religious, racial, or ethnic groups; or

(2) Urging the overthrow or destruction of the United States.

[FR Doc. E9–550 Filed 1–15–09; 8:45 am]

BILLING CODE 4410–05–P

DEPARTMENT OF LABOR

Mine Safety and Health Adminisration

30 CFR Part 74

RIN 1219–AB61

Coal Mine Dust Personal Monitors

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

ACTION: Proposed rule and close of comment period.

SUMMARY: This proposed rule would revise requirements that the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) apply to approve sampling devices that monitor miner exposure to respirable coal mine dust. The proposal would establish criteria for approval of a new type of technology, the ''continuous personal dust monitor,'' which would be worn by the miner and would report exposure to dust levels continuously during the shift. In addition, the proposal would update application requirements for the existing ''coal mine dust personal sampler unit'' to reflect improvements in this sampler over the past 15 years. This rulemaking is limited to approval requirements and does not address requirements concerning how sampling devices must be used to determine compliance, *e.g.*, who and when to sample. Those requirements are addressed in existing 30 CFR parts 70, 71, and 90.

DATES: MSHA and NIOSH invite comments on this proposed rule from interested parties. All comments must be received by midnight Eastern Standard Time on March 17, 2009.

ADDRESSES: Comments must clearly be identified with ''RIN 1219–AB61'' and may be submitted to MSHA by any of the following methods:

(1) *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

(2) *Electronic mail: zzMSHA-Comments@dol.gov.* Include ''RIN 1219–AB61'' in the subject line of the message.

(3) *Facsimile:* (202) 693–9441. Include ''RIN 1219–AB61'' in the subject line of the message.

(4) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939.

(5) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939. Sign in at the receptionist's desk on the 21st floor.

Comments can be accessed electronically at *http://www.msha.gov* under the ''*Rules and Regs*'' link. MSHA will post all comments on the Internet without change, including any personal information provided. Comments may also be reviewed at the Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia. Sign in at the receptionist's desk on the 21st floor.

MSHA maintains a list that enables subscribers to receive e-mail notification when rulemaking documents are published in the **Federal Register**. To subscribe to the list, go to *http://www.msha.gov/subscriptions/subscribe.aspx.*

Information Collection Requirements: Comments concerning the information collection requirements of this proposed rule must be clearly identified with ''RIN 1219–AB61'' and sent to both the Office of Management and Budget (OMB) and MSHA. Comments to OMB may be sent by mail addressed to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for MSHA. Comments to MSHA may be transmitted either electronically to *zzMSHA-Comments@dol.gov,* by facsimile to (202) 693–9441, or by regular mail, hand delivery, or courier to MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA, at *silvey.patricia@dol.gov* (e-mail), (202) 693–9440 (voice), or (202) 693–9441 (facsimile).

SUPPLEMENTARY INFORMATION: The outline of this proposal is as follows:

I. Background

A. Introduction

The Coal Mine Health and Safety Act of 1969, the predecessor to the Federal Mine Safety and Health Act of 1977, specified that the average concentration of respirable coal mine dust be measured by a device approved by the Secretary of Interior and the Secretary of Health Education and Welfare (Secretaries). In 1972, the Secretary of Interior promulgated 30 CFR part 74—Coal Mine Dust Personal Sampler Units. That rulemaking established the requirements for joint approval of the device by both Secretaries and specified that MSHA's role was to determine if the unit was intrinsically safe. NIOSH would determine if the unit met the requirements of part 74.[1]

Since 1970, coal mine operators and MSHA have used approved coal mine dust personal sampler units (CMDPSUs) to determine the concentration of respirable dust in coal mine atmospheres. These devices sample the mine atmosphere by drawing mine air through a filter cassette that collects respirable coal mine dust. At the end of a full shift or 8 hours, whichever time is less, the cassette is sent to MSHA for processing. Each cassette is precisely weighed under controlled conditions to determine the average concentration of respirable coal mine dust to which the miner was exposed.

In the 1990s, NIOSH began research and development to produce a prototype technology for a new type of personal dust monitor that could provide readings of dust levels in the mine immediately during the shift and at the end of the shift. This would eliminate the delay of obtaining an offsite laboratory analysis which requires days before the results are made available to the mine operator and MSHA. The promise of the new technology, which is referred to generically as a ''continuous personal dust monitor'' (CPDM), was that it would allow mine operators to identify and immediately respond to high dust exposures. Operators would evaluate causes of over exposures, implement solutions to reduce exposures, and adjust them as necessary.

In 2003, a private sector monitoring technology company, Rupprecht and Patashnick Co., Inc., now Thermo Fisher Scientific, developed an initial prototype CPDM under contract with NIOSH. The prototype incorporates a unique mechanical mass sensor system called Tapered Element Oscillating Microbalance (TEOM®). The TEOM mass sensor is made up of a hollow tapered tube, which is clamped at its base and free to oscillate at its narrow or free end on which the collection filter is mounted. Electronics positioned around the sensor cause the tube to oscillate (or resonate) at its natural frequency. When dust particles are deposited on the collection filter, the mass of the collection filter increases, causing the natural oscillating frequency of the tapered element to decrease. Because of the direct relationship between mass and frequency change, the amount of respirable dust deposited on the filter can be determined by measuring the frequency change. The concentration of respirable dust in the mine atmosphere is then determined by a computer internal to the monitor, which divides the mass of dust collected by the volume of mine air that passed through the system during the time period sampled. The result is reported on the monitor's digital display. The cumulative average dust concentration is calculated and reported continuously over the duration of the shift and at the end of the shift. The data are also retained by the computer for downloading onto any personal computer with a Microsoft Windows® operating system using accompanying software. The prototype also projects the end-of-shift average dust concentration continuously during the shift. These projections can serve as a warning system to mine operators, assisting them in recognizing exposure levels that, if not reduced, would result in full-shift exposures exceeding regulatory limits.[2]

In 2006, NIOSH, in collaboration with MSHA and stakeholders representing the mining industry and labor, completed extensive testing to evaluate the accuracy of the pre-commercial unit and its suitability for use in the coal mine in terms of ergonomics and durability. The testing verified that the device achieved with 95 percent confidence end-of-shift measurements within ±25 percent of reference measurements[3] taken in a variety of coal mines. The testing also demonstrated that the device was acceptable to miners from an ergonomics standpoint, and was sufficiently durable to withstand the conditions of transportation and use in the mines. Thus, the testing demonstrated to MSHA and NIOSH that it is technically feasible to introduce the CPDM as an innovative new measurement tool for the protection of coal miners.[4]

B. Need for Rulemaking

Existing 30 CFR part 74, ''Coal Mine Dust Personal Sampler Units,'' specifies procedures and requirements by which MSHA and NIOSH[5] jointly approve the design, construction, performance, and manufacturing quality of the CMDPSU. These regulatory requirements, which were issued in 1972, are design-specific and do not permit the approval of any monitoring device of a different design. The CMDPSU is currently the only personal dust monitor approved for use in coal mines to monitor miners' exposure to respirable coal mine dust.

As discussed above, NIOSH, in collaboration with a private technology firm, MSHA, and representatives of industry and labor, has developed and evaluated a prototype for a new type of personal monitoring device, the ''continuous personal dust

[1] In 1978, responsibility for mine safety and health was transferred from the Department of Interior to the Department of Labor. In 1980 the Department of Health Education and Welfare became the Department of Health and Human Services (HHS).

[2] For a more complete description of the technology, see: Volkwein, J.C., Vinson, R.P., S.J. Page, L.J. McWilliams, G.J. Joy, S.E. Mischler, and D.P. Tuchman. Laboratory and field performance of a continuously measuring personal respirable dust monitor. CDC RI 9669. September 2006. 47 pp. and Volkwein, J.C., R.P. Vinson, L.J. McWilliams, D.P. Tuchman, and S.E. Mischler, Performance of a New Personal Respirable Dust Monitor for Mine Use. CDC RI 9663. June 2004.

[3] Reference measurements were established using multiple gravimetric samplers in dust exposure chambers for laboratory testing and using CMDPSUs in a variety of coal mines for field testing.

[4] See: Volkwein, J.C., R.P. Vinson, S.J. Page, L.J. McWilliams, G.J. Joy, S.E. Mischler, and D.P. Tuchman. Laboratory and field performance of a continuously measuring personal respirable dust monitor. CDC RI 9669. September 2006. 47 pp. and Volkwein, J.C., R.P. Vinson, L.J. McWilliams, D.P. Tuchman, and S.E. Mischler. Performance of a New Personal Respirable Dust Monitor for Mine Use. CDC RI 9663. June 2004.

[5] MSHA's role is to approve the ''intrinsic safety'' of the device, which assures that the device could be operated safely in the potentially explosive atmosphere of an underground coal mine.

monitor''(CPDM). The unit is capable of continuously monitoring and immediately displaying concentrations of respirable coal mine dust during the shift and also provides the end-of-shift summary measurements.

MSHA and NIOSH recognize that the ability to measure in real time the amount of respirable coal mine dust to which a miner is exposed offers the best solution for protecting miners from occupational lung disease. Knowing the actual respirable dust level and being able to project the end-of-shift dust exposure continuously during the shift will enable mine operators to take immediate action to prevent overexposure. This new technology can be a critical element in the strategy used by mine operators and MSHA to control respirable dust exposure.

The 1995 Advisory Committee on the Elimination of Pneumoconiosis Among Coal Mine Workers, which was established by the Secretary of Labor to make recommendations for improving the program to control respirable coal mine dust, also supported the use of continuous monitoring devices. That committee, which included representatives from the mining industry, the United Mine Workers of America and technical experts with no economic interests in mining, unanimously concluded that continuous monitors have the potential to improve monitoring of the work environment significantly and to contribute to the effective control of exposure.

However, existing MSHA standards and procedures for operator and agency monitoring of respirable coal mine dust specify that sampling must be conducted with an approved sampling device. The new CPDM technology cannot be approved under the existing part 74 requirements. MSHA and NIOSH are proposing to revise part 74 to accommodate this new technology.

While the proposed requirements under part 74 would allow the Secretaries to approve new types of sampling devices, existing standards under 30 CFR parts 70, 71 and 90 would need to be revised prior to using any new monitoring technology in coal mines for compliance purposes. Compliance issues are not within the scope of this rulemaking.

The proposed part 74 addresses performance-based and other requirements by which MSHA and NIOSH would approve CPDM devices for use in coal mines. The performance-based approach would allow for continued innovation in CPDM designs, which would accommodate improvements or alternative designs in the technology to be introduced in the future.

MSHA and NIOSH are also proposing in this rulemaking to revise the existing requirements in part 74 applicable to the approval of CMDPSUs. This proposed revision reflects improvements incorporated voluntarily by the manufacturer into the sampler design since the mid-1990s.

C. Public Hearings

MSHA and NIOSH will hold two hearings to provide the public with an opportunity to present oral statements, written comments, and other data on this rulemaking. One of the hearings will be held in the eastern part of the United States and the other will be held in the west. The hearings will be announced in a separate **Federal Register** notice. As indicated above, the nature of this rulemaking involves establishing performance-based approval requirements for manufacturers of monitoring devices. MSHA and NIOSH anticipate that two hearings will allow for full public input to the proposed rule.

II. Summary of Proposed Rule

This proposed rule would revise requirements for the approval of personal dust monitoring devices in 30 CFR part 74, currently titled ''Coal Mine Dust Personal Sampler Units,'' and would retitle the part ''Coal Mine Dust Personal Monitors.'' This rulemaking would establish performance-based and other requirements for approval of the new CPDMs. The requirements would facilitate innovation among direct-reading device manufacturers for the continued improvement of this technology.

The proposal also updates the existing design-based requirements for CMDPSUs. It is not the intent of this rulemaking to require changes in the current technology of CMDPSUs, although MSHA and NIOSH invite the public to comment on any aspect of this rulemaking.

Part 74 would be renumbered in this rulemaking as follows:

Subpart A—Introduction—Purpose and definitions.

Subpart B—Requirements for Coal Mine Dust Personal Sampler Unit—specifications for existing technology.

Subpart C—Requirements for Continuous Personal Dust Monitors—specifications for new technology.

Subpart D—General Requirements for All Devices—administrative provisions applicable to both the CMDPSU and CPDM.

III. Section-by-Section Analysis

The section-by-section analysis below describes and explains the proposed provisions of part 74. The proposed regulatory text is provided in the last section of this notice.

Subpart A—Introduction would be a new section which would cover the purpose and definitions.

A. Section 74.1 Purpose

Proposed § 74.1 describes the purpose of the rule and would be essentially unchanged from the existing provision. The scope has been expanded to include both CPDMSU and CPDM technology.

B. Section 74.2 Definitions

Proposed § 74.2 would be a new section to define key terms in the proposal.

Proposed paragraphs (a) and (b) would define the concepts of accuracy and bias as they apply to measurement devices such as the CPDM. They are key performance parameters for testing and approving of the CPDM.

Proposed paragraphs (c) and (d) would define the two types of sampling devices covered by this proposal, the CMDPSU and the CPDM. The definitions are included to distinguish between the two types of dust monitoring technology.

Proposed paragraph (e) would define the International Organization for Standardization (ISO), a voluntary consensus standards-setting organization. An ISO standard is relied on in this proposal (see § 74.9).

Proposed paragraph (f) would define the concept of precision as it applies to the CPDM. Precision is the third key performance parameter for the testing and approval of CPDMs.

Subpart B contains the requirements that apply to the CMDPSU.

C. Section 74.3 Sampler Unit

Proposed § 74.3 would renumber existing § 74.2, which specifies the major components of a CMDPSU and would be substantially unchanged from the existing provisions.

D. Section 74.4 Specifications of Sampler Unit

Proposed § 74.4 would renumber existing § 74.3 and update the requirements of the existing provision to reflect the sampling technology approved for use in coal mines today.

Existing paragraph (a) would update the existing design requirements for the pump unit of the CMPDSU.

Proposed paragraph (a)(1) would update pump dimensions to reflect the smaller size of the device used today: 4 inches (10 centimeters) in height; 4

inches (10 centimeters) in width; and 2 inches (5 centimeters) in thickness. The existing specifications allow for dimensions of up to 8 inches (20 centimeters), 6 inches (15 centimeters), and 4 inches (10 centimeters), respectively.

Proposed paragraph (a)(2), which specifies the maximum pump weight, would be updated to reflect the reduction in the weight of these units, from 4 pounds (1.814 kilograms) to 20 ounces (567 grams).

Proposed paragraph (a)(3), which specifies the characteristics of the construction of the pump case and pump components, would be updated to add the requirement that they must protect against radio frequency interference and electromagnetic interference. This improvement, implemented in the 1990s, is necessary to prevent potential instrument error or malfunction due to exposure to electromagnetic fields and various radio frequency ranges and signal strengths encountered in coal mines from power stations, electric motors and remote control transmitters. The proposal would retain the existing requirement that the case and components of the pump unit must be of durable construction and tight-fitting.

Proposed paragraphs (a)(4) and (a)(5) would be unchanged from the existing provisions. These paragraphs require that the pump exhaust into the pump case to maintain a slight positive pressure and the pump unit be equipped with an ON/OFF switch to protect against accidental operation during use.

Existing paragraph (a)(6), which specifies pump design characteristics for flow rate adjustment, would be revised to provide more flexibility in the design to avoid inadvertent changes in the flow rate. The existing specification requires the use of a flow rate adjusting ''tool'' to prevent inadvertent changes in the flow rate. This specific requirement would be deleted.

Proposed paragraph (a)(7), like the existing provision, would require that the power supply for the pump be a suitable battery located in the pump case or in a separate case which is attached by a permissible electrical connection.

Existing paragraph (a)(8), which concerns regulating the effect of pulsation on the flow rate of the pump, would be revised to delete the reference to the expired date (July 1, 1974) in paragraph (ii).

Proposed paragraphs (9) and (10), like the existing provisions, would require that the pump unit be equipped with a belt clip and that a suitable connection be provided to allow the battery to be recharged without removing it from the pump case or battery case.

Existing paragraph (a)(11), which requires a visual indication of the flow rate and specifies the calibration of the flow rate indicator, would be updated to require that it be calibrated within ±5 percent at 2.2, 2.0, and 1.7 liters per minute, versus at 2.0, 1.8, and 1.6 liters per minute as required under the existing rule. The proposed higher flow rates better reflect the operating flow rate range specified in proposed paragraph (a)(12).

Proposed paragraph (a)(12), like the existing provision, would require that the pump operate within a range from 1.5 to 2.5 liters per minute and be adjustable over this range.

Existing paragraph (a)(13), which requires the flow rate to remain consistent or stable during sampling, would be revised to require that the consistency be sustained over at least a 10-hour period, versus an 8-hour period under the existing provision. This change reflects the operating performance of these devices today and the prevalence of 10-hour shifts in coal mining. The existing requirements for readjustment of the flow rate would be deleted since all units currently in use have constant flow pumps and do not require readjustment.

Proposed paragraph (a)(14) would be a new provision that would require a flow restriction indicator. This new requirement would reflect current technology and would be incorporated to prevent the shutdown of a pump and loss of a sample if the flow restriction is not corrected. This helps assure that the mine atmosphere is accurately sampled. The requirements in existing paragraph (a)(14), which address duration of operation of the pump unit, would be transferred to new proposed paragraph (a)(15).

Existing paragraph (a)(14) would be redesignated as paragraph (a)(15). This provision would specify the required maximum expected operating time that the pump with a fully charged battery pack must be capable of operating at specific flow rates and sampling device loading. This paragraph would be revised to reflect the extended and higher level of performance achieved by existing technology. This increased capacity is necessary to enable the sampling of work shifts longer than 8 hours, which are prevalent today. The existing resistance requirement for 8 hours of operation at a flow rate of 2 liters per minute would be increased from 4 inches (10 centimeters) of water to 25 inches (64 centimeters) of water, as measured at the inlet of the pump. The proposal adds a new provision that reflects existing technology by requiring the pump to operate for not less than 10 hours at a flow rate of 2.5 liters per minute against a resistance of 15 inches (38 centimeters) of water.

Proposed paragraph (a)(16) is a new provision which would require the pump unit to be equipped with a low battery indicator. This provision reflects existing technology and is an important feature for ensuring the successful sampling of the mine atmosphere. Failure of the battery during sampling results in invalidation of the sample and the inability to determine the respirable coal mine dust concentration measured by the CMDPSU.

Proposed paragraph (a)(17) is a new provision which would require the pump unit to be equipped with an elapsed time indicator displaying the actual pump run time after the pump is shut down due to a flow restriction or low battery power, or at the end of the sampling shift. This proposal reflects existing technology and is necessary to determine if sampling was conducted for the required duration, which is essential for the accurate measurement of the respirable coal mine dust concentration that occurred during the work shift.

Proposed paragraph (b) addresses requirements for the sampling head assembly of the CMDPSU.

Proposed paragraphs (b)(1) and (b)(2)(i), retain the requirements of the existing provisions for the cyclone and the filter (with a minor wording change).

Proposed paragraph (b)(2)(ii), which specifies characteristics of the capsule enclosing the filter, would be revised to require that the capsule prevent visual inspection of the filter surface or filter loading. This reflects existing technology and is intended to safeguard the accuracy, integrity, and validity of the sample.

Existing paragraph (b)(2)(iii), which specifies characteristics of the cassette enclosing the capsule, would be revised to add the requirement that the cassette be designed to prevent intentional or inadvertent alteration of the dust deposited on the filter. The proposal would also add a requirement that the capsule covers be designed to prevent reversal of the air flow through the capsule or other means of removing dust collected on the filter. These provisions would reflect existing technology and are intended to safeguard the accuracy, integrity, and validity of the sample.

Proposed paragraphs (b)(3) and (b)(4) are the same as the existing provisions. Proposed paragraph (b)(3) relates to the connections between the cyclone vortex

finder and the capsule and between the capsule and hose. Proposed paragraph (b)(4) requires that the clamping and positioning of the cyclone-cassette assembly be firmly in contact, airtight and be attached firmly to a backing plate.

Existing paragraph (b)(5), which specifies the characteristics of the hose connecting the sampler pump and the filter assembly, would be revised to require that the hose be clear plastic. This proposed revision would reflect existing technology and allow the examination of the external tubing to assure that it is clean and free of leaks, as accumulations or leaks could affect the accuracy of the sampling results.

Proposed paragraph (c) would address requirements for the battery charger of the CMDPSU.

Existing paragraph (c)(1), which specifies the voltage and frequency requirements for the battery charger, would be updated to reflect currently used power supply voltage of 110 (VAC) (nominal), versus 117 volt in the existing standard.

Proposed paragraphs (c)(2) and (c)(3) are identical to existing (c)(2) and (c)(3), which require that the battery charger be provided with a cord and polarized connector and that it be fused and have a grounded power plug.

Existing paragraph (c)(4), which specifies the recharging rate of the battery charger, would be revised to reflect current technology, which fully recharges the battery in the pump unit within 16 hours.

E. Section 74.5 Tests of Coal Mine Dust Personal Sampler Units

Proposed § 74.5 renumbers existing § 74.4 and would provide authority for NIOSH and MSHA testing to evaluate whether the CMDPSU meets the requirements of this rule. This section has not been substantively changed.

F. Section 74.6 Quality Control

Proposed § 74.6 is derived from existing § 74.6(d) regarding applications. The proposal makes only clarifying changes by referencing proposed § 74.13 (filing applications).

Subpart C—Requirements for Continuous Personal Dust Monitors (CPDMs)

G. Section 74.7 Design and Construction Requirements

Proposed § 74.7 would provide design and construction requirements for the CPDM. The requirements would be performance oriented to the extent possible to allow manufacturers flexibility for continued innovation in this new technology. Design-specific requirements are proposed when necessary and appropriate for assuring miner safety or accommodating mining conditions.

Proposed paragraph (a) would require that the CPDM be designed and constructed to allow miners to work safely and be suited to work requirements and working conditions of coal mining.

Proposed paragraph (b) addresses ergonomic design and would require that, prior to filing an application under proposed § 74.13, the applicant must develop a testing protocol to determine if coal miners can wear the CPDM safely and without discomfort or impairment in the performance of their work duties throughout a full work shift. The protocol would be required to include provisions for testing in one or more active mines under routine operating conditions. NIOSH would approve the protocol prior to testing and would review the written results as a component of the application for approval. NIOSH would advise and assist the applicant in developing an adequate testing protocol and arranging for adequate and competent testing resources, including but not limited to identifying testing experts and facilitating the cooperation of coal operators and miners. NIOSH would reserve the authority to waive the requirement for the applicant to conduct such testing when it is apparent ''that the device can be worn safely, without discomfort, and without impairing a coal miner in the performance of duties throughout a full work shift.''

Proposed paragraph (c) would require that the weight of a CPDM add no more than 2 kg to the total weight carried by the miner. However, a CPDM combined with other functions, such as communications or illumination, could weigh more than 2 kg if offset by other means. The result should be that the total extra weight is no more than 2 kg more than the weight normally carried by miners without the CPDMs. The 2-kg limit is proposed based on the professional judgment of MSHA and NIOSH field staff that the added load to miners needs to be minimized, considering that the safety gear and equipment currently worn and carried by underground coal miners can weigh up to approximately 16 kg. The proposed limit accommodates the weight of the prototype CPDM, which in NIOSH testing was worn and used by miners for full shifts and proved to be acceptable. The prototype weighed approximately 3 kg, but served to power the cap lamp as well, so that a separate battery was not required for the cap lamp. In combination, the prototype with its dual-use battery increased the personal equipment load of the miners by less than 2 kg.

Proposed paragraph (d) would require that the CPDM provide accurate measurements of respirable coal mine dust concentrations within the range of 10% to 2 times the permissible exposure limit (PEL) for respirable coal mine dust (currently 2.0 mg/m^3 when quartz content does not exceed 5%) for an end-of-shift average measurement, and provide a reliable indication when the concentration exceeds 2 times the PEL.

Proposed paragraph (e) would require that the CPDM operate reliably and accurately within the full range of environmental conditions encountered in coal mines. It would require that the CPDM operate reliably and accurately at any ambient temperature and varying temperatures ranging from minus 30 to plus 40 degrees centigrade; at any atmospheric pressure from 700 to 1000 millibars; at any ambient humidity from 10 to 100 percent relative humidity; and while exposed to water mists generated for dust suppression and while monitoring atmospheres including such water mists. These proposed parameters, in addition to those in proposed paragraphs (f) and (g) of this section, would address the full range of environmental conditions found in coal mines. MSHA and NIOSH specifically solicit comments on these parameters, as well as any others that might be appropriate.

Proposed paragraph (f) would require that the CPDM meet standards for the control of and protection from electromagnetic interference established by the American National Standards Institute (ANSI), the Federal Communications Commission (FCC), and the International Electrotechnical Commission (IEC). The FCC is an independent federal agency that regulates radiofrequency emitting devices. ANSI and IEC are voluntary standards-setting organizations, the former covering a wide array of technical and management fields and the latter specializing in electrotechnology. The use of these standards would address the potential for interference associated with the increasing use of radiofrequency controls for mining machinery and mine communication systems.

Proposed paragraph (g) would require that the CPDM be designed and constructed to remain intrinsically safe and accurate after undergoing vibration and shock tests representative of conditions of use in the mine. In testing for vibration, NIOSH proposes to use Military Standard 810F, 514.5. This test

would measure the degree of vibration expected while the device is worn by miners on and operating mining equipment and during transport in and out of the mine. The shock test that NIOSH would apply would involve three 3-foot drops onto a bare concrete surface (one drop testing each axis of the device). This test would represent the occasional drops and knocking of the device expected during use of the device by miners. NIOSH would conduct the testing regime on test units prior to further testing by the applicant under § 74.8 and intrinsic safety testing by MSHA under § 74.11(d).

Proposed paragraphs (h)(1) and (2) would require adequate legibility or audibility of monitoring results, computer (*i.e.*, digital) recording of results in a form compatible with widely available computer technology, and reporting of results as cumulative mass concentration in units of mass per volume of air (mg/m^3). The proposed visibility requirement for a minimum digital character height of 6 millimeters is based on testing during CPDM prototype development. All other proposed requirements in this provision allow flexibility for new innovative designs that would provide timely, reliable, and appropriately quantified information.

Proposed paragraph (i) would require that the power source for the CPDM have sufficient capacity to enable continuous sampling for 12 hours in a coal mine dust atmosphere of 2 times the PEL. This requirement would provide reasonable assurance that the power supply would be sufficient to enable accurate measurement of respirable dust concentrations for 12 hour work shifts, which are the longest current work shifts in U.S. coal mines. If the dust concentrations in a mine exceeded 4 mg/m^3 continuously for 12 hours, a power supply meeting this proposed standard might not be sufficient to sustain monitoring for the complete shift, since a higher dust concentration would place higher power demands on certain types of filtering technology. Nevertheless, this proposed standard would be sufficient to assure that the CPDM would have the power capacity to measure high dust concentrations during the shift, and to cumulatively document that they substantially exceeded the PEL for the full shift. These are the essential performance considerations for the CPDM for continuous and end-of-shift monitoring.

Proposed paragraph (i) also would require that a CPDM that uses a rechargeable battery must be recharged using the standard power supplies in mines (110 VAC).

Proposed paragraph (j) would require that if a CPDM uses a pump to sample the atmosphere, it must perform with a flow stability within ± five percent of the calibrated flow for a continuous duration of 12 hours.[6] This requirement is integral to achieving representative, accurate measurements of respirable coal mine dust concentrations. The paragraph would also require that the applicant specify in the calibration instructions for the device the flow calibration maintenance interval required to achieve this level of flow stability.

Proposed paragraph (k) would require that a CPDM using a rechargeable battery have a feature to indicate to the user that the unit is adequately recharged to provide accurate measurements for an entire shift of 12 hours. This feature is necessary to avoid monitoring failures due to power deficiency. The requirement of ''* * * under normal conditions of use'' is included to account for the possibility that exceptionally high dust concentrations, exceeding 4 mg/m^3, which normally should not occur, might deplete the battery power before the end of the shift. CPDM battery power does not have to be sufficient to continue accurate monitoring under such excessive exposure conditions for an entire 12-hour shift, since the non-compliant exposure would be measured and documented within the initial portion of the shift during which the device would operate with adequate battery power.

Proposed paragraph (l) sets forth requirements for CPDMs that share components with other personal equipment carried by an underground miner, such as cap lamps.

Proposed paragraph (l)(1) would require that the applicant obtain any necessary approvals required for the non-CPDM equipment prior to receiving final certification of the CPDM from NIOSH. This provision will enable NIOSH to assure that all approvals for devices not approved by NIOSH are obtained, as appropriate.

Proposed paragraph (l)(2) would require that the CPDM operate effectively with the integrated function or functions. This provision would assure that the CPDM is not compromised by integration of functions and provide reasonable assurance that the integrated non-CPDM functions operate as intended.

Proposed paragraph (m) would specify performance requirements that would help assure that CPDMs are designed to prevent intentional tampering and limit inadvertent altering of monitoring results. It would require that the CPDM have a safeguard or indicator which either prevents altering the measuring or reporting function of the device or indicates if these functions have been altered.

This proposed provision is intended to direct manufacturers to design tampering safeguards and indicators that address foreseeable actions by users. In addition, the provision would allow NIOSH to require, to the extent feasible, changes in the design of an already approved device, following the discovery of tampering methods or inadvertent actions that can alter monitoring results.

Proposed paragraph (n) would require that the CPDM be designed to assure it can be properly cleaned and maintained to perform accurately and reliably for the duration of its service life. The infiltration and accumulation of dust and moisture in components might adversely affect the operability and monitoring accuracy of a CPDM.

H. Section 74.8 Measurement, Accuracy, and Reliability Requirements

Proposed § 74.8 is new and would establish the performance requirements for CPDMs. These proposed requirements reflect current evaluation methods regarding the assessment of direct reading monitors. These methods have been summarized and issued as general guidelines by NIOSH (Components for the Evaluation of Direct-Reading Monitors for Gases and Vapors).[7] The proposed requirements also reflect the state-of-the-art technology of the CPDM prototype. Accordingly, this proposed rulemaking establishes a science-based, feasible baseline for the performance of this new CPDM technology. Upon request, NIOSH will provide a report on the performance of the prototype CPDMs, which are partially summarized in several peer-reviewed journal articles.[8]

Proposed paragraph (a) would require that the CPDM be capable of measuring

[6] NIOSH Manual of Analytic Methods, Method 0600, Issue 3, Fourth Edition, January 15, 1998.

[7] Kennedy, E. R., T.J. Fischbach, R. Song, P.M. Eller, and S.A. Shulman, 1995. Guidelines for air sampling and analytical method development and evaluation, DHHS (NIOSH) Publication No. 95–117.

[8] Volkwein, J.C., R.P. Vinson, S.J. Page, L.J. McWilliams, G.J. Joy, S.E. Mischler and D.P. Tuchman. Laboratory and field performance of a continuously measuring personal respirable dust monitor. CDC RI 9669. September 2006. 47 pp. and Volkwein, J.C., R.P. Vinson, L.J. McWilliams, D.P. Tuchman, and S.E. Mischler. Performance of a New Personal Respirable Dust Monitor for Mine Use. CDC RI 9663. June 2004.

respirable dust within the personal breathing zone of the miner whose exposure is being monitored. The breathing zone is generally considered to be the area surrounding the worker's nose and mouth. This zone is pictured by drawing a sphere with a 10-inch radius which is centered on the nose. Current industrial hygiene principles accept breathing zone samples as most representative of the atmosphere to which workers are exposed.[9] The proposed rule provides a reasonably specific definition of the breathing zone to guide applicants.

Proposed paragraph (b) would provide requirements for the measurement accuracy of the CPDM.

Proposed paragraph (b)(1) would require for full-shift measurements of 8 hours or more, a 95 percent confidence that the recorded measurements are within ±25 percent of the true dust concentration, as determined by CMDPSU reference measurements, over a concentration range of 10% to 2 times the PEL. The specific quantified degree of accuracy proposed is based on the current state of the technology of direct reading monitors and on the need for reasonable accuracy in industrial hygiene assessments to assure worker protection. NIOSH has demonstrated the feasibility of this accuracy requirement through testing of the CPDM prototype.[10]

The proposed measurement range over which the CPDM must be accurate is also based on the current CPDM technology, as represented by the pre-commercial unit. This technology requires a minimum quantity of filter loading on the microbalance filter before the CPDM can measure accurately, distinguishing actual exposure quantities from small measurement variations due to imperfections of the CPDM equipment. The lower bound assures that accuracy is maintained for situations where silica is present and the permitted levels of respirable dust are reduced. Similarly, there is an upper bound of loading, which is likely to exceed the specified 4.0 mg/m^3 level,[11] after which current CPDM technology may lose sensitivity as a result of the heavily loaded filter on the microbalance. Nonetheless, the proposed standard would assure that the range of average, full-shift dust concentrations over which the CPDM would perform accurately would be adequate to quantify full shift exposures that range from exceptionally low to exceptionally high, allowing for identification of overexposures.

For intra-shift measurements of less than 8 hours, proposed paragraph (b)(2) would require a 95 percent confidence that the recorded measurements are within ±25 percent of the true dust concentration, as determined by CMDPSU reference measurements, over the dust concentration of 10% to 2 times the PEL for an 8-hour period. The proposal includes a formula for calculating the equivalent dust concentration range for assessing the accuracy of intra-shift measurements.

Proposed paragraph (c) would require the CPDM to meet the accuracy requirements regardless of the variation in density, composition, size distribution of respirable coal mine dust particles, or presence of spray mist found in U.S. coal mines. Some monitoring devices, such as light scattering detectors, use technologies that have potential for monitoring aerosol dust concentrations. These devices currently lack the ability to distinguish differences in density and composition of coal mine dust particles and other aerosols in the mine, or to accommodate variation in the coal mine dust particle distribution. To be effective, the CPDM must produce accurate measurements for any coal mine atmosphere.

Proposed paragraph (d) would establish a requirement for the CPDM to monitor with sufficient precision, meaning the degree to which it is able to closely replicate its measurement result, when monitoring identical dust concentrations. The proposed precision requirement is a relative standard deviation of less than 0.1275 without bias for multiple measurements. The proposed precision requirement will enable MSHA and mine operators to monitor changes in dust concentrations with reasonable confidence.

Proposed paragraph (e) would require the bias of CPDM measurements to be limited such that the uncorrectable discrepancy between the mean of the distribution of measurements and the true dust concentration being measured during testing shall be no greater than 10 percent. The proposal requires that measurement bias be constant over the range of dust concentration levels tested, between 10% and 2 times the PEL, for an 8-hour sampling period. The proposed bias requirement is sufficient to assure that the CPDM does not consistently either overestimate or underestimate respirable coal mine dust concentrations to a substantial degree. This provides further assurance of the accuracy of the CPDM with respect to multiple measurements and would also provide useful information to MSHA in support of compliance determinations and actions.

Proposed paragraph (f) would require that applicants use the NIOSH testing procedure ''Continuous Personal Dust Monitor Testing Procedures'' to evaluate the accuracy (including reliability, precision, and bias) of a CPDM. The procedure is available at the NIOSH Web site: *http://www.cdc.gov/niosh/mining.* The protocol would assure that all CPDMs are evaluated consistently. NIOSH will provide assistance to applicants, as necessary, to make the arrangement of such testing feasible.

I. Section 74.9 Quality Assurance

Proposed § 74.9 is new and would establish quality assurance requirements for CPDM manufacturers.

Proposed paragraph (a) would require that the applicant establish and maintain a quality control system that assures devices produced under the applicant's certificate of approval meet the specifications to which they are certified under this part and are reliable, safe, effective, and otherwise fit for their intended use. The proposed quality control system must be compliant with ISO Q9001–2000 standard established by the ISO.[12] The ISO standard is incorporated by reference. This consensus standard for quality management is in widespread use in U.S. and international manufacturing and service industries. It requires a comprehensive quality management system, which is essential for the manufacture of sophisticated technical equipment used in worker safety and health.

Proposed paragraph (a) would also require the applicant to submit a copy of the most recent registration under ISO Q9001–2000 to NIOSH, together with the application and, subsequent to

[9] Guffy, S.E., M.E. Flanagan, G. VanBelle. Air Sampling at the chest and ear as representative of the breathing zone. AIHAJ, 62:416–427, 2001, show that ear locations are preferred and that dust sources relative to sample position are important. A NIOSH study on miners shows that the chest and cap lamp positions are representative of exposures at the miner's nose (Vinson, R.P. and J.C. Volkwein, Determining the Spatial Variability of Personal Sampler Inlet Locations (in press) JOEH, 2007).

[10] Volkwein, J.C., R.P. Vinson, L.J. McWilliams, D.P. Tuchman, and S.E. Mischler. Performance of a New Personal Respirable Dust Monitor for Mine Use. CDC RI 9663. June 2004.

[11] NIOSH testing of the CPDM prototype used 4.0 mg/m^3 dust concentrations as the upper limit in challenging the device for accuracy. NIOSH did not conduct testing to identify the upper bound at which the accuracy of the prototype would be degraded below the testing standard, although the ultimate occurrence of such degradation is predictable based on engineering principles.

[12] ISO Q9001:2000 is the International Standard: *Quality management systems—Requirements, 3rd edition,* approved on December 15, 2000 and available from the International Organization for Standardization and the American National Standards Institute.

an approval, upon request. Registration under any updated version of ISO Q9001–2000 would be considered evidence of compliance with the ISO Q9001–2000 standard. Registration under the ISO quality management standard would represent evidence that the applicant has established a sound quality assurance program, and allow for the use of existing and widely available independent auditing services.

Proposed paragraph (b) would require applicants or approval holders to allow NIOSH to conduct quality management audits when requested or in response to quality-related complaints. NIOSH has similar authority under its respirator certification program (42 CFR part 84), which has been used to assure product quality in the respirator market. This authority is essential in the event of substantial quality management problems in the manufacture of CPDMs.

Proposed paragraph (c) would require a manufacturer to remedy a quality management deficiency identified by NIOSH or an independent audit within a reasonable time as determined by NIOSH. Refusal by the manufacturer would potentially result in the disapproval of a pending application or revocation of an approval until such time as NIOSH has determined that the deficiency is remedied. NIOSH has similar authority under its respirator certification program, although NIOSH has rarely had to employ it.

J. Section 74.10 Operating and Maintenance Instructions

Proposed § 74.10(a) is new and would require the manufacturer to include operating and maintenance instructions with each new CPDM unit sold.

Proposed paragraph (b) would require the manufacturer to submit the instructions to NIOSH with the application for approval. It would also require that revised instructions be submitted if any substantive changes are made to the unit or the approved instructions after initial approval. Adequate instructions must be provided to facilitate effective use of sophisticated monitoring equipment. NIOSH review and approval of instructions would serve an important final quality control function for the manufacturer and assure that instructions are clearly written and easily understood. NIOSH has similar authority under its respirator certification program (42 CFR part 84).

K. Section 74.11 Tests of the Continuous Personal Dust Monitor

This section is new and would establish testing requirements and services for the evaluation of CPDMs.

Proposed paragraph (a) would require the applicant to conduct all testing regarding design, construction, and measurement accuracy requirements specified in §§ 74.7–74.8 of this part, with the exception of durability testing under § 74.7(g). It would further require that the testing be performed by an independent testing entity approved by NIOSH. This requirement would reduce concerns about conflicts of interest and would provide reasonable assurance of the quality of the testing and the reliability of the results.

NIOSH considered the alternative of developing an in-house testing program for the evaluation of CPDMs. This alternative is not being proposed because NIOSH does not expect a substantial number of CPDM applications.

Proposed paragraph (b) would provide for NIOSH to assist the applicant in identifying appropriate testing services and in assuring that testing protocols used by the independent testing entity are adequate. Applicants would be required to submit testing protocols to NIOSH prior to testing. It is unlikely that a manufacturer would be familiar with testing resources capable of addressing every element of the proposed requirements. NIOSH would be able to provide the applicant with information on private and university laboratories available for testing. In addition, NIOSH review of testing protocols would minimize the possibility of inadequate testing, which might result in the applicant incurring unnecessary delay and costs.

Proposed paragraph (c) would require the applicant to arrange for the independent testing entity to report testing protocols and results directly to NIOSH. This direct reporting relationship between the testing entity and NIOSH would further establish the independence of the testing from the applicant.

Under proposed paragraph (d) MSHA would evaluate and determine the intrinsic safety of a CPDM submitted for approval. MSHA conducts all intrinsic safety testing for mining equipment used in underground coal mines. A CPDM that does not pass such testing would not be approved for use in U.S. coal mines.

Subpart D—General Requirements for All Devices

L. Section 74.12 Conduct of Tests; Demonstrations

Proposed § 74.12, concerning the conduct of tests, renumbers existing § 74.5 and would make clarifying changes to the existing provision. This section, which concerns the management of testing information prior to and after the issuance of a certificate of approval, would clarify that MSHA and NIOSH may reveal test protocols and results considered for approval of the device.

M. Section 74.13 Applications

Proposed § 74.13 would renumber existing § 74.6 and add requirements necessary for filing an application for CPDMs. The application requirements for CMDPSUs remain substantively unchanged.

Proposed paragraph (a) would require that a written application in duplicate be submitted to NIOSH and MSHA for approval of a CMDPSU (*i.e.*, a total of four applications). Also, 10 complete units must be submitted to NIOSH with the application and one pump must be sent to MSHA. This is the same as the existing requirement for the CMDPSU.

Proposed paragraph (b) would require the submission of an application in duplicate and 4 complete CPDM units, 3 to NIOSH and one to MSHA. The 4 units would allow MSHA to conduct intrinsic safety testing and NIOSH to evaluate compliance with the ''Design and Construction Requirements'' (See § 74.7), verify any testing results, evaluate the use and maintenance instructions, and address quality assurance matters.

Proposed paragraph (c) would require that drawings and specifications provided in the application identify the design, dimension, and materials of the CMDPSU or CPDM. This information is necessary for a complete evaluation of compliance with design and construction requirements proposed under this part.

N. Section 74.14 Certificate of Approval

Proposed § 74.14 renumbers existing § 74.7 and would specify procedures by which NIOSH and MSHA would approve or disapprove an application for either a CMDPSU or CPDM. Proposed § 74.14 is unchanged from the existing provision, except to expand the scope to include the CPDM.

O. Section 74.15 Approval Labels

Proposed § 74.15 renumbers existing § 74.8 and would specify labeling procedures, requirements, and related obligations of the applicant. Proposed § 74.15 is unchanged from the existing provision, except to expand the scope to include the CPDM.

P. Section 74.16 Material Required for Record

Proposed § 74.16 renumbers existing § 74.9 and would provide for adequate records on each application, the return of CMDPSU or CPDM test units to the applicant, and the delivery of a commercially produced unit to NIOSH. Proposed § 74.16 is unchanged from the existing provision, except to expand the scope to include the CPDM.

Q. Section 74.17 Changes After Certification

Proposed § 74.17 renumbers § 74.10 and would specify procedures by which the applicant could seek to change features of an approved CMDPSU or CPDM. This section requires the manufacturer to file an application to change any feature and to test the modified device if NIOSH determines that testing is required. Proposed § 74.17 is unchanged from the existing provision, except to expand the scope to include the CPDM.

R. Section 74.18 Withdrawal of Certification

Proposed § 74.18 renumbers § 74.11 and would authorize NIOSH or MSHA to revoke for cause any certification of approval for a CMDPSU or CPDM. Proposed § 74.18 is unchanged from the existing provision, except to expand the scope to include the CPDM.

IV. Regulatory Economic Analysis

A. Executive Order 12866

Under Executive Order (E.O.) 12866 (58 FR 51735), as amended by Executive Order 13258 (amending Executive Order 12866 on Regulatory Planning and Review (67 FR 9385), the Agency must determine whether a regulatory action is ''significant'' and subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. MSHA has determined that the proposed rule would not have annual effect of $100 million or more on the economy and, therefore, it is not an economically ''significant regulatory action'' pursuant to section 3(f) of Executive Order 12866. MSHA, however, has concluded that the proposed rule is otherwise significant under Executive Order 12866 because it raises novel legal or policy issues.

This proposed rule would update existing requirements for the approval of a CMPDSU to reflect the current state of this technology. The current approval holder of this device has voluntarily incorporated these improved requirements into the device. The proposal would also provide procedures and requirements by which NIOSH and MSHA could approve a new monitoring technology, CPDM devices, for use in coal mines.

Providing requirements to allow the approval of a new monitoring technology, the CPDM, for use in coal mines, does not have any potential for adversely impacting the economy. No such device has been commercialized for the mining industry. This proposal does not establish compliance requirements. It addresses the approval of dust monitoring devices.

B. Benefits

Coal mine dust is produced when material is extracted from the coal seam by drilling, blasting, and cutting, and during loading and transporting of that material from the mine. Respirable coal mine dust consists of a mixture of very small particles of coal, silica, and other mineral and organic materials found in the mine environment that can be inhaled and deposited in the lungs. It presents a significant health hazard if not adequately controlled. Long-term exposure to excessive levels of respirable coal mine dust causes coal workers' pneumoconiosis (CWP), commonly known as ''black lung.'' Overexposure to respirable silica dust can lead to silicosis. These occupational lung diseases can devastate a miner's quality of life, create a heavy burden on the victim and the victim's family, and in some cases lead to premature death. While significant progress has been made over the years in reducing respirable dust levels, coal miners continue to be at risk of developing CWP and silicosis, including progressive massive fibrosis (PMF), the most disabling and potentially fatal form of CWP. While there is no cure for these disabling lung diseases, they are entirely preventable.

According to the U.S. Department of Labor's (DOL) Office of Workers' Compensation Programs, which administers the Black Lung benefits program to compensate victims of dust exposure in mines and certain eligible survivors of deceased miners, black lung benefits (monthly wage replacement and medical benefits) totaled $676 million in FY 2005.[13]

Under the Federal Coal Mine Health and Safety Act of 1969 (Pub. L. 91–173), the predecessor to the Federal Mine Safety and Health Act of 1977 (Pub. L. 95–164), the dust sampling technology used to measure miners' exposure to respirable coal mine dust has basically remained unchanged since 1970. The existing approved dust sampler used by coal mine operators and MSHA consists of a person-wearable battery-powered pump that draws mine air through a cyclone that separates respirable dust that can enter the inner lung and deposits it on a filter that is then weighed by MSHA. The dust concentration is calculated based on the volume of air sampled and the mass of dust collected. Usually, this procedure takes several days before mine operators and MSHA receive the results. By that time, the mining workplace has moved and conditions may have changed substantially. Under the existing sampling method, it may be difficult for a mine operator to identify conditions of high dust exposure as they occur, often preventing necessary and timely intervention to reduce the exposures.

CPDMs represent an innovative technology that provides real-time and continuous accurate measurement of respirable coal mine dust during a working shift. Continuous exposure readings enable mine management to be proactive and take immediate preventive action to avoid potentially excessive exposures. The devices can also be used as an engineering tool to permit the operator to rapidly evaluate the effectiveness of various dust control strategies.

MSHA and NIOSH recognize that the major benefits to be derived from real-time continuous monitoring will occur when monitoring devices with this new technology and strategies for their use are developed and implemented. However, before CPDMs can be introduced in coal mines, they must be approved for use by MSHA and NIOSH. The existing regulations limit approval to dust sampling devices of the current design and do not permit the Agencies

[13] U.S. DOL Employment Standards Administration, Office of Workers' Compensation Programs, Annual Report to Congress FY 2005, Submitted to Congress 2008.

to approve other technologically advanced sampling devices that are capable of monitoring dust concentrations on a real-time and continuous basis.

MSHA and NIOSH have developed new procedures that would allow manufacturers to apply for approval of the new CPDM technology. This proposal would require manufacturers to demonstrate that devices using continuous monitoring technology are durable and can withstand the mine environment; can be worn by miners performing normal tasks for an entire work shift; provide accurate and precise measurements; and can be safely used in mine atmospheres where explosive mixtures of gases may occur.

This proposed revision to the approval regulations is an important initial step to permit the introduction of the new continuous monitoring technology in coal mines. The use of real-time monitoring devices in the future would allow mine management to take immediate action to prevent miner overexposure and thereby reduce occupational lung disease.

This proposed rule would assure that existing health benefits associated with the CMDPSU are maintained by updating existing requirements for the approval of a CMDPSU to reflect the current state of this technology.

The introduction of the CPDM likely would establish some degree of competition in the broader market of personal monitoring technology for coal mining, since the CPDM is likely to evolve as a potential substitute for the existing CMDPSU, which is currently unique to this broader market and produced by a single manufacturer. Moreover, the proposed requirements for the approval of the CPDM, which are essentially performance-oriented, would provide incentives for continued innovation of this technology.

C. Compliance Costs

There is only one manufacturer of the existing sampler technology, CMDPSU. No new applications for approval have been received in over 30 years. The proposed revisions to the design requirements for the CMDPSU would not require this manufacturer to submit an application for a new approval or any additional information to MSHA and NIOSH. The CMDPSU approved under existing requirements already meets the proposed updated requirements since the requirements have been integrated by policy into existing approvals.

MSHA and NIOSH are aware of only one prospective manufacturer capable of mass producing a CPDM that could be submitted for approval under this proposal. The Agencies believe that very few instrument manufacturers have the capacity or interest to develop technology suitable for directly and continuously measuring concentrations of respirable coal mine dust in mine atmospheres. The current pre-commercial CPDM required a federal investment of approximately $5.3 million, an additional private investment of approximately $750,000, and more than four years of development before a suitable device could be produced that could accurately measure respirable dust concentrations in coal mine atmospheres. It is likely that few, if any, firms would undertake this substantial level of research and development given the limited market for such a product.

Consequently, MSHA and NIOSH expect that in the first year under the proposed rule, there would be one manufacturer filing an application seeking approval of a CPDM. The cost of the proposed rule in the first year is estimated to be $293,000. The first year approval costs are annualized over an indefinite time period by using a 7 percent discount factor that results in a cost of approximately $20,500 ($293,000 × 0.07). The $293,000 consists of approximately: $250,000 for the applicant to have tests performed on the CPDM by a third party (under proposed §§ 74.7 and 74.8); $9,500 for MSHA to evaluate and test the CPDM for intrinsic safety (under proposed § 74.11); $3,200 to file an application for approval of the CPDM (under proposed § 74.13); and $30,000 for the cost of the CPDMs provided to NIOSH and MSHA by the applicant (under proposed §§ 74.16(a) and (b)). Derivation of the proposed rule costs are detailed below.

Proposed §§ 74.7 and 74.8 would require tests that the applicant must have performed by a third party. These tests are for: Ergonomic design (under proposed § 74.7(b)); environmental conditions (under proposed § 74.7(e)); electromagnetic interference (under proposed § 74.7(f)); flow stability and calibration of pump (under proposed § 74.7(j)); and accuracy testing which includes reliability measurement, precision, and bias testing (under proposed §§ 74.8(c), (d), and (e)). MSHA estimates that it would cost the applicant approximately $250,000 to conduct the tests that are required by proposed §§ 74.7 and 74.8. The annualized cost is $17,500 ($250,000 × 0.07).

Proposed § 74.11 requires that the applicant submit the CPDM to MSHA for testing and evaluation, pursuant to 30 CFR § 18.68 to determine whether the electronic components of the CPDM unit submitted for approval meet the applicable permissibility provisions. The following tests would be performed by MSHA under § 18.68(a)(1): Current limiting resistor adequacy test; coal dust thermal ignition test; optical isolator test; impact test and force test of encapsulated electrical assemblies; drop testing intrinsically safe apparatus; mechanical test of partitions; piezoelectric device impact test; and dielectric strength test. The battery flash current test would be performed under §§ 18.68(a)(1) and (b)(1). The methane thermal ignition test would be performed under §§ 18.68(a)(1) and (b)(6). The maximum surface temperature test would be performed under § 18.68(a)(1) and (b)(3). The spark ignition test would be performed under §§ 18.68(a)(1), (a)(2), (a)(4), (a)(5), (b)(4), and (b)(5).

The estimated time per application is 45 hours for evaluation and 40 hours for testing. MSHA charges an hourly fee of $84 per hour for evaluation and testing time. In addition, MSHA applies a support factor of 1.617 to cover the administrative, clerical and technical support services involved in evaluating an application. Thus, the cost for MSHA evaluation and testing is approximately $9,500 [(45 hrs. × $84 × 1.617) + (40 hrs. × $84)]. The annualized cost is approximately $700 ($9,500 × 0.07).

Proposed § 74.13(b) requires that a written application for approval be submitted to MSHA and NIOSH in duplicate. MSHA estimates that it would take an engineer, earning $74.32 per hour, a total of 40 hours to prepare and compile the materials needed to accompany an application. MSHA estimates that it would take a clerical employee, earning $26.37 per hour, 0.25 hours (15 minutes) to copy an application, averaging 250 pages, at $0.15 per page. The postage cost per application is estimated to be $5. Thus, the cost to file an application is estimated at $3,200 [(1 application × 40 hrs. x $74.32 per hr.) + (0.25 hrs. × $26.37 per hour × 4 copies) + (250 pages x $0.15 cost per page × 4 copies) + ($5 × 4 copies)]. The annualized cost is approximately $200 ($3,200 × 0.07).

Proposed § 74.16(a) would require that MSHA and NIOSH each retain one CPDM that is submitted with the application. In addition, proposed § 74.16(b) would require that NIOSH receive one commercially produced CPDM free of charge, if it is approved by NIOSH and MSHA. MSHA estimates that the cost of a CPDM would range between $8,000 and $12,000 (for an average of $10,000 per device). Thus, the cost to provide two CPDMs with the application and one subsequent to the

approval of the application is estimated to be $30,000 (3 CPDMs × $10,000 per CPDM). The annualized cost is $2,100 ($30,000 × 0.07).

D. Economic and Technological Feasibility

Although the CPDM is a new type of sampling device, the proposed rule is technologically feasible. The device has been developed and successfully tested in underground coal mines. This proposed rule would put in place the necessary requirements to enable a prospective manufacturer to seek NIOSH and MSHA approval of a CPDM for use in coal mines. The one-time, first year cost to obtain an approval for the CPDM is estimated to be approximately $293,000, which MSHA concludes is economically feasible for a CPDM manufacturer.

V. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act

Pursuant to the Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), MSHA has analyzed the impact of the proposed rule on small entities. Based on that analysis, MSHA has notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification under the Regulatory Flexibility Act at 5 U.S.C. 605(b) that the proposed rule would not have a significant economic impact on a substantial number of small entities.

The proposed rule establishes procedures and requirements for approving a CPDM for use in coal mines. A manufacturer of a CPDM receiving such an approval would thus be able to market the device to U.S. coal mine operators and MSHA. This U.S. market might also provide a commercial base for marketing the device to coal mine operators internationally.

Currently, such device has not been commercialized because the existing design specifications of 30 CFR Part 74 provide for the approval of only one, substantially different type of technology for monitoring concentrations of respirable dust in coal mine atmospheres. The proposed requirements take into account the design and performance of a prototype CPDM, which was developed with the financial and technical support of MSHA and NIOSH, in collaboration with a private sector monitoring technology company, as discussed under section I(A) of this preamble. NIOSH has carefully evaluated the design and performance of this prototype. This empirical basis assures the feasibility of the proposed requirements.

Accordingly, since this proposed rule would foster rather than inhibit such commercialization, since there is not currently a CPDM commercialized by any entity, and since the proposed rule takes into account the capabilities of the single currently available prototype for such devices, the proposed rule should not have a significant economic impact on a substantial number of small entities.

VI. Paperwork Reduction Act of 1995

The proposed rule will impose estimated information collection requirements of 41 burden hours which are related to filing approval applications required by proposed § 74.13. This burden would occur in the first year that the rule is in effect. MSHA estimates that it would take an engineer 40 hours to compile the material for the application, and a clerical employee 1 hour to prepare and send four copies of the application (0.25 hours per application × 4 copies). Two copies each of the application would need to be sent to MSHA and NIOSH. Based on hourly wage rates of $74.32 for an engineer and $26.37 for a clerical employee, the related burden costs are estimated to be approximately $3,000 (40 hrs. × $74.32) + (0.25 hrs. × $26.37 × 4 copies). The proposed burden will be accounted for in OMB control No. 1219–0066 which contains the burden for applications filed with MSHA that involve intrinsic safety testing.The information collection package has been submitted to the Office of Management and Budget (OMB) for review under 44 U.S.C. 3504(h) of the Paperwork Reduction Act of 1995, as amended. A copy of the information collection package can be obtained from the Department of Labor by e-mail request to *king.darrin@dol.gov* or by phone request at (202) 693–4129.

MSHA requests comments to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Comments regarding the information collection requirements should be sent to both OMB and MSHA. Addresses for both offices can be found in the **ADDRESSES** section of this preamble. The regulated community is not required to respond to any collection of information unless it displays a current, valid, OMB control number. MSHA displays OMB control numbers in 30 CFR part 3.

VII. Other Regulatory Considerations

A. The Unfunded Mandates Reform Act of 1995

MSHA has reviewed the proposed rule under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). MSHA has determined that this proposed rule would not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments; nor would it increase private sector expenditures by more than $100 million in any one year or significantly or uniquely affect small governments. Accordingly, the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) requires no further agency action or analysis.

B. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

This proposed rule would have no effect on family well-being or stability, marital commitment, parental rights or authority, or income or poverty of families and children. Accordingly, section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires no further agency action, analysis, or assessment.

C. Executive Order 12630: Government Actions and Interference With Constitutionally Protected Property Rights

This proposed rule would not implement a policy with takings implications. Accordingly, E.O. 12630 requires no further Agency action or analysis.

D. Executive Order 12988: Civil Justice Reform

This proposed rule was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. Accordingly, this proposed rule meets the applicable

standards provided in section 3 of E.O. 12988.

E. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule would have no adverse impact on children. Accordingly, E.O. 13045 requires no further Agency action or analysis.

F. Executive Order 13132: Federalism

This proposed rule would not have ''federalism implications'' because it would not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Accordingly, E.O. 13132, requires no further Agency action or analysis.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule would not have ''tribal implications'' because it would not ''have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' Accordingly, E.O. 13175 requires, no further Agency action or analysis.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 requires agencies to publish a statement of energy effects when a rule has a significant energy action that adversely affects energy supply, distribution, or use. This proposed rule does not directly affect coal mines, only prospective manufacturers of CPDMs that seek to obtain the Agencies' approval for use of such monitoring devices in coal mines. Accordingly, MSHA has concluded that the proposed rule is not a ''significant energy action'' because it is not ''likely to have a significant adverse effect on the supply, distribution, or use of energy * * * (including a shortfall in supply, price increases and increased use of foreign supplies).'' Accordingly, E.O. 13211 requires no further Agency action or analysis.

I. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

MSHA has reviewed the proposed rule to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. MSHA has determined and certified that the proposed rule would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 30 CFR Part 74

Mine safety and health, Incorporation by reference, Occupational safety and health, Direct reading devices, Monitoring technology.

Dated: January 8, 2009.

Richard E. Stickler,

Acting Assistant Secretary for Mine Safety and Health.

For the reasons set out in the preamble, and under the authority of the Federal Mine Safety and Health Act of 1977 as amended by the Mine Improvement and New Emergency Response Act of 2006, MSHA proposes to amending chapter I of title 30 of the Code of Federal Regulations by revising part 74 to read as follows:

PART 74—COAL MINE DUST PERSONAL MONITORS

Subpart A—Introduction

Subpart B—Requirements for Coal Mine Dust Personal Sampler Unit

Subpart C—Requirements for Continuous Personal Dust Monitors (CPDMs)

Subpart D—General Requirements for All Devices

Authority: 30 U.S.C. 957.

Subpart A—Introduction

§ 74.1 Purpose.

The regulations in this part set forth the requirements for approval of coal mine dust measurement units designed to determine the concentrations of respirable dust in coal mine atmospheres; procedures for applying for such approval; test procedures; and labeling.

§ 74.2 Definitions.

(a) *Accuracy:* The ability of a monitor to determine the ''true'' concentration of the environment sampled. Accuracy describes the closeness of a typical measurement to the quantity measured, although it is defined and expressed in terms of the relative discrepancy of a typical measurement from the quantity measured. The accuracy of a monitor is the theoretical maximum error of measurement, expressed as the proportion or percentage of the amount being measured, without regard for the direction of the error, which is achieved with a 0.95 probability by the method.

(b) *Bias:* the uncorrectable relative discrepancy between the mean of the distribution of measurements from a monitor and the true concentration being measured.

(c) *Coal mine dust personal sampler unit (CMDPSU):* a personal device for measuring concentrations of respirable dust in coal mine atmospheres that meets the requirements specified under Subpart B of this part.

(d) *Continuous personal dust monitor (CPDM):* a personal device for continuously measuring concentrations of respirable dust in coal mine atmospheres that reports within-shift and end-of shift measurements of dust concentrations immediately upon the completion of the period of exposure that was monitored and that meets the requirements specified under Subpart C of this part.

(e) *ISO:* the International Organization for Standardization, an international standard-setting organization composed of representatives from various national standards-setting organizations. ISO produces industrial and commercial voluntary consensus standards used worldwide.

(f) *Precision:* the relative variability of measurements from a homogeneous atmosphere about the mean of the population of measurements, divided by the mean at a given concentration. It reflects the ability of a monitor to replicate measurement results.

Subpart B—Requirements for Coal Mine Dust Personal Sampler Unit

§ 74.3 Sampler unit.

A CMDPSU shall consist of (a) a pump unit, (b) a sampling head assembly, and (c) if rechargeable batteries are used in the pump unit, a battery charger.

§ 74.4 Specifications of sampler unit.

(a) *Pump unit:*

(1) *Dimensions.* The overall dimensions of the pump unit, hose connections, and valve or switch covers shall not exceed 4 inches (10 centimeters) in height, 4 inches (10 centimeters) in width, and 2 inches (5 centimeters) in thickness.

(2) *Weight.* The pump unit shall not weigh more than 20 ounces (567 grams).

(3) *Construction.* The case and all components of the pump unit shall be of sufficiently durable construction to endure the wear of use in a coal mine, shall be tight fitting to minimize the amount of dust entering the pump case, and shall be designed to protect against radio frequency interference and electromagnetic interference.

(4) *Exhaust.* The pump shall exhaust into the pump case, maintaining a slight positive pressure which will reduce the entry of dust into the pump case.

(5) *Switch.* The pump unit shall be equipped with an ON/OFF switch or equivalent device on the outside of the pump case. This switch shall be protected against accidental operation during use and protected to keep dust from entering the mechanisms.

(6) *Flow rate adjustment.* Except as provided in the last sentence of this paragraph, the pump unit shall be equipped with a suitable means of flow rate adjustment accessible from outside the case. The flow rate adjuster shall be recessed in the pump case and protected against accidental adjustment. If the pump is capable of maintaining the flow rate consistency required in this part without adjustment, an external flow rate adjuster is not required.

(7) *Battery.* The power supply for the pump shall be a suitable battery located in the pump case or in a separate case which attaches to the pump case by a permissible electrical connection.

(8) *Pulsation.* (i) The irregularity in flow rate due to pulsation shall have a fundamental frequency of not less than 20 Hz.

(ii) The quantity of respirable dust collected with a sampler unit shall be within ±5 percent of that collected with a sampling head assembly operated with nonpulsating flow.

(9) *Belt clips.* The pump unit shall be provided with a belt clip which will hold the pump securely on a coal miner's belt.

(10) *Recharging connection.* A suitable connection shall be provided so that the battery may be recharged without removing the battery from the pump case or from the battery case if a separate battery case is used.

(11) *Flow rate indicator.* A visual indicator of flow rate shall be provided either as an integral part of the pump unit or of the sampling head assembly. The flow rate indicator shall be calibrated within ±5 percent at 2.2, 2.0, and 1.7 liters per minute to indicate the rate of air passing through the accompanying sampling head assembly.

(12) *Flow rate range.* The pump shall be capable of operating within a range of from 1.5 to 2.5 liters per minute and shall be adjustable over this range.

(13) *Flow rate consistency.* The flow shall remain within ±0.1 liters per minute over at least a 10-hour period when the pump is operated at 2 liters per minute with a standard sampling head assembly.

(14) *Flow restriction indicator.* The pump shall be capable of detecting restricted flow and providing a visual indication if it occurs. The flow restriction indicator shall remain activated until the cause is corrected. The pump shall shut down automatically if flow is restricted for one minute.

(15) *Duration of operation.* The pump with a fully charged battery pack shall be capable of operating for (i) not less than 8 hours at a flow rate of 2 liters per minute against a resistance of 25 inches (64 centimeters) of water measured at the inlet of the pump; and (ii) for not less than 10 hours at a flow rate of 2 liters per minute against a resistance of 15 inches (38 centimeters) of water measured at the inlet of the pump.

(16) *Low battery indicator.* The pump unit shall be equipped with a visual indicator of low battery power.

(17) *Elapsed time indicator.* The pump unit shall be capable of (i) displaying the actual pump run time in minutes (up to 999 minutes) and (ii) retaining the last reading after the pump is shut down due to either a flow restriction described in paragraph (a)(14) or low battery power described in paragraph (a)(16) or at the end of the sampling shift.

(b) *Sampling head assembly.* The sampling head assembly shall consist of a cyclone and a filter assembly as follows:

(1) *Cyclone.* The cyclone shall consist of a cyclone body with removable grit cap and a vortex finder and shall be constructed of nylon or a material equivalent in performance. The dimensions of the components, with the exception of the grit cap, shall be identical to those of a Door-Oliver 10 millimeter cyclone body, part No. 28541/4A or 01B11476–01 and vortex finder, part No. 28541/4B.

(2) *Filter assembly.* The filter assembly shall meet the following requirements:

(i) *Filter.* The filter shall be a membrane filter type with a nominal pore size not over 5 micrometers. It shall be nonhydroscopic and shall not dissolve or decompose when immersed in ethyl or isopropyl alcohol. The strength and surface characteristics of the filter shall be such that dust deposited on its surface may be removed by ultrasonic methods without tearing the filter. The filter resistance shall not exceed 2 inches (0.5 centimeters) of water at an airflow rate of 2 liters per minute.

(ii) *Capsule.* The capsule enclosing the filter shall not permit sample air to leak around the filter and shall prevent visual inspection of the filter surface or filter loading. The capsule shall be made of nonhydroscopic material. Its weight, including the enclosed filter, shall not exceed 5 grams and it shall be pre-weighed by the manufacturer with a precision of ± 0.001 milligrams. Impact to the capsule shall not dislodge any dust from the capsule, which might then be lost to the weight measurement.

(iii) *Cassette.* The cassette shall enclose the capsule so as to prevent contamination and the intentional or inadvertent alteration of the dust deposited on the filter. The cassette must be easily removable without causing a loss or gain of capsule weight. Covers enclosing the capsule shall be designed to prevent contaminants from entering or dust from leaving the capsule when it is not in use, and to prevent the reversal of airflow through the capsule and other means of removing dust collected on the filter.

(3) *Arrangement of components.* The connections between the cyclone vortex finder and the capsule and between the capsule and the ¼-inch (0.64 centimeters) (inside diameter) hose mentioned in paragraph (b)(5) of this section shall be mechanically firm and shall not leak at a rate of more than 0.1 liters per hour under a vacuum of 4 inches (10 centimeters) of water.

(4) *Clamping of components.* The clamping and positioning of the cyclone body, vortex finder, and cassette shall be rigid, remain in alignment, be firmly in contact and airtight. The cyclone-cassette assembly shall be attached firmly to a backing plate or other means of holding the sampling head in position. The cyclone shall be held in position so that the inlet opening of the cyclone is pointing perpendicular to, and away from, the backing plate.

(5) *Hose.* A 3-foot (91 centimeter) long, ¼-inch (0.64 centimeters) (inside diameter) clear plastic hose shall be provided to form an airtight connection between the inlet of the sampler pump and the outlet of the filter assembly. A device, capable of sliding along the hose and attaching to the miner's outer garment, shall be provided.

(c) *Battery charger.*

(1) *Power supply.* The battery charger shall be operated from a 110 (VAC)(nominal), 60 Hz power line.

(2) *Connection.* The battery charger shall be provided with a cord and polarized connector so that it may be connected to the charge socket on the pump or battery case.

(3) *Protection.* The battery charger shall be fused, shall have a grounded power plug, and shall not be susceptible to damage by being operated without a battery on charge.

(4) *Charge rates.* The battery charger shall be capable of fully recharging the battery in the pump unit within 16 hours.

§ 74.5 Tests of coal mine dust personal sampler units.

(a) The National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services, shall conduct tests to determine whether a CMDPSU that is submitted for approval under these regulations meets the requirements set forth in § 74.4.

(b) The Mine Safety and Health Administration (MSHA), Department of Labor, will conduct tests and evaluations to determine whether the pump unit of a CMDPSU that is submitted for approval under these regulations complies with the applicable permissibility provisions of this 30 CFR part 18.68.

§ 74.6 Quality control.

The applicant shall describe the way in which each lot of components will be sampled and tested to maintain its quality prior to assembly of each sampler unit. In order to assure that the quality of the CMDPSU will be maintained in production through adequate quality control procedures, MSHA and NIOSH reserve the right to have their qualified personnel inspect each applicant's control-test equipment procedures and records and to interview the employees who conduct the control tests. Two copies of the results of any tests made by the applicant on the CMDPSU or the pump unit thereof shall accompany an application provided under § 74.13 of this part.

Subpart C—Requirements for Continuous Personal Dust Monitors

§ 74.7 Design and construction requirements.

(a) *General requirement.* Continuous Personal Dust Monitors (CPDMs) shall be designed and constructed for coal miners to wear and operate without impeding their ability to perform their work safely and effectively, and shall be sufficiently durable to perform reliably in the normal working conditions of coal mines.

(b) *Ergonomic design testing.* Prior to submitting an application under § 74.13, the applicant shall develop a testing protocol and test the CPDM to assure that the device can be worn safely, without discomfort, and without impairing a coal miner in the performance of duties throughout a full work shift. The results of the test or tests shall also demonstrate that the device will operate consistently throughout a full work shift under representative working conditions of underground coal miners, including representative types and durations of physical activity, tasks, and changes in body orientation.

(1) The testing protocol shall specify that the tests be conducted in one or more active mines under routine operating conditions during production shifts.

(2) The applicant shall submit the testing protocol, in writing, to NIOSH for approval prior to conducting such testing.

(3) The applicant shall include the testing protocol and written test results in the application submitted to NIOSH as specified in § 74.13.

(4) NIOSH will advise and assist the applicant, as necessary, to develop a testing protocol and arrange for the conduct of testing specified in this paragraph.

(5) NIOSH may further inspect the device or conduct such tests as it deems necessary to assure the safety, comfort, practicality, and operability of the device when it is worn by coal miners in the performance of their duties.

(6) NIOSH may waive the requirement for the applicant to conduct testing under paragraph (b) of this section if NIOSH determines that such testing is unnecessary to assure the safety, comfort, practicality, and operability of the device when it is worn by coal miners in the performance of their duties.

(c) *Maximum weight.* A CPDM shall not add more than 2 kg to the total weight carried by the miner. CPDMs that are combined with other functions, such as communication or illumination, may exceed 2 kg provided that the resulting total added weight carried by the miner by such combination does not exceed 2 kg.

(d) *Dust concentration range.* The CPDM shall measure respirable coal mine dust concentrations accurately, as specified under § 74.8, for an end-of-shift average measurement, for concentrations within the range from 10% to 2 times the PEL for respirable coal mine dust. For end-of-shift average concentrations exceeding 2 times the PEL, the CPDM shall, at minimum, provide a reliable indication that the concentration exceeded 2 times the PEL.

(e) *Environmental conditions.* The CPDM shall operate reliably and measure respirable coal mine dust concentrations accurately, as specified under § 74.8, under the following environmental conditions:

(1) At any ambient temperature and varying temperatures from minus 30 to plus 40 degrees centigrade;

(2) At any atmospheric pressure from 700 to 1000 millibars;

(3) At any ambient humidity from 10 to 100 percent relative humidity; and

(4) While exposed to water mists generated for dust suppression and while monitoring atmospheres including such water mists.

(f) *Electromagnetic interference.* The CPDM shall meet the following standards for the control of and protection from electromagnetic interference.

(1) Emissions: ANSI C95.1–1982 (Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields) and 47 CFR part 15 (FCC Radio Frequency Devices). Persons must proceed in accordance with ANSI C95.1–1982. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Persons may obtain a copy from American National Standards Institute (ANSI), 25 West 43rd Street, New York, NY 10036, *http://www.ansi.org.*

Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(2) Immunity/Susceptibility: IEC 61000–4 and –6 (Electromagnetic compatibility—Part 4–6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields). Persons must proceed in accordance with IEC 61000–4 and 6. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Persons may obtain a copy from the International Electrotechnical Commission at the address provided below. International Electrotechnical Commission, IEC Central Office, 3, rue de Varembé, P.O.

Box 131, CH–1211 GENEVA 20, Switzerland, *http://www.standardsinfo.net*.

Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(g) *Durability testing.* The CPDM shall be designed and constructed to remain safe and measure respirable coal mine dust concentrations accurately, as specified under § 74.8 of this part, after undergoing the following durability tests, which NIOSH will apply to test units prior to their use in further testing under § 74.8 of this subpart:

Vibration	Mil-Std-810F, 514.5	US Highway vibration, restrained figure 514.5C–1	1 Hours/axis, 3 axis; total duration = 3 hrs, equivalent to 1,000 miles
Drop	3-foot drop onto bare concrete surface	In standard in-use configuration	1 drop per axis (3 total).

Persons must proceed in accordance with Mil-Std-810F, 514.5. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Persons may obtain a copy from the U.S. Department of Defense at the address provided below. ASC/ENOI, Bldg. 560, 2530 Loop Road West, Wright-Patterson AFB OH 45433–7101, *http://www.dtc.army.mil/navigator/*.

Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(h) *Reporting of monitoring results.*

(1) The CPDM shall report continuous monitoring results legibly and/or audibly during use. A digital display, if used, shall be illuminated and shall provide a minimum character height of 6 millimeters. Other forms of display (*e.g.*, analogue) must provide comparable visibility. Auditory reporting, if used, shall be clear, have adjustable volume, and provide means for the user to obtain data reports repetitively. The CPDM shall also report end-of-shift results using computer software compatible with current, commonly used personal computer technology.

(2) The CPDM shall report results as cumulative mass concentration in units of mass per volume of air (mg/m^3).

(i) *Power requirements.*

The power source of the CPDM shall have sufficient capacity to enable continuous sampling for 12 hours in a coal mine dust atmosphere of 4.0 mg/m^3. If the CPDM uses a rechargeable battery, the battery charger shall be operated from a 110 (VAC) (nominal), 60 Hz power line.

(j) *Flow stability and calibration of pump.* If a pump is used, the flow shall not vary more than ±5 percent from the calibrated flow for 95 percent of samples taken of any continuous duration for up to 12 hours. The flow calibration maintenance interval to assure such performance shall be specified in the calibration instructions for the device.

(k) *Battery check.* If the CPDM uses a rechargeable battery, the CPDM shall have a feature to indicate to the user that the unit is adequately charged to provide accurate measurements for an entire shift of 12 hours under normal conditions of use.

(l) *Integration with other personal mining equipment.*

(1) If the CPDM is integrated or shares functions with any other devices used in mines, such as cap lights or power sources, then the applicant shall obtain approvals for such other devices, as might be required under federal regulations, prior to receiving final certification of the CPDM under this part.

(2) A CPDM that is integrated with another device shall be tested, pursuant to all the requirements under this part, with the other device coupled to the CPDM and operating.

(m) *Tampering safeguards or indicators.* The CPDM shall include a safeguard or indicator which either prevents intentional or inadvertent altering of the measuring or reporting functions or provides an indication that the measuring or reporting functions have been altered.

(n) *Maintenance features.* The CPDM shall be designed to assure that the device can be cleaned and maintained to perform accurately and reliably for the duration of its service life.

§ 74.8 Measurement, accuracy, and reliability requirements.

(a) *Breathing zone measurement requirement.* The CPDM shall be capable of measuring respirable dust within the personal breathing zone of the miner whose exposure is being monitored.

(b) *Accuracy.* The ability of a CPDM to determine the true concentration of respirable coal mine dust at the end of a shift shall be established through testing that demonstrates the following:

(1) For full-shift measurements of 8 hours or more, a 95 percent confidence that the recorded measurements are within ±25 percent of the true respirable dust concentration, as determined by CMDPSU reference measurements, over a concentration range of 10% to 2 times the PEL; and

(2) For intra-shift measurements of less than 8 hours, a 95 percent confidence that the recorded measurements are within ± 25 percent of the true respirable dust concentration, as determined by CMDPSU reference measurements, over the concentration range equating to 10% to 2 times the PEL for an 8-hour period.[1]

(c) *Reliability of measurements.* The CPDM shall meet the accuracy requirements under paragraph (b) of this section, regardless of the variation in density, composition, or size distribution of respirable coal mine dust particles, or the presence of spray mist.

(d) *Precision.* The precision of the CPDM shall be established through testing to determine the variability of multiple measurements of the same dust concentration, as defined by the relative standard deviation of the distribution of measurements. The relative standard

[1] The equivalent dust concentration range to the 8-hour range of 10% to 2 times the PEL (currently 0.2 − 4 mg/m^3) is calculated by multiplying this 8-hour range by the dividend of eight hours divided by the duration of the intrashift measurement specified in units of hours. For example, for a measurement taken at exactly one hour into the shift, the 8-hour equivalent dust concentration range would be a one-hour average concentration range of: 8 hours/1 hour × (0.2 − 4 mg/m^3) = *1.6 − 32 mg/m³*; for a two-hour measurement, the applicable concentration range would be calculated as: 8 hours/2 hours × (0.2 − 4 mg/m^3) = *0.8 − 16 mg/m³*; for a 4-hours measurement, the equivalent range would be: *0.4 − 8 mg/m³*; * * * etc. A CPDM must perform accurately, as specified, for intrashift measurements within such equivalent concentration ranges.

deviation shall be less than 0.1275 without bias for both full-shift measurements of 8 hours or more, and for intra-shift measurements of less than 8 hours within the dust concentration range equating to 10% to 2 times the PEL for an 8-hour period, as specified under paragraph (b)(2) of this section.

(e) *Bias.* The bias of the CPDM measurements shall be limited such that the uncorrectable discrepancy between the mean of the distribution of measurements and the true dust concentration being measured during testing shall be no greater than 10 percent. Bias must be constant over the range of dust concentration levels tested, between 10% and 2 times the PEL for an 8-hour sampling period.

(f) *Testing conditions.* Laboratory and mine testing of the CPDM for accuracy, precision, bias, and reliability under diverse environmental conditions (as defined under § 74.7(e) and (g)) shall be determined using the NIOSH testing procedure: ''Continuous Personal Dust Monitor Testing Procedures'' available at: *http://www.cdc.gov/niosh/mining*. All testing results shall be submitted to NIOSH in writing on the application filed under § 74.13.

§ 74.9 Quality assurance.

(a) *General requirements.* The applicant shall be responsible for the establishment and maintenance of a quality control system that assures that devices produced under the applicant's certificate of approval meet the specifications to which they are certified under this part and are reliable, safe, effective, and otherwise fit for their intended use. To establish and to maintain an approval under this part, the applicant shall:

Submit a copy of the most recent registration under ISO Q9001–2000, or under any updated version of this quality management standard published by ISO:

(i) With the application for approval under § 74.13 of this part; and

(ii) Upon request by NIOSH, subsequent to the approval of a CPDM under this part.

Persons must proceed in accordance with Q9001–2000. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Persons may obtain a copy from the International Organization for Standardization at the address provided below. International Organization for Standardization, ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case Postale 56, CH–1211 GENEVA 20, Switzerland, *http://www.standardsinfo.net*.

Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) *Quality management audits.* Upon request, applicants or approval holders must allow NIOSH to inspect the quality management procedures and records, and to interview any employees who may be knowledgeable of quality management processes associated with the production of the CPDM. Audits may be conducted either on an occasional or periodic basis or in response to quality-related complaints or concerns.

(c) *Applicant remediation of quality management deficiencies.*

An applicant or approval holder must correct any quality management deficiency identified by an audit within a reasonable time as determined by NIOSH. Failure to correct a deficiency may result in NIOSH disapproving the pending application or, in the case of an approved device, revoking the approval of the device, until such time as NIOSH has determined that the deficiency is remedied.

§ 74.10 Operating and maintenance instructions.

(a) *Contents.* The manufacturer must include operating instructions and a maintenance and service life plan with each new CPDM unit sold. These documents must be clearly written.

(1) Operating and storage instructions must address the following topics and elements:

(i) An explanation of how the CPDM works;

(ii) A schematic diagram of the CPDM;

(iii) Procedures for wearing and use of the CPDM;

(iv) Procedures for calibration of the CPDM;

(v) Procedures for inspecting the operating condition of the CPDM;

(vi) Procedures and conditions for storage, including the identification of any storage conditions that would likely impair the effective functioning of the CPDM; and

(vii) Procedures and conditions of use, including identification of any conditions of use that would likely impair the effective functioning of the CPDM.

(2) The maintenance and service life plan must completely address the following topics:

(i) Any conditions that should govern the removal from service of the CPDM; and

(ii) Any procedures by which a user or others should inspect the CPDM, perform any maintenance and calibration procedures, and determine when the CPDM should be removed from service.

(b) *Submission to NIOSH for approval.* A copy of the instructions and plan under paragraph (a) of this section shall be submitted to NIOSH for approval with the application for approval of the device and resubmitted to NIOSH if substantive changes are made to the approved unit or approved instructions.

§ 74.11 Tests of the continuous personal dust monitor.

(a) *Applicant testing.* The applicant shall conduct tests to determine whether a CPDM that is submitted for approval under these regulations meets the requirements specified in §§ 74.7–74.8 of this part, with the exception of durability testing, which shall be conducted by NIOSH as specified in § 74.7(g) of this part. Applicant testing shall be performed by an independent testing entity approved by NIOSH.

(b) *NIOSH testing assistance.* NIOSH will provide consultation to the applicant to identify and secure necessary testing services for meeting the requirements specified in §§ 74.7–74.8 of this part. Applicants must submit testing protocols to NIOSH prior to the conduct of testing to verify that protocols are adequate to address the requirements.

(c) *Reporting of applicant testing results.* The applicant shall arrange for the protocols and results from testing specified under paragraph (a) of this section to be reported by the independent testing entity directly to NIOSH when submitting the application under § 74.13 of this part.

(d) *Intrinsic safety testing.* The applicant shall submit the CPDM to MSHA for testing and evaluation, pursuant to 30 CFR 18.68, to determine whether the electronic components of the CPDM submitted for approval meet the applicable permissibility provisions.

Subpart D—General Requirements for All Devices

§ 74.12 Conduct of tests; demonstrations.

(a) Prior to the issuance of a certificate of approval, only personnel of MSHA and NIOSH, representatives of the applicant, and such other persons as may be mutually agreed upon may observe the tests conducted. MSHA and NIOSH shall hold as confidential, and

shall not disclose, principles of patentable features, nor shall MSHA or NIOSH disclose any details of the applicant's drawings or specifications or other related material.

(b) After the issuance of a certificate of approval, MSHA or NIOSH will conduct such public demonstrations and tests of the approved device as MSHA or NIOSH deem appropriate, and may reveal the protocols and results of testing considered for the approval of the device. The conduct of any additional investigations, tests, and demonstrations shall be under the sole direction of MSHA and NIOSH and any other persons shall be present only as observers. The Freedom of Information Act governs disclosure of applicant materials requested by the public.

§ 74.13 Applications.

(a) Testing of a CMDPSU will be undertaken by NIOSH, and testing of the pump unit of such a sampler unit will be undertaken by MSHA, only pursuant to a written application in duplicate. Each copy of the application must be accompanied by complete scale drawings, specifications, and a description of materials. Ten complete CMDPSUs must be submitted to NIOSH with the application, and one pump unit must be sent to MSHA.

(b) Testing of a CPDM will be undertaken by the applicant as specified under § 74.11 and by MSHA only pursuant to a written application in duplicate. Each copy of the application must be accompanied by complete scale drawings, specifications, a description of materials, and a copy of the testing protocol and test results which were provided directly to NIOSH by the independent testing entity, as specified under § 74.11. Three complete CPDM units must be sent to NIOSH with the application, and one CPDM unit must be sent to MSHA.

(c) Complete drawings and specifications shall be adequate in number and fully detailed to identify the design of the CMDPSU or pump unit thereof or of the CPDM and to disclose the dimensions and materials of all component parts.

§ 74.14 Certificate of approval.

(a) Upon completion of the testing of a CMDPSU or the pump unit thereof, or after review of testing protocols and testing results for the CPDM, NIOSH or MSHA, as appropriate, shall issue to the applicant either a certificate of approval or a written notice of disapproval, as the case may require. NIOSH shall not issue a certificate of approval unless MSHA has first issued a certificate of approval for either the pump unit of a CMDPSU or for the CPDM. No informal notification of approval will be issued. If a certificate of approval is issued, no test data or detailed results of tests will accompany such approval. If a notice of disapproval is issued, it will be accompanied by details of the defects, resulting in disapproval, with a view to possible correction.

(b) A certificate of approval will be accompanied by a list of the drawings and specifications covering the details of design and construction of the CMDPSU and the pump unit thereof, or of the CPDM, as appropriate, upon which the certificate of approval is based. The applicant shall keep exact duplicates of the drawings and specifications submitted to NIOSH and to MSHA relating to the CMDPSU, the pump unit thereof, or the CPDM, which has received a certificate of approval. The approved drawings and specifications shall be adhered to exactly in the production of the certified CMDPSU, including the pump unit thereof, or of the CPDM, for commercial purposes. In addition, the applicant shall observe such procedures for, and keep such records of, the control of component parts as either MSHA or NIOSH may in writing require as a condition of certification.

§ 74.15 Approval labels.

(a) Certificates of approval will be accompanied by photographs of designs for the approval labels to be affixed to each CMDPSU or CPDM, as appropriate.

(b) The labels showing approval by NIOSH and by MSHA shall contain such information as MSHA or NIOSH may require and shall be reproduced legibly on the outside of a CMDPSU or CPDM, as appropriate, as directed by NIOSH or MSHA.

(c) The applicant shall submit full-scale designs or reproductions of approval labels and a sketch or description of the position of the labels on each unit.

(d) Use of the approval labels obligates the applicant to whom the certificates of approval were issued to maintain the quality of the complete CMDPSU or CPDM, as appropriate, and to guarantee that the complete CMDPSU or CPDM, as appropriate, is manufactured or assembled according to the drawings and specifications upon which the certificates of approval were based. Use of the approval labels is authorized only on CMDPSUs or CPDMs, as appropriate, that conform strictly to the drawings and specifications upon which the certificates of approval were based.

§ 74.16 Material required for record.

(a) As part of the permanent record of the investigation, NIOSH will retain a complete CMDPSU or CPDM, as appropriate, and MSHA will retain a CMDPSU or CPDM, as appropriate, that has been tested and certified. Material not required for record purposes will be returned to the applicant at the applicant's request and expense upon receipt of written shipping instructions by MSHA or NIOSH.

(b) As soon as a CMDPSU or CPDM, as appropriate, is commercially available, the applicant shall deliver a complete unit free of charge to NIOSH at the address specified on the NIOSH Web page: *http://www.cdc.gov/niosh/mining*.

§ 74.17 Changes after certification.

(a) If the applicant desires to change any feature of a certified CMDPSU or a certified CPDM, the applicant shall first obtain the approval of NIOSH pursuant to the following procedures:

(1) Application shall be made as for an original certificate of approval, requesting that the existing certification be extended to encompass the proposed change. The application shall be accompanied by drawings, specifications, and related material, as in the case of an original application.

(2) The application and accompanying material will be examined by NIOSH to determine whether testing of the modified CMDPSU or CPDM or components will be required. Testing will be necessary if there is a possibility that the modification may adversely affect the performance of the CMDPSU or CPDM. NIOSH will inform the applicant whether such testing is required.

(3) If the proposed modification meets the pertinent requirements of these regulations, a formal extension of certification will be issued, accompanied by a list of new and revised drawings and specifications to be added to those already on file as the basis for the extension of certification.

(b) If a change is proposed in a pump unit of a certified CMDPSU or in electrical components of a CPDM, the approval of MSHA with respect to intrinsic safety shall be obtained in accordance with the procedures set forth in § 74.11(d).

§ 74.18 Withdrawal of certification.

Any certificate of approval issued under the regulations in this part may be revoked for cause by NIOSH or MSHA which issued the certificate.

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