

substituted for environmental control measures in the active workings. Each operator shall maintain an adequate supply of respiratory equipment.

(b) When required to make respirators available, the operator shall provide training prior to the miner's next scheduled work shift, unless the miner received training within the previous 12 months on the types of respirators made available. The training shall include: The care, fit, use, and limitations of each type of respirator.

(c) An operator shall keep a record of the training at the mine site for 24 months after completion of the training. An operator may keep the record elsewhere if the record is immediately accessible from the mine site by electronic transmission. Upon request from an authorized representative of the Secretary, Secretary of HHS, or representative of miners, the operator shall promptly provide access to any such training records. The record shall include:

- (1) The date of training;
- (2) The names of miners trained; and
- (3) The subjects included in the training.

[79 FR 24986, May 1, 2014]

**§ 72.701 Respiratory equipment; gas, dusts, fumes, or mists.**

Respiratory equipment approved by NIOSH under 42 CFR part 84 shall be provided to persons exposed for short periods to inhalation hazards from gas, dusts, fumes, or mists. When the exposure is for prolonged periods, other measures to protect such persons or to reduce the hazard shall be taken.

[79 FR 24986, May 1, 2014]

**§ 72.710 Selection, fit, use, and maintenance of approved respirators.**

In order to ensure the maximum amount of respiratory protection, approved respirators shall be selected, fitted, used, and maintained in accordance with the provisions of the American National Standards Institute's "Practices for Respiratory Protection ANSI Z88.2-1969," which is hereby incorporated by reference. This publication may be obtained from the American National Standards Institute, Inc., 25 W. 43rd Street, 4th Floor, New York,

NY 10036; <http://www.ansi.org>, and may be inspected at any MSHA Coal Mine Safety and Health District Office, or at MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5452; 202-693-9440; 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>. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

[80 FR 52990, Sept. 2, 2015]

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

The Secretary will use a single, full-shift measurement of respirable coal mine dust to determine the average concentration on a shift since that measurement accurately represents atmospheric conditions to which a miner is exposed during such shift. Non-compliance with the applicable respirable dust standard or the applicable respirable dust standard when quartz is present, in accordance with subchapter O of this chapter, is demonstrated when a single, full-shift measurement taken by MSHA meets or exceeds the applicable ECV in Table 70-1, 71-1, or 90-1 that corresponds to the applicable standard and the particular sampling device used. Upon issuance of a citation for a violation of the applicable standard, and for MSHA to terminate the citation, the operator shall take the specified actions in subchapter O of this chapter.

[79 FR 24986, May 1, 2014]

**PART 74—COAL MINE DUST SAMPLING DEVICES**

**Subpart A—General**

Sec.

74.1 Purpose.

74.2 Definitions.

## § 74.1

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AUTHORITY: 30 U.S.C. 957.

SOURCE: 75 FR 17523, Apr. 6, 2010, unless otherwise noted.

### Subpart A—General

#### § 74.1 Purpose.

The regulations in this part set forth the requirements for approval of coal mine dust sampling devices for determining 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 continuous personal dust monitor (CPDM) 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 CPDM 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 CPDM 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 sampling 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 CPDM to replicate measurement results.

### Subpart B—Approval 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  $\pm 5$  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  $\pm 5$  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  $\pm 0.1$  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 displaying the actual pump run time in minutes (up to 999 minutes) and retaining the last reading after the pump is shut down due to either a flow restriction described in paragraph (a)(14) of this section or low battery power described in paragraph (a)(16) of this section 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:

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(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 Dorr-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  $\pm 0.001$  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 intentional or inadvertent alteration of dust deposited on the filter. The cassette must be easily removable without causing a loss or gain of capsule weight. The cassette 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 or 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  $\frac{1}{4}$ -inch (0.64 centimeters) (inside diameter) hose mentioned in paragraph (b)(5) of this sec-

tion 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,  $\frac{1}{4}$ -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 30 CFR 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 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 total added weight carried by the miner 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 a range from 0.2 to 4.0 mg/m<sup>3</sup> for respirable coal mine dust. For end-of-shift average concentrations exceeding 4.0 mg/m<sup>3</sup>, the CPDM shall provide a reliable indication that the concentration exceeded 4.0 mg/m<sup>3</sup>.

(e) *Environmental conditions.* The CPDM shall operate reliably and 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 control of and protection from electromagnetic interference.

(1) For emissions control, operators must follow: IEEE Std C95.1-2005, (IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz) and 47 CFR 15.1 through 15.407 (FCC Radio Frequency Devices). Persons must proceed in accordance with IEEE Std C95.1-2005 (IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz).

(i) 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>.

(ii) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5452, 202-693-9440, 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) For immunity/susceptibility protection, operators must follow: IEC

61000-4-6, International Standard (Electromagnetic compatibility—Part 4-6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields), Edition 3.0, 2008-10. Persons must proceed in accordance with IEC 61000-4-6, International Standard (Electromagnetic compatibility—Part 4-6: Testing and measurement techniques—Immunity to conducted disturbances, induced by radio-frequency fields), Edition 3.0, 2008-10. 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.

(i) Persons may obtain a copy from the International Electrotechnical Commission at the address provided below:

International Electrotechnical Commission, IEC Central Office, 3, rue de Varembe, P.O. Box 131, CH-1211 GENEVA 20, Switzerland. <http://www.standardsinfo.net>.

(ii) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5452, 202-693-9440, 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 section after undergoing the following durability tests, which NIOSH will apply to test devices prior to their use in further testing under § 74.8 of this-subpart:

Vibration .....	Mil-Std-810F, 514.5 .....	U.S. 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).

(1) Persons must proceed in accordance with Mil-Std-810F, 514.5, Depart-

ment of Defense Test Method for Environmental Engineering Considerations

and Laboratory Tests, 1 January 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 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/>.

(2) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5452; 202-693-9440; 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 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<sup>3</sup>) with two significant figures of accuracy rounded as customary.

(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 up to 4.0 mg/m<sup>3</sup>. 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 of the calibrated flow for 95 percent of samples taken for 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 device is sufficiently charged to operate and 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, prior to receiving final certification of the CPDM under this section.

(2) A CPDM that is integrated with another device shall be tested, according 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 indicates 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.

[75 FR 17523, Apr. 6, 2010, as amended at 80 FR 52990, Sept. 2, 2015]

#### § 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

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within  $\pm 25$  percent of the true respirable dust concentration, as determined by CMDPSU reference measurements, over a concentration range from 0.2 to 4.0 mg/m<sup>3</sup>; and

(2) For intra-shift measurements of less than 8 hours, a 95 percent confidence that the recorded measurements are within  $\pm 25$  percent of the true respirable dust concentration, as determined by CMDPSU reference measurements, over the concentration range equivalent to 0.2 to 4.0 mg/m<sup>3</sup> for an 8-hour period.<sup>1</sup>

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

(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 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 equivalent to 0.2 to 4.0 mg/m<sup>3</sup> 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, 0.2 to 4.0 mg/m<sup>3</sup> 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 Accuracy Testing,” June 23, 2008, available at: <http://www.cdc.gov/niosh/mining/pubs/pubreference/outputid3076.htm>. All testing results shall be submitted to NIOSH in writing on the application filed under § 74.11.

(1) Persons must proceed in accordance with NIOSH testing procedure “Continuous Personal Dust Monitor Accuracy Testing,” June 23, 2008. 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 at the address below: NIOSH—Publications Dissemination, 4676 Columbia Parkway, Cincinnati, OH 45226. <http://www.cdc.gov/niosh/mining>.

(2) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5452; 202-693-9440; 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

[75 FR 17523, Apr. 6, 2010, as amended at 80 FR 52990, Sept. 2, 2015]

### § 74.9 Quality assurance.

(a) *General requirements.* The applicant shall establish and maintain a quality control system that assures that CPDM devices produced under the applicant’s certificate of approval meet the required specifications and are reliable, safe, effective, and otherwise suitable for their intended use. To establish and to maintain an approval under this part, the applicant shall:

<sup>1</sup>The equivalent dust concentration range to the 8-hour range of 0.2 – 4 mg/m<sup>3</sup> 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  $\times$  (0.2 – 4 mg/m<sup>3</sup>) = 1.6 – 32 mg/m<sup>3</sup>; for a two-hour measurement, the applicable concentration range would be calculated as: 8 hours/2 hours  $\times$  (0.2 – 4 mg/m<sup>3</sup>) = 0.8 – 16 mg/m<sup>3</sup>; for a 4-hours measurement, the equivalent range would be: 0.4 – 8 mg/m<sup>3</sup>; \* \* \* etc. A CPDM must perform accurately, as specified, for intrashift measurements within such equivalent concentration ranges.



(1) Submit a copy of the most recent registration under ISO Q9001-2000, American National Standard, Quality Management Systems-Requirements, 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.

(2) Persons must proceed in accordance with ISO Q9001-2000, American National Standard, Quality Management Systems-Requirements. 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>.

(3) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Arlington, VA 22202-5452; 202-693-9440; 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 disapproval of a pending application or, in the case of an approved

device, revocation of approval until NIOSH determines that the deficiency is corrected.

[75 FR 17523, Apr. 6, 2010, as amended at 80 FR 52990, Sept. 2, 2015]

#### § 74.10 Operating and maintenance instructions.

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

(1) Operating and storage instructions must include:

(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) A one page "quick start guide" that will enable a novice to start and operate the CPDM.

(v) Procedures for calibration of the CPDM;

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

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

(viii) 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 address:

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

(ii) Procedures that a user or others should follow when inspecting, performing maintenance and calibration, and determining 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 with the application for approval of the CPDM and if substantive changes are made to the approved device or approved instructions.

## § 74.11

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### § 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 testing to verify that the testing protocols adequately address the requirements.

(c) *Reporting of applicant testing results.* The applicant shall include the results from testing specified under paragraph (a) of this section when submitting the application under § 74.13 of this part to NIOSH.

(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 test-

ing 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.

#### § 74.13 Applications.

(a) Testing of a CMDPSU will be performed by NIOSH, and testing of the pump unit of the CMDPSU will be conducted by MSHA. The applicant must submit a written application in duplicate to both NIOSH and MSHA. 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 submitted to MSHA.

(b) Testing of a CPDM will be performed by the applicant as specified under § 74.11. The applicant must submit a written application in duplicate to both NIOSH and MSHA. 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 by an independent testing entity, as specified in § 74.11(a). Three complete CPDM units must be sent to NIOSH with the application, and one CPDM device must be sent to MSHA.

(c) Complete drawings and specifications accompanying each copy of the application shall be 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 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. NIOSH will 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. 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, 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 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 approval.

#### § 74.15 Approval labels.

(a) Certificate 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 sampling device.

(d) Use of the approval labels obligates the applicant to whom the certificate of approval was 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 certificate of approval was based. Use of the approval labels is authorized only on CMDPSUs or CPDMs, as appropriate, that conform to the drawings and specifications upon which the certificate of approval was based.

#### § 74.16 Material required for record.

(a) As part of the permanent record of the approval application process, 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 sampling device 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.

(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.

## § 74.18

(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 this part may be revoked for cause by NIOSH or MSHA which issued the certificate.

## PART 75—MANDATORY SAFETY STANDARDS—UNDERGROUND COAL MINES

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