

## § 74.9

## 30 CFR Ch. I (7–1–14 Edition)

Parkway, Cincinnati, OH 45226. <http://www.cdc.gov/niosh/mining>.

(2) Persons may inspect a copy at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, (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).

### § 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:

(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, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, (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).

(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.

### § 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