Post-approval product audit. Examination, testing, or both, by MSHA of approved products selected by MSHA to determine whether those products meet the applicable technical requirements and have been manufactured as approved.

Technical requirements. The design and performance requirements for a product, as specified in a subpart of this part.

Test procedures. The methods specified in a subpart of this part used to determine whether a product meet the performance portion of the technical requirements.

[53 FR 23500, June 22, 1988; 53 FR 25569, July 7, 1988, as amended at 68 FR 36418, June 17, 2003]

§ 7.3 Application procedures and requirements.

(a) *Application.* Requests for an approval or extension of approval shall be sent to: U.S. Department of Labor, Mine Safety and Health Administration, Approval and Certification Center, RR #1, Box 251, Industrial Park Road, Triadelphia, West Virginia 26059.

(b) *Fees.* Fees calculated in accordance with part 5 of this title shall be submitted in accordance with § 5.40.

(c) *Original approval.* Each application for approval of a product shall include—

(1) A brief description of the product;

(2) The documentation specified in the appropriate subpart of this part;

(3) The name, address, and telephone number of the applicant's representative responsible for answering any questions regarding the application;

(4) If appropriate, a statement indicating whether, in the applicant's opinion, testing is required. If testing is not proposed, the applicant shall explain the reasons for not testing; and

(5) If appropriate, the place and date for product testing.

(d) *Subsequent approval of a similar product.* Each application for a product similar to one for which the applicant already holds an approval shall include—

(1) The approval number for the product which most closely resembles the new one;

(2) The information specified in paragraph (c) of this section for the new product, except that any document which is the same as one listed by MSHA in prior approvals need not be submitted, but shall be noted in the application;

(3) An explanation of any change from the existing approval; and

(4) A statement as to whether, in the applicant's opinion, the change requires product testing. If testing is not proposed, the applicant shall explain the reasons for not testing.

(e) *Extension of an approval.* Any change in the approved product from the documentation on file at MSHA that affects the technical requirements of this part shall be submitted to MSHA for approval prior to implementing the change. Each application for an extension of approval shall include—

(1) The MSHA-assigned approval number for the product for which the extension is sought;

(2) A brief description of the proposed change to the previously approved product;

(3) Drawings and specifications which show the change in detail;

(4) A statement as to whether, in the applicant's opinion, the change requires product testing. If testing is not proposed, the applicant shall explain the reasons for not testing;

(5) The place and date for product testing, if testing will be conducted; and

(6) The name, address, and telephone number of the applicant's representative responsible for answering any questions regarding the application.

(f) *Certification statement.* (1) Each application for original approval, subsequent approval, or extension of approval of a product shall include a certification by the applicant that the product meets the design portion of the technical requirements, as specified in the appropriate subpart, and that the applicant will perform the quality assurance functions specified in § 7.7. For a subsequent approval or extension of approval, the applicant shall also certify that the proposed change cited in the application is the only change that affects the technical requirements.

(2) After completion of the required product testing, the applicant shall

certify that the product has been tested and meets the performance portion of the technical requirements, as specified in the appropriate subpart.

(3) All certification statements shall be signed by an authorized company official.

[53 FR 23500, June 22, 1988, as amended at 60 FR 33722, June 29, 1995]

§ 7.4 Product testing.

(a) All products submitted for approval under this part shall be tested using the test procedures specified in the appropriate subpart unless MSHA determines, upon review of the documentation submitted, that testing is not required. Applicants shall maintain records of test results and procedures for three years.

(b) Unless otherwise specified in the subpart, test instruments shall be calibrated at least as frequently as, and according to, the instrument manufacturer's specifications, using calibration standards traceable to those set by the National Bureau of Standards, U.S. Department of Commerce or other nationally recoginzed standards and accurate to at least one significant figure beyond the desired accuracy.

(c) When MSHA elects to observe product testing, the applicant shall permit an MSHA official to be present at a mutually agreeable date, time, and place.

(d) MSHA will accept product testing conducted outside the United States where such acceptance is specifically required by international agreement.

[53 FR 23500, June 22, 1988; 53 FR 25569, July 7, 1988; 60 FR 33722, June 29, 1995]

§ 7.5 Issuance of approval.

(a) An applicant shall not advertise or otherwise represent a product as approved until MSHA has issued the applicant an approval.

(b) MSHA will issue an approval or a notice of the reasons for denying approval after reviewing the application, and the results of product testing, when applicable. An approval will identify the documents upon which the approval is based.

§ 7.6 Approval marking and distribution record.

(a) Each approved product shall have an approval marking, as specified in the appropriate subpart of this part.

(b) For an extension of approval, the extension number shall be added to the original approval number on the approval marking.

(c) Applicants shall maintain records of the initial sale of each unit having an approval marking. The record retention period shall be at least the expected shelf life and service life of the product.

[53 FR 23500, June 22, 1988, as amended at 60 FR 33722, June 29, 1995]

§ 7.7 Quality assurance.

Applicants granted an approval or an extension of approval under this part shall—

(a) Inspect or test, or both, the critical characteristics in accordance with the appropriate subpart of this part;

(b) Unless otherwise specified in the subparts, calibrate instruments used for the inspection and testing of critical characteristics at least as frequently as, and according to, the instrument manufacturer's specifications, using calibration standards traceable to those set by the National Bureau of Standards, U.S. Department of Commerce or other nationally recognized standards and use instruments accurate to at least one significant figure beyond the desired accuracy.

(c) Control production documentation so that the product is manufactured as approved;

(d) Immediately report to the MSHA Approval and Certification Center, any knowledge of a product distributed with critical characteristics not in accordance with the approval specifications.

[53 FR 23500, June 22, 1988, as amended at 60 FR 33722, June 29, 1995]

§ 7.8 Post-approval product audit.

(a) Approved products shall be subject to periodic audits by MSHA for the purpose of determining conformity with the technical requirements upon which the approval was based. Any approved product which is to be audited