

§ 84.42

42 CFR Ch. I (10–1–03 Edition)

Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888. Incoming bulk raw material inspection or verification of specification, and in-process inspection shall be sufficient to ensure control of product quality through the manufacturing cycle.

(c) The sampling procedure shall include a list of the characteristics to be tested by the applicant or his agent.

(d) The characteristics listed in accordance with paragraph (c) of this section shall be classified according to the potential effect of such defect and grouped into the following classes:

(1) *Critical*. A defect that judgment and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator;

(2) *Major A*. A defect, other than critical, that is likely to result in failure to the degree that the respirator does not provide any respiratory protection, or a defect that reduces protection and is not detectable by the user;

(3) *Major B*. A defect, other than Major A or critical, that is likely to result in reduced respiratory protection, and is detectable by the user; and

(4) *Minor*. A defect that is not likely to materially reduce the usability of the respirator for its intended purpose, or a defect that is a departure from established standards and has little bearing on the effective use or operation of the respirator.

(e) The quality control inspection test method to be used by the applicant or his agent for each characteristic required to be tested shall be described in detail.

(f) Each item manufactured shall be 100 percent inspected for defects in all critical characteristics and all defective items shall be rejected.

(g) The Acceptable Quality Level (AQL) for each major or minor defect so classified by the applicant shall be:

- (1) *Major A*. 1.0 percent;
- (2) *Major B*. 2.5 percent; and
- (3) *Minor*. 4.0 percent.

(h) Except as provided in paragraph (i) of this section, inspection level IV as described in MIL–STD–414, 11 June 1957, including Change Notice No.1, “Sampling Procedures and Tables for Inspection by Variables for Percent Defective,” or an equivalent procedure,

shall be used for major and minor characteristics and 100 percent inspection for critical characteristics. Inspection level II as described in MIL–STD–105D, 29 April 1963, “Sampling Procedures and Tables for Inspection by Attributes,” is an example of an equivalent procedure.

(i) Subject to the approval of the Institute, where the quality control plan provisions for raw material, processes, manufacturing, and fabrication, inspections are adequate to ensure control of finished article quality, destructive testing of finished articles may be conducted at a lower level of inspection than that specified in paragraph (h) of this section.

(The information collections contained in this section are approved under OMB control number 0920–0109)

**§ 84.42 Proposed quality control plans; approval by the Institute.**

(a) Each proposed quality control plan submitted in accordance with this subpart shall be reviewed by the Institute to determine its effectiveness in ensuring the quality of respiratory protection provided by the respirator for which an approval is sought.

(b) If the Institute determines that the proposed quality control plan submitted by the applicant will not ensure adequate quality control, the Institute shall require the applicant to modify the procedures and testing requirements of the plan prior to approval of the plan and issuance of any certificate of approval.

(c) Approved quality control plans shall constitute a part of and be incorporated into any certificate of approval issued by the Institute, and compliance with such plans by the applicant shall be a condition of approval.

**§ 84.43 Quality control records; review by the Institute; revocation of approval.**

(a) The applicant shall keep quality control inspection records sufficient to carry out the procedures required in MIL–STD–414, 11 June 1957, including Change Notice No. 1, “Sampling Procedures and Tables for Inspection by Variables for Percent Defective,” or an approved equivalent sampling procedure. MIL–STD–105D, 29 April 1963,

“Sampling Procedures and Tables for Inspection by Attributes,” is an example of an approved equivalent sampling procedure. MIL-STD-414 is incorporated by reference and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from DODSSP, Standardization Document Order Desk, 700 Robbins Avenue, Bldg. 4D, Philadelphia, Pa. 19111-5094. Copies may be inspected at the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505-2888, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies of MIL-STD-105D may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505-2888.

(b) The Institute reserves the right to have its representatives inspect the applicant’s quality control test methods, equipment, and records, and to interview any employee or agent of the applicant in regard to quality control test methods, equipment, and records.

(c) The Institute reserves the right to revoke, for cause, any certificate of approval where it is found that the applicant’s quality control test methods, equipment, or records do not ensure effective quality control over the respirator for which the approval was issued.

(The information collections contained in this section are approved under OMB control number 0920-0109)

### **Subpart F—Classification of Approved Respirators; Scope of Approval; Atmospheric Hazards; Service Time**

#### **§ 84.50 Types of respirators to be approved; scope of approval.**

Approvals shall be issued for the types of respirators which have been classified pursuant to this subpart F, have been inspected, examined and tested by the Institute, in accordance with the provisions of subparts G through L of this part, and have been found to provide respiratory protection

for fixed periods of time against the hazards specified in such approval.

#### **§ 84.51 Entry and escape, or escape only; classification.**

Respirators described in subparts H through L of this part shall be classified for use as follows:

(a) *Entry and escape.* Respirators designed and approved for use during entry into a hazardous atmosphere, and for escape from a hazardous atmosphere; or

(b) *Escape only.* Respirators designed and approved for use only during escape from a hazardous atmosphere.

#### **§ 84.52 Respiratory hazards; classification.**

Respirators described in subparts H through L of this part shall be classified as approved for use against any or all of the following respiratory hazards:

- (a) Oxygen deficiency;
- (b) Gases and vapors; and
- (c) Particles, including dusts, fumes and mists.

#### **§ 84.53 Service time; classification.**

(a) Respirators described in subparts H through L of this part shall be classified, where applicable, as approved for use during the following prescribed service times:

- (1) Four hours;
  - (2) Three hours;
  - (3) Two hours;
  - (4) One hour;
  - (5) Forty-five minutes;
  - (6) Thirty minutes;
  - (7) Fifteen minutes;
  - (8) Ten minutes;
  - (9) Five minutes; or
  - (10) Three minutes.
- (b) Other service times may be prescribed by the Institute.

### **Subpart G—General Construction and Performance Requirements**

#### **§ 84.60 Construction and performance requirements; general.**

(a) The Institute shall issue approvals for the types of respirators described in subparts H through L of this part which have met the minimum requirements set forth for such respirators in this part.