

§ 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,