respirator, request a modification of the original certificate of approval issued by the Institute for such respirator by filing an application for such modification in accordance with the provisions of this section.

(b) Applications shall be submitted as for an original certificate of approval, with a request for a modification of the existing certificate to cover any proposed change.

(c) The application shall be accompanied by appropriate drawings and specifications, and by a proposed quality control plan which meets the requirements of subpart E of this part.

(d) The application for modification, together with the accompanying material, shall be examined by the Institute to determine whether testing will be required.

(e) The Institute shall inform the applicant of the fee required for any additional testing and the applicant will be charged for the actual cost of any examination, inspection, or test required, and such fees shall be submitted in accordance with the provisions of subpart C of this part.

(f) If the proposed change or modification meets the requirements of this part, a formal certificate of modification will be issued, accompanied, where necessary, by a list of new and revised drawings and specifications covering the change(s) and reproductions of revised approval labels.

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

§ 84.41 Quality control plans; contents.

(a) Each quality control plan shall contain provisions for the management of quality, including:

1. Requirements for the production of quality data and the use of quality control records;
2. Control of engineering drawings, documentation, and changes;
3. Control and calibration of measuring and test equipment;
4. Control of purchased material to include incoming inspection;
5. Lot identification, control of processes, manufacturing, fabrication, and assembly work conducted in the applicant's plant;
6. Audit of final inspection of the completed product; and
7. The organizational structure necessary to carry out these provisions.

(b) Each provision for incoming and final inspection in the quality control plan shall include a procedure for the selection of a sample of respirators and the components thereof for testing, in accordance with procedures set forth in Military Standard 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, or an approved combination of sampling procedures. The procedure of Military Standard MIL-STD-105D, 29 April 1963, “Sampling Procedures and Tables for Inspection by Attributes,” is an example of an 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 National Archives and Records Administration.
§ 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.

(3) Minor. 4.0 percent.

(b) 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)