Public Health Service, HHS

§ 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 National Archives and Records Administration.

Subpart E—Quality Control

§ 84.40 Quality control plans; filing requirements.

As a part of each application for approval or modification of approval submitted pursuant to this part, each applicant shall file with the Institute a proposed quality control plan which shall be designed to assure the quality of respiratory protection provided by the respirator for which approval is sought.