§ 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.

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.