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## 42 C.F.R. § 84.41

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### Quality control plans; contents.

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(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, documentations, 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, National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Copies of MIL-STD-105D may be inspected or obtained from the NIOSH, National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236. 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.

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