

§ 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, "Sampling Procedures and Tables for Inspection by Attributes," is an example of an approved 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 (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. Copies of MIL-STD-105D may be inspected or obtained from the NIOSH, Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505-2888.

(b) The Institute reserves the right to have its representatives inspect the applicant's quality control test methods, equipment, and records, and to interview any employee or agent of the applicant in regard to quality control test methods, equipment, and records.

(c) The Institute reserves the right to revoke, for cause, any certificate of approval where it is found that the applicant's quality control test methods, equipment, or records do not ensure effective quality control over the respirator for which the approval was issued.

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

Subpart F—Classification of Approved Respirators; Scope of Approval; Atmospheric Hazards; Service Time

§ 84.50 Types of respirators to be approved; scope of approval.

Approvals shall be issued for the types of respirators which have been classified pursuant to this subpart F, have been inspected, examined and tested by the Institute, in accordance with the provisions of subparts G through L of this part, and have been found to provide respiratory protection for fixed periods of time against the hazards specified in such approval.

§ 84.51 Entry and escape, or escape only; classification.

Respirators described in subparts H through L of this part shall be classified for use as follows:

(a) *Entry and escape.* Respirators designed and approved for use during entry into a hazardous atmosphere, and for escape from a hazardous atmosphere; or

(b) *Escape only.* Respirators designed and approved for use only during escape from a hazardous atmosphere.

§ 84.52 Respiratory hazards; classification.

Respirators described in subparts H through L of this part shall be classified as approved for use against any or all of the following respiratory hazards:

- (a) Oxygen deficiency;
- (b) Gases and vapors; and
- (c) Particles, including dusts, fumes and mists.

§ 84.53 Service time; classification.

(a) Respirators described in subparts H through L of this part shall be classified, where applicable, as approved for use during the following prescribed service times:

- (1) Four hours;
- (2) Three hours;
- (3) Two hours;
- (4) One hour;
- (5) Forty-five minutes;
- (6) Thirty minutes;
- (7) Fifteen minutes;
- (8) Ten minutes;
- (9) Five minutes; or

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- (10) Three minutes.
- (b) Other service times may be prescribed by the Institute.

Subpart G—General Construction and Performance Requirements

§ 84.60 Construction and performance requirements; general.

(a) The Institute shall issue approvals for the types of respirators described in subparts H through KK of this part which have met the minimum requirements set forth for such respirators in this part.

(b) In addition to the types of respirators specified in subparts H through L of this part, the Institute shall issue approvals for other respiratory protective devices not specifically described in this part subject to such additional requirements as may be imposed in accordance with § 84.63(c).

[60 FR 30355, June 8, 1995, as amended at 77 FR 14192, Mar. 8, 2012]

§ 84.61 General construction requirements.

(a) Respirators will not be accepted by the Institute for examination, inspection and testing unless they are designed on sound engineering and scientific principles, constructed of suitable materials and evidence good workmanship.

(b) Respirator components which come into contact with the wearer's skin shall be made of nonirritating materials.

(c) Components replaced during or after use shall be constructed of materials which will not be damaged by normal handling.

(d) Mouthpieces, hoods, helmets, and facepieces, except those employed in single-use respirators, shall be constructed of materials which will withstand repeated disinfection as recommended by the applicant in his instructions for use of the device.

§ 84.62 Component parts; minimum requirements.

(a) The component parts of each respirator shall be:

- (1) Designed, constructed, and fitted to insure against creation of any hazard to the wearer;

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(2) Assembled to permit easy access for inspection and repair of functional parts; and

(3) Assembled to permit easy access to parts which require periodic cleaning and disinfecting.

(b) Replacement parts shall be designed and constructed to permit easy installation and to maintain the effectiveness of the respirator.

§ 84.63 Test requirements; general.

(a) Each respirator and respirator component shall when tested by the applicant and by the Institute, and meet the applicable requirements set forth in subparts H through KK of this part.

(b) Where a combination respirator is assembled from two or more types of respirators, as described in this part, each of the individual respirator types which have been combined shall, as applicable, meet the minimum requirements for such respirators set forth in subparts H through KK of this part, and such combination respirators, except as specified in § 84.70(b)(2), will be classified by the type of respirator in the combination which provides the least protection to the user.

(c) In addition to the minimum requirements set forth in subparts H through KK of this part, the Institute reserves the right to require, as a further condition of approval, any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

(d) Where it is determined after receipt of an application that additional requirements will be required for approval, the Institute will notify the applicant in writing of these additional requirements, and necessary examinations, inspections, or tests, stating generally the reasons for such requirements, examinations, inspections, or tests.

[60 FR 30355, June 8, 1995, as amended at 77 FR 14192, Mar. 8, 2012]

§ 84.64 Pretesting by applicant; approval of test methods.

(a) Prior to making or filing any application for approval or modification