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Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators[1]

This standard is issued under the fixed designation F3407; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This standard provides detailed instructions for performing a respirator fit capability test to determine the fit of air-purifying, half-facepiece respirators, which will include both filtering facepiece respirators and elastomeric respirators equipped with any type of particulate filter. The purpose is to increase the probability that available respirators fit a general worker population. The standard provides increased assurance to respirator purchasers and users that respirators that meet the requirement of this standard can be expected to effectively fit persons with various lengths and widths of faces, such as long and narrow or short and wide, when fit tested in the workplace as part of a complete respiratory protection program in accordance with 29 CFR 1910.134.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 It is the responsibility of the investigator to determine whether good laboratory practices (GLP standards—40 CFR, Part 160 of FIFRA) are required and to follow them when appropriate.

1.4 This standard does not address specific product performance standards established by regulatory authorities; see 2.2 for details.

1.5 This standard does not eliminate the need for every wearer to undergo a personal respirator fit test.

1.6 This standard does not guarantee that every respirator wearer will be able to achieve the required fit factor on a particular manufacturer's single-size or multi-size respirator model. Respirator wearers must always be given the opportunity to try other models or other manufacturers' respirators.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]
F3387 Practice for Respiratory Protection

2.2 *Federal Standards:*[3]
29 CFR Part 1910.134 Respiratory Protection
30 CFR Part 11 Respiratory Protective Apparatus, Tests for Permissibility, Fees
42 CFR Part 84 Respiratory Protective Devices

3. Terminology

3.1 *Definitions:*

3.1.1 *fit test, n*—the use of a protocol to qualitatively or quantitatively evaluate the fit of a particular respirator on an individual.

3.1.2 *high-efficiency particulate air (HEPA) filter, n*—a filter with a minimum particle removal efficiency of no less than 99.97 % for monodisperse particles having an aerodynamic diameter of 0.3 µm.

3.1.3 *individual exercise RFC result, n*—a numeric assessment of how well a tight-fitting respirator facepiece fits a test subject during each exercise performed during a subject respirator fit capability (RFC) test. It is the ratio of the concentration outside the facepiece (C_{out}) to the concentration inside the facepiece (C_{in}) not adjusted for respiratory tract deposition. (C_{out}/C_{in}).

[1] This test method is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.65 on Respiratory.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, http://www.access.gpo.gov.

3.1.4 *respirator fit capability (RFC) test, n*—an assessment of a respirator model's ability to achieve passing face seal performance on either the complete NIOSH Bivariate Panel or a specified subset of the panel representing the population of respirator wearers when the wearers are properly trained and fit tested in compliance with the manufacturer's user instructions and Practice F3387 and the Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134.

3.1.5 *respirator model, n*—a group or series of identical half-facepiece respirators (that is, utilizing the same components such as facepiece blank, head straps, exhalation valves, and composed of the same construction materials) differing only in the size of the facepiece in order to fit the NIOSH Bivariate Model. A respirator model may consist of only one unique half-facepiece respirator.

3.1.6 *subject RFC result, n*—the harmonic mean of the seven individual exercise RFC results for a particular subject and respirator model.

3.1.7 *subject RFC test, n*—an RFC test performed by one subject wearing a particular respirator model.

3.1.8 *test panel, n*—an organized group of people with varying facial dimensions representing the respirator wearer population. The RFC test uses the NIOSH Bivariate Panel, which is based on face length and face width (Fig. A1.1).

3.1.9 *user, n*—person or organization who makes use of the respirator; for example, one involved in selecting, maintaining, or wearing the respirator.

3.1.10 *wearer, n*—the person who actually wears the respirator in the workplace.

3.1.11 *wearer seal check (namely, user seal check), n*—a procedure conducted by the wearer to determine if a tight-fitting respirator is properly donned. This is consistent with Practice F3387 and the Occupational Safety and Health Administration 29 CFR 1910.134 user seal check.

4. Summary of Test Method

4.1 This standard defines performance requirements for ensuring that a respirator model, available in either a unique single size or multiple sizes, is capable of achieving the pass/fail criteria fit on a specified percentage of the NIOSH Bivariate Test Panel (NIOSH Panel) representing a range of face sizes. These performance requirements will increase the likelihood that most respirator wearers will be able to achieve the required pass/fail criteria when fit tested on either a manufacturer's unique single-size respirator model or on at least one unique size of a manufacturer's multi-size respirator model. The exercises and pass/fail criteria are based on those found in Title 29, Code of Federal Regulations, Part 1910.134.

5. Significance and Use

5.1 In the U.S., when 42 Code of Federal Regulations Part 84 (42 CFR 84) was promulgated in 1995, the isoamyl acetate tightness test as described in 30 Code of Federal Regulations Part 11 for certain particulate-removing respirators was removed. These particulate-removing respirators were designed as protection against: (*1*) fumes of various metals having an air contamination level not less than 0.05 mg/m^3, and (*2*) dusts, fumes, and mists having an air contamination level less than 0.05 mg/m^3 or radionuclides. The isoamyl acetate test was removed because particulate respirators had to be modified before they could be tested and there were no other available fit tests suitable to the National Institute for Occupational Safety and Health (NIOSH) for approval testing at the time (**1**).[4] There was a concern that the modified respirators may have had different fitting characteristics from the versions marketed. According to NIOSH, removing this requirement also allowed for further research on the effectiveness of certification fit testing methods (**1**).

5.2 NIOSH conducted benchmark testing of 101 respirator models on the market during 2008 and 2009, using a similar test to that described herein (**2**). The results were analyzed to develop key test parameters and pass/fail criteria options for a respirator fit capability test for half-facepiece air-purifying particulate respirators (**3**). According to NIOSH, approximately 30 % of the models tested did not have good fitting characteristics (**2**). This was also supported by published research (**4**, **5**). This standard establishes a performance requirement called respirator fit capability to assess respirator face-sealing characteristics.

5.3 This standard can be used to evaluate all particulate-removing respirators on a population of wearers. A respirator model meeting the fit capability requirement will be capable of fitting the facial sizes and shapes for which it was designed. To achieve this goal, it is necessary for the method to reject poor-fitting respirators, while still passing well-fitting respirators meeting the pass/fail criteria established in this standard. It is thought that this standard will increase the likelihood that respirators meeting this requirement will fit a wide variety of their prospective wearers when properly fit tested, donned, and used.

6. Interferences

6.1 *Particles in the Test Subject's Exhaled Breath*—Each test wearer shall not be permitted to eat or smoke for at least 30 min before the start of the test.

6.2 *Facial Hair*—Each test subject shall be cleanly shaven before being able to participate in the test. Mustaches are permitted if they do not interfere with the facepiece seal as assessed by the test administrator.

6.3 *Other Facial Characteristics*—Any condition that could potentially interfere with the face-to-facepiece seal or valve function such as jewelry, scars, etc., will be permitted if the test administrator determines that it will not interfere.

7. Apparatus

7.1 Condensation nuclei counter with particle classifier technology (for example, a differential mobility analyzer). The particle classifier technology shall only allow nominal 55 nm negatively charged particles to pass through to the condensation nuclei counter for counting while eliminating the zero-charge and positive-charge particles from the sample.

[4] The boldface numbers in parentheses refer to a list of references at the end of this standard.

7.2 Software to control the condensation nuclei counter.

7.3 High-efficiency particulate (HEPA) filter for diagnostic checks recommended by the instrument manufacturer.

7.4 *Test Chamber:*

7.4.1 *Size*—Large enough to permit each of the test subjects conducting an RFC test to freely perform all required exercises without disturbing the positioning of the facepiece or the measurement apparatus, or interfering with the movements of any other test subjects in the chamber.

7.4.2 *Isolation*—The test chamber shall be equipped and constructed so that the chamber air containing the sodium chloride test agent is effectively isolated from the ambient air outside the chamber. The access door to the chamber should be tight to avoid leakage. The test subject(s) must be able to safely enter and exit from the chamber.

7.4.3 *Subject Visibility*—The test chamber shall have a window or other means for the test subject(s) to be visible to the test administrator at all times.

7.4.4 *Aerosol Concentration*—The aerosol concentration shall be well mixed (that is, uniformly distributed) throughout the chamber (±10 %) where the test subject(s) will be performing the test. For N99 testing, the concentration shall be stable (that is, ±10 % of the initial concentration of between 2000 and 8000 particles/cm^3) for the duration of the test. For N95 mode testing, the concentration shall be stable (that is, ±10 % of the initial concentration of between 200 and 800 particles/cm^3) for the duration of the test.

7.4.5 *Particle Size*—The particles in the chamber should be between 0.02 µm and 1 µm with a geometric standard deviation ≤2.2.

7.4.6 *Temperature and Humidity*—The airflow through the test chamber shall be sufficient to maintain the temperature between 21 °C and 24 °C, the relative humidity below 40 % to prevent agglomeration of the sodium chloride test agent, and the oxygen level above 19.5 %.

7.5 *Particle Generator*—An aerosol generator capable of producing the sodium chloride concentration specified in 7.4.4.

7.6 *In-Facepiece Sampling Apparatus*—For filtering facepiece respirators, a flush-mounted probe equipped with a push nut specifically designed to be attached to this type of respirator. For elastomeric respirators, a fit test adapter placed between the facepiece and the filter can be used. The flush-mounted filtering facepiece probe (N95 probe) shall not be used for elastomeric respirators.

7.6.1 The probe should be placed on the midline between the nose and the mouth, whenever possible. If a different position is necessary, every effort should be made to avoid contact with the face, placement on a seam, or interference with other features of the respirator. The sampling apparatus should be supported in a way that it does not affect or interfere with the fit of the respirator (that is, the respirator with the sampling apparatus connected must fit the test subject in the same manner as it would without the sampling apparatus). Annex A2 contains more information on probe location.

7.7 *Respirators*—The number of respirators required for testing is:

7.7.1 Filtering facepiece respirators: 35.

7.7.2 Elastomeric facepiece respirators: three complete respirator assemblies with ten sets of filters for a unique one-size model, and three complete respirator assemblies in each unique size and ten sets of filters when a respirator is designed and manufactured in two or more unique sizes.

7.8 *Facial Size Measurement Calipers*—To measure the test subject.

7.8.1 Calibrated sliding measurement calipers, 0 mm to 200 mm length and 0 mm to 50 mm depth.

7.8.2 Calibrated spreading measurement calipers capable of measuring 0 mm to 300 mm width.

7.9 Other accessories and supplies required by the condensation nuclei counter manufacturer in order to perform the RFC test.

8. Reagents and Materials

8.1 *Sodium chloride solution,* 2 % NaCl solution in distilled water.

8.2 *Isopropyl alcohol,* or other working fluid as specified by the instrument manufacturer. Reagent grade (>99.5 %).

9. Hazards

9.1 *Working Fluid*—Avoid eye and skin contact.

10. Sampling, Test Specimens, and Test Units

10.1 *Test Subjects*—All human subject testing conducted in accordance with this RFC standard will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects conducting this testing, including obtaining informed consent and screening the subjects to ensure their safety while performing the RFC test. If applicable, it must be approved by an Institutional Review Board or other appropriate body. Twenty-five test subjects meeting the participation and qualification criteria for the testing of respirators having facial dimensions falling within the requirements of the NIOSH Bivariate Panel for the size of the respirator to be recruited. See Annex A1. If any test subject is measured and the facial dimensions are not within the boundaries of the NIOSH Bivariate Panel, the test subject shall not be tested.

11. Preparation of Apparatus

11.1 Several diagnostic checks shall be performed at least daily. These shall include:

11.1.1 *Chamber Particle Concentration Check*—To ensure the chamber concentration is within the range specified in 7.4.4.

11.1.2 Particle classifier check.

11.1.3 *Zero Check*—To provide assurance that there are no leaks in the system.

11.1.4 *Maximum Fit Factor Check*—To ensure the condensation nuclei counter is capable of measuring high fit factors.

11.2 Follow the condensation nuclei counter and particle classifier manufacturer's instructions for performing these checks.