Designation: F3407 – 20

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 (FRC) 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 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. 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.

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.

12. Calibration and Standardization

12.1 At a minimum, all measuring equipment utilized for this testing must have been calibrated by the manufacturer

within the timeframe specified in the equipment's operation manual. The calibration shall use methods traceable to National Institute of Standards and Technology (NIST) standards.

12.2 Equipment calibration records shall be available for examination at each testing facility.

12.3 Prior to beginning any testing, a statement that all test equipment is within calibration shall be attested by the lab technician, laboratory manager, or other designated person on each test report.

13. Conditioning

13.1 The respirators received for testing shall be free of visual damage such as distorted face seals. There are no other specific conditioning requirements.

14. Procedure

14.1 *Facial Measurement:*

14.1.1 Face width is the maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches (Annex A1). The test subject sits looking straight ahead with teeth together (lightly occluded). Only enough pressure is exerted to ensure that the caliper tips are on the zygomatic arches. The test administrator will take two measurements of face width, removing the caliper between measurements. If the two measurements for face width are within 2 mm, then stop. Otherwise, take a third measurement.

14.1.2 Face length is the distance in the mid-sagittal plane between the menton landmark at the bottom of the chin and the sellion landmark at the deepest point of the nasal root depression and is measured with a sliding caliper (Annex A1). The test subject sits looking straight ahead with teeth together (lightly occluded). The fixed blade of the caliper is placed on the sellion. Only enough pressure is exerted to obtain contact between the caliper and the skin is exerted. The test administrator will take two measurements of face length, removing the caliper between measurements. If the two measurements for face width are within 3 mm, then stop. Otherwise, take a third measurement.

14.1.3 The average of the face width and face length measurements will be used to determine the placement of the test subject in the NIOSH Bivariate Panel (Annex A1) **(6)**.

14.2 *Conducting the Subject RFC Test:*

14.2.1 Check the respirator to make sure the sampling probe and line are securely attached to the facepiece and that the particle classifier technology is being used with the condensation nuclei counter.

14.2.2 The test administrator will familiarize the test subjects on the donning procedures, completing the appropriate seal checks, and doffing procedures as specified by the manufacturer's user instructions (UI).

14.2.3 The test administrator shall provide a description of the exercises and demonstrate them to the test subjects before the test begins.

14.2.4 *Donning:*

14.2.4.1 To reduce the inter- and intra-wearer variability, each test wearer shall don the respirator under the supervision of the test administrator. The test wearer and test administrator will be permitted to make adjustments to the facepiece until he/she and the test administrator are satisfied that the respirator is being worn in compliance with the manufacturer's UI, including passing the appropriate seal checks.

14.2.4.2 Have the test subject wearing the respirator do the appropriate seal check. Every test subject must pass a seal check before performing the subject RFC test. If the seal check fails (that is, leakage is detected), the test administrator will allow the test subject to reposition the respirator and redo the seal check after explaining the seal check procedure again. For a unique single-size respirator model, if the second seal check is a failure, the test subject will not be allowed to perform the RFC test. Another test subject in the same test panel cell will be recruited and the procedure will be started over. For multiple size respirator models, the test subject will be allowed to don a different size of the respirator and perform the seal check. The test subject will continue to don a different size of the respirator until either the seal check is passed or all sizes are tried. If the test subject cannot pass the seal check with any of the unique sizes, he/she will not be allowed to perform the subject RFC test. Another test subject in the same test panel cell will be recruited and the procedure will be started over.

14.2.4.3 The test subject shall wear the respirator for 1 min prior to the subject RFC test to ensure the he/she can wear it for the duration of the test and purge the particles trapped inside the facepiece during donning.

14.2.4.4 After verifying the fit of the respirator using the UI, no further adjustments to the facepiece are permitted before commencing and during the subject RFC test.

14.2.5 *Subject RFC Testing Procedure:*

14.2.5.1 The test subject shall enter the chamber. The concentration of particles in the chamber shall be measured prior to the subject entering the chamber to ensure that it is between 2000 and 8000 particles/cm^3. The concentration of particles in the chamber shall remain within ±10 % of the concentration measured at the beginning of the test for the duration of the test. This can be verified by having a separate condensation nuclei counter monitor the chamber concentration continuously or having a single condensation nuclei counter measure the chamber concentration for approximately 20 s before switching to sampling in the facepiece before each exercise and after the final exercise.

14.2.6 Follow the manufacturer's instructions for operating the condensation nuclei counter with particle classifier technology and proceed with the test.

14.2.7 A subject RFC test consists of following exercises:

14.2.7.1 Normal breathing. In a normal standing position, without talking, the test subject shall breathe normally.

14.2.7.2 Deep breathing. In a normal standing position, the test subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

14.2.7.3 Turning head side to side. Standing in place, the test subject shall slowly turn his/her head from side to side between the extreme positions on each side, taking approximately 2 s to go from one extreme to the other (that is, taking 2 s to turn the head from left to right). The head shall be held at each extreme momentarily so the test subject can inhale at each side.

14.2.7.4 Moving head up and down. Standing in place, the test subject shall slowly move his/her head up and down, taking approximately 2 s to go from one extreme to the other (that is, head tilted up to head tilted down). The test subject shall be instructed to inhale in the up position (that is, when looking toward the ceiling).

14.2.7.5 Talking. The test subject shall be instructed to talk out loud slowly. The test subject can read from a prepared text such as a modified Rainbow Passage (14.2.7.6) or Grandfather Passage (14.2.7.7), count backward from 100, or recite a memorized poem or song.

14.2.7.6 *Rainbow Passage*—"When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a person looks for something beyond reach, friends say the person is looking for the pot of gold at the end of the rainbow."

14.2.7.7 *Grandfather Passage*—"You wished to know all about my grandfather. Well, he is nearly 93 years old. He dresses himself in an ancient black frock coat, usually minus several buttons; and with a thick hood, yet he still thinks as swiftly as ever. A long, flowing beard clings to his chin, giving those who observe him a pronounced feeling of the utmost respect. When he speaks his voice is just a bit cracked and quivers a trifle, but it pulls the listener in. Twice each day he plays skillfully and with zest upon our small organ. Except in the winter when the ooze or snow or ice prevents, he slowly takes a short walk in the open air each day. We have often urged him to walk more and smoke less, but he always answers, 'Banana oil!' Grandfather likes to be modern in his language."

14.2.7.8 Grimace. Keeping his/her upper and lower lips together, the test subject shall smile and frown without any other facial movement while breathing normally.

14.2.7.9 Bending over. The test subject shall bend at the waist, and keeping the head and back parallel to the floor as if touching his/her toes. The test subject will pause long enough to inhale twice. The test subject will stand up straight, pausing long enough to inhale twice. These movements will be repeated at a comfortable pace.

14.2.7.10 Normal breathing. Same as exercise in 14.2.7.1.

14.2.8 Each test exercise shall be performed for 1 min, except for the grimace exercise, which shall be performed for 15 s.

15. Calculation or Interpretation of Results

15.1 The calculation of the subject RFC result using the individual exercise RFC factors is described in the following equation:

$$\text{Subject RFC Result} = \frac{7}{\frac{1}{ERFCF_1}+\frac{1}{ERFCF_2}+\frac{1}{ERFCF_3}+\frac{1}{ERFCF_4}+\frac{1}{ERFCF_5}+\frac{1}{ERFCF_7}+\frac{1}{ERFCF_8}} \quad (1)$$

where $ERFCF_1$, $ERFCF_2$, $ERFCF_3$, etc., are the individual exercise RFC factors for exercises 1, 2, 3, etc. The grimace exercise (14.2.7.8) is not included in the calculation.

15.2 *For Unique One-Size Models:*

15.2.1 If the test subject does not obtain a subject RFC result ≥100, he/she shall doff the respirator and wait at least 1 min.

15.2.2 The test subject will then re-don the same or different respirator of the same size and model and repeat the seal check and subject RFC test procedure.

15.2.3 If a subject RFC result ≥100 is not obtained after the additional separate donning, the test subject will be recorded as failing the subject RFC test.

15.2.4 At least 13 of 25 (>50 %) test subjects must obtain a subject RFC result ≥100 for the model to be considered as having passed the RFC test.

15.3 *For Multiple Size Models:*

15.3.1 The test subject will select the unique facepiece size they believe will be most likely to fit. The test subject will repeat the seal check and RFC test procedure.

15.3.2 If the test subject does not obtain a subject RFC result ≥100, he/she shall doff the respirator, wait at least 1 min, then re-don another respirator of the same unique size and repeat the test procedure.

15.3.3 If the test subject does not achieve a subject RFC result ≥100, he/she shall select another unique size (from the same respirator model) and repeat the procedure described in Section 14. This procedure shall be repeated for each additional different unique size available.

15.3.4 If the test subject does not achieve a subject RFC result ≥100 on any of the unique facepiece sizes, the test subject shall be recorded as a failing the RFC test.

15.3.5 At least 13 of 25 (>50 %) test subjects must obtain a subject RFC result ≥100. At least 50 % of test subjects must obtain a subject RFC result ≥100, based on the following cell group designations: Group A consisting of NIOSH Bivariate Panel cells 1, 2, and 3 based on population distribution of two subjects per cell (Fig. A1.1). At least one of the six subjects in Group A must obtain a subject RFC result ≥100. Group B consisting of NIOSH panel cells 4, 5, 6, and 7 based on the population distribution of Fig. A1.1. At least one of the 14 subjects in Group B must obtain a subject RFC result ≥100. Group C consisting of NIOSH Bivariate Panel cells 8, 9, and 10 based on population distribution of two subjects per cell (Fig. A1.1). At least one of the six subjects in Group C must obtain a subject RFC result ≥100.

15.4 It is the respirator model and not the unique individual sizes that passes or fails the RFC test.

16. Report

16.1 The subject RFC result, respirator face size worn, test subject ID number, and test subject cell number shall be recorded, as well as the overall RFC factor.

16.2 It is recommended that the manufacturer provide the actual passing rate of the respirator model to the user and the respirator wearer in the workplace.

17. Precision and Bias

17.1 NIOSH conducted a study to determine how many subjects are needed for an RFC test using a simple binomial approach for determining both the required sample size and the minimum number of subjects needed to achieve a passing result (**7**). The study essentially conducted a global search of the Type I (falsely passing a respirator) and Type II (falsely failing a respirator) errors under different null and alternative hypotheses, across the range of possible sample sizes, to find the lowest sample size which yielded at least one cut-off satisfying or approximately satisfying all predetermined limits for the different error rates. Variability in fit test data has been recognized for a long time. The most commonly recognized variabilities are the inter- and intra-subject variabilities (**8**, **9**). NIOSH conducted another study to investigate the inter-panel variability between different anthropometric panels used to determine the inward leakage (IL) of N95 filtering facepiece respirators (FFRs) and elastomeric half-facepiece respirators (EHRs) (**10**, **11**). Inter-panel variability was found, but it was small relative to the other sources of variation in fit testing data. The two NIOSH study results were used to estimate the repeatability probability and reproducibility probability for this standard.

17.2 *Precision*—The repeatability probability has been determined to be 99.9 % for a respirator model that truly fits 80 % of the user population, and 84.6 % for a respirator model that truly fits 60 % of the user population. The reproducibility probability has been determined to be the same as the repeatability probability.

17.3 *Bias*—No information is presented about the bias of Test Method F3407 for measuring respirator fit capability of half-facepiece particulate respirators, since the test result is a respirator passes or fails the RFC test. Other reasons are described in 1.5 and 1.6.

18. Certification

18.1 None required.

19. Keywords

19.1 half-facepiece; RFC test panel

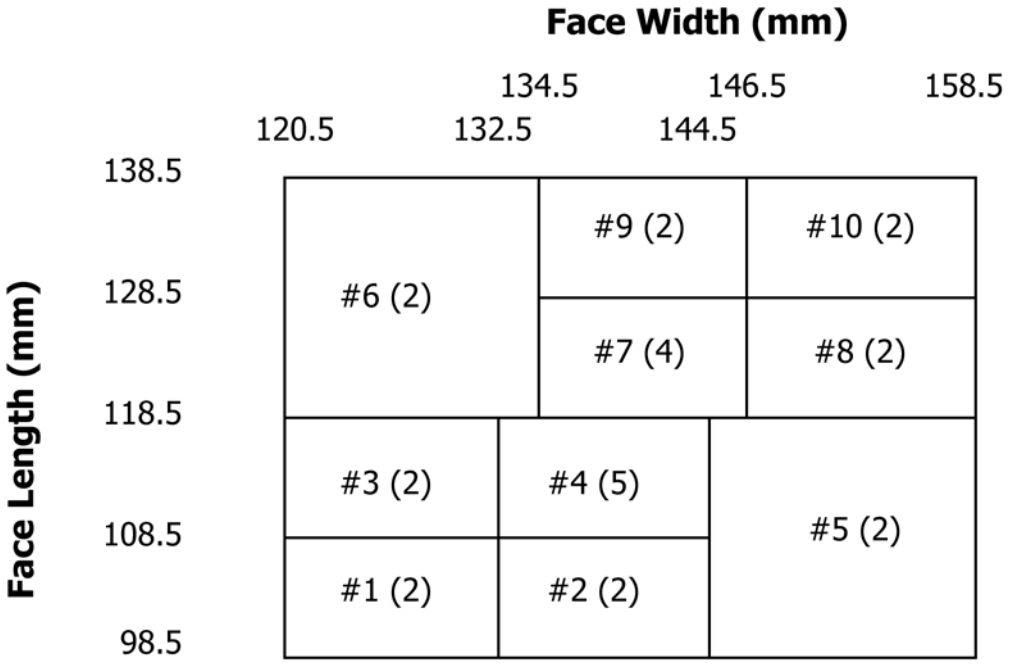
ANNEXES

(Mandatory Information)

A1. NIOSH BIVARIATE TEST PANEL (NIOSH PANEL)

A1.1 The NIOSH Bivariate Panel represents approximately 98 % of U.S. respirator test subjects (**5**). Cell number and the number of test subjects from a 25-subject panel representing the percentage of the total respirator wearing population having the facial dimensions represented by that cell are indicated in each cell (Fig. A1.1). The cell numbers are for the sole purpose of obtaining a panel representative of the population of respirator wearers. Since the panel is two dimensional, meaning it includes bizygomatic breadth (face width) and menton-sellion length (face length), it is not fully descriptive of face size and shape but is a tool for laboratory testing. See Table A1.1.

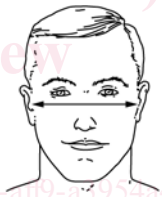
A1.2 *Panel Use*—For the purpose of measuring the respirator fit capability, 25 test subjects will be chosen for a one-size or multiple-size respirator model(s) designed to fit a variety of facial shapes and sizes using the NIOSH Panel (Fig. A1.1).



NOTE 1—The cells are numbered 1 to 10 and the numbers in parentheses indicate the number of test subjects to be sampled from each cell. When the test subject's face length or face width falls on the boundaries, the test subject is classified into the higher number cells with greater face dimensions.

FIG. A1.1 NIOSH Panel Based on Face Length and Width

TABLE A1.1 Measurement of Face Dimensions

Description	Definition	Diagram
Bizygomatic Breadth	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches	
Menton-Sellion Length	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark