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Standard Guide for Respirator Fit Testing Methods[1]

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1. Scope

1.1 This guide provides guidance on how to conduct fit testing of tight-fitting respirators and appropriate methods to be used. Fit testing is only one element of a complete respiratory protection program. Examples of complete respiratory protection programs are defined in Practice F3387, 29 CFR 1910.134, and so forth.

1.2 *Purpose*—This guide provides requirements for conducting respirator fit testing and includes:

1.2.1 Qualifications for fit test operators,

1.2.2 Specific fit test methods,

1.2.3 Interpretation of fit test results,

1.2.4 Recordkeeping, and

1.2.5 Methods to validate new fit test methods.

1.3 *Should and Shall*—The provisions of this guide are mandatory in nature when the word "shall" is used and advisory in nature when the word "should" is used.

1.4 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *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.*

1.6 *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 *ANSI Standards:*[3]

ANSI/ASSE Z88.2 Practices for Respiratory Protection

ANSI/AIHA Z88.6 Respiratory Protection—Respirator Use—Physical Qualifications for Personnel

2.3 *Federal Standard:*[4]

29 CFR Part 1910.134 Respiratory Protection

3. Terminology

3.1 *Definitions:*

3.1.1 *aerodynamic diameter, n*—diameter of a unit density sphere having the same settling velocity as the particle in question.

3.1.2 *aerosol, n*—particles, solid or liquid, suspended in air.

3.1.3 *canister/cartridge, n*—container with a filter, sorbent, catalyst, or combination of these items that removes specific contaminants from the air passed through the container.

3.1.4 *challenge agent, n*—aerosol, vapor, or gas used by the fit test method for detecting respirator leakage.

3.1.5 *challenge pressure, n*—negative static pressure established inside the respirator facepiece during a controlled negative-pressure fit test.

3.1.6 *facepiece, n*—see *tight-fitting respirator*.

3.1.7 *filter, n*—component used in respirators to remove aerosols from the inspired air.

3.1.8 *fit factor, n*—numeric expression of how well a tight-fitting respirator fits a wearer during a quantitative fit test.

3.1.8.1 *Discussion*—It is the ratio of the measured challenge agent concentration outside the respirator (C_{out}) to its concentration inside the respirator (C_{in}). (Fit factor = C_{out} / C_{in}).

3.1.9 *fit test, n*—use of a qualitative or quantitative protocol to evaluate sealing surface leakage of a specific tight-fitting respirator while worn by an individual.

3.1.10 *fit test method, n*—combination of instrumentation, technology, and protocols used to conduct a respirator fit test.

3.1.10.1 *Discussion*—An accepted method may have more than one accepted protocol.

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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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from U.S. Government Publishing Office (GPO), 732 N. Capitol St., NW, Washington, DC 20401, http://www.gpo.gov.

3.1.11 *fit test operator, n*—person qualified by training and experience with demonstrated ability to perform properly qualitative or quantitative fit tests and evaluate test results.

3.1.12 *fit test protocol, n*—specific step-by-step instructions for conducting a respirator fit test.

3.1.13 *penetration, n*—numerical expression of how well a tight-fitting respirator fits a wearer during a quantitative fit test.

3.1.13.1 *Discussion*—For aerosol-based quantitative fit test methods, it is the ratio of the measured challenge agent concentration inside the respirator (C_{in}) to its concentration outside the respirator (C_{out}). (Penetration = C_{in} / C_{out}).

3.1.14 *qualitative fit test, QLFT, n*—pass/fail fit test included in this guide that relies on the subject's sensory response to detect a challenge agent.

3.1.15 *quantitative fit test QNFT, n*—fit test included in this guide that uses an instrument to measure face seal leakage.

3.1.16 *required fit factor, RFF, n*—numeric value established as a pass/fail point or acceptance criterion for a quantitative fit test.

3.1.17 *respirator, n*—personal protective device designed to protect the wearer from the inhalation of hazardous atmospheres.

3.1.18 *tight-fitting respirator, n*—respirator with a facepiece, hood, or helmet that is designed to form a complete seal with the face or neck.

3.1.18.1 *Discussion*—This includes a hood or helmet with a neck seal (neck dam).

3.1.19 *user seal check, n*—procedure conducted by the wearer to determine if a tight-fitting respirator is properly donned.

4. Significance and Use

4.1 The purpose of this guide is to provide clear and consistent guidance with regard to the respirator fit-testing components of an effective respiratory protection program.

4.2 The respirator fit test itself is simply one facet of fit testing. An effective program requires much more, including a qualified person to perform the fit test. This guide provides guidance on exactly what knowledge and skills are necessary to perform as a qualified fit test operator.

4.3 This guide contains information to aid program managers and fit test operators in preparing to perform a proper fit test. This includes guidance regarding potential interference from other personal protective equipment (PPE) with the respirator, detailed information on respirators used for fit testing, selection of respirators before fit testing, and other considerations that shall be met if the fit test is to be effective.

4.4 A single fit test exercise protocol cannot model all workplace activities encountered by respirator users. Recognizing this, this guide provides flexibility regarding fit test exercise protocols. Exercises may be selected that are more representative of actual workplace activities, including repeated respirator donning.

4.5 *Exceptions*—Users of this guide should be aware that regulatory agencies may have requirements that are different from this guide.

5. Fit-Testing Rationale

5.1 The purpose of respirator fit testing is to verify that the selected make, model, and size of a tight-fitting respirator adequately fits the wearer. This is accomplished so there is reasonable assurance that the wearer has learned to don the respirator properly and can achieve the anticipated protection during use. Fit testing is a critical component of a respirator training program.

6. Qualifications for Fit Test Operators

6.1 *General Qualifications:*

6.1.1 Fit test operators shall be properly trained and demonstrate a proficiency in the fit test method(s) being used. The respiratory protection program administrator is responsible for evaluating and verifying the training and qualification of operators.

6.1.2 Program administrators may wish to consider the benefits of formal training programs from outside providers for fit test operators. An evaluation form for fit test operators is in Annex A2. Continue training fit test operators until all questions on the form can be marked "acceptable" by the evaluator. Determination of acceptability for each item is left to the discretion of the respiratory protection program administrator.

6.2 *Specific Qualifications for Fit Test Operators:*

6.2.1 They shall be familiar with this guide along with the appropriate sections of the respiratory protection program concerning respirator fit testing, inspection, cleaning, maintenance, and storage.

6.2.2 They shall demonstrate a general knowledge of respirators used by the wearer in the workplace by:

6.2.2.1 Identifying respirator components and their functions;

6.2.2.2 Demonstrating respirator inspection, cleaning, and maintenance procedures;

6.2.2.3 Identifying different make, model, style, and size respirators;

6.2.2.4 Discussing respirator capabilities and limitations as related to respirator fit testing; and

6.2.2.5 Demonstrating and evaluating proper donning and doffing procedures, including user seal checks.

6.2.3 They shall demonstrate knowledge and application of the fit test method(s) being used by:

6.2.3.1 Explaining the purpose of respirator fit testing;

6.2.3.2 Explaining fit test procedures;

6.2.3.3 Explaining the limitations of the fit test method;

6.2.3.4 Identifying indications of erroneous fit test results (for example, quantitative fit factors that are unusually low or high); and

6.2.3.5 Demonstrating knowledge of the health and safety hazards associated with the chemicals or equipment, or both, used in the fit test.

6.2.4 They shall demonstrate the ability to set up all applicable equipment for the fit test method(s) being used by:

6.2.4.1 Selecting the proper canisters/cartridges or filters for the fit test method;

6.2.4.2 Preparing, inspecting, and performing operational checks of fit-testing equipment and materials; and

6.2.4.3 Proper assembly and use of probes and adapters for quantitative fit test methods.

6.2.5 They shall demonstrate the ability to conduct the respirator fit test(s) being used by:

6.2.5.1 Properly evaluating persons being fit tested and understanding when to refuse to conduct a fit test by recognizing facial characteristics, facial hair, or other problems that may interfere with respirator fit or the test;

6.2.5.2 Explaining the fit test purpose and procedures to persons being fit tested;

6.2.5.3 Observing that the correct donning procedure is used without physically assisting the person being fit tested;

6.2.5.4 Observing that user seal checks are performed according to the procedures recommended by the respirator manufacturer;

6.2.5.5 Observing the person being fit tested throughout the entire fit test procedure to ensure the fit test is performed correctly;

6.2.5.6 Conducting the chosen test method according to the procedures specified in Sections 8 and 9;

6.2.5.7 Evaluating and recording the results of the fit test; and

6.2.5.8 Performing respirator cleaning and sanitizing according to manufacturer instructions.

6.2.6 They shall demonstrate the ability to identify causes of fit test failure such as:

6.2.6.1 Improperly donned or adjusted respirator;

6.2.6.2 Incorrectly assembled or damaged respirator; and

6.2.6.3 Incorrect size, shape, or style respirator.

7. General Considerations

7.1 *Medical Evaluation*—Persons being fit tested shall be medically cleared to wear the respirator before fit testing. Refer to ANSI/AIHA Z88.6, 29 CFR 1910.134, or other applicable regulatory standards.

7.2 *Training for Respirator Wearers:*

7.2.1 Persons to be fit tested shall receive training before the fit test. A mirror may be helpful to assist with positioning and adjusting the respirator. They shall be informed of the identity of the challenge agent and any potential health and safety hazards of challenge agents used. They shall be able to:

7.2.1.1 Properly inspect the respirator and recognize conditions that may compromise its integrity, such as missing components or deformities;

7.2.1.2 Properly don the respirator without assistance; and

7.2.1.3 Perform a user seal check.

7.2.2 Instruction in proper donning may occur immediately before the fit test or earlier and may involve assistance. After training, the fit test shall be conducted only after the respirator is donned without any physical or verbal assistance. If assistance is provided, the person being fit tested shall completely remove the respirator and don it again.

7.3 *Interference Concerns:*

7.3.1 *Facial Hair*—Skin contacting respirator facepiece sealing surfaces shall have been clean shaved within 24 h of testing, preferably within 12 h. A person shall not be fit tested if:

7.3.1.1 Hair comes between the sealing surface of the respirator and the face or neck, and

7.3.1.2 Hair interferes with valve or respirator function or both.

7.3.2 *Foreign Material*—A fit test shall not be conducted if there is any foreign material or substance between the sealing surface of the respirator and the face or neck. Examples include temple bars or straps for eyewear, gels, creams, and so forth.

7.3.3 *PPE and Other Items That May Interfere with Fit*—When any PPE or respirator accessory or both has the potential to interfere with the seal, it shall be worn during the fit test to ascertain compatibility with the respirator. For example, eyeglasses, goggles, face shield, head protection, skull cap, hearing protection, welding helmet, or other protective devices can potentially interfere with the seal of the respirator. This applies to all tight-fitting respirators, including half facepieces.

7.3.4 *Other Conditions That May Adversely Affect Fit*—The fit test should be conducted with the respirator worn in the manner in which it is used.

7.3.4.1 Not every individual may be able to obtain a satisfactory fit. For example, certain facial characteristics may interfere with respirator fit, such as: hollow temples, excessively protruding cheekbones, deep skin creases, the absence of teeth or dentures, injury to the face, and swelling of the mouth or face.

7.3.4.2 Respirator wearers who have dentures shall be fit tested:

(1) With dentures if they wear them while wearing the respirator in the workplace, or

(2) Without dentures if they do not wear them while wearing the respirator in the workplace.

7.3.4.3 Other factors may alter the seal of a respirator. Examples include cosmetics, facial jewelry, and certain hair styles.

7.4 *Frequency of Fit Tests:*

7.4.1 Individuals wearing a tight-fitting respirator shall be fit tested before initial use of the respirator whenever a different respirator (size, style, model, or make) is used and at least annually thereafter.

7.4.1.1 One purpose of the annual fit test is to verify and refresh user training.

7.4.2 A fit test shall also be repeated when a person has a condition that may interfere with the respirator seal, such as:

7.4.2.1 A significant change in weight,

7.4.2.2 A change to the face in the sealing area (for example, scarring, facial surgery),

7.4.2.3 Dental changes, or

7.4.2.4 User discomfort.

7.5 *Respirators Used for Fit Testing:*

7.5.1 Fit testing of tight-fitting respirators shall be done using either:

7.5.1.1 The wearer's individually assigned respirator, or

7.5.1.2 A surrogate respirator facepiece having sealing surfaces, materials, and head straps that are the same as the respirator to be assigned to the wearer.

7.5.2 Respirators used for fit testing shall be equipped with filtration or sorbent media or adapters, or both, appropriate for the selected fit test method. The filtration or sorbent medium used for fit testing may be different than those used in the workplace. The weight of cartridges, filters, and/or fit test adapters used for fit testing can affect fit. Where possible, the respirator assembly used during the fit test should be representative of the respirator used in the workplace. For example, the weight of combination chemical/particulate cartridges may be significantly higher than a particulate filter alone.

7.5.3 Tight-fitting positive-pressure respirators shall be fit tested only in the negative-pressure mode regardless of the mode of operation used for respiratory protection. This is accomplished by either:

7.5.3.1 Following the manufacturer's instructions for temporarily converting the wearer's individually assigned respirator into a negative-pressure respirator with appropriate filters, cartridges, and/or adapters, or

7.5.3.2 Using a surrogate negative-pressure respirator facepiece with sealing surfaces and materials that are the same as the respirator to be assigned to the wearer. For example, a negative-pressure air-purifying facepiece may be used as a surrogate facepiece for a powered air-purifying or SCBA facepiece made by the same manufacturer if the sealing surfaces and materials are identical.

7.5.4 When fit testing tight-fitting hoods, the requirements for full facepiece respirators shall be used.

7.5.5 Respirator modifications made to accommodate fit testing shall not significantly alter the fit of the respirator.

7.5.6 *Respirators Used for QLFT*—Respirators used for QLFT do not require modifications beyond those discussed before. (In-facepiece sampling instrumentation is not used for QLFT.)

7.5.7 *Respirators Used for QNFT:*

7.5.7.1 Respirators used for QNFT shall allow in-facepiece sampling. This can be accomplished by:

(1) Using a fit test sampling adapter on an individually assigned respirator facepiece,

(2) Using a fit test sampling adapter on a surrogate respirator facepiece, or

(3) Using a permanently probed surrogate respirator facepiece.

7.5.7.2 *Respirators Temporarily Modified with Adapters*—Fit test sampling adapters used for QNFT shall be completely removed and the respirator restored to its NIOSH-approved configuration before that respirator is used for respiratory protection.

7.5.7.3 *Permanently Probed Surrogate Respirator Facepieces*—Respirators used for QNFT may be permanently probed to provide a sampling port for the purpose of obtaining an in-facepiece sample. Permanently probed respirators shall not be used for respiratory protection unless the respirator is NIOSH approved in the probed configuration.

7.5.8 *Sampling for Aerosol Systems*—In-facepiece aerosol sampling devices shall be designed and used such that the sample is drawn at a point midway between the nose and mouth. The sample probe location shall follow the recommendations of the fit test equipment manufacturer. The sample probe should extend into the respirator cavity but not close enough to be blocked by the face. The in-facepiece sampling point shall not be isolated from the nose or mouth by a physical partition. For example, if a nose cup is used on a full facepiece, the sample point shall be inside the nose cup.

7.5.9 *Maintenance of Equipment and Respirators Used for Fit Testing*—Fit-testing equipment such as adapters, hoods, and tubing shall be kept in a clean and sanitary condition consistent with manufacturer recommendations. Respirators used for fit testing shall be properly inspected and maintained according to the respirator manufacturer's recommendations.

7.5.9.1 Respirators shall be cleaned and sanitized before being donned by different individuals. See the respirator manufacturer's instructions for recommended practices. Surrogate respirator facepieces that cannot be sanitized (for example, filtering facepieces) shall not be used by more than one individual.

7.6 *Choosing the Respirator*—No one size or model of respirator can be expected to fit all faces. Different sizes and models will accommodate more individuals. Therefore, an appropriate number of sizes and models shall be made available from which a satisfactory respirator may be selected. The actual number of models and sizes necessary to fulfill the intent of this requirement will vary by workplace. Factors that should be considered in determining the number of respirators to be made available include the number of employees and employee acceptance factors.

7.6.1 Fit test operators shall not force-fit the respirator being fit tested. Force-fitting is the practice of repeating a failed fit test with the same respirator by re-donning or otherwise adjusting the respirator (for example, overtightening the straps), until a passing fit test is finally achieved. Offering a reasonable assortment of respirator types or sizes or both should eliminate the inclination to force-fit.

7.6.2 *Selecting a Suitable Respirator for the Fit Test*—Initial respirator wearers and anyone needing to change size or model of respirators shall select from the assortment offered. The respirator assortment shall include a sufficient number of respirator models and sizes so that all respirator wearers can obtain an acceptable fit. The selection should be based on comfort and results of user seal checks, as well as personal preferences. They shall be fit tested with the respirator that they select.

7.6.2.1 Respirator comfort is an important factor in wearer acceptance. Other factors that influence wearer acceptance include breathing resistance, impairment of vision, impairment of communications, and respirator weight. Respirators with greater wearer acceptance are likely to be worn.

7.6.2.2 Repeat fit testing can be accomplished on the same make, model, style, and size respirator without repeating the selection process if the wearer still finds that respirator acceptable.

7.6.2.3 If fit testing shows that a person can obtain an acceptable fit with two or more models of the selected class of respirator, then the person should be permitted to use the preferred respirator model.

7.6.3 *Comfort Assessment Period*—Initial respirator wearers and anyone who changes the model or brand of respirator shall wear the respirator for a comfort assessment period of approximately 5 min immediately before the fit test. If necessary, the person being fit tested may make adjustments to achieve a comfortable fit during this period.

7.6.3.1 Experienced respirator wearers previously fit tested with the same respirator may bypass the comfort assessment period. Wearing a respirator for a period of time before the start of the fit test may be more representative of respirator use conditions.

7.6.3.2 The comfort assessment period allows the respirator wearer time to determine if the respirator is truly comfortable or not and make any necessary adjustments. Discomfort may become apparent only after the respirator is worn for a period of time. For example, overtightened straps may not be noticed immediately. If the respirator wearer finds the comfort of the respirator to be unacceptable at any time, they shall be given the opportunity to try another respirator.

7.6.3.3 It is critical that all respirator wearers don and adjust their respirators just as they would when wearing it for respiratory protection.

7.7 *Test Requirements Common to All Fit Tests:*

7.7.1 *Fit Test Operator Requirements*—The fit test shall be administered by a fit test operator who meets the requirements of Section 6 and follows all the procedures in this guide.

7.7.2 *Environmental Requirements*—The following conditions shall be met:

7.7.2.1 The ability to observe and communicate with the person being fit tested at all times during the fit test,

7.7.2.2 The ability to establish and maintain an appropriate challenge agent concentration during the test,

7.7.2.3 Exposures of persons being fit tested and fit test operators shall not exceed established exposure limits for any challenge agents used, and

7.7.2.4 Sufficient space to complete specified fit test exercises without interference.

7.7.3 *Other Requirements:*

7.7.3.1 The person being fit tested shall don the respirator without physical or verbal assistance and perform a user seal check;

7.7.3.2 The person being fit tested shall perform a series of exercises designed to stress the respirator seal in ways that simulate actual workplace motions. Follow the test protocols specified in Sections 8 and 9 to conduct fit testing;

7.7.3.3 The respirator shall not be adjusted once the fit test exercises begin. Adjustments void the test, requiring the entire exercise protocol to be restarted from the beginning. An exception is the re-donning exercise;

7.7.3.4 The person tested shall be informed of the results and told that another fit test with a different respirator can be obtained if problems are experienced with the respirator at any time; and

7.7.3.5 Persons passing a fit test shall be issued a facepiece identical to the one used for the fit test or the model represented by the surrogate facepiece used for the fit test.

7.7.4 *Required Fit Factor*—Refer to ANSI/ASSE Z88.2, 29 CFR 1910.134, or other applicable regulatory standards for required fit factors.

8. Quantitative Fit Test (QNFT) Methods

8.1 This section contains the QNFT methods that were found to be acceptable when this guide was published. These specific instructions were written to document the important requirements of the method without being tied to a specific manufacturer's instrumentation. As such, the instructions may not be specific enough to be used as the only guidance for fit test operators. It will usually be necessary to use the instrument manufacturer's detailed instructions to perform a specific quantitative fit test. Follow the manufacturer's recommendations for periodic service and calibration.

8.2 *Generated Aerosol Quantitative Fit Test Procedure:*

8.2.1 *Operating Principles*—An aerosol challenge agent is introduced into a test chamber that surrounds the head and shoulders, or the entire body, of the respirator wearer. An instrument is used to measure concentration of the challenge aerosol outside (C_{out}) and inside (C_{in}) the respirator, while the person being fit tested performs a series of exercises designed to stress the face seal in ways that approximate anticipated workplace conditions.

8.2.1.1 The test respirator shall be equipped with filters that do not allow the challenge aerosol to penetrate significantly into the respirator. Thus, it is assumed that all particles sampled from inside the respirator have entered through a face seal leak.

8.2.1.2 The fit factor is calculated as the ratio of the two relative aerosol concentrations:

$$\text{Fit Factor} = \frac{C_{out}}{C_{in}} \quad (1)$$

8.2.2 *Equipment*—Equipment needed for aerosol QNFT:

8.2.2.1 *Aerosol Generation and Distribution System*—The challenge aerosol shall have a mass median aerodynamic diameter (MMAD) less than 1 µm;

8.2.2.2 Aerosol detection system;

8.2.2.3 Device for recording fit test results;

8.2.2.4 Test chamber to contain challenge aerosol;

8.2.2.5 Respirator equipped with sampling probe or fit test sampling adapter and appropriate filters; and

8.2.2.6 Other accessories and supplies as required by the equipment manufacturer.

8.2.3 *Equipment Setup*—Follow manufacturer's instructions as necessary to:

8.2.3.1 Verify that all components are assembled according to the manufacturer's instructions. This includes the hoses supplying aerosol to the test chamber and returning exhaust air from the chamber, sample lines, electrical connections, and so forth;

8.2.3.2 Perform necessary maintenance and visual inspection;

8.2.3.3 Power up system and allow proper warmup;

8.2.3.4 Perform any preliminary adjustments, for example, sample flow, generator pressure, dilution air flow, and so forth; and

8.2.3.5 Allow time for the aerosol concentration to stabilize in the test chamber.

8.2.4 *Conducting the Fit Test:*

8.2.4.1 Enter all pertinent data into the test record as described in Section 11,

8.2.4.2 Instruct the person being fit tested to don the respirator as trained,

8.2.4.3 Have the person being fit tested enter the test chamber and connect the test respirator to the sample line,

8.2.4.4 Perform fit test according to instrument manufacturer instructions using the exercises specified in Section 10, and

8.2.4.5 The test results shall be recorded in accordance with Section 11.

8.2.5 *Interpretation of Results*—The average penetration is the arithmetic mean of the measured penetration (*Pen*) for each exercise:

$$\text{Average Penetration} = \frac{Pen_1 + Pen_2 + Pen_3 + \ldots\ Pen_N}{N} \quad (2)$$

where:

N = number of exercises.

8.2.5.1 The overall fit factor is calculated by: Overall FF = 1/Average Penetration.

8.2.5.2 Example: Pen_1 = 0.0015, Pen_2 = 0.0007, Pen_3 = 0.0017, Pen_4 = 0.0005, Pen_5 = 0.0009, and Pen_6 = 0.0011.

$$\text{Avg Pen} = \frac{0.0015 + 0.0007 + 0.0017 + 0.0005 + 0.0009 + 0.0011}{6} \quad (3)$$

$$= 0.001076$$

$$\text{Overall Fit Factor} = 1/0.001067 = 937 \quad (4)$$

8.2.5.3 When a strip chart is used, the *Pen* for each exercise is estimated by drawing a line through the midpoint of the trace for that exercise. The midpoint of this line represents the percent penetration taking into account the range to which the instrument is set.

8.2.5.4 The person has passed the fit test if the overall fit factor equals or exceeds the required fit factor.

8.3 *Ambient Aerosol Condensation Nuclei Counter (CNC) Quantitative Fit Test Procedure:*

8.3.1 *Operating Principles*—CNC instruments are capable of measuring the number concentration of particles in a given aerosol sample by counting single particles. When used for QNFT, the particle concentration of the challenge aerosol (C_{out}) and the particle concentration inside the respirator (C_{in}) are both measured while the person being fit tested performs a series of exercises designed to stress the face seal in ways that approximate anticipated workplace conditions.

8.3.1.1 CNC instruments typically use the particles in the ambient air as the challenge aerosol. This permits the use of an aerosol generator, if needed, and does not require the use of a test chamber.

8.3.1.2 The respirator shall be equipped with particulate filters that do not allow the challenge aerosol to penetrate significantly. Thus, it is assumed that all particles sampled from inside the respirator have entered though a face seal leak.

8.3.1.3 The fit factor is computed from the two aerosol concentration measurements:

$$\text{Fit Factor} = \frac{C_{out}}{C_{in}} \quad (5)$$

8.3.1.4 Care shall be taken to minimize body-generated particles inside the respirator. Since the system cannot differentiate between body-generated particles and ambient aerosol penetration, this can result in erroneously low fit factors. For example, particles may be released from the lungs for a period of time after smoking a cigarette. Therefore, fit testing should not be conducted within 30 min of smoking.

8.3.2 *Equipment Needed:*

8.3.2.1 Condensation nuclei counter QNFT instrument,

8.3.2.2 Filter for diagnostic checks recommended by the instrument manufacturer,

8.3.2.3 Other accessories and supplies required by instrument manufacturer, and

8.3.2.4 Respirators equipped with probes or fit test sampling adapters and particulate filters that do not allow the challenge aerosol to penetrate significantly.

8.3.3 *Diagnostic Checks*—The following diagnostic checks shall be performed at least daily. The instrument shall pass all three checks before fit testing can begin. Refer to the manufacturer's instructions for specifications and guidance.

8.3.3.1 *Particle Check*—Measure the concentration of particles in the environment where fit testing will be conducted to make sure that the instrument is working and within the concentration range specified by the instrument manufacturer to permit reliable measurements.

8.3.3.2 *Zero Check*—After the particle check is successfully completed, with the instrument in particle-counting mode, attach the high-efficiency particulate air (HEPA) filter to the sample hose. Watch the particle concentration display to make sure it drops to near zero within the time specified by the manufacturer. This confirms there are no leaks in the system.

8.3.3.3 *System Check*—After the zero check is successfully completed, leave the filter on the sample hose and perform a fit factor measurement on the filter. The result should comply with the manufacturer's instructions and specifications. This confirms that high fit factors can be measured.

8.3.4 *Prepare to Fit Test:*

8.3.4.1 Follow the manufacturer's instructions to set the instrument to perform the required fit test exercise protocol;

8.3.4.2 Connect the instrument sample hose to the respirator to be tested;

8.3.4.3 Instruct the person being fit tested to don the respirator as trained (see Section 7); and

8.3.4.4 Allow the person's breathing to purge ambient particles trapped inside the respirator during donning. A half facepiece will usually purge in a few breaths, while a full facepiece may take a full minute.

8.3.5 *Fit Testing*—Initiate the instrument's fit test cycle. Instruct the person being fit tested to begin and follow through with the exercise protocol (see Section 10). During this process, the instrument will sample the particle concentration

in the test environment and the concentration of those particles that leak into the respirator.

8.3.6 *Interpretation of Results*—At the completion of the fit test, the instrument provides a pass/fail indication or a numeric overall fit factor result, or both, for the entire test calculated according to Eq 6. The person has passed the fit test if the overall fit factor equals or exceeds the required fit factor.

$$\text{Overall Fit Factor} = \frac{N}{\frac{1}{FF_1}+\frac{1}{FF_2}+\cdots\frac{1}{FF_N}} \quad (6)$$

where:

N = number of exercises,
FF_1 = fit factor for the first exercise,
FF_2 = fit factor for the second exercise, and
FF_N = fit factor for the N^{th} exercise.

8.3.6.1 Example: Given the following fit factors for a series of six exercises: FF_1 = 666, FF_2 = 1429, FF_3 = 588, FF_4 = 2000, FF_5 = 1111, and FF_6 = 909.

$$\text{Overall Fit Factor} = \frac{6}{\frac{1}{666}+\frac{1}{1429}+\frac{1}{588}+\frac{1}{2000}+\frac{1}{1111}+\frac{1}{909}} = 937 \quad (7)$$

8.4 *Controlled Negative Pressure (CNP) Quantitative Fit Test Procedure:*

8.4.1 *Operating Principle*—The CNP fit test method is based on exhausting air from a temporarily sealed respirator. Measurement of the air exhaust rate required to hold the in-facepiece pressure constant yields a direct measure of leakage air flow into the respirator. The rate of air leakage is directly related to the amount of negative pressure created inside the respirator during inspiration. The primary factors affecting in-facepiece negative pressure during inhalation are work rate and air flow resistance through the filters/cartridges. During CNP fit testing, in-facepiece negative challenge pressures are selected that simulate low-to-moderate work rates rather than resting conditions.

8.4.1.1 Air molecules are the challenge agent for a CNP fit test. The amount of air that leaks into the respirator is assumed to represent face seal leakage. The rate of air leakage is directly related to the pressure differential created inside the respirator during inspiration. The primary determinants of in-facepiece inspiratory pressure include work rate and air-purifying cartridge resistance. CNP challenge pressures approximate inspiratory pressure differentials associated with low-to-moderate work rates rather than resting conditions.

8.4.1.2 A CNP fit factor is calculated from the ratio of the modeled inspiratory flow rate and measured leakage flow rate. Fit factors cannot be measured during exercises in controlled negative-pressure fit testing. Therefore, measurements of facepiece leakage are made at the end of each exercise.

8.4.2 *Equipment Needed*—Controlled negative pressure (CNP) fit test instrument and CNP fit test adapters are the equipment needed.

8.4.2.1 Filter cartridges are replaced with leak-tight test adapters to seal the normal air pathways into the respirator. The adapters are equipped with a breathing valve as well as air exhaust and pressure-monitoring ports.

NOTE 1—The inhalation valve downstream from the test adapter containing the air exhaust port shall be either removed or propped open during the fit test.

8.4.3 *System Calibration and Operational Checks:*

8.4.3.1 Calibrate the pressure and flow rate transducers according to manufacturer recommendations.

8.4.3.2 The pressure/flow rate relationship of the bypass orifice should be checked on a daily basis.

8.4.4 *Prepare to Fit Test:*

8.4.4.1 Equip the test respirator with appropriate CNP test adapter(s).

NOTE 2—Inhalation valve shall be removed or propped open.

8.4.4.2 Tell the person being fit tested to don the respirator as trained (see Section 7).

8.4.4.3 Select the instrument test parameters.

8.4.5 *Fit Testing:*

8.4.5.1 Tell the person being fit tested to take a breath and hold it for the duration of the measurement. The person shall remain motionless in the specified head position during the measurement.

8.4.5.2 It is important that the in-facepiece pressure equilibrates to ambient pressure before the initiation of the test.

8.4.5.3 The CNP test system is activated to establish and maintain a negative challenge pressure in the temporarily sealed respirator. The exhaust flow rate required to maintain a constant challenge pressure is averaged over the duration of the measurement and represents a direct measure of respirator leakage flow rate.

8.4.6 *Interpretation of CNP Test Results:*

8.4.6.1 A CNP fit factor is calculated as the ratio of inspiratory flow rate to measured leakage flow rate.

8.4.6.2 At the completion of the fit test, the instrument provides a pass/fail indication or a numeric overall fit factor result, or both, for the entire test calculated according to Eq 8. The person has passed the fit test if the overall fit factor equals or exceeds the required fit factor.

$$\text{CNP Fit Factor} = IFR / LFR \quad (8)$$

where:

IFR = inspiratory flow rate associated with CNP challenge pressure, and
LFR = mean leakage flow rate measured with the head held in a motionless position at the end of each test exercise.

8.4.6.3 Example: Given a modeled inspiratory flow rate of 53 800 mL/min (equivalent to a moderate work rate): LFR_1 = 48 mL/min, LFR_2 = 69 mL/min, LFR_3 = 59 mL/min, LFR_4 = 53 mL/min, and LFR_5 = 58 mL/min. Average LFR = (LFR_1 + LFR_2 + … LFR_N) / N = 287 / 5 = 57.4. Fit factor = 53 800 / 57.4 = 937.

9. Qualitative Fit Test (QLFT) Methods

9.1 This section contains the QLFT methods reviewed by the committee that were found to be acceptable when this guide was published. A qualitative fit test uses a person's ability to sense a challenge agent (such as by taste or smell) to determine if respirator leakage occurs. The tests do not give a numerical indication of fit; no direct measurements of the challenge agent