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# Respirator Fit
## Testing Methods

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# American National Standard — Respirator Fit Testing Methods

Secretariat

**American Industrial Hygiene Association**

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American National Standard

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## Contents

**FOREWORD** (This foreword is not part of the American National Standard/AIHA Z88.7–2010)

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

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 standard provides guidance on exactly what knowledge and skills are necessary in order to perform as a qualified fit test operator.

This standard 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 with the respirator, detailed information on respirators used for fit testing, selection of respirators prior to fit testing, and other considerations that must be met if the fit test is to be effective.

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

Annex A1 is informative and is not considered part of the standard.

Annex A2 is mandatory for future inclusion of new fit test methodologies into this standard.

Annex B is informative and is not considered part of the standard.

Suggestions for the improvement of this standard are welcome. They should be sent to the American Industrial Hygiene Association®, 2700 Prosperity Avenue, Suite 250, Fairfax, VA 22031.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee Z88 on Respiratory Protection. Consensus was reached through a process involving the entire Z88 Committee in a series of reviews and in the final vote of approval. Committee approval of the standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z88 Committee had the following members:

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John Steelnack

Note: Some members were added to or removed from the sub-committee at various times.

# American National Standard — Respirator Fit Testing Methods

## 1 Scope and Purpose

**1.1 Scope.** This standard 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 ANSI Z88.2, 29 CFR 1910.134 (OSHA), etc.

**1.2 Purpose.** This standard provides requirements for conducting respirator fit testing and includes:

- qualifications for fit test operators
- specific fit test methods
- interpretation of fit test results
- record keeping
- methods to validate new fit test methods

The intent of fit testing is to evaluate sealing surface leakage. Other sources of leakage may contribute to the total leakage detected.

**1.3 "SHOULD and SHALL."** The provisions of this standard are mandatory in nature where the word "shall" is used and advisory in nature where the word "should" is used.

**1.4 Exceptions.** Users of this standard should be aware that regulatory agencies may have requirements that are different from this standard.

## 2 Normative References

American National Standard for Respiratory Protection ANSI/AIHA Z88.2.

American National Standard for Respiratory Protection – Respirator Use: Physical Qualifications for Personnel. ANSI/AIHA® Z88.6–2006.

## 3 Definitions

**3.1 Aerodynamic diameter:** The diameter of a unit density sphere having the same settling velocity as the particle in question.

**3.2 Aerosol:** Particles, solid or liquid, suspended in air.

**3.3 Canister/cartridge:** A container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

**3.4 Challenge agent:** An aerosol, vapor, or gas used by the fit test method for detecting respirator leakage.

**3.5 Challenge pressure:** The negative static pressure established inside the respirator facepiece during a controlled negative pressure fit test.

**3.6 Facepiece:** See tight-fitting respirator.

**3.7 Filter:** A component used in respirators to remove aerosols from the inspired air.

**3.8 Fit factor:** A numeric expression of how well a tight-fitting respirator fits a wearer during a quantitative fit test. 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 = $C_{out}$/ $C_{in}$).

**3.9 Fit test:** The use of a qualitative or quantitative protocol to evaluate sealing

surface leakage of a specific tight-fitting respirator while worn by an individual.

**3.10 Fit test method:** A combination of instrumentation, technology, and protocols used to conduct a respirator fit test. An accepted method may have more than one accepted protocol.

**3.11 Fit test operator:** A person qualified by training and experience with demonstrated ability to properly perform qualitative or quantitative fit tests and evaluate test results.

**3.12 Fit test protocol:** Specific step-by step instructions for conducting a respirator fit test.

**3.13 Qualitative fit test (QLFT):** A pass/fail fit test included in this standard that relies on the subject's sensory response to detect a challenge agent.

**3.14 Quantitative fit test (QNFT):** A fit test included in this standard that uses an instrument to measure faceseal leakage.

**3.15 Required fit factor (RFF):** The numeric value established as a pass/fail point or acceptance criterion for a quantitative fit test.

**3.16 Respirator:** A personal protective device designed to protect the wearer from the inhalation of hazardous atmospheres.

**3.17 Tight-fitting respirator:** A respirator with a facepiece, hood or helmet that is designed to form a complete seal with the face or neck. This includes a hood or helmet with a neck seal (neck dam).

**3.18 User seal check:** A procedure conducted by the wearer to determine if a tight-fitting respirator is properly donned.

## 4 Fit Testing Rationale

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.

## 5 Qualifications of Fit Test Operators

**5.1 General Qualifications.** 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.

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 A1. 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.



**5.2 Specific Qualifications for Fit Test Operators**

**5.2.1** They shall be familiar with ANSI Z88.10 along with the appropriate sections of the respiratory protection program concerning respirator fit testing, inspection, cleaning, maintenance, and storage.

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

a. Identifying respirator components and their functions;
b. Demonstrating respirator inspection, cleaning, and maintenance procedures;
c. Identifying different make, model, style, and size respirators;
d. Discussing respirator capabilities and limitations as related to respirator fit testing; and
e. Demonstrating and evaluating proper donning and doffing procedures including user seal checks.

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

a. Explaining the purpose of respirator fit testing;
b. Explaining fit test procedures;
c. Explaining the limitations of the fit test method;
d. Identifying indications of erroneous fit test results (e.g., quantitative fit factors that are unusually low or high); and
e. Demonstrating knowledge of the health and safety hazards associated with the chemicals and/or equipment used in the fit test.

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

a. Selecting the proper canisters/cartridges or filters for the fit test method;
b. Preparing, inspecting and performing operational checks of fit testing equipment and materials; and
c. Proper assembly and use of probes and adapters for quantitative fit test methods.

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

a. 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;
b. Explaining the fit test purpose and procedures to persons being fit tested;
c. Observing that the correct donning procedure is used without physically assisting the person being fit tested;
d. Observing that user seal checks are performed according to the procedures recommended by the respirator manufacturer;
e. Observing the person being fit tested throughout the entire fit test procedure to ensure it is performed correctly;
f. Conducting the chosen test method according to the procedures specified in Clauses 7 and 8;
g. Evaluating and recording the results of the fit test; and
h. Performing respirator cleaning and sanitizing according to manufacturer instructions.

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

– improperly donned or adjusted respirator
– incorrectly assembled or damaged respirator
– incorrect size, shape or style respirator

## 6 General Considerations

**6.1 Medical Evaluation.** Persons being fit tested shall be medically cleared to wear the respirator prior to fit testing. Refer to ANSI/AIHA® Z88.6, 29 CFR 1910.134 (OSHA), or other applicable regulatory standards.

**6.2 Training for Respirator Wearers.** Persons to be fit tested shall receive training prior to 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:

a. Properly inspect the respirator and recognize conditions that may compromise its integrity, such as missing components or deformities;
b. Properly don the respirator without assistance; and
c. Perform a user seal check.

Instruction in proper donning may occur immediately prior to 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.

### 6.3 Interference Concerns

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

a. hair comes between the sealing surface of the respirator and the face or neck.
b. hair interferes with valve and/or respirator function.

**6.3.2 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, etc.

**6.3.3 Personal Protective Equipment (PPE) and Other Items That May Interfere with Fit.** When any PPE and/or respirator accessory has the potential to interfere with the seal, it shall be worn during the fit test to ascertain compatibility with the respirator. For example, eye glasses, 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.

**6.3.4 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.

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.

Respirator wearers who have dentures shall be fit tested:

a. With dentures if they wear them while wearing the respirator in the workplace, or
b. Without dentures, if they do not wear them while wearing the respirator in the workplace.

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

### 6.4 Frequency of Fit Tests

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

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

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

a. A significant change in weight;
b. A change to the face in the sealing area (e.g., scarring, facial surgery);
c. Dental changes; or
d. User discomfort.



### 6.5 Respirators Used for Fit Testing.

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

– The wearer's individually assigned respirator; or
– A surrogate respirator facepiece having sealing surfaces, materials and head straps that are the same as the respirator to be assigned to the wearer.

Respirators used for fit testing shall be equipped with filtration or sorbent media and/or adapters 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.

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:

– 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
– 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 self-contained breathing apparatus (SCBA) facepiece made by the same manufacturer if the sealing surfaces and materials are identical.

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

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

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

**6.5.2 Respirators Used for QNFT.** Respirators used for QNFT must allow in-facepiece sampling. This can be accomplished by either:

a. Using a fit test sampling adapter on an individually assigned respirator facepiece; or
b. Using a fit test sampling adapters on a surrogate respirator facepiece; or
c. Using a permanently probed surrogate respirator facepiece.

**6.5.2.1 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.

**6.5.2.2 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.

**6.5.3 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 must 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.

**6.5.4 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.

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 (e.g., filtering facepieces) shall not be used by more than one individual.

**6.6 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.

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 (e.g., over-tightening the straps), until a passing fit test is finally achieved. Offering a reasonable assortment of respirator types and/or sizes should eliminate the inclination to force fit.

**6.6.1 Selecting a Suitable Respirator for the Fit Test.** Initial respirator wearers and anyone needing to change size or model respirators shall select from the assortment offered. The respirator assortment must 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.

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.

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.

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.

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

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

The comfort assessment period allows the respirator wearer time to determine if the respirator is truly comfortable or not, and to make any necessary adjustments. Discomfort may become apparent only after the respirator is worn for a period of time. For example, over-tightened 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.

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

**6.7 Test Requirements Common to all Fit Tests**

**6.7.1 Fit Test Operator Requirements**
The fit test shall be administered by a fit test operator who meets the requirements of Clause 5 and follows all of the procedures in this standard.

**6.7.2 Environmental Requirements**
The following conditions must be met:

a. The ability to observe and communicate with the person being fit tested at all times during the fit test;

b. The ability to establish and maintain an appropriate challenge agent concentration during the test;
c. Exposures of persons being fit tested and fit test operators shall not exceed established exposure limits for any challenge agents used; and
d. Sufficient space to complete specified fit test exercises without interference.

### 6.7.3 Other Requirements

a. The person being fit tested shall don the respirator without physical or verbal assistance and perform a user seal check;
b. 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 Clauses 7 and 8 to conduct fit testing;
c. 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;
d. 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
e. 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.

### 6.7.4 Required Fit Factor

Refer to ANSI Z88.2, 29 CFR 1910.134 (OSHA), or other applicable regulatory standards for required fit factors.

## 7 Quantitative Fit Test (QNFT) Methods

This clause contains the QNFT methods reviewed by the committee that were found to be acceptable when this standard 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.

### 7.1 Generated Aerosol Quantitative Fit Test Procedure

**7.1.1 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.

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

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

$$\text{Fit Factor} = \frac{C_{out}}{C_{in}}$$

### 7.1.2 Equipment

Equipment needed for aerosol QNFT:

a. Aerosol generation and distribution system. The challenge aerosol shall have a mass median aerodynamic diameter (MMAD) less than 1 micrometer;
b. Aerosol detection system;
c. Device for recording fit test results;
d. Test chamber to contain challenge aerosol;

e. Respirator equipped with sampling probe or fit test sampling adapter and appropriate filters; and
f. Other accessories and supplies as required by the equipment manufacturer.

**7.1.3 Equipment Setup**

Follow manufacturer's instructions as necessary to;

a. 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, etc.;
b. Perform necessary maintenance and visual inspection;
c. Power up system and allow proper warm-up;
d. Perform any preliminary adjustments, i.e., sample flow, generator pressure, dilution air flow, etc.; and
e. Allow time for the aerosol concentration to stabilize in the test chamber.



**7.1.4 Conducting the Fit Test**

a. Enter all pertinent data into the test record as described in Clause 10;
b. Instruct the person being fit tested to don the respirator as trained;
c. Have the person being fit tested enter the test chamber and connect the test respirator to the sample line;
d. Perform fit test according to instrument manufacturer instructions using the exercises specified in Clause 9.
e. The test results shall be recorded in accordance with Clause 10.

**7.1.5 Interpretation of Results.** The average penetration is the arithmetic mean of the measured percent penetration (Pen) for each exercise:

Average Penetration

$$= \frac{Pen_1 + Pen_2 + Pen_3 + \ldots . Pen_N}{N}$$

N = number of exercises

The overall fit factor is calculated by:

Overall FF = 1/ Average Penetration

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

Average Penetration

$$= \frac{0.0015+0.0007+0.0017+0.0005+0.0009+0.0011}{6}$$

= 0.001067

Overall Fit Factor = 1/ 0.001067 = 937

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.

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

**7.2 Particle-counting Instrument Quantitative Fit Test Procedure**

**7.2.1 Operating Principles.** Particle-counting 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.

Particle-counting instruments typically use the particles in the ambient air as the challenge aerosol. This eliminates the need for aerosol generators and test chambers.

The respirator must 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.

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

$$\text{Fit Factor} = \frac{C_{out}}{C_{in}}$$

Care must 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 minutes of smoking.

**7.2.2 Equipment Needed**

a. Particle counting QNFT instrument;
b. Filter for diagnostic checks recommended by the instrument manufacturer;
c. Other accessories and supplies required by instrument manufacturer; and
d. Respirators equipped with probes or fit test sampling adapters and particulate filters that do not allow the challenge aerosol to penetrate significantly.

**7.2.3 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.

a. 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.

b. 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.

c. 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.

**7.2.4 Prepare to Fit Test**

a. Follow the manufacturer's instructions to set the instrument to perform the required fit test exercise protocol;
b. Connect the instrument sample hose to the respirator to be tested;
c. Instruct the person being fit tested to don the respirator as trained (see Clause 6); and
d. 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.

**7.2.5 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 Clause 9). 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.

**7.2.6 Interpretation of Results.** At the completion of the fit test the instrument provides a pass/fail indication and/or a numeric overall fit factor result for the entire test calculated according to the formula below. The person has passed

the fit test if the overall fit factor equals or exceeds the required fit factor.

$$\text{Overall Fit Factor} = \frac{N}{\frac{1}{FF_1} + \frac{1}{FF_2} + \ldots \frac{1}{FF_N}}$$

Where:

N = The number of exercises
$FF_1$ = The fit factor for the first exercise
$FF_2$ = The fit factor for the second exercise
$FF_N$ = The fit factor for the Nth exercise

Example:

Given the following fit factors for a series of six exercises:

$FF_1 = 666$, $FF_2 = 1429$, $FF_3 = 588$, $FF_4 = 2000$, $FF_5 = 1111$, $FF_6 = 909$

Overall Fit Factor

$$= \frac{6}{\frac{1}{666} + \frac{1}{1429} + \frac{1}{588} + \frac{1}{2000} + \frac{1}{1111} + \frac{1}{909}}$$

= 937

### 7.3 Controlled Negative Pressure (CNP) Quantitative Fit Test Procedure

**7.3.1 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.

Air molecules are the challenge agent for a CNP fit test. The amount of air that leaks into the respirator is assumed to represent faceseal 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.

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.

**7.3.2 Equipment Needed**

a. Controlled negative pressure (CNP) fit test instrument
b. CNP fit test adapters



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: The inhalation valve downstream from the test adapter containing the air exhaust port must be either removed or propped open during the fit test.

**7.3.3 System Calibration and Operational Checks**

a. Calibrate the pressure and flow rate transducers according to manufacturer recommendations.
b. The pressure/flow rate relationship of the bypass orifice should be checked on a daily basis.

**7.3.4 Prepare to Fit Test**

a. Equip the test respirator with appropriate CNP test adapter(s). NOTE:

Inhalation valve must be removed or propped open.

b. Tell the person being fit tested to don the respirator as trained (see Clause 6).

c. Select the instrument test parameters.

### 7.3.5 Fit Testing

a. 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.

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

c. 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.

### 7.3.6 Interpretation of CNP Test Results

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

b. At the completion of the fit test the instrument provides a pass/fail indication and/or a numeric overall fit factor result for the entire test calculated according to the formula below. The person has passed the fit test if the overall fit factor equals or exceeds the required fit factor.

CNP Fit Factor = IFR / LFR

Where:

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

Example:

Given a modeled inspiratory flow rate of 53,800 ml/min (equivalent to a moderate workrate):

LFR1 = 48 mL/min, LFR2 = 69 ml/min, LFR3 = 59 mL/min, LFR4 = 53 ml/min, LFR5 = 58 mL/min

Average LFR = (LFR1+LFR2+….LFRn)/n
= 287/5 = 57.4
Fit Factor = 53,800/57.4 = 937

## 8 Qualitative Fit Test (QLFT) Methods

This section contains the QLFT methods reviewed by the committee that were found to be acceptable when this standard 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 and leak concentrations are made. The reliability of the test depends upon the person's ability to detect and indicate whether the challenge agent is sensed and requires that the operator carefully follow the accepted test protocol.

**8.1 Isoamyl Acetate (banana oil) Fit Test.** The isoamyl acetate (IAA) fit test uses a person's sense of smell to detect leakage into the respirator. The person being fit tested first must demonstrate the ability to detect a known low (~ 1 ppm) concentration of IAA. Next, while wearing a respirator, the person enters a test enclosure with a higher (> 100 ppm) concentration of IAA. If the banana-like odor of IAA is not detected, the person passes the fit test and is assumed to have a fit factor of at least 100.

Note: Any variation from the procedure specified below may invalidate the results, especially changes in solution concentrations, amount of IAA used during the test, and the size of the test enclosure.

Precautions: The screening test and fit test shall be done in separate areas that do not allow the transfer of IAA vapors

from the fit test area to the screening area. The sense of smell is adversely affected by even brief exposures to IAA. The fit test should be conducted immediately after the screening test. Review the MSDS for any handling and use precautions.

### 8.1.1 Odor Threshold Screening

Use of the IAA fit test method requires that the person being fit tested have the ability to smell low concentrations of IAA.

#### 8.1.1.1 Equipment Required

a. Three or more identical 1-liter (1-quart) glass jars with metal lids (e.g., Mason or Ball canning jars);
b. A 1-mL eye dropper, syringe, or other device capable of dispensing in 0.1 mL increments;
c. Odor-free water (e.g., distilled or spring water) at room temperature about 20 to 25°C (~70–77° F); and
d. Isoamyl acetate (IAA), reagent grade (also known as isopentyl acetate, CAS number 123–92–2).



#### 8.1.1.2 Solution Preparation

a. Prepare a stock solution by adding 1 mL of reagent grade IAA to 800 mL water in a glass jar labeled “stock solution” and shake for 30 seconds. This solution shall be prepared at least weekly;
b. Label the remaining jars described below using a switchable identification system (e.g. switchable numbers) so that only the person who conducts the fit test can identify the contents of each jar by sight;
c. Prepare an odor test solution by placing 0.4 ml of the stock solution into 500 ml water in a second jar. Close the lid, shake, and let the jar stand for two minutes before use. This solution is prepared daily;
d. Prepare a blank jar by adding 500 mL water to one or more jars. (Note: more than one blank jar should be used to make it more difficult for someone to guess); and
e. Switch the jar identification labels between tests so that the same jar is not always the one that smells like bananas.

#### 8.1.1.3 Odor Screening Test

a. Ask the person being fit tested to determine which jar smells like bananas by instructing the person to shake each jar briefly, remove the lid, sniff at the mouth of the jar, and recap the lid;
b. If the person correctly identifies which jar contains IAA, then the person may continue with the test. If the correct jar cannot be identified, the IAA fit test method shall not be used.
c. NOTES:

   1) Prevent olfactory fatigue by not allowing IAA vapor to be present in the screening area. The odor-screening test must be done in a separate area (i.e., a different room) to prevent transfer of IAA vapors from the fit testing area.

   2) A card may be prepared with instructions that the person being fit tested can follow to shake the jars, remove the lids, and determine which jar smells like bananas.

   3) Take care not to contaminate the blank jar(s) by switching jar lids.

### 8.1.2 Fit Testing

The person is fit tested while wearing a respirator in a test enclosure containing a controlled concentration of IAA.

#### 8.1.2.1 Equipment Needed

a. Test enclosure: A clear plastic bag approximately 24 inches (60 cm) in diameter and 60 inches (150 cm) long, (e.g., a 55-gallon plastic drum liner) equipped with a frame to hold the bag open and a suitable device or clip for holding the absorbent paper;
b. A piece of absorbent paper (e.g., a paper towel), approximately 6 by 5 inches (15 x 12 cm). A new piece of

absorbent paper is needed for each fit test;

c. A quantity of 0.75 mL of IAA (reagent grade) is needed for each fit test; and

d. Respirators used for testing shall be equipped with cartridges that remove organic vapors. Cartridges should be replaced before breakthrough occurs. This could be as often as weekly.

#### 8.1.2.2 Conducting the Test

a. Instruct the person being fit tested to don the respirator, equipped with a cartridge capable of removing organic vapors, as trained (see Clause 6). Adjust the ceiling of the enclosure to a distance about 6 inches (15 cm) above the person's head;

b. Apply 0.75 mL of reagent grade IAA to one piece of absorbent paper, which is folded in half. Hand it to the person in the enclosure, who then attaches it to the inside top of the enclosure. A freshly wetted piece of absorbent paper shall be used for each fit test;

c. Wait two minutes for the IAA concentration to stabilize in the enclosure;

d. Instruct the person that any detection of the smell of IAA (banana-like odor) during the test is to be reported immediately;

e. Instruct the person to begin the series of test exercises according to Clause 9;

f. The fit test is failed if the person reports smelling IAA at any time while conducting the test exercises. At this point a decision must be made, either to retest or select another respirator according to Clause 6. In either case the entire procedure must be repeated (odor screening and fit testing). It may take several minutes for the person being fit tested to regain the ability to smell low concentrations of IAA. Do not repeat the fit test until the person being fit tested successfully completes the odor threshold screening test again;

g. If the person being fit tested does not report smelling the IAA, instruct the person to momentarily break the respirator seal and inhale. If IAA is not detected after breaking the respirator seal, the test is null and void and the reason why the person did not smell the IAA must be identified. If the IAA is detected after breaking the seal, the test is passed;

h. A person who passes the IAA test is assumed to have a fit factor of at least 100;

i. At the end of a passed or failed test, have the person remove the absorbent paper and seal it in a small plastic bag or similar container to lessen the build up of IAA vapor in the fit testing area.

NOTE: The absorbent paper shall not be used for other IAA fit tests.
Note: Operators should be aware that wearing a respirator within a fit test enclosure may elevate inspired carbon dioxide levels and decrease inspired oxygen levels. The operator should inform the person that they may feel hot or experience distress. If this occurs the person should stop the test, exit the enclosure, and remove the respirator.

### 8.2 Sodium Saccharin Aerosol Fit Test.

The saccharin aerosol fit test uses a person's sense of taste to detect leakage into the respirator. The person being tested must be able to detect a weak solution of sweet-tasting saccharin. This is determined by spraying a weak solution of saccharin into a fit test hood placed over the head. Next, while the person is wearing a respirator, the hood is placed over the head and a stronger saccharin solution (~100 times stronger) is sprayed into the fit test hood. If the person being fit tested does not detect the taste of saccharin, the person passes the fit test and is assumed to have a fit factor of at least 100.

Note: Any variation from the procedure specified below may invalidate the results, including changes in solution concentration, how the bulb is squeezed, the number of squeezes, and the size of the fit test hood.

Precautions: Since a person's ability to taste the sweet solution is used to determine whether the respirator fits, he or she should refrain from activities that would affect the sense of taste such as consuming any food or beverage (other than plain water), using tobacco products, or chewing gum for about 15 minutes prior to threshold screening. The fit test should be done immediately after the threshold screening test. Review the MSDS for any handling and use precautions.

Note: Operators should be aware that wearing a respirator with a fit test hood will elevate inspired carbon dioxide levels and decrease inspired oxygen levels. The operator should inform the person that they may feel hot or experience distress. If this occurs the person should stop the test and remove the hood and respirator.

### 8.2.1 Taste Threshold Screening

Use of the saccharin fit test requires that the person being fit tested demonstrate the ability to taste a low concentration of saccharin.



#### 8.2.1.1 Equipment Needed

a. An inhalation nebulizer (DeVilbiss Model 40 or 45 or equivalent). Aerosol particle size and concentration is determined by the characteristics of the nebulizer. An alternative nebulizer shall produce an aerosol concentration and particle size distribution equivalent to the Model 40/45 using the procedure specified below;
b. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle; and
c. Sensitivity screening solution with 0.83 g sodium saccharin (CAS number 128-44-9, USP grade) in 100 ml distilled water.

#### 8.2.1.2 Taste Threshold Screening Procedure

a. Place the fit test hood over the person's head. The person being fit tested shall not be wearing a respirator at this time. Ask the person to breathe through the mouth only. Instruct the person to immediately report if the sweet taste of saccharin is detected.
b. Add a small amount of the taste screening solution (~ 3 mL) into the nebulizer.
c. Insert the nebulizer nozzle into the opening at the front of the fit test hood. Direct the nozzle away from the nose and mouth of the person. Be careful not to spray the aerosol onto the surface of the fit test hood or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the procedure.

d. Squeeze the nebulizer bulb up to 10 times. If the person reports the sweet taste during the 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 10.
e. If the person being fit tested is unable to detect the sweet taste after 10 squeezes, apply up to another 10 squeezes. If the person reports the sweet taste during the second 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 20.
f. If the person is unable to detect the sweet taste after the second 10

squeezes, apply up to another 10 squeezes. If the person reports the sweet taste during the third set of 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 30.

g. If the person is unable to detect the sweet taste after 30 squeezes, he or she is unable to taste saccharin and the saccharin fit test method shall not be used. The operator should recognize that some people may not detect the sweet taste of saccharin and therefore should not encourage the person to respond in a falsely positive manner.

### 8.2.2 Fit Testing

The person is fit tested while wearing a respirator inside the fit test hood while the test solution is sprayed into the hood.

#### 8.2.2.1 Equipment Needed

a. A second nebulizer of the same make and model as that used for the threshold screening test;
b. Fit test solution with 83 g sodium saccharin (CAS number 128-44-9, USP grade) in 100 ml distilled water;
c. Respirators used for testing must be equipped with particulate filter(s); and
d. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole, approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle.

#### 8.2.2.2 Conducting the Test

a. Place the fit test hood over the person's head. The person being fit tested shall wear the respirator as trained (see Clause 6).
b. Ask the person to breathe through their mouth only. Instruct the person to immediately report if the sweet taste of saccharin is detected.
c. Add a small amount of the test solution (~ 3 mL) into the nebulizer.

Note: If the test solution has crystallized, do not use it until all of the crystals have been dissolved by gently warming the solution.

d. Position the fit test hood to maximize the space between the front of the hood and the respirator. Insert the nebulizer nozzle into the opening at the front of the hood and direct the aerosol into the void between the side of the respirator and the hood. Spray saccharin aerosol into the fit test hood by squeezing the nebulizer bulb 10, 20, or 30 times based on the taste threshold assigned during the threshold screening test. Be careful not to direct the aerosol spray onto the hood, respirator, or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the test.

e. Instruct the person to begin the series of test exercises according to Clause 9.
f. Replenish the concentration in the fit test hood every 30 seconds by adding half the original number of squeezes (5, 10, or 15).
g. The person fails the fit test if they report tasting saccharin at any time while conducting the test exercises. At this point a decision must be made, either to retest or select another respirator according to Clause 6. In either case the entire procedure must be repeated (taste threshold screening and fit testing). It may take several minutes for the per-

son being fit tested to regain the ability to taste low concentrations of saccharin. Rinsing the mouth out with plain water and wiping the lips with a wet towel may help. Do not repeat this test until the person being fit tested successfully completes the taste threshold screening test again;

h. If the person being fit tested does not report tasting saccharin, instruct them to reach into the hood and momentarily break the respirator seal while inhaling through their mouth. If the sweet taste is not detected after breaking the respirator seal, the test is null and void and the reason why the person did not taste the saccharin must be identified. If the sweet taste is detected after breaking the seal, the test is valid and the person passes the fit test;

i. A person who passes the sodium saccharin test is assumed to have a fit factor of at least 100.

Note: Since the saccharin test solution has a tendency to clog during use, the test operator must make periodic checks to determine that it is not clogged. If clogging occurs during the test and it is not immediately cleared, the test is invalid.

### 8.3 Bitrex™ (denatonium benzoate) Solution Aerosol Fit Test

The bitter aerosol fit test uses a person's sense of taste to detect leakage into the respirator. The person being tested must be able to detect a weak solution of Bitrex™. This is determined by spraying a weak solution of Bitrex™ into a fit test hood placed over the head. Next, while the person is wearing a respirator, the hood is placed over the head and a stronger Bitrex™ solution is sprayed into the fit test hood. If the person being fit tested does not detect the taste of Bitrex™ in the respirator, the fit test is passed and the person is assumed to have a fit factor of at least 100.

Note: Any variation from the procedure specified below may invalidate the results, including changes in solution concentration, how the bulb is squeezed, the number of squeezes, and the size of the fit test hood.

Precautions: Since a person's ability to taste the bitter solution is used to determine whether the respirator fits, they should refrain from activities that would affect the sense of taste such as consuming any food or beverage (other than plain water), or using tobacco products or gum for about 15 minutes prior to threshold screening. The fit test should be done immediately after the threshold screening test. Review the MSDS for any handling and use precautions.

Note: Operators should be aware that wearing a respirator with a fit test hood will elevate inspired carbon dioxide levels and decrease inspired oxygen levels. The operator should inform the person that they may feel hot or experience distress. If this occurs the person should stop the test and remove the hood and respirator.

#### 8.3.1 Taste Threshold Screening



Use of the bitter aerosol fit test requires that the person being fit tested demonstrate the ability to taste a low concentration of Bitrex™.

##### 8.3.1.1 Equipment Needed

a. An inhalation nebulizer (DeVilbiss Model 40 or 45 or equivalent). Aerosol particle size and concentration is determined by the characteristics of the nebulizer. An alternative nebulizer shall produce an aerosol concentration and particle size distribution equivalent to the Model 40/45 using the procedure specified below;

b. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle; and

c. Sensitivity screening solution with 13.5 mg Bitrex™ (CAS number 3734-33-6, USP grade) in 100-mL of a 5% sodium chloride by weight solution in distilled water.

#### 8.3.1.2 Taste Screening Procedure

a. Place the fit test hood over the person's head. The person being fit tested shall not be wearing a respirator at this time. Ask the person to breathe through the mouth only. Instruct the person to immediately report if the bitter taste of Bitrex™ is detected.
b. Add a small amount of the taste screening solution (~ 3 mL) into the nebulizer.
c. Insert the nebulizer nozzle into the opening at the front of the fit test hood. Direct the nozzle away from the nose and mouth of the person. Be careful not to spray the aerosol onto the surface of the fit test hood or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the procedure.

d. Squeeze the nebulizer bulb up to 10 times. If the person reports the bitter taste during the 10 squeezes, stop squeezing the bulb; the threshold screening is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 10.
e. If the person being fit tested is unable to detect the bitter taste after 10 squeezes, apply up to another 10 squeezes. If the person reports the bitter taste during the second 10 squeezes, stop squeezing the bulb; the threshold screening is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 20.
f. If the person is unable to detect the bitter taste after the second 10 squeezes, apply up to another 10 squeezes. If the person reports the bitter taste during the third set of 10 squeezes, stop squeezing the bulb; the screening test is completed. Regardless of the number of squeezes actually completed, assign the taste threshold as 30.
g. If the person is unable to taste the bitter taste after 30 squeezes, he or she is unable to taste Bitrex™ and the Bitrex™ fit test method shall not be used. The operator should recognize that some people may not detect the bitter taste of Bitrex™ and therefore should not encourage the person to respond in a falsely positive manner.

### 8.3.2 Fit Testing

The person is fit tested while wearing a respirator inside the fit test hood while the test solution is sprayed into the hood.

#### 8.3.2.1 Equipment Needed

a. A second nebulizer of the same make and model as that used for the threshold screening test;
b. Fit test solution with 337.5 mg of Bitrex™ in 200 mL of a 5% sodium chloride by weight solution in distilled water;
c. Respirators used for testing must be equipped with particulate filter(s); and
d. A fit test hood with a nominal size of 12 inches (300 mm) in diameter by 14 inches (355 mm) high with at least the front portion clear. The fit test hood must allow free movement of the head when a respirator is worn. A hole, approximately 1 inch (25 mm) in diameter shall be located at a point that will be in front of the person's nose and mouth to accommodate the nebulizer nozzle.

#### 8.3.2.2 Conducting the Test

a. Place the fit test hood over the person's head. The person being fit tested shall be wearing the respirator as trained (see Clause 6).
b. Ask the person to breathe through their mouth only. Instruct the person to immediately report if the bitter taste of Bitrex™ is detected.
c. Add a small amount of the test solution (~ 3 mL) into the nebulizer.
d. Position the fit test hood to maximize the space between the front of the hood and the respirator. Insert the nebulizer nozzle into the opening at the front of the hood and direct the aerosol into the void between the side of the respirator and the hood. Spray Bitrex™ aerosol into the fit test hood by squeezing the nebulizer bulb, either 10, 20, or 30 times based on the taste threshold assigned during the threshold screening test. Be careful not to spray the aerosol onto the hood, respirator, or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol.

   Note: Determine that the nebulizer is working by observing that a visible mist is produced throughout the test.

e. Instruct the person to begin the series of test exercises according to Clause 9.
f. Replenish the concentration in the hood every 30 seconds by adding half the original number of squeezes (5, 10, or 15).
g. The person fails the fit test if they report tasting Bitrex™ at any time while conducting the test exercises. At this point a decision must be made, either to retest or select another respirator according to Clause 6. In either case the entire procedure must be repeated (taste threshold screening and fit testing). It may take several minutes for the person being fit tested to regain the ability to taste low concentrations of Bitrex™. Rinsing the mouth out with plain water and wiping the lips with a wet towel may help. Do not repeat this test until the person being fit tested successfully completes the taste threshold screening test again;
h. If the person being fit tested does not report tasting Bitrex™, instruct them to reach into the hood and momentarily break the respirator seal while inhaling through their mouth. If the bitter taste is not detected after breaking the respirator seal, the test is null and void and the reason why the person did not taste the Bitrex™ must be identified. If the bitter taste is detected after breaking the seal, the test is valid and the person passes the fit test;
i. A person who passes the Bitrex™ test is assumed to have a fit factor of at least 100.



## 9 Fit Test Exercises

Exercises are performed during a fit test to simulate the movements that occur during respirator use.

### 9.1 Duration of Fit Test Exercises

Each fit test exercise shall be at least 30 seconds in duration, unless otherwise specified in Table II.

### 9.2 Required and Elective Exercises

Table I lists the required and elective exercises for each type of fit test method. At least one elective exercise is to be performed along with the required exercises. Table II describes how the required and elective exercises are to be performed. Additional elective and/or optional exercises can be performed, if desired.

### 9.3 Optional Exercises

Table II also provides examples of optional exercises that could be added, if desired.

## 10 Record Keeping

Fit test records shall be kept in a manner consistent with current legal requirements and company policies.

### 10.1 Fit Test Records

The records should include the following:

a. Name and/or identification number of respirator user;
b. Test date;
c. Name of the person who conducted the test;
d. Name of the fit test method and exercises used:
e. For quantitative tests, record the fit factor and indication of pass or fail;
f. For qualitative tests, record an indication of pass or fail;
g. Make, model, style, size, and other pertinent information (e.g., facepiece material, type of straps, etc.);
h. Fit test expiration date or next test due date;
i. Other factors such as, safety equipment worn during the test(s), e.g., hard hat, eye wear, etc.; and
j. If fit test certification cards are issued, they shall contain as a minimum the person's name; make, model, style, and size facepiece(s) permitted to be used; and fit test expiration date.

Note: It may be desirable for some programs to maintain records of unsuccessful fit tests.

### 10.2 Equipment Records

The equipment records should include the following:

a. Test equipment used;
b. Where applicable, identify the equipment model and serial number;
c. Test equipment maintenance, repair, and calibration records; and
d. A copy of the equipment manual(s) for fit testing instrument(s).

### 10.3 Training Records of Fit Test operators

The training records of the person conducting the fit test should include.

a. Name;
b. Training date;
c. Training content; and
d. Method of instruction (for example workshop, seminar, etc.).

**Table I Required and Elective Fit Test Exercises**

| Test Method | Normal Breathing | Deep Breathing | Side to Side | Up & Down | Re-don/ follow NB | Bending Over | Talking | Jog in Place | Stepping | Grimace & Normal Breathing | Vigorous head shake |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Generated aerosol or particle counting | Req. | Req. | Req. | Req. | Elect. | Req. | Req. | Elect. | Elect. | Elect. | Elect. |
| Controlled negative pressure | Req. | Elect. | Elect.[1] | Elect.[1] | Req.* | Req. | N/A | N/A | Elect. | Elect. | Req. |
| Sodium saccharin, Bitrex™, or IAA | Req. | Req. | Req. | Req. | N/A | Elect. | Req. | Elect. | Elect. | N/A | Elect. |

Perform all required and at least one elective exercise for any fit test method.
[1] Requires two measurements.
Req. = Required Exercise
Elect. = Elective Exercise
N/A = Not Applicable
* One re-donning is required for CNP. A second re-donning can be used as an elective exercise

**Table II Exercise Description**

This table describes the required and elective exercises in Table I. Exercises can be conducted in the sitting or standing position. It also shows examples of other job specific exercises that may be added if desired.

For controlled negative pressure where measurement of a fit factor cannot be done during the exercise, static fit factors shall be measured at the end of the exercise. For example, in the side to side exercise, the head is moved side to side for 30 seconds. Fit factors are then measured with the head facing left and right.

| Exercise | Description |
|---|---|
| Normal breathing | The person shall breathe normally, without talking. |
| Deep breathing | The person shall breathe deeply at a comfortable pace with no head movement. |
| Side to side | The person shall turn the head from side to side, pausing at each extreme position for two breath's duration. Warn the person not to bump the respirator or filters/cartridges on the shoulder. For controlled negative pressure, one measurement is made at each extreme position. |
| Up and down | The person shall move the head up and down, pausing at each extreme position for two breath's duration. Warn the person not to bump the respirator or filters/cartridges on the chest. For controlled negative pressure, one measurement is made at each extreme position. |
| Re-don followed by normal breathing | The fit factor is measured after the person loosens all straps and completely removes the respirator from the head and dons it again as trained. |
| Bending over | The person shall bend at the waist, and try to keep the head and back parallel to the floor. Repeat the movement at a comfortable pace pausing long enough to inhale twice at each extreme position. For controlled negative pressure the measurement is made while in the bent position. |
| Talking | The person shall speak loudly enough to be heard by the person who conducts the test. A person may count, recite letters of the alphabet, chat, or read a prepared passage such as the one below. |
| Jogging in place | The person shall jog in place comfortably. |
| Stepping | The person shall continuously step up and down at a comfortable pace using a platform that is approximately 6 inches (15 cm) in height. |
| Grimace and normal breathing | This elective exercise is used for QNFT only. The person shall grimace for approximately 15 seconds followed by the normal breathing exercise. The grimace is an attempt to break the seal of the respirator to the face by smiling or frowning. The purpose is to determine if the respirator reseals itself to the face. The fit factor for the grimace portion of this exercise is excluded from the calculation of the overall fit factor. |
| Vigorous head Shake | The person shall shake the head vigorously from side to side while making a "BRRRR" sound loudly. This exercise shall be performed for at least one exhalation and may be less than 30 seconds in duration. |
| **Examples of Optional Exercises** | |
| Abrasive blasting | The person shall hold a rod in both hands, and slowly swing the arms from side to side in a fashion similar to a blaster's movements. |
| Job specific | The person shall move in a fashion that simulates a specific work activity. The abrasive blasting exercise is an example of a job specific exercise. |



Suggested passage for reading during the talking exercise.

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 man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

## Annex A1: Evaluation Form for Respirator Fit Test Operator

Name of operator evaluated: _____ ____ Date: _____

Fit test method: _____ _____

Evaluated by (program administrator or designee): _____ ____

| Demonstration of knowledge and performance | Acceptable | Not Acceptable |
|---|---|---|
| 5.2.2 Demonstrates knowledge of respirators to be fit tested: | | |
| – Respirator components and their function. | ❑ | ❑ |
| – Respirator inspection, cleaning, and maintenance. | ❑ | ❑ |
| – Different make, model, style, & size respirators. | ❑ | ❑ |
| – Respirator capabilities and limitations as related to respirator fit testing. | ❑ | ❑ |
| – Proper donning and doffing procedures including user seal checks. | ❑ | ❑ |
| 5.2.3 Demonstrates knowledge of the fit test method: | | |
| – Purpose of respirator fit testing. | ❑ | ❑ |
| – Fit test procedures. | ❑ | ❑ |
| – Limitations of the fit test method. | ❑ | ❑ |
| – Questionable fit test results. | ❑ | ❑ |
| – Health and safety hazards associated with the chemicals and equipment used in the fit test. | ❑ | ❑ |
| 5.2.4 Demonstrates ability to set up fit test equipment: | | |
| – Selection of proper cartridges or filters for the fit test method. | ❑ | ❑ |
| – Preparation of required equipment and materials. | ❑ | ❑ |
| – Performance of operational checks. | ❑ | ❑ |
| – Proper installation of probes or fit test adapters used in quantitative fit test methods. | ❑ | ❑ |
| 5.2.5 Demonstrates the ability to conduct the respirator fit test: | | |
| – When to refuse to conduct a fit test. | ❑ | ❑ |
| – Explanation of fit test purpose and procedures to person being fit tested. | ❑ | ❑ |
| – Observation and evaluation of unassisted donning procedure. | ❑ | ❑ |
| – Observation that user seal checks are performed according to manufacturer's recommended procedures. | ❑ | ❑ |
| – Observes the person being fit tested throughout the entire fit test procedure to ensure it is conducted correctly. | ❑ | ❑ |
| – Conducts the fit test method according to ANSI Z88.10. | ❑ | ❑ |
| – Properly interprets and records results. | ❑ | ❑ |
| – Performs respirator cleaning, sanitizing, or disposal. | ❑ | ❑ |
| 5.2.6 Identifies likely causes of fit test failure. | ❑ | ❑ |

## Annex A2: Criteria for Evaluating New Fit Test Methods

**A2.1 Introduction.** The sub-committee recognizes that a universally accepted measurement standard for respirator fit testing does not exist. Previously, generated aerosol systems have been specified by OSHA and others as the reference standard against which all other fit test methods are compared. Qualitative and quantitative fit testing methods have been compared to generated aerosol fit testing methods. This evaluation procedure was developed to ensure that the new fit test method identifies poorly fitting respirators as effectively as the accepted reference method.

While the ideal comparison procedure has yet to be proven, this annex provides a specific procedure for evaluating fit test methods against the current body of knowledge. This procedure was developed to compare new fit test methods with an accepted quantitative method. It involves a statistical comparison of a new fit test method against the generated aerosol method described in this standard.



A proposed modification to an accepted QNFT protocol can be evaluated using the accepted protocol for that instrument as the reference standard.

**A2.2 Requirements.** This procedure involves performing sequential paired fit tests with the new fit test method and the reference fit test method during the same respirator donning. As noted in Annex A2.1, the generated aerosol fit test method (as specified in Clause 7 of this standard) shall be used as the reference standard.

After the exclusion criteria outlined below have been applied, there must be a minimum of 100 sequential paired tests from at least 25 different subjects in the analysis data set.

Any reference fit factor below 10% of the required fit factor accepted by the new fit test method shall disqualify the method. For example, a reference fit factor of 8 that is accepted by the new fit test method as a passing respirator shall disqualify the new method.

At least 50 of these paired tests must have reference method fit factors greater than 5% of the required fit factor and less than the required fit factor.

Reference fit factors less than the required fit factor should be evenly distributed (i.e., not weighted toward the lower fit factors).

Reference method fit factors within one (1) Coefficient of Variation (CV) of the required fit factor should be excluded. One Coefficient of Variation for the reference method can be approximated by identifying a subject having a fit factor near the required fit factor and making multiple measurements on this subject during a single facepiece donning to determine system repeatability.

The order of sequential fit tests should be randomized with respect to test method.

Respirators used for testing shall represent a variety of different sizes and models. The primary purpose of selecting different model respirators is to achieve a variety of different air flow and leak patterns. When evaluating reference fit factors of 500 or higher, the study shall include a representative number of respirators that require that reference fit factor.

The acceptance of a new fit test method is limited to the measurement or detection range over which the method was compared against the reference method. For example, if a required fit factor of 100 was used during the comparison with the reference method, the new fit test method is limited to resolving fit factors of 100.

The following information should be documented:

1. A detailed description of the new fit test method/protocol.
2. A detailed description of the study materials and methods used.
3. A cumulative distribution plot or histogram to visually confirm that the fit factors obtained from the reference method brackets the required fit factor.

4. A table that provides respirator make, model, style, size, individuals tested, and the paired results of the new test and the reference test. Similar information should be provided for any test results which were excluded from analysis.
5. A description of the method and results used to calculate the Coefficient of Variation for the reference fit test method.

**A2.3 Data Analysis:** A 2 × 2 contingency table of the test results should be summarized as shown in Table A 2.1.

**Table 2.1**

| Result | Failed Reference Test FF < RFF | Passed Reference Test FF > RFF |
|---|---|---|
| Passed New Test | A | B |
| Failed New Test | C | D |

The test shall meet a test sensitivity of at least 0.95.

Test Sensitivity:

This criterion provides the probability that the new test will correctly identify an inadequate fit. Report the fraction of fit tests for the new fit test method having fit factors less than the RFF. This fraction must be 0.95 or greater to ensure that those respirators with unacceptable fits will fail the new fit test method. This is expressed as:

$C / (A+C) \geq 0.95$

Beta error is defined as:

Beta error = (1 – Sensitivity)

In addition, for the purpose of comparing all aspects of the two fit test methods the following descriptive statistics should be provided.

1. Predictive Value of a Pass:

   Of those tests that passed the new fit test method, the fraction of reference fit factors equal to or greater than the required fit factor should be reported. This fraction should be 0.95 or greater to ensure that those who pass the new fit test method will have acceptable fits. This is expressed as:

   $B / (A + B) \geq 0.95$

2. Test Specificity:

   Of those fit tests that passed the reference method, the fraction that passed the new fit test method should be reported. This fraction should be greater than 0.50 to ensure that most wearers with acceptable fits will pass the new fit test method. This criterion assures that at least half the cases that pass the reference fit test also pass the new test. This is expressed as:

   $B / (B + D) > 0.50$

3. Predictive Value of a Fail:

   The probability of failing the reference fit test method when the new fit test failed should be reported. This fraction should be greater than 0.50 to ensure that most of those who fail actually have unacceptable fits. This is expressed as:

   $C / (C + D) > 0.50$

4. Kappa statistic:

   The Kappa statistic (K) can be used to calculate the degree of agreement between two fit tests. The Kappa statistic compares the observed proportion of fit tests that are concordant, and the proportion that would be expected if the two tests were statistically independent.

   The observed proportion of concordant fit tests is calculated as:

$$P_o = \frac{B + C}{A + B + C + D}$$

The expected proportion of concordant fit tests is calculated as:

$$P_e = \frac{(A + B)(B + D) + (C + D)(A + C)}{(A + B + C + D)^2}$$

The Kappa statistic is calculated as:

$$K = \frac{P_o - P_e}{1 - P_e}$$

The Kappa statistic can assume a value between -1 and +1, inclusively, where a positive K indicates agreement between two competing tests. A K value > 0.70 is recommended.

### A2.4 Other Considerations

There are a number of important parameters which must be considered when using a Generated Aerosol Quantitative Fit Test Procedure.

Sampling bias associated with the generated aerosol method has been demonstrated with both half and full facepieces. Parameters influencing this bias are:

1. Location and depth of probe;
2. Position of the face-seal leak (nose vs. chin, etc);
3. Interaction of breathing pattern (nose versus mouth) with position of face-seal leak;
4. The design of the facepiece;
5. Measurement sample rate;
6. When the measurement was taken (only on inhalation, only on exhalation, or continuously); and
7. The aerosol size distribution.

## Annex B: Future Research Areas

During the update of this standard, several areas requiring further research were identified. These include developing validation protocols for both qualitative and quantitative fit test methods, research on fit test exercises and their relationship to repeated donnings, studies to investigate the relationship of workplace protection factors to fit factors and fit factors obtained with different quantitative fit test methods to each other.

### Validation Protocols and Studies

Previously, generated aerosol systems have been specified by the Occupational Safety and Health Administration (OSHA) and others as the “reference” or “gold” standard against which all other fit test methods are compared. It is recognized, however, that generated aerosol methods themselves have not been validated.

In 1981, NIOSH used the signal detection theory (SDT) model to evaluate results of paired QLFT and QNFT fit decisions in response to OSHA’s rule-making process with the lead standard. The model was used to evaluate the probabilities of committing type I (alpha) and type II (beta) errors when using a proposed qualitative fit test system. A “false alarm” or alpha error occurs when a wearer is judged to have a fit factor >100 by QNFT but fails the qualitative test. A “miss” or beta error occurs when a wearer is judged to have a fit factor <100 by QNFT but passes the qualitative test. NIOSH proposed that the most important statistic in evaluating the effectiveness of a qualitative fit test method, from the standpoint of worker health, is the beta error (sensitivity).

NIOSH made two important assumptions in using an oil mist generated aerosol QNFT system as a true representation of the actual fit of the respirator. First, NIOSH estimated the coefficient of variation (CV = standard deviation/mean) for QNFT to be 0.08. Secondly, NIOSH assumed that there were no systematic errors or biases in the QNFT measurements.

Subsequent studies have shown both assumptions to be flawed. Data indicate that NIOSH substantially underestimated the CV associated with generated aerosol QNFT. CV’s ranging from 0.23 to 0.82

were observed when leak location and breathing patterns were varied while studying the effects of probe placement on measured fit. It was concluded that common techniques used to sample aerosols from inside a respirator do not provide precise measures of face seal leakage.

NIOSH's second assumption regarding no systematic errors or biases in aerosol-based QNFT measurements has also been proven to be incorrect by several investigators. Generated aerosol QNFT sampling biases as high as - 41 ± 3.4% were measured in five brands of half facepiece respirators. The magnitude of the bias was found to be facepiece dependent. A negative bias indicates that the aerosol QNFT method overestimated the "true" respirator fit as determined by vapor penetration to the bellows region of the mannequin/breathing machine. The high numbers of alpha errors observed by NIOSH during its assessment of QLFT validation studies submitted during OSHA rulemaking for the lead standard support this finding.

**Biological Monitoring Methods**

Biological monitoring methods can be used for comparing fit factors to actual measurements of exposure (respirator's "true" fit factor) by utilizing the wearer as the means to determine the actual fit factor afforded by the respirator during a laboratory study. Using the wearer to determine the "true" fit factor is free of the biases associated with in-facepiece sampling.

**Direct Measurement of Known Respirator Leakage**

Respirator fit test methods assess fit by attempting to measure or detect respirator leakage. Determining the ability of a system to measure or detect a known amount of leakage introduced into a respirator can therefore be used as a means of validating system capability and performance.

Air is the medium that transports contaminants and/or fit test challenge agents through leakage paths into a respirator. For purposes of this method, respirator leakage is therefore defined as air leakage. Since air flow through a leak source is a direct function of the pressure gradient across it, determination of the mean inspiratory pressure inside a test respirator during a fit test provides a basis for introducing a known leak rate through a fixed leak source. Both the pressure gradient across the source and the leakage flow rate through it can be measured and validated using primary calibration standards such as water manometers and frictionless piston flow meters.

**Research on Fit Test Exercises**

There is a need to better understand how different exercises affect the outcome of a respirator fit test. Specifically, research is needed to:

- Compare high work rate exercises (e.g., jogging in place) with low work rate exercises. Studies are required to determine the importance of repeat donnings being included in a fit test protocol.
- Research is needed to determine whether the fit differs if the measurement is taken while the subject is performing the exercise or after the exercise is completed.

**Correlation Studies**

- It is recognized that workplace protection factor studies do not show a strong correlation with fit factor determinations obtained from respirator fit testing. Therefore, workplace protection factor studies can not be used to validate current methods. Further research on using fit factors to predict actual workplace performance is needed.
- It has been noted that the three quantitative fit test methods listed in the standard (i.e., generated aerosol/photometer, particle counting, and controlled negative pressure) provide different fit factor values for the same fit. The relationship between the fit factors obtained from the three methods needs to be better defined.

**New Fit Test Methods**

- A small size (approximately 1 micrometer) particulate qualitative fit test is needed to supplement saccharin/ Bitrex™. This would make the particle qualitative fit test methods more comparable to the particle quantitative fit test methods and eliminate concerns regarding whether a respirator fit tested with a large size aerosol would provide sufficient protection against a smaller size aerosol in the workplace.

  A means for generating a continuous uniform challenge atmosphere for qualitative fit testing needs to be developed.
- A statistical comparison method for evaluating new fit test methods over a range of fit factors needs to be developed.

  Alternative Analysis for New Fit Test Method Validation

**Binary Logistic Regression Analysis**

An alternative approach to evaluate a new fit test method is to use a binary logistic regression analysis.

The relationship between increasing reference fit factors and the probability of passing a new method can be quantified by a regression equation. Since the outcome of a fit test is pass/fail, a binary logistic regression analysis can be used to access the probability of passing a new fit test as a function of the reference method fit factor. Using regression analysis function software (for example, MiniTabTM)the reference fit factor is compared with the outcome of the fit test under evaluation (pass/fail).

A strength of this technique is that it uses all of the fit test data. The sensitivity of a new fit test method is influenced by the distribution of the fit factors in the data set. The extent to which this limitation can be accounted for in the logistic regression model needs to be defined. This sub-committee evaluated the binary logistic regression model and was unable to determine appropriate decision criteria for using the logistic regression method.

The subcommittee felt the method has merit, but requires additional research before being used to evaluate new fit test methods.

- Results of existing and future validation studies of fit test methods need to be corroborated by independent investigators.

**Informational Supporting Documentation**

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# ANSI/AIHA Z88.10–2010 Respirator Fit Testing Methods

BY THE ANSI/AIHA Z88.10 SUBCOMMITTEE

Respiratory protection program managers receive clear and consistent guidance on the respirator fit-testing components of an effective respiratory protection program. This guide includes instructions regarding potential interference from personal protective equipment, detailed information on respirator face pieces, selection of face pieces, and other considerations for effective fit testing.



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