RESPIRATOR FIT TESTING

I. FIT TESTING GENERAL INFORMATION

A. Fit Testing. Fit testing is a qualitative or quantitative protocol used to evaluate sealing surface leakage of a specific tight-fitting respirator while worn by an individual. Individuals do not have to be issued the same respirator that they are fit tested with as long as they are issued a respirator that is the same make, model, style, size, and material of respirator with which they are fit tested. There are two categories of respirator fit testing, which include qualitative and quantitative fit testing methods.

1. Qualitative Fit Testing. Qualitative fit testing (QLFT) involves a test subject's response (either voluntary or involuntary) to a fit test challenge agent during a series of test exercises while wearing a respirator. These tests are fast and easily performed using inexpensive equipment. Because they are based on the respirator wearer's subjective response, accuracy may vary. Qualitative fit tests include the irritant smoke test, the odorous vapor test, and two taste tests. Each type of qualitative fit test requires a sensitivity screening test to ensure that the individuals being fit tested can detect the fit test agent. Individuals who cannot detect the challenge agent cannot be fit tested by that method.

a. Passing a qualitative fit test is equivalent to achieving a fit factor[1] of 100 during quantitative fit testing. In qualitative fit test protocols (except for irritant smoke), the concentration during the fit tests is about 100 times higher than the sensitivity screening tests concentration.

b. Analogously, a quantitative fit test fit factor of 100 means that the concentration outside the respirator is 100 times greater than the concentration inside the respirator. Therefore, in qualitative fit testing, if the challenge agent is not detected the person passes the qualitative fit test and is assumed to have a fit factor equivalent to passing a quantitative fit test with a fit factor of 100.

2. Quantitative fit testing. Quantitative fit testing (QNFT) uses an instrument to determine the amount of leakage between the sealing surface of the respirator and the face by measuring the concentration of a test agent both inside and outside of the respirator during a series of test exercises and then calculating an overall fit factor.

B. Resistance to Fit Testing. Reference 1 reported that over three million American workers are required to wear respirators. However, reference 2, which was a follow-up study to reference 1, indicated that fit testing was not provided by approximately half of the establishments where tight-fitting respirators are used. This is largely due to the cost of fit testing. The preamble to the Occupational Safety and Health Administration (OSHA) Respirator Standard (reference 3) stated that, "*The most costly provisions [to the respirator program] are those requiring annual fit testing of respirators and annual refresher training. These two provisions together account for approximately 90 percent of the standard's compliance costs.*"

[1] According to ANSI Z88.2, a fit factor is 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})

C. Reasons for Fit Testing. According to the preamble of reference 3, OSHA included the annual fit test requirement in the final rule because fit testing not only determines whether a facepiece seal is adequate; it also provides an opportunity to check that fit is acceptable. Fit testing permits the employee to reduce unnecessary discomfort and irritation by selecting a more comfortable respirator and reinforces respirator training by providing users with a hands-on review of the proper methods of donning and wearing the respirator. As well as providing the opportunity to detect poorly fitting respirator facepieces, the annual fit testing requirement complements OSHA's requirement for annual respirator training.

1. According to reference 4, there are many reasons why fit testing should be conducted. Some of the more significant reasons to conduct fit testing are summarized as follows:

a. Fit testing can identify poorly fitting respirators that will not provide adequate protection due to face seal leakage. Failure to identify individuals with poorly fitting respirators could put them at significant and unnecessary risk.

b. Fit testing has been successfully used to identify defective respirators that were not identified during routine inspection by the user. Defective respirators may result from improper storage, maintenance, care, or simply due to degradation that naturally occurs with aging respirator components.

c. Perhaps the most beneficial aspect of fit testing respirator wearers is the training opportunity it provides. Fit testing is one of the rare situations that permits an individual to have personalized training. During fit testing, the respirator wearer can have their respirator inspected by the fit test operator who has had more experience inspecting respirators. In addition, the wearer can be observed during donning to evaluate their donning and user seal check techniques, evaluate deficiencies, and make recommendations. Finally, the fit test operator can provide insight not generally available in a classroom training session.

d. Information available at the time of the fit test is vitally important. For example, the process of fit testing respirators can provide a level of training not generally appreciated, especially when fit testing is used to help select a better fitting respirator. Another function is the positive feedback it can provide during mask donning during the fit test. This kind of feedback may be vital to determine whether the mask is donned correctly. The ability to practice donning procedures while simultaneously conducting a fit test is a very valuable training tool. **Individuals who practice mask donning without access to fit testing (in the absence of any feedback) may simply reinforce improper donning techniques.** Feedback should be provided to every respirator wearer and is considered an indispensable part of an effective respirator training program.

e. In the industrial environment, the fit test is often used as the final exam to assess the wearer’s ability to don the facepiece without any assistance and then subsequently pass the fit test. When used in this fashion, the fit test provides a method to evaluate the level and understanding of information provided during respirator training. Testing is a common practice used to evaluate an

individual's level of understanding. For example, a driving test is used to "prove" the individual can operate a car. Other testing is frequently used to demonstrate a minimum level of proficiency. In this case, the fit test can be used to demonstrate that the user can properly don the facepiece and adjust the straps without any assistance.

2. In summary, the advantage of fit testing is that respirator wearers who successfully pass fit testing and achieve competent training in respirator use, care, and donning techniques are more likely on average to achieve a higher level of protection than individuals who do not participate in fit testing.

D. Reasons for Annual Fit Testing. The preamble to reference 3 discusses OSHA rulemaking decisions concerning the annual fit test requirement and included comments from the industrial respirator user community. An employer that performed fit testing every two years reported that 7% of their employees switched to different respirator sizes and/or models each time they were fit tested. OSHA considered 7% too high and unacceptable and adopted the policy to require annual fit testing and training.

1. The preamble further explains that physiological changes that affect respirator facepiece fit can occur gradually over time and are easily overlooked by observers, and by the users themselves and that is why annual fit testing is necessary. However, if observed changes in an employee's physical condition indicate the need for retesting then an additional fit testing is performed.

a. The preamble warned that retesting facepiece fit solely based on observing physical changes in individual respirator users is not a reliable substitute for fit testing on an annual basis.

b. The preamble specifically stated that,

"*Individuals with poorly fitting respirators were often detected only through fit testing, and not by other methods such as observation of changes in facepiece fit, failure to pass a user seal check, or an employee reporting problems with the fit of the respirator.*"

II. FIT TESTING REQUIREMENTS

A. OSHA Fit Testing Requirements. OSHA defines fit testing as the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual. Per 29 CFR 1910.134(f)(1) and (f)(2), all personnel wearing tight-fitting facepieces must be either qualitatively or quantitatively fit tested initially and at least annually with the same make and model of respirators that they wear.

1. Paragraphs (f)(3) and (f)(4) state that if the program administrator or the employee observe or perceive reasons that the fit of the assigned respirator is unacceptable, then the employee will be allowed to select a different respirator and be re-fit tested.

2. Paragraph (f)(5) requires that fit testing be performed according to OSHA-accepted protocols that are contained in Appendix A of reference 3. Appendix A qualitative protocols include:

a. Isoamyl Acetate,

b. Saccharin Solution Aerosol,

c. Bitrex™ (Denatonium Benzoate) Solution Aerosol, and

d. Irritant Smoke.

3. With the exception of Bitrex™, the qualitative tests were modified from the lead standard, 29 CFR 1910.1025.

4. Fit testing negative pressure respirators. Non-powered air-purifying respirators operate by the wearer creating negative pressure inside the facepiece during inhalation. This negative pressure results in protecting the wearer from inhaling contaminated ambient air by pulling the air through air-purifying filter(s), which clean the air before it enters the lungs. The same negative pressure can also result in drawing contaminated workplace air into the facepiece if there are leaks in the facepiece seal. Like negative pressure air-purifying respirators, the pressure in the facepieces of demand type atmosphere supplying respirators is negative during inhalation because regulators of demand respirators permit airflow only during inhalation. Due to negative pressure during inhalation, the protection level of half mask and full face demand type atmosphere supplying respirators is identical to half mask and full face non-powered air purifying respirators.

a. Per paragraph (f)(6), negative pressure air-purifying respirators that are qualitatively fit tested can only be worn in atmospheres up to 10 times the exposure limit. Passing a qualitative fit test method is equivalent to achieving a fit factor of 100 by a quantitative fit test method (Half mask respirators must achieve a fit factor of 100 to pass a quantitative fit test.) The fit factor of 100 includes a safety factor of 10 and equates to a protection factor of 10, which is the referred to as the "assigned protection factor" (APF)[2] for half mask air-purifying respirators. Full face air-purifying respirators can be fit tested qualitatively; however, they cannot be worn in atmospheres with contaminant concentrations greater than 10 times the exposure limits.

i. According to page 1225 of the preamble to the OSHA Respirator Standard (reference 3), the fit factor achieved by qualitatively fit testing negative pressure air-purifying respirators is limited to 100. The preamble's explanation is reproduced below:

(i) *"This limitation is based on the fact that the existing evidence only validates the use of qualitative fit testing to identify users who pass the QLFT with a respirator that achieves a minimum fit factor of 100. Dividing the fit factor of 100 by a standard safety factor of 10 means that a negative pressure air purifying respirator fit tested by QLFT cannot be relied upon to reduce exposures by more than a protection factor of 10. The safety factor of 10 is used because protection factors*

[2] APFs are defined as the workplace levels of respiratory protection provided by properly functioning and properly worn respirators or class of respirators when all elements of an effective respiratory protection program are established and are being enforced. APFs indicate the protection level of a respirator or a class of respirators. For example, the APF of 10 for half mask respirators correlates to the workplace contaminant concentration being ten times lower inside the respirator than outside – protects up to 10 times the occupational exposure limit.

in the workplace tend to be much lower than the fit factors achieved during fit testing; the use of a safety factor is a standard practice supported by most experts to offset this limitation."

ii. Therefore, qualitatively fit tested half mask and full face negative pressure, air-purifying respirators cannot be worn in concentrations greater than 10 times the occupational exposure limits (OELs).

iii. To wear full face air-purifying respirators in atmospheres up to their assigned protection factor of 50, they must be quantitatively fit tested and achieve a fit factor of at least 500, which includes a safety factor of 10.

b. Demand type atmosphere supplying respirators. Demand airline respirators and demand open-circuit SCBA (self contained breathing apparatus) used for entering hazardous atmospheres are no longer manufactured. However, the same fit testing policy for negative pressure air-purifying respirators would apply to negative pressure atmosphere supplying respirators if they were still being used. For instance, a full face demand SCBA must be quantitatively fit tested, with a passing fit factor of at least 500, to be worn with the higher APF of 50 and a full face demand SCBA that is qualitatively fit tested only has an APF of 10.

5. Fit testing positive pressure respirators. Tight-fitting, positive pressure respirators, including PAPRs shall be fit tested in the negative pressure mode (fit tested as negative pressure air-purifying respirators). This can be accomplished by either temporarily converting the facepiece, per manufacturer's instructions, into a negative pressure air-purifying respirator or by using a "surrogate" negative-pressure facepiece with sealing surfaces and materials that are identical to the wearer's positive pressure facepiece. In other words, if the facepiece sealing surfaces and materials are indistinguishable from the positive pressure respirator facepiece, then the negative pressure, air-purifying respirator can be worn as a surrogate during fit testing.

a. For industrial use, including firefighting, OSHA allows positive pressure respirators to be either qualitatively or quantitatively fit tested. Fit testing positive pressure respirators is to ensure there is no gross leakage in the facepiece seal.

b. According to OSHA, positive pressure half mask and full face respirators that are quantitatively fit tested shall pass with a minimum fit factor of 100 and 500, respectively. Individuals may wear positive pressure respirators up to the assigned protection factor of the respirator after passing either qualitative or quantitative fit testing.

6. Table 1, which is adapted from reference 5, summarizes acceptable qualitative and quantitative fit testing for types of tight-fitting negative and positive pressure respirators. Table 1 also indicates the assigned protection factor for classes of respirators depending upon the type of fit test.

Table 1 Assigned Protection Factors for Classes of Respirators Qualitatively or Quantitatively Fit Tested			
Type of Respirator	**APF**	**Qualitative Fit Testing**	**Quantitative Fit Testing**
Filtering Facepiece Respirator	5	Yes	Yes
Half Mask Elastomeric Air-purifying Respirator	10	Yes	Yes
Full Facepiece Elastomeric Air-purifying Respirator	10	Yes	–
Full Facepiece Elastomeric Air-purifying Respirator	50	**No**	Yes
Powered Air Purifying Respirators (PAPR) (half mask)	50	Yes	Yes
Powered Air Purifying Respirators (full face or hood with tight-sealing neck dam)	1,000	Yes	Yes
Positive Pressure Supplied-Air Respirator (Pressure Demand and Continuous Flow) (half mask)	50	Yes	Yes
Positive Pressure Supplied-Air Respirator (Pressure Demand and Continuous Flow) (full face)	1,000	Yes	Yes
Negative Pressure Supplied-Air Respirator (Demand) (half mask)	10	Yes	Yes
Negative Pressure Supplied-Air Respirator (Demand) (full face)	10	Yes	–
Negative Pressure Supplied-Air Respirator (Demand) (full face)	50	**No**	Yes
Negative Pressure Self Contained Breathing Apparatus (Demand) (half mask)	10	Yes	Yes
Negative Pressure Self Contained Breathing Apparatus (Demand) (full facepiece or hood with tight-sealing neck dam)	10	Yes	–
Negative Pressure Self Contained Breathing Apparatus (Demand) (full facepiece or hood with tight-sealing neck dam)	50	**No**	Yes
Pressure Demand Self Contained Breathing Apparatus (full facepiece or hood with tight-sealing neck dam)	10,000	Yes	Yes
Loose-fitting hoods and helmet respirators	Fit testing is not applicable.		
Mouth-piece respirators	Fit testing is not applicable.		

7. Voluntary Use Respirators. Per the OSHA Respirator Standard (reference 3), respirators issued for voluntary use do not require fit testing.

8. Fit Test Operators. OSHA qualifications for fit test operators are set forth in Sections B.1(a), B.1(b), C.1.(a), and C.1(b) of the OSHA Respirator Standard Appendix A. Fit test operators must have the ability to:

a. Prepare test solutions;

b. Calibrate equipment;

c. Perform the fit tests correctly;

d. Recognize invalid tests;

e. Ensure qualitative and quantitative test equipment is properly maintained to ensure proper performance;

f. Calculate fit factors properly;

g. Ensure that the qualitative and quantitative fit test equipment is cleaned, calibrated, and maintained to operate within the parameters for which it was designed;

h. Calculate fit factors;

i. Clean and inspect test respirators. Fit test respirators must be cleaned after each use and inspected before each use.

i. Per paragraph I.1. of CPL 2-0.120 (reference 5), during fit testing the use of individually-wrapped cleaning towelettes may be used between employees being tested, however these respirators must be thoroughly cleaned at the end of each day.

ii. However, most of the respirator community, including the ANSI Z88.10 and Z88.2 Subcommittees, do not consider using towelettes a proper respirator cleaning method and do not recommended their use. Therefore, have a sufficient number of respirators during fit test sessions so that they do not have to be cleaned in-between fit tests. Clean and sanitize them later per manufacturer's instructions.

j. Recognize properly conducted user seal checks.

B. ANSI Z88.2-1992 Fit Testing Requirements. ANSI Z88.2 (reference 6) required fit testing each person issued a tight-fitting respirator (clause 4.5.6). Fit testing was an annual requirement (clause 9.1.4) and fit testing and could be either a qualitative or a quantitative fit test (clause 9). Clause 9 referred the reader to ANSI Z88.10 for acceptable fit test methods.

1. Clause 9.1 states that if a quantitative fit test is used for negative pressure respirators the fit factor must be at least 10 times greater than the assigned protection factor. For example:

a. Since half mask air-purifying respirators have an APF of 10, the passing fit factor is 100 with the safety factor of 10.

b. Similarly, since full facepiece air-purifying respirators have an APF of 50, the passing fit factor is 500 with the safety factor of 10.

2. Clause 9.1.2 required positive pressure respirators to be either qualitatively or quantitatively fit tested as negative pressure respirators and only required a quantitative fit factor of at least 100. Since these respirators were positive pressure, the logic for performing these fit tests was to detect gross leakage in the facepiece sealing surface.

C. ANSI Z88.10 Respirator Fit Test Standard. ANSI Z88.10 (reference 7) provides guidance for respiratory protection program managers (RPPMs) on performing this critically important element of the respirator program. It not only provides qualitative and quantitative fit test protocols, but also provides in-depth requirements for training fit test operators, and includes a large section entitled *General Considerations* covering in detail important considerations for performing all respirator fit testing protocols.

1. Clause 6, General Considerations. Important considerations from this section of ANSI Z88.10 are summarized below:

a. Medical Evaluation - Prior to fit testing, everyone receives medical evaluation to ensure they are medically fit to wear the respirator. For respirator medical evaluation, ANSI Z88.10 refers readers to ANSI Z88.6 (reference 8), 29 CFR 1910.134 (reference 3), or other regulatory standards, which includes Navy occupational safety and health instructions OPNAVINST 5100.23 and 19 series.

b. Pre Fit Test Training - Respirator wearers receive respirator training prior to fit testing, including:

i. How to don the respirator without assistance. Z88.10 recommends using a mirror to see how to position and adjust the respirator.

ii. Receive training on the fit test challenge agent, including any health and safety hazards.

iii. Learn how to inspect the respirator.

iv. Learn and demonstrate how to accomplish user seal checks.

c. Respirator Sealing Surface Interference – Including:

i. Facial hair. Hair shall not interfere with respirator sealing surfaces or valve function. This includes the requirement for being clean shaven (with 24 hours required, 12 hours preferable).

ii. Do not perform fit testing if any foreign material such as eyewear straps or temple bars, gels, or creams are present between the sealing surfaces of the person and the respirator.

iii. Personal protective equipment must not interfere with respirator sealing surfaces and must be worn during fit testing.

iv. Other conditions that can adversely affect fit include:

1. Possible facial feature interference can include hollow temples, exceedingly protruding cheekbones, deep skin creases,

absence of teeth or dentures, facial injury including mouth or facial swelling.

2. The absence of one or both dentures. If dentures are worn during respirator use, then dentures shall be worn during fit testing. If dentures are not worn during respirator use, then dentures are not worn during fit testing.

3. Cosmetics, facial jewelry, and certain hair styles can interfere with the respirator sealing surface.

d. Fit Testing Frequency. Fit testing is performed initially, whenever a different respirator is issued, and during annual fit testing.

i. Fit testing is also accomplished when any of the following occurs:

(i) Significant weight gain or loss.

(ii) Change in facial sealing surface, such as facial surgery and scarring.

(iii) Dental changes.

(iv) Respirator wearer discomfort.

e. Fit Testing is performed in the negative pressure air-purifying mode. Both negative pressure and positive pressure tight-fitting respirators are fit tested as negative pressure air-purifying respirators.

i. Negative pressure respirators are used during fit testing. Respirators used in fit testing may be either the respirator already assigned to the individual or a surrogate. According to clause 6.5 of Z88.10, "*A surrogate respirator facepiece having sealing surfaces, materials and head straps that are the same as the respirator to be assigned to the wearer.*" In other words, respirator wearers do not have to be issued the exact same respirator they were fit tested with, but they must wear one of the same make, style, model, material, and size.

ii. Fit test positive pressure respirators in the negative pressure mode. Positive pressure respirators may be temporarily converted to negative pressure air-purifying respirators by one of the following two methods:

(i) Air-purifying facepieces that are identical to positive pressure respirator facepieces may be used as surrogate facepieces. These surrogate air-purifying facepieces must be produced by the same respirator manufacturer and must be made of the same material, with the same sealing surfaces, and straps and be the same facepiece size as the positive pressure respirator facepiece.

(ii) Convert positive pressure respirators into negative-pressure respirators according to respirator manufacturer's instructions and equipped with filters appropriate for the fit test. These modifications shall not significantly alter how the respirator sealing surfaces fit the wearer.

(iii) After fit testing, positive pressure respirators must be restored to their NIOSH approved configuration before being worn as respiratory protection to control worker exposure.

(iv) Positive pressure tight-sealing hoods with neck dams are fit tested using requirements for fit testing full facepiece respirators.

f. Fit Test Filters/Cartridges/Canisters. Fit test respirators must be equipped with filters/cartridges/canisters appropriate for the fit test method.

i. Isoamyl Acetate Fit Test Protocol requires organic vapor canisters or cartridges.

ii. Saccharin Solution Aerosol Fit Test Protocol was designed for 95 % efficiency filters but any particulate filter can be used.

iii. Bitrex™ (Denatonium Benzoate) Solution Aerosol Fit Test Protocol was designed for 95 % efficiency filters but any particulate filter can be used.

iv. Irritant Smoke Fit Test Protocol requires high efficiency filters (N, R, P 100 filters).

(i) Unlike the 2001 version of this standard, ANSI Z88.10-2010 did not include the irritant smoke protocol because it did not pass the ANSI Z88.10 *Test Sensitivity* criteria for validating fit test methods. The *Test Sensitivity* is the most important ANSI fit test validation criteria because it determines the probability that the test method will correctly identify inadequately fitting respirators.

(ii) ANSI Z88.10 requires that fit test methods correctly detect at least 95% of respirators with unacceptable fits. Three out of four of the studies performed on the irritant smoke protocol showed that this protocol did not meet this criterion.

v. The weight of cartridges, and filters can significantly affect fit. For example, the weight of combination chemical cartridges with particulate filters will be significantly heavier than a particulate filter alone. Therefore, whenever possible, the respirator used during the fit test should be equipped with the type of filtration required for protection in the workplace.

D. Navy Shore Based Fit Testing Requirements. Paragraph 1509.a of OPNAVINST 5100.23 Series (reference 9), requires fit testing each individual who must wear a tight-fitting facepiece respirator at the time of initial fit testing and annually thereafter. Perform fit testing according to 29 CFR 1910.134 (See Appendices A – F of this document). To summarize Navy fit testing policy:

1. All tight-fitting positive and negative pressure respirators must be either qualitatively or quantitatively fit tested initially and annually. All CBRN respirators (except for CBRN escape only respirators, which cannot be fit tested) must be quantitatively fit tested (See Chapter 26 of reference 9).

2. To wear full face, air purifying respirators in atmospheres up to their assigned protection factor of 50 they must be quantitatively fit tested and achieve a fit factor of at least 500, which equates to a safety factor of 10 (paragraph 1509.b).

3. Paragraph 1503.c. states that activities shall fit test, issue, and train personnel to wear respirators and ensure personnel are medically qualified. Navy policy requires medically evaluating civilian respirator wearers according to the Medical Surveillance Procedures Manual/Medical Matrix. Navy military personnel, who have been confirmed as "Fit for Full Duty" (that is having no deployment-limiting conditions) and having a current annual Periodic Health Assessment are deemed medically qualified for use of all types of respirators (See references 9 and 10).

4. There is an exception for medically evaluating visitors and personnel not assigned to work areas where activities provide escape-only respirators for potential emergencies.

a. The intent of paragraph 1503.c. is to wave medical evaluation requirements for visitors and other personnel NOT assigned to work areas requiring escape-only respirators. Policy is not intended to wave medical evaluation for personnel assigned to these areas. Personnel assigned to these areas shall be included in the complete respirator program, including medical evaluation and training in the use and limitations of escape respirators.

b. Any respirator that protects adequately against a suddenly occurring hazardous atmosphere may be used for escape purposes; however, this does not make that respirator an "escape-only" respirator. Escape-only respirators are devices designed and approved for use only during escape from hazardous atmospheres. Although medical evaluation is required for personnel assigned to wear escape-only respirators, most of these escape-only respirators are either mouthpiece respirators or hooded devices, which are lightweight and do not lend themselves to be fit tested.

c. However, some work areas require full face pressure demand open-circuit SCBAs or tight-fitting gasmasks for escape and personnel may have to walk for two miles or climb a ladder to escape from the complex while wearing these respirators.

i. According to paragraph 1503.c., all personnel, including visitors, who may need to escape while wearing tight-fitting respirators, such as these shall be found medically able to do so.

ii. Also, these respirators come in different sized facepieces and fit testing is critical not only to ensure that facepieces do not leak for prevention of inhalation exposure; but also in the case of SCBAs, to prevent excess leakage that causes loss of air supply during escape.

d. Although the Navy does not require medically evaluating visitors and personnel not assigned to worksites where activities provide escape-only respirators for potential emergencies; they shall be trained in how to don and use the escape-only respirator according to the respirator manufacturer's instructions

and be escorted at all times by personnel who are trained in the use of the respirator and who can guide and assist them in emergencies.

e. To reiterate this important point, personnel assigned to work in areas where escape-only respirators are provided for potential emergencies shall be medically evaluated to determine if they can wear the escape-only respirator - the exception for medical evaluation is for visitors to these areas.

5. Navy Voluntary Respirator Use Fit Test Policy. Voluntary respirator use is allowed when respirators are not required to control exposures if the respirators are issued and controlled by the RPPM. NIOSH approved filtering facepiece respirators may be issued without medical screening and fit testing when the contaminant of concern to the employee is a particulate. When the contaminant of concern to the employee is a gas or vapor, NIOSH approved elastomeric respirators equipped with appropriate chemical cartridges may be issued for voluntary respirator use. However, all elements of the respiratory protection program must be met, including medical screening and fit-testing. Hooded positive pressure respirators are also permitted for voluntary use. Their use requires compliance with all elements of the respiratory protection program.

6. OPNAVINST 5100.23 Series Fit Test Operator Training. Qualifications for fit test operators are covered in paragraph 1512.e., which states, "*Personnel assigned by the RPPM to conduct respirator fit testing should be trained and evaluated according to clause 5 and Annex A1 of* [ANSI Z88.10-2010]." Please see the ***QUALIFICATIONS FOR FIT TEST OPERATORS*** in Appendix H, which contains the crux of the information for training fit test operators in clause 5 and Annex A1 of ANSI Z88.10-2010.

E. Navy Shipboard Fit Testing Requirements. Paragraph B0608 of OPNAVINST 5100.19 (reference 10) Series states that "*Each individual who is required to use a respirator shall be qualitatively or quantitatively fit tested before being issued a respirator and annually thereafter unless the user is to wear a SCBA. SCBA are exempt from the requirement to fit test.*"

1. Qualitative Fit Testing. Qualitative fit testing may be performed using isoamyl acetate (banana oil), saccharin mist, irritant smoke, or Bitrix method according to the protocols in Appendix B6-C. This shipboard fit testing annex is based on OSHA fit testing protocols (See Appendices A – F of this document.).

2. Quantitative Fit Testing. Personnel using respirators to protect against asbestos and lead exposure may require quantitative fit testing, per Federal regulations. (This is for full face respirators worn in concentrations exceeding 10 times the OEL.) This type of fit testing can only be performed by, and shall be requested from, shore activities.

3. Shipboard Fit Test Operators. For all ships, anyone trained to fit test via training detailed in paragraph B0612 can perform fit testing. Paragraph B0612 identifies that training as the *Respiratory Protection Program Management course (CIN A-493-0072)* or the *Respiratory Protection Manager course (CIN A-4J-0082)* taught by the

Naval Occupational Safety and Health and Environmental Training Center (NAVOSHENVTRACEN).

III. REFERENCES

1 Bureau of Labor Statistics/ National Institute for Occupational Safety and Health: *Respirator Usage in Private Sector Firms, 2001*. Washington, D.C.: U.S. Department of Labor/Bureau of Labor Statistics and U.S. Department of Health and Human Services/Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health, 2003. pp 67 and 219.

2 Campbell, D.C., Doney B., Groce D., et al.: Respirator fit testing practice in the U.S. Journal of the International Society for Respiratory Protection, 22(I-II): 11-16 (2005).

3 Occupational Safety and Health Administration (OSHA): 29 CFR Parts 1910 and 1926 Respiratory Protection: Final Rule. Federal Register 63(5):1278–1279. Washington, D.C.: U.S. Government Printing Office, Office of the Federal Register, January 8, 1998, as amended 8June 2011.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards

4 McKay, R, T.: Fit Testing and Use of Negative Pressure Respirators for Protecting Military Personnel Against Chemical Warfare Agents, University of Cincinnati Report for NAVSEA (1998) 69 pages.

5 Occupational Safety and Health Administration (OSHA): Inspection Procedures for the Respiratory Protection Standard. OSHA Directive CPL 2-0.120, 1998, as amended on 14 July 2004.
http://www.osha.gov/Publications/SECG_RPS/CPL_2-0_120.pdf

6 American National Standards Institute (ANSI): American National Standard for Respiratory Protection (ANSI Z88.2). New York: ANSI, 1992.

7 American National Standards Institute (ANSI) ANSI)/American Industrial Hygiene Association (AIHA)**:** American National Standard for Respirator Fit Testing Methods (ANSI/AIHA-Z88.10).Fairfax, VA: AIHA, 2010.

8 American National Standards Institute (ANSI) ANSI)/American Industrial Hygiene Association (AIHA): American National Standard for Respirator Use: Physical Qualifications for Personnel (ANSI/AIHA-Z88.6). Fairfax, VA: AIHA, 2006.

9 OPNAVINST 5100.23 Series.
http://doni.daps.dla.mil/allinstructions.aspx?RootFolder=/Directives/05000%20General%20Management%20Security%20and%20Safety%20Services/05-100%20Safety%20and%20Occupational%20Health%20Services&View={1FF912B1-1BC6-444A-8943-B769C77880F2}

10 OPNAVINST 5100.19 Series.
http://doni.daps.dla.mil/allinstructions.aspx?RootFolder=/Directives/05000%20General%20Man

agement%20Security%20and%20Safety%20Services/05-100%20Safety%20and%20Occupational%20Health%20Services&View={1FF912B1-1BC6-444A-8943-B769C77880F2}

APPENDIX A

FIT TESTING

RESPIRATOR SELECTION PROCESS

I. FIT TEST RESPIRATOR SELECTION PROCESS

A. OSHA Qualitative Fit Test Protocols. OSHA qualitative fit test protocols are in *Mandatory Appendix A of 29 CFR 1910.134* (reference 1). Prior to selecting a respirator, OSHA requires instructing the person being fit tested on how to don the respirator, how to position it on their face, how to set strap tension, and how to determine a "comfortable" respirator. These fit testing instructions are no substitute for respirator training. These instructions are a brief training review prior to fit testing. The following procedures apply to all fit test protocols, both qualitative and quantitative.

1. The OSHA Respirator Standard requires that, "*The employee shall select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user*." In contrast, the lead and asbestos standards used to require selection from at least five sizes from at least two respirator manufacturers.

Note: When performing the Isoamyl Acetate Protocol, conduct the respirator selection process in a room separate from the fit test chamber and the room where odor threshold screening is performed to prevent olfactory fatigue.

2. Ensure that a mirror is available to assist the subject in positioning the respirator and in evaluating the fit.

3. Have the test subject hold each facepiece up to their face and eliminate those facepieces, which are obviously not giving them a comfortable fit.

4. Inform the test subjects that they are to select the respirator, which provides them the most comfortable fit. In general, the most comfortable respirator will also fit the best. If the person being fit tested is not familiar with using a particular respirator they may don it several times and adjust the straps to become accustomed with proper strap tension.

5. To assess comfort, allow the person being fit tested to wear the respirator they have chosen as most comfortable for at least 5 minutes. According to reference 2, the comfort assessment period allows the respirator wearer time to determine if the respirator is truly comfortable and to make adjustments. Respirator 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. Reference 2 also states that it is critical that all respirator wearers don and adjust their respirators just as they would when wearing it for respiratory protection and that wearing a respirator for a period of time prior to the start of the fit test may be more representative of respirator use conditions. To help assess comfort, the person conducting the fit testing shall review the following points with the test subject:

a. Proper chin placement;

b. Positioning of mask so that hair does not break the sealing surface;

c. Ensure that straps are lying flat against the head and neck with no twists;

d. Sequence of tightening straps ;

e. Strap tension;

f. Importance of a comfortable fitting respirator;

g. Interference with ability to talk;

h. Tendency of respirator to slip;

i. Visibility through the lens;

j. Self-observation in mirror; and

k. Adequate time for assessment.

6. Have the person being fit tested conduct user seal checks. OSHA states in the preamble to reference (1) that there are respirators that user seal checks cannot be performed on and that these respirators cannot be used to control exposure. User seal checks are not substitutes for fit testing. Reference 3 examined whether user seal checks are appropriate substitutes for respirator fit testing. Their research consisted of fit testing populations of both experienced and non-experienced (naïve) N95 filtering facepiece respirator users immediately after they performed user seal checks and indicated that they had an adequate face seal prior to fit testing. Their research results are reproduced below:

> *Only four of the 647 naïve subjects (0.62%) identified an inadequate seal during their user seal check. Of the 643 remaining naïve subjects who indicated that they had an adequate face seal prior to fit testing, 158 (25%) failed the subsequent quantitative fit-test and 92 (14%) failed the qualitative fit-test. All 137 experienced users indicated that they had an adequate seal after performing the user seal check; however, 41 (30%) failed the subsequent quantitative fit-test, and 30 (22%) failed the qualitative fit-test. These findings contradict the argument to eliminate fit-testing and rely strictly on a user seal check to evaluate face seal.*

a. For filtering facepiece respirators, have the fit test subject perform user seal checks according to the manufacturer's instructions provided with the respirator. These instructions are also found on the NIOSH website "*Manufacturer's Donning Procedure User Instructions*."

b. User seal checks for elastomeric facepieces are described in Appendix B-1 of the OSHA Respirator Standard. Before conducting the user seal checks, have person "seat" their mask by rapidly moving the head side to side and up and down, and taking a few deep breaths. Select another facepiece if user seal checks are unsuccessful.

i. Negative pressure user seal check (Figure A-1). The inlet opening of the respirator's canister, cartridge(s), or filter(s) is closed off by covering with the palm of the hand(s) or by squeezing a breathing tube or blocking its inlet so that it will not allow the passage of air.

(i) The wearer is instructed to inhale gently and hold their breath for at least 10 seconds.

(ii) If the facepiece collapses slightly and no inward leakage of air is detected, the respirator has been properly donned and the facepiece is not leaking.

ii. Positive pressure user seal check (Figure A-2). The exhalation valve or breathing tube, or both, is closed off and the wearer is instructed to exhale gently.

(i) If a slight positive pressure can be built up inside the facepiece (e.g., facepiece bulges slightly outward) without detecting any outward leakage of air between the sealing surface of the facepiece and the wearer's face, the respirator has been properly donned.

(ii) For some respirators, this test method requires that the respirator wearer first remove the exhalation valve cover from the respirator and then replace it after completing the test. These tasks are often difficult to carry out without disturbing the respirator fit.

Figure A-1
Negative Pressure User Seal Check

Figure A-2
Positive Pressure User Seal Check

7. Important! OSHA states that fit testing shall not be conducted if there is hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache, or sideburns, which cross the respirator sealing surface. Facial hair must also not interfere with the respirator valve function.

8. During the comfort assessment period is a good time to inform personnel being qualitatively fit tested of the information provided on the material safety data sheet of the fit test agent.

9. If the respirator is still comfortable and the person being fit tested has successfully passed user seal checks, have them proceed to the fit testing room. Ensure the test subject has worn the respirator for at least five minutes before being fit tested. According to reference 2, experienced respirator wearers previously fit tested with the same respirator may bypass the comfort assessment period.

B. ANSI Z88.10 addresses additional requirements, which include:

1. Observe and communicate with the person being fit tested at all times during the fit test.

2. Establish and maintain an appropriate challenge agent concentration during the test.

3. Do not exceed established exposure limits for any challenge agents used for both the persons being fit testing and for the fit test operator.

4. Ensure there is sufficient space to complete specified fit test exercises without interference.

5. The person being fit tested shall don the respirator without physical or verbal assistance and perform user seal checks.

6. The respirator must not be adjusted once the fit test exercises begin. Any adjustments void the qualitative fit test, requiring the entire exercise protocol to be restarted from the beginning.

7. Inform the person being fit tested of the test results and inform them that they can be fit tested with a different respirator if they experience problems with the current respirator.

8. Issue personnel passing a fit test with a facepiece identical to the one used for the fit test or the model [make, size, style, and material] represented by the surrogate facepiece used for the fit test.

II. REFERENCES

1 Occupational Safety and Health Administration (OSHA): 29 CFR Parts 1910 and 1926 Respiratory Protection: Final Rule. Federal Register 63(5):1278–1279. Washington, D.C.: U.S. Government Printing Office, Office of the Federal Register, January 8, 1998, as amended 8June 2011.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards

2 American National Standards Institute (ANSI) ANSI)/American Industrial Hygiene Association (AIHA)**:** American National Standard for Respirator Fit Testing Methods (ANSI/AIHA-Z88.10).Fairfax, VA: AIHA, 2010.

3 Danyluk, Q., Hon, C., Neudorf, M., Yassi, A, Bryce, E., Janssen, B. and Astrakianakis, G.: Health Care Workers and Respiratory Protection: Is the User Seal Check a Surrogate for Respirator Fit-Testing?. J. Occup. Environ. Hyg. 8(5): 267 - 270 (2011)

APPENDIX B

FIT TEST EXERCISES

I. FIT TEST EXERCISES

A. OSHA Appendix A. OSHA fit test exercises are performed for one minute and include:

1. Normal breathing in a normal standing position.

2. Deep breathing in a normal standing position, taking slow deep breaths to not hyperventilate.

3. Turning head from side to side. Make sure movement is complete and momentarily pausing at the extreme right and left positions to inhale. Alert test subject not to bump the respirator on their shoulders.

4. Nodding head up and down. Make sure nodding is a complete movement. Alert test subject not to bump respirator on their chest. Inhale when head is in full up position.

5. Talking by slowly reading the "Rainbow Passage" or equivalent to get full range of facial movements. OSHA considers counting backward from 100, or reciting a memorized poem or song for one minute to be equivalent to reading the Rainbow Passage.

Rainbow Passage

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

6. Bending over. Bend at the waist as if to touch the toes. Substitute jogging in place if bending over cannot be accomplished in fit test environments, such as shroud-type fit test enclosures (e.g., Bitrex™ Fit Test Protocol enclosure).

7. The grimace exercise is only performed during QNFT because it is intended to test the respirator's ability to reseal to the wearer's face. The person being fit tested will make a facial grimace for the first 15 seconds of the minute set aside for the grimace exercise, then revert to normal breathing. The grimace exercise is not included in calculating the overall fit factor.

8. Normal breathing (same as exercise 1).

B. ANSI Z88.10 Fit Test Exercises. ANSI Z88.10, clause 9 and Tables 10 and 11 include ANSI Z88.10 fit test exercises. Note that these differ from the OSHA fit test exercises, which the Navy follows, and will not be described. They were only mentioned for the interested reader.

APPENDIX C

ISOAMYL ACETATE PROTOCOL

I. GENERAL INFORMATION

A. Uses isoamyl acetate (IAA) as fit test challenge agent. IAA is commonly called banana oil because of its odor. IAA is also known as isopentyl acetate.

B. According to reference 1, the odor threshold for IAA is 0.1 to 1.0 ppm. Some people cannot smell isoamyl acetate. Testing fit test subject's detection ability (odor threshold screening) is part of the protocol.

C. The OEL for IAA is a 100 ppm, 8 hr TWA, based on its narcotic effect.

D. Test respirators must be equipped with organic vapor cartridges.

E. Methods of using the banana oil for testing:

Figure C-1
IAA Fit Test Enclosure

1. The incorrect method uses stencil brush or cotton swab to administer the test agent by passing a brush or swab around the sealing surface of the respirator and having the test subject perform a series of test exercises.

2. The correct method is the IAA protocol in 29 CFR 1910.134 Appendix A, which is based on suspending 1/4 of a folded paper towel that contains 3/4 ml of IAA inside a test enclosure, such as an inverted 55-gallon drum liner (See Figure C-1, provided courtesy of TSI). The test enclosure contains the test atmosphere and provides a more controlled environment in which the test exercises can be performed.

II. IAA HISTORY

A. The IAA protocol is based on studies conducted by NIOSH, DuPont, 3M, and American International Steel Institute.

1. When the OSHA lead standard was first published, it required quantitative fit testing exclusively, which is very expensive for small companies. Several small companies requested variances to use qualitative procedures.

2. OSHA wanted data so fit testing studies were initiated. OSHA concluded that employees could be reasonably assured of adequate protection when qualitatively fit tested **IF** strict testing procedures were followed.

3. OSHA amended the lead standard to allow qualitative fit testing for exposures at <10 times the OEL **IF** one of the approved fit test protocols (saccharin, IAA or irritant smoke) was used.

III. IAA PROTOCOL ADAPTED FROM 29 CFR 1910.134 APPENDIX A

A. Prepare all solutions in an area separate from where fit testing will be performed to prevent olfactory fatigue in the fit test subject.

B. Conduct odor the threshold screening test in a room separate from the room used for actual fit testing (also to prevent olfactory fatigue).

C. The screening room and testing room must be well ventilated to control the buildup of isoamyl acetate to ensure that there is no detectable odor of IAA prior to either a screening test or a fit test.

D. Prepare odor threshold screening stock solution. IAA odor threshold screening procedure requires three one liter jars with metal lids (e.g., Mason or Bell jars as shown in Figure C-2).

1. Use odor-free water (e.g., distilled or spring water) at approximately 25°C (77°F) to make the solutions.

2. Prepare IAA stock solution by adding 1 cc of pure isoamyl acetate to 800 cc of odor free water in a l liter jar. Shake 30 seconds.

a. Stock solution must be freshly prepared at least <u>weekly</u>.

E. Prepare the odor test solution in a second jar. Using a clean dropper or pipette, add 0.4 cc of the stock solution to 500 cc of odor-free water. Label the jar #1. Shake 30 seconds. Allow to stand for 2 - 3 minutes to equilibrate.

1. The IAA concentration in the jar is about 1 ppm IAA).

2. Odor test solution may be used for only <u>one day</u>.

Figure C-2
IAA Threshold Screening

F. Prepare a test blank by adding 500 cc of odor-free water to a third jar. Label as #2.

G. Perform odor threshold screening to determine if the test subject can smell isoamyl acetate. If the subject cannot detect IAA, this procedure cannot be used to fit test them.

H. The following printed instructions should be placed in front of the two test jars.

> The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.

I. If the person being fit tested is unable to correctly identify the jar containing the odor test solution, the isoamyl acetate qualitative fit testing procedure may not be used. If the

person being fit tested correctly identifies the jar containing the odor test solution, they may proceed to respirator selection and fit testing.

J. Have test subject select their respirator, undergo the comfort assessment, and perform user seal checks.

K. The fit test chamber is a clear 55 gallon drum liner inverted and suspended over a two foot diameter circular frame (or "substantially similar" to this). See Figure C-1. The top of the chamber should be about 6 inches above the test subject's head. Place a small hook in the top center of the chamber to attach the IAA source. Tape a copy of the test exercises and rainbow passage (or equivalent) to the inside of the test chamber.

L. Equip the respirator being used for fit testing with organic vapor cartridges. Change the cartridges at least weekly to be conservative.

Note: Changing cartridges weekly is conservative. For example, 3M Respirator Service Life Software indicates that 3M 07046-6000 Series Organic Vapor Cartridges are estimated to last 60 hours at 100 ppm IAA.

M. Upon entering the test chamber, have the person being fit tested hang a folded towel, wetted with 3/4 cc of pure IAA, from the hook at the top of the chamber. The concentration will build up to a little over 100 ppm, which is 100 times the odor threshold testing solution.

1. Warning! According to Appendix A of 29 CFR 1910.134, an IAA test swab or ampoule may be substituted for the IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

2. However, DO NOT use an IAA test swab or ampoule or any other alternate IAA source inside the test enclosure. These alternative IAA sources cannot ensure the appropriate 100 ppm fit test challenge concentration inside the fit test enclosure upon which this fit test protocol is based.

N. Allow two minutes for the 100 ppm, IAA test concentration to be reached before starting the fit test exercises. Use this time to explain the fit test, the importance of subject's cooperation, the purpose for the exercises or to demonstrate some of the exercises.

O. Have the person being fit tested perform the fit test exercises for at least 1 minute each.

P. If at any time during the test the person being fit tested detects the banana-like odor of isoamyl acetate, have them quickly exit the test chamber and leave the test area to avoid olfactory fatigue, and select another respirator, repeat the comfort assessment and return to the test chamber for another fit test.

1. Should the person fail the odor sensitivity test wait at least 5 minutes before retesting. Odor sensitivity will usually have returned try this time.

2. Continue until the person being fit tested successfully completes the fit test. **Never try to force fit the same respirator**.

3. When a respirator is found that passes the fit test, prove to the subject that the respirator is working by having them break the face seal and take a breath before exiting the chamber.

4. When the person being fit tested leaves the chamber, have them remove the saturated towel and place it in a self-sealing bag to prevent the area from becoming contaminated and to prevent accumulation of IAA in the test chamber.

Q. A person passing the fit test is assumed to have a fit factor of at least 100.

IV. REFERENCE

1 American Industrial Hygiene Association (AIHA). Odor Thresholds for Chemicals with Established Occupational Health Standards, Second Edition, Fairfax, Va.: AIHA, 2013.

APPENDIX D

IRRITANT SMOKE PROTOCOL

I. GENERAL INFORMATION

A. This fit test protocol (Figure D-1) uses smoke tubes that produce an irritating "smoke," which historically was considered to have an advantage over other methods because the smoke supposedly produces an involuntary response.

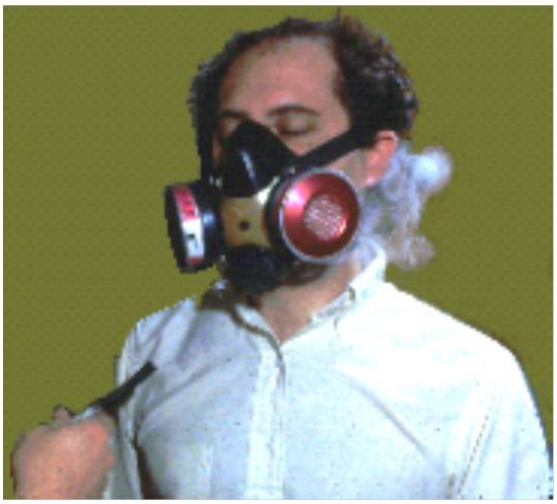


Figure D-1
Irritant Smoke Fit Testing

1. It was once thought that the test subject could not lie about their reaction because most people could not prevent coughing after the smoke has irritated the mucous membranes of the respiratory tract.

2. The irritant smoke test requires high efficiency filters because the test particles are small (~0.34 μm) enough to pass through 95% efficiency filters.

B. Smoke tubes vary, but commonly contain stannic chloride ($SnCl_4$), which according to reference 1, on exposure to the moisture in the air produces a white smoke consisting of tin oxides and corrosive hydrochloric acid fumes, which have a pungent, strong irritating odor.

1. Reference 2 illustrates smoke tube variation by reporting that Sensidyne No. 501 smoke tubes produce a hydrogen chloride concentration of 1500 ppm *(*<20 seconds) while MSA No. 5645 smoke tubes produce a hydrogen chloride concentration >2000 ppm *(*<10 seconds), which can lead to different results during fit testing.

2. Also, some smoke tubes contain titanium tetrachloride, which is not as irritating as the stannic chloride tubes. Therefore, titanium tetrachloride tubes should not be used because they do not elicit the involuntary response.

C. There is not an OEL for stannic chloride. However, the MSA Ventilation Smoke Tube MSDS reports an OEL for stannic chloride as an ACGIH TLV of 2 mg/m^3 for tin. HCl has an OSHA Ceiling Limit of 5 mg/m^3.

1. Smoke tubes vary from lot to lot in irritation properties. Each lot should be tested by the person performing the fit test to ensure there is enough irritation.

2. Depending on humidity, one box will perform about 100 qualitative fit tests.

D. The problems with this protocol are:

1. The irritant smoke protocol cannot control the concentration during the sensitivity screening test or during the fit test. In the other qualitative fit test protocols, there is a known sensitivity screening test concentration that is about 100

times lower than the fit test concentration, which is the basis for the qualitative fit tests equivalent fit factors of 100.

2. The irritant smoke protocol was dropped from ANSI Z88.10-2010 because the validation criteria for the Z88.10 standard requires that qualitative fit test protocols must detect 95 percent of the respirators measured by sequential paired quantitative fit testing as not fitting properly during fit test validation testing. Three out of four of the studies performed on irritant smoke protocol showed that this protocol does not meet this criterion. Reference 2 found additional problems with the irritant smoke fit test protocol.

a. Reference 2 reported an experiment in which they successfully quantitatively fit tested 20 subjects wearing full face respirators equipped with P100 filters and then replaced the exhalation valves with damaged valves to produce fit factors below 100. Next, subjects were tested with irritant smoke delivered with a 200 ml/min continuous flow pump while performing the normal breathing exercise.

b. Test results showed that the irritant smoke did not detect 40 % of respirators with leaking exhalation valves, which is well below the ANSI Z88.10 required 95 % criterion to detect respirator leakage during fit testing. In addition, 25% of the subjects were able to suppress the cough reflex[3], verifying that a person could lie during the fit test and fake passing the test.

3. Even though ANSI Z88.10 dropped the irritant smoke test, it is still an acceptable OSHA respirator fit test method. Since the irritant smoke test is accepted by OSHA, Navy policy allows its use. However, **Navy RPPMs need to be aware of the problems with this fit test.**

II. IRRITANT SMOKE PROTOCOL ADAPTED FROM 29 CFR 1910.134 APPENDIX A

A. Have test subject select their respirator, undergo the comfort assessment, and perform user seal checks. Respirators must have high efficiency (N, R, P series 100) filters. Fit test PAPRs equipped with HEPA filters.

B. The fit test room should be equipped with exhaust ventilation to prevent contaminating the testing area with the irritant smoke test agent. **Do not use an enclosure** - Concentration inside can become IDLH![4]

[3] In the study's most extreme case, one subject suspected the presence of the smoke for several minutes; however, the concentration of the smoke was not sufficient to induce a cough reflex until 4:53 minutes into the test. A respirator's fit may be judged to be inadequate as soon as the subject merely detected the irritant smoke; however the OSHA protocol does not clearly define a "response." It is common practice for those performing an irritant smoke fit-test to use the involuntary cough reflex to determine whether a respirator will offer adequate protection for the subject.

[4] NIOSH investigation of irritant smoke fit testing conducted inside of hoods at the Anchorage Fire Department measured HCl concentrations up to 11,900 ppm, greatly exceeding the NIOSH 50 ppm IDLH.

C. Perform the sensitivity test by having the person being fit tested smell a weak concentration of irritant smoke to familiarize them with the characteristic odor. Dispense a small amount of smoke and let them waft it to their face with a wave of their hand.

D. Review the Irritant Smoke Protocol with the person being fit tested before fit testing.

E. Advise the subject that the smoke can be irritating to the eyes. Instruct them to keep their eyes closed during the test if wearing a half mask respirator.

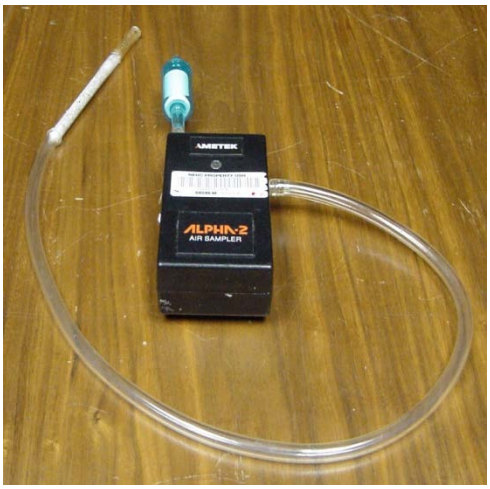


Figure D-2
IAA Threshold Screening

F. Break both ends of a smoke tube containing stannic chloride. Attach a short length of tubing to one end of the smoke tube (to ensure subject is not injured by the jagged end of the tube). Attach the other end of the smoke tube to a dispenser (i.e. low flow air sampling pump) calibrated to deliver a 200 milliliter per minute air flow (Figure D-2).

G. Direct the stream of irritant smoke from the tube towards the face seal area of the test subject. Use either:

1. Low flow air sampling pump set to deliver 200 ml/minute, or

2. If a rubber squeeze bulb is used, then use the number of squeezes per minute to deliver 200ml/minute. See Table D-1.

Note: Smoke delivery using a low flow air sampling pump is the method of choice to ensure consistent delivery of smoke.

3. Begin at least 12 inches from the facepiece and gradually move to within six inches, moving around the whole perimeter of the mask while the subject performs the fit test exercises (See Attachment B) for one minute.

H. If at any time during the test the test subject detects the irritant smoke, stop the test. Detecting irritant smoke usually produces an involuntary reaction (cough) from the test subject.

1. Have them select another respirator and repeat the entire test procedure, including comfort assessment, taste threshold screening, and fit testing.

Table D-1
Squeeze Bulb Smoke Delivery

Bulb Size (ml)	# of Bulb Squeezes/ minute
27	8
30	7
39	5
50	4

2. Continue trying different respirator models and sizes until the person being fit tested successfully completes the fit test. **Never try to force fit the same respirator**.

3. When a respirator is found that passes the fit test, prove to the subject that the respirator is working by doing a sensitivity check on the test subject using the same smoke tube used during the fit test.

a. Dispense a small amount of smoke and let them waft it to their face with a wave of their hand. This ensures that the subject reacts to the smoke used for the fit test when not protected by the respirator.

b. Failure to evoke a response during this sensitivity check voids the fit test.

I. A person passing the irritant smoke fit test is assumed to have a fit factor of at least 100.

III. REFERENCE

1 Sensidyne, Inc.: Material Safety Data Sheet for Air Flow Indicator Tubes. MSDS #0501. Sensidyne, Inc., Clearwater, FL (1999).

2 Snyder, E. M. & McKay, R. T.: An Evaluation of Irritant Smoke to Detect Exhalation Valve Leakage in Respirators, Applied Occupational and Environmental Hygiene, 18:9, 702-707 (2003)

APPENDIX E

SACCHARIN MIST PROTOCOL

I. GENERAL INFORMATION

A. This fit test protocol was originally developed by the 3M Company for single use dust respirators and dust/mist respirators. The large size challenge particles are effectively filtered by the mask material so that challenge agent detected inside the facepiece enters through leaks in the sealing surface.

1. This fit test is based on the person's ability to detect the sweet taste of sodium saccharin. Saccharin was found to be a cancer promoter, not a carcinogen itself. Cancer promoters may help induce cancer in the presence of other carcinogens. Monosodium glutamate, used a lot in Chinese cuisine, is another example of a cancer promoter.

2. As in the IAA protocol, the challenge agent does not solicit an involuntary response so the fit test relies on the subject's honesty about detecting saccharin during the fit test.

3. Particulate filters must be worn on the respirator (N, R, or P series 95, 99, or 100 filters).

4. Similar to the IAA Protocol, this protocol also requires taste threshold screening.

Figure E-1
Saccharin Mist Fit Testing

B. Nebulizer Generated Saccharin Mist.

1. Originally, the aerosol was generated using a DeVilbiss Model 40 Inhalation Medication Nebulizer, shown in Figure E-1, which produced a particle mist size averaging 2.4 microns.

2. Automated nebulizers are available that deliver either sodium saccharin or Bitrex™ without having to use a squeeze bulb nebulizer. These devices reduce the ergonomic stress caused by having to repeatedly squeeze the nebulizer bulbs.

C. The original enclosure for taste threshold screening and fit testing procedures is a 3M hood (parts # FT 14 and FT 15). The hood is approximately 12 inches in diameter by 14 inches tall. The front portion consists of clear plastic to allow viewing of the person being fit tested. The enclosure also has a 3/4 inch hole in front of the person's nose and mouth to accommodate the nebulizer nozzle. Other hood enclosures are now available.

II. SACCHARIN MIST AEROSOL PROTOCOL ADAPTED FROM APPENDIX A OF 29 CFR 1910.134

A. Prepare the fit test solution by adding 83 grams of sodium saccharin to 100 cc of warm water, or use the prepared solution that is included in the Fit Test Kit.

1. Prepare the threshold check solution by adding 1 cc of the test solution to 100 cc of water (yields threshold check solution with 0.83 grams saccharin per 100 cc of water). Alternatively, use the prepared solution that is included in the Fit Test Kit.

2. Use separate nebulizers for screening and fit testing. Each should be labeled appropriately. Nebulizers should have no more than 1 cc liquid added. Nebulizers shall be thoroughly rinsed in water, shaken dry, and refilled at least every morning and afternoon or at least every 4 hours during fit testing.

B. Explain the entire screening and testing procedure to the subject prior to conducting the screening test.

C. Perform screening test.

1. Place 1 cc of threshold check solution in the screening nebulizer.

2. To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

3. Have subject don the test hood and extend their tongue. Rapidly squeeze the nebulizer ten times into the test hood.

a. Ask the person being fit tested if they tasted the saccharin. If the person being fit tested tastes the sweetener then record 10 as the number of squeezes for the threshold test.

b. If the response is negative, squeeze the nebulizer 10 more times (total 20 times). Again, ask the person being fit tested if they tasted saccharin.

c. If the person being fit tested tastes the sweetener then record 20 as the number of squeezes for the threshold test.

d. If the second response is negative, squeeze nebulizer 10 more times (total 30 squeezes). Ask the person being fit tested again if they taste the saccharin. If the person being fit tested tastes the sweetener then record 30 as the number of squeezes for the threshold test.

e. If the saccharin is not tasted after 30 squeezes, the person being fit tested cannot be fit tested using this method.

f. If a taste response is elicited, ask the person being fit tested to remember the taste for reference during the fit test.

D. Have test subject select their respirator, undergo the comfort assessment, and perform user seal checks. Respirators must have particulate filters (N, R, or P series 95, 99, or 100 filters). Fit test PAPRs equipped with HEPA filters.

E. Perform fit test.

1. The person being fit tested may not eat, drink (except plain water), or chew gum for 15 minutes before the test because eating or drinking can interfere with saccharin detection.

2. Have the person being fit tested don the hood while wearing the respirator selected for the fit test.

3. Add 1 cc of fit test solution to the fit testing nebulizer.

4. Instruct the person being fit tested to breathe with their mouth open and their tongue extended (inside the respirator).

5. Insert the nebulizer into the hole in front of the enclosure. Squeeze 10, 20, or 30 times, based on the threshold screening test.

6. Ask the person being fit tested to perform each of the fit test exercises in Attachment B for one minute.

7. Replenish the saccharin concentration inside the hood every 30 seconds by squeezing the nebulizer half the original number of squeezes (5, 10, or 15).

a. Since the nebulizer has a tendency to clog during use, the fit test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.

F. If at any time during the test the person being fit tested detects saccharin, have them remove the hood, select a different respirator and repeat the entire test procedure, including comfort assessment, taste threshold screening, and fit testing.

a. Continue trying different respirators until the person being fit tested successfully completes the fit test. **Never try to force fit the same respirator**.

b. A person passing the fit test is assumed to have a fit factor of at least 100.

APPENDIX F

Bitrix™ AEROSOL PROTOCOL

I. GENERAL INFORMATION

A. The Bitter Aerosol Fit Test (Denatonium benzoate – Bitrix™) is very similar to the Saccharine Mist Protocol and uses the same enclosure for taste threshold screening, fit testing procedures, and 3M hood (parts # FT 14 and FT 15). Other hood enclosures are now available.

B. 3M developed this protocol in attempting to replace the irritant smoke protocol.

Bitrix Fit Testing

C. The aerosol is generated using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent. FT-30 FIT Test kits, available from 3M Company, include Bitrix™ test solution, screening test solution, two nebulizers, a test enclosure, and cost about $105.00 through General Services Administration (70-0707-0964-0). This protocol requires taste threshold screening analogous to the IAA Protocol's odor sensitivity testing.

II. BITTER AEROSOL FIT TEST PROTOCOL ADAPTED FROM APPENDIX A OF 29 CFR 1910.134

A. Prepare the fit test solution by adding 338.2 mg of Bitrix™ in 200 ml of 5% salt (sodium chloride) solution in water. Or use the prepared solution that is included in the Fit Test Kit.

1. Prepare the threshold check solution by adding 13.5 mg Bitrix™ in 100 ml of 5% salt (sodium chloride) solution in water. Or use the prepared solution that is included in the Fit Test Kit.

2. Use separate nebulizers for screening and fit testing. Each should be labeled appropriately. Nebulizers should have no more than 1 cc liquid added.

3. Nebulizers shall be thoroughly rinsed in water, shaken dry, and refilled at least every morning and afternoon OR at least every 4 hours during fit testing.

B. Explain the entire screening and testing procedure to the subject prior to conducting the screening test.

C. Perform Screening Test

1. Have the person being fit tested to don the test enclosure and breathe through their open mouth with tongue extended.

a. Place 1 cc of threshold check solution in the screening nebulizer.

b. To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand. As described in Appendix E, Automated nebulizers are available that deliver either sodium saccharin or Bitrex™ without having to use a squeeze bulb nebulizer to reduce the ergonomic stress.

i. Have subject don the test hood and extend their tongue. Rapidly squeeze the nebulizer ten times into the test hood. Ask the person being fit tested if they tasted the Bitrix™. If the person being fit tested tastes the bitter taste then record 10 as the number of squeezes for the threshold test.

ii. If the response is negative, squeeze the nebulizer 10 more times (total 20 times). Again, ask the person being fit tested if he tasted Bitrix™. If the person being fit tested tastes the bitter taste then record 20 as the number of squeezes for the threshold test.

iii. If the second response is negative, the squeeze nebulizer 10 more times (total 30 squeezes). Ask the person being fit tested again if Bitrix™ is tasted. If the person being fit tested tastes the bitter taste then record 30 as the number of squeezes for the threshold test.

iv. If the Bitrix™ is not tasted after 30 squeezes, the subject cannot be fit tested using this method.

c. If a taste response is elicited, ask the subject to remember the taste for reference during the fit test.

i. Have test subject select their respirator, undergo the comfort assessment, and perform user seal checks. Respirators must have particulate filters (N, R, or P series 95, 99, or 100 filters).

D. Perform fit test

1. The subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test. Eating or drinking can interfere with Bitrix™ detection.

2. Have the subject don the 3M hood while wearing the respirator selected for the fit test.

3. Add 1 cc of fit test solution to the fit testing nebulizer.

4. Instruct the subject to breathe with their mouth open and their tongue extended (inside the respirator).

5. Insert the nebulizer into the hole in front of the enclosure. Squeeze 10, 20, or 30 times, based on the threshold screening test.

6. Ask the subject to perform each of the fit test exercises in Attachment B for one minute.

7. Replenish the saccharin concentration inside the hood every 30 seconds by squeezing the nebulizer half the original number of squeezes (5, 10, or 15).

a. Since the nebulizer has a tendency to clog during use, the fit test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.

E. If the Bitrix™ is detected, have the subject remove the hood, select a different respirator and repeat the entire test procedure, including comfort assessment, taste threshold screening, and fit testing.

a. Continue until the person being fit tested successfully completes the fit test. **Never try to force fit the same respirator**.

2. If the subject successfully completes the test protocol, they will be allowed to use the respirator in atmospheres up to 10 times the contaminant OEL.

APPENDIX G
QUANTITATIVE FIT TESTING

I. GENERAL INFORMATION

A. Quantitative fit testing (QNFT) uses an instrument to determine the amount of leakage between the sealing surface of the respirator and the face by measuring the concentration of a test agent both inside and outside of the respirator during a series of test exercises and then calculates an overall fit factor. The fit factor numerically quantifies the amount of facial sealing surface leakage. Fit factor is calculated by dividing the concentration of the test atmosphere outside (C_{out}) of the respirator by the concentration of test atmosphere that has leaked inside (C_{in}) the respirator (Fit factor = C_{out}/ C_{in}). Generally, higher fit factors are obtained when respirators are most comfortable. The overall fit factor calculation is shown below:

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

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:

FF1 = 666, FF2 = 1429, FF3 = 588, FF4 = 2000, FF5 = 1111, FF6 = 909

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

II. COMPARISON BETWEEN QLFT AND QNFT

A. The only way to obtain evidence that a respirator fits is accomplished by actual measurement of the amount of challenge agent that leaks into the mask while the individual is wearing a particular sized mask during a fit test. With qualitative fit tests, like banana oil the respirator leakage measurement instrument is the human senses of the person being fit tested. Qualitative fit tests are good. However, they are subjective. According to the reference 1, the average odor threshold of isoamyl acetate (banana oil) is 0.22 ppm. However, human variation of being able to detect the smell of banana oil is vast. Some people can detect this odor at very low concentrations, whereas others cannot detect the odor at all. Also, individuals' ability to detect odors can vary with time for a variety of physiological and environmentally triggered reasons. This is why Appendix A

of the OSHA Respirator Standard (reference 2) and ANSI Z88.10 (reference 3), require an odor screening test as the first step in the banana oil fit testing protocol. If the person being fit tested cannot detect the odor of banana oil then they cannot be fit tested by this method. All qualitative fit test protocols have an odor screening test as the first step to determine if the person being fit tested can detect the challenge agent.

B. In contrast, quantitative fit testing, such as the light scattering laser photometry aerosol method in the Joint Services Mask Leakage Tester (JSMLT), uses sensitive instrumentation for detecting the concentration of the challenge agent (EMERY 3004 Oil). During each fit test exercise, both the outside challenge concentration and the amount of EMERY Oil aerosol that leaks into the mask are measured and a fit factor is calculated for each particular exercise. At the end of the fit test, the overall fit factor is calculated from the individual fit factors determined for each test exercise. This differs greatly from qualitative methods, which are all or none - Once the person being fit tested detects the challenge agent, they fail the test.

1. Unlike the variable human senses, which are the detection system for qualitative fit test methods, like banana oil, the JSMLT uses precision instrumentation to measure the fit of the mask. There are orders of magnitude difference in the slight variation between measurements of individual JSMLT apparatuses as compared to the wide variation in detection capabilities of the human senses of individuals being fit tested with qualitative methods.

2. Another problem with qualitative fit test methods is that they rely on the honesty of the person being fit tested. If a person chose to, they could lie during the fit test and either fake passing or failing the test.

C. Both the OSHA Respirator Standard and ANSI Z88.10 limit qualitative fit testing to situations where the user of a negative pressure air-purifying respirator must achieve a minimum fit factor of 100. Respirators which must achieve a minimum fit factor of 100 include negative pressure half masks and full face respirators worn under 10 times the occupational exposure limit. According to the preamble to the OSHA Respirator Standard, this limitation is based on the existing evidence, which only validates achieving a fit factor of 100 for passing qualitative fit tests. Therefore, using a safety factor of 10, qualitatively fit tested respirators only provide protection up to 10 times the OEL.

III. OSHA QNFT REQUIREMENTS

A. Per paragraphs (f)(1) and (f)(2) of reference 2, all personnel wearing tight-fitting facepieces must be either qualitatively or quantitatively fit tested initially and at least annually with the same make and model of respirators that they wear. OSHA approved quantitative fit test protocols include:

1. Aerosol-generated forward light scattering photometry

2. Ambient aerosol condensation nuclei counter (Thermo-Systems Inc.(TSI) e.g., Portacount™)

3. Controlled negative pressure (Occupational Health Dynamics (OHD) e.g., Fit Tester 3000™)

B. When reference 2 was revised in 1998, all provisions addressing respirator use, selection, and fit testing were deleted from the OSHA substance-specific standards, making these standards consistent with the final OSHA respiratory protection standard with respect to these requirements. For example:

1. The requirements in previous OSHA chemical specific standards (i.e., Benzene Standard, 29 CFR 1910.1028) for performing three quantitative fit tests were removed - the new standard requires only one quantitative fit test.

2. OSHA revised the frequency of respirator fit testing from semi-annually to annually for the Asbestos (29 CFR 1910.1001 and 1926.1101), Arsenic (29 CFR 1910.1018), Lead (29 CFR 1910.1025 and 1926.62) and Acrylonitrile (29 CFR 1910.1045) standards. OSHA believes that this revision will not diminish the effectiveness of respiratory protection provided by these standards.

C. To wear full face air-purifying respirators in atmospheres up to their assigned protection factor of 50, they must be quantitatively fit tested and achieve a fit factor of at least 500, which includes a safety factor of 10.

NOTE: The qualitative fit test protocol concentrations for saccharin mist, isoamyl acetate, and irritant smoke are calculated to simulate an atmosphere that is 10 times the PEL for lead, which is the assigned protection factor for half mask respirators.

D. Tight-fitting, positive pressure respirators, including powered air purifying respirators (PAPRs) must be fit tested in the negative pressure mode (fit tested as negative pressure air-purifying respirators).

1. This can be accomplished by either temporarily converting the facepiece, per manufacturer's instructions, into a negative pressure air-purifying respirator or by using a “surrogate” negative-pressure facepiece with sealing surfaces and materials that are identical to the wearer's positive pressure facepiece. In other words, if the facepiece sealing surfaces and materials are indistinguishable from the positive pressure respirator facepiece, then the negative pressure, air-purifying respirator can be worn as a surrogate during fit testing.

2. Respirators temporarily modified for fit testing must be completely restored to their NIOSH-approved configuration before being used for respiratory protection.

E. OSHA allows positive pressure respirators to be either qualitatively or quantitatively fit tested. Fit testing positive pressure respirators is to ensure there is no gross leakage in the facepiece seal. Positive pressure half mask and full face respirators that are quantitatively fit tested must pass with a minimum fit factor of 100 and 500, respectively. Individuals may wear positive pressure respirators up to the assigned protection factor of the respirator after passing either qualitative or quantitative fit testing.

IV. QUANTITATIVE FIT TESTING METHODS

There are two basic quantitative fit testing technologies, which are aerosol challenge and controlled negative pressure.

A. Aerosol challenge quantitative fit testing. These methods measure and compare the concentration of a particulate challenge test agent aerosol (e.g., 0.6 micron corn oil aerosol, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride)[5] inside and outside of the respirator during a series of test exercises. Aerosol challenge quantitative fit testing methods require probed respirators (see Figure G-1) with high-efficiency filters (i.e., N100, R100, or P100 filters or PAPR HEPA filters). As an alternative to probed respirators, fit test adapters (see Figure G-2) made by the respirator manufacturer or the quantitative fit test apparatus manufacturer can be used to sample inside an individual's own respirator.

Figure G-1
Probed Respirators

Figure G-2
MASK SAMPLING ADAPTER

1. The *Generated Aerosol Quantitative Fit Testing Protocol* in Appendix A of reference 2 was based on the original quantitative fit test apparatus developed by Burgess, et al. (reference 4), which used a uranine challenge aerosol. The first practical system was developed by Los Alamos Scientific Laboratory and described by Hyatt (reference 5) and used dioctyl phthalate (DOP) as the challenge agent. Generated aerosol QNFT was considered the "Gold Standard" to which all other quantitative fit test methods were measured. This type apparatus is probably now only found in laboratory situations, such as Edgewood Chemical Biological Center (See Figure G-3).

   a. In 1965, the U.S. Bureau of Mines, in their Approval Schedule 21B (reference 6), adopted quantitative fit testing using uranine and DOP for man test certification protocols for approving particulate respirators for protection against highly toxic airborne particulates.

Some of the language in OSHA, Appendix A *Generated Aerosol Quantitative Fit Testing Protocol* is antiquated because OSHA is describing the original forward light

[5] Challenge agents used for quantitative fit testing have also included uranine dye aerosol, helium, dichlorodifluoromethane (Freon®-12), argon, daughter products of radon, and an oil mist of dioctyl phthalate (DOP).

scattering photometric based apparatuses, which contained strip cart recorders and other antiquated technology.

Figure G-3
Edgewood Laboratory QNFT Apparatus

2. The OSHA *Generated Aerosol Quantitative Fit Testing Protocol* also includes technology on which the TDA-99M is based. The TDA-99M (also commercially called the Protective Mask Leakage Tester) is a newer, more compact forward light scattering fit testing apparatus. The TDA-99M can also be used to test facepiece serviceability by checking for leaks on a portable test stand. The Armed Services jointly developed the TDA-99M technology into the Joint Services Mask Leakage Tester (JSMLT), which is used for both mask serviceability testing and for quantitatively fit testing military gasmasks worn during military unique operations. See Figure G-4.

Figure G-4
Joint Services Mask Leakage Tester

a. This technology uses a non-hazardous test aerosol (such as corn oil, polyethylene *glycol* 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber worn over the shoulders, and uses forward light scattering photometry to quantify the fit of the respirator. These challenge agents replaced DOP, which was found to be carcinogenic.

3. Ambient aerosol challenge quantitative fit testing. Condensation nuclei counting or CNC (i.e., TSI, Portacount® Pro Model 8030) is an aerosol fit testing method that measures ambient room air particles as the test atmosphere. As with the generated aerosol quantitative fit testing methods, CNC requires probed respirators with high-efficiency filters (i.e., N100, R100, or P100 filters or PAPR HEPA filters). Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Either probed respirators or fit test adapters made by TSI or the respirator manufacturer can be used to sample inside an individual's own respirator. The Model 8030 is designed to measure fit factors of masks with an efficiency of 99% or greater.

a. TSI developed the N95-Companion™ Model 8095, which combined with the PortaCount® Plus 8030 quantitatively fit tests N95 filtering facepiece respirators. The N95-Companion works with the PortaCount® Plus 8030 to fit test masks with series-95 filters, including N95 filtering-facepiece respirators. The device can easily be switched back to fit test respirators with 99 and 100 % efficiency filters.

b. Reference 7 researched the filter penetration of the N95-Companion. The N95-Companion operates by an electrostatic classifier separating negatively charged particles in the 40 – 60 nm size range from the other particles, allowing only those charged particles to be counted. Recent nanoparticle related studies have shown that 40 – 60 nm particles were the most penetrating particle size (MPPS) for NIOSH-approved filtering facepiece respirators containing electrostatic filter media, rather than 300 nm as originally thought. Test results showed that filter penetration for **negatively charged** 40 – 60 nm particles was less than 0.05%. In other words, electrostatic filter media effectively captured >95% of the negatively charged particles of this size . This research confirms that the fit factors measured by the N95-Companion are due primarily to particle penetration through respirator facepiece seal leakage and not through filter penetration, which makes this apparatus appropriate for quantitatively fit testing respirators with low efficiency filters, including filtering facepiece respirators.

c. The N95-Companion was discontinued because TSI developed a new apparatus, shown in Figure G-5 called the PortaCount® Pro+ (Model 8038), which has a built in TSI N95-Companion.

Figure G-5
Portacount Model 8030

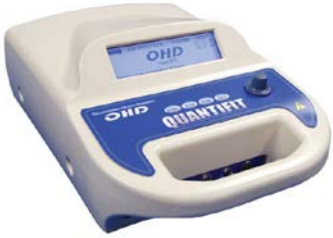
d. TSI also manufacturers the MITA (Mask Integrity Test Accessory) that works with the M41 PATS, the military version of the Portacount, to perform mask serviceability testing similar to the JSMLT. See Figures G-6 and G-7.

Figure G-6
M41 PATS

Figure G-7
MITA (MASK INTEGRITY TEST ACCESSORY)

B. Controlled negative pressure (CNP) quantitative fit testing. The CNP method (e.g., Fit Tester 3000 by Occupational Health Dynamics (OHD)) measures the rate of pressure decay as a function of the rate of controlled leakage into an otherwise sealed respirator. OHD has a new version of the Fit Tester 3000 called the Quantifit, shown in Figure G-8. When fit testing with CNP, the air-purifying filter is replaced with a leak-tight test adapter to seal the normal air pathways into the respirator (therefore filtering facepiece respirators cannot be fit tested with the CNP method). Test exercises are performed just prior to face seal leakage measurements. OSHA accepted an abbreviated "CNP REDON" protocol, which includes only five test exercises instead of the eight test exercises required by the originally approved CNP protocol. OSHA addresses this procedure at the following website. Also, see Appendix A of the OSHA Respirator Standard.

Figure G-8
Quantifit



1. When using the Controlled Negative Pressure (CNP) method, the heavy CBRN canister is replaced with the CNP leak-tight test adapter to seal the normal air pathways into the respirator. Occupational Health Dynamics (OHD), the manufacturer of the Fit Tester 3000 makes a CBRN leak-tight test adapter that approximates the weight and the size of CBRN canisters.

2. Ensure the CBRN leak-tight test adapter is worn when fit testing CBRN gas masks with the CNP method. The OHD part number for the CBRN leak-tight test adapter is 9513-0207 (Kit number 24).

C. The following is a comparison between Aerosol Based and Controlled Negative Pressure Quantitative Fit Testing.

1. A moderate work rate inhalation is about 30 lpm. In contrast, the Portacount in-mask sampling probe flow rate is 0.7 lpm. If a particle is drawn between these two flow rates it will probably go into the lungs instead of the sampling probe, which lowers the in-mask concentration, thus increasing the fit factor. All aerosol based technology has problems such as streamlining of the challenge aerosol into the nose, which gives higher protection factors because much of the inhaled challenge agent remains in the respiratory tract and does not add to the denominator in calculating the fit factor. In addition, aerosol technology has problems with the probe location biasing the inside mask concentration along with incomplete aerosol mixing within the mask.

2. CNP does not have these problems. However, CNP has other problems such as any pressure change on the masks is registered as a leak. If someone wiggled their nose during the test, which caused the facepiece material to slightly change shape, the pressure difference would be reflected as mask seal leakage. The traditional fit test exercises cannot be performed during the fit test. With CNP, the exercise is performed, then the person being fit tested remains still and holds their breath while the pressure measurement is made. Also, the fit factors derived by CNP are about four to ten times lower than fit factors derived with the aerosol methods making comparison of these two fit test technologies difficult to compare.

D. Special Considerations for Fit Testing CBRN Respirators. According to paragraph 2605.c.(5) of reference 8, all negative and positive pressure tight-fitting CBRN respirators shall be quantitatively fit tested by any of the quantitative fit testing methods in Appendix A of reference 2, which include forward light scattering photometry (Joint Services Mask Leakage Tester (JSMLT)), condensation nuclei counting (PortaCount™), and controlled negative pressure [(CNP)(Fit Tester 3000 or Quantifit)]. This is in contrast to fit testing positive pressure respirators for industrial use, which may be either qualitatively or quantitatively fit tested.

1. There has been confusion in the CBRN respirator community concerning the required fit factor. The passing fit factor for full face tight fitting respirators, including CBRN respirators is 500 (see paragraph 2605.c.(5) of reference 8). However, Appendix A of reference 1, the NIOSH *Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Full Facepiece Air Purifying Respirator (APR)* (reference 9), and some CBRN respirator manufactures' instruction manuals have been a source of confusion over the fit factor for CBRN respirators.

a. The following quote from Appendix A of 29 CFR 1910.134 for the Generated Aerosol Quantitative Fit Testing Protocol, has been misinterpreted. This quote states, "*The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000."* This quote only requires that the fit test apparatus be sensitive

enough to record fit factors of 2,000, which is not the same as setting the passing fit factor to 2,000.

b. The laboratory protection level test (LRPL) required in reference 9 is another source of confusion. The LRPL is a fit testing certification requirement that shall be passed with a minimum fit factor of 2,000 by 95% of the fit test panel required for NIOSH CBRN approval. However, the purpose of the LRPL is for certifying CBRN respirators - not for requiring respirator wearers to pass with a fit factor of 2,000.

c. Certain CBRN respirator manufacturers' instruction manuals require passing fit factors higher than 500. However, according to OSHA (reference 10), respirator manufacturers are not in the position to prescribe passing fit factors - OSHA is the only legal authority to declare a passing fit factor, which is 500 for full face respirators.

d. There is very little protection gained in respiratory protection efficiency by increasing the passing quantitative fit factor as shown in Table G-1. Understanding the following terms will help explain the logic in Table G-1.

i. Protection Factor = 100 / % Leakage

Where:

% Leakage = Face seal % leakage + Filter % leakage

Note: This illustration assumes that the respirators are equipped with high efficiency filters, which have essentially no filter leakage.

Example: Total leakage for half mask with high efficiency filter.

$\%\ Leakage_{(half\ mask)} = 100 / 10\%_{(half\ mask)} + 0\%_{(filter\ leakage)} = 10\%$

ii. % Respirator Leakage = (1 / Fit factor) X 100

iii. Respirator Efficiency (%) = 100 – % Respirator Leakage

Table G-2 Respirator Efficiency Increases Only Slightly With Increasing Fit Factors

Measured Fit Factor	% Respirator Leakage (1/Fit Factor) X 100	Respirator Efficiency (%) (100 – % Leakage)
10	10	90
50	2	98
100	1	99
500	0.2	99.8
1,000	0.1	99.9
2,000	0.05	99.95
3,000	0.033	99.97
5,000	0.02	99.98
10,000	0.01	99.99
20,000	0.005	99.995
100,000	0.001	99.999

e. It is important to reiterate that the CBRN Respirator Program requires quantitative fit testing with a passing fit factor of 500 for all tight-fitting respirators worn by first responders during a CBRN incident. Although the minimum passing fit factor is 500, RPPMs are encouraged to fit test using a higher fit factor if they wish. If an individual is fit tested with more than one sized respirator, issue them the respirator for which they passed with the highest fit factor, which will probably also be the most comfortable.

i. Fit factors obtained by the CNP method are at least five times lower than aerosol quantitative fit test methods. CNP probably would not pass many fit tests if the required passing fit factor was 2,000.

2. When fit testing CBRN approved Millennium gasmasks with the TSI, PortaCount™ Plus, use the *MSA Speaking Diagram Fit Test Adapter Kit* for Millennium (MSA # 10006227), priced at ~ $20.00 to sample inside the respirator. Also, equip the Millennium with a CBRN canister instead of just a light-weight high efficiency filter (i.e., N, R, or P 100). The CBRN canister is much heavier than the HEPA filter and will make a difference as to how the respirator seals to the wearer's face (CBRN canisters can weigh up to 500 grams (17.64 oz.)). Also, the wearer needs to become aware of how the large CBRN canister feels on the mask.

a. The *MSA Speaking Diagram Fit Test Adapter Kit* (MSA P/N 10006227) for the Millennium gasmask gives more accurate readings than the TSI Military Drink Tube Adapter, which restricts the flow to the PortaCount™ to a degree. Also, fit testing via the drink tube puts stress on the drink tube, which is one of the most vulnerable parts of the mask to leak.

b. Please note that TSI has a version of the speaking diagram adapter kit (TSI PN 8025-29), but is priced at ~ $125.00 for the kit. TSI's kit is sold with P100 filters for Advantage and Millennium masks. The MSA kit only contains the probed disc that replaces the speaker diaphragm and filters are ordered separately. The TSI instructions for using the *Speaking Diaphragm Fit Test Adapter Kit* are provided at the following website link.

c. **Again, fit test with a CBRN canister (which includes a P100) - not with only a light-weight high efficiency filter.**

3. When using the CNP method, the heavy CBRN canister is replaced with the CNP leak-tight test adapter to seal the normal air pathways into the respirator. Occupational Health Dynamics (OHD), the manufacturer of the Fit Tester 3000 and the Quantifit makes a CBRN leak-tight test adapter that approximates the weight and the size of CBRN canisters. Ensure the CBRN leak-tight test adapter is worn when fit testing CBRN gasmasks with the CNP method. The OHD part number for the CBRN leak-tight test adapter is 9513-0207 (Kit number 24).

V. REFERENCES

1 AIHA (1986) *AIHA: Odor Thresholds for Chemicals with Established Occupational Health Standards*; American Industrial Hygiene Association, Fairfax, VA.

2 Occupational Safety and Health Administration (OSHA): 29 CFR Parts 1910 and 1926 Respiratory Protection: Final Rule. Federal Register 63(5):1278–1279. Washington, D.C.: U.S. Government Printing Office, Office of the Federal Register, January 8, 1998, as amended 8June 2011.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards

3 American National Standards Institute (ANSI) ANSI)/American Industrial Hygiene Association (AIHA): American National Standard for Respirator Fit Testing Methods (ANSI/AIHA-Z88.10).Fairfax, VA: AIHA, 2010.

4 Burgess,W.A., Silverman, L., and Stein, F.: A New Technique for Evaluating Respirator Performance. Am. Ind. Hyg. Assoc. J. 22:6, 422–429 (1961).

5 Hyatt, E. C., et al. Respirator efficiency measurement using quantitative DOP man tests. Am Ind Hyg Assoc J 33:635-643 (1972).

6 Respiratory Protective Apparatus-Tests for Permissibility; Fees: Schedule 21B, Filter-Type Dust, Fume, and Mist Respirators, Code of Federal Regulations Ref. 30 CFR Part 14, Jan. 19, 1965; amended March 23, 1965, and June 12, 1969.

7 Rengasamy, S., Eimer, B. C. and Shaffer, R. E.: (2012): Evaluation of the Performance of theN95-Companion: Effects of Filter Penetration and Comparison with Other Aerosol Instruments, Journal of Occupational and Environmental Hygiene, 9:7, 417-426(2012).

8 OPNAVINST 5100.23 Series.
http://doni.daps.dla.mil/allinstructions.aspx?RootFolder=/Directives/05000%20General%20Management%20Security%20and%20Safety%20Services/05-100%20Safety%20and%20Occupational%20Health%20Services&View={1FF912B1-1BC6-444A-8943-B769C77880F2}

9 NIOSH Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Full Facepiece Air Purifying Respirator (APR) updated 30 Jan 2004.
http://www.cdc.gov/niosh/npptl/standardsdev/cbrn/apr/

10 PHONCON OSHA Mr. J. Steelnack/ NAVMCPUBHLTHCEN Mr. D. Spelce of 24 May 07

APPENDIX H
QUALIFICATIONS FOR FIT TEST OPERATORS

I. OPNAVINST 5100. 23 SERIES FIT TEST OPERATOR TRAINING

A. Qualifications for fit test operators are covered in paragraph 1512.e. of OPNAVINST 5100.23G, which states, *"Personnel assigned by the RPPM to conduct respirator fit testing should be trained and evaluated according to clause 5 and Annex A1 of* [ANSI Z88.10-2010]*."*

B. The RPPM is responsible for ensuring fit test operators are properly trained and possess the necessary skills for performing fit testing per ANSI Z88.10. The RPPM can either send fit test operators to commercially available training courses or train them in-house. The RPPM will use the Fit Test Operator Evaluation Form, modified from Annex A of ANSI Z88.10, to evaluate and verify fit test operators' qualifications (A *Fit Test Operator Evaluation Form* adapted from Annex A of ANSI Z88.10 is provided at the end of this appendix.). Fit test operators must demonstrate mastery of the fit test procedures in Appendix A of 29 CFR 1910.134 along with being proficient in the appropriate sections of the command respiratory protection instruction concerning respirator fit testing, inspection, cleaning, and storage.

C. Fit test operators will receive training and demonstrate proficiency in the following areas:

1. respiratory protective devices used in activity workplaces;
2. respirator components and their function;
3. respirator inspection, cleaning and maintenance;
4. brands and models of respirators worn;
5. respirator capabilities and limitations;
6. proper donning/doffing procedures along with positive and negative pressure user seal checks;
7. Fit test methods:
    a. purpose of fit testing (be able to explain the fit test purpose and procedures to personnel being fit tested);
    b. fit testing procedures;
    c. limitations of the test methods (e.g., sensitivity tests and subjective responses of qualitative methods);
    d. fit test results;
    e. proper respirator cleaning and sanitizing;
    f. proper cartridges/filters for each fit test method used;
    g. probes or fit test adapters used in quantitative fit testing;
    h. qualitative fit test materials;
    i. quantitative fit test equipment, including assembly and operational checks;

j. understand when not to perform fit testing based on facial characteristics, features, jewelry, or other problems, such as facial hair, that would interfere with the facepiece sealing surface;

k. evaluating and recording fit test results;

FIT TEST OPERATOR EVALUATION FORM

Name of fit test operator evaluated: _____ Date: _____

Fit test method: _____

Evaluated by (RPPM): _____

Demonstration of knowledge and performance	Acceptable	Not Acceptable
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.	☐	☐
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.	☐	☐
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.	☐	☐
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 Appendix A of 29 CFR 1910.134.	☐	☐
– Properly interprets and records results.	☐	☐
– Performs respirator cleaning, sanitizing, or disposal.	☐	☐
Identifies likely causes of fit test failure.	☐	☐