This discussion is intended for persons who are unfamiliar with the qualitative fit test (QLFT) and quantitative fit test (QNFT) procedures used in the United States to fit test industrial respirators. It includes brief descriptions of each type of fit test used, and the differences between QLFT and QNFT in general.

**Background**

Industrial respirators are worn by persons who must work in environments where the air is unfit to breathe. Respirators fall into two basic types: Air Purifying Respirators (APR) that filter contaminants from the ambient air, and Supplied Air Respirators (SAR) that provide clean air from a separate source such as a compressor or high-pressure cylinder.

APR and SAR can both be further separated into tight-fitting and loose-fitting styles. Tight-fitting respirators form a tight seal to the wearer’s face, and will not provide protection if they do not adequately match the individual’s facial features. Loose-fitting respirators are typically hoods that fit over the entire head and have a neck seal that is not dependent on the wearer’s features.

Positive-pressure respirators are special subclass available in both APR and SAR versions, which can in-turn, be either tight- or loose-fitting. They provide high levels of protection by pumping air into the mask at all times rather than relying on the wearer’s lung power to draw air in (as do negative-pressure respirators). Tight-fitting positive-pressure respirators are fit tested in "negative-pressure mode" by temporarily converting them in an APR with appropriate filters. This is done because the effectiveness of the face seal by itself cannot be evaluated properly while the air supply is turned on.

In the United States, government regulations require all persons using tight-fitting respirators to be fit tested by their employer on an annual basis. Loose-fitting respirators are exempt from fit testing requirements. The balance of this article pertains to tight-fitting respirators only.
The Reason for Fit Testing

Humans come in many shapes and sizes, as do respirators. This results in wide variability of physical dimensions and features of both people and respirators. The ability of a respirator to form a satisfactory seal or barrier between the wearer and the contaminated environment may be significantly affected by these variabilities. If the respirator-user match (fit) is not checked, an unsatisfactory seal/barrier may unknowingly exist. This could allow excessive leakage of airborne contaminants into the wearer’s breathing zone, even though the user is wearing a respirator correctly selected for the application. A fit test is used to assess whether a specific type, model and size of respirator can adequately fit a specific individual.

Another equally important reason for fit testing is to ensure that an individual knows how to properly don (put on) and wear the respirator. The proper size respirator will provide little protection if it is not worn correctly. This is why it is extremely important that the fit test operator not assist the test subject when the respirator is donned. The fit test is not the time to teach a person how to put on a respirator. This should have been done during an earlier training session. Half of the reason for the fit test is to find out if the test subject knows how to wear the respirator properly without help.

There are two basic types of fit tests: (1) qualitative (QLFT) and (2) quantitative (QNFT). QLFT test is a pass/fail test relying on the subject’s voluntary or involuntary response to a challenge agent; i.e., taste, smell or irritation. If the subject detects the challenge agent at any time during the test, the subject fails the test. When the fit test is passed, the person is deemed to have a fit factor that is at least as high as the QLFT was designed to determine. That fit factor is 100 for all currently accepted QLFT protocols. This means that in most cases, QLFT is only used for half-mask respirators, since a fit factor of 100 is considered adequate. Respirators that require a fit factor above 100 must be fit tested using QNFT.

QNFT measures the challenge agent leakage into the respirator without dependence on a test subject’s voluntary or involuntary response to the challenge agent. The instrumentation is typically capable of measuring fit factors of 10,000 and higher. Respirators that require a fit factor above 100 must be fit tested using QNFT.

All fit test protocols require the test subject to perform a series of exercises meant to simulate workplace motions. In the USA, there are typically eight 60-second exercises:

1. Normal breathing  
2. Deep breathing  
3. Head side to side  
4. Head up and down  
5. Talking out loud  
6. Grimace for 15 seconds (QNFT only)  
7. Bend and touch toes (or jog in place)  
8. Normal breathing

The final result of a QNFT is computed as a weighted average of the individual exercise fit factors. It is called the Overall Fit Factor.

The grimace exercise is only 15 seconds long because it is really not an "exercise" like the others. The reason for doing the grimace is to try and intentionally break the face seal to see if the mask will reseat itself afterwards. The fit factor measured after the grimace is what’s important, not the fit factor measured during the grimace. This is the reason why there is no requirement to include the grimace fit factor (if measured) in the overall fit factor computation. The grimace exercise is not included in QLFT protocols because breaking the face seal intentionally (thereby forcing the person to sense the challenge chemical) would always result in a failed fit test.
Qualitative Fit Testing (QLFT)

Some U.S. standards and regulations have historically permitted the use of either QLFT or QNFT for both half-face and full-face respirators. However, if you examine the research that has been done, you will discover that QLFT is not adequate for determining whether or not a person is achieving the high level of fit required for full-face respirators.

OSHA recognized this fact in the OSHA Respiratory Protection Standard 29CFR1910.134 that was released on January 8, 1998. QLFT is only permitted for fit testing tight-fitting respirator facepieces that are allowed to pass with a minimum fit factor of 100. Since OSHA requires a fit factor of 500 for full-face masks, and since there is currently no approved QLFT protocol capable of determining a fit factor higher than 100, employers using tight-fitting full-face respirators must either install engineering controls to eliminate the need for full-face masks or adopt QNFT.

OSHA's position on this issue makes sense. A fit factor below 500 for a full-face mask indicates an extremely poor fit. It is actually very easy (and common) to achieve much higher fit factors with the full-face respirators now on the market. OSHA has provided a detailed explanation of the rationale used for the standard in the Preamble to 29CFR1910.134. For your convenience, TSI has prepared Application Note ITI-056: Respirator Fit Testing Highlights for OSHA Respiratory Protection Standard 29CFR1910.134 listing the major fit test related issues contained in the standard along with associated page references. A copy can be found on the TSI Website www.tsi.com.

OSHA and the various other U.S. organizations that publish fit testing regulations and standards invariably use 100 as the minimum acceptable fit factor for half-face masks. Full-face respirators require a minimum fit factor of 500, and in some consensus standards such as ANSI Z88.2-1992, a fit factor of at least 1000 is required.

There are four types of QLFT currently accepted by OSHA:

- Isoamyl Acetate
- Sodium Saccharin
- Bitrex
- Irritant Smoke

The OSHA protocol for these fit test methods can be found in Appendix A of the OSHA Respiratory Protection Standard 29CFR1910.134. Each method is discussed below.

**Isoamyl Acetate (banana oil) QLFT Protocol**

The Isoamyl Acetate Protocol uses isoamyl acetate, more commonly known as banana oil or IAA, as a test agent. It is a qualitative fit test that relies on a person's sense of smell. If a banana odor is detected during the fit test, the fit is not acceptable.

The first part of the test involves testing the employee's sense of smell. Two jars of water are prepared, one with a low concentration of isoamyl acetate, the other with plain water. The employee must correctly identify the jar with the banana odor to qualify for this fit test method. Those who cannot identify the correct jar must wait until their sense of smell recovers (they could be suffering from a cold or olfactory fatigue), or be fit tested using another technique.

During the test, a repeatable concentration of IAA around the test subject’s head is established by using a plastic 55-gallon drum liner for a test booth. IAA is introduced into the booth by applying 0.75 cc of IAA on a paper towel of exactly 5 by 6 inches (folded in half), hanging it above the person’s head, and then waiting two minutes. Each employee must use a newly prepared paper towel.
The Isoamyl Acetate Fit Test Protocol was developed and tested in the laboratory by comparing it to QNFT. This process is called validation. The Isoamyl Acetate Protocol has been validated for a fit factor of 100 only. In other words, a person who successfully passes a properly conducted isoamyl acetate fit test can claim a fit factor of 100 but no more.

**Saccharin Solution Aerosol QLFT Protocol**

Another type of QLFT is the Saccharin Solution Fit Test. Sodium saccharin is the true chemical name of the test agent used. This technique is most commonly used for disposable filtering-facepiece type respirators but can be used for other masks as well. The saccharin test relies on a person’s sense of taste. If the sweet taste of the saccharin is detected, the mask does not fit well enough.

A repeatable concentration of saccharin solution is maintained by putting a hood over the test subject's head and spraying saccharin solution into it using a hand operated atomizer.

A threshold test is conducted before the test subject dons the respirator to determine what concentration of saccharin is required to reach the test subject's taste threshold. The threshold test is made using a weaker concentration of saccharin than is used for the actual fit test. The number of atomizer squeezes required to elicit a taste response from the test subject is recorded. If more than 30 squeezes are needed, that person cannot be tested with this method because his or her sense of taste (for saccharin) is inadequate.

After the threshold test, the subject dons the respirator and hood, and then begins the exercise sequence. Every 30 seconds during the exercises, the test operator must apply from 5 to 15 squirts of saccharin solution into the hood. The exact number of squeezes that must be sprayed into the hood ranges between 5 and 15 depending on the results of the threshold test. This maintains the proper concentration of saccharin aerosol around the test subject's head. A properly executed saccharin fit test requires from 75 to 225 squeezes of the atomizer bulb.

The person being fit tested must be instructed to breathe through his or her mouth with tongue extended during the test. The reason for this should be obvious. The test subject will never taste the sweet saccharin if he or she is breathing through the nose.

The saccharin protocol has been validated in the lab with the same limitation as the IAA test. A person who successfully passes a properly conducted saccharin solution fit test can claim a fit factor of 100 but no more.

Sodium saccharin is considered to be a potential occupational carcinogen. NIOSH has stated that "Because sodium saccharin is a potential occupational carcinogen, we recommend that it not be used for respirator fit-testing." Technically speaking, however, the amount of saccharin that a person is exposed to during a fit test is very low and is below the level used in many consumer products. OSHA is indifferent to the NIOSH position and continues to allow saccharin fit testing. See the 29CFR1910.134 Preamble for an explanation.

**Bitrex Solution Aerosol QLFT Protocol**

This protocol uses a bitter-tasting test agent called Bitrex. Bitrex is an FDA-approved flavoring originally developed as an aversion agent in toxic household chemicals to deter children from swallowing them. The technical name for the chemical is denatonium benzoate.

The Bitrex test uses the same hood, atomizer, threshold test and general procedure as the saccharin test. Bitrex is said to produce a strong reaction from test subjects when leaks do
As with saccharin, the person being fit tested must be instructed to breathe through his or her mouth with tongue extended during the test.

The Bitrex protocol has been validated in the lab with the same limitation as the IAA and saccharin protocols. A person who successfully passes a properly conducted Bitrex solution fit test can claim a fit factor of 100 but no more. As with the saccharin fit test, anywhere from 75 to 225 squeezes of the atomizer bulb are required for each fit test.

**Irritant Smoke QLFT Protocol**

The fourth method that OSHA permits for QLFT is the Irritant Smoke Protocol. This test utilizes a chemical called stannic chloride (SnCl$_4$), which is sprayed out of a ventilation tube around the test subject’s head with the use of a squeeze bulb. As ambient air is forced through the tube, SnCl$_4$ reacts with moisture in the air producing a white hydrochloric acid fume (HCl) and tin compounds. If enough of the irritant smoke leaks into the mask it will result in a reaction such as coughing or watery eyes (OSHA requires that the person being fit tested close his or her eyes when using this protocol).

The Irritant Smoke Protocol cannot be truly validated because of the lack of a true threshold test. A 100 percent concentration of irritant smoke is directed at the test subject’s face prior to the test just to show him/her what it feels like. Since the concentration of irritant smoke is high and uncontrolled, this is by no means a threshold test. Also, the concentration of irritant smoke around the test subject’s head during the fit test is not controlled or repeatable. There is no enclosure as with the saccharin and IAA test. Technically speaking, a claim of a specific fit factor cannot be made after passing this test. Like the other QLFT protocols, OSHA allows a person who successfully passes a properly conducted irritant smoke fit test to claim a fit factor of 100 but no more.

The irritant smoke QLFT protocol could be called the hydrochloric acid protocol. Many organizations refuse to allow it because of the potential exposure for fit test subjects and test operators alike. It’s also worth noting that the Material Safety Data Sheet (MSDS) for stannic chloride warns:

**CAUSES BURNS ---- DO NOT GET IN EYES, ON SKIN, ON CLOTHING. AVOID BREATHING DUST.**

In addition, irritant smoke fit testing has been studied by NIOSH in a NIOSH Health Hazard Evaluation Report (HETA 93-040-2315). In this report, NIOSH asserts that unhealthy concentrations of hydrogen chloride resulting from the reaction of stannic chloride with ambient humidity can occur during the fit test. On August 4, 1999 NIOSH released an updated Respirator Use Policy that states:

"NIOSH reviewed the revised protocol for the irritant smoke test in OSHA's final respiratory protection standard and concluded that a risk still exists for overexposure to hydrogen chloride during a facepiece fit test. To check their sensitivity, test subjects are required to breathe irritant smoke both before and after a successful fit test. Generated concentrations to which test subjects are subjected are not measured in the test protocol. A concentration of 5 ppm is the accepted threshold level at which a response is evoked from most persons. A fit test is a failure when a test subject experiences an involuntary cough or irritation. Retesting requires repeating the sensitivity check. In each case, the responses of coughing and irritation are the adverse health effects for which hydrogen chloride’s exposure limits are intended to protect against. Consequently, NIOSH maintains its recommendation against the use of irritant smoke as a fit testing agent."

Nonetheless, OSHA has included the irritant smoke protocol in 29CFR1910.134. OSHA addresses the exposure concerns by prohibiting the use of a chamber or hood and requiring the eyes to be
Quantitative Fit Testing (QNFT)

There are several QNFT methods in use today. These include aerosol generator/booth systems, ambient aerosol challenge systems, and controlled negative pressure systems. All quantitative methods require the use of a specially modified respirator. The modification can be in the form of a permanently probed respirator that is otherwise the same as the respirator that the person will be issued, or by using special fit test adapters that temporarily add a sampling port to the person’s own respirator.

True quantitative fit testing involves a direct numerical measurement of the respirator face seal performance called a fit factor. A fit factor is simply the ratio of a challenge agent concentration outside the respirator to the concentration of challenge agent that leaks into the inside of the respirator. A fit factor of 100 means that the air inside the respirator is 100 times cleaner than the air outside. Controlled negative pressure (CNP) systems do not measure fit factor, however, they provide an “equivalent fit factor” that is used the same way.

Generated Aerosol/Booth Systems (QNFT)

This is the conventional method that has been used for many years. The system consists of an aerosol generator, a booth or chamber, and a photometer based aerosol detector.

The aerosol generator produces a high concentration of challenge aerosol (usually corn oil) that is injected into a booth or chamber used to contain the aerosol. The test subject stands inside the chamber and performs a series of exercises as the instrument samples how much challenge agent leaks into the respirator.

The reason for the generator and chamber is because the photometers used cannot measure very low concentrations of aerosol. To overcome this limitation these systems maintain an extremely high concentration outside the respirator allowing for correspondingly high aerosol concentrations inside the respirator. In other words, in order to use a photometer the outside concentration must be very high such that a typical leak will allow a measurable quantity of aerosol to enter the respirator. The typical concentration of corn oil is so high that the chamber appears to be filled with fog. Generated aerosol systems require very high maintenance levels (cleaning of internal components) in order to keep them functioning properly.

Generated aerosol systems were once available in a wide range of configurations ranging from 50-pound transportable units to permanently installed computerized systems that fill a room. The aerosol generator / booth systems are largely obsolete for commercial use. They are still used by respirator manufacturers and research agencies.
Ambient Aerosol QNFT Systems

Ambient aerosol QNFT instruments measure aerosol concentration outside and inside the respirator and compute a true fit factor just like the older aerosol generator / booth systems. The difference is that there is no chamber and no aerosol generator. The challenge agent used is the ambient microscopic dust and other aerosols that are present in the air we breathe at all times. This allows the instrument to be small, light weight, easier to maintain, and less expensive. The PORTACOUNT® is an ambient aerosol fit tester.

Ambient aerosol fit testers use a technology known as condensation nuclei counting (CNC). It is also known as condensation particle counting (CPC). These instruments use laser technology to count microscopic particles that always exist in the air, and use those particles to directly measure respirator fit factors. During the fit test the respirator must be equipped with high-efficiency filters that prevent the ambient particles from passing through. That way, any particles counted inside the mask have to have come in through a leak, since they cannot get inside any other way. The particle concentration outside the mask is measured followed by an inside measurement. The ratio of those two measurements is the fit factor.

Quantitative aerosol fit test methods may be used for lower efficiency particulate respirators such as class-95 filtering-facepieces (i.e., disposable respirators, dust masks, TB masks, etc.) if care is taken to limit the particle sizes used for the challenge aerosol. For example, the TSI PORTACOUNT can fit test class-95 respirators when used with the N95-Companion™ accessory.

Controlled Negative Pressure (CNP) Systems (QNFT)

In the early 1990's, a technique for "quantitative" fit testing was introduced called controlled negative pressure or CNP. CNP instruments do not actually measure fit factors, they estimate an "equivalent fit factor" which is used the same way as a measured fit factor. Special adapters that allow the breathing air supply to be temporarily cut off replace the filter cartridges. The instrument pulls a fixed vacuum on the mask and measures the airflow (leak rate) needed to maintain the vacuum. The fixed vacuum level is assumed to produce the same face seal leakage as actual breathing does. The equivalent fit factor is computed by taking an average breathing rate for an average person and dividing that number by the measured leak rate. The person being tested must hold his/her breath during the measurement and remain absolutely motionless, otherwise the leak rate measurement cannot be made reliably. Since measurements cannot be made while the test subject performs the exercises, the test subject must stop moving and breathing between exercises while the measurement is made. CNP systems cannot fit test filtering-facepiece respirators because there is no way to stop air from entering through the filter/mask, since they are one and the same.
Quantitative vs. Qualitative

There are advantages and disadvantages to either method of fit testing respirators. While in the U.S. there are some regulations requiring quantitative fit testing, most companies are allowed to choose which method is best for them. The table below lists some advantages and disadvantages of each method.

### Qualitative Fit Testing (QLFT)

**Advantages**
- Inexpensive up-front cost
- Low maintenance

**Disadvantages**
- Imprecise
- Easy to do wrong (tedious)
- No documentation of results
- Subject to deception
- Limited to fit factor of 100 (half masks)
- People dislike wearing the hood
- Slow (because of threshold test)

### Quantitative Fit Testing (QNFT)

**Advantages**
- No fit factor limit
- Precise
- Faster
- Hard copy documentation of results
- No chance of deception
- Easy to do right
- Useful for employee respirator training

**Disadvantages**
- More expensive up front cost
- Requires probed respirator or sampling adapter
- Annual factory recalibration recommended

Related Documents

- TSI Application Note ITI-040: Occupational Health Risks Associated with the Use of Irritant Smoke for Qualitative Fit Testing of Respirators
- OSHA Directive CPL2-0.120 released on 9/25/98
- OSHA Small Entity Compliance Guide released on 9/30/98