WHY QUANTITATIVE RESPIRATOR FIT TESTING BEATS QUALITATIVE

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Qualitative or Quantitative Fit Testing for Respirators: Background

Since the first gas masks used in World War I, it has been clear that poorly fitting masks put wearers at risk. To improve outcomes, researchers developed methods to test the fit of a mask to its wearer. Early respirator fit testing usually involved exposing the wearer to a concentrated smell inside a hood. If the wearer detected the odor, the respirator fit was inadequate.

For decades, this qualitative method was the only test available. It relied entirely on the subject's honesty and ability to sense odors or chemical irritants. Concerns about the effectiveness and subjectivity of qualitative fit tests were widespread. Researchers applied themselves to developing better, more data-driven fit test methods.

What is Quantitative Fit Testing?

Quantitative fit testing (QNFT) first came on the scene in mid-1980s. The PortaCount® Respirator Fit Tester was a pioneering product for quantitative respirator fit testing. Developed by TSI, the PortaCount Respirator Fit Tester features a sampling device installed on the respirator allowing the probe to sample air from inside the mask.

The PortaCount Respirator Fit Tester uses ambient aerosol as the challenge agent to test a respirator while worn. Using an instrument called a Condensation Nuclei Counter, the PortaCount Respirator Fit Tester grows microscopic particles to an optically detectable size. It then counts them, measuring both inside and outside the respirator. The PortaCount software calculates this ratio—C_{out}/C_{in}—to give a fit factor (FF) for the respirator. Quantitative respirator fit testing doesn't depend on the wearer's sense of smell or taste, but instead counts particles and calculates a fit factor to give an objective reading.

Shift from QLFT to QNFT

Health and safety experts recognized that measuring fit factor by quantitative fit testing is a superior method to qualitative fit testing. Recognition soon became employment law. On January 8, 1998, the U.S. Occupational Health and Safety Administration released OSHA Respiratory Protection Standard 29 CFR 1910.134.

OSHA 29 CFR 1910.134 establishes the type of respirator fit testing required for specific types of respirators. OSHA assigns a number to the class of respirators, the Assigned Protection Factor or APF. It signifies the amount of protection provided by the respirator.

OSHA's Assigned Protection Factor (APF)

OSHA assigns half-face elastomeric and N95 filtering face piece respirators an APF of 10. In other words, those respirators qualify as respiratory protection for up to 10x the Permissible Exposure Limit of a particular hazard. Full-face elastomeric respirators have an APF of 50.

OSHA 29 CFR 1910.134 permits qualitative respirator fit testing only for tight-fitting respirator face pieces or filtering face pieces with an Assigned Protection Factor (APF) of 10, with a pass/fail level of 100. OSHA requires tight-fitting full-face masks with an APF of 50 to achieve a pass/fail level of 500. There is currently no approved QLFT protocol capable of determining a pass/fail level for respirators with APFs greater than 10.

As a result, employers using tight-fitting full-face respirators must either install engineering controls to eliminate the need for the use of full-face masks, or adopt quantitative fit testing.

Learn more about the difference between Fit Factors and Protection Factors.

Permissible Exposure Limit (PEL) and Maximum Use Concentration (MUC)

OSHA establishes permissible exposure limits (PEL) in the U.S. A PEL is the legal limit for exposure of a worker to a physical, chemical or biological substance. Maximum Use Concentration (MUC) is another important limit to understand. To calculate MUC, two numbers are required, the respirator's APF and the PEL of the hazardous substance. The formula is MUC = PEL x APF.

Here is an example using the chemical benzene. Benzene's PEL is 0.5 ppm. For respirators with an APF of 10, the calculation for providing respiratory protection against benzene would be MUC = 0.5 ppm x 10 = 5 ppm benzene. For respirators with APF of 50, the calculation for benzene would be MUC = 0.5 ppm x 50 = 25 ppm benzene.

More Support for OSHA's Position

OSHA's position on this issue makes sense. A fit factor below 500 for a full-face mask indicates an extremely poor fit. Full-face respirators now on the market commonly achieve much higher fit factors. OSHA and the various other organizations that publish fit testing regulations and standards invariably use 100 as the minimum acceptable fit factor for half-face masks. Some standards for full-face masks require a FF of at least 1000. TSI's article, Standards and Regulations Pertaining to Respirator Fit Testing, includes a table matching fit testing requirements to relevant standards.

OSHA provides a detailed explanation of the rationale behind 29 CFR 1910.134 in the standard's preamble. You can find this and other related articles on www.osha.gov. TSI has also published a helpful guide to the standard in Respirator Fit Testing Highlights for OSHA Respiratory Protection Standard 29 CFR 1910.134.

Limited Use of Qualitative Respirator Fit Testing Methods

OSHA permits just four QLFT methods, to be used under limited circumstances—Isoamyl Acetate, Sodium Saccharin Solution, Bitrex® Solution, and Irritant Smoke. Each of them are examined separately 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. This qualitative fit test relies on a person's sense of smell. If the wearer detects a banana odor during the fit test, the fit is not acceptable.

The first test evaluates the worker's sense of smell. Two jars of water are prepared, one with a low concentration of isoamyl acetate, the other with plain water. The worker must correctly identify the jar with the banana odor in order to qualify for this fit test method. Those who cannot identify the correct jar must wait until their sense of smell recovers (they may temporarily suffer from a cold or olfactory fatigue). Workers with permanent sensory impairment do not qualify for this QLFT method.

Test administrators use a plastic 55-gallon drum liner to serve as a booth and create a repeatable concentration of IAA around the test subject's head. The administrator applies 0.75 cc of IAA on a paper towel that is exactly 5 by 6 inches, folded in half. The administrator introduces IAA into the booth by hanging the towel above the subject's head. A two-minute wait follows. Each test requires a newly prepared paper towel.

With quantitative fit testing as the standard of comparison, researchers tested the effectiveness of Isoamyl Acetate Fit Test Protocol. Isoamyl Acetate Protocol achieves validation for a fit factor of 100. In other words, a properly conducted IAA fit test can bestow 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 chemical name of the test agent used. Most commonly used for disposable, filtering face-piece respirators, the saccharin test can apply to other masks as well. The saccharin test relies on a person's sense of taste. If the respirator wearer detects the sweet taste of the saccharin, the mask does not fit well enough.

Administrators of the saccharin test first conduct a sensitivity test to determine the concentration of saccharin required to reach the test subject's taste threshold. As with the IAA test, administrators introduce a repeatable concentration of saccharin test solution into a hood placed over the respirator wearer's head, using a DeVilbiss nebulizer. The subject's threshold test determines the number of nebulizer squeezes required (usually between 10 and 30). The administrator must

instruct the test subject to breathe through his or her mouth—with tongue extended—throughout the test.

The Saccharin Solution Protocol has the same FF limits as the IAA test. A successful saccharin solution fit test can claim a fit factor of 100 but no more.

NIOSH, the U.S. National Institute of Occupational Safety and Health, spoke out against using the Saccharin Solution Protocol, stating, "Because sodium saccharin is a potential occupational carcinogen, we recommend that it not be used for respirator fit-testing.[1]" OSHA is indifferent to the NIOSH position and continues to allow saccharin fit testing. See the 29 CFR 1910.134 Preamble for more information.

Bitrex® Solution Aerosol QLFT Protocol

Bitrex® is an FDA-approved, bitter tasting flavoring originally developed as an aversion agent. Manufacturers added Bitrex® to toxic household chemicals to discourage children from swallowing them. Bitrex's chemical name is denatonium benzoate.

The Bitrex® test uses the same hood, nebulizer, procedure, and sensitivity solution to determine taste threshold as the saccharin test. Bitrex® has a reputation for producing a strong reaction from test subjects in failed fit tests. As with saccharin, the test administrator must instruct the subject to breathe through his or her mouth, with tongue extended, during the test.

The Bitrex® Solution Aerosol Protocol has achieved identical FF limits as the IAA and saccharin tests. A properly conducted and successful Bitrex® test validates to a fit factor of 100 but no more.

Irritant Smoke QLFT Protocol

The Irritant Smoke Protocol uses a corrosive chemical, stannic chloride ($SnCl_4$). $SnCl_4$ sprays out of a ventilation tube around the test subject's head by way of a squeeze bulb. A squeeze of the bulb forces ambient air through the tube. The $SnCl_4$ reacts with moisture in the air, producing hydrogen chloride (HCl) acid gas. As $SnCl_4$ emerges from the tube, it reacts with the moisture in the air to form a visible smoke. If enough of the irritant smoke leaks into the mask, the wearer reacts with coughing or watery eyes. OSHA requires that a person undergoing Irritant Smoke testing must close his or her eyes.

Irritant Smoke is problematic for a number of reasons. In 1983,[2] Los Alamos National Laboratory conducted a study of the method's effectiveness. Researchers reported only a 92 percent confidence level for a fit factor of 100. Industry experts generally agree that a 95 percent confidence level is required.

Due to the lack of an accepted threshold test, the Irritant Smoke Protocol cannot truly validate. Prior to testing, administrators direct a 100% percent concentration of irritant smoke at the test subject's face as a reference. Since the concentration of irritant smoke is high—as well as uncontrolled and unrepeatable—this does not qualify as a threshold test. Unlike the IAA and saccharin tests, the Irritant Smoke Protocol does not use a hood or enclosure.

Irritant Smoke Protocol methods do not qualify for a specific fit factor after a successful test. Some studies cited by OSHA suggest that it is effective for determining a fit factor of 100. Like other QLFT protocols, OSHA allows a successful and properly conducted irritant smoke fit test to claim a fit factor of 100 but no more.

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[1] Letter from J. Donald Millar, M.D., Director of NIOSH to Mr. Darell A. Bevis, Industrial Hygienist, January 31, 1992.

[2] James L. Marsh, Evaluation of Irritant Smoke Qualitative Fitting Test for Respirators, Los Alamos National Laboratory document LA-9778-MS, 1983

NIOSH identified another problem with the Irritant Smoke Protocol. In a 1993 Health Hazard Evaluation Report,[3] NIOSH stated that unhealthy concentrations of hydrogen chloride acid gas could result from the reaction of irritant smoke with ambient humidity. Subjects in one case encountered hydrogen chloride concentrations of 100 ppm to 14,400 ppm during fit testing. The permissible exposure limit (PEL) for hydrogen chloride is 5 ppm and 100 ppm is the concentration determined by NIOSH to be immediately dangerous to life and health.

Additionally, there have been published reports of respiratory fatigue related to Irritant Smoke tests. The MSDS for stannic chloride warns users not to breathe the smoke or allow it to touch your clothing or skin. Concerns about liability have caused some ventilation tube suppliers to discontinue promotion of the product for respirator fit testing purposes.
On May 4, 1999, NIOSH issued a Respirator Use Policy Statement. In this document, NIOSH stated its position that irritant smoke is unsafe for fit testing. Nevertheless, OSHA included Irritant Smoke Protocol in 29 CFR 1910.134. OSHA addresses the exposure concerns by prohibiting the use of a chamber or hood and by requiring the subject's eyes to close during testing. A detailed explanation of OSHA's reasoning for retaining the irritant smoke protocol is in the Preamble to 29 CFR 1910.134.

Conclusion

Current qualitative fit testing protocols are unsuitable to fit test respirators with APF's greater than10, where a fit factor of more than 100 is required. OSHA's Respiratory Protection Standard 29 CFR 1910.134 recognizes this reality and codifies it into employment law. The standard replaced varied fit testing provisions in the other substance-specific regulations, thereby ensuring that employers and their representatives carry out respirator fit testing safely and consistently in all situations.

Ambient Aerosol Condensation Nuclei Counter (CNC) Quantitative Fit Testing Method is the standard for safe respirator use. The evidence is clear and well supported. Using quantitative versus qualitative fit testing ensures better fit, better documentation, and better compliance for a better-protected workforce.

[3]HETA 93-040-2315 Anchorage Fire Department Anchorage, Alaska, U.S. Dept. of Health and Human Services, National Institute for Occupational Safety and Health, May 1993 (for a free copy FAX a request to the NIOSH Publications Office at (513) 533-8573.)

