Personal Protective Equipment

3M and the Science of Fit Testing

Brought To You by 3M | Dec 20, 2017

The National Institute for Occupational Safety and Health's (NIOSH) theme for "N95" Day this year is "The Science behind Respirator Fit Testing in the Workplace: Past, Present, and Future." What might not be known is that 3M has been applying fit test science to respirator wearers' life for years. 3M even pioneered the creation of the saccharin qualitative fit test protocol – the first qualitative fit test for filtering facepiece respirators based on taste of a test agent.

A fit test is a technique using either a qualitative or quantitative protocol to evaluate sealing-surface leakage of a specific tight-fitting respirator while worn by an individual.[1] A qualitative fit test (QLFT) is a fit test that relies on the wearer's sensory response to detect the test agent. In order to evaluate sealing-surface (face-seal) leakage only, it is important that the fit test method does not allow significant filter penetration because the test agent coming though face-seal leaks or through the filter cannot be differentiated from each other by the measuring instrument or the wearer. This means that careful consideration needs to be given to the selection of a test agent for the respirator being fit tested. It must be able to identify face-seal leaks while not penetrating through the filter and be detectable (e.g., smell or taste) by the wearer.

The Saccharin Solution Aerosol Method was developed by 3M in the early 1980s so that an accurate QLFT method would be available that did not require the use of respirators that were probed or had filters other than the particulate filter used by employees. For example, standard quantitative fit testing (QNFT) requires the use of probed high-efficiency respirators instead of N95 filters that may actually be used in the workplace.

In 1981 OSHA proposed to permit the use of QLFT as an alternative to QNFT in the lead standard (29 CFR 1910.25) (Prior to this amendment QNFT was the only allowable method for fit testing in environments with lead aerosol) only if the employer follows strict protocols which are designed to increase the accuracy of QLFT. This "strict" protocol needed to include, according to OSHA, the following steps:

1. A respirator selection procedure so that a respirator which fits most comfortably is selected,
2. An odor or taste sensitivity pre-screening because each individuals sense of smell or taste has a different threshold,
3. A procedure to ensure constant generation of an adequate amount of the test atmosphere, and
4. Test exercises to test whether the respirator still fits during the user's regular activities.[2]

3M developed a protocol using saccharin as the test agent meeting these criteria. This protocol was accepted by OSHA and is currently called the "Saccharin Solution Aerosol Protocol" listed in 29 CFR 1910.134, OSHA's Respiratory Protection Standard. To gain OSHA acceptance the results of three studies designed to answer questions concerning the ability of the Saccharin Solution Aerosol Protocol to reject poor fitting respirators were submitted to OSHA. In addition, an independent study was conducted by JL Marsh at Los Alamos National Laboratory to evaluate the saccharin fit test protocol.[3] Marsh obtained similar results following the 3M saccharin protocol.

As a result of the rulemaking for the amendment to the lead standard, two other QLFT protocols (isoamyl acetate and irritant smoke) were added in addition to saccharin. These QLFT protocols are widely used with good success. However, each protocol and test agent has its own set of positive and negative features such as the types of respirators that can be fit tested, number of models that can be

fit tested with each agent, simplicity or difficulty to use, potential health effects such as irritation. Additional options for qualitative fit testing would clearly be useful. Work in this area resulted in 3M developing a second QLFT protocol in the 1990s. 3M concluded that the test agent should be a particle, suitable for use with any type of approved particulate filter. Such a test agent would allow the test to be used with all classes of particulate respirators. In addition, gas and vapor respirators could be tested by adding a particulate filter. An additional positive feature would be a test agent with a more unpleasant characteristic than saccharin or isoamyl acetate, but not as severe as irritant smoke. Finally, this test agent should have low toxicity. 3M decided on denatonium benzoate, commonly known by the trade name Bitrex™ (McFarland Smith Ltd., Montvale, NJ). Bitrex is commonly used as a taste aversion agent in household liquids that children or animals should not be drinking. It has been endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control.[4] Finally, a suitable fit test protocol was needed that met the OSHA requirements stated earlier. The protocol used by the OSHA saccharin solution aerosol was chosen. Validation of this protocol with Bitrex was conducted by performing a series of paired qualitative and quantitative fit tests as done with saccharin.[5] This 3M QLFT has also been included in the OSHA respirator standard and is called the Bitrex solution Aerosol Fit Test Procedure." Both the saccharin and Bitrex protocols are appropriate for fit testing N95 filtering facepiece respirators.

For more information on disposbale respiratiors from 3M, visit ***MSCDirect.com.***

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[1]American National Standards Institute (ANSI): American National Standard – Respirator Fit Testing Methods (ANSI Z88.10). Fairfax, VA: American Industrial Hygiene Association, 2010.

[2]Occupational Exposure to Lead: Qualitative Fit Testing Provision (Notice of Proposed Rule Making) 46 Federal Register 96. pp. 27359, 1981.

[3]Marsh, JL: Evaluation of saccharin qualitative fitting test for respirators. Am Ind Hyg Assoc J 45(6):371-376, 1984.

[4]Kleing-Schwartz, W. Denatonium benzoate: review of efficacy and safety. Vet Hum Toxicol 33:545-547, 1991.

[5]Mullins, HE, SG Danisch, and AR Johnston: Development of a new qualitative test for fit testing respirators. AIHA Journal 56:1068-1073, 1995.

