THE ESSENCE OF N95 RESPIRATOR FIT-TESTING

APPLICATION NOTE RFT-006

Be Prepared with a Complete Respiratory Protection Plan

by Jeff Weed
Reprinted from July 2009 issue of "Managing Infection Control."

The brisk pace of recent novel influenza A (H1N1) outbreak has come as a shock to many healthcare professionals, and has focused a spotlight on respiratory protection preparedness for healthcare workers. Hospitals that have been vigilant in implementing a formal CDC and OSHA-required respiratory protection program should take a moment to pat themselves on the back. Those that have yet to implement a program are fortunate that this particular H1N1 strain is (currently) not more virulent.

Proper implementation of an organization-wide respiratory protection program can be a huge undertaking that requires coordination and cooperation between infection control, occupational health and industrial hygiene professionals. Conscientious healthcare administrators know that an effective respiratory protection program has a lot more to it than just regulatory compliance. They have to know that the protection is actually being delivered to the healthcare worker, and that workers are confident that their respirators work. This is where respirator fit-testing comes in.

There are several types of respirators that use N95 filter media. This article is specific to NIOSH-approved N95 filtering-facepiece respirators like those commonly used in hospitals and other healthcare facilities. For simplicity, they will be referred to as N95 respirators.

A fit-test is used to assess whether a specific type, model and size of respirator can adequately fit a specific individual. In all cases, the individual must be fit-tested in the same make, model and size respirator that they will actually use later. OSHA requires the fit-test to be repeated annually. If your organization changes to a different respirator model, fit-testing will need to be repeated at that time. A fit-test must also be repeated in the unlikely event that a person's face changes during the year, perhaps due to a significant weight change.

An even more important reason for fit-testing is to ensure that an individual knows how to properly don (put on) and wear the respirator. A proper size respirator will provide little protection if it is not worn correctly. Respirator training includes instruction on how to adjust the respirator straps, the bendable nose band, and how to perform the mandatory user seal checks. The annual fit-test is done to make sure that training knowledge is retained, and properly put to use.

Despite claims to the contrary, it is not possible to simply look at a person wearing an N95 respirator and tell if it was donned correctly. One thing that is often overlooked is the interference caused by eye protection or eyeglasses. Getting an N95 respirator to seal properly while wearing eyeglasses is not easy. The respirator and the eyeglasses compete for the same nose space, and a compromise must be reached. It is not possible to look at a person and determine if leak-inducing interferences exists.

These are reasons why it is extremely important that the fit-test operator not assist the person when the respirator is donned. The fit-test is not the time to teach a person how to put on a respirator. The employee should be taught how to don the respirator before the fit-test session. Passing a fit-test means that the person knows how to don the respirator correctly, knows how to wear potentially interfering accessories, and lastly, has a respirator size that is appropriate to her or his unique facial features. If the test operator provides assistance, no one will ever know whether that employee learned how to don the respirator correctly.

Think of the fit-test as a final exam. The employee receives training, and then a fit-test is performed to verify that the person actually learned what was taught. Without a fit-test, there is absolutely no way to know that the person is capable of achieving the protection level expected from the respirator. I am dumbfounded by those who have no objection to annual respirator training, but oppose annual fit-testing. Annual respirator training and the subsequent fit-test are inseparable.

Those who oppose annual fit-testing, claim that the benefit to healthcare workers is unproven. Proponents of annual fit-testing are comfortable with the existing science. The Toronto, Canada experience with SARS in 2003 is one example where hospital respiratory protection programs have been truly put to the test. This statement from the Canadian SARS Commission Final Report puts the issue into perspective:

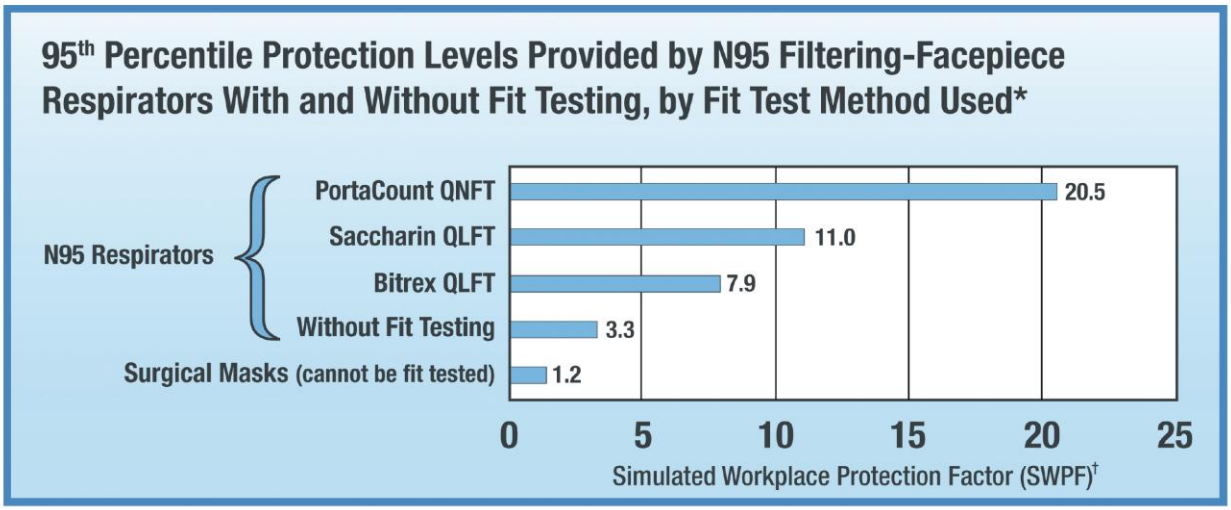
> *"It would be too easy to personalize this debate and point out that some of those who most vociferously oppose the N95 and fit testing, and who were most disdainful of nurses and independent safety experts who prefer precaution, were the very people on whose watch nurses became sick despite the assurances that they were safe."*

I have to agree in part with those who dislike annual repeat fit-testing. Work needs to be done to make fit-testing less objectionable, without sacrificing efficacy. Faster, cheaper, better, etcetera. There are currently efforts being made to do this. Unfortunately, there are also efforts underway to increase the interval or virtually eliminate repeat fit-testing by ignoring the skill retention issue and focusing only on facial changes. The claim is that fit-testing need not be repeated unless a person has facial changes. This is a red herring in my opinion. Facial changes are brought to light in the OSHA regulation (and others) only because they are exception that may prompt an early repeat fit-test. The annual fit-test requirement and the retest-due-to-facial-changes requirement are contained in separate paragraphs. I have participated in fit-testing at a Canadian hospital where the repeat fit-test interval is two years. Few people remembered how to don the respirator. Many did not even recall the respirator model they were fit-tested with. Two years is simply too long.

The issue of healthcare worker absenteeism in the event of a pandemic has been a cause for concern. Indications are that an alarming percentage of healthcare workers will simply not show up for work during a contagious outbreak, due in large part to concern for their own and/or their family's health. One way to maximize healthcare worker participation during such an event is to instill confidence in the use of N95 respirators. A strong respiratory protection program that includes thorough respirator training and verification of donning competence (i.e. a fit-test) will help give dedicated healthcare workers the courage to come to work, despite the risk.

Debate on the efficacy of N95 respirators in healthcare settings continues, but there is no doubt that fit-testing works. Studies have shown that respirator wearers who have been fit-tested achieve protection levels that far exceed those who were not fit-tested. A study performed by the National Institute of Occupational Safety and Health (NIOSH) in 2007 was especially revealing. The study explored the protection levels provided by N95 respirators with and without fit-testing, by the fit-test method used. Some of the results are summarized in Figure 1. You can see that any fit-test method significantly improves protection and quantitative fit-testing

Figure 1. Fit-testing works.



* Duling, M.G., Lawrence, L.B., Slaven, J.E., Coffey, C.C., [HHS/PHS/CDC/NIOSH], **Simulated Workplace Protection Factors for Half-Facepiece Respiratory Protective Devices**. *Journal of Occupational and Environmental Hygiene*, Vol. 4, No. 6, pp. 420-431, June, 2007.

† SWPF is the protection provided by a respirator, measured during a laboratory simulation of a workplace environment. A SWPF of 10 means that the air inside the respirator was 10 times cleaner than the air outside.

(QNFT) was particularly beneficial. NIOSH also tested some surgical masks and found they provided almost no protection at all. To help interpret the numbers, a value of 1.0 means no protection whatsoever; a value of 10 means that the airborne hazard concentration was reduced by a factor of 10.

It has been suggested that healthcare organizations should have a “rapid fit-testing plan” ready in case a bioterrorism or pandemic event occurs. This is totally absurd. Providing respirator training and fit-testing to the needed number of healthcare workers is not something that can be done rapidly, especially not when they are simultaneously needed to care for a flood of infectious patients. If a respiratory protection plan, respirator training and fit-testing program are not already in place when a catastrophe happens, it’s going to be too late.

Experts have been telling us for some time that a pandemic could hit us at any moment. Now that we have experienced the stunning speed with which SARS and the novel influenza outbreaks can spread, healthcare organizations need to take a close look at their respiratory protection program to make sure they are really ready. Healthcare administrators need to make sure their employees have learned what’s necessary to get the protection that respirators provide, and that they have the confidence to depend on them when it counts. Respirator training and fit-testing are necessary if respirators are expected to work, and must not be trivialized, separated or postponed.

Jeff Weed is president of the consulting firm, Weed Respiratory Protection Solutions LLC, and has been focused on respirator fit-testing for the last 22 years. He was the fit-testing expert for TSI Inc. from 1987 through 2008, and then founded WeedRPS. Mr. Weed served on the ANSI Z88.10-2001 subcommittee on respirator fit-test methods and is co-chairman of the current Z88.10 subcommittee working on the next revision. He is a member of the AIHA Respiratory Protection Committee and served on the board of advisors for the NIOSH No Fit-Test Respirator Workshop administrated by the University of Minnesota in 2008. He can be contacted by via email: Jeff@WeedRPS.com.

OSHA-Accepted Methods

THE FOLLOWING IS A BRIEF SUMMARY OF THE OSHA-ACCEPTED METHODS THAT CAN BE USED FOR FIT-TESTING N95 FILTERING FACEPIECE RESPIRATORS.

QLFT Fit-testing Methods

Qualitative fit-testing (QLFT) is a subjective pass/fail test that involves exposing the respirator wearer to a chemical stimulant that can only be detected if the respirator leaks unacceptably. If the person says that the chemical is detected, the leakage is too high and the fit is not acceptable (fail). When the chemical is not detected, the person is deemed to have an acceptable fit (pass).

Qualitative fit-test in progress.

There are four types of QLFT currently accepted by OSHA, but only two of them are useable for N95 respirators.

- ► Saccharin Solution Aerosol QLFT Protocol
- ► Bitrex® Solution Aerosol QLFT Protocol

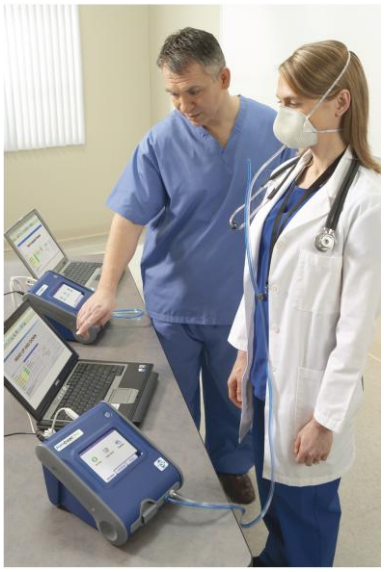
Both rely on the respirator wearer's sense of taste, and are virtually identical except for the chemical stimulant used. One is sweet-tasting and the other is bitter-tasting. The respirator wearer must breathe through their mouth, with tongue extended, during the fit-test to enable detection (tasting) of leakage. The respirator wearer's sense of taste must be tested prior to the fit-test to make sure he or she is capable of detecting low concentrations of the stimulant. A hand-held nebulizer is used to spray "challenge aerosol" into a fit-test hood that is worn over the person's head while they wear the respirator and perform specific exercises.

These fit-test protocols are scientifically proven to work, as long as the protocol is precisely adhered to. This is not necessarily easy, as QLFT is a manual type of fit-test that cannot be automated using computers or software. All too often, QLFT methods are compromised by well-meaning test operators who skip some of the important steps and thereby unknowingly invalidate the whole fit-test. The temptation to make the fittest go faster is intense, especially when the same test operator fit-tests dozens of people per day, day after day. To properly follow the protocol, a fit-test operator must squeeze the nebulizer bulb between 75 and 225 times for each fit-test performed. Clogging of nebulizer nozzles is also a common problem, especially for the saccharin method.

Each fit-test method has its pros and cons. QLFT requires a very low initial investment in equipment to get up and running. There are numerous manufacturers of QLFT kits and most respirator manufacturers and suppliers offer them for sale.

QNFT Fit-Testing Methods

Quantitative fit-testing (QNFT) is an objective test that involves the use of an instrument to measure how well the respirator fits. The measurement is not dependent on the person's voluntary response. An aerosol challenge agent concentration (C_{out}) is measured outside the respirator and then again inside the respirator (C_{in}). The ratio of the two measurements (C_{out}/C_{in}) is called a fit factor. OSHA requires half-mask respirators like N95 filtering-facepieces to have a fit factor of at least 100 to pass the fit-test. The fit factor pass level of 100 is not to be confused with the OSHA workplace rating of 10 for N95 respirators called the Assigned Protection Factor. Fit-testing employs a safety factor.



Quantitative respirator fit-test in progress.

®Bitrex is a trademark of Johnson Matthey Public Limited Company.

There are two OSHA-accepted QNFT methods that can be used for fit-testing N95 filtering-facepiece respirators.

► Generated Aerosol

► Ambient Aerosol

Generated aerosol fit-testing systems are considered to be the “gold standard,” but are complex and lack portability. They are only found in research laboratories and product development labs maintained by respirator manufacturers. Ambient aerosol systems, on the other hand, are commercially available and very portable. They are becoming more and more common in healthcare settings due to their many advantages.

Ambient aerosol QNFT instruments measure aerosol concentration outside and inside the respirator and compute a fit factor. The challenge agent used is the ambient microscopic particles that are present at all times in the air we breathe. These particles can’t penetrate the respirator filter, so any particles measured inside the respirator have to have come through a face seal leak.

Ambient aerosol fit-test instruments were first introduced more than 20 years ago by TSI Incorporated, Shoreview, Minnesota. Several versions have been developed over the years. The latest model for fit-testing N95 respirators is called the PORTACOUNT® PRO+ Model 8038.

QNFT methods are objective and take the respirator wearer’s individual sensitivity and attitude out of the equation. The instrument measures the fit while the person performs a series of special exercises and automatically records the results. QNFT methods have a technological advantage in that they lend themselves well to automation using computers and software to conduct the test, maintain records, and facilitate printing of fit-test certification cards that workers can carry. Software ensures precise adherence to the fit-test protocol and makes it virtually impossible to make mistakes. The tendency to take short-cuts that plagues qualitative methods is eliminated.

QNFT systems use computers and software to make the fit-test process as painless as possible. There is no way for the test operator to skip important steps, because the test is under programmatic control. Persons being fit-tested cannot deceive the QNFT instrument. Record keeping and report generation are easily accomplished and a respirator fit-test card can be automatically created for the healthcare worker to keep. The card helps people remember what model and size respirator they are qualified to use and if necessary, proves that they have a current fit-test.

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RFT-006 Rev. B Printed in U.S.A.