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The Importance of Performance Validation Testing:
New Standards for Evaluating the Quality of Fit Provided by Filtering Facepiece Respirators, Elastomeric Respirators and "COVID Face Masks"

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Protecting our workers and the population at large from exposure to respiratory hazards has been a long-standing public health imperative. In occupational settings, OSHA requirements are in place to ensure workers are wearing appropriate and effective breathing protection to mitigate respiratory hazards in their environment. Outside the workplace, COVID-19 mask mandates in some jurisdictions require the public to wear barrier face coverings for source control and personal protection. But what does it mean for breathing protection to be "effective" and how can workers and members of the public feel confident they're achieving the intended level of protection? The answer lies in conducting testing to evaluate filtration efficiency, resistance, and fitting characteristics. Two new ASTM standards address this need. ASTM F3407-20 provides guidance on testing of negative-pressure half-facepiece particulate respirators (e.g. N95 filtering facepiece or any elastomeric half-face respirator equipped with a particulate filter). ASTM F3502-21 provides guidance on testing of barrier face coverings (e.g. "COVID masks"). These standards do not currently apply to full facepiece respirators.

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OSHA mandates that, "In any workplace where respirators are necessary to protect the health of the employee or whenever respirators are required by the employer, the employer shall establish and implement a written respiratory protection program with worksite-specific procedures. The program shall be updated as necessary to reflect those changes in workplace conditions that affect respirator use." Occupational inhalation exposure hazards can vary widely and can include chemical, biological, and radiological hazards. Because of the number and nature of potential respiratory hazards, OSHA regulations specify that workplace respiratory protection programs must, among other elements, include annual fit testing for tight fitting respirators when they are required to be worn. This includes N95 filtering facepiece respirators (FFRs).

Respirator Fit Capability (RFC) testing is the process used to assess whether a specific make and model respirator provides acceptable fitting characteristics for a broad spectrum of potential wearers with varying face sizes. This is accomplished by quantitatively measuring the level of fit among a group of people representative of an adult population. NIOSH has conducted studies to identify the required number of people and combination of face sizes to develop what is known as the "NIOSH bivariate panel". The NIOSH bivariate panel essentially identifies anthropometric measurements that encompass 98% of expected face size combinations for an adult population. While RFC testing includes measurement of respirator fit, it does not replace the need for fit testing an individual when required for compliance with OSHA regulations. Put another way, fit-testing is designed to evaluate the fit of a specific respirator to a unique individual, while RFC testing is designed to evaluate how well a particular make and model respirator is likely to fit a group of individuals with a range of facial characteristics. A respirator fit-test focuses on the individual, while respirator fit capability (RFC) testing is focused on the respiratory protection product.

In workplaces where respirators are required, employers must fit test employees annually for each respirator they wear. After passing a fit test, the individual is required to wear the same make, model, style, and size respirator when respiratory protection is required to be worn; this includes N95 FFRs. Historically, N95 respirators were most commonly used by employees in industrial settings. More recently N95 respirators have been worn by employees in health care settings, and due to heightened concerns surrounding the transmission of SARS-CoV-2 (the virus that causes COVID-19), their use by the general public in non-occupational settings has become more prevalent.

There are well over 500 NIOSH-approved N95 FFRs on the market from different manufacturers with different design, style, and size options. There are different designs such as vertical fold, pre-formed, molded, cup-shaped, duckbill, and trifold. Some models are available in "one size", while other models are available in multiple sizes. Some have exhalation valves while others do not. With all of these choices and options, how is a purchaser to know whether the N95 FFR they intend to purchase is likely to fit their employees? How does an employer go about selecting N95 FFRs capable of fitting their employees? For workplaces where employee fit testing is required, selecting a N95 FFR that has demonstrated good fitting characteristics can help an employer avoid the expense associated with numerous failed fit-tests due to facepieces with poor fitting characteristics. For N95 FFR wearers in the general public, a common perception is that an N95 FFR certified by NIOSH ensures an acceptable fit. With few exceptions, nearly all N95 FFRs are not required to undergo testing to evaluate fitting characteristics in order to receive NIOSH approval. NIOSH certification is focused on numerous N95 FFR design, construction, and performance elements, such as how well the filter media removes particles of various sizes attempting to travel through the filter media. NIOSH certification does not quantitatively evaluate how well N95 respirators fit different face sizes/shapes and whether the amount of leakage around the mask compromises overall efficacy. In our experience having tested several versions of N95 respirators certified by NIOSH, the fitting characteristics are an extremely important consideration. Poor fitting characteristics can lead to very low fit factors, resulting in the costly process of repeating the fit test or purchasing an alternative size or model.

NIOSH Bivariate Panel (NIOSH Panel)
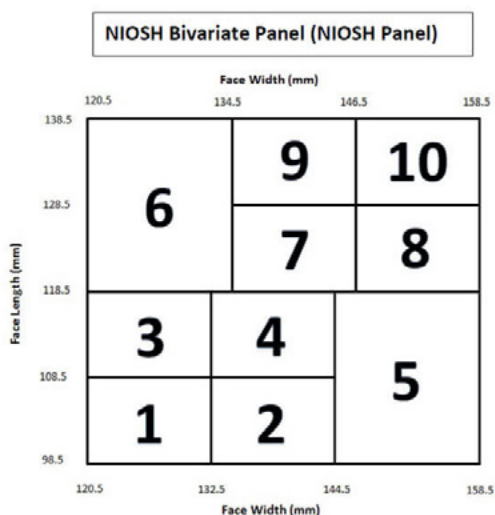
ASTM F3407-20 and ASTM F3502-21 Standards

On October 13, 2020, ASTM International approved ASTM F3407-20 Standard Test Method for Respirator Fit Capability (RFC) for Negative-Pressure Half-Facepiece Particulate Respirators. Compliance with this standard is voluntary and it was developed to provide respirator manufacturers and consumers with valuable data regarding the fitting characteristics of respirators. This test method can be applied to respirators that come in single or multiple sizes. To make determinations about the fitting characteristics of respirators, the ASTMF3407-20 Standard can be used to test the fit of a specific make and model respirator against a panel of 25 test subjects with varying face size measurements that are categorized into 10 different "cells" conforming to the NIOSH bivariate panel criteria.

RFC testing is performed on each of the 25 test subjects. To "pass" an RFC test on an individual test subject, the tested respirator must achieve an average fit factor of at least 100 while performing different head and breathing exercises (looking up, down, side-to-side, talking, etc.) A fit factor of 100 means that the concentration of particles outside the respirator is 100 times greater the concentration of particles inside the respirator. To meet the minimum performance criteria of the ASTM F3407-20 standard, at least 13 of the 25 (>50%) test subjects must obtain an RFC result of 100 or greater for the specific respirator model. It is expected that respirators that meet this minimum performance criteria will provide better fitting characteristics for a population overall. However, it does not guarantee an individual wearer will experience an acceptable fit in a particular facepiece.

By conducting RFC testing in accordance with the criteria detailed in the ASTM F3407-20 Standard, a manufacturer can demonstrate the fitting characteristics of a particular respirator model. Further, RFC testing in accordance with ASTM F3407-20 affords manufacturers the opportunity to identify product models that provide sub-optimal fitting characteristics and incorporate such findings into process improvement through design revisions. Employers would have a higher level of confidence that a specific make and model facepiece will fit individual employees when ASTM testing is passed. Employers can look for designations that indicate ASTM testing has been passed and may request to see the data to compare respirator fit performance prior to making a purchase.

In October 2021, the Canadian Standards Association (CSA) issued CSA Z94.4.1:21 National Standard of Canada: "Performance of Filtering Respirators". The CSA felt the need to develop their own performance standard when it became apparent that many NIOSH-approved FFRs were not passing fit tests conducted by employers during the COVID-19 pandemic. Consequently, they responded with their own performance requirements including a mandatory requirement for fit capability. Similar to the ASTM F3407-20 standard, but with some slight differences, CSA Z94.4.1:21 utilizes a panel of 25 volunteer test subjects with various facial dimensions to make a quantitative determination of adequate respirator fit. Also similar to the ASTM Standard, the requirements of this new Canadian Standard may be referenced by government and regulatory agencies for mandatory compliance or for regulatory administration in the development of respirator user guidance.

Test subject wearing barrier face mask with ear loops prior to the start of testing.

ASTM International has recently approved a new corollary standard, ASTM F3502-21, that applies to barrier face coverings ("COVID masks") and establishes a set of uniform testing methods and performance criteria to mitigate the risk of infectious disease transmission. Unlike respirators, the barrier face coverings worn to help prevent the spread of COVID-19 are not regulated or approved by NIOSH or FDA, and do not have to meet federal standards for performance. The lack of standardized testing has left mask users with no way to effectively compare the performance of face covering products and make informed purchase decisions. Manufacturer performance claims abound on product packaging, often referring to the purported filtration efficiency of the material that the mask is constructed with and are generally silent as to the overall level of protection likely afforded.

Further, with the discovery of the highly transmissible COVID-19 Omicron variant underscoring the immediate need for more effective source control, the CDC now recommends individuals seek out masks that meet the criteria established in ASTM F3502, as these masks have been tested to ensure they meet minimum performance criteria. Mask fit capability testing is currently an option that can be used to identify masks that have good fitting characteristics, similar to the manner in which ASTM F3407-20 is used for respirators.

The release of ASTM F3502-21 provides a uniform testing approach to compare product performance on four (4) important parameters: filtration efficiency, air flow resistance, re-use potential, and leakage. ASTM aspires to influence purchase decisions by increasing consumer confidence in barrier face coverings marked as F3502-21 compliant.

At RHP's Exposure Sciences Laboratory in Chicago, for many years we have been conducting OSHA-compliant qualitative and quantitative respirator fit testing. Responsive to the newly presented challenges of the COVID-19 pandemic and release of ASTM F3407-20 and F3502-21 Standards, we have constructed an isolation chamber (test booth) for testing respirators and barrier face coverings (masks) in accordance with these ASTM standards. We have developed a database of volunteer test subjects representative of the NIOSH bivariate panel and completed several projects for manufacturers of respirators seeking certification to the ASTM and CSA standards.

For more information about RHP's services, please contact
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visit our website at https://rhprisk.com/astm-mask-testing.

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