Respiratory Protection Newsletter November 2021

Featured Courses:

Respirator Selection & Change Out Schedules: May 17-18, 2022
Fit Testing Refresher & Advanced Topics: May 19, 2022

In the this issue:

In the this issue, continued:

Fitting Characteristics of N95 FFRs

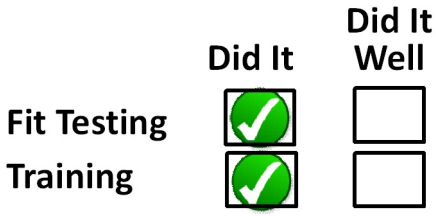
If you've following this *Newsletter*, you're well aware many N95 Filtering Facepiece Respirators (FFRs) have poor fitting characteristics. One reason, is fitting characteristics are not quantitatively evaluated by NIOSH for approval. They're tested for filter efficiency, resistance to airflow, etc. It's up to the employer to provide employees with respirators that can pass an OSHA accepted fit test. Let me share with you a quote taken from the AIHA Catalyst this summer:

"*With respect to poor fitting FFRs one of our hospitals tested over 200 different brands/models of FFRs. They found only eight (8) that could be reliably used in their workforce.*"

Dr. McKay's Comment:

An interesting finding is more than 192 brands/models were unacceptable because they had unreliable fit. Yet, these same respirators are routinely used elsewhere. How is this possible if fit testing is conducted in healthcare? My experience is that many healthcare facilities don't administer fit testing correctly. Consequently, poorly fitting respirators are **not** identified and healthcare workers are unknowingly issued poorly fitting respirators. Since checking off boxes is commonplace in healthcare, perhaps they should add a 2nd column to their respirator program checklist as follows:

Healthcare Respirator Program Checklist



Makes you wonder, how many COVID positive healthcare workers have been issued a poorly fitted respirator? Were fit test exercises shortened or skipped? Was an appropriate challenge concentration given and maintained? Or, was it Squeeze, Squeeze, Squeeze, you pass?

Mini Respiratory Protection Program

My July 2021 Newsletter summarized OSHA's Mini Respirator Program (29 CFR1910.504) for Healthcare. In that issue, I summarized how it differs from OSHA's Respiratory Protection Standard in 1910.134. From my perspective the "Mini Program" will simply add another layer of confusion and not backed by science.

On July 21, 2021 the American Industrial Hygiene Association (AIHA) submitted comments to the OSHA docket regarding the Emergency Temporary Standard on Occupational Exposure to COVID-19. Here's what they said about the "Mini-Program":

"There is no need for a "mini respiratory protection program" in this or any OSHA standard."

In addition, the AIHA suggested OSHA make it very clear that respirators worn voluntarily are not likely to gain any degree of respiratory protection from a non-fit tested respirator.

Mini versus Regular Respirator Program

I'm still getting questions regarding the "Mini" program. One of the most common questions involves respirator medical clearance.

Understanding OSHA's logic may help. Apparently, OSHA believes the physiologic effects of wearing a respirator differ when a respirator is worn voluntarily than when the same respirator is required to be worn.

Is there any science to support this? **No**.

OSHA doesn't put a time limit on voluntary use. For example, if two healthcare workers wear an identical make and model elastomeric half-facepiece respirator for the exact length of time, the employer is required to perform medical clearance for the employee required to wear the respirator, but not for the person wearing it voluntarily.

OSHA must also believe healthcare workers have a different physiologic response to wearing a respirator than non-healthcare workers.

Is there any science to support this? **No**.

The physiologic response to wearing a respirator does not change if a person switches employment from healthcare to non-healthcare.

So if you have difficulty remembering the difference's between the mini program and a required program for healthcare, just remember, OSHA believes:

Physiologic response differs when worn voluntarily, and

Healthcare workers have different physiologic responses to wearing respirators than other people.

Simple, but **not** based on science.

Respirator Tidbits

This section explores respirator related facts, points of interest, and tidbits.

Did you know that face to face-seal leakage usually contributes more leakage when wearing a NIOSH-approved respirator than penetration through the filter? With respect to non-NIOSH-approved face coverings such as common masks , the opposite is usually true. The relatively high penetration through the filter material, such as cloth masks, makes fit testing essentially irrelevant.

Let's Think About This:

Using Ventilation

Like many readers of this Newsletter, I have expertise in respiratory protection and selection of respiratory protective equipment for hazardous airborne environments from multiple sources. Persons trained and experienced in respiratory protection, are also capable of determining when respiratory protection is **not** needed.

Recently I read an excellent article regarding the "The Flawed Science of Antibody Testing for SARS-CoV-2 Immunity", published online in *JAMA*, on October 21, 2021. However, it reminded me of other articles making recommendations regarding protection from airborne hazards, unrelated to the topic or authors expertise. The 2nd to last sentence in this otherwise excellent article had the following statement:

> "*Ultimately, her advice for avoiding a SARS-CoV-2 infection in the first place comes down to a now-familiar combination of measures: "getting vaccinated, frequently washing your hands, wearing a mask, and avoiding high congregate in-door settings, particularly in areas that have high case rates.*""

Not bad advice, but why does the medical profession and others, avoid or downplay the role of ventilation and air purification? Is it unfamiliar territory?

So think about this.

With respect to protection in workplaces, how is it that improvements in ventilation, such as increasing fresh air supply, increasing air changes per hour, use of directional air flow, and/or use of portable air purification units, etc., enables me to **eliminate** the need for respiratory protection against a hazardous airborne contaminant, but similar changes in other environments **don't** allow elimination of a less effective barrier face covering (mask)? Keep in mind barrier face coverings are worn without formal training, not fit tested, frequently worn incorrectly, etc.

Note: "Let's Think About This" is intended to provide readers information "outside the box" of traditional thinking. The content may at times be funny, light-hearted, spirited or identify unusual observations. It's tongue and cheek and does not necessarily represent the views of Dr. McKay.

Self-reported vs Directly Observed Mask Use

Although not a study on respirator use, a recent July 2021 article by Jakubowski regarding self-reported mask use has relevance to respiratory protection.

In this study, the authors observed mask use behavior of 9,533 individuals and collected survey data from 1,960 individuals who self-reported mask use at a total of 6,225 public outings. They documented a large and statistically significant discrepancy between self-reported and observed mask use. Specifically they found that 4,685 individuals (75.9%) self-reported always wearing a mask in public and 748 individuals (11.7%) self-reported sometimes wearing masks in public. However, 448 individuals (4.7%) were observed wearing a mask correctly in public and another 575 individuals (5.7%) carried a mask. In other words, while only 12% of people admitted to not wearing a mask, 90% were observed not using them.

In this cross-sectional study, they found very limited compliance with a national mask mandate. Only 10% of observed people used masks, which is on par with a finding from Bangladesh. Conversely, a high proportion of participants (88%) self-reported wearing masks. This discrepancy suggests that although most people are aware that masks are mandated, they have not adopted this new health behavior. Studies relying solely on self-reported mask use may suffer from bias and should be interpreted with caution.

For details regarding this study, go to:
JAMA Network Open. 2021;4(7):e2118830. doi:10.1001/jamanetworkopen.2021.18830
or Click here

Dr. McKay's Comment: This study is consistent with others and raises serious concerns regarding self-reporting of masks and perhaps N95 filtering facepiece respirators. Historical studies are often cited to support opinions comparing effectiveness of masks versus respirators. If self-reporting isn't reliable, neither are the conclusions. Furthermore, many early studies with filtering facepiece respirators don't mention if fit testing was conducted. When it is conducted in, it's unclear if the fit testing was conducted properly.

Let's Think About This:

"N95 Respirators are Designed to Fit"

You see this everywhere. It's in research articles, CDC publications, TV, newspapers, magazines, etc. While some N95 FFRs are specifically designed to include different shapes, sizes, and special features to improve fitting characteristics, many don't. Many come from the same mold. With exception to a few novel designs, NIOSH doesn't require N95 filtering facepiece respirators (FFRs) to pass human testing as part of the current certification process. This is why so many NIOSH-approved N95 FFRs don't fit well. In U.S. workplaces, it's OSHA that requires the individual wearer to pass a fit test, when required to be worn. If not, then another make, model, style, or size facepiece is tried. So the next time you read or hear N95 respirators are "designed" to fit, just say:

That's not true for all of them.

Rather than randomly picking respirators for your employees, consider asking for test results from studies using the methodology in ASTM F3407-20 or equivalent protocol. This standard was developed to identify the fitting characteristics for air-purifying, half-facepiece respirators, including N95 FFRs. One purpose of this standard is increase the probability that available respirators can potentially fit a general worker population. Respirators that perform well, provide an increased level of assurance that they can effectively fit persons with various facial shapes and sizes (length and width). So rather than randomly selecting from the hundreds of different make and model respirators, consider this. Before yo give away your money, ask for the data. I've performed this type of testing in the past. Fortunately, there are now several independent laboratories and manufacturers that conduct this type of testing.

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My Onsite Fit Testing Experience

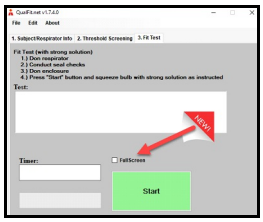
During August of this year, I conducted two days of annual onsite respirator fit testing and training for one of my clients. This particular client is a large multinational company using a wide variety of respiratory protective equipment. Although, I've been fully vaccinated, I knew a face covering was required for entry. I decided to wear my NIOSH-approved N95 filtering facepiece respirator (FFR), to which I've passed quantitative fit testing, seal checks, and know how to use properly. Upon entry into the lobby, I was immediately directed to a small office for thermal scanning of temperature and a brief health questionnaire screening. As soon as I entered the room, the security guard asked me to remove my "mask" and use the mask provided on the table. I explained I was wearing a fit tested N95 FFR, but that was to no avail. He insisted I wear their "mask", which had no visible markings and ear loops. No box available to identify make and/or model. His mask and those of persons nearby had massive visible gaps at the face-to-mask interface. I made it clear my respirator was more protective and offered a higher level of protection to others as well as myself. They insisted I wear their mask. I insisted on wearing my N95 FFR. Ultimately, they allowed me to wear my respirator, but only if I put their mask on top of it. To avoid confrontation, I complied. However, their mask was so large it wouldn't stay in place. In addition to its size, the doubling of their mask on top of my respirator, partially blocked my inferior vision. This caused me to trip over an equipment bag the program administrator left in the doorway of the fit testing room.

Cardiopulmonary Effects of Mask Wearing at Rest & Maximal Exercise

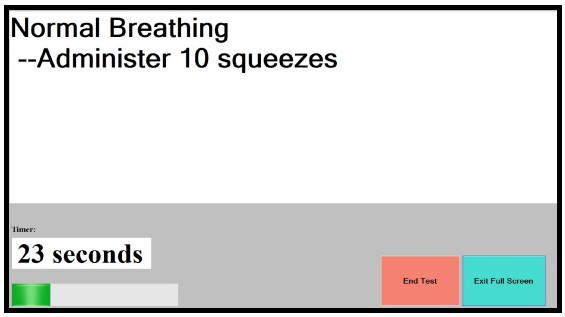
A 2021 study published in the *European Respiratory Journal* by Mapelli and colleagues, they reported that protective masks are associated with significant but modest worsening of spirometry and cardiorespiratory parameters at rest and peak exercise. This effect is driven by a reduction in ventilation due to increased airflow resistance. Despite measurable differences in cardiorespiratory parameters and spirometry, the authors conclude the use of these masks is safe, even during maximal exercise, with a slight reduction in performance.

The study included 12 healthy subjects with and without a protective mask, surgical mask, or filtering face piece particles class 2 (FFP2). Measurement included basic spirometry, oxygen uptake, carbon dioxide production, ventilation, and dyspnoea using the Borg scale. For details, go to the source: *European Respiratory Journal* 2021 58: 2004473; DOI: 10.1183/13993003.04473-2020
Or Click Here

Full Screen Option Added to QualFit Software



A new full screen exercise option makes it easier for the test operator to visualize the exercise testing screens during the test procedure, even when standing 8 or more feet away. In addition, audio beeps and changes in font color help to ensure the aerosol is delivered at the proper time and sequence as required by OSHA, ANSI, ASTM, ISO and other organizations.



The full screen feature is included with QualFit purchases made after June 1, 2021. Existing customers can get it free. Just double click the updater file (QualFitUpdate2.0.exe) on the QualFit flash drive.

A 5 minute video demonstrating the Full Screen option is available. Just use this link:

https://youtu.be/RJr-IIKTLas
Or, Click here

Fit Testing Refresher & Advanced Topics

This 1-day course is specifically designed for the person who has been conducting fit testing, but needs a better understanding as to why poorly fitting respirators pass can pass a fit test and why good fitting respirators fail. This class provides an opportunity to discuss advanced topics not covered during a typical 2-day fit testing workshop due to time limitations. This course is also valuable for respirator program administrators who need a better understanding of fit testing procedures and assurance that their fit testing program is being run properly. **This program identifies tricks and omissions some fit test operators' use to allow poorly fitting respirators to pass fit testing (QLFT & QNFT).**

May 19, 2022 in Cincinnati

Question:

I recently purchased a face mask and the label says it meets ASTM F3502-21 Level 1 performance criteria for filter efficiency. I'm uncertain if it fits my face, but seems to fit pretty good. A local company offers quantitative respirator fit testing, should I have it fit tested?

Answer:

Regardless of how well you try, this mask will likely have too much filter penetration, making it impossible to properly evaluate fit. As a result, the quantitative fit test will **not** be able to determine if your mask fits well or not, because filter penetration is likely too high for this type of test. However, the person who administers the fit test may be able to improve your donning technique (i.e., assist with positioning on your face and/or adjust a nose band, if available). He/she may even be able to suggest an alternative mask, if needed.

Respirator Selection & Development of Cartridge Change Out Schedules

May 17-18, 2022 in Cincinnati

Go to www.DrMcKay.com for details.

Testing Masks on Mannequins

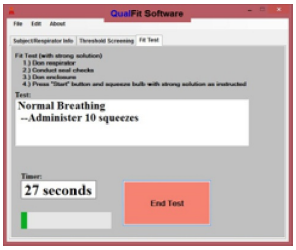
Extensive research is currently underway to determine the effectiveness of masks and other barrier face coverings for source control and protection. Many of these studies use mannequins. For these studies, the investigator positions the mask or other barrier face covering on the mannequin.
The question is:

Who wears the mask or facepiece better, mannequins or people?

Turn to the next page for the answer.

The answer is obvious - **Mannequins**

An easier way to conduct sweet & bitter fit testing
QualFit© software automates and records qualitative respirator fit testing using Saccharin and/or Bitrex aerosol solutions. The software prompts the operator to deliver the aerosol solution with the correct number of squeezes for each exercise, at the proper time, and in the proper order. This improves fit testing accuracy. The software displays the current exercise in progress, automates the timing sequence and calculates the number of squeezes to be administered, based on threshold screening results. Visual and audible prompts allow the operator to focus their attention on the respirator wearer. The entire procedure becomes less frustrating for the operator and subject being tested. The software tracks each step of the fit testing procedure required in mandatory Appendix A of the OSHA Respirator Standard. **QualFit**© software improves the quality and efficiency of respirator fit testing. An OSHA compliant report can be printed or electronically saved. The employer benefits by knowing the test procedure was properly administered and provides written documentation for compliance with record keeping requirements specified in paragraph "m" of the OSHA standard. The employee benefits by knowing a standardized procedure was followed, rather than what often appears to be a random procedure.



For Information visit: www.QualFit.net
To place a secure online credit card order visit: https://qualfit-software.square.site/

ACOEM News

ACOEM Updates Guidance on Respirator Fit Testing & Spirometry During COVID-19

Released August 31, 2021, released an updated interim guidance document for conducting spirometry testing and respirator fit testing. More than one year ago (March 16, 2020), ACOEM recommended routine spirometry be postponed due to COVID-19. One month later, OSHA issued an enforcement memo instructing compliance officers to avoid citing or fining employers who made good faith efforts. In July of 2020, ACOEM updated the March recommendations. Now, ACOEM, released another revision with information regarding how to safely resume spirometry testing and respirator fit testing.
A key aspect of the ACOEM recommendation is for programs to evaluate the risk need for these tests. ACOEM points out that the hazard level associated with testing varies considerably over time, by community, and according to the characteristics of the clinic and worker population. The risk associated with the hazard is therefore characterized into 4 broad tiers, using an approach that extends a CDC classification scheme. This approach recognizes risk may be higher or lower in one locality than another. This updated statement provides recommendations, but lacks specifics on how some tasks are to be accomplished. For example, the document states that bacterial-viral filters "should" be used for spirometry and to use filters recommended by the spirometer manufacturer. Criteria for "acceptable" viral filters are not identified and some manufacturers have been slow to recognize the need for bacterial-viral filters. Some bacterial-viral filters may be inadequate. ACOEM recommends staff who administer spirometry testing should have documentation of vaccination, but does not mention natural immunity. For respirator fit testing, ACOEM recommends disinfecting certain equipment according to manufacturer guidelines. As a result, professional judgement will still come into play as these recommendations can differ. ACOEM recommends: "Technicians performing fit testing should wear gloves, a fit-tested N95 or higher level of filter efficiency, or PAPR respirator, and eye protection or face shield". To read the ACOEM Guidance Statement Click Here or go to: https://acoem.org/acoem/media/News-Library/Guidance-Statement-Updated-Spirometry-8-31-2021.pdf

OSHA News

OSHA Penalties After 2 COVID Deaths
On May 14, 2021 OSHA cited a New Jersey group home operator for failing to adequately protect employees from SARS-CoV-2 resulting in two deaths.

OSHA cited the company with a serious violation of the respiratory protection standard and the general duty clause that requires employers to ensure workplaces are free of recognized hazards that may cause death or serious physical harm.

According to the citation OSHA determined the facility failed to develop and implement a respiratory protection program, provide appropriate respirators to employees who provided care to patients with the virus, respirator medical clearance, provide respirator fit testing, nor effective training on proper use, cleaning and storage of respirators.

Proposed penalties for the violations total **$27,306**.

Interim Enforcement Changes for COVID-19 for All Workplaces (other than Healthcare)
In case you missed it, on July 7, 2021 OSHA issued revisions to how it will enforce COVID-19 issues for workplaces **not** covered by the Emergency Temporary Standard (ETS) for Healthcare. Therefore, these changes affect all workplaces using respiratory protection. One of the key points of this updated enforcement plan is:

> "Therefore, where respirator supplies and services are readily available, OSHA will cease to exercise enforcement discretion for temporary noncompliance with the Respiratory Protection standard based on employers' claims of supply shortages due to the COVID-19 pandemic. Similarly, the agency will no longer exercise enforcement discretion of requirements in other health standards. As such, OSHA is rescinding its previous temporary enforcement discretion memoranda."

To get a copy of this change Click here.

OSHA Updates COVID-19 Workplace Guidance
On August 13, 2021, OSHA released revisions to its previous guidance on COVID-19 in workplaces titled:

> *Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace*

The updated guidance expands information on appropriate measures for protecting workers in higher-risk workplaces with mixed-vaccination status workers, particularly for industries such as manufacturing; meat, seafood and poultry processing; high volume retail and grocery; and agricultural processing, where there is often prolonged close contact with other workers and/or non-workers.

OSHA's latest guidance:

- Recommends that fully vaccinated workers in areas of substantial or high community transmission wear masks in order to protect unvaccinated workers;
- Recommends that fully vaccinated workers who have close contacts with people with coronavirus wear masks for up to 14 days unless they have a negative coronavirus test at least 3-5 days after such contact;
- Clarifies recommendations to protect unvaccinated workers and other at-risk workers in manufacturing, meat and poultry processing, seafood processing and agricultural processing; and
- Includes links to guidance for K-12 schools and CDC's statements on public transit.

OSHA plans to update this guidance over time to reflect what they believe to be important new developments in science, best practices, and standards. To read the entire document Click Here or copy and paste the following link into your favorite browser:
https://www.osha.gov/coronavirus/safework

Already, challenges to OSHA's ETS are in motion. My understanding is the Fifth Circuit court of appeals has issued a preliminary injunction blocking enforcement of the ETS while challenges to it are heard in the federal court system. Because so many lawsuits are challenging the ETS, a single federal appeals court is expected to rule on this matter.

Lead and Respirator Violations

On September 30, 2021, OSHA cited a Tampa smelter for willfully exposing workers to unsafe levels of airborne lead, despite experts' warning. As a result, OSHA proposes $319,000 in penalties to address violations. With respect to respirator issues, the company was cited for failure to provide adequate respiratory protection and requiring workers to wear respirators that were not fit tested on an annual basis.

Top 10 OSHA Violations: Fiscal Year 2021

In October 2021, OSHA released preliminary data for the top 10 most-cited standards in fiscal year 2021. The data includes violations cited between Oct. 1, 2020, and Sept. 30, 2021. The preliminary data was presented at the 2021 NSC Safety Congress by Patrick Kapust, deputy director of the Directorate of Enforcement Programs at OSHA.

Violations of the Respiratory Protection Standard rank as the 2nd most frequently violated OSHA standard. Here's a quick peak at the preliminary ranking:

1. Fall Protection - General Requirements
2. **Respiratory Protection**
3. Ladders
4. Scaffolding
5. Hazard Communication
6. Lockout/Tagout
7. Fall Protection - Training Requirements
8. Personal Protection, Life, Eye, & Face Equipment
9. Powered Industrial Trucks
10. Machine Guarding

OSHA Releases COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS)

This ETS was released on November 4, 2021 and goes into effect on November 5, 2021 and affects employers with 100 or more employees.

Under this standard, covered employers must develop, implement and enforce a mandatory COVID-19 vaccination policy, unless they adopt a policy requiring employees to choose to either be vaccinated or undergo regular COVID-19 testing and wear a face covering at work. Violations can result in a $14,000 fine per occurrence.

Released the same day was an announcement by the Centers for Medicare and Medicaid Services (CMS) details of its requirement that health care workers at facilities participating in Medicare and Medicaid are fully vaccinated. In addition, These two rules (OSHA ETS & CMS) should not be confused with a previously implemented policy requiring federal employees and federal contractors to be fully vaccinated.

To obtain a copy of the OSHA ETS, Click Here or type the following URL into your browser: https://www.osha.gov/coronavirus/ets2

The above link will also provide access to other documents OSHA has available on this ETS, such as:

Materials Incorporated by Reference
News Releases
Fact Sheets about the ETS and a Summary
Frequently Asked Questions and OSHA Answers
Access to a Webinar and more.

To read the 154 page, small font, 3-column regulatory text as printed in the Federal Register: Click Here or type the following URL into your browser: https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard

I realize the OSHA Vaccination ETS is not necessarily a "respirator" issue, but it may be relevant to some readers of this Newsletter involved with masks, other barrier face coverings, and/or using N95 FFRs rather than masks, etc.

Respirator Program Administrator Training

Attend at least four days of respirator training from three different training categories and earn a certificate for Respirator Program Administrators.

This program can be given onsite.

For additional information, email us at info@DrMcKay.com

NIOSH News

Announcements from NIOSH

Don't Knot These Respirators

On August 5, 2021 NIOSH released a Conformity Assessment letter (CA 2021-1037) regarding user instructions for three N95 filtering facepiece respirators with approval numbers issued to BNX Converting, LLC.

The affected BNX approvals & models affected are:

TC-84A-9298 (Model A96)
TC-84A-9308 (Model A96-2)
TC-84A-9315 (Models H95W / H95B)

The issue was that a limited number of respirators were distributed with user instructions indicating if leakage was detected, the uses should:

> ... adjust the nosepiece and headbands until the leakage is corrected. Pull the headbands back, up, or, if necessary, **shorten them by knotting**."

NIOSH wants to notify users that if they cannot achieve a fit, the respirator should not be modified in any way to achieve a satisfactory fit. In particular it is not acceptable to shorten the straps by knotting them. The approval holder (BNX Converting LLC), was informed about the concern and took immediate action to remove the problematic statement from the user instructions.

To read the Conformity Assessment letter(CA 2021-1037), Click here

Dr. McKay's Comment:

Don't confuse these knots, with the article in my July Newsletter describing how to follow CDC's guidance for knotting a "mask". Back in July, I discussed the **Knot and Tuck** technique recommended by CDC to improve the fit of commonly available disposable masks having a rectangular shape with ear loops. The N95 FFRs mentioned above are NIOSH-approved respirators. They are not "masks". The bottom line: Knots are not permitted for NIOSH-approved respirators, but in some cases recommended by CDC for certain style masks. Just another reason why correct terminology is important (refer to my "Think About This" comments regarding confusing terminology.

NIOSH Table of BFC & Performance Masks

NIOSH now provides a table of Barrier Face Coverings (BFCs) and Workplace Performance/Performance Plus masks that manufacturers claim to conform with ASTM F3502-21 and/or NIOSH requirements, respectively. For information about these tests, refer to my March and July 2021 Respiratory Protection Newsletters for details. Both newsletters are available on my public folder (Click here). When applicable, the **optional** quantitative leakage assessment results for ASTM 3502-21 will be included. These results are provided by the manufacturer, so you can contact the manufacturer for details. Keep in mind, NIOSH is not conducting these tests, private laboratories, universities, and manufactuerers do. Listing of products on this NOSH website does not constitute NIOSH endorsement of the sponsoring organizations or their products.

To view the table Click Here or copy and paste the following link into your favorite browser: https://wwwn.cdc.gov/PPEInfo/RG/FaceCoverings

Dr. McKay's Comment:

Quantitative leakage assessment published in ASTM F3502-21, is under review and may be revised. It's unclear, how NIOSH will list manufacturer data for leakage assessment if the test methodology and criteria change.

NIOSH Revokes 38 Previously Approved FFRs

NIOSH has revoked ALL approvals issued to Shanghai Dasheng Health Products Manufacture Co., Ltd. The revoked approval numbers are provided below. The revocation includes all private label versions.

As of August 13 , 2021, any Shanghai Dasheng Health Products Manufacture Co., Ltd. respirator marked with a NIOSH approval label indicating any of the approval numbers below is **no longer NIOSH-approved**:

TC-84A-4329, TC-84A-4330, TC-84A-4331, TC-84A-4332, TC-84A-4334, TC-84A-4335, TC-84A-4336, TC-84A-4337, TC-84A-4398, TC-84A-4399, TC-84A-4400, TC-84A-4401, TC-84A-4463, TC-84A-4464, TC-84A-4465, TC-84A-4466, TC-84A-4467, TC-84A-4468, TC-84A-4469, TC-84A-4470, TC-84A-4471, TC-84A-4472, TC-84A-4473, TC-84A-4483, TC-84A-4484, TC-84A-4485, TC-84A-4486,

TC-84A-4487, TC-84A-8150, TC-84A-8425, TC-84A-8543, TC-84A-8544, TC-84A-8545, TC-84A-8546, TC-84A-8547, TC-84A-8634, TC-84A-8635, and TC-84A-8636

Revocation also means that respirators bearing any of the NIOSH approval numbers listed above may no longer be manufactured, assembled, sold, or distributed. As of August 13, 2021, respirators bearing the NIOSH approval numbers listed above are no longer considered approved and may not be used in fulfillment of any standard or statute requiring the use of a NIOSH-approved respirator.

According to the NIOSH announcement, Shanghai Dasheng Health Products Manufacture Co., Ltd. failed to control the design, labeling, and quality management as required by 42 C.F.R. Part 84.

Dr. McKay's Comment:

According to the Shanghai Dasheng Health Products website as of Aug 19th, their manufacturing facility located in China claims to export over 100 different types of respirators and masks worldwide. They claim to meet a variety of global standards, including those of in the U.S. (NIOSH & FDA), Europe, Australia, and Japan. Users should check the NIOSH approval numbers to determine if their respirators are affected by the NIOSH revocation of approval.

NIOSH Releases 2 New Fact Sheets

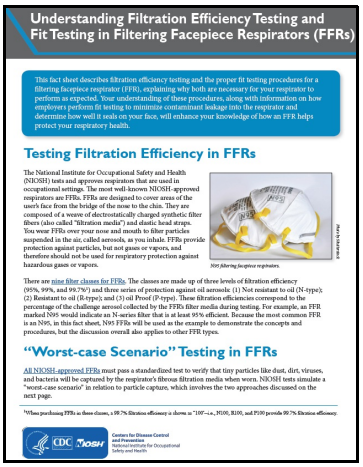
How to Tell if your N95 Respirator is NIOSH Approved

This fact sheet explains what you should look for to determine if an N95 is NIOSH approved and tips to spot counterfeit respirators.

To get a copy, Click Here

Understanding Filtration Efficiency Testing and Fit Testing in Filtering Facepiece Respirators (FFRs)

This fact sheet describes filtration efficiency testing and fit testing procedures for filtering facepiece respirators and explains why both are necessary for respirators to perform as expected.



To get a copy, Click Here

NIOSH Switched to Bivariate Panel for CBRN

Effective November 15, 2021, NIOSH will begin using the NIOSH Bivariate Panel for evaluation of all new chemical, biological, radiological, and nuclear (CBRN) SCBA, CBRN APR, and CBRN PAPR approvals. As a result, the Standard Testing Procedure (STP) protocols needed to be revised. The affected STPs are listed here with the corresponding link to the revised protocl.

TEB-CBRN-APR-STP-0352

Determination of Laboratory Respirator Protection Level (LRPL) Values for CBRN Self-Contained Breathing Apparatus (SCBA) Facepieces or CBRN Air-Purifying Respirator (APR).

TEB-CBRN-APR-STP-0552

Determination of Laboratory Respirator Protection Level (LRPL) Values for CBRN Tight-Fitting Powered Air-Purifying Respirator (PAPR).

TEB-CBRN-APR-STP-0553

Determination of Laboratory Respiratory Protection Level (LRPL) Values for CBRN Loose-Fitting Powered Air-Purifying Respirator (PAPR).

Prior to this change, NIOSH used the Los Alamos National Laboratory (LANL) panel with an Isoamyl Acetate fit testing procedure. The essential changes

to each of the STPs shown above incorporate use of the NIOSH Bivariate Panel and general revisions to reflect the use of an ambient aerosol particle counting instrumentation.

ISRP News

ISRP International Conference
The ISRP is holding its 20th international conference May 10 - 12, 2022. The conference will be preceded with a professional development session, the day before (May 9th). This will be the first time the international conference will be held as a virtual event. Held once every two years, the ISRP Conference 2022 serves as a global forum for the exchange of knowledge related to the science, technology, regulation, development, and practice of respiratory protection.

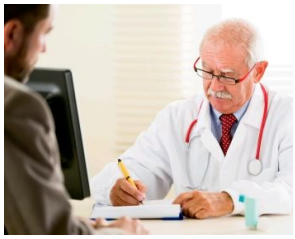
The deadline to submit abstracts is 28 February 2022.

For any general enquiries, contact:
isrp2022@isrp.com
For any questions related to program content:
isrp2022.technical@isrp.com

EPA News

EPA Terminated Temporary Respirator Guidance
During the summer of 2020 (June), the U.S. EPA issued temporary guidance that offered flexibility during the COVID-19 public health emergency to agricultural employers and pesticide handlers regarding respiratory protection requirements related to pesticide uses covered by the Agricultural Worker Protection Standard (WPS). However, at this time, due to improvements in access to NIOSH-approved respirators, fit testing supplies and related services, EPA terminated the temporary guidance, effective August 19, 2021.
This decision to end the flexibility permitted with the temporary guidance, is now in alignment with other federal agencies such as CDC, FDA, and OSHA, which have terminated crisis capacity strategies for respirators.
To read the memorandum addressing this termination, visit:
https://www.epa.gov/enforcement/termination-june-1-2020-statementmay-6-2021-amendment-regarding-respiratory-protection
Or, Click Here

Medical Complications from Respirator Use



OSHA requires respirator medical clearance for persons required to wear respiratory protection. Researchers at the University of Cincinnati are collecting information on persons who:
1) Developed a medical complication while wearing a respirator, and
2) Identify pre-existing medical conditions causally related to the complication that developed.

If you have information (published or un-published) that establishes a link between a specific medical condition and a complication that developed as a result from wearing a respirator or during fit testing, please share this information with us. We're particularly interested in cases where a medical complication was induced by respirator use. Information such as the specific type of respirator worn, work environment, duration of use, level of physical exertion, underlying medical conditions that contributed to the complication, etc., is needed. You can send this information to:
info@DrMcKay.com

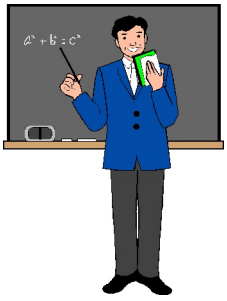
Share Your Respirator Experience
Here's an opportunity to contribute your knowledge and experience to others. If you have an interesting respirator selection or other challenging respirator problem (and solution), please submit it to info@DrMcKay.com. I may use your real-life problem to help train students in our graduate and continuing education programs in respiratory protection. This transfer of information will benefit others, maybe even your children or grandchildren.

Wanted: Damaged Fit Test Adapters
Rather than throwing away damaged fit test adapters, consider donating them to our fit testing workshops. We strive to make our fit testing workshops as realistic as possible. Incorporating damaged along with good fit testing adapters can provide a valuable training experience. If you wish to send a damaged fit test adapter or a damaged facepiece with unusual or difficult to find leakage for our respirator inspection workshops, send us an email at info@DrMcKay.com and we'll provide shipping information.

Undamaged fit test adapters are also needed. On average, we lose one (1) fit test adapter every workshop due to wear and tear, poor adapter design, and other causes.

Wanted: Photos & Videos of Improper Fit Testing
Far too often respirator fit testing is conducted incorrectly. If you have a good photo or video, send it to us at info@DrMcKay.com. I might incorporate it into a future fit testing workshop or newsletter.

Respirator Training Courses:
Dr. McKay and the University of Cincinnati is pleased to announce the following programs on Respiratory Protection and Fit Testing to your staff. They are:



Overview of Respiratory Protection:
http://www.drmckay.com/rtc-overview.shtml
November 1, 2021 **(course full)**
April 19, 2022
October 18, 2022

Fit Testing Workshop (2-day):
http://www.drmckay.com/rtc-workshop.shtml
December 1-2, 2021 **(course full)**
April 20-21, 2022
October 19-20, 2022

Respirator Selection & Cartridge Change Out Schedule Workshop.
http://www.drmckay.com/rtc-resp_selection.shtml
May 17-18, 2022

Fit Testing Refresher & Advanced Topics
http://www.drmckay.com/rtc-resp-refresher-advanced.shtml
May 19, 2022

All courses are held in Cincinnati, unless noted otherwise. On-site training is available.

Respirator Selection & Change Out Schedules
This workshop provides guidance on respirator selection and the development of OSHA compliant change out schedules for respirator cartridges. A combination of lecture with practice problem sessions is used. The course is designed to teach students how to select a respirator based on workplace conditions (exposure level, type of contaminant, length of time to be worn, etc.). The selection process goes beyond the typical recommendation to "use a NIOSH approved air purifying respirator". Students will learn how to select a specific respirator as well as a specific filter/cartridge (when appropriate). More than a dozen guidelines for development of an OSHA compliant cartridge change out policy will also be taught, including common computer models and how to use them.

Partial Listing of Topics
Respirator Selection
* Review of facepiece definitions and modes of operation.
* Practical and theoretical basis for respirator selection based upon:
  Assigned Protection Factors (APF)
  - MUC's, HR's, IDLH, etc.
* OSHA guidelines for respirator selection.
  - IDLH and non-IDLH atmospheres.
* Selection steps and information gathering procedures.
* Minimum respiratory protection versus practical alternatives.
* Filter selection issues
  - How to select an N, R, or P filter.
  - Why filter selection is influenced by exposures below the exposure limit.
  - How to choose a 95 versus 100 filter.
* Practical methods for handling unknown concentrations without defaulting to an SCBA.
* Calculating MUC's for mixtures.
* Saturated Vapor Concentrations (SVC's) and selection concerns.
* When a particulate filter may be needed for organic solvents.
* Equilibrium Vapor Concentrations.
* Selection Workshop
  - Practical problems and solutions.

Development of Cartridge Change Out Schedules

* OSHA recommendations for a change out policy.
* Factors that affect cartridge service life.
* Learn how to develop an OSHA compliant change out schedule.
* Understanding the breakthrough curve.
* Common methods used to define breakthrough.
* What level of breakthrough should be used?
* Work rate tables.
* Effect of high relative humidity.
* Methods for determining service life (use, limitations, and practice problems)
  - OSHA recommendations
  - Rules of thumb
  - Using laboratory data
  - Using math models
  - Using computer (software) models
  - Cartridge testing methods (3 methods) Combining methods
* Learn how to develop a change schedule when computer models are not available.
* Recommendations for mixtures:
  - OSHA compliance method
  - mole fraction method
  - multi vapor model
* How to confirm your change-out schedule.
* Storage and migration concerns.
* Immediate Breakthrough Upon Reuse (IBUR) concepts

Gain confidence your current procedures are correct! Former students have found this information to be extremely valuable.

Fit Testing Workshop:

This two (2) day workshop provides comprehensive lecture and "hands-on" training for students who need to learn how to conduct an OSHA accepted qualitative or quantitative respirator fit test. Students will have an opportunity to fit test a variety of different style facepieces, including filtering facepieces, half, & full. A combination of lecture and "hands-on" testing in the presence of a trained and experienced instructors will be used to help participants learn how to conduct respirator fit testing to satisfy regulatory requirements. Hands-on fit testing will include qualitative and quantitative methods. The following types of fit testing equipment will be available: Saccharin (sweetener) and Bitrex (bitter) qualitative fit test kits using squeeze-bulb nebulizers, including **QualFit** software©. Quantitative fit testing with the TSI PortaCount, AccuFIT 9000, and the OHD QuantiFit©. Class size will be limited to ensure a favorable faculty to student ratio. Students will learn how to set-up, operate, maintain, troubleshoot, analyze, and interpret fit test results. Where appropriate, students will learn how to calibrate testing equipment and record results. All course materials, supplies, equipment, and reference manuals will be provided.

Students will also disassemble, reassemble, and inspect respirators for common problems. The workbook alone is a valuable reference for solving fit testing problems in the future.

This course uses a combination of lecture and small practicum groups to ensure students have ample time to practice and learn fit testing techniques. The second day provides students sufficient time to concentrate on the particular methods of interest to them. The "Hands-On" approach is emphasized in this course. Students will have the opportunity to fit test several different make and model respirators. The fit testing workshop provides an opportunity to see and experience many different types of commonly used fit testing methods (qualitative and quantitative).

Individuals who plan to attend the fit testing workshop, but have little or no experience with respiratory protection should take our 1-day "Overview" class, routinely offered before the fit testing workshop. A substantial discount is given when both courses are taken.

Dr. McKay is the past chair of the ANSI Z88.10 Respirator Fit Testing sub-committee, a voting member of the full ANSI Z88 Respiratory Protection Committee, the AIHA Respiratory Protection Committee, and others.

Fit Testing Refresher & Advanced Topics:

This 1-day course is specifically designed for the person who has been conducting fit tests, but has not had formal training or needs a review. This course reviews OSHA fit testing requirements and helps the operator understand **why poorly fitting respirators pass fit testing and why good fitting respirators fail**. It also provides an opportunity to discuss advanced topics not covered during a typical 2-day fit testing workshop due to time limitations. This course is also valuable for respirator program administrators who need a better understanding of fit testing procedures and assurance that their fit testing program is being run properly. The emphasis of this course is on quantitative fit testing, although many of the concepts are applicable to all fit test methods.

Partial Listing of Topics

Review of fit test procedures
- Facial hair: issues & solutions
- Selection process
- Comfort assessment
- Interference with PPE

Establishing pass/fail criteria

Interpretation of fit test results
Why user seal checks fail to detect leakage
Why user seal checks create leaks not present
Proper use of fit test adapters
Selecting sample probe location
Why leaking respirators pass fit testing
Why good fitting respirators fail fit testing
What does a high fit factor really mean?
Wear time & non wear time issues
Understanding fit factor vs protection
When is quantitative fit testing required?
Opportunity to get answers to your questions

This course can also be given on-site.

Overview of Respiratory Protection:
This one day course provides a practical overview of respirators, standards, guidelines, use, and limitations of commonly used air purifying respirators. This class also provides an excellent overview of the OSHA Respirator Standard. Little or no prior formal training is required. The morning session includes lectures on the types and use of respirators and basic respirator selection procedures using APFs and MUCs. The advantages and disadvantages of different respirator facepieces, filters (N, R, & P), cartridges, PAPR's, and the physiologic effects of wearing a respirator will also be discussed. Respirator standards and program requirements will be reviewed to help the student comply with OSHA regulations. Discussion of qualitative and quantitative fit testing, user seal checks, worker training, and respirator medical clearance requirements will be provided. This course is essential for those individuals who oversee respirator users in their work place or new to respiratory protection.

Respirator Training at Your Location:
A variety of respirator training programs are available on-site. Courses available include:
* Fit Testing Refresher & Advanced Topics
* How to Develop a Cartridge Change Out Schedule (1 day)
* Respirator Selection (1 to 1.5 days)
* Fit Testing for Health Care Professionals (1 day)
* Basics of a Respiratory Protection Program (2 days)
* Overview of Respiratory Protection (1 day)
* Respirator Fit Testing: Quantitative (1 or 2 days)
* Respirator Fit Testing: Qualitative (1day)
* Fit Testing at your workplace. Not a course, but a hands-on program with your staff and equipment.

Respirator Videos
For information about **QualFit**© Software for qualitative respirator fit testing with sweet and/or bitter agents, go to www.QualFit.net

Video What is **QualFit**© software?
12 minutes
https://youtu.be/RwdMfrQXdTY

Video Basic Operation of **QualFit**© Software:
18 minutes
https://youtu.be/vfwfuVOkAKw

Video **Comprehensive Fit Test Training Video**
54 minutes
https://youtu.be/FxpVsm3OhLY

Video **Respirator Fit Testing Errors and Solutions** - 21 minutes
https://youtu.be/0RsQEeOcS7o

New Video

Video **QualFit**© **Full Screen Option** - new video (5 minutes)
https://youtu.be/RJr-IIKTLas

The new full screen exercise option makes it easier for the test operator to visualize the exercise testing screens during the test procedure, even when standing 8 or more feet away. In addition, audio beeps and changes in font color help to ensure the aerosol is delivered at the proper time and sequence as required by OSHA, ANSI, ASTM, ISO and other organizations.

I hope you enjoy this newsletter. Dr. McKay volunteers his time to many standard setting organizations and governmental agencies. Dr. McKay does not receive public or private funding for these services. Therefore, donations are appreciated and help this practice to continue. The opinions in this newsletter are Dr. McKay's and not the University of Cincinnati.
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Click "reply" and put "Remove" in the subject heading of the email address you wish to have removed as described above.

Roy McKay, Ph.D.
University of Cincinnati
www.DrMcKay.com

Dr. McKay has approximately 40 years of national and international experience in all areas of respiratory protection including **research, teaching, clinical practice, peer reviewed publications, and consultation** as a faculty member at the University of Cincinnati. Dr. McKay is the past chair of ANSI/AIHA Z88.10, the committee responsible for "Respirator Fit Test Methods" and a member of ANSI/ASSE Z88.2-2015 which published the "American National Standard Practices for Respiratory Protection. Respirator committee assignments include the American Industrial Hygiene Association's Respiratory Protection committee. He has conducted respirator fit testing, training, and consultation services for governmental agencies, including OSHA, NIOSH, NPPTL, CDC, private industry, and respirator manufacturers. He's developed more than a dozen different continuing education courses on respiratory protection, which include fit testing, respirator selection, cartridge change out, program administration, filter penetration, protection factors, and other topics.