

Respiratory Protection Newsletter July 2021

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Respirator Fit Testing Workshop:	October 20-21, 2021

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NIOSH: Workplace “Performance Masks”

On May 18, 2021 NIOSH released a new guidance document for “masks” which they believe will help protect workers from the SARS-CoV-2 virus. These new guidelines have test criteria that exceed those of the American Society for Testing and Materials (ASTM) Specification for Barrier Face Coverings (F3502-21) released earlier this year (refer to my March 2021 Newsletter). For example, NIOSH requires a quantitative inward mask leakage test, which is currently an optional requirement for ASTM. These “inward” mask leakage tests should not be confused with fit testing employers conduct on respirator wearers. Both ASTM and NIOSH have test criteria evaluating mask filtration and airflow resistance. A mask that meets NIOSH guidelines are to be labeled as:

- Meets Workplace Performance, or
- Meets Workplace Performance Plus



Here’s a brief overview of the new NIOSH Workplace Performance Mask requirements. Keep in mind NIOSH has criteria that distinguishes two (2) types of masks. The mask having the more

challenging criteria is identified with the addition of the word: “Plus”.

Workplace Performance Mask
 Filtration criterion: $\geq 50\%$
 Breathability criterion: $\leq 15 \text{ mm H}_2\text{O}$
 Leakage ratio: ≥ 5

Workplace Performance **Plus** Mask
 Filtration criterion: $\geq 80\%$
 Breathability criterion: $\leq 15 \text{ mm H}_2\text{O}$
 Leakage ratio: ≥ 10

The NIOSH filter efficiency requirement for the “Plus” mask is higher than ASTM’s Level 2 requirement.

Filtration efficiency and breathability testing must be performed by an ISO accredited laboratory following the methods in ASTM F3502. In other words, this is likely, but not required, to be conducted by a laboratory other than the mask manufacturer.

To read the NIOSH announcement [Click Here](#)

Dr. McKay’s Comments:

Some individuals may have difficulty even when the NIOSH “breathability” criterion is met. According to ASTM F3502-21, airflow resistance between 5 to 15 mm H₂O can be perceived as difficult for long-term wearing by some individuals having medical conditions that impact breathing.

A higher leakage ratio means better fit during “inward” leakage testing. NIOSH makes the claim that a higher leakage ratio will “provide better source control”, but this has not been established. Fit testing for the wearer of a “mask” is not a requirement.

Keep in mind that the new NIOSH “mask criteria” are **not** replacements or substitutes for respiratory protection. Furthermore, face coverings that claim to meet ASTM F3502 specifications are not intended for use as medical procedure masks for source control or respirators for worker protection.

Strangely, NIOSH now has quantitative leakage criteria for masks, yet does **not** have a similar requirement for approval of N95 filtering facepiece respirators. Shouldn't NIOSH's priority be on improving the fitting characteristics of respirators required for use in workplaces? For decades, some N95 filtering facepiece respirators with poor fitting characteristics have passed the NIOSH certification process. When purchased by hospitals, industry, and governmental agencies, they end up with respirators that don't fit employees very well.

The very first paragraph of the NIOSH announcement says the following:

“The new mask criteria and ASTM Specification for Barrier Face Coverings, F3502-21 (ASTM Standard) determine an expected level of **source control** performance for workers when wearing the mask according to manufacturer's instructions.”

This **not** true. Nothing in either the NIOSH or ASTM testing procedure measures source control performance. At this time, there are no accepted standard test methods for measurement of outward particle penetration for evaluating source control. Research is currently being conducted in this area, but the equipment is not commercially available and not used for compliance with ASTM or NIOSH guidelines.

The 2021 NIOSH guidance has a “breathability” criterion. This is somewhat misleading, since breathability is not measured. The NIOSH requirement defers to section 8.2 of ASTM F3502-21 which has a requirement for measurement of airflow resistance through a filter under a standard set of experimental conditions. However, breathability is affected by factors other than airflow resistance through a fabric. In short, resistance to airflow is measured, not breathability.

Prior to the release of these new performance requirements for masks, was NIOSH aware that the ASTM standard used as a basis for their own requirements were under revision?

Yes. Months earlier ASTM created an official work item to address concerns in their standard.

Was NIOSH aware that the section on quantitative assessment of mask leakage in ASTM F3502-21 may be revised?

Yes.

After reading and inserting my own data into the current ASTM F3502-21 specification, I no longer support this document in it's current form. Fortunately, it's already under revision and I

reluctantly agreed to participate in the revision process. In some places ASTM F3502-21 claims to be a specification for source control. In other places it states otherwise. Regardless, ASTM F3502-21 does **not** quantify any level of source control and does **not** effectively evaluate face-to-facepiece leakage. With respect to NIOSH, it's unclear why they would refer to an ASTM specification currently under revision. Months before NIOSH released their Workplace Performance Mask criteria, an ASTM Work Item (WK76274) was created on March 15, 2021 to address concerns about the ASTM document. ASTM describes this project as:

“ASTM F3502 was rapidly developed to meet an urgent demand for standardized qualification of barrier face coverings. As a result of its approval, further new information has emerged related to needed clarifications, open issues, and potential improvements of the standard.”

As mentioned above, fit testing for the wearer is not a requirement. However, in the absence of fit testing, it's unknown what level of fit a wearer will achieve. Face-to-mask leakage is still likely to overwhelm filter penetration during actual use. In the absence of a formal training program, the level of personal protection a mask will provide users in the workplace remains unknown. Unfortunately, use of these masks in the workplace may end up replacing NIOSH-approved respiratory protective equipment, creating a false sense of security.

OSHA Issues COVID-19 Emergency Temporary Standards for Healthcare: 29 CFR 1910.502 and 29 CFR 1910.504

On June 21, 2021 OSHA submitted it's COVID-19 Emergency Temporary Standard (ETS) for healthcare to the Office of the Federal Register (OFR).



What is an emergency temporary standard (ETS)?

OSHA issues an emergency temporary standard (ETS) when it believes workers are exposed to a grave danger from new hazards or toxic substances or agents determined to be physically harmful. Once published in the Federal Register, an ETS takes effect immediately and remains in effect until replaced by a permanent standard. The ETS also serves as a proposal for a permanent standard and is subject to the usual notice and comment rulemaking procedure for adopting a permanent standard except that it must be finalized within six months. State Plans are required to have an ETS at least as effective as an ETS issued by federal OSHA 30 days following publication.

Located in Subpart U, the ETS contains two parts:
1910.502 Healthcare
1910.504 Mini Respiratory Protection Program

For the full text of the ETS go to 29 CFR 1910.502 or use the following URL:

<https://www.osha.gov/coronavirus/ets>

Or, [Click Here](#)

The links above will give you access to the regulatory text, fact sheets, and a 916 page preamble to the ETS.

To skip these options and directly access the regulatory text, use these URLs:

[Click here for 1910.502](#)

[Click here for 1910.504](#)

The ETS requires healthcare employers to develop and implement a COVID-19 safety plan and specific policies and procedures. These must include a designated safety coordinator, a workplace-specific hazard assessment, involvement of non-managerial employees in hazard assessment and plan development, and policies and procedures to minimize the risk of transmission of COVID-19 to employees. Exceptions to many of the requirements of the Emergency Temporary Standard (ETS) exist for fully vaccinated workers in “well-defined areas”. The language is confusing, but in some circumstances, fully-vaccinated employees in well-defined areas, do not have to wear masks or adhere to distancing requirements.

Perhaps the OSHA Summary taken directly from the 916 page preamble is all you need for now.

Summary: (in quotes)

“The Occupational Safety and Health Administration (OSHA) is issuing an emergency temporary standard (ETS) to protect healthcare and healthcare support service workers from occupational exposure to COVID-19 in settings where people with COVID-19 are reasonably expected to be present. During the period of the emergency standard, covered healthcare employers must develop and implement a COVID-19 plan to identify and control COVID-19 hazards in the workplace. Covered employers must also implement other requirements to reduce transmission of COVID-19 in their workplaces, related to the following: patient screening and management; Standard and Transmission-Based Precautions; personal protective equipment (PPE), including facemasks or respirators; controls for aerosol-generating procedures; physical distancing of at least six (6) feet, when feasible; physical barriers; cleaning and disinfection; ventilation; health

screening and medical management; training; anti-retaliation; recordkeeping; and reporting. The standard encourages vaccination by requiring employers to provide reasonable time and paid leave for employee vaccinations and any side effects. It also encourages use of respirators, where respirators are used in lieu of required facemasks, by including a **mini respiratory protection program** (see my comments below) that applies to such use. Finally, the standard exempts from coverage certain workplaces where all employees are fully vaccinated and individuals with possible COVID-19 are prohibited from entry; and it exempts from some of the requirements of the standard fully vaccinated employees in well-defined areas where there is no reasonable expectation that individuals with COVID-19 will be present.”

Effective dates: The effective date for 1910.502 (Healthcare) and 1910.504 Mini Respiratory Protection Programs are both June 21, 2021.

Compliance dates for 1910.502

Employers must comply with all requirements of 1910.502 (except for paragraphs (i), (k), and (n)) by July 6, 2021.

Employers must be in compliance with paragraphs (i), (k), and (n) by July 21, 2021.

Paragraph (i): Physical barriers

Paragraph (k): Ventilation

Paragraph (n): Training

OSHA Mini Respiratory Protection Program 29 CFR 1910.504

So what is the OSHA mini respiratory protection program? In short, it can be confusing. First I’ll give you OSHA’s explanation, then I’ll give you a simple way to remember it.

To access the regulatory text for 1910.504 Mini Respiratory Protection Program [Click here](#).

What are the key elements of a mini respiratory protection program for healthcare? Basically, it’s a normal respiratory protection program, with the following key elements removed:

Medical evaluation

Fit Testing

Written program

The mini respiratory protection program for healthcare **can be used** when Section 1910.502(f)(4): “Use of respirators when not required” is satisfied.

The mini respiratory program can **not** be used:
For exposure to person with suspected/confirmed COVID-19.
For aerosol generating procedures (as defined in 1910.502) on a person with suspected/confirmed COVID-19.
For standard and transmission-based precautions.

Dr. McKay's Understanding of the "Mini" Respirator Program:

Here's my take on the mini-respiratory protection program.

- 1) The mini program avoids using the words "filtering facepiece respirator" and "N95", except for the sections that define different types of respirators and reuse of respirators.
- 2) We know OSHA is trying to encourage use of elastomeric half facepiece respirators and PAPRs in healthcare settings.

Therefore, my conclusion is the mini program is essentially identical to the requirements in the Respirator Standard (1910.134) for voluntary use, but it expands the "Exception" found in paragraph 1910.134(c)(2)(ii). This is essentially accomplished by substituting the words "filtering facepieces" with "respirators" in 1910.134 (The Respirator Standard). As a result, when the conditions for voluntary use are met, the "mini" program for healthcare eliminates the requirement for a medical evaluation and formal written program if an elastomeric half facepiece is used. The same would be true for a full facepiece respirator. As in all voluntary use situations, respirator fit testing is not required. Is there any science to support that voluntary use has less physiologic effects than required use? Not in my opinion.

The "mini" program for healthcare has a section on user seal checks. Unfortunately, rather than simply making seal checks a requirement for employees who use tight fitting respirators, they provide guidance on two "Acceptable methods". Strangely, this section doesn't differentiate how to conduct seal checks on filtering facepiece respirators versus elastomeric facepieces. It's different from the recommendations in 1910.134, but still inadequate. With over 500 NIOSH approved filtering facepiece respirators and thousands of elastomeric facepieces available, the OSHA guidance for conducting seal checks is bad, not backed by science, and not consistent with manufacturer recommendations. OSHA guidance for seal checks in 1910.504 is also inconsistent with their own guidance in the Respiratory Protection Standard 1910.134.

Two areas I see as problematic in healthcare are employee training and fit testing. Rather than simply checking the box that these two elements were completed, healthcare needs:

- 1) More effective training, and
- 2) Respirator fit testing administered correctly.

Just doing it, isn't sufficient. Would there had been fewer healthcare workers with COVID-19, if training and fit testing had been done differently?

Let's Think About This: What's Next?

Let me begin by stating I fully understand how masks and other barrier face coverings contribute to source control. Despite wide variability in performance, reducing the number of exhaled bioaerosols can be helpful. I'm also familiar with increasing general and local ventilation, introduction of fresh air, distance from the source, duration of potential exposure, particle size, proper use and/or placement of partitions, etc. In fact, I've conducted calculations using these factors to determine if a worker can stay in an area without respiratory protection or stay longer with it. I've done the same with masks. However, now that NIOSH has introduced requirements for masks that look like respirators, will employers and employees be able to easily distinguish between them? Can we expect the following in the future?

Workplace Performance eyewear. This test uses lifesaver candy (any flavor) dropped from a height of 3 feet onto a lens. Any observed crack is recorded as a fail.

Workplace Performance footwear. For this test, a number 2 pencil, sharpened to a fine point is dropped from a height of 4 feet, point first, onto the top of work shoes. Any penetration observed on the inside of the footwear, is recorded as a fail.

Mini Respiratory Protection program. In this case, a well established respirator program is modified so that previously successful requirements are no longer necessary. Never mind, OSHA already did this for healthcare.

Have we started down a slippery slope?

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.



FDA Revokes EUA for Certain Respirators and Decontamination Systems

A June 30, 2021 FDA press announcement ends the emergency use authorizations (EUAs) for non-NIOSH-approved respirators as well as decontamination and bioburden reduction systems to disinfect disposable respirators. This includes imported KN95s.

As explained by an FDA representative, the FDA is taking additional action by announcing the revocation of EUAs for imported, non-NIOSH-approved respirators because of an increase in domestically-manufactured NIOSH-approved N95s available throughout the country. As access to domestic supply of disposable respirators continues to significantly improve, health care organizations are advised to transition away from crisis capacity conservation strategies that were implemented at the onset of the pandemic.

This FDA action is consistent with OSHA’s recently published Emergency Temporary Standard (ETS) to protect health care workers, which requires health care employers to provide NIOSH-approved or FDA-authorized respirators for workers potentially exposed to COVID-19.

The FDA recommends health care personnel transition from extended use of disposable respirators to single-use for single-patient interactions as appropriate. On this same day (June 30, 2021), the FDA released a separate letter to health care personnel and facilities announcing they no longer authorize the use of non-NIOSH-approved or decontaminated disposable respirators.

Dr. McKay’s Comment:

The bottom line can be simplified as:

Go back to using NIOSH-approved respirators and use them in a manner in which they were approved.

Missing from the FDA announcement is a **strong** recommendation reminding healthcare facilities that switching from non-NIOSH approved to NIOSH-approved respirators, requires fit testing for the new supply. Training will be needed for differences in donning/doffing technique, seal check procedures, etc. This time, let’s do the fit testing correctly.

To read the entire FDA announcement [Click Here](#)

Was I Too Critical?

Now that I’ve had time to reflect on my previous comments regarding poorly designed respirator studies, let me share some new quotes from the published literature:

“When attaching a PortaCount to a filtering facepiece respirator use a "catheter".”

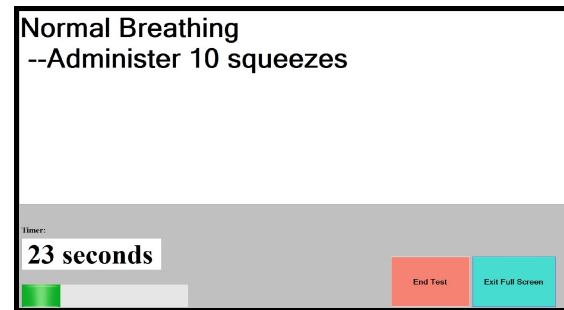
“Testing men with facial hair may cause lower fit factors than women without facial hair.”

“Respirator training, prior to fit testing, may affect facepiece fit.”

Your tax dollars were used to fund the above research.

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](#)

OSHA Issues COVID-19 Enforcement Directive

You knew this was coming. On June 28, OSHA issued an enforcement directive (DIR 2021-02 (CPL 02)) for its COVID-19 emergency temporary standard (ETS). The directive establishes inspection procedures and enforcement policies for both 29 CFR §1910.502, and 29 CFR § 1910.504.

The new directive provides OSHA compliance safety and health officers (CSHOs) with guidance and procedures for enforcing the new COVID ETS standard requirements and the mini respirator program. This includes enforcement of written prevention plans for COVID-19, patient screening and management, employee health screenings, etc.

The purpose of the compliance directive is to provide guidelines and establish uniform inspection and enforcement procedures for the (COVID-19 emergency temporary standard. The two main sections of the ETS, 29 CFR § 1910.502 and 29 CFR § 1910.504, published in the Federal Register, became effective on June 21, 2021. Compliance with most provisions is required by July 6, 2021, and with training, ventilation, and barrier provisions by July 21, 2021.

If you want to read the 67 page inspection procedures OSHA will use to enforce the new COVID-19 ETS, [Click Here](#).

EPA Extends Delay in Annual Fit Testing

In a May 6, 2021 Memorandum, the U.S. EPA has extended until September 30, 2021 the provision on “annual fit test delay” in its temporary guidance intended to help protect workers who handle agricultural pesticides during COVID-19. The original memorandum was issued in June of 2020. The May 6, 2021 extension is for handlers and employers facing shortages of filtering facepiece respirators and challenges related to fit testing. The guidance includes delaying the annual fit test. The remainder of the guidance remains unchanged.



EPA still expects handler employers and handlers to make every effort to comply with all applicable pesticide product label and WPS requirements, and to exhaust all available compliance options, including those identified in Section II of the June 2020 memorandum, before considering the options presented in Section III.B. “Completion of Respirator Fit Testing”. EPA will, on a case-by-case basis, exercise its enforcement discretion provided that handlers and handler employers demonstrate that they

have exhausted all available compliance options and are implementing the recommended terms and conditions, as outlined in the June 2020 memorandum.

Delaying the fit test is however, only one option. If the EPA extension possibly applies to your situation, you should review the May 6, 2021 memorandum. To do so, copy & paste the following URL: <https://www.epa.gov/enforcement/amended-statement-regarding-respiratory-protection-shortages-and-reduced-availability> or [Click Here](#)

An easier, more accurate way to administer respirator fit tests using sweet or bitter fit test methods.

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/>

Respirator Selection & Development of Cartridge Change Out Schedules

2022 Course date to be determined in Cincinnati
Go to www.DrMcKay.com for details.

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).

2022 Course date to be determined in Cincinnati

representative sample location for quantitative fit testing, may be providing less donning assistance, etc. Alternatively, maybe the wearers became lax on their donning technique and need refresher training. Without visual observation, it's difficult to determine which program was doing the better job.



Respirator Tidbits

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

According to the CDC website, as of July 5, 2021, they report:

“About 60% KN95 masks in the United States are counterfeit (fake) and DO NOT meet NIOSH requirements.”

Reader Questions:

Note: Due to time restrictions, Dr. McKay may not respond to all reader questions. However, selected questions and answers will be published in future newsletters.



Question:

We recently changed to another provider for respirator fit testing at our facility. While everyone passed, I noticed most employees have fit factors considerably lower than those from our previous provider. Does this suggest a problem with our new provider?

Answer:

You can blame it on a change in body weight, which is the excuse everyone likes to use. However, the real answer is difficult to access without visual observation of the fit testing, both past and present. You may want to request information regarding training and qualifications of the fit test operators, such as formal training certificates, experience, etc. However, without being present to visually observe the testing, it's difficult to know why fit factors are now lower. It's possible the lower, but passing fit factors are actually closer to the truth. The new fit test operator may be more aggressive with his or her testing technique, may be selecting a more



How to Knot and Tuck a Mask:

The Knot and Tuck technique can be used to improve the fit of commonly available



disposable masks having a rectangular shape with ear loops. If you're unfamiliar with this approach, take a quick look at this 1 minute video produced by the CDC:

<https://youtu.be/GzTAZDsNBe0>

Or, [Click here](#)

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

OSHA Cites Employer for COVID Death Using General Duty Clause

I'm sure readers of this Newsletter are familiar with OSHA citing healthcare facilities for violations of the Respiratory Protection Standard due to exposure to SARS-CoV-2. However, far less common are OSHA citations for COVID violations issued under the General Duty Clause for **non-healthcare facilities**. In an April 27, 2021 *OSHA News Release*, OSHA Region 5 announced it cited an employer using the General Duty Clause. According to the news release, a few days after employees at Midwestern distribution facility gathered together for a luncheon, some workers experienced symptoms consistent with coronavirus exposure. Afterwards, employees began reporting to the company that they had tested positive for the coronavirus on Oct. 27, 2020. By Nov. 9th, twenty three (23) employees tested positive for coronavirus, including one worker who died from complications on Nov. 4th. A subsequent OSHA investigation alleges the company failed to take immediate steps to identify, inform, isolate and quarantine all potentially exposed employees. OSHA's inspection found the company failed to follow its own internally developed controls for potential coronavirus exposure or take immediate steps to contain the outbreak. The agency has proposed a penalty of **\$12,288** for one serious violation of OSHA's general duty clause. Certainly, not much for a fatality, but the point here is the **General Duty Clause** was cited, rather than the respirator standard.



Strangely, a few days earlier, OSHA Region 1 announced it cited a tax preparation service company **\$136,532** in penalties for prohibiting her employees and customers from wearing masks, failing to ensure employees and customers practiced social distancing, and refusing to implement other safeguards against the coronavirus. In this case, OSHA determined the tax service:

Prohibited employees and customers from wearing face coverings in the workplace despite a statewide mask order that mandated the business to require employees and customers to wear masks.

Required employees to work within 6 feet of each other and customers for multiple hours while not wearing face coverings.

Failed to provide adequate means of ventilation at the workplace.

Failed to implement controls such as physical barriers, pre-shift screening of employees, enhanced cleaning and other methods to reduce the potential for person-to-person transmission of the virus.

My expertise is respiratory protection, not how OSHA issues citations. However, using the General Duty Clause for a proposed penalty of **\$12,288** at a distribution center resulting in 23 COVID cases and one death is far less than **\$136,532** in penalties at a tax preparation service company without any positive COVID cases reported.



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 these violations total **\$27,306**.



Once again, this penalty with 2 deaths is not in the same ballpark as the tax preparation service company, which didn't have any positive reported cases.



Announcements from NIOSH

NIOSH Revokes Approval of Respirator Model PLASMA N95-01

On May 4, 2021, NIOSH released a conformity assessment announcement (CA 2021-1035) revoking Plastikon Industries respirator model

PLASMA N95-01. This N95 filtering facepiece respirator (FFR) is no longer NIOSH-approved.

Revocation also means that respirators bearing the previous NIOSH approval numbers TC-84A-PH19 may no longer be manufactured, assembled, sold, or distributed. During a product audit the PLASMA N95-01 N95 respirator, tested samples failed to meet the filter efficiency requirements identified in 42 CFR § 84.174.

To see the NIOSH notice, [Click Here](#) or, copy and paste the following URL:
<https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/resprotect/CA-2021-1035.html>

PPE Use for Underserved User Populations

NIOSH published a Federal Register Notice ([Click here](#)) requesting information on the needs and challenges in personal protective equipment (PPE) use for under served user populations. Members of these populations may include, but are not limited to members of a gender, racial, ethnic, or linguistic minority group. It may also include non-traditional worker activities or who are members of sub-disciplines that are not the primary focus of the current PPE activities.

The deadline to submit comments must be received by August 23, 2021.

Spirometry Refresher:

September 21, 2021

Interpretation of Spirometry: Beyond the Numbers
September 22, 2021

Go to www.DrMcKay.com for details.



Updated Respirator Standard Testing Procedures

Since my last Newsletter, NIOSH has updated the following Standard Testing Procedures (STP):

STP-0105A—*Determination of Airflow—Demand and Pressure-Demand, Type C and CE, Supplied-Air Respirators Standard Testing Procedure (STP)*—has been updated to Revision 1.2, dated June 9, 2021.

<https://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-ASR-0105A-508.pdf>

Reason for revision:

Updated NIOSH Logo. Updated test procedure and figures to reflect new PC based recording system using LabVIEW, and other procedural changes related to calibration.

STP-0106—*Determination of Inhalation Airflow Resistance, Pressure-Demand, Type C and CE, Supplied-Air Respirators Standard Testing Procedure (STP)*—has been updated to Revision 1.2, dated June 10, 2021

<https://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-ASR-0106-508.pdf>

Reason for revision:

Updated NIOSH Logo. Updated test procedure and figures to reflect new PC based recording system using LabVIEW, and other procedural changes related to calibration.

STP-0107—*Determination of Exhalation Airflow Resistance, Pressure-Demand, Type C and CE, Supplied-Air Respirators Standard Testing Procedure (STP)*—has been updated to Revision 1.2, dated June 10, 2021.

<https://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-ASR-0107-508.pdf>

Reason for revision:

Updated NIOSH Logo. Updates to procedure and figures to reflect current test setup. The older version of STP used the silica dust chamber to perform the testing; this system is no longer used..

On June 18, 2021, NIOSH also posted updates to its Conformity Assessment requirements with two minor updates. They are:

NIOSH CA 2021-1033R1: [Guidance for respirator users regarding NIOSH Approved surgical N95 filtering facepiece respirators \(surgical N95s\) exempt from 510\(k\) pre-market notification in accordance with the Food and Drug Administration regulations at 21 CFR § 878.4040.](#)

This version of the notice, supersedes NIOSH CA 2021-1033 released May 2021.

What does this mean?

NIOSH-approved surgical N95s offer the same level of respiratory protection as a NIOSH-approved N95 FFR. Additionally, the surgical N95 has demonstrated conformance to FDA specified flammability, fluid resistance, and biocompatibility requirements and is intended for use in all healthcare settings and for all medical purposes in which an N95 level of respiratory protection is needed to protect the wearer.

Users can recognize a NIOSH-approved surgical N95 because the words “**Surgical N95 Respirator**” is printed directly onto the facepiece. In addition, you’ll also find the company name, model/part number, NIOSH assigned TC number, lot number, and the word “NIOSH” printed on the respirator

In essence, the June 2021 revision incorporates recommendations from HHS review and comments.

NIOSH CA 2021-1034R1: [Summarized Information about NIOSH Respirator Approval Program \(i\) Basic Application Procedures \(ii\) Quality Assurance Requirements and \(iii\) Supplier or Subcontractor Agreements.](#)

This version of the notice supersedes NIOSH 2021-1034 released March 2021.

What does this mean?

This document is for respirator manufacturers and contractors. The original clarifies the basic application procedures, quality assurance (QA) requirements for 42 CFR Part 84, and requirements for supplier and subcontractor agreements. The June 2021 revision simply incorporates recommendations from HHS review and comments.

Share Your Respirator Experience

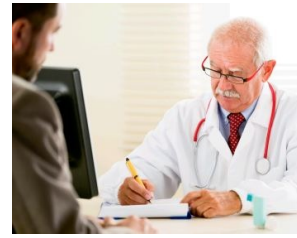
Here’s an opportunity to contribute your knowledge and experience to others. If you have an interesting respirator selection or other challenging respirator problem (and solution), please submit it to info@DrMcKay.com. I may use your real-life problem to help train students in our graduate and continuing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

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



2021 McKay Publications

S Grinshpun, H Haruta, R Eninger, T Reponen, R T McKay & Shu-An Lee (2021)

Eficacia de la mascarilla facial con filtro de partículas N95 y de la mascarilla quirúrgica durante la respiración humana: dos vías para la penetración de partículas, *Journal of Occupational and Environmental Hygiene*, 18:sup1, S1-S14, 2021
DOI:10.1080/15459624.2021.1877051

X He, T Reponen, R McKay & S Grinshpun (2021)
¿Cómo afecta la frecuencia respiratoria el desempeño de una mascarilla respiratoria autofiltrante N95 y de una mascarilla quirúrgica contra sustitutos de partículas virales?, *Journal of Occupational and Environmental Hygiene*, 18:sup1, S15-S24, 2021
DOI: 10.1080/15459624.2021.1877069

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.

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>

October 19, 2021

Fit Testing Workshop (2-day):

<http://www.drmckay.com/rtc-workshop.shtml>

October 20-21, 2021

Respirator Selection & Cartridge Change Out Schedule Workshop.

http://www.drmckay.com/rtc-resp_selection.shtml

2022 Date to be determined

Fit Testing Refresher & Advanced Topics

<http://www.drmckay.com/rtc-resp-refresher-advanced.shtml>

2022 Date to be determined

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. 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 (1 day)
- * Fit Testing at your workplace. Not a course, but a hands-on program with your staff and equipment.

I hope you enjoy this newsletter. Dr. McKay volunteers his time to many standard setting organizations and advises governmental agencies. Dr. McKay does not receive public or private funding for these services. Therefore, donations are appreciated and help this practice to continue. Lastly, the opinions in this newsletter are those of Dr. McKay and not the University of Cincinnati.

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To be Added to our Newsletter:

To be added to our Newsletter, go to

www.DrMcKay.com

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If you Receive Duplicate Newsletters:

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.

QualFit Videos



What is **QualFit** software?

12 minutes

<https://youtu.be/RwdMfrQXdTY>



Basic Operation of **QualFit** Software:

18 minutes

<https://youtu.be/vfwfuVOKAKw>



Comprehensive Fit Test Training Video

54 minutes

<https://youtu.be/FxpVsm3OhLY>



Respirator Fit Testing Errors and Solutions - 21 minutes

<https://youtu.be/0RsQEeOcS7o>

New Video



QualFit Full Screen Option - new video (5 minutes)

<https://youtu.be/RJr-IKTLas>

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.