

## Respiratory Protection Newsletter - May 2024

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**2-day Fit Testing Workshop** October 23-24, 2024 (limited space available)

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### No Respirator → Worker Dies

This happens far too many times, so let this March 7, 2024 *OSHA News Release* be a reminder of the hazards associated with entry into spaces not designed for occupancy. The news release briefly describes an incident in Kansas where three (3) workers entered an over-the-road tanker trailer to perform cleaning. However, since the company failed to conduct atmospheric testing before workers entered the tanker, one worker died and two others required hospitalization. In this particular incident that occurred back on September 1<sup>st</sup>, the truck washing and service center failed to evaluate the tanker for hazardous conditions, which should have included atmospheric testing and failed to train workers on potential hazards associated with entry into the tanker, which is a confined space. The OSHA report, reminds us that:

"Wherever organic matter such as crops and other materials are stored, hydrogen sulfide may be present as a natural byproduct. Workers must never enter storage facilities, tankers or other confined spaces without doing atmospheric testing and wearing protective equipment such as respirators capable of preventing inhalation of this colorless and toxic gas" explained OSHA Area Director Todd Underwood in Wichita, Kansas.

Although OSHA cited the company for two willful and 24 serious violations, and proposed \$171,680 in penalties, it doesn't bring back the deceased employee. I don't need anymore examples for my

respirator selection class, so let this be a reminder that a fatality may occur when entry is made into a space that may have limited ventilation or not designed for human occupancy.

To read the *OSHA News Release* use this URL:  
<https://www.osha.gov/news/newsreleases/region7/03072024>

Or, [Click Here](#)

### **Respiratory Protection for Surgical Smoke**

An April 2024 study by Meretsky conducted a literature review evaluating the effectiveness of standard surgical masks and N95 filtering facepiece respirators (FFRs) in reducing exposure to electrocautery smoke. Electrocautery is a commonly used technique in surgical procedures, which generates smoke that poses health risks to surgical staff. Through a systematic review of literature spanning two decades, they found significant disparities in the protection offered by different masks and underscore the importance of adequate respiratory protection in surgical settings. Specifically, they said N95 FFRs have the potential to provide a higher level of protection against both particulate matter and volatile organic compounds [50] (see my comment below).

The authors wrote:

“In conclusion, the systematic review provided robust evidence to support the superiority of N95 respirators over standard surgical masks in minimizing exposure to smoke and the health risks associated with it during electrocautery procedures. The results clearly show that N95 respirators provide an excellent level of protection. They successfully filter out the particulate matter and volatile organic compounds found in electrocautery smoke. This reduction in smoke exposure demonstrates the important role that respiratory protection plays in the well-being of surgical personnel by reducing respiratory symptoms and complications.”

To read the entire study, go to the following source:  
Meretsky C R, Mahmoodi A, Knecht E M, et al. (April 12, 2024) The Impact of Electrocautery Smoke on Surgical Staff and the Efficacy of Normal Surgical Masks Versus N95 Masks. *Cureus* 16(4): e58106.  
doi:10.7759/cureus.58106

### **Dr. McKay's Comments:**

While the conclusion supporting the greater effectiveness of N95 FFRs compared to standard surgical/medical masks is consistent with their data, the claim that N95 FFRs are effective against volatile organic compounds is **not** true. N95 FFRs are designed to remove particulate matter and not vapor or gases. They use

reference #50, a 2023 study published by K. A. Anudeep to support their claim, but my quick review of reference #50 doesn't include any statements about the effectiveness of N95 FFRs for vapors or gases.

This is the penalty we pay when articles on respiratory protection are published in journals not familiar with respiratory protection or don't have editors/reviewers with expertise in respiratory protection. Also notice the title refers to N95 FFRs as “N95 Masks”, which in the media gets shortened to just a “mask”.

### **Mail from Readers:**



Mail from Readers is an opportunity to share real-life experiences not found in traditional publications or research articles. Yet, these experiences can be informative to others.

“In the middle of the pandemic we hired a new physician who wears a turban and has a beard. On his first day working I assessed him for PAPR training/use and determined that our current PAPRs would not fit over his turban. He said, "Why can't I just wear an N95 mask when I'm going into COVID rooms?" I explained why this is not allowed per OSHA and for his safety and he responded, "Wow, I've been working through the first few years of the pandemic wearing an N95 mask, that's what the previous hospitals I worked at told me to do." So, he had never been given or trained on the use of a PAPR and had been entering airborne isolation rooms for years while having a beard and wearing an N95 mask, not to mention the patients who were having AGP who would have required a PAPR.

I was able to find and purchase a PAPR that fit over his turban so that he could safely care for his patients. He was shocked to hear all of this, and also shocked (but thankful) that I excluded him from caring for COVID patients until his PAPR arrived and he was trained appropriately on its use.

Over and over from new hires who have beards I hear, "Well my previous employer just fit tested me and I passed, even though I have a beard".”  
email received 2/15/24

Note: Mail from Readers having spelling errors, duplicate words and/or grammar may be corrected. Any changes made

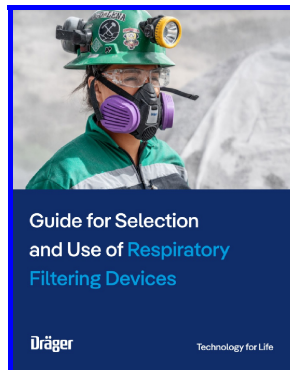
do not change context. Portions not relevant to the topic may be removed. Names and/or identifiers are removed.

**Comment:**

After reading the above email regarding PAPRs as a potential alternative to tight fitting N95 FFRs, I reached out to Sarah Binstadt, BSN, CIC (Manager Infection Prevention and Employee Health), who has experience with this matter. She confirmed my own experience that some PAPR facepieces accommodate turbans and others don't. The type of facepiece used with the PAPR is one consideration, the other is the size/style of the turban itself. Many hooded PAPR facepieces will accommodate turbans and provide an acceptable level of respiratory protection.

**Dräger Provides Respirator Selection Guide**

Dräger just released an easy to use 110-page color respirator selection guide, available as a pdf file. The guide can be used to assist respirator program administrators, safety & health professionals, students, and others, select respiratory protective equipment for workplace applications. Another nice feature of the guide is it identifies an appropriate filter and/or cartridge for use with a specific Dräger respirator (i.e., elastomeric half facepiece, PAPR, etc.).



The guide contains a comprehensive list of chemicals against which Dräger respirators can provide protection. Contaminant names listed in the guide are generally those used in the Threshold Limit Values and Biological Exposure Indices published by the American Conference of Governmental Industrial Hygienists (ACGIH). Pesticides and chemicals without established occupational exposure limits are not included. Once the workplace contaminants and their concentrations have been identified, the guide can be used to select an appropriate Dräger respirator.

To obtain a free copy of the guide, use the following URL

<https://www.draeger.com/Content/Documents/Products/filter-selection-guide-niosh-interactive-br-dmc-104642-en-master.pdf>

Or, [Click Here](#)

**QualFit® Software®**

**An easier, more accurate, and defensible 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.

**QualFit® - Making Respirator Fit Testing Simple**

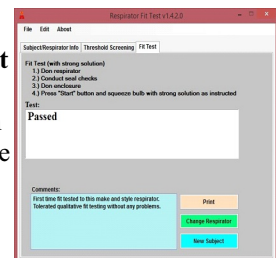
For Information visit: [www.QualFit.net](http://www.QualFit.net)  
To place a secure online credit card order visit: <https://qualfit-software.square.site/>

The name (mark) QualFit® is registered with the U.S. Patent & Trademark Office.

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**Final screen indicating test passed and operator comments.** Includes option to print now or later, change to a different respirator, or select a new subject.



## Test Your Fit Testing Knowledge

The photo below was taken from a company's website on March 9, 2024 promoting their nationwide respirator fit testing services. In this photo, there are two (2) major mistakes that could allow poorly fitting respirators to pass the fit test, putting employees at risk of exposure at their workplace. **Can you spot the errors?** Is this how your employees are fit tested?

**Answer** appears in "Training Opportunities" located toward the end of this newsletter.



This company also offers quantitative respirator fit testing, which is technically more sophisticated with potentially more errors.

## MSHA Changes Silica Respirator Requirements

On April 18, 2024, the Mine Safety & Health Administration (MSHA) issued its final rule, lowering miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection. The impact of this rule affects the selection of respirators to be used and reduce e miner exposures to respirable crystalline silica.

The final rule:

- \* Lowers the permissible exposure limit (PEL) for respirable crystalline silica to 50 micrograms per cubic meter of air ( $\mu\text{g}/\text{m}^3$ ) for a full shift, calculated as an 8-hour time-weighted average (TWA) for all miners;
- \* Establishes an action level for respirable crystalline silica at 25  $\mu\text{g}/\text{m}^3$  for a full shift, calculated as an 8-hour TWA for all miners;
- \* Includes uniform requirements for controlling and monitoring exposures to respirable crystalline silica at coal and metal and nonmetal (MNM) mines;
- \* Includes medical surveillance requirements for MNM mines, modeled on the existing medical surveillance requirements for coal mines; and
- \* Updates existing respiratory protection requirements by incorporating by reference a voluntary consensus standard by the American Society of Testing and Materials (ASTM) that reflects the latest advances in respiratory protection technologies and practices – ASTM

## F3387-19 Standard Practice for Respiratory Protection.

In 2016, OSHA established a PEL of 50 and an action level of 25  $\mu\text{g}/\text{m}^3$  as an 8-hour TWA in the general and construction industries and maritime sector that it regulates. In the mining industry, however, the higher PELs have remained in place for miners in both the metal and nonmetal (MNM) sector and the coal sector.

With respect to just respiratory protection, the primary changes affect the following two sections regarding use of respirators. They are:

- \* Requires temporary use of respirators at metal and nonmetal mines when miners must work in concentrations above the PEL. When metal and nonmetal (MNM) miners must work in concentrations of respirable crystalline silica above the PEL while engineering controls are being developed and implemented or it is necessary by nature of the work involved, the mine operator shall use respiratory protection as a temporary measure.
- \* The respiratory protection standard published in ASTM F3387-19, Standard Practice for Respiratory Protection, is incorporated by reference. When approved respirators are used,

the mine operator must have a written respiratory protection program to protect miners from airborne contaminants, including respirable crystalline silica, in accordance with ASTM requirements. Note: Dr. McKay was a member and contributor to this publication.

The final rule will take effect on June 17, 2024. Coal mine operators have 12 months to come into compliance with the final rule's requirements while metal and nonmetal mine operators have 24 months to come into compliance (including medical surveillance).

To read the 268 page, small font, 3-column final rule as published in the Federal Register on April 18, 2024, [Click Here](#).



### **Georgia Manufacturer Facing \$289,439 Fine**

According to an article posted in the EHS Daily Advisor by Guy Burdick on Mar 13, 2024, an Atlanta chemical manufacturer is facing \$289,439 in OSHA penalties. OSHA cited the employer with 67 serious violations, including, but not limited to:

- 1) failure to establish and implement a respiratory protection program, and
- 2) provide a medical evaluation before workers were fit tested or required to use respirators.

### **Steel Fabricator Fined \$348,683**

According to a Feb 23, 2024 article reported in BLR Safety (Safety.BLR.com), a New Jersey steel fabricator is facing **\$348,683** in OSHA fines. Four of these were willful and seven represented serious safety and health violations. Among the many violations, a portion included the employer's failure to medically evaluate new employees who were required to wear respirators.

Regarding respiratory protection, OSHA's citations included a willful and serious violation of the respiratory protection standard. In this particular case, the employer provided employees with respirators, including 3M model 7700 half-facepiece elastomeric respirators and 3M Versaflo powered air-purifying respirators (PAPRs) without performing employee medical evaluations for respirator use. In case you forgot, persons required to wear PAPRs, must be medically cleared.

My understanding of this case is the investigation

began in response to a complaint in the summer of 2013. Prior to the investigation, the company hired a safety consultant, but failed to implement the recommendations of the consultant. I believe this is why some of the violations are defined as "willful".

### **Auto Parts Manufacturer Fined \$182,344**

The following was taken from a February 22, 2024 *OSHA News Release* (#24-263-ATL). Six days after opening a complaint at a Georgia auto parts manufacturer in August 2023, investigators learned that a 41-year-old maintenance worker endured severe injuries from an electrical transformer explosion and opened a second investigation. From both inspections, OSHA cited the company for 22 serious and three other-than-serious violations with proposed fines totaling \$182,344. With respect to respiratory protection, OSHA found the employer:

Exposed workers to an airborne concentration of respirable silica of up to 15 times above the permissible time-weighted average.  
Failed to provide NIOSH-approved respirators to employees exposed to silicosis hazards.  
Did not provide fit testing to workers required to wear respirators while exposed to crystalline silica.

This particular company is a global manufacturer of aluminum, magnesium and iron cast and automotive components. The company has more than 30 facilities in North America, South America, Europe and China.

### **Fined \$120,212 Excessive Silica Dust Exposure**

In separate Feb 2024 postings including *Bloomberg Law*, *Selma Times Journal*, *EHS Daily Advisor*, and others, an Alabama bricklayer has been cited by OSHA with 11 serious violations and hit with over \$124,000 in proposed penalties after allegedly over-exposing workers to respirable crystalline silica.

In brief, workers were exposed to concentrations of crystalline silica 6.5 times the permissible exposure limit (PEL), required affected workers to wear respirators prior to being trained on respirator use, failed to provide respirator medical clearance, failed to provide respirator fit testing, and permitting employees to work in areas that required respiratory protection without providing a respiratory protection program that met OSHA requirements.

### **Battery Manufacturer Facing \$77,200 in Fines**

An April 8 report in Yahoo News by David Shepardson reports a battery maker in Georgia faces \$77,200 in fines for workers suffering potentially

permanent respiratory damage in an October lithium battery fire. On multiple occasions the manufacturer failed to meet health & safety standards. Following an October 2023 fire, OSHA said the battery manufacturer "failed to train its employees on how to protect themselves adequately in the toxic atmosphere that left multiple workers injured." Inhalation hazards included **hydrofluoric acid** vapors, which are produced in lithium battery fires. In a previous investigation, OSHA reported the battery manufacturer exposed employees to cobalt, nickel and manganese and failed to ensure employees were given clean, disinfected and sanitary respirators; properly stored.

In addition, the staffing agency that supplied workers at the site failed to inform employees about the hazards associated with lithium battery fires.



### **Wanted: Photos & Videos of Improper Fit Testing**

To my readers, please continue sending photos, videos and testimonials of improperly conducted fit testing. If you worked for an employer that conducted fit testing improperly, share your story. If your employer knowingly had the fit test operator administer the test incorrectly, share this too. I promise to keep your name and employer name confidential. If you have a good story, photo or video, send it to [Roy@DrMcKay.com](mailto:Roy@DrMcKay.com)

### **Getting Rid of Suction Cups**

Previous newsletters announced the coming release of **Fit Test Tubing Holders™** for use with ambient aerosol quantitative fit testing methods (i.e., TSI PortaCount® & AccuFIT 9000®). Tubing holders make the process of fit testing faster and more reliable. More importantly, they help eliminate passing of poorly fitting respirators. Unfortunately, I've had to temporarily suspend public release of this product to figure out a cost-effective way to produce these in volume, pack, and ship. Consequently, if you're tired of suction cups falling off during the middle of fit testing or getting unreliable results, you'll need to wait a little longer. I'll consider making these available to researchers, who want confidence they're getting a reliable in-facepiece sample.



## **NIOSH News**

### **Revised MultiVapor Software Released**

On April 26<sup>th</sup>, users of the NIOSH/NPPTL list serv received notice of an updated version of MultiVapor™ software, used to identify breakthrough times for chemical cartridges used for protection against certain organic vapors. The update to Version 2.2.6, reportedly resolves errors users experienced with a missing MSSTDFMT.DLL file, and other minor typographical errors. The updated version also includes the addition of 26 new chemicals to the existing database. However, I've not yet been able to confirm the exact number or a listing of the additional chemicals.



To download the new version, visit the NIOSH MultiVapor™ webpage at: <https://www.cdc.gov/niosh/npptl/multivapor/multivapor.html>  
Or, just [Click Here](#)

### **My Comments:**

When installing the updated version, the instructions state: "You may also need to delete any previous version of this application before downloading this newer version." Prior to doing this, consider making a copy of any customized cartridge data you may have previously created. Otherwise it may be lost.

As of the date of this newsletter, after successful installation, be aware the version number and date on the opening screen will **not** reflect the updated version 2.2.6! Instead the old version number and date will be displayed. I notified NIOSH about this issue and explained the confusion this may create for some users. For technical reasons too complicated to explain here, this may or may not be readily resolved. However, I'm hopeful they'll follow-up with my recommendation to revise the installation instructions of the NIOSH web page, to reflect this issue.

I also request a list of the newly added chemicals. If these become available or if the correction to the updated version number and date become available, I'll share that with my readers.

If you want to learn more about MultiVapor™ and other methods to develop a cartridge change out schedule, consider taking my 1-day annual

course titled: “**Development of Cartridge Change Out Schedules**”. At this course you’ll learn far more than just identification of breakthrough time. Unfortunately, registration for my May 2024 class is closed, but it will be held again in 2025.

## **Notice of Proposed Rulemaking CDC/NIOSH Notice of Proposed Rule-making**

Here are some upcoming changes in respiratory protection that have been proposed. Follow the links for additional information.

### **Combination Unit Respirators**

March 14, 2024: The Department of Health and Human Service (HHS) proposes to amend regulatory requirements that would be used by CDC/NIOSH to test and approve combination unit respirators. This rulemaking would establish a new class of respiratory protective devices, **combination unit respirators (CURs)**, by incorporating by reference the performance requirements established in the National Fire Protection



Source: CDC/NIOSH 9/2019

Association (NFPA) voluntary consensus standard NFPA 1987, Standard on Combination Unit Respirator Systems for Tactical and Technical Operations. The proposed regulation may be reviewed here

<https://www.federalregister.gov/d/2024-03849>

Or, [Click Here](#)

### **What is a combination unit respirator?**

A combination unit respirator (CUR) is a respiratory protective device that employs the technology of at least two different types of respiratory protective devices, with one being an open-circuit self-contained breathing apparatus (SCBA) and at least one other method being air-purifying or powered air-purifying, and that allows the wearer to select the operating mode.

### **Why is This Needed?**

According to the proposal, they state: “Providing a mechanism to allow manufacturers to obtain NIOSH approvals of respirators conforming to the proposed standard for the new CUR class in subpart P would benefit those workers and employers who encounter various types of hazardous exposures and currently rely on multiple types of NIOSH Approved respiratory protective devices in the course of their duties on OSHA-regulated worksites. The

flexibility provided using one NIOSH Approved respirator that can perform multiple functions might also benefit employers by allowing them to purchase fewer respirators, which NIOSH expects will result in cost savings. This rulemaking would also benefit employers who are required by OSHA to provide workers with NIOSH Approved respirators but currently use CURs that do not have NIOSH approval; HHS assumes that, as a result of this rulemaking, employers will choose to purchase NIOSH Approved products, allowing them to come into compliance with OSHA rules.”

Despite the current lack of a NIOSH approval standard for CURs, they are used today in military, law enforcement, and some industrial settings where the versatility of these devices allows users to perform in various hazardous environments. A CUR allows the worker to carry or wear one respirator into an environment in which the hazards are either unknown or might change rapidly, and to readily switch between types of respiratory protection after assessing their individual risk.

Comments must be received by May 14, 2024. Comments on the information collection approval request sought under the Paperwork Reduction Act must be received by May 14, 2024.

## **Standard Test Procedure Changes User Notices**

### **New Test Procedure for PAPRs**

On February 13, 2024, NIOSH/NPPTL announced that they have combined and updated two Standard Testing Procedures (STP). Here’s what the announcement says:

1) CVB-APR-STP-0009 and CVB-APR-STP-0010 - Determination of Facepiece Fit - have been made obsolete.

2) NPPTL-APR-STP-0009-0010 - Determination of Respirator Fit, Quantitatively Using Corn Oil Aerosol, for Powered Air-Purifying Respirators with Loose- or Tight-Fitting Respiratory Inlet Coverings, Standard Testing Procedure - has replaced CVB-APR-STP-0009 and CVB-APR-STP-0010 and updated to Revision 1.0, dated 12 January 2024.

Putting this in plain English, NIOSH looked at two standard testing procedures, which they felt were obsolete, and combined them into a single new standard procedure. The purpose of the new procedure is to establish a standard protocol using laboratory generated corn oil aerosol to determine if PAPRs with loose or tight fitting inlet coverings meet

minimum criteria set forth in 42 CFR Part 84, Subpart K, Section 84.176.

According to the above announcement, this new procedure (APR-STP-0009-0010) has a date of January 12, 2024. However, my review of the procedure indicates a date of February 12, 2024. Regardless, to review the changes, copy & paste the following URL:  
<https://www.cdc.gov/niosh/npptl/stps/pdfs/NPPTL-A-PR-STP-0009-0010-508.pdf>  
or simply [Click Here](#)

## Conformity Assessment Notices

### Masprot Respirator Approvals Rescinded

On Feb 15, 2024 NIOSH honored a request by Masprot S.C., EI. LTDA to voluntarily rescind eight NIOSH respirator approvals. According to the notice, as of February 13, 2024, any respirator marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these eight approval numbers:

Approval Number	Part / Model
TC-23C-1918	M-1.2 w/MGA-1A
TC-84A-2749	M-1.2 w/MLE-1A
TC-84A-2864	M-1.2 w/MHE-1B and MGA-1A
TC-84A-2529	M-2.2 w/MLE-2 N95 FILTER
TC-23C-0872	M-2.2 w/MGA-2
TC-84A-2671	M-2.2 w/MGA/MHE-2
TC-84A-2826	M-2.2 w/MGV/MLE-2
TC-84A-4633	M-2.2 w/MGA/MHE-2S

The complete text of NIOSH CA 2024-1074 may be found at:  
<https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2024-1074.html>  
or, [Click Here for Rescinded Respirators](#)

### Masprot Respirator Approvals Rescinded

In a February 23, 2024 announcement, NIOSH honored an additional request by Masprot S.C., EI. LTDA to voluntarily rescind six (6) NIOSH respirator approvals. As of February 22, 2024, any respirator marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these two approval numbers:

Approval Number	Part / Model
23C-2506	Model Supreme Half Mask M-203 w/MGV-1P

84A-7785	Model M800 Half Mask w/MGV/MHE-500
84A-7786	Model M800 Half Mask w/MGA/MHE-500
84A-7787	Model M800 Half Mask w/MHE-500
23C-3217	Model M800 Half Mask w/MVO-500
23C-3218	Model M800 Half Mask w/MGV-500

The full text of NIOSH CA 2024-1075 may be found at:  
<https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2024-1075.html>.  
Or, [Click Here](#)

### Honeywell Respirator Approvals Rescinded

In a February 23, 2024 announcement, NIOSH has honored a request by Honeywell International Inc. to voluntarily rescind two NIOSH respirator approvals. As of January 18, 2024, any respirator marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these two approval numbers:

Approval Number	Part / Model
19C-0400	Series CF2300, Mask / Hood 5400, Protection SA/CF
19C-0401	Series CF2300, Mask / Hood 5400, Protection SA/CF

The complete text of NIOSH CA 2024-1073 may be read at:  
<https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/CA-2024-1073.html>.  
Or, [Click Here](#)

### NIOSH-approved Spirometry Refresher:

Sept 24, 2024

### Interpretation of Spirometry: Beyond the Numbers

Sept 25, 2024

email [roy@drmckay.com](mailto:roy@drmckay.com) for information

### 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](mailto:info@DrMcKay.com)



## Manufacturer User Notices:

### Champak Respirator Stop Sale



On Feb 28, 2024 released an announcement stating that **Champak Enterprise Co., Ltd.** posted a user notice to inform end users of a voluntary **stop sale** for all of their NIOSH Approved® respirators. The user notice is dated 27 February 2024 and information can be found on the NIOSH Respirator User Notices Issued by Manufacturers webpage under the Champak Enterprise Co., Ltd section.

The Champak website provides more detail, including a letter by the General manager (Lin, Jing-Jyr). In this letter it becomes clear that the stop sale is a “temporary” situation, while they address unspecified NIOSH concerns. Here’s part of the Champak announcement:

“Recently, NIOSH has requested for an analysis to be made on the quality management system, in particular what has been utilized at the Singapore manufacturing site producing respirator models AP520M, AP520L, AP520VM, AP520VL, AP521VM, AP521VL, AP522VL. As our commitment to industry compliance and customer satisfaction, we have volunteered to issue a temporary stop sale of all NIOSH-approved respirators until we have addressed NIOSH's concerns.”

If you want to read the General Manager’s announcement, [Click Here](#).

### 3M Scott Cylinder Valve Leakage

3M Scott Fire & Safety posted a notice dated December 2023 to make 3M Scott cylinder and valve assembly users aware of a small number of cylinder valves experiencing noticeable rates of leakage when the valve handwheel is initially opened. As stated in User Safety Notice SN122223, an investigation found the cause to be due to O-ring failure at the bonnet due to incorrect torque on the specific units in question. The root cause has been identified and mitigated, but 3M is notifying users of potentially affected units to perform inspections of their respirators on a regular basis as defined in their User Instructions provided with the respirator. Specific inspection procedures

are also included with the User Safety Notice.

For additional information, refer to the NIOSH/NPPTL user notice dated December 2023 for more information. It can be found on the NIOSH Respirator User Notices Issued by Manufacturers webpage [Click Here](#) under the 3M Scott Fire & Safety section. Or, simply [Click Here for 3M Notice](#)

### Shigematsu Corrected Donning Instructions

At the request of NIOSH, Shigematsu Works Co., Ltd. released a user notice (dated March 22, 2024) correcting the donning procedure for their N95 Lambda-Line series respirators. The original donning instructions permitted the lower neck strap to be placed over the crown of the head. Apparently, they believed this improved the fit around the chin for customers with smaller faces.



However, NIOSH requires the lower strap to be positioned around the neck. In response, to NIOSH, the user instructions have since been modified.

However, perhaps, NIOSH didn’t notice, but the corrected figure is still incorrect as it shows the lower strap going on top of the hair, rather than underneath. The correct position is along the skin to avoid pulling with head movement. You can read Shigematsu’s user notice at the following URL: [https://www.sts-japan.com/upload/news\\_asia/2BQS1KF-news\\_asia\\_file.pdf](https://www.sts-japan.com/upload/news_asia/2BQS1KF-news_asia_file.pdf) Or, [Click Here](#)

### Makrite Rescinds Approval # 84A-4107

NIOSH has honored a request by **Makrite Industries, Inc.** to voluntarily rescind one NIOSH respirator approval. As of March 27, 2024, any respirator marked with a NIOSH approval label and approval number listed below is no longer NIOSH approved. The NIOSH Certified Equipment List will no longer includes this approval number.

<u>Approval Number</u>	<u>Part / Model</u>
84A-4107	910-N95S N95

Unfortunately, I couldn’t find a photo of this respirator to share with readers.

Due to the voluntary rescission of this approval, respirators bearing this NIOSH approval number may no longer be used, manufactured, assembled, sold, or distributed.

The full text of the NIOSH Conformity Assessment announcement (document number CA 2024-1076) is available at:  
<https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/resprotect/CA-2024-1076.html>

Or, [Click Here](#)

### Dräger: Filters a Little Too Small

NIOSH shared a notice from Dräger Safety AG & Company, KGaA to alert customers that multiple batches of N95 and R95 particulate filter pads (parts numbers 6738020 and 6738021, respectively) were manufactured a few millimeters too small. As a result, they don't fit properly and will have reduced filter performance. For details listing affected batch numbers, refer to the Dräger user notice dated November 2023. It can be found on the NIOSH Respirator User Notices Issued by Manufacturers webpage. Look specifically for the Dräger Safety AG & Company, KGaA section.

My review of the Dräger announcement reveals that the affected filters are used with the X-plore facepiece having bayonet style connectors. To see a list of affected N95 and R95 filter pads with affected batch numbers, you can go to the NIOSH website as mentioned above, or go directly to the user notice posted by Dräger, which can be accessed directly, if you [Click Here](#)

The Dräger N95 filter pad looks nearly identical to the R95 filter pad. To help my readers understand what the affected product looks like, a picture of a N95 filter pad is shown below.



**Dräger N95 Pad # 6738020**

Dräger advisers' customers to stop using any of the affected filter pads and to remove them from your inventory. Users should contact their Dräger Customer Success team to arrange for free replacement.

The above announcement was distributed by the NIOSH/NPPTL listserv on April 15, 2024, but the Dräger announcement is dated November 2023!

### Aswan International Rescinds 9 Respirators

Effective April 1, 2024 NIOSH has honored a request by Aswan International Corp. to voluntarily rescind nine (9) respirator approvals. As of this date, any respirator marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these approval numbers:

<u>Approval No.</u>	<u>Part / Model</u>
84A-5628	M714
84A-5638	M713
84A-6248	M34R
84A-6249	M36RV
84A-6250	M34RV
84A-6264	M815
84A-6758	M814R
84A-6804	M23V
84A-6849	M23

To read the entire text of the NIOSH Conformity Assessment document CA 2024-1077, use the following URL:

<https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/resprotect/pdfs/CA-2024-1077-P.pdf>

Or, [Click Here](#)



### Wanted: 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 and undamaged fit testing adapters provides 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 and fit testing workshops, send us an email at [info@DrMcKay.com](mailto:info@DrMcKay.com) and we'll provide shipping information.

**Undamaged** fit test adapters are also needed. On average, we lose one to two fit test adapters every workshop due to wear and tear, poor adapter design, improper removal, and other causes. If you've switched to another method of fit testing, rather than putting unwanted adapters into a landfill or taking-up space in your cabinet, donate them to our workshop.



### ISRP International Conference Sept 22-26, 2024



The European Section of the International Society for Respiratory Protection (ISRP) will hold its 21<sup>st</sup> International Conference September 22 - 26, 2024 in Oxford, United Kingdom. The venue will be the historic University city of Oxford, at Pembroke College. I've been to Oxford and can say that it's a wonderful place to visit. This year's conference will focus on "Use and Users" of respiratory protective devices.

For those interested in presenting at the conference, submission of abstracts are due by June 30, 2024. Abstracts can be submitted electronically to [oxford.technical@isrp.com](mailto:oxford.technical@isrp.com) as an editable Word document and should be no more than 250 words long, excluding the title and the names and affiliations of the authors. For additional instructions go to: <https://www.isrp.com/events/next-international-conference>

#### Registration Info:

Early Bird member fees will be £700 to include all four days of the conference, registration, reception on Sunday, Monday evening event and the Awards dinner on Wednesday. Other fees apply to non-members, late bookers and day delegates.

#### Lodging:

In addition to a wide variety of local options, rooms have been reserved at Pembroke College, available at: <https://www.isrp.com/events/next-international-conference>  
The booking code to use is ISRP2024.

For a PDF brochure, [Click Here](#)

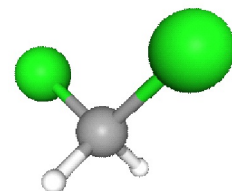
For questions regarding the conference, email: [oxford@isrp.com](mailto:oxford@isrp.com)

## EPA News



### Methylene Chloride Rule Change

The EPA has finalized its methylene chloride rule. The rule is anticipated to publish in the Federal Register shortly and a pre-publication of the 181-page final regulation is available [here](#). This regulation will establish an "Existing Chemical Exposure Limit" (ECEL) as part of a Workplace Chemical Protection Program, which is intended to align with, to the extent possible, certain elements of the existing OSHA standard for regulating methylene chloride under 29 CFR 1910.1052. However, EPA is finalizing new, lower regulatory exposure thresholds, derived from the TSCA 2020 Risk Evaluation for Methylene Chloride.



I became aware of this EPA announcement just days before the release of this newsletter. Consequently, I've not yet had time to fully investigate how this regulation will affect respiratory protection, other than where respirators may now be used. As a reminder, OSHA (nor the final EPA rule) allows for negative pressure respirators to be used for methylene chloride (except for emergency escape). However, changes to exposure limits will affect respirator selection, or put another way, areas where respiratory protection previously wasn't required, may be required when the rule becomes effective.

Within the final rule, the ECEL and EPA STEL are defined in 751.103. The new regulatory occupational exposure limits for uses not prohibited by the EPA rule are:

ECEL: 2 ppm (as 8-hr TWA)

EPA STEL: 16 ppm (as a 15-min TWA)

For comparison, the OSHA PEL is: 25 ppm as an 8-hour TWA

The respiratory protection measures (in 751.109(f)) for the rule generally go into effect 450 days after the publication in the Federal Register as part of the Workplace Chemical Protection Program (found in 751.109).

For information about EPA's ban to limit use of Methylene chloride, copy and paste the following URL:

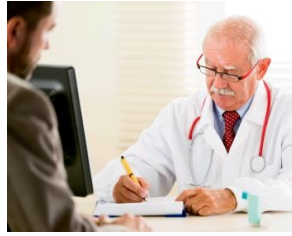
<https://www.epa.gov/newsreleases/biden-harris-administration-finalizes-ban-most-uses-methylene-chloride-protecting>

Or, [Click Here](#)

Inquiries to EPA can be directed to: [MethyleneChlorideTSCA@epa.gov](mailto:MethyleneChlorideTSCA@epa.gov)

## 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](mailto: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](mailto: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.

## 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 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.

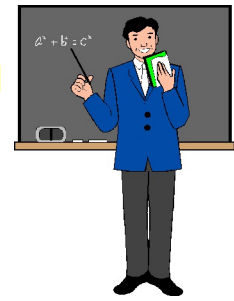
**Learn the tricks fit test operators' use to enable poorly fitting respirators to pass respirator fit testing (both QLFT & QNFT).**

2025 Course Date to Be Determined

## Training Opportunities

### Respirator Training Courses:

Dr. McKay and the University of Cincinnati is pleased to announce the following Respirator Training programs. They are:



### Overview of Respiratory Protection:

<http://www.drmcKay.com/rtc-overview.shtml>

October 22, 2024

### Fit Testing Workshop (2-day):

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

October 23-24, 2024

### Respirator Selection & Cartridge Change Out Schedule Workshop.

[http://www.drmcKay.com/rtc-resp\\_selection.shtml](http://www.drmcKay.com/rtc-resp_selection.shtml)

May 14-15, 2024 (**Registration closed**)

2025 Course Date to be Determined

### Fit Testing Refresher & Advanced Topics

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

May 16, 2024 (**Registration closed**)

2025 Course 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.
- \* Selection Workshop
  - Practical problems and solutions.



### Answer to Fit Testing Errors:



The two (2) major errors are:

- 1) The nebulizer bulb is excessively tilted to the point of being held in a horizontal position. This prevents liquid from being aerosolized.
- 2) The nebulizer bulb is being squeezed with the fingertips from both hands, rather than being held in the palm of one hand and being firmly squeezed.

In both cases, the delivery of the challenge agent is reduced. If the proper amount of challenge agent isn't delivered, the ability to identify a poorly fitting respirator is significantly reduced. On the other hand, you can get more people done in less time!

### 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!

### Fit Testing Workshop (2-days):

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**<sup>®</sup> software<sup>®</sup>. Quantitative fit testing with the TSI PortaCount, AccuFIT 9000, and the OHD QuantiFit<sup>®</sup>. 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 ASTM sub-committee on respirator fit test methods, 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 1-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. This class will help the student understand the most significant physiologic effects of wearing a respirator and OSHA requirements for respirator medical clearance. An introduction to qualitative and quantitative fit testing and seal check procedures will be covered (unless all attendees are participating in the fit testing workshop, where these topics will be covered more comprehensively). 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.

## QualFit® Respirator Training Videos

For information about **QualFit® Software®** for qualitative respirator fit testing with sweet and/or bitter agents, go to [www.QualFit.net](http://www.QualFit.net)



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>



**QualFit® Full Screen Option** - (5 min)

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

The 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 feet away. In addition, audio beeps and changes in font color help the operator to deliver the aerosol at the proper time and sequence as required by OSHA, ANSI, ASTM, ISO and other organizations.

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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](http://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 past chair of ANSI/AIHA Z88.10 (now ASTM), 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 also 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.

## Disclaimer:

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