Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Who Does What? The Roles of NIOSH, OSHA, and the FDA in Respiratory Protection in the Workplace

September 9, 2021 by Maryann M. D'Alessandro, PhD; Suzanne B. Schwartz, MD, MBA; Andrew Levinson, MPH; and Jaclyn Krah Cichowicz, MA

Over the years, the National Institute for Occupational Safety and Health (NIOSH) has built complex partnerships with the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA) to address the specific respiratory protection needs of workers in different industries. Each of these federal organizations is dedicated to ensuring that workers who rely on respiratory protection have the necessary tools to stay protected. Understanding "who does what" can help a respiratory protection manager and respirator users understand where to find the information that they need.

A Little Bit of History (it *IS* both NIOSH's and OSHA's 50th anniversary year after all) …

The responsibility for ensuring proper respiratory protection availability and training for workers in all U.S. occupational settings has long been a joint venture within the federal government. Coordinated efforts date back to when the Bureau of Mines approved the first respirator in 1920 and the American National Standards organizations were developing national standards for how to use personal protective equipment, including respirators.

The Occupational Safety and Health Act of 1970 established both NIOSH, within the Department of Health and Human Services, and OSHA within the Department of Labor. NIOSH is responsible for the testing and approval of all respirators used in occupational settings. OSHA's mission is *to ensure safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education, and assistance*. Under its authority in the OSH Act, OSHA promulgated the Respiratory Protection Standard 29 CFR 1910.134, which requires workplaces using respirators to establish a respiratory protection program and use only NIOSH-approved respirators. This standard also establishes requirements for proper selection, use, and maintenance to ensure the effectiveness of the respirator, as well as medical evaluations, fit testing, and training to maximize protection for the user.

NIOSH's Role in Respiratory Protection

To be approved by NIOSH, respirators must meet the minimum performance requirements defined in Title 42, Part 84 of the Code of Federal Regulations (42 CFR 84). Currently there are about 10,700 approvals issued to 122 approval holders, sourced from 244 manufacturing sites located in 30 countries. This approval process uses Standard Test Procedures to

ensure that when employers purchase NIOSH-approved respirators, they can be sure of the level of protection that the device provides.

The NIOSH National Personal Protective Technology Laboratory is responsible for all activities associated with respirators – including research, standards development and user guidance, and the respirator approval program. The respirator approval program activities are comprehensive and, in addition to the testing of new respirators, include the evaluation of devices' engineering designs and manufacturing quality processes, as well as post-market evaluation after the approval is in place.

The post-market evaluation is in place to ensure that respirators available for purchase maintain the level of quality that NIOSH initially approved. This process includes ongoing surveillance activities of both manufacturing site quality assurance practices and of the approved manufactured respirators themselves.

OSHA's Role in Respiratory Protection

According to OSHA's Respiratory Protection Standard, when respirators are required in a workplace, they must be NIOSH approved and employers must have a respiratory protection program that includes staff medical evaluations, fit testing, and training for employees as well as a hazard evaluation for proper respirator selection. The program must cover each employee for their specific worksite and task where a respirator is required. In addition, certain program elements may be required for voluntary use to prevent potential hazards associated with use of the respirator. Employers are responsible for the establishment and maintenance of a respiratory protection program and for evaluating the effectiveness of the program in protecting their employees.

OSHA's Respiratory Protection standard requires that employers implement feasible engineering and administrative controls first to control worker exposure to airborne contaminants. When engineering and administrative controls are not feasible, adequate, or while they are being instituted, the employer must provide appropriate respiratory protection, if needed, to each employee exposed to airborne hazards.

OSHA has assigned protection factors (APF) for all classes of respirators. An APF is the workplace level of respiratory protection that a class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program. For example, N95 filtering facepiece respirators (FFRs) have an APF of 10. This means that a person's exposure to a hazard is reduced by a factor of 10 when wearing a properly fitted N95 FFR. Fit testing each individual wearer of a tight-fitting respirator is vital to assure that the OSHA APF can be achieved by the respirator.

FDA's Role in Respiratory Protection

Up until May 2018, all surgical N95 respirators and N95 FFRs used in healthcare needed approval from NIOSH and marketing clearance from the FDA. At that time, the FDA published a final order in the *Federal Register* to exempt surgical N95 respirators and N95 FFRs regulated under 21 CFR 878.4040 from premarket notification requirements subject to certain conditions and limitations. NIOSH and the FDA signed a Memorandum of Understanding (MOU) in 2017, effective in 2018, that provides a framework for efficient and coordinated regulatory oversight between the two agencies and outlines their mutually agreed upon review process.

This MOU helps to increase the efficiency of regulatory oversight by both agencies. Based on this MOU, most surgical N95 respirators and N95 FFRs are evaluated by NIOSH alone. In general, a surgical N95 respirator or N95 FFR needs to be further reviewed by the FDA if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or it contains coating technologies unrelated to filtration such as to reduce and or kill microorganisms.

As part of their guidance on healthcare facility respiratory protection programs, OSHA recommends that healthcare workers use surgical N95s respirators or NIOSH-approved FFRs with a face shield if respiratory and fluid protection are needed.

Thus, today for U.S. healthcare settings, respiratory protection responsibilities are shared among NIOSH, OSHA, and the FDA.

Working Together to Support Workers Through Trying Times

Collaboration is more important now than ever. If serious outbreak conditions cause a shortage of the NIOSH-approved FFRs, other reliable options must be found. That is why, early on during the COVID-19 pandemic, FDA authorized the use of non-NIOSH-approved respirators in healthcare. Similarly, OSHA exercised enforcement discretion for employers in other industries when they were unable to obtain NIOSH-approved respirators.

When possible, NIOSH recommends the use of reusable elastomeric half-mask respirators (EHMRs) and powered air-purifying respirators (PAPRs) as alternatives to FFRs. However, the demand for respiratory protection extended beyond what these two alternative respirator types could supplement earlier in the COVID-19 pandemic. The FDA issued emergency use authorizations (EUAs) to authorize the emergency use of certain non-NIOSH-approved respirators that, among other things, had at least a 95% particulate filtration efficiency level, due to earlier shortages of NIOSH-approved respirators. Of note, the FDA no longer authorizes use of non-NIOSH-approved or decontaminated disposable respirators.

To further reduce the burden on healthcare employers during a time of high demand, OSHA had provided temporary enforcement discretion policies for OSHA standards, such as the Respiratory Protection standard. These policies provided enforcement discretion for periodic respiratory protection equipment shortages and associated constraints (*i.e.*, fit-testing supplies and provision of related services) because of the COVID-19 pandemic. However, OSHA recently revoked its temporary enforcement discretion policies after reviewing CDC guidance, which indicates that the supply and availability of NIOSH-approved respirators have increased significantly, and after the FDA cited an increased availability of domestically-manufactured NIOSH-approved N95 respirators throughout the country as a reason to revoke its EUAs for imported, non-NIOSH-approved respirators, as well as for decontamination and bioburden reduction systems to disinfect disposable respirators.

NIOSH's role in these efforts was to contribute to the CDC guidance and offer assessments of respirators received from non-U.S. countries. Interested parties were able to send a small sample size of respirators received from other countries to be tested at the NIOSH National Personal Protective Technology Laboratory. NIOSH posted the results of these assessments to provide users with an assessment of some of the products available on the market.

Additionally, NIOSH research continues to inform and improve the use of EHMRs within U.S. healthcare and emergency response organizations. EHMRs are reusable respirators that can be cleaned and disinfected, unlike surgical N95 respirators, which are meant to be disposed of after every use. NIOSH research into these types of respirators includes: (1) how exhalation valves impact the level of source control; (2) how to most efficiently fit test and train healthcare workers to use EHMRs and (3) how to best disinfect these types of respirators.

NIOSH is hands-on when it comes to ensuring quality respiratory protection in the workplace and conducting the research necessary to inform the policies surrounding respiratory protection. But we can't do it alone. Together, NIOSH, the FDA, and OSHA are on a mission to keep the nation's workers safe across all industry sectors.

Maryann M. D'Alessandro, PhD, is the Director of the NIOSH National Personal Protective Technology Laboratory.

Suzanne B. Schwartz, MD, MBA, is the Director of the Office of Strategic Partnerships & Technology Innovation, within the Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST), U.S. Food and Drug Administration.

Andrew Levinson, MPH, is the Acting Director of the OSHA Directorate of Standards and Guidance.

Jaclyn Krah Cichowicz, MA, is a Health Communications Specialist for the NIOSH National Personal Protective Technology Laboratory.

This week is Respiratory Protection Week. For more information see the Respiratory Protection Week webpage.

Additional Resources

Further Reading on the History of Respiratory Protection:

History of U.S. Respirator Approval

100 Years of Respiratory Protection History

Milestones in Respiratory Protection (Infographic)

100 Years of Respiratory Protection (Video)

More about Respiratory Protection

Respirator Trusted Source (New and improved!)

Types of Respiratory Protection (Infographic)

Key Requirements of a Respiratory Protection Program (Infographic)

September 9, 2021 by Maryann M. D'Alessandro, PhD; Suzanne B. Schwartz, MD, MBA; Andrew Levinson, MPH; and Jaclyn Krah Cichowicz, MA
Respirators

2 comments on "Who Does What? The Roles of NIOSH, OSHA, and the FDA in Respiratory Protection in the Workplace"

Comments listed below are posted by individuals not associated with CDC, unless otherwise stated. These comments do not represent the official views of CDC, and CDC does not guarantee that any information posted by individuals on this site is correct, and disclaims any liability for any loss or damage resulting from reliance on any such information. Read more about our comment policy ».

Presentation today was excellent and closed the gap on understand each agency's role.
Reply

We appreciate your feedback and are delighted that you found the webinar valuable.

Post a Comment

Your email address will not be published.

Comment

All comments posted become a part of the public domain, and users are responsible for their comments. This is a moderated site and your comments will be reviewed before they are posted. Read more about our comment policy »

Name

Email

Post Comment

Page last reviewed: September 10, 2021
Page last updated: September 10, 2021
Content source: Centers for Disease Control and Prevention