

Small Business Respiratory Protection and Face Covering Guide

This online document was created by the National Occupational Research Agenda (NORA) Manufacturing Sector Council's COVID-19 workgroup. The NORA Manufacturing Sector Council brings together individuals from business, labor, academia and government to share information, form partnerships, and promote solutions that improve workplace safety. The COVID-19 workgroup is primarily led and operated by non-government members, in order to tailor practices to manufacturing-specific needs. Shortly after the pandemic began, the workgroup assembled to identify information that was not readily available and would be helpful to keep workers safe.

Small Business Respiratory Protection and Face Covering Guide

The COVID-19 pandemic has forced all businesses to examine and retool existing workplace safety plans, including the need for additional personal protective equipment (PPE) for employees to wear while at work. Many employers have purchased varying types of facial coverings for employees, including surgical-type disposable masks, cloth masks and respirators. It is important to understand the difference between National Institute for Occupational Safety and Health (NIOSH)-approved respirators (e.g. N95) and other face coverings since the use of NIOSH-approved respirators introduces additional requirements under the Occupational Safety and Health Administration (OSHA) regulations. Face coverings are primarily used for source control, that is to protect those around the wearer from the exhaled breath of the person wearing the face covering. Respirators such as N95s, on the other hand, protect the person wearing the respirator from inhaling exhaled particulate from others.

A NIOSH-approved respirator is a form of personal protective equipment and is intended to protect the wearer from exposures to harmful agents including SARS-CoV-2, the virus that causes COVID-19. It does so by preventing or limiting a person's ability to breathe in harmful substances by filtering a percentage of the particles. Different types of respirators are approved for different types of hazards. For example, air-purifying respirators may be approved for particulate, gas, and/or vapor hazards depending on the cartridge type that is included in the approved configuration.

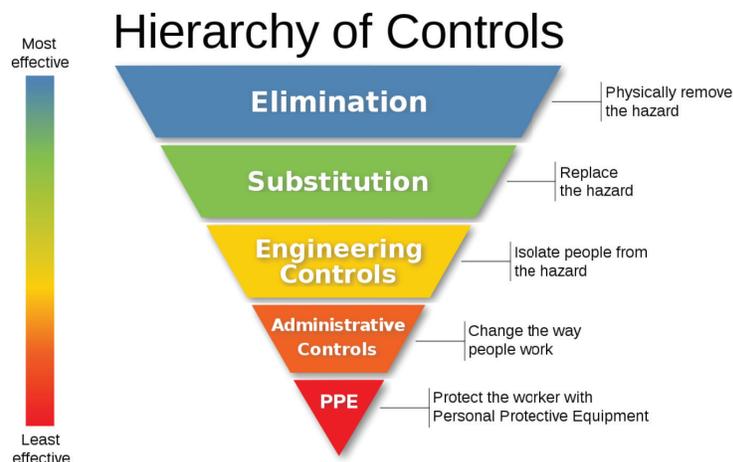
NIOSH approves air-purifying respirators with three different series of filters (N-not resistant to oil, R-somewhat resistant to oil, and P-strongly resistant to oil) and three filtration efficiency levels (95, 99, and 100).

The selection and use of a respirator requires an evaluation of the hazard against which the respirator has been selected to ensure it will provide the appropriate level of protection. See question #1 below for more information about NIOSH-approved respirators. Businesses that use respirators for occupational protection from environmental hazards such as dust, chemicals, and vapors must make sure that workers are medically approved to wear a respirator, fit-tested, and trained for its use.

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A mask or facial covering is a form of source control and is intended to protect others from the person wearing the face covering. The effectiveness varies by the style and material with which the face covering is made. Multiple layers and a tighter fit improve the effectiveness of a face covering by decreasing the ability to spread germs such as SARS-CoV-2 when a person coughs, sneezes or during normal breathing. Depending on the quality of the mask, its fit, and material selection, when everyone wears a mask or facial covering, the amount of SARS-CoV-2 virus in the air can drop significantly. ASTM International, a standards organization that develops and publishes voluntary consensus technical standards for a wide range of products, has developed a new standard specification for barrier face coverings that identifies recommended materials of construction and designs. However, not all face coverings meet these recommendations and lower quality masks may not be as effective in removing particulate. The lower viral load in the air achieved by everyone wearing a mask, in addition to reducing the exposure time and increasing physical distancing, will help to minimize the likelihood of infection.

According to the Centers for Disease Control and Prevention (CDC), controlling exposures to occupational hazards is the fundamental method of protecting workers. Traditionally, a hierarchy of controls has been used as a means of determining how to implement feasible and effective control solutions. Preference should be given to the controls higher on the hierarchy but, PPE such as respirators, may be one part of a layered safety plan as shown below. Having a program in place to try to ensure that sick people don't come to work is important and would be an example of eliminating the hazard. Engineering controls, such as barriers and improving ventilation strategies, and physical (social) distancing, an administrative control, are actions that should be implemented rather than relying on PPE alone.



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Businesses, especially small businesses should be aware that OSHA requires employers to have a written respiratory protection program if the environmental hazards in a workplace require employees to wear respirators and the employer directs the employees to wear respirators at work. The OSHA respirator regulation requires that a hazard assessment be performed to determine if controls are necessary and states that engineering controls must be implemented first if feasible. For all higher-risk workplaces where there are unvaccinated or otherwise at-risk workers, OSHA suggests implementing strategies (tailored to individual workplaces) to improve ventilation that protects workers as outlined in CDC's Ventilation in Buildings and in the OSHA Alert: COVID-19 Guidance on Ventilation in the Workplace. This guide provides an overview of respirators, OSHA's respiratory protection program requirements, and information that may be helpful in the development of a written program specifically focused on N95 and particulate respirators with higher levels of protection (i.e. filtration efficiencies). Note that other types of NIOSH-approved respirators are available to protect against other types of workplace hazards such as vapors or gases, but this guide does not cover these.

Questions and Answers

What is a respirator and are they different than surgical masks or face coverings?

A respirator is a device designed to protect the wearer from inhaling hazardous contaminants, including airborne microorganisms. The mandated use of respirators as required by OSHA and the result of a hazard evaluation requires the proper use of NIOSH-approved respirators. There are two main categories:

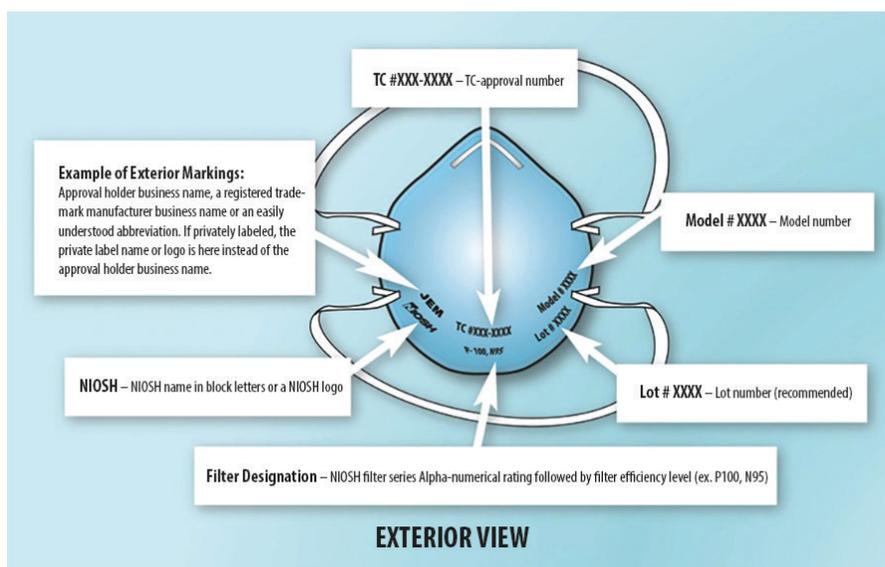
- Air-purifying respirators are the type primarily used for protection against the virus that causes COVID-19. This type of respirator filters contaminated air to make it safer. These are only appropriate when there is not an oxygen-deficiency in the air. N95 filtering facepiece respirators, in which the filtering media is the entire facepiece, are the most commonly used respiratory protection against the virus that causes COVID-19. The following table shows the types of NIOSH-certified respirators that provide protection against the virus. More information about approved particulate respirators is available from NIOSH.

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| NIOSH Rating | Description |
|--------------|---|
| N95 | Filters at least 95% of airborne particles; not resistant to oil |
| Surgical N95 | A NIOSH-approved N95 respirator that has also been cleared by the Food and Drug Administration (FDA) as a surgical mask |
| N99 | Filters at least 99% of airborne particles; not resistant to oil |
| N100 | Filters at least 99.97% of airborne particles; not resistant to oil |
| R95 | Filters at least 95% of airborne particles; somewhat resistant to oil |
| R99 | Filters at least 99% of airborne particles; somewhat resistant to oil |
| R100 | Filters at least 99.97% of airborne particles; somewhat resistant to oil |
| P95 | Filters at least 95% of airborne particles; strongly resistant to oil |
| P99 | Filters at least 99% of airborne particles; strongly resistant to oil |
| P100 | Filters at least 99.97% of airborne particles; strongly resistant to oil |

- Air-supplied respirators are respirators in which an alternate supply of breathable air is delivered via an air-line or breathing air cylinder. The source of the air may be compressed and filtered, bottled, or from a fresh outside source. The strategy used for the supplied air requires evaluation and depends on the hazard being protected against, the surrounding atmosphere, and the task to be performed.

In the U.S., respirators must be approved by NIOSH. Here is a NIOSH graphic of a generic filtering facepiece respirator with appropriate markings:



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During the pandemic, many counterfeit and misrepresented N95 respirators appeared on the market. Please visit this NIOSH website with information about counterfeit respirators and the misrepresentation of the NIOSH approval. Counterfeits/misrepresentations include units with a vague approval message meant to confuse purchasers, a clear fake approval but the respirator is not listed at all in the NIOSH Certified Equipment List or a complete copy of an approval from a legitimate company such as 3M.

What is a surgical mask?

A surgical mask is a loose-fitting disposable mask that is regulated by the Food and Drug Administration (FDA). Surgical masks are intended to reduce exposure of the wearer's saliva and respiratory secretions to others, as well as provide some blockage of large particle droplets and sprays. Because they are loose-fitting, they do not provide protection against smaller droplets or aerosols. Surgical masks are often called face masks but not all face masks meet the requirements to be labeled as a surgical mask.

The following graphic from NIOSH shows the differences between a surgical mask and an N95 respirator. Note that there are also NIOSH-approved surgical N95 respirators.

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Understanding the Difference

| |  |  |  |
|---------------------------------|---|---|---|
| | Surgical Mask | N95 Respirator | Elastomeric Half Facepiece Respirator |
| Testing and Approval | Cleared by the U.S. Food and Drug Administration (FDA) | Evaluated, tested, and approved by NIOSH as per the requirements in <i>42 CFR Part 84*</i> | Evaluated, tested, and approved by NIOSH as per the requirements in <i>42 CFR Part 84</i> |
| Intended Use and Purpose | Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions. | Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols) | Reusable device made of synthetic or rubber material |
| Face Seal Fit | Loose-fitting | Tight-fitting | Tight-fitting |
| Fit Testing Requirement | No | Yes | Yes |
| Designed for Reuse | No | No | Yes |
| User Seal Check | No | Yes. Required each time the respirator is donned (put on) | Yes. Required each time the respirator is donned (put on) |
| Filtration | Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection | Filters out at least 95% of airborne particles including large and small particles | May be equipped with filters that block 95%, 99%, or 100% of very small particulates. Also may be equipped to protect against vapors/gases. |
| Leakage | Leakage occurs around the edge of the mask when user inhales | When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales | When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales |
| Use Limitations | Disposable. Discard after each patient encounter. | Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids. | Reusable and must be cleaned/disinfected and stored between each patient interaction |

*As of July 2, 2018, NIOSH evaluates N95 FFRs intended for use in healthcare for biocompatibility, flammability, and fluid resistance to ensure conformity to relevant standards during the approval process. These tasks were previously performed by the FDA.

Resources:
Hospital Respiratory Protection Program Toolkit, <https://www.cdc.gov/niosh/docs/2015-117/pdfs/2015-117.pdf>
Implementing Hospital Respiratory Protection Programs: Strategies from the Field, https://www.jointcommission.org/assets/1/18/Implementing_Hospital_RPP_2-19-15.pdf



Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

This information provides clarification regarding respirator and mask use in workplaces in which employees are exposed to respiratory hazards, it is not specific for the COVID-19 pandemic.

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What is a face covering?

A face covering is a simple barrier, not certified by NIOSH or regulated by FDA, that covers the nose and mouth and protects others nearby from being exposed to the wearer's respiratory droplets. To be effective, it needs to cover both the nose and mouth. It may be a disposable paper mask or a cloth covering but, per the CDC, should be two or more layers thick. The tighter fitting the face covering, the greater its effectiveness due to less leakage between the face and the face covering. Stretching a cheap covering, especially a single layer one, may lessen its effectiveness. ASTM International, a standards organization that develops and publishes voluntary consensus technical standards for a wide range of products, has developed with input from NIOSH, a new standard specification for barrier face coverings that identifies recommended baseline requirements including filtration efficiency and air flow. More information from NIOSH on this topic is available at <https://blogs.cdc.gov/niosh-science-blog/2021/04/23/bfc-standard/>.

What is a respiratory protection program?

A respiratory protection program covers all the elements required by OSHA to ensure that respirators worn in the workplace are effective at protecting worker health. Requirements of a respiratory protection program include medical approval to ensure that a wearer is physically able to wear a respirator, fit-testing for respirators with a tight face-to-facepiece seal, and training in proper use, maintenance and storage and the limitations of the respirator. A template for preparing a respiratory protection program is available from OSHA.

A hazard assessment must be performed to ensure that the proper respiratory protection is selected.

A medical evaluation determines the ability for a worker to use a respirator and must include evaluation and approval from a healthcare professional. This may be done in-person or using various on-line computer programs. Some on-line options are provided in the Links/References section at the end of this document.

A fit test is a qualitative or quantitative evaluation of the air seal between the respirator and an individual's face. Note that anyone who wears a tight-fitting respirator, including a filtering facepiece respirator, must be clean shaven in the sealing area between the face and the respirator.

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Training for the use of a respirator includes information provided to the employee on why the respirator is necessary, limitations and capabilities of the respirator, how to inspect, put on and remove, use, and check the seals and other topics. You can find more information on general OSHA respirator requirements [here](#).

Which businesses must have a respiratory protection program?

Any business which requires its employees to use respirators must have a written respiratory protection program. This includes respirators that are worn to protect workers against the virus that causes COVID-19, even if that is the only hazard for which respirators are required in the workplace. A hazard assessment must be performed to determine if respiratory protection is necessary.

Information about OSHA requirements is available in the publication, *All About OSHA*. Only the following businesses are not covered under the OSH Act:

- The self-employed;
- Immediate family members of farm employers; and
- Workplace hazards regulated by another federal agency (for example, the Mine Safety and Health Administration, the Department of Energy, or the Coast Guard).

How should a business develop a respiratory protection program and what needs to be included?

OSHA has numerous resources to help businesses develop a respiratory protection plan. The *Small Entity Compliance Guide for the Respiratory Protection Standard* is especially targeted to help small businesses understand the requirements of the OSHA respirator standard.

A written respiratory protection plan should include the following information, based on each unique workplace:

- Procedure to identify and evaluate the hazard through the safety data sheet (SDS), manufacturer data, and government and industry resources such as the American Conference of Governmental Industrial Hygienists (ACGIH®) and others
- Procedure to consider replacement products (i.e. substitute a less hazardous material) if possible, effective, or reasonable to remove the hazard

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- Procedure for selecting respirators for use in the workplace
- Medical evaluation of employees required to wear respirators
- Fit testing procedures for tight fitting respirators
- Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations
- Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, and discarding and otherwise maintaining respirators
- Procedure to ensure adequate quality, quantity, and flow of clean and safe air for atmosphere-supplying air respirators
- Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use and their maintenance
- Procedures for regularly evaluating the effectiveness of the program
- Procedures for ensuring that workers who voluntarily wear respirators (excluding filtering facepieces) comply with the medical evaluation, and cleaning, storing, and maintenance requirements of the standard

Note that the respirators should only be used to protect against the hazard for which they have been selected by workers who have been medically approved, trained and fit-tested.

Here are some additional guides provided by respirator manufacturers:

- [3M](#)
- [Honeywell](#)
- [MSA](#)

If workers voluntarily provide their own respirators and wear them at work to protect against the virus that causes COVID-19, does a business need to have a respiratory protection program?

If a worker voluntarily wears a respirator when the hazard evaluation says it isn't required, the company does not need to have a respiratory protection plan. If workers are required to wear the respirator or if a business supplies the respirator, then there needs to be a respiratory protection plan. However, if there is only voluntary use of respirators and the company supplies only filtering facepiece respirators, then a full respiratory protection program is not required. In this case, workers must be given a copy of Appendix D to the OSHA respirator standard.

We had a respiratory protection program for some workers before the pandemic. Do workers wearing face coverings trigger new OSHA requirements?

No, having additional workers that wear face coverings does not trigger new requirements because face coverings are intended to protect people around the wearer, not the wearers themselves, and are not considered PPE by OSHA.

Do fully vaccinated workers need to wear face coverings?

During the COVID-19 pandemic, employers should implement infection control policies and practices to protect both fully vaccinated and unvaccinated workers who are in contact with each other and/or the public. Employers and workers may consult several workplace resources as case, hospitalization, and death rates drop and vaccination rates increase. Businesses should stay up to date on workplace guidance from CDC, OSHA and state and local health officials. [CDC guidance for fully vaccinated people is available here](#). OSHA updated its guidance, [Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace](#), on June 10. These links should be checked to determine if there is any newer guidance.

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Links/References

3M

ASTM F3502 – 21, Standard Specification for Barrier Face Coverings

CDC Ventilation in Buildings

CDC When You've Been Fully Vaccinated

CDC Your Guide to Masks

CDC/NIOSH Counterfeit Respirators

CDC/NIOSH Hierarchy of Controls

CDC/NIOSH Respirator Protection Program FAQs

CDC/NIOSH Understanding the Differences

Honeywell

MSA

NIH Respiratory Protection Program

NIOSH Approved Particulate Respirators

NIOSH Blog Article on ASTM F3502-21

NIOSH Certified Equipment List

NIOSH Guide to the Selection & Use of Particulate Respirators | NIOSH | CDC

NIOSH Personal Protective Equipment Information (PPE-Info)

On-line Medical Certification program (Examintetics)

On-line Medical Certification program (Salud Systems)

On-line Medical Certification program (3M)

OSHA 29 CFR 1910.134 - Respiratory Protection

OSHA 29 CFR 1910.134 Appendix D

OSHA All About OSHA

OSHA Major Requirements of OSHA's Respiratory Protection Standard

OSHA Small Entity Compliance Guide for the Respiratory Protection Standard

OSHA Respirator Medical Evaluation InfoSheet

OSHA Respirator Program Template

OSHA Respiratory Protection Program

Protecting Workers: Guidance on Mitigating and Preventing the Spread of

COVID-19 in the Workplace (osha.gov)

Respiratory Protection Program (nih.gov)

Ventilation Strategies to Reduce the Risk of COVID-19 in Manufacturing