To health!
NJHA
New Jersey Hospital Association

N95 Respirator Resource Guide

FDA, OSHA, NIOSH, CDC Guidance

Version 2 | April 28, 2020

This guide contains resources for healthcare providers as they continue to respond to COVID-19 .

For additional non-clinical resources, visit the New Jersey Hospital Association's COVID-19 website
http://www.njha.com/coronavirus

This document is intended to summarize the important updates, requirements, and guidelines around use of N95 respirators as of April 28, 2020. This includes:

- FDA: EMERGENCY USE AUTHORIZATIONS
- OSHA REGULATIONS AND GUIDANCE
- NIOSH MASK SELECTION RESOURCES
- CDC GUIDANCE
- OTHER RESOURCES

FDA: Emergency Use Authorizations

On the following dates, the FDA issued Emergency Use Authorizations (EUA) for the following PPE topics:

March 28, 2020:
Imported, non-NIOSH-approved Disposable Filtering Facepiece Respirators

March 28, 2020:
NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency

March 29, 2020:
Battelle Decontamination System

April 3, 2020:
Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China

April 9, 2020:
STERIS Sterilization Systems for Decontamination of N95 Respirators

April 9, 2020:
Face Shields

April 11, 2020:
Advanced Sterilization Products (ASP) STERRAD Sterilization System

April 15, 2020:
Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle

April 20, 2020:
Sterilucent, Inc. Sterilization System

CLICK HERE TO VIEW ALL FDA EUAS FOR PPE DURING THE COVID-19 PANDEMIC:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe

OSHA Regulations and Guidance

OSHA 29 CFR § 1910.134 Requirement for Personal Protective Equipment: Respiratory Protection

These are the general requirements in a non-crisis time for healthcare organizations to follow to ensure respiratory protection for healthcare providers.

Link to full guidance:
https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134

OSHA Temporary Enforcement Guidance Issued on March 14, 2020

SUBJECT

Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak

KEY ISSUE ADDRESSED:

- "Inform workers that the employer is temporarily suspending the annual fit testing of N95 filtering facepiece respirators to preserve and prioritize the supply of respirators for use in situations where they are required to be worn."- See guidance link for full details.

Link to full guidance:
https://www.osha.gov/memos/2020-03-14/temporary-enforcement-guidance-healthcare-respiratory-protection-annual-fit

OSHA Temporary Enforcement Guidance Issued April 3, 2020

SUBJECT

Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic.

KEY ISSUE ADDRESSED

- **Extended use or reuse of N95s:** "In the event extended use or reuse of N95 FFRs becomes necessary, the same worker is permitted to extend use of or reuse the respirator."- See guidance link for full details.
- **Use of expired N95s:** "In the event that N95s are not available and the employer has shown a good faith effort to acquire the respirators or to use alternative options, as outlined below, CSHOs should exercise enforcement discretion for the use of N95 FFRs beyond the manufacturer's recommended shelf life, including surgical N95s."- See guidance link for full details.
    - **For HCP:** "Expired N95s generally must not be used when HCP perform surgical procedures on patients infected with, or potentially infected with, SARS-CoV-2, or perform or are present for procedures expected to generate aerosols or procedures where respiratory secretions are likely to be poorly controlled." – See guidance link for full details.

Link to full guidance:
https://www.osha.gov/memos/2020-04-03/enforcement-guidance-respiratory-protection-and-n95-shortage-due-coronavirus

OSHA Temporary Enforcement Guidance Issued April 3, 2020

SUBJECT

Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic

KEY ISSUE ADDRESSED

- **Non-US-manufactured/certified N95s:** "Employers may consider using respirators and filters certified under standards of other countries or jurisdictions." – *See guidance link for full details.*
  - **For HCP:** When HCP perform surgical procedures on patients infected with, or potentially infected with, SARS-CoV-2 or perform or are present for procedures expected to generate aerosols or procedures where respiratory secretions are likely to be poorly controlled (e.g., cardiopulmonary resuscitation, intubation, extubation, bronchoscopy, nebulizer therapy, sputum induction);
    - Respiratory protection equipment certified exclusively in accordance with standards of the People's Republic of China and manufactured by companies that are not NIOSH-approval holders must not be used unless the only feasible alternative is a facemask or improvised nose/mouth cover;
  - In accordance with CDC guidance for optimizing the supply of respirators, employers should prioritize the use of N95 respirators by activity type. When HCP perform or are present for aerosol-generating procedures or procedures where respiratory secretions are likely to be poorly controlled, use respirators (including N95 FFRs; other FFRs; non-disposable, elastomeric respirators; and powered, air-purifying respirators (PAPRs)) that are still within their manufacturer's recommended shelf life, if available, before using respirators that are beyond their manufacturer's recommended shelf life. – *See guidance link for full details.*

Link to full guidance:
https://www.osha.gov/memos/2020-04-03/enforcement-guidance-use-respiratory-protection-equipment-certified-under

OSHA Temporary Enforcement Guidance Issued April 8, 2020

SUBJECT

Expanded Temporary Enforcement Guidance on Respiratory Protection Fit-Testing for N95 Filtering Facepieces in All Industries During the Coronavirus Disease 2019 (COVID-19) Pandemic

KEY ISSUES ADDRESSED

- Memorandum to Compliance Safety and Health Officers for enforcing annual fit-testing requirements of the Respiratory Protection standard, 29 CFR § 1910.134(f)(2), with regard to supply shortages of N95s or other filtering facepiece respirators (FFRs) due to the coronavirus disease 2019 (COVID-19) pandemic. Earlier guidance released March 14 for healthcare providers now applies to all workplaces covered by OSHA where there is required use of respirators. This memorandum will take effect immediately and remain in effect until further notice. This guidance is intended to be time-limited to the current public health crisis.
- Further, given additional concerns regarding a shortage of fit-testing kits and test solutions (e.g., Bitrex™, isoamyl acetate), employers are further encouraged to take necessary steps to prioritize use of fit-testing equipment to protect employees who must use respirators for high-hazard procedures.

Link to full guidance:
https://www.osha.gov/memos/2020-04-08/expanded-temporary-enforcement-guidance-respiratory-protection-fit-testing-n95

OSHA Temporary Enforcement Guidance Issued April 24, 2020

SUBJECT

Enforcement Guidance on Decontamination of Filtering Facepiece Respirators in Healthcare During the Coronavirus Disease 2019 (COVID-19) Pandemic

KEY ISSUE ADDRESSED

- This memorandum provides interim guidance to Compliance Safety and Health Officers (CSHOs) for enforcing the Respiratory Protection standard, 29 CFR § 1910.134, with regard to the reuse of filtering facepiece respirators (FFRs) that have been decontaminated through certain methods.
- All employers whose employees are required to use or are permitted voluntary use of respiratory protection must continue to manage their respiratory protection programs (RPPs) in accordance with the OSHA respirator standard, and should pay close attention to shortages of FFRs during the COVID-19 pandemic.
- Due to the impact on workplace conditions caused by limited supplies of FFRs, employers should reassess their engineering controls, work practices and administrative controls to identify any changes they can make to decrease the need for respirators.
- If respiratory protection must be used, and acceptable alternatives are not available for use in accordance with OSHA's previous COVID-19 enforcement memoranda, NIOSH has identified limited available research that suggests the following methods offer the most promise for decontaminating FFRs:
    - Vaporous hydrogen peroxide;[9]
    - Ultraviolet germicidal irradiation; and/or
    - Moist heat (e.g., using water heated in an oven).

If such methods are not available, the above-referenced NIOSH-evaluated research showed the following methods could also be suitable decontamination options:

- Microwave-generated steam; and/or
- Liquid hydrogen peroxide

Based on the above-referenced NIOSH-evaluated research, **employers should not use the following methods** unless objective data that sufficiently demonstrate the safety and effectiveness of such methods become available:

- Autoclaving
- Dry heat
- Isopropyl alcohol
- Soap
- Dry microwave irradiation
- Chlorine bleach; and/or Disinfectant wipes, regardless of impregnation (i.e., chemical saturation), and/or
- Ethylene oxide (EtO)

All employers should:

- Make a good-faith effort to provide and ensure workers use the most appropriate respiratory protection available for the hazards against which workers need to be protected. Efforts should be consistent with flexibilities outlined in OSHA's previous COVID-19 enforcement memoranda.
- When respirators must be decontaminated to facilitate their reuse in ways consistent with OSHA's previous COVID-19 enforcement memoranda and the U.S. Centers for Disease Control and Prevention (CDC) Strategies for Optimizing the Supply of N95 Respirators, ensure that decontamination is accomplished according to the methods described above and detailed in CDC's Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies.

- Ensure users perform a user seal check each time they don a respirator. Employers should not permit use of a respirator on which the user cannot perform a successful user seal check. See 29 CFR § 1910.134, Appendix B-1, User Seal Check Procedures.
- Train employees to follow appropriate precautionary measures prior to using a decontaminated filtering facepiece respirator (FFR). See www.cdc.gov/coronavirus/2019- ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html.
- Train employees using decontaminated respirators to understand that if the structural and functional integrity of any part of the respirator is compromised, it should not be used by that individual as respiratory protection. The inability to achieve a successful user seal check could be an indicator that the integrity of the respirator is compromised.
- Visually inspect, or ensure that workers visually inspect, the FFRs to determine if the structural and functional integrity of the respirator has been compromised. Over time or as a result of the decontamination process, components such as the straps, nose bridge, and nose foam material may degrade, which can affect the quality of the fit and seal.
- Train employees on the procedures for the sequence of donning/doffing to prevent selfcontamination. See www.cdc.gov/niosh/npptl/pdfs/PPE-Sequence-508.pdf.
- If no manufacturer or third-party guidance or procedures are available to support the specific decontamination method(s) employed, avoid the use of decontaminated FFRs when healthcare personnel perform surgical procedures on patients infected with, or potentially infected with, SARS-CoV-2 or perform or are present for procedures expected to generate aerosols or procedures where respiratory secretions are likely to be poorly controlled (e.g., cardiopulmonary resuscitation, intubation, extubation, bronchoscopy, nebulizer therapy, sputum induction). If decontamination methods degrade FFR performance, including filtration and fit, or otherwise affect structural integrity, the decontaminated FFR may not provide the level of protection needed or expected during aerosol-generating procedures.

Link to full guidance:
https://www.osha.gov/memos/2020-04-24/enforcement-guidancedecontamination-filtering-facepiece-respirators-healthcare

NIOSH Mask Selection Resources

NIOSH-Approved N95 Particulate Filtering Facepiece Respirators

https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html

NIOSH Counterfeit Respirators / Misrepresentation of NIOSH Approval

https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

Personal Protective Equipment FAQs including questions about N95 masks

Key FAQ: How can I tell if a respirator is NIOSH approved?

The NIOSH approval number and approval label are key to identifying NIOSH-approved respirators. The NIOSH approval label can be found on or within the packaging of the respirator or sometimes on the respirator itself. The required labeling of NIOSH-Approved N95 filtering facepiece respirators pdf icon includes the NIOSH name, the approval number, filter designations, lot number, and model number to be printed on the respirator. You can verify that your respirator approvals are valid by checking the NIOSH Certified Equipment List (CEL).

Key FAQ: How do I know if a respirator is falsely advertising NIOSH approval?

When NIOSH becomes aware of counterfeit respirators or those misrepresenting NIOSH approval on the market, these respirators are posted on the Counterfeit Respirators / Misrepresentation of NIOSH-Approval webpage to alert users, purchasers, and manufacture.

Link for full FAQ:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

CDC guidance

CDC Guidance:
Summary List for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response

Link to full guidance:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html

CDC Guidance:
Considerations for Release of Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response
(Updated April 16, 2020)

Link to full guidance:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/release-stockpiled-N95.html

CDC Guidance:
Decontamination and Reuse of Filtering Facepiece Respirators
(updated April 1, 2020)

Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. This document summarizes research about decontamination of FFRs before reuse.

KEY ISSUE ADDRESSED:

The healthcare worker will wear one respirator each day and store it in a breathable paper bag at the end of each shift. The order of FFR use should be repeated with a **minimum of five days** between each FFR use. This will result in each worker requiring a minimum of five FFRs, providing that they put on, take off, care for them, and store them properly each day. Healthcare workers should treat the FFRs as though they are still contaminated and follow the precautions outlined in our reuse recommendations. **If supplies are even more constrained and five respirators are not available for each worker who needs them, FFR decontamination may be necessary**.

At present, FFRs are considered one time use and there are no manufacturer-authorized methods for FFR decontamination prior to reuse. On March 28, 2020, FDA issued an Emergency Use Authorization (EUA) permitting the **Battelle Decontamination System at Battelle Memorial Institute to be authorized for use in decontaminating "compatible N95 respirators**.

Decontamination might cause poorer fit, filtration efficiency, and breathability of disposable FFRs as a result of changes to the filtering material, straps, nose bridge material, or strap attachments of the FFR. **CDC and NIOSH do not recommend that FFRs be decontaminated and then reused as standard care.** This practice would be inconsistent with their approved use, but we understand in times of crisis, this option may need to be considered when FFR shortages exist.

Link to full guidance:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

CDC Guidance: Elastomeric Respirators: Strategies During Conventional and Surge Demand Situations

KEY ISSUE ADDRESSED:

- Elastomeric respirators, such as half facepiece or full facepiece tight-fitting respirators where the facepieces are made of synthetic or natural rubber material, can be repeatedly used, cleaned, disinfected, stored, and re-used. They are available as alternatives to disposable half mask filtering facepiece respirators (FFRs), such as N95 FFRs, for augmenting the total supply of respirators available for use by HCP. While elastomeric respirators are not cleared by FDA for fluid resistance, based on their NIOSH approval, they can provide at least equivalent protection to N95 FFRs.
- Some types of elastomeric respirators can offer higher assigned protection factors (APFs) than N95 FFRs. They are equipped with replaceable filter cartridges or flexible, disc or pancake-style filters, which are not housed in a cartridge body. All elastomeric respirators equipped with the proper air-purification filters, cartridges, or canisters would also have utility in this application. Elastomerics may also have sealing surfaces and adjustable straps that accommodate a better fit.
- This guidance describes options for deploying air-purifying reusable elastomeric particulate respirators to provide respiratory protection to healthcare practitioners (HCP) when supplies of N95 filtering facepiece respirators (FFRs), including surgical N95s, are limited or not available.

Link to full guidance:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomericrespirators-strategy/index.html

CDC Guidance: Considerations for Optimizing the Supply of Powered Air-Purifying Respirators (PAPRs)

KEY ISSUE ADDRESSED:

- NIOSH-approved respirators are available in many types, models, and sizes from many manufacturers for a wide variety of uses in many occupational settings. The most common types of respirators in healthcare are N95 filtering facepiece respirators (FFRs), surgical N95 FFRs, and PAPRs. Of these three options, many healthcare practitioners are the least familiar with PAPRs.
- A PAPR is an air-purifying respirator that uses a blower to force air through filter cartridges or canisters and into the breathing zone of the wearer. This process creates an air flow inside either a tight-fitting facepiece or loose-fitting hood or helmet, providing a higher assigned protection factor (APF) than the reusable elastomeric non-powered air-purifying half facepiece (half mask) or N95 FFRs. A PAPR can be used for protection during healthcare procedures in which HCP are exposed to greater risks of aerosolized pathogens causing acute respiratory infections.
- CDC has published recommendations for HCP respiratory protection and of commonly used NIOSH-approved, FDA-cleared, single-use filtering facepiece N95 surgical respirators. Properly fitted FFR and half facepiece reusable elastomeric respirators are expected to reduce exposures to one-tenth of the concentration that is in the air, based on OSHA's APF of 10 for these respirator types. All PAPR APFs exceed the APF of 10 for N95 FFR or elastomeric half facepiece respirators
- This guidance describes considerations for the use of powered air-purifying respirators (PAPRs) to provide respiratory protection to healthcare practitioners (HCP) as a component of a formally developed and implemented written respiratory protection program. It addresses conventional, contingency, and crisis surge PAPR use and maintenance practices.

Link to full guidance:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/poweredair-purifying-respirators-strategy.html

Other Resources

ECRI Clinical Evidence Assessment: Safety of Extended Use and Reuse of N95 Respirators

https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-ECRI-N95-Respirators-updated.pdf

Qualitative Fit Testing Information

https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html

FDA FAQ on Shortages of Surgical Masks and Gowns

https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns