



# N95 Respirator Resource Guide

FDA, OSHA, NIOSH, CDC Guidance

Version 1 (April 6, 2020)

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

**For additional 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 5, 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**



**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**

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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**

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### **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**

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### **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>

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## OSHA Temporary Enforcement Guidance Issued April 3, 2020

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### 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>

# NIOSH Mask Selection Resources

## NIOSH-Approved N95 Particulate Filtering Facepiece Respirators

[https://www.cdc.gov/niosh/npptl/topics/respirators/disp\\_part/default.html](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**

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Link to full guidance:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>

## **CDC Guidance: Release of Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response**

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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)**

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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>

# 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](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>