

Enforcement Memos

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

April 3, 2020

MEMORANDUM FOR:

REGIONAL ADMINISTRATORS
STATE PLAN DESIGNEES

THROUGH:

AMANDA EDENS
Deputy Assistant Secretary

FROM:

PATRICK J. KAPUST, Acting Director
Directorate of Enforcement Programs

SUBJECT:

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

This memorandum provides interim guidance to Compliance Safety and Health Officers (CSHOs) for enforcing the Respiratory Protection standard, 29 CFR § 1910.134, and certain other health standards, with regard to supply shortages of disposable N95 filtering facepiece respirators. Specifically, it outlines enforcement discretion to permit the extended use and reuse of respirators, as well as the use of respirators that are beyond their manufacturer's recommended shelf life (sometimes referred to as "expired"). This guidance applies in all industries, including workplaces in which:

- Healthcare personnel (HCP) are exposed to patients with suspected or confirmed coronavirus disease 2019 (COVID-19) and other sources of SARS-CoV-2 (the virus that causes COVID-19).
- Protection of workers exposed to other respiratory hazards is impacted by the shortage resulting from the response to the COVID-19 pandemic. Such workplace respiratory hazards may be covered by one or more substance-specific health standards.

Our previous memorandum, *Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak*, issued on March 14, 2020, provided temporary guidance for 29 CFR § 1910.134, regarding required annual fit testing of HCP. [1] This memorandum provides additional guidance on enforcing OSHA's respirator standard for all workers, including HCP. In light of the essential need for adequate supplies 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. Please frequently check OSHA's webpage at www.osha.gov/coronavirus for updates.

Background

The COVID-19 outbreak, which the World Health Organization recently declared a global pandemic, has created an increased demand for N95 filtering facepiece respirators, limiting availability for use in protecting workers in healthcare and emergency response from exposure to the virus. As a result, the President directed the Secretary of Labor to “take all appropriate and necessary steps to increase the availability of respirators.”[2]

The Food and Drug Administration (FDA) also issued an Emergency Use Authorization (EUA) letter permitting National Institute for Occupational Safety and Health (NIOSH)-approved, disposable filtering facepiece respirators, including those that were NIOSH-approved but have since passed the manufacturer’s recommended shelf life, to be used in healthcare settings to mitigate further transmission of SARS-CoV-2.[3]

During N95 filtering facepiece respirator (FFR) shortages, the federal government advises that specific N95 FFRs that are beyond their manufacturer’s recommended shelf life will provide greater protection than surgical masks (i.e., facemasks, other than surgical N95s; see below) or non-NIOSH-approved masks (e.g., homemade masks or improvised mouth and nose covers, such as bandanas). NIOSH has tested a sample of N95 FFRs that are beyond their manufacturer’s recommended shelf life from facilities across the United States and determined that certain N95 models continue to protect against the hazards for which they would ordinarily be appropriate (for N95 FFRs, this means they are still expected to filter out 95% of particles of the most penetrating particle size, or 0.3 µm). However, the Centers for Disease Control and Prevention (CDC) and NIOSH have recommended that expired N95 FFRs be used only as outlined in their *Strategies for Optimizing the Supply of N95 Respirators*. [4] For more information, see www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html.

Enforcement Guidance

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 N95s during the COVID-19 pandemic. [5] Paragraph (d)(1)(iii) in section 1910.134 requires such employers to identify and evaluate respiratory hazards in the workplace, and paragraph (c)(1) requires employers to develop and implement written RPPs with worksite-specific procedures and to update their written programs as necessary to reflect changes in workplace conditions that affect respirator use. CSHOs should generally refer to CPL 02-00-158, *Inspection Procedures for the Respiratory Protection Standard*, 6/26/2014, for further guidance. [6]

Due to the impact on workplace conditions caused by limited supplies of N95 FFRs, all employers should reassess their engineering controls, work practices, and administrative controls to identify any changes they can make to decrease the need for N95 respirators. Employers should, for example, consider whether it is possible to increase the use of wet methods or portable local exhaust systems or to move operations outdoors. In some instances, an employer may also consider taking steps to temporarily suspend certain non-essential operations.

If respiratory protection must be used, employers may consider use of alternative classes of respirators that provide equal or greater protection compared to an N95 FFR, such as NIOSH-approved, non-disposable, elastomeric respirators or powered, air-purifying respirators (PAPRs). Other filtering facepiece respirators, such as N99, N100, R95, R99, R100, P95, P99, and P100, are also permissible alternatives for those who are unable to obtain N95 FFRs. However, per 29 CFR § 1910.134(d)(1)(ii), when considering N95 alternatives, check to ensure that they are NIOSH-approved, at www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html. When these alternatives are not

available, or where their use creates additional safety or health hazards, employers may consider the extended use or reuse of N95 FFRs or use of N95 FFRs that were NIOSH-approved but have since passed the manufacturer's recommended shelf life.

The following specific enforcement guidance is provided for CSHOs inspecting workplaces where workers are using N95 FFRs.

All employers:

▪ **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, as long as the respirator maintains its structural and functional integrity and the filter material is not physically damaged, soiled, or contaminated (e.g., with blood, oil, paint).[7] Employers must address in their written RPPs the circumstances under which a disposable respirator will be considered contaminated and not available for extended use or reuse. Extended use is preferred over reuse due to contact transmission risk associated with donning/doffing during reuse. When respirators are being re-used, employers should pay particular attention to workers' proper storage of the FFRs in between periods of reuse.

- Users should perform a user seal check each time they don a respirator and should not use a respirator on which they cannot perform a successful user seal check. See 29 CFR § 1910.134, Appendix B-1, *User Seal Check Procedures*. [8]
- Employers should train workers to understand that if the structural and functional integrity of any part of the respirator is compromised, it should be discarded, and that if a successful user seal check cannot be performed, another respirator should be tried to achieve a successful user seal check.
- If reuse of respirators is necessary, an appropriate sequence for donning/doffing procedures should be used to prevent contamination, and training needs to address appropriate donning/doffing procedures. See www.cdc.gov/niosh/npptl/pdfs/PPE-Sequence-508.pdf.

▪ **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.[9]

- Employers may use only previously NIOSH-certified expired N95 FFRs found at www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html. Workers should be notified that they are using expired N95s.
- Purchasers and users of personal protective equipment should not co-mingle products that are past their manufacturer's recommended shelf life (i.e., expired) with items that are within their shelf life.
- Employers should visually inspect, or ensure that workers visually inspect, the N95 FFRs to determine if the structural and functional integrity of the respirator has been compromised. Over time, components such as the straps, nose bridge, and nose foam material may degrade, which can affect the quality of the fit and seal.
- Where an employer has expired N95s available from their own stored cache (i.e., not from the U.S. Strategic National Stockpile), the employer should seek assistance from the respirator manufacturer or independent lab regarding testing of those stored respirators prior to use.

Healthcare employers only:

- 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 (e.g., cardiopulmonary resuscitation, intubation, extubation, bronchoscopy, nebulizer therapy, sputum induction).
 - 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 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 www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/contingency-capacity-strategies.html. The CDC guidance also addresses scenarios in which other crisis standards of care may need to be considered, but this enforcement guidance is not intended to cover those scenarios.

As mentioned above, the FDA has concluded that respirators approved by NIOSH, but not currently meeting the FDA's requirements, may be protective against SARS-CoV-2. The FDA is providing a list of authorized emergency-use respirators for HCP. Healthcare employers may view the list of approved respirators, and respirator manufacturers and stockpile managers may find information about how to obtain approval for expired respirators, at: www.fda.gov/media/135763/download and www.fda.gov/media/135921/download.

Citation guidance:

OSHA will, on a case-by-case basis, exercise enforcement discretion when considering issuing citations under 29 CFR § 1910.134(d) and/or the equivalent respiratory protection provisions of other health standards in cases where:

- The employer has made a good faith effort to obtain other alternative filtering facepiece respirators, reusable elastomeric respirators, or PAPRs appropriate to protect workers;
- The employer has monitored their supply of N95s and prioritized their use according to CDC guidance (www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html; www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html);
- Surgical masks and eye protection (e.g., face shields, goggles) were provided as an interim measure to protect against splashes and large droplets (note: surgical masks are **not** respirators and do not provide protection against aerosol-generating procedures); and
- Other feasible measures, such as using partitions, restricting access, cohorting patients (healthcare), or using other engineering controls, work practices, or administrative controls that reduce the need for respiratory protection, were implemented to protect employees.

Where the above efforts are absent and respiratory protection use is required, or voluntary use is permitted, and an employer fails to comply with fit testing, maintenance, care, and training requirements, cite the applicable provision(s) of 29 CFR § 1910.134 and/or other applicable expanded health standards as serious violations. If you have any questions regarding this policy, please contact the Directorate of Enforcement Programs at (202) 693-2190.

cc: DCSP
DTSEM
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[1] OSHA Memorandum on *Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak*, March 14, 2020, at www.osha.gov/memos/2020-03-14/temporary-enforcement-guidance-healthcare-respiratory-protection-annual-fit. Back to Text

[2] www.whitehouse.gov/presidential-actions/memorandum-making-general-use-respirators-available/. Back to Text

[3] www.fda.gov/media/135763/download. Back to Text

[4] www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-supply-strategies.html. Back to Text

[5] See also, OSHA letter of interpretation to John Boren, *Voluntary Use of Surgical Masks*, 12/20/2017, at: www.osha.gov/laws-regs/standardinterpretations/2017-12-20. Back to Text

[6] www.osha.gov/enforcement/directives/cpl-02-00-158. Back to Text

[7] See NIOSH webpage defining the difference between extended use and re-use of N95s at: www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html. Back to Text

[8] *User Seal Check Procedures*, at: www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppB1. OSHA tutorial videos are available at: www.youtube.com/watch?v=Tzpz5fko-fg (English); www.youtube.com/watch?v=jgRKuRcTGeE (Spanish). Back to Text

[9] Surgical N95s are NIOSH-approved N95 FFRs that are also certified by the FDA for use as a surgical mask. Surgical N95s are normally tested for fluid resistance and flammability. These requirements were not evaluated as part of the NIOSH shelf life testing discussed in this memorandum. CDC/NIOSH does not recommend using N95s beyond the manufacturer-designated shelf life in surgical settings. Back to Text

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