

CHERIE K. BERRY COMMISSIONER

SCOTT MABRY ASSISTANT DEPUTY COMMISSIONER OCCUPATIONAL SAFETY AND HEALTH DIVISION

<u>MEMO</u>

To: OSH Division

From: Scott Mabry, Assistant Deputy Commissioner

Date: April 30, 2020

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

On April 24, 2020 the Occupational Safety and Health Administration (OSHA) issued interim enforcement guidance for enforcing the Respiratory Protection standard, 29 CFR § 1910.134, regarding the reuse of filtering facepiece respirators (FFRs) that have been decontaminated through certain methods. This guidance applies only in workplaces where employees are at risk of exposure to infectious agents through inhalation, including during the care and treatment of patients with suspected or confirmed coronavirus disease 2019 (COVID-19) and other activities that could result in exposure to SARS-CoV-2, the virus that causes COVID-19. This guidance is not intended to permit the reuse of FFRs laden with other air contaminants (e.g., silica and lead).

The OSH Division will, on a case-by-case basis, exercise enforcement discretion related to the reuse of FFRs that have been decontaminated using the methods recommended in the April 24, 2020 enforcement memorandum when considering issuing citations for violations of 29 CFR § 1910.134(d). Where efforts by the employer to comply with the standard that are described in this guidance are absent and the use of respiratory protection is required, or where voluntary use is permitted, and the employer fails to comply with fit testing, maintenance, care, and training requirements, CSHOs will cite the applicable provision(s) of 29 CFR § 1910.134 as serious violations.

This enforcement policy will be effective on the date of signature by the OSH Assistant Director and will remain in effect until notified that it no longer applies.

Per this memorandum, the OSH Division of the NCDOL adopts the above-mentioned OSHA enforcement procedure for use in North Carolina. The referenced memorandum is attached.

April 24, 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 on Decontamination of Filtering Facepiece Respirators in Healthcare During 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, with regard to the reuse of filtering facepiece respirators (FFRs) that have been decontaminated through certain methods.[1]

This guidance applies in workplaces in which workers need respirators to protect against exposure to infectious agents that could be inhaled into the respiratory system, including during care of patients with suspected or confirmed coronavirus disease 2019 (COVID-19) and other activities that could result in respiratory exposure to SARS-CoV-2 (the virus that causes COVID-19). The guidance describes decontamination methods for FFRs contaminated with pathogens, and is not intended to facilitate re-use of FFRs laden with other contaminants (e.g., FFRs overloaded with silica dust).

This memorandum further expands flexibilities outlined in OSHA's previous COVID-19 enforcement memoranda posted at www.osha.gov/enforcementmemos.[2] 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

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared the COVID-19 outbreak a public health emergency.[3] The President also declared a national emergency due to COVID-19.[4]

The response to the pandemic has created an increased demand for FFRs, limiting their 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 "*consider all appropriate and necessary steps to increase the availability of respirators*."[5]

Although the Secretary, through OSHA, has allowed for enforcement flexibility around respirators—including with regard to fit-testing, the use of respirators that are beyond their manufacturer's recommended shelf life, extended use and reuse of respirators, and the use of alternative equipment certified by the National Institute for Occupational Safety and Health (NIOSH) or in accordance with standards of certain other countries and jurisdictions—the availability of FFRs remains a concern throughout the country.

In some circumstances, employers may find it necessary to decontaminate FFRs to facilitate their reuse. However, because of the potential for decontamination methods to affect respirator fit and/or performance, there are no NIOSH-approved methods for such processes. That is, decontamination voids the NIOSH certification for the respirator. Still, during periods of shortages of FFRs when other preferred alternative respirators (as described in *Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the* 2019 Novel Coronavirus Disease (COVID-19) Pandemic and Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic) are not available, filtering facepiece respirator decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability of respiratory protection equipment.[6]

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 FFRs during the COVID-19 pandemic.[7] Paragraph (d)(1)(iii) in section 1910.134 requires 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.[8]

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).[10]

The NIOSH-evaluated research provides justification for each method evaluated.

Note that, according to NIOSH, only respirator manufacturers can reliably provide guidance on how to decontaminate their specific models of FFRs. In the absence of manufacturers' recommendations, third parties (e.g., respiratory protection or other industrial hygiene consultants) may also provide guidance or procedures on how to decontaminate respirators without impacting respirator performance.

Further, the effectiveness of using any of the methods mentioned in this guidance should be explored with specific filtering facepiece respirator models and with manufacturer, and, if needed, third party expert, input and support to better understand the impact on respirator performance, including filtration and fit, and structural integrity (including integrity of head straps and other parts). Employers should be able to demonstrate effectiveness of any decontamination method(s) used against the likely contaminant(s) (i.e., pathogens) of concern. Employers should also ensure that any decontamination method(s) used do not produce additional safety hazards (e.g., electrical arcs resulting from placing FFRs with metal parts into microwaves), or that workers are adequately protected from those hazards through appropriate engineering and administrative controls, safe work practices, and personal protective equipment.

OSHA will continue to consider methods for decontamination of FFRs on a case-by-case basis as objective data demonstrating the safety and effectiveness of such methods become available, and the agency will provide updated guidance, as appropriate.

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

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.[11]
- Train employees to follow appropriate precautionary measures prior to using a decontaminated filtering facepiece respirator (FFR). See www.cdc.gov/coronavirus/2019-ncov/hcp/ppestrategy/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.

Citation guidance:

OSHA will, on a case-by-case basis, exercise enforcement discretion related to the reuse of FFRs that have been decontaminated using the methods recommended above when considering issuing citations under 29 CFR § 1910.134(d) and/or the equivalent respiratory protection provisions of other health standards in cases where:

- Other feasible measures, such as using partitions, restricting access, cohorting patients, or using other engineering controls, work practices, or administrative controls that reduce the need for respiratory protection, were implemented to protect employees;
- The employer has made a good faith effort to obtain other alternative FFRs, reusable elastomeric respirators, or PAPRs, including NIOSH-certified equipment or equipment that was previously NIOSH-certified but that has surpassed its manufacturer's recommended shelf life (in accordance with OSHA's April 3, 2020 memo), that is appropriate to protect workers;
- The employer has monitored its supply of FFRs, prioritized their use according to CDC guidance (www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html; www.cdc.gov/coronavirus/2019ncov/hcp/respirators-strategy/index.html), and controlled the number of times a respirator is decontaminated before issuing a new one given supply level and burn rate considerations; and
- 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 during aerosol-generating procedures).

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 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 DSG

[1] For the purposes of this memorandum, *filtering facepiece respirators (FFRs)* means disposable filtering facepiece respirators designated as N95, N99, N100, R95, R99, R100, or P95, P99, and P100. Back to text

[2] "OSHA's previous COVID-19 enforcement memoranda" refers to: *Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak; Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic; Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic;* and *Expanded Temporary Enforcement Guidance on Respiratory Protection Fit-Testing for N95 Filtering Facepieces in All Industries During the Coronavirus Disease 2019 (COVID-19) Pandemic. See* **www.osha.gov/enforcementmemos. Back to text**

[3] The Secretary of Health and Human Services (HHS) declared on January 31, 2020 that the COVID-19 pandemic was a public health emergency. HHS, *Determination of Public Health Emergency*, 85 FR 7316

(February 7, 2020). Back to text

[4] Proclamation 9994 of March 13, 2020, 85 FR 15337 (March 18, 2020). Back to text

[5] Presidential Memorandum, *Memorandum on Making General Use Respirators Available*, March 11, 2020, www.whitehouse.gov/presidential-actions/memorandum-making-general-use-respirators-available/. Back to text

[6] According to guidance on decontamination and reuse of FFRs, the Centers for Disease Control and Prevention (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, in times of crisis, this option may need to be considered when FFR shortages exist. *See* www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html. Back to text

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

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

[9] As of the date of issuance of this memorandum, the U.S. Food and Drug Administration had issued Emergency Use Authorizations for several decontamination systems that rely on vaporous hydrogen peroxide. Back to text

The recommendation against EtO in this category is based on OSHA's concern about worker (particularly those wearing decontaminated respirators) exposure to levels of EtO, including above the action level (0.5 ppm as an eight-hour time weighted average) in the OSHA standard (29 CFR § 1910.1047) for this substance—a known human carcinogen and teratogen. While EtO has been demonstrated to effectively deactivate viral pathogens on FFRs, additional information is needed about worker exposure to EtO associated with use of particular decontamination systems, including while conducting decontamination operations and while wearing particular FFRs that have been decontaminated using such methods. Back to text

[11] 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