

Enforcement Memos

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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 Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions 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, and certain other health standards, with regard to supply shortages of disposable N95 filtering facepiece respirators (FFRs). Specifically, it outlines enforcement discretion to permit the use of FFRs and air-purifying elastomeric respirators that are either:

- Certified under certain standards of other countries or jurisdictions, as specified below; or
- When equipment certified under standards of other countries or jurisdictions is not available, previously certified under the standards of other countries or jurisdictions but are beyond their manufacturer's recommended shelf life (i.e., 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 memoranda, *Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak*, issued on March 14, 2020, and *Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic*, issued on April 3, 2020, provided temporary guidance for 29 CFR § 1910.134, regarding required annual fit testing of HCP and use of respirators beyond their manufacturer's recommended shelf life, respectively.[1] This memorandum provides additional guidance on enforcing OSHA's Respiratory Protection standard (and other health standards that require respiratory protection) 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 World Health Organization declared the COVID-19 pandemic on March 11, 2020. The pandemic has created an increased demand for N95 FFRs, 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]

Although the Secretary, through OSHA, has allowed for enforcement flexibility with regard to some provisions of the Respiratory Protection standard, the availability of N95 FFRs or other respirators certified by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR Part 84 remains a concern throughout the country.

In some circumstances, additional supplies of respirators certified under standards from other countries or jurisdictions may be available. During periods of shortages of N95 FFRs, the federal government advises that FFRs, air-purifying elastomeric respirators, and compatible filters certified under the following standards of other countries or jurisdictions will provide greater protection than surgical masks (i.e., facemasks, other than surgical N95s[3]), homemade masks, or improvised mouth and nose covers, such as bandanas and scarves:

- Australia: AS/NZS 1716:2012
- Brazil: ABNT/NBR 13694:1996; ABNT/NBR 13697:1996; and ABNT/NBR 13698:2011
- People's Republic of China: GB 2626-2006; and GB 2626-2019
- European Union: EN 140-1999; EN 143-2000; and EN 149-2001
- Japan: JMHLW-2000
- Republic of Korea: KMOEL-2014-46; and KMOEL-2017-64
- Mexico: NOM-116-2009

Certification in accordance with these standards ensures that devices provide similar filtration as NIOSH-certified equipment, as described in Tables 1 and 2, below, and, accordingly, have an assigned protection factor greater than or equal to 10.

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.[4] 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.[5]

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, and either acceptable NIOSH-certified alternatives or alternatives that were NIOSH-certified except for having exceeded their manufacturer's shelf life are not available for use in accordance with OSHA's April 3, 2020 memorandum, employers may consider using respirators and filters certified under standards of other countries or jurisdictions, as described in Tables 1 and 2 of Appendix A.

The following specific enforcement guidance is provided for CSHOs inspecting workplaces where workers are using respirators and/or filters in accordance with standards of other countries or jurisdictions in lieu of NIOSH-certified devices.

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. This should be accomplished through, in this order:
 - Implementing the hierarchy of controls in an effort first to eliminate or substitute out workplace hazards, then using engineering controls, administrative controls, and safe work practices to prevent worker exposures to respiratory hazards.
 - Prioritizing efforts to acquire and use equipment in the following order:
 - NIOSH-certified equipment; then
 - Equipment certified in accordance with standards of other countries or jurisdictions except the People's Republic of China, unless equipment certified in accordance with standards of the People's Republic of China is manufactured by a NIOSH certificate holder[6]; then
 - Equipment certified in accordance with standards of the People's Republic of China, the manufacturer of which is not a NIOSH certificate holder[6]; then
 - Facemasks (e.g., medical masks, procedure masks).
 - Prioritizing efforts to acquire and use equipment that has not exceeded its manufacturer's recommended shelf before allowing workers to use equipment that is beyond its manufacturer's recommended shelf life. Equipment used beyond its manufacturer's recommended shelf life must be used in accordance with OSHA's April 3, 2020 memorandum.
 - Prioritizing efforts to use equipment that has not exceeded its intended service life (e.g., disposable FFRs used for the first time) before implementing protocols for extended use or reuse of equipment. Extended use or reuse of equipment should follow the Centers for Disease Control and Prevention's *Strategies for Optimizing the Supply of N95 Respirators*.
 - Using homemade masks or improvised mouth and nose covers only, as a last resort (i.e., when no respirators or facemasks are available). Improvised masks are not personal protective equipment and, ideally, should be used with a face shield to cover the front and sides of the face. When this measure is the only resort, refer to the Centers for Disease Control and Prevention (CDC) guidance at www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html.
- Ensure users perform a user seal check each time they don a respirator, regardless of whether it is a NIOSH-certified device or device certified under standards of other countries or jurisdictions, and do not use a respirator on which a user cannot perform a successful user seal check. See 29 CFR § 1910.134, Appendix B-1, *User Seal Check Procedures*. [7]
- 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.
- 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, components such as the straps, nose bridge, and nose foam material may degrade, which can affect the quality of the fit and seal.
- Avoid co-mingling products from different categories of equipment. NIOSH-certified equipment, equipment that was previously NIOSH-certified but that has surpassed its manufacturer's recommended shelf life, equipment certified under standards of other countries or jurisdictions, and equipment that was previously certified under standards of other countries or jurisdictions but that has surpassed its manufacturer's recommended shelf life should be stored separately.
- Train employees on the procedures for the sequence of donning/doffing to prevent self-contamination. See www.cdc.gov/niosh/npptl/pdfs/PPE-Sequence-508.pdf.

Healthcare employers only:

- 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[6];
- 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 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.
- It is reasonable for healthcare employers to reserve some NIOSH- or foreign-certified N95 FFRs or better respirators for use by HCP who are expected to perform surgical procedures on patients infected with, or potentially infected with, SARS-CoV-2 or perform or be present for procedures expected to generate aerosols or procedures where respiratory secretions are likely to be poorly controlled. In such cases, and particularly when workers performing other tasks are provided with alternative equipment, employers should be able to provide a reasonable rationale for their decision to stockpile respirators appropriate to protect workers during aerosol-generating procedures.

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:

- 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.
- The employer has made a good faith effort to obtain other appropriate 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 memorandum);
- In healthcare, 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); 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 against 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 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
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Appendix A

This appendix includes tables referenced in the memorandum, covering respirators that are similar to NIOSH-approved N95 FFRs (Table 1) and respirator-cartridge units that are similar to NIOSH-approved air-purifying elastomeric half-facepiece respirators (Table 2), which are approved under standards used in other countries or

jurisdictions.

Table 1. Respirators Approved Under Standards Used in Other Countries or Jurisdictions That Are Similar to NIOSH-Approved N95 Filtering Facepiece Respirators

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13698:2011	PFF2	N95
		PFF3	N99 or lower
China (People's Republic of)	GB 2626-2006	KN/KP95	N95
		KN/KP100	N99 or lower
Europe	EN 149-2001	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	DS/DL2	N95
		DS/DL3	N99 or lower
Korea (Republic of)	KMOEL-2017-64	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

Table 2. Respirator-Cartridge Units Approved Under Standards Used in Other Countries or Jurisdictions That Are Similar to NIOSH-Approved Elastomeric Half-Facepiece Respirators

Country	Performance Standard	Acceptable Product Classification	May Be Used in Lieu of NIOSH-Certified Products Classified as
Australia	AS/NZS 1716:2012	P2	N95
		P3	N99 or lower
Brazil	ABNT/NBR 13694:1996; ABNT/NBR 13697:1996	P2	N95
		P3	N99 or lower
China (People's Republic of)	GB 2626-2006; GB 2626-2019	KN/KP95	N95
		KN/KP100	N99 or lower
Europe	EN140-1999; EN 143-2000	P2	N95
		P3	N99 or lower
Japan	JMHLW-2000	RS/RL2	N95
		RS/RL3	N99 or lower
Korea (Republic of)	KMOEL-2014-46	Special 1st	N95
Mexico	NOM-116-2009	N95	N95
		R95	R95 or lower
		P95	P95 or lower
		N99	N99 or lower
		R99	R99 or lower
		P99	P99 or lower
		N100	N100 or lower
		R100	R100 or lower
		P100	P100 or lower

[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; OSHA memorandum on *Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic*, April 3, 2020, at www.osha.gov/memos/2020-04-03/enforcement-guidance-respiratory-protection-and-n95-shortage-due-coronavirus. Back to Text

[2] 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

[3] Surgical N95s are NIOSH-approved N95 FFRs that are also certified by the U.S. Food and Drug Administration (FDA) for use as a surgical mask. Surgical N95s are normally tested for fluid resistance and flammability. Back to Text

[4] 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

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

[6] According to the National Institute for Occupational Safety and Health (NIOSH), it has observed that products from the People's Republic of China may not meet the requirements of the standards to which they are certified and may not offer or sustain the protection claimed as typically expected when using NIOSH-approved N95 respirators. However, devices supplied by current NIOSH approval holders producing respirators under the standards authorized in the countries and/or jurisdictions addressed in this memorandum are expected to provide the protection indicated, given that a proper fit is achieved. Back to Text

[7] *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

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