FDA Recommends Transition from Use of Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities

April 9, 2021

The U.S. Food and Drug Administration (FDA) is recommending health care personnel and facilities transition away from crisis capacity conservation strategies, such as decontaminating or bioburden reducing disposable respirators for reuse. Based on the increased domestic supply of new respirators approved by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) currently available to facilitate this transition, the FDA and CDC believe there is adequate supply of respirators to transition away from use of decontamination and bioburden reduction systems.

Recommendations

The FDA recommends that health care personnel and facilities:

- Limit decontamination of disposable respirators. Decontaminated respirators and respirators that have undergone bioburden reduction should be used only when there are insufficient supplies of new FFRs or if you are unable to obtain any new respirators.
- Transition away from a crisis capacity strategy (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html) for respirators, such as decontamination of N95 and other FFRs.
- Increase inventory of available NIOSH-approved respirators (/medical-devices/coronavirus-covid-19-and-medical-devices/considerations-selecting-respirators-your-health-care-facility)—including N95s and other FFRs, elastomeric respirators, including new elastomeric respirators without an exhalation valve that can be used in the operating room, and powered air-purifying respirators (PAPRs). Even if you are unable to obtain the respirator model that you would prefer, the FDA recommends that you obtain and use a new respirator before decontaminating or bioburden reducing a preferred disposable respirator.

Background

The FDA continues to work closely with other government partners, including CDC/NIOSH and Occupational Safety and Health Administration (OSHA), in a whole-of-government approach to help make available critical respiratory protection to address the needs of health care personnel.

If a reusable respirator is needed, organizations should first try to acquire respirators like elastomeric respirators and PAPRs, which are designed to be reusable. For more information on reusing FFRs in workplaces in which workers need respirators to protect against exposure to infectious agents that could be inhaled into the respiratory system, please see OSHA's Enforcement Guidance on Decontamination of Filtering Facepiece Respirators in Healthcare During the COVID-19 Pandemic (https://www.osha.gov/memos/2020-04-24/enforcement-guidance-decontamination-filtering-facepiece-respirators-healthcare).

During the COVID-19 public health emergency, NIOSH-approved respirators, including N95 respirators, are authorized on a continual basis under the FDA emergency use authorization (EUA) for NIOSH-Approved air purifying respirators (/media/135763/download) (includes single-use respirators and those designed to be reusable) until the U.S. Department of Health and Human Services (HHS) Secretary's declaration that circumstances exist justifying authorization is terminated or the EUA is revoked. Once a respirator receives NIOSH approval, it is automatically authorized under this umbrella EUA. From January 2020 through April 2021, NIOSH has approved over 875 respirator models or configurations with some of these manufactured by approximately 20 new, domestic NIOSH approval holders. In addition, as of today, there are over 6,400 total respirator models or configurations on the NIOSH certified equipment list which met the NIOSH-Approved EUA criteria and thus had been FDA-authorized, including:

- Over 600 FFR models (of which there are over 530 N95 FFR models)
- Over 5,500 elastomeric respirator configurations, including new elastomeric respirators without an exhalation valve (/news-events/fda-voices/elastomeric-respirator-innovations-play-critical-role-response-covid-19)
- Over 360 PAPR configurations

CDC/NIOSH has also updated its Strategies for Optimizing the Supply of N95 Respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html) to clarify the application of surge capacity strategies.

FDA Actions

The FDA and CDC believe there is adequate supply of respirators to transition away from use of decontamination and bioburden reduction systems. However, the FDA is not revoking the EUAs for decontamination and bioburden reduction systems at this time. If there are insufficient supplies of FFRs resulting from the COVID-19 pandemic, health care personnel may continue to use currently-authorized decontamination and bioburden reduction systems (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-

devices/decontamination-systems-personal-protective-equipment-euas), though such reuse of respirators should be limited to when no other respirators are available, including reusable respirators such as elastomeric respirators or PAPRs.

Of note, while there is an increase in domestic supply of respirators for healthcare personnel, the FDA will continue to monitor supply and demand to assess respirator availability as facilities systematically transition away from the most extreme measures of respirator conservation (that is, crisis capacity strategies) to contingency and eventually conventional use. Therefore, respirators, specifically surgical respirators, presently remain on the FDA's device shortage list (/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency). The shortage list reflects the categories of devices the FDA has determined to be in shortage at this time and will be maintained and updated as the COVID-19 public health emergency evolves. The presence of a device type on this list does not necessarily indicate that patient care has been affected.

The FDA will continue to keep health care personnel and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

The FDA encourages health care personnel to report any adverse events or suspected adverse events experienced with any medical devices, including decontamination systems, bioburden reduction systems, or respirators.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) (DICE).