Update: FDA Recommends Transition from Use of Non-NIOSH-Approved and Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities

May 27, 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 using non-NIOSH-approved disposable respirators, including non-NIOSH-approved imported respirators such as KN95s. This recommendation is in follow-up to the April 9, 2021, letter (/medical-devices/letters-health-care-providers/fda-recommends-transition-use-decontaminated-disposable-respirators-letter-health-care-personnel-and) in which the FDA recommended a transition away from decontamination or bioburden-reduction systems for cleaning and disinfecting disposable respirators, which were being reused by health care personnel.

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) and consistent with CDC's updated recommendations (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html), the FDA believes health care personnel and facilities can transition away from using non-NIOSH-approved respirators and from utilizing decontamination and bioburden reduction systems. These crisis capacity conservation strategies have been used to address respirator shortages during the COVID-19 outbreak.

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 filtering facepiece respirators (FFRs) or when any new respirators are unavailable.
- Limit use of all non-NIOSH-approved respirators, including imported respirators, to only when there are insufficient supplies of new NIOSH-approved FFRs or when any new respirators are unavailable.
- Transition away from a crisis capacity strategy (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html) for respirators, such as use of non-NIOSH approved respirators and 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
    - Powered air-purifying respirators (PAPRs).

Even if health care personnel and facilities are unable to obtain the respirator model that they would prefer, the FDA recommends obtaining and using a new NIOSH-approved respirator before using a non-NIOSH-approved respirator or decontaminating or bioburden-reducing a preferred disposable respirator.

Background

The FDA continues to work closely with other government partners, including CDC/NIOSH and the 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).

The number of available NIOSH-approved respirators has continued to increase throughout the COVID-19 pandemic. 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. After a respirator receives NIOSH approval, it is automatically authorized under this umbrella EUA.

From January 2020 through May 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 indicate healthcare facilities should not be using crisis capacity strategies.

FDA Actions

The FDA believes, consistent with CDC/NIOSH recommendations, that the increased supply and availability of NIOSH-approved respirators supports transition away from use of non-NIOSH-approved respirators as well as decontamination and bioburden reduction systems.

On April 30, 2021, the FDA revoked the EUA for the Battelle CCDS Critical Care Decontamination System (https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#decontamination) in response to Battelle's request for voluntary withdrawal of the authorization. In response to changing customer needs, Battelle has ceased all Battelle CCDS decontamination site operations and marketing activities.

On March 24, 2021, the FDA revised the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#imported) to authorize for emergency use only those respirators listed in the EUA's Exhibit 1 as of the date of the reissuance.

On October 15, 2020, the FDA reissued the EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators manufactured in China (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#nonniosh) to authorize for emergency use only those respirators listed in the EUA's Appendix A as of the date of the reissuance.

The FDA is not revoking the EUAs for non-NIOSH-approved respirators or for other decontamination and bioburden reduction systems at this time. If NIOSH-approved FFRs are in limited supply or not available 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-system-euas-personal-protective-equipment) and currently-authorized non-NIOSH-approved respirators (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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, as described in the Recommendations above.

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 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).