Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System for Reuse by Other Healthcare Facilities

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ (hereafter referred to as the "Battelle Decontamination System") operated by the Battelle Memorial Institute ("Battelle"), for use in decontaminating compatible N95 respirators for multiple-user reuse by healthcare personnel. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by Battelle using the Battelle Decontamination System, so that the decontaminated, compatible N95 respirators may be reused by healthcare personnel at another healthcare facility.

The Battelle Decontamination System has been authorized by FDA under an EUA for use in decontaminating compatible N95 respirators for multiple-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 outbreak. The Battelle Decontamination System has neither been cleared nor approved for this use. The Battelle Decontamination System is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, unless the authorization is terminated or revoked sooner.

Respirators that are NIOSH-approved before decontamination (https://wwwn.cdc.gov/niosh-cel/) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer.

- **The Battelle Decontamination System is not authorized for use with the following:**
  - **Respirators containing cellulose-based materials;**
  - **Respirators containing exhalation valves; and**
  - **Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.**
- **All compatible N95 respirators provided to Battelle must be free of any visible damage and soiling/contamination (e.g., blood, bodily fluids, makeup).**
- **Discard and do not collect compatible N95 respirators that are visually soiled or damaged.**
- **Compatible N95 respirators may be decontaminated a maximum of 20 times.**
- **Discard any compatible respirator with illegible markings to indicate the number of decontamination cycles completed.**

On-Site Collection:

1. Your organization will create a collection station at the point of generation (i.e., hospital floor/unit).
2. Each station will have a bag provided by the healthcare facility to collect compatible N95 respirators. **NOTE: Bags are for compatible N95 respirators only. Do not throw other personal protective equipment (such as gloves), paper towels, or waste in the collection bag.**
3. Healthcare personnel will follow the instructions provided by Battelle in Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle

Memorial Institute Using the Battelle Decontamination System for Reuse by Other Healthcare Facilities.

Preparation for Shipment:

1. Close bags containing the contaminated, compatible N95 respirators to be decontaminated by Battelle ("primary collection bag").
2. Place the primary collection bag into another bag ("secondary collection bag") (provided by the healthcare facility), which is then closed.
3. Decontaminate the secondary collection bag with alcohol or other suitable decontaminant.
4. Place the decontaminated bags into a rigid, closed box (supplied by the healthcare facility) clearly labeled with a biohazard symbol, and tape the box securely shut.
5. Label the outside of the box with the 3-digit site code provided by Battelle to the healthcare facility.

Site Code
(Assigned by Battelle Point Of Contact)

Shipment under the Healthcare Facility's Agreement with Battelle:

1. Gather all boxes; complete one chain of custody form (provided by Battelle) per shipment, noting the number of boxes.
2. Coordinate with your organization's courier service to arrange transfer to designated Battelle location.

Reuse Information:

Following decontamination, the **decontaminated, compatible N95 respirators** that have been processed through a decontamination system for multiple-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic will be provided to healthcare personnel in need of compatible N95 respirators. Before reuse, the healthcare facility that receives the **decontaminated, compatible N95 respirators** must review the chain of custody form, which indicates successful decontamination, accompanying the returned respirators. The healthcare facility must also inspect each returned, decontaminated compatible N95 respirator for:

1. Numeric indication of the decontamination cycle number. **NOTE: Compatible N95 respirators will be disposed of after 20 decontamination cycles.**
2. Visible damage or soiling. NOTE: **Compatible N95 Respirators must be discarded and not reused if visually damaged or soiled.**

Reporting:

Healthcare facilities will report any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator to Battelle, and the healthcare facility must discard the respirator.

Healthcare facilities will report adverse events of which they become aware. This includes, but is not limited to, monitoring healthcare personnel using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections, and monitoring healthcare personnel handling contaminated, compatible N95 respirators.

Report Adverse events to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.

Any problems should be immediately reported to Battelle.
Battelle Contact: 1-800-201-2011 or solutions@battelle.org