BATTELLE

Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System for Return to the Same Healthcare Facility

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 to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. 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.

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 pandemic. 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, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is 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 and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

- **The Battelle Decontamination System is not authorized for use with the following:**
  - **Respirators containing cellulose-based materials or antimicrobial agents;**
  - **Respirators with an exhalation valve or a duck-billed design; 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 4 times.**
- **Discard any compatible N95 respirator with illegible markings to indicate the number of decontamination cycles completed.**
- **The Battelle Decontamination System has neither been cleared or approved by FDA, but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.**
- **The emergency use of 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, under Section 564(b)(1) of**

the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

On-Site Collection and Marking:

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. With a permanent marker, the healthcare personnel label their compatible N95 respirator with a 3-digit site code and a 2-digit site location ID (as shown below). The unique site code corresponds to the healthcare facility delivery address and will be assigned by Battelle. Your organization may designate the site location ID to correspond to a specific location/floor/unit within your site.
4. 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 Return to the Same Healthcare Facility.

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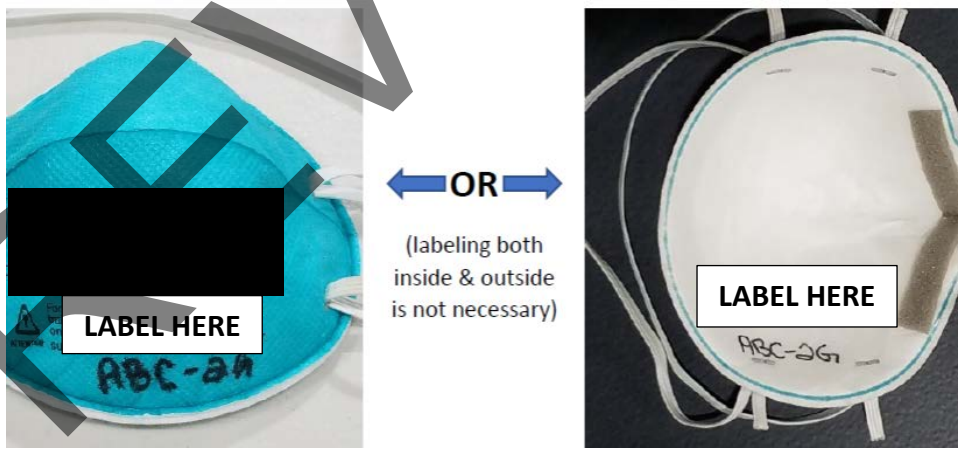
Site Code (Assigned by Battelle Point Of Contact) **Site Location ID** (Assigned by Healthcare Facility)



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 and 2-digit site location ID.

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, your healthcare facility will be provided with **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. Before reuse, the healthcare facility 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 exceeding 4 decontamination cycles.**
2. Visible damage or soiling. **NOTE**: **Compatible N95 respirators must be discarded and not reused if visually damaged or soiled.**

Healthcare facilities must ensure that HCP receive the same model of decontaminated compatible N95 respirator for which they have been fit tested. If such model of respirator is unavailable, then healthcare facilities must provide HCP with fit testing prior to using an alternative model of decontaminated compatible N95 respirator.

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