

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

The U.S. Food and Drug Administration has authorized 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 or N95-equivalent respirators (“compatible N95 respirators”), for 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.

- **Due to incompatibility, the Battelle Decontamination System is not authorized for use with respirators containing cellulose-based materials**
- **All compatible N95 respirators provided to Battelle must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup)**
- **If N95 respirators are soiled or damaged, they will be disposed of and not returned after decontamination**

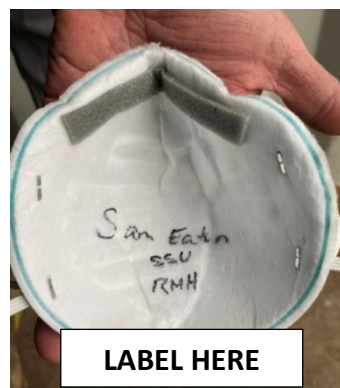
On-Site Collection/Marking

1. Your organization should create a collection station at the point of generation (i.e. hospital floor/unit)
2. Each station should 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 should label their own individual compatible N95 respirators with a three-digit site code and a 2-digit location identifier (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 location identifier to correspond to a specific location/floor/unit within your site.
4. Healthcare personnel should 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.

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Site Code **Site Location ID**

(Assigned by Battelle Point Of Contact) (Assigned by Healthcare Facility)



Preparation for Shipment:

1. Bags containing the contaminated compatible N95 respirators to be decontaminated by Battelle (“primary collection bag”) should be closed.
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 location identifier.

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, you will be provided **decontaminated compatible N95 respirators** that have been processed through a decontamination system for reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic. Before reuse, the healthcare facility should review the chain of custody form, which indicates successful decontamination, accompanying the returned respirators. The healthcare facility should 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 should be discarded and not reused if visually damaged or soiled.**

Any problems should be immediately reported to Battelle.

Battelle Contact: 1-800-201-2011 or solutions@battelle.org