

Battelle CCDS Critical Care Decontamination System™



DELIVERING CRITICAL VALUE

The Battelle CCDS Critical Care Decontamination System™ addresses the current shortage of critical Personal Protective Equipment (PPE) across the United States. Battelle CCDS™ is designed to decontaminate N95 respirators for the novel coronavirus (SARS-CoV-2).

THE PROCESS

Battelle CCDS™ can decontaminate thousands of N95 respirators using high concentration, vapor phase hydrogen peroxide. The respirators are exposed for hours at the validated concentration level to decontaminate biological contaminants, including the SARS-CoV-2. CCDS™ can decontaminate the same respirator up to 20 times without degrading N95 filter mask performance.

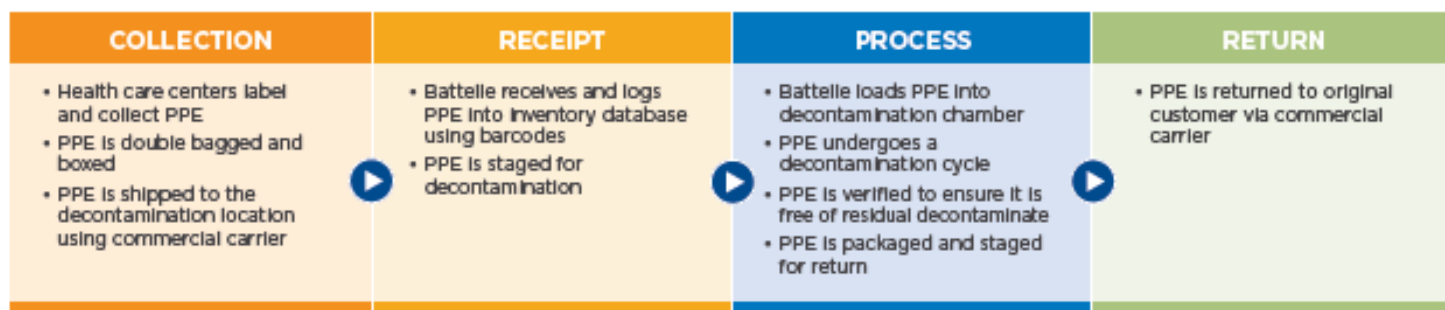
Healthcare systems will collect worn respirators each day in accordance with an approved procedure, and the PPE will be labeled with a barcoded serial number that will be used for tracking the PPE chain-of-custody throughout the

decontamination process. This procedure ensures that the hospital system receives its own respirators back.

REGULATORY, SAFETY AND EFFICACY

Battelle CCDS™ draws on decades of research and is grounded on an FDA study Battelle completed in 2016 to investigate decontamination and durability of N95 respirators in the event of a pandemic. Battelle is currently conducting research to validate that other materials, such as surgical masks and ventilator components, will continue to function as designed following multiple decontamination cycles.

Battelle CCDS™ Process



To learn more about how to enroll in the Battelle CCDS™ system, please contact Battelle directly at 800.201.2011 | solutions@battelle.org

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit www.battelle.org.

800.201.2011 | solutions@battelle.org | www.battelle.org

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BATTELLE
It can be done

Battelle CCDS™ Process

HEALTH CARE PROVIDER SIGN-UP PROCESS Battelle CCDS Critical Care Decontamination System™

BATTELLE

1 Sign up with Battelle

- Visit battelle.org/decon to fill out the enrollment form
- Battelle emails enrollee links to the enrollment contract, instructions, and the Battelle POC

battelle.org/decon



2 Contact Us to Get Your Code

- Enrollee signs contract and contacts Battelle POC to receive their 3-digit codes for each facility



3 Properly Label Respirators

- Once the 3-digit codes are received from Battelle, enrollee collects N95 respirators
- N95 respirators must be unsoiled (free of blood, mucus, make-up, lip balm, etc.) and labeled with a permanent marker



4 Collect & Bag All N95 Respirators

- Enrollee collects all N95 respirators into a single plastic bag
- Once the plastic bag is filled, tie off the bag and put it into another plastic bag



5 Properly Package

- Clean the outside bag with disinfectant
- Shipping box must be labeled with the 3-digit code and a biohazard sticker



6 Ship to CCDS Site

- Enrollee contacts their chosen logistics provider to coordinate pick-up and delivery of their N95 respirators
- Enrollee can either use a logistics provider of their choice or Battelle's preferred logistics provider



7 Decontaminated & Returned

- Your shipments are barcoded to ensure chain of custody
- Your N95 respirators are processed and then verified to ensure they are free of decontaminant
- Your decontaminated N95 respirators are returned to your facility



Battelle CCDS™ Process

HOW IT WORKS

Battelle CCDS Critical Care Decontamination System™

BATTELLE

Your Facility's Responsibility

- Your Battelle POC will provide you with 3-digit codes for each facility
- The 3-digit code must be written on each individual N95

- Collect all N95 respirators into a single plastic bag
- Once the plastic bag is filled, tie off the bag and put it into another plastic bag

- Clean the outside bag with disinfectant
- Shipping box must be labeled with the 3-digit code and a biohazard sticker

- You can either use a logistics provider of your choice or Battelle's preferred logistics provider

Battelle CCDS™ Process

- Your shipments are barcoded to ensure chain of custody
- Your N95 respirators are exposed to the vapor phase hydrogen peroxide process
- After processing, your N95 respirators are verified to ensure they are free of decontaminant

- The logistics provider returns your decontaminated N95 respirators back to your facility



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.

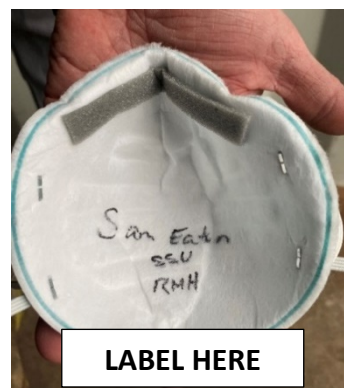
- Due to incompatibility, the Battelle Decontamination System is not authorized for use with respirators containing cellulose-based materials
- All compatible N95 respirators provided to Battelle must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup)
- If N95 respirators 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.

— — — — —
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

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

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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).

Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and will be disposed of and not returned after decontamination.

N95 Respirator Marking and Collection

1. Label your own individual compatible N95 respirator using a permanent marker; do not label others’ or ask others to label for you.
2. Labeling should be legibly written on the outside OR inside of each compatible N95 respirator, as shown below.
3. Label ALL compatible N95 respirators with the three-digit site code and 2-digit location identifier provided below.
4. Place your compatible N95 respirator in the collection bag provided by your healthcare facility at a designated collection station at your facility.

NOTE: Collection bags are for compatible N95 respirators only; do not throw other personal protective equipment (such as gloves), paper towels or waste in the collection bags.

