



Personal Protective Equipment: N95 Mask Decontamination for Reuse

April 17th, 2020

Overview

- Battelle is using Vapor Phase Hydrogen Peroxide (VPHP) process to decontaminate PPE. N95 respirators are the only PPE currently approved by FDA for reprocessing.
 - Battelle conducted a comprehensive study for the FDA in 2016 proving this method effective on N95 respirators
 - The current process Battelle is deploying was granted EUA by the FDA to decontaminate N95 masks up to 20 times for each mask
 - Technical information regarding prior studies completed with FDA (2016) and subsequent technical summaries are all available on Battelle's website at www.battelle.org/decon
- A system is soon to be operational in New Haven, CT to serve Connecticut and the communities adjacent to Connecticut's borders with other states.
 - Battelle is currently processing thousands of masks per day in Boston, New York, Seattle, and Columbus
 - Capacity soon to be available in CT for at least 20,000 masks per day
 - Battelle will continue to expand capacity in CT up to 80,000 masks per day if needed in the region

Battelle CCDS™ Process

HOW IT WORKS

Battelle CCDS Critical Care Decontamination System™

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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



Battelle CCDS™ Enrollment & Activation

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

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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



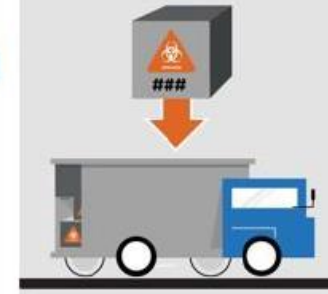
5 Properly Package

- 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



Enrollment Summary

- Battelle Point of Contact for enrollment is Andre LaFreniere
 - Battelle website www.battelle.org/decon is source of all initial forms and information for enrollment
 - Battelle trying to streamline process to allow organizations to sign up efficiently and start collecting N95 masks for future decontamination.
 - Contact POC with questions at (401) 935-0084 or lafreniere@battelle.org
- Establishing unique codes for your facility will be the first step for the process so please have available a roster of facility names, addresses, and a point of contact for your hospital/system to coordinate activities as a single POC for your group.
- A services contract is required even though the processing is at zero cost to healthcare providers across Connecticut. The contract allows for operation to occur under the FDA EUA

FAQ

- Can we see the research and authorization?

[Critical Care Decontamination System Tech Summary](#)

[FDA Report on Decontamination and Reuse of N95 Respirators](#)

[FDA EUA - March 29, 2020](#)

- Does each System get its own N-95 masks back?

- Yes

- Where else is this being done?:

- 300+ Health systems in Ohio, New York, New Jersey, Washington, Illinois, and Massachusetts. Adding up to 60 sites across the United States by the end of April.

- What are the transportation requirements?

- In Ohio, systems are using their normal Bio courier services, internally or outsourced

FAQ (cont'd)

- What are the Labelling requirements?
 - Each N95 respirator is to be labeled at the health system with permanent Sharpie marker and include:
 - 3-digit Hospital Code, Site Location (floor, dept., etc) - additional identifying information (i.e. “Owners” Initials) is at discretion of hospital systems
 - The number of decontamination cycles is marked by Battelle to track over life of respirator
- What is the yield?
 - In Ohio we started at about 88% of received masks, now up to about 95% - major issue was make-up
- Is Battelle planning to decontaminate other PPE?
 - We are currently running several items in our research chamber in Ohio (ventilator parts, face shields, gowns...)
 - As soon as data supports adding these items, Battelle will work with FDA to expand the EUA
- 2016 Research indicates N95 respirators can undergo 20 decontamination cycles without significant degradation in operational performance
 - Other factors such as the number of donning and doffing cycles and proper fit need to be considered



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It can be done

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