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™

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

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™

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

2. Contact Us to Get Your Code
   - Enrollee signs contract and contacts Battelle POC to receive their 3-digit codes for each facility

3. Property Label Respirators
   - Once the 3-digit codes are received from Battelle, enrollee collects N95 respirators
   - N95 respirators must be unsold (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](http://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 maker 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