



Thank you for your interest in the <u>Battelle CCDS Critical Care Decontamination</u> <u>System.^{TM1}</u>

The Battelle CCDS[™] is grounded on a study Battelle completed for the FDA in 2016 in the event of a pandemic.

Battelle received an <u>FDA Emergency Use Authorization</u> (EUA) for the Battelle CCDSTM and we are now standing up decontamination sites across the United States.

This guide is designed to help you understand the process from CCDS enrollment to receiving your decontaminated N95.

Questions? Please visit our website: www.battelle.org/N95 or reach out to your Battelle point-of-contact (POC).



About Battelle CCDSTM



Battelle CCDS™ - The Mission to Help

- 2016 FDA study: Proves Vapor Phase Hydrogen Peroxide (VPHP) process to decontaminate N95 respirators is effective in the event of a pandemic
 - FDA Report on Decontamination and Reuse of N95 Respirators
- January 2020: Battelle scientists begin research on the novel coronavirus (SARS-CoV-2)
- March 6-22: Battelle builds the first CCDS system, tests validity, proves capacity effectiveness on thousands of N95 per cycle
 - Critical Care Decontamination System Tech Summary



Testing Run Cycles



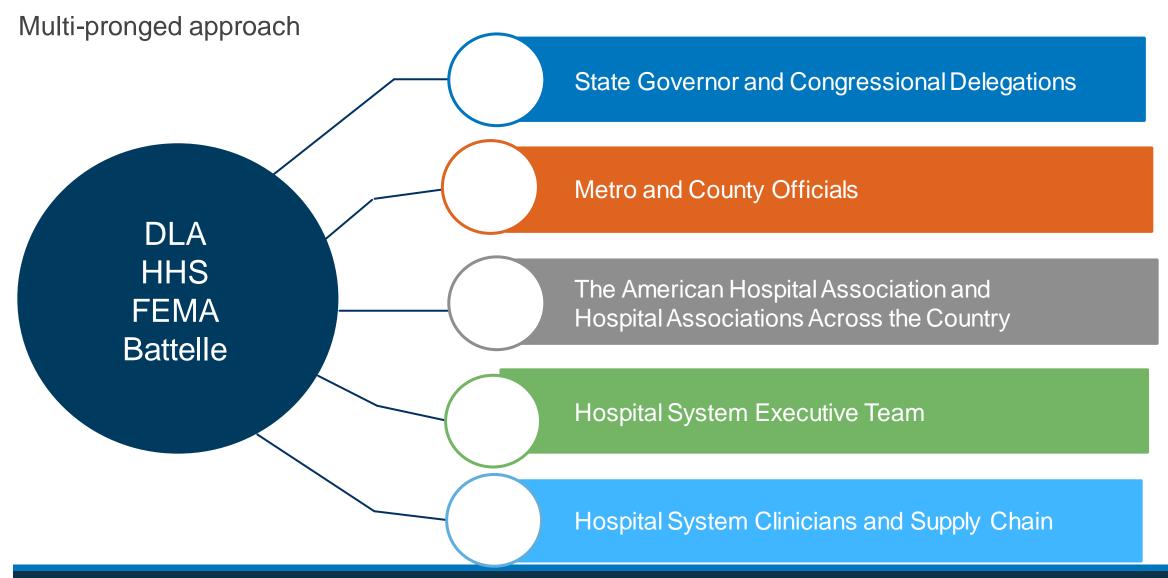
Zero Cost and Scaling Up Across the U.S.

- March 29: Awarded <u>FDA EUA</u> to decontaminate N95 respirators up to 20 times for each mask and deployment across the U.S.
- April 9: Federal Government contract awarded
 - Zero cost to healthcare providers
 - Rapid scale and deployment of 60 CCDS systems to regions across the U.S.





CCDS: Communication



Enrollment and CCDS Process



Battelle CCDS™ Process

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



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





Contact Us to **Get Your Code**

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





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





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



Properly Package

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





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

- 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







CCDS: Fast Facts

- The Battelle Critical Care Decontamination System[™] is a self-contained, mobile decontamination system that uses vapor phase hydrogen peroxide (VPHP) to decontaminate N95 respirator masks
- The Battelle CCDS[™] decontamination cycle successfully generates a microcondensation through the dwell phase and provide > 6-log reduction as indicated by collocated chemical indicator.
- Battelle CCDS™ renders SARS-CoV-2 non-infectious on N95 respirators and enables up to 20 reuses without degrading filter performance to help address the current U.S. PPE shortage
- Battelle CCDS™ is effective against both viral and bacterial agents. Battelle tested VPHP decontamination efficacy against SARS-CoV-2 in our Bio Safety Level 3 (BSL 3) laboratories.
- Battelle is the largest, private, non-profit research and development organization in the world.



CCDS: PPE Collection

Detailed information on the N95 collection process and how to prep your N95s are included in instructions when you enroll.

- Your organization should create a collection station at the point of generation (i.e. hospital floor/unit)
- Each station should have a large plastic bag placed in a rigid container provided by the healthcare facility to collect compatible N95 respirators
- 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

Important bagging tip: Bag N95s in large plastic bags. Double bag. Wipe the outside with disinfectant. Place in a shipping box labeled with a bio-hazard label.

Visit our FAQ page for more information: www.battelle.org/N95 or contact your Battelle point-of-contact (POC) directly.

CCDS: PPE Labeling

3-Digit Site Code

- Your 3-digit site code is hospital site specific and assigned by your Battelle POC
- Each N95 respirator and the outside of each shipping box must be labeled with the 3-digit site code
- Healthcare Systems adds 2-digits with additional identifying information (i.e. floor, department)
- Each healthcare system receives their own decontaminated N95 back.

Important tip: All N95s must be labeled correctly and be free of **blood**, **mucus**, **makeup** etc.







CCDS: FAQs

Q: Does each system get its own N-95 respirators back?

A: Yes. Each N95 respirator and external shipping box is labeled with a 3-digit site specific hospital code that is assigned by Battelle

Q: Will labeling respirators with permanent marker damage their performance?

A: No. Battelle has tested N95 respirators from multiple manufacturers by labeling with permanent marker as described in the FDA EUA, then decontaminating via multiple cycles of CCDS. No performance issues have been observed.

Q: Will labeling respirators with permanent marker impact decontamination effectiveness?

A: No. Battelle tested CCDS decontamination performance with N95 respirators labeled with permanent marker, which has a known chemistry. No issues were observed.



Questions?
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It can be done