



# Personal Protective Equipment – Decontamination for Reuse

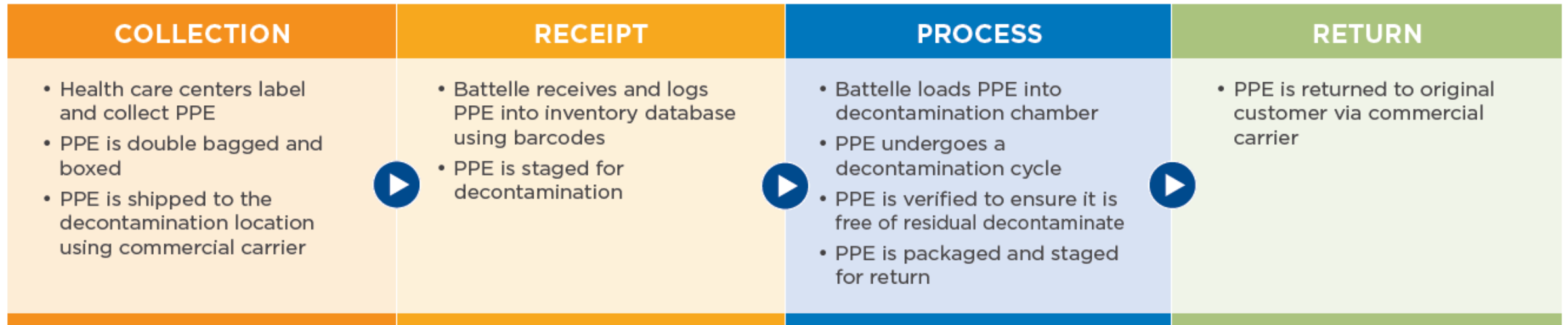
5<sup>th</sup> April 2020

# 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
- A system is operational at Camp Murray, Tacoma, to serve Washington and the Pacific Northwest
  - Battelle is processing thousands of N95 mask per day in Ohio and NY
  - Capacity available in WA for up to 20k units today
  - Battelle will expand that to 80K units per day if needed by the region

# PPE Decontamination Process Flow

## Battelle CCDS™ Process



[Battelle.org/decon](https://www.battelle.org/decon)

# Enrollment Process

- Contact Jon Cartlidge at (614) 519-2318 or [cartlidgej@battelle.org](mailto:cartlidgej@battelle.org)
- We will put a contract in place between Battelle and the system for liability
- Contract allows operation to occur under the FDA EUA
- The contract currently shows a \$3.25/mask cost
- Battelle is working hard to get financial support to make this cost \$0.00 per mask and will update all contracts to reflect that costs if/when financing is secured

[Battelle.org/decon](https://www.battelle.org/decon)

# 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?:

- 125+ Health systems in Ohio, Long Island, NYC. Adding Boston and Chicago this week, 55 other locations this month

- 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



# ***BATTELLE***

**It can be done**

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