Personal Protective Equipment – Decontamination for Reuse

5th 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**

<table>
<thead>
<tr>
<th>COLLECTION</th>
<th>RECEIPT</th>
<th>PROCESS</th>
<th>RETURN</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Health care centers label and collect PPE</td>
<td>• Battelle receives and logs PPE into inventory database using barcodes</td>
<td>• Battelle loads PPE into decontamination chamber</td>
<td>• PPE is returned to original customer via commercial carrier</td>
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<tr>
<td>• PPE is double bagged and boxed</td>
<td>• PPE is staged for decontamination</td>
<td>• PPE undergoes a decontamination cycle</td>
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<tr>
<td>• PPE is shipped to the decontamination location using commercial carrier</td>
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<td>• PPE is verified to ensure it is free of residual decontaminant</td>
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<tr>
<td></td>
<td></td>
<td>• PPE is packaged and staged for return</td>
<td></td>
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</tbody>
</table>

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Enrollment Process

• Contact Jon Cartlidge at (614) 519-2318 or 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

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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 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