**Assessment of Filtration Efficiency, Manikin Fit Performance, and Strap Performance for Decontaminated N95 Filtering Facepiece Respirators**

**Introductory Information**

Supplies of N95® filtering facepiece respirators (FFRs) can become depleted during widespread outbreaks of infectious respiratory illnesses. To supplement the national inventory of NIOSH Approved® N95 FFRs during times of extreme shortages, FFR reuse following decontamination is a possible strategy. Decontamination is a process to reduce the number of pathogens on used FFRs before reuse. An effective FFR decontamination technique should significantly reduce the pathogen burden, but not reduce a respirator’s filtration performance or its ability to fit properly. Another consideration is that no hazardous chemical residue should be left on the FFR following the decontamination process.

During non-emergencies, FFRs are considered limited-use products and are not approved for decontamination and reuse; however, when there are known FFR shortages, FFR decontamination and reuse may need to be implemented as a crisis capacity strategy to ensure continued availability after conventional and contingency strategies have been implemented. On March 29, 2020, the U.S. Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a decontamination technique to be considered to offset N95 FFR supply shortages with subsequent EUAs and revisions issued. The purpose of this assessment was to determine the effects of various decontamination processes on the particulate filtration performance, manikin fit, and strap integrity of various N95 FFR models. The assessment did not assess the reduction of the pathogen burden by the decontamination procedure.

**Methods Collection**

Assessment Requests

* Received from multiple organizations (e.g., hospitals, universities, private companies performing sterilization services, and government and private research laboratories)
* Requestor Provided
  + Respirator manufacturer name
  + Model number
  + Detailed description of the decontamination method
  + Number of decontamination cycles
  + Decontaminated and control (i.e., new, unused, not decontaminated respirators of the same manufacturer and model) N95 FFRs

Respirators

* N95 FFRs (model at the discretion of the requestor) that had not been worn or exposed to any pathogenic microorganisms and decontaminated up to 30 cycles
  + 15 decontaminated and five new (controls) tested—some submitting organizations provide fewer samples because of scarce resources
* Total of 1,354 tested
* Models tested
  + 3M 1860, 1860S, 1870, 1870+, 8000, 8200, 8210, 8210+, 8210V, 8511, 9205+, V-Flex 1804, V-Flex 1805, and V-Flex 9105
  + BYD DE2322
  + Crosstex GPRN95
  + Gerson 1730 and 1740
  + Halyard 46727, 46767, and 62126
  + Makrite 9500-N95S
  + Moldex 1512 and 2200
  + Prestige Ameritech RP88020
  + Sperian N1105, N1125, and One-Fit
  + VWR 89201-508

Decontamination Methods

* Aerosolized Peracetic Acid (PAA)
* Chlorine dioxide gas
* Commercial steamer
* DiKlor-G® sterilization
* Dry heat (commercial laundry dryer)
* Dry heat (environmental chamber)
* Electron beam irradiation
* Gaseous ozone
* Gravity steam
* Methylene blue plus light
* Stryker STERIZONE VP4 Sterilizer
* Supercritical carbon dioxide (CO2)
* Microwave generated plasma
* Moist heat
* Plasma Discharge Reactive Oxygen Species
* Sterrad NX100 HPV/low temp plasma
* Ultraviolet Germicidal Irradiation (UVGI)
* UVGI in combination with infrared heat
* Vapor Phase Hydrogen Peroxide (VPHP)

Performance Test Methods

* Visual inspection for signs of component damage or discoloration compared to controls
* Particulate Filter Efficiency
  + Ten respirators
  + Exhalation valves were sealed (if equipped)
  + Tested on a TSI 8130 and/or 8130A Automated Filter Tester
  + Flow rate: 85.0 ± 4.0 Liters/min.
  + Aerosol concentration: ≤ 200 mg/m3
  + Particle size distribution: count median diameter 0.075 ± 0.020 µm with a geometric standard deviation not exceeding 1.86
  + Tested for 10 minutes
  + Maximum penetration recorded
* Manikin Fit
  + Respirator fit was assessed on static advanced headform (StAH), either medium size (Hanson Robotics Inc., Plano, TX) (corresponding to the medium size dimensions of the NIOSH Principal Component Analysis Panel) or large size (Lunar Studios, Wylie, TX)
  + Overall manikin fit factor (mFFO) was determined
    - 5 respirators that were subjected to decontamination procedures
    - 2 control respirators that are new and were not decontaminated
  + Respirators donned to the headform following the respirator manufacturer’s guidance for correct headstrap placement and adjustment of the bendable noseclip (if equipped)
  + Two cyclic minute-volumes
    - Normal breathing (14 breaths / min (bpm) x 800 ml tidal volume = 11.2 lpm
    - Deep breathing (12 bpm x 1700 ml tidal volume = 20.4 lpm
  + Measured using a PortaCount® Pro+ model 8038 Respirator Fit Tester (TSI, Inc., Shoreview, MN) operating in the N95-enabled mode.
    - Ambient room aerosol supplemented with generated sodium chloride aerosol
  + Three successive 86-sec exercises
    - Initial normal breathing exercise (NB1)
    - Deep breathing exercise (DB)
    - Second normal breathing exercise (NB2).
    - Four manikin fit factors (mFFs) are obtained for each test—one for each of the three exercises and mFFO, calculated as the harmonic mean of the mFFs from the three individual exercises
* Strap Integrity
  + Top and bottom straps removed from 5 respirators
  + Assessed using an Instron 5943 tensile tester
  + Straps sectioned into 10-cm segments
  + Each strap was inserted into an Instron tensile tester and pulled at 1 cm/s until 200% strain (30 cm sample length) and then held extended for 2 minutes.
  + Straps were returned to their original position and the new segment length was measured after 5 minutes
  + Straps were then pulled at 1 cm/s until reaching 150% strain of the new length, held extended for 30 seconds, and the force at the end of the 30 seconds was recorded
* Manufacturer lot-to-lot product variability was not evaluated for any tests.

**Attribution**

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