

## Evaluation of Decontaminated N95 Respirators

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**Date Tested:** 4/22/2020

**Respirator Model:** 3M 8200

**Tests:** Filtration with NaCl (modified version of STP-0059) and Strap Integrity with Tensile Testing

**Decontamination Method:** High energy (10 MeV), high dose rate (3 kGy/s) electron beam irradiation at 25 kGy per decontamination cycle.

**Decontamination Cycles:** 1, 2, and 3

While decontamination and reuse of FFRs are not consistent with standard and approved usage, these options may need to be considered when FFR shortages exist. This assessment was developed to quantify the filtration efficiency and manikin fit factor<sup>1</sup> of an N95 respirator that has been decontaminated. This assessment is not to determine the effectiveness of the decontamination procedure at killing pathogenic microorganisms. The results provided in this report are specific to the subset of samples that were provided to NPPTL for evaluation. These results may be used to update the CDC guidance for Crisis Capacity Strategies (during known shortages).

Twelve respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 3 respirators that were subjected to 1 cycle of the electron beam irradiation process, 3 respirators that were subjected to 2 cycles, 3 respirators that were subjected to 3 cycles, and 3 respirators that served as controls. Manikin fit factor testing was not conducted as part of this assessment due to the limited number of samples provided. Figure 1 photos document the procedures used. The samples were tested using a modified version of the NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059 to determine particulate filtration efficiency. The TSI, Inc. model 8130 using sodium chloride aerosol was used for the filtration evaluation. Additionally, tensile strength testing of the straps was performed to determine changes in strap integrity. The Instron® 5943 Tensile Tester was used for this evaluation. The full assessment plan can be found [here](#).

**Filtration Efficiency Results:** The minimum and maximum filter efficiencies were; 46.6% and 55.7% (1 cycle); 47.2% and 51.1% (2 cycles); 47.4% and 50.6% (3 cycles). All samples measured less than 95%. See Table 1.

**Strap Integrity Results:** No visual degradation of the straps was observed. Increases in recorded force were found in the treated samples for the top (3.49%) and bottom (0.80%) straps subjected to 1 cycle, the top (11.78%) and bottom (0.99%) straps subjected to 2 cycles, and the top (14.64%) and bottom (7.19%) straps subjected to 3 cycles. While the exact correlation between the force exerted by straps and fit is not well understood, higher force values may be associated with a tighter fit of the respirator to the face. Significant reductions in this force would be associated with a loss of elasticity of the straps, thereby reducing their ability to create a tight fit. See Table 2.

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<sup>1</sup>The American Industrial Hygiene Association defines the Manikin Fit Factor as “An expression related to the amount of leakage measured through the face or neck seal of a respirator mounted to a manikin under specified airflow and environmental conditions. If the challenge to the seal is an airborne substance, it is the ratio of its airborne concentration outside the respirator divided by the concentration that enters the respirator through the seal. If the challenge is airflow or air pressure, conditions and assumptions for quantifying leakage must be specified. Leakage from other sources (e.g., air purifying elements) must be essentially zero. The respirator may be mounted to the manikin without sealants; be partially sealed to the manikin; or be sealed to the manikin with artificially induced leaks.”



**Figure 1. Laboratory Test Photos**

**Table 1. Filter Efficiency Evaluation – 3M 8200, Electron beam irradiation (1,2, and 3 cycles)**

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
<b>3M 8200 electron beam irradiation 1 cycle</b>  Min Fil Eff: 46.6%  Max Fil Eff: 55.7%	<b>1</b>	85	10.4	44.3	44.3	<b>55.7%</b>
	<b>2</b>	85	10.0	52.1	52.1	<b>47.9%</b>
	<b>3</b>	85	10.1	53.4	53.4	<b>46.6%</b>
<b>3M 8200 electron beam irradiation 2 cycles</b>  Min Fil Eff: 47.2%  Max Fil Eff: 51.1%	<b>1</b>	85	10.9	51.3	52.3	<b>47.7%</b>
	<b>2</b>	85	10.2	52.8	52.8	<b>47.2%</b>
	<b>3</b>	85	11.1	48.9	48.9	<b>51.1%</b>
<b>3M 8200 electron beam irradiation 3 cycles</b>  Min Fil Eff: 47.4%  Max Fil Eff: 50.6%	<b>1</b>	85	12.0	49.4	49.4	<b>50.6%</b>
	<b>2</b>	85	11.7	51.0	51.0	<b>49.0%</b>
	<b>3</b>	85	10.5	52.6	52.6	<b>47.4%</b>
<b>3M 8200 (control)</b>	<b>1</b>	85	12.4	1.33	1.33	98.7%
	<b>2</b>	85	10.4	1.06	1.08	98.9%
	<b>3</b>	85	11.5	0.96	0.99	99.0%

Notes:

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not necessarily meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- **BOLD** filter efficiencies < 95%.

**Table 2. Strap Integrity Evaluation – 3M 8200, Electron beam irradiation (1, 2, and 3 cycles)**

Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)		
# of cycles, Straps from Treated Sample #	Force in Top Strap (N)	Force in Bottom Strap (N)
1 cycle, sample #1	4.61	5.062
1 cycle, sample #2	4.286	4.881
1 cycle, sample #3	4.446	4.777
<b>Decontaminated Strap Average (1 cycle)</b>	<b>4.447</b>	<b>4.907</b>
2 cycles, sample #1	4.631	4.916
2 cycles, sample #2	4.534	4.67
2 cycles, sample #3	5.244	5.162
<b>Decontaminated Strap Average (2 cycles)</b>	<b>4.803</b>	<b>4.916</b>
3 cycles, sample #1	4.79	5.069
3 cycles, sample #2	4.92	5.332
3 cycles, sample #3	5.069	5.254
<b>Decontaminated Strap Average (3 cycles)</b>	<b>4.926</b>	<b>5.218</b>
Control 1	4.411	5.035
Control 2	4.183	4.701
<b>Control Strap Average</b>	<b>4.297</b>	<b>4.868</b>
% Change – 1 cycle ((Deconned-Control) / Controls)	3.49%	0.80%
% Change – 2 cycles ((Deconned-Control) / Controls)	11.78%	0.99%
% Change – 3 cycles ((Deconned-Control) / Controls)	14.64%	7.19%