Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 10/21/2020 – 10/22/2020

Respirator Model(s): 3M 8200

Tests: Filtration with NaCl (modified version of STP-0059), Manikin Fit Factor with Static Advanced Headform, and Strap Integrity with Tensile Testing

Decontamination Method: Three N95 FFRs were sealed in a 6"x 9" Tyvek envelope and placed in its own 2 L glass jar with 1/3 of a paper towel and a 10 mL glass beaker. Between 50-100 µL saturated aqueous solution of technical grade sodium chlorite (80% by mass $NaClO_2$, 18% NaCl) and the same volume of saturated aqueous sodium hydrogen sulfate were added as separate drops to the bottom of the 10 mL beaker. The jar was sealed with a metal screw-on lid with Luer lock feedthroughs and stop cocks or a single #000 rubber stopper. The jar was tipped to mix solutions and begin chlorine dioxide gas generation. After 120 minutes, 5-10 mL saturated aqueous sodium sulfite was added by syringe needle or Pasteur pipet to wet the paper towel. After another 120 minutes, the FFR was removed from the Tyvek envelope. This process was repeated a total of 5 cycles for each set of FFRs. The total dose of chlorine dioxide gas to each FFR was approximately 5 x 850 ppm-hours, as measured by gas sampling through the feedthroughs and measurement of the optical absorbance at 351 nm.

Decontamination Cycles: 5 cycles

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[1] 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).

Twenty respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 15 respirators that were subjected to 5 cycles of the chlorine dioxide gas decontamination process and an additional 5 respirators that served as controls. 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. For the laboratory fit evaluation, a static manikin headform was used to quantify changes in manikin fit factor. The TSI, Inc. PortaCount® PRO+ 8038 in "N95 Enabled" mode was used for this 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 98.74% and 99.52%, respectively. All ten respirators measured efficiencies greater than 95%. See Table 1.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for all respirators evaluated. The manikin fit test procedure used in this assessment did not show any detriments in fit associated with the decontamination method used. See Table 2.

Strap Integrity Results: The top straps showed a 6.70% decrease in recorded force and the bottom straps showed a 11.05% decrease in force. See Table 3.

Other Notes: Discoloration of the treated FFRs nose foam and straps (yellow/brown nose foam and straps) when compared to the control samples (grey nose foam, white straps) were observed. See Figures 1D and 1E.

[1]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

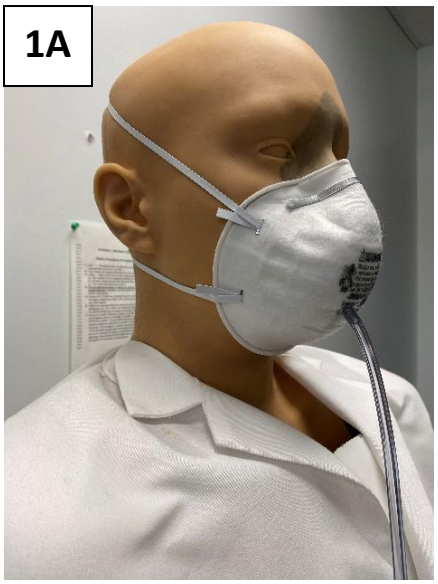

Fig. 1A. Medium Static Advanced Headform

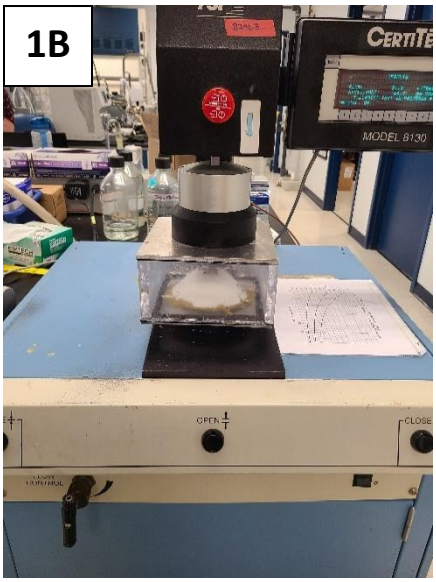

Fig. 1B. TSI 8130 Filter Tester

Fig. 1C. Instron 5934 Tensile Tester

Fig. 1D. Nose Foam Discoloration (Left-Control, Right-Treated)

Fig. 1E. Strap Discoloration (Top-Control, Bottom-Treated)

Table 1. Filter Efficiency Evaluation

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M 8200, controls	**Control 1**	85	12.3	0.780	0.968	99.03
	Control 2	85	13.1	0.667	0.751	99.25
	Control 3	85	13.1	0.537	0.587	99.41
3M 8200, chlorine dioxide gas, 5 cycles	**1**	85	11.1	0.420	0.488	99.51
	2	85	11.4	0.564	0.634	99.37
	3	85	11.2	0.453	0.481	99.52
	4	85	13.3	0.997	1.05	98.95
	5	85	13.2	1.16	1.19	98.81
	6	85	12.2	0.736	0.761	99.24
Min Fil Eff: 98.74%	**7**	85	12.2	0.933	1.26	98.74
Max Fil Eff: 99.52%	**8**	85	16.8	1.13	1.13	98.87
	9	85	13.4	0.638	0.701	99.30
	10	85	13.2	0.998	1.02	98.98

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.

Table 2. Manikin Fit Evaluation

Manikin Fit Factor of Decontaminated N95s					
Respirator Model, Decon Method, # of cycles	**Treated Sample #**	**mFF Normal Breathing 1**	**mFF Deep Breathing**	**mFF Normal Breathing 2**	**Overall Manikin Fit Factor**
3M 8200, controls	**Control 4**	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+
3M 8200, chlorine dioxide gas, 5 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	200+	200+	200+	200+
	14	200+	200+	200+	200+
	15	200+	200+	200+	200+

Notes:

- Per OSHA 1910.134(f)(7), if the fit factor as determined through an OSHA-accepted quantitative fit testing protocol is equal to or greater than 100 for tight-fitting half facepieces, then the fit test has been passed for that respirator.
- This assessment does not include fit testing of people and only uses two exercises (normal and deep breathing) on a manikin headform.
- This assessment is a laboratory evaluation using a manikin headform and varies greatly from the OSHA individual fit test. This headform testing only includes normal breathing and deep breathing on a stationary (non-moving) headform; therefore, fit results from this assessment cannot be directly translated to using the standard OSHA-accepted test. Instead, this testing provides an indication of the change in fit performance (if any) associated with the decontamination of respirators.

Table 3. Strap Integrity Evaluation

Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)			
Respirator Model, Decon Method, # of cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
3M 8200, controls	**Control 1**	3.673	3.692
	Control 2	3.618	3.525
	Control 3	3.459	3.380
	Control Strap Average	3.583	3.532
3M 8200, chlorine dioxide gas, 5 cycles	**1**	3.229	3.282
	2	3.390	3.136
	3	3.411	3.008
	Decontaminated Strap Average	3.343	3.142
	% Change ((Deconned – Controls)/ Controls)	-6.70%	-11.05%