Date Tested: 5/8/2020-5/11/2020 and 5/15/2020 – 5/18/2020

Respirator Model: 3M 8000

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

Decontamination Method: Treatment with gas phase chlorine dioxide at 1000~2000 ppm·hr

Decontamination Cycles: 5, 10, and 20 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).

60 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 15 respirators that were subjected to 20 cycles of the chlorine dioxide gas decontamination process, 15 respirators subjected to 10 cycles, 15 respirators subjected to 5 cycles, and an additional 15 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 98.84% and 99.30%, respectively for the 3M 8000 (20 cycles). All respirators measured more than 95%. See Table 1. Filter efficiencies for the 3M 8000 (5 and 10 cycles) were not assessed.

Manikin Fit Factor Results: One control respirator did not achieve acceptable fit (mFF ≥ 100). However, since all other control respirators achieved acceptable fit, the treated samples were assessed for manikin fit. All samples treated at 5 cycles and 10 cycles achieved acceptable fit, while one sample at 20 cycles did not. See Table 2.

Strap Integrity Results: The 3M 8000 decontaminated straps (5, 10, and 20 cycles) were discolored (brownish), compared to the control straps (white). Top and bottom straps showed decreases in recorded force at 5 cycles (10.24% and 6.14%), 10 cycles (15.03% and 6.14%), and 20 cycles (7.87% and 4.73%). While the exact correlation between the force exerted by straps and fit is not well understood, higher force values may be

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[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."

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 3.
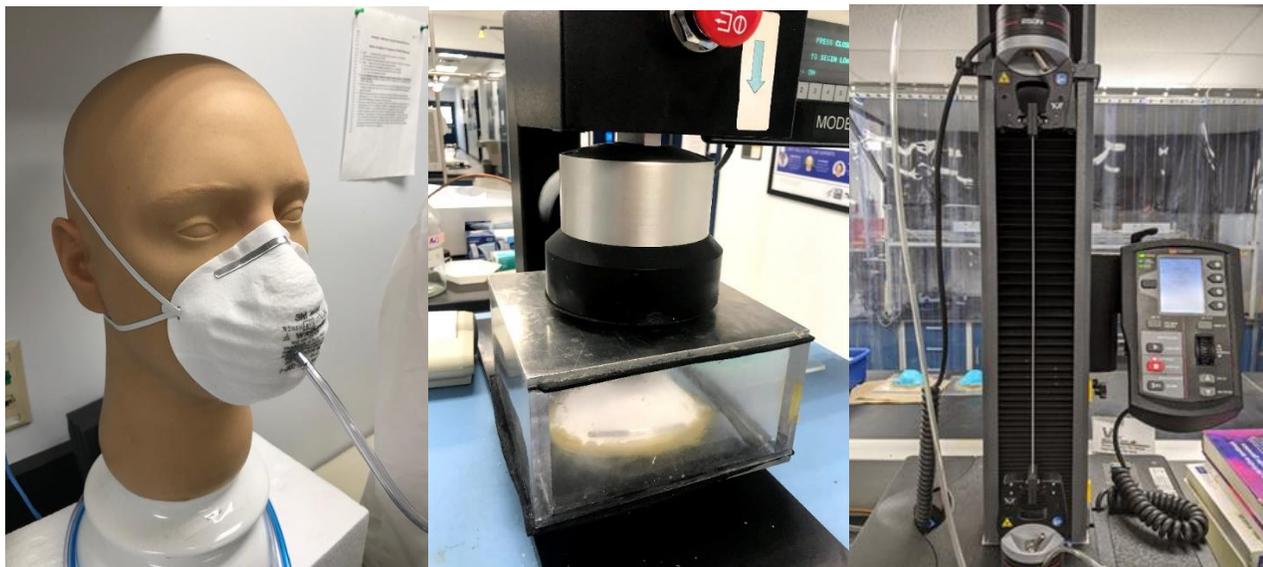

Figure 1. Laboratory Test Photos

Table 1. Filter Efficiency Evaluation

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH$_2$O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M 8000, Chlorine Dioxide, 20 cycles Min Fil Eff: 98.84% Max Fil Eff: 99.30%	1	85	12.6	0.399	0.706	99.29
	2	85	12.0	0.437	0.704	99.30
	3	85	11.3	0.730	1.160	98.84
	4	85	11.5	0.534	0.898	99.10
	5	85	11.8	0.407	0.778	99.22
	6	85	11.3	0.512	0.891	99.11
	7	85	11.8	0.497	0.862	99.14
	8	85	12.1	0.421	0.837	99.16
	9	85	12.4	0.381	0.797	99.20
	10	85	12.0	0.526	0.920	99.08
	Control 1	85	12.2	0.354	0.583	99.42
	Control 2	85	11.8	0.446	0.761	99.24
	Control 3	85	11.6	0.368	0.624	99.38

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 8000, Chlorine Dioxide, 0 cycles (control) Static Advanced Large Headform (Lunar Studios)	**Control 4**	70	57	62	**62**
	Control 5	186	94	82	106
	Control 10	200+	200+	200+	200+
	Control 11	200+	200+	200+	200+
	Control 12	200+	200+	200+	200+
	Control 13	200+	200+	200+	200+
3M 8000, Chlorine Dioxide, 5 cycles Static Advanced Large Headform (Lunar Studios)	**11**	153	107	73	101
	12	200+	200+	200+	200+
	13	200+	200+	200+	200+
	14	200+	200+	200+	200+
	15	200+	200+	200+	200+
3M 8000, Chlorine Dioxide, 10 cycles Static Advanced Large Headform (Lunar Studios)	**11**	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	200+	170	169	179
	14	200+	200+	200+	200+
	15	139	112	73	100
3M 8000, Chlorine Dioxide, 20 cycles Static Advanced Large Headform (Lunar Studios)	**11**	167	129	115	134
	12	104	93	81	**92**
	13	200+	200+	200+	200+
	14	200+	191	159	182
	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.
- **BOLD** overall manikin fit factor < 100.

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 8000, Chlorine Dioxide, 0 cycles (control)	Control 1	4.003	3.544
	Control 2	4.006	3.669
	Control 6	4.052	3.566
	Control 7	3.861	3.578
	Control 8	3.848	3.433
	Control 9	3.782	3.515
	Control Strap Average	**3.925**	**3.551**
3M 8000, Chlorine Dioxide, 5 cycles	1	3.459	3.308
	2	3.560	3.361
	3	3.549	3.330
	Decontaminated Strap Average	**3.523**	**3.333**
	% Change ((Deconned - Controls) / Controls)	-10.24%	-6.14%
3M 8000, Chlorine Dioxide, 10 cycles	1	3.499	3.231
	2	3.249	3.357
	3	3.256	3.410
	Decontaminated Strap Average	**3.335**	**3.333**
	% Change ((Deconned - Controls) / Controls)	-15.03%	-6.14%
3M 8000, Chlorine Dioxide, 20 cycles	1	3.535	3.487
	2	3.614	3.324
	3	3.700	3.339
	Decontaminated Strap Average	**3.616**	**3.383**
	% Change ((Deconned - Controls) / Controls)	-7.87%	-4.73%