Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 10/29/2020 – 11/5/2020

Respirator Model(s): 3M VFlex 1804, 3M Aura 9205+, 3M 1860, 3M 1860S, 3M Aura 1870+

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

Decontamination Method: Dry heat decontamination was performed in a 2 ft^3 environmental chamber. Each respirator was sealed in its own Tyvek sterilization pouch and loaded into the chamber. All respirators were exposed to cycles of 75-78°C recirculating hot air for 45 minutes, followed by cooling to ambient. 10 consecutive cycles of heat treatment were performed. A chemical indicator was affixed to each pouch to verify that all respirators reached the target decontamination temperature. Temperature profiles were also recorded to confirm that the air temperature in the chamber remained within specification for the entirety of the soak segment during each cycle.

Decontamination Cycles: 10 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).

One hundred respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 75 respirators that were subjected to 10 cycles of the dry heat decontamination process and an additional 25 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.

Other Notes: The 3M VFlex 1804, 3M 1860 and 3M 1860S treated respirators had observable blurring of the printed information found on the front side of the respirators. Figure 1A-1F shows a comparison between a control sample and a treated sample of the noted respirator models.

3M VFlex 1804

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 98.98% and 99.85%, 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 five out of seven respirators evaluated. One control and one treated sample received failing fit factors < 100. See Table 2.

[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."

Strap Integrity Results: The top straps showed a 4.82% decrease in recorded force and the bottom straps showed a 0.59% increase in force. See Table 3.

3M Aura 9205+

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 99.39% and 99.91%, respectively. All ten respirators measured efficiencies greater than 95%. See Table 4.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for all respirators evaluated. See Table 5.

Strap Integrity Results: The top straps showed a 5.90% increase in recorded force and the bottom straps showed a 6.83% increase in force. See Table 6.

3M 1860

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 97.70% and 98.96%, respectively. All ten respirators measured efficiencies greater than 95%. See Table 7.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for all respirators evaluated. See Table 8.

Strap Integrity Results: The top straps showed a 5.62% decrease in recorded force and the bottom straps showed a 0.11% increase in force. See Table 9.

3M 1860S

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 97.86% and 98.79%, respectively. All ten respirators measured efficiencies greater than 95%. See Table 10.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for all respirators evaluated. See Table 11.

Strap Integrity Results: The top straps showed a 8.71% decrease in recorded force and the bottom straps showed a 5.79% decrease in force. See Table 12.

3M Aura 1870+

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 98.95% and 99.98%, respectively. All ten respirators measured efficiencies greater than 95%. See Table 13.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for all respirators evaluated. See Table 14.

Strap Integrity Results: The top straps showed a 3.25% increase in recorded force and the bottom straps showed a 1.28% decrease in force. See Table 15.

Figure 1. Sample Observations

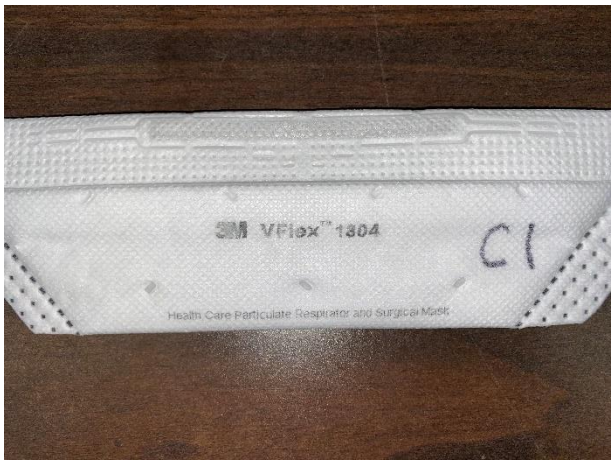

Fig. 1A. 3M VFlex 1804 - Control

Fig. 1B. 3M VFlex 1804 - Treated

Fig. 1C. 3M 1860 - Control

Fig. 1D. 3M 1860 - Treated

Fig. 1E. 3M 1860S - Control

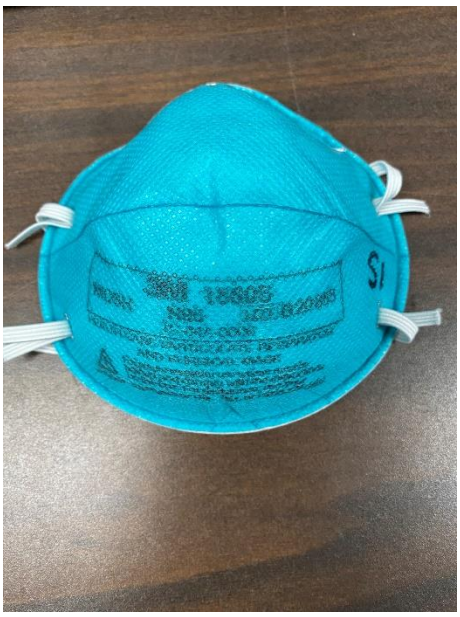

Fig. 1F. 3M 1860S - Treated

Figure 2. Laboratory Test Photos

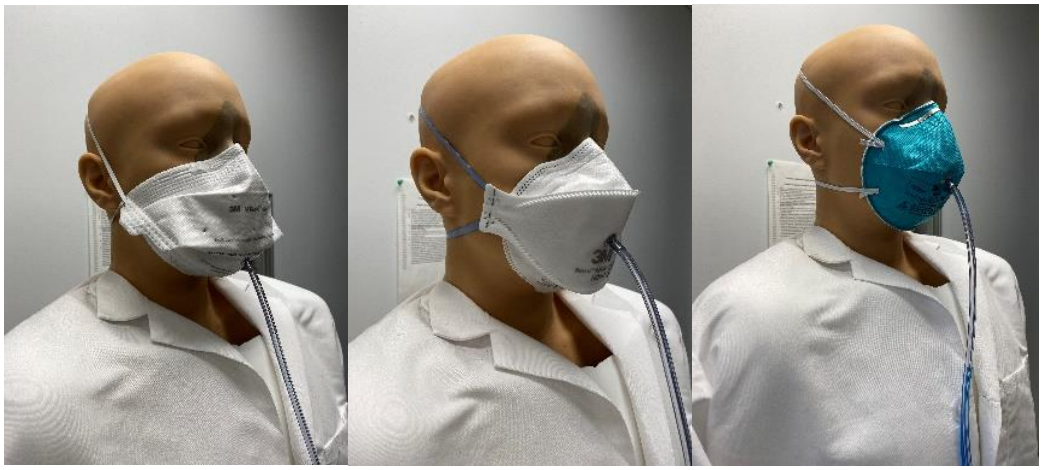

Fig. 2A. Medium Static Advanced Headform

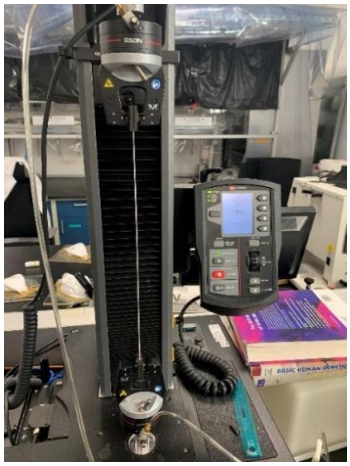

Fig. 2B. Instron 5943 Tensile Tester

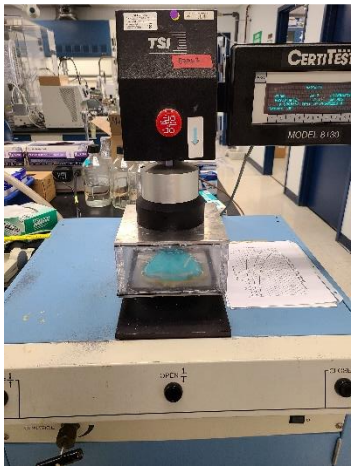

Fig. 2C. TSI 8130 Filter Tester

Table 1. Filter Efficiency Evaluation – 3M VFlex 1804

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 VFlex 1804, Controls	**Control 1**	85	6.0	0.170	0.218	99.78
	Control 2	85	4.6	0.084	0.192	99.81
	Control 3	85	5.6	0.292	0.318	99.68
3M VFlex 1804, Dry Heat, 10 cycles Min Fil Eff: 98.98% Max Fil Eff: 99.85%	**1**	85	4.7	0.085	0.147	99.85
	2	85	4.7	0.160	0.242	99.76
	3	85	4.5	0.236	0.531	99.47
	4	85	4.3	0.862	1.020	98.98
	5	85	4.3	0.122	0.271	99.73
	6	85	4.5	0.108	0.185	99.82
	7	85	4.9	0.330	0.433	99.57
	8	85	4.5	0.100	0.189	99.81
	9	85	4.6	0.137	0.218	99.78
	10	85	4.9	0.137	0.245	99.76

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 – 3M VFlex 1804

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 VFlex 1804, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	169	93	200+	138
	Control 5	108	85	61	**80**
3M VFlex 1804, Dry Heat, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	200+	200+	200+	200+
	14	147	39	97	**70**
	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 factors < 100.

Table 3. Strap Integrity Evaluation – 3M VFlex 1804

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 VFlex 1804, Controls	**Control 1**	2.923	2.793
	Control 2	2.791	2.746
	Control 3	2.708	2.911
	Control Strap Average	2.807	2.817
3M VFlex 1804, Dry Heat, 10 cycles	**1**	2.706	2.778
	2	2.721	2.882
	3	2.614	2.869
	4	2.646	2.805
	Decontaminated Strap Average	2.672	2.834
	% Change ((Deconned - Controls)/ Controls)	-4.82%	0.59%

Table 4. Filter Efficiency Evaluation – 3M Aura 9205+

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 Aura 9205+, Controls	**Control 1**	85	8.1	0.060	0.105	99.90
	Control 2	85	8.5	0.239	0.306	99.69
	Control 3	85	8.5	0.004	0.034	99.97
3M Aura 9205+, Dry Heat, 10 cycles Min Fil Eff: 99.39% Max Fil Eff: 99.91%	**1**	85	7.9	0.080	0.254	99.75
	2	85	7.7	0.448	0.610	99.39
	3	85	8.1	0.033	0.167	99.83
	4	85	8.3	0.061	0.211	99.79
	5	85	9.1	0.127	0.288	99.71
	6	85	8.6	0.182	0.391	99.61
	7	85	8.4	0.023	0.095	99.91
	8	85	7.5	0.045	0.181	99.82
	9	85	7.6	0.047	0.108	99.89
	10	85	8.7	0.084	0.185	99.82

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 5. Manikin Fit Evaluation – 3M Aura 9205+

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 Aura 9205+, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	198	104	170	146
	Control 5	116	79	139	106
3M Aura 9205+, Dry Heat, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	122	106	146	123
	12	142	109	149	131
	13	162	116	132	134
	14	104	98	117	106
	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 6. Strap Integrity Evaluation – 3M Aura 9205+

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 Aura 9205+, Controls	**Control 1**	1.793	1.772
	Control 2	1.698	1.770
	Control 3	1.786	1.753
	Control Strap Average	1.759	1.765
3M Aura 9205+, Dry Heat, 10 cycles	**1**	1.921	1.962
	2	1.838	1.867
	3	1.785	1.811
	4	1.907	1.902
	Decontaminated Strap Average	1.863	1.886
	% Change ((Deconned - Controls)/ Controls)	5.90%	6.83%

Table 7. Filter Efficiency Evaluation – 3M 1860

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 1860, Controls	Control 1	85	8.5	0.540	1.030	98.97
	Control 2	85	9.6	0.316	0.713	99.29
	Control 3	85	9.2	0.362	0.744	99.26
3M 1860, Dry Heat, 10 cycles Min Fil Eff: 97.70% Max Fil Eff: 98.96%	1	85	8.6	0.510	1.170	98.83
	2	85	8.5	0.558	1.040	98.96
	3	85	8.9	0.509	1.380	98.62
	4	85	8.7	0.422	1.420	98.58
	5	85	8.5	0.820	1.280	98.72
	6	85	10.7	1.490	1.940	98.06
	7	85	13.4	1.860	2.300	97.70
	8	85	9.1	0.572	1.080	98.92
	9	85	9	0.642	1.040	98.96
	10	85	9.2	0.924	1.620	98.38

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 8. Manikin Fit Evaluation – 3M 1860

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 1860, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+
3M 1860, Dry Heat, 10 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+	80	182	130

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 9. Strap Integrity Evaluation – 3M 1860

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 1860, Controls	**Control 1**	2.974	2.640
	Control 2	3.147	2.726
	Control 3	2.967	2.657
	Control Strap Average	3.029	2.674
3M 1860, Dry Heat, 10 cycles	**1**	2.766	2.676
	2	2.972	2.817
	3	2.736	2.638
	4	2.961	2.577
	Decontaminated Strap Average	2.859	2.677
	% Change ((Deconned - Controls)/ Controls)	-5.62%	0.11%

Table 10. Filter Efficiency Evaluation – 3M 1860S

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 1860S, Controls	**Control 1**	85	11.6	0.968	1.680	98.32
	Control 2	85	11.2	0.844	1.500	98.50
	Control 3	85	11.2	1.260	2.010	97.99
3M 1860S, Dry Heat, 10 cycles Min Fil Eff: 97.86% Max Fil Eff: 98.79%	**1**	85	11.3	1.260	2.080	97.92
	2	85	11.6	0.970	1.470	98.53
	3	85	12	0.763	1.210	98.79
	4	85	12.2	0.790	1.400	98.60
	5	85	11.5	0.683	1.360	98.64
	6	85	11.7	0.736	1.296	98.70
	7	85	11.8	0.763	1.240	98.76
	8	85	10.8	1.150	2.140	97.86
	9	85	12.2	1.020	1.700	98.30
	10	85	11.9	1.050	1.690	98.31

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 11. Manikin Fit Evaluation – 3M 1860S

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 1860S, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+
3M 1860S, Dry Heat, 10 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 12. Strap Integrity Evaluation – 3M 1860S

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 1860S, Controls	**Control 1**	3.053	3.148
	Control 2	3.160	3.065
	Control 3	3.018	2.978
	Control Strap Average	3.077	3.064
3M 1860S, Dry Heat, 10 cycles	**1**	2.802	2.847
	2	2.786	2.826
	3	2.749	2.907
	4	2.899	2.966
	Decontaminated Strap Average	2.809	2.887
	% Change ((Deconned - Controls)/ Controls)	-8.71%	-5.79%

Table 13. Filter Efficiency Evaluation – 3M Aura 1870+

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 Aura 1870+, Controls	**Control 1**	85	7.1	0.000	0.064	99.94
	Control 2	85	7.6	0.000	0.065	99.94
	Control 3	85	8.6	0.011	0.068	99.93
3M Aura 1870+, Dry Heat, 10 cycles Min Fil Eff: 98.95% Max Fil Eff: 99.98%	**1**	85	7.4	0.007	0.055	99.95
	2	85	7.7	0.005	0.030	99.97
	3	85	7.8	0.007	0.022	99.98
	4	85	7.5	0.092	0.152	99.85
	5	85	9.2	0.702	0.800	99.20
	6	85	6.9	0.014	0.042	99.96
	7	85	7.4	0.098	0.148	99.85
	8	85	7.7	0.963	1.050	98.95
	9	85	7.7	0.156	0.236	99.76
	10	85	7.2	0.011	0.048	99.95

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 14. Manikin Fit Evaluation – 3M Aura 1870+

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 Aura 1870+, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	200+	185	200+	195
	Control 5	200+	169	200+	189
3M Aura 1870+, Dry Heat, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	200+	176	200+	191
	14	200+	197	200+	199
	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 15. Strap Integrity Evaluation – 3M Aura 1870+

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 Aura 1870+, Controls	**Control 1**	1.817	1.595
	Control 2	1.840	1.670
	Control 3	1.770	1.613
	Control Strap Average	1.809	1.626
3M Aura 1870+, Dry Heat, 10 cycles	**1**	1.871	1.617
	2	1.806	1.664
	3	1.842	1.599
	4	1.952	1.541
	Decontaminated Strap Average	1.868	1.605
	% Change ((Deconned - Controls)/ Controls)	3.25%	-1.28%