Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 4/14/2020

Respirator Model: N95 3M 1860S

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

Decontamination Method: Methylene Blue [10 µM] sprayed on face and underside (~7 mL / cycle). Cycle includes treatment with 100,000 lux white light for 60 minutes to face side and 30 minutes to underside.

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 Methylene Blue 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. The strap testing procedure for this evaluation is included in this report because it differs from subsequent report.

Filtration Efficiency Results: The maximum and minimum filter efficiency was 98.65% and 93.59%, respectively. Eight of the ten respirators measured more than 95%. Two of the ten respirators measured efficiencies less 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: No visual degradation of the straps was observed. Inconsistent changes were shown between the top and bottom straps with the top strap showing a 4.47% decrease in recorded force at 200% strain and the bottom strap showing a 4.87% increase in force at 200% strain. 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 3.

[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."

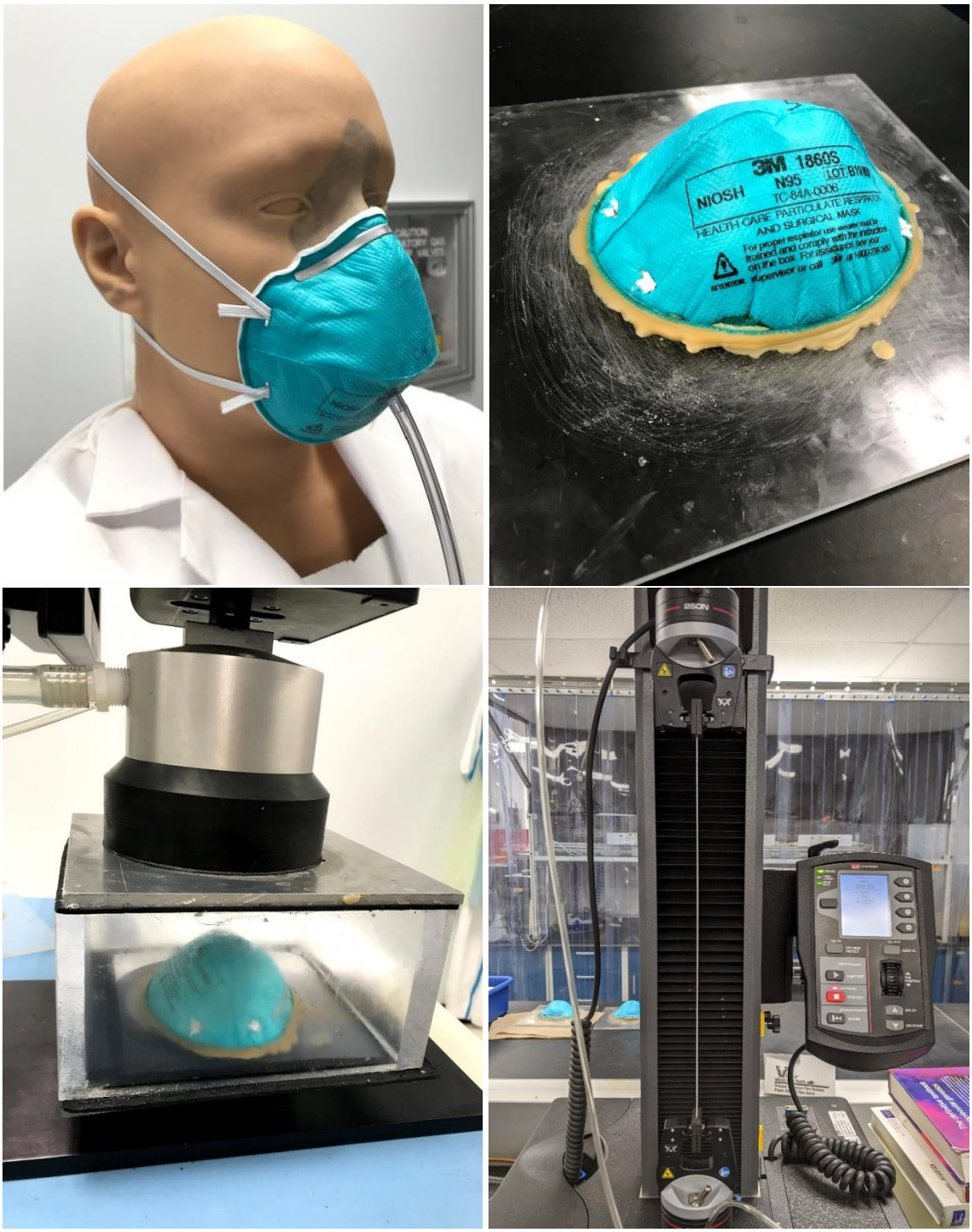

Figure 1. Laboratory Test Photos

Table 1. Filter Efficiency Evaluation

Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	Technical difficulties with testing treated sample #1. Data not reportable.				
2	85	10.7	1.32	2.02	97.98
3	85	11.4	6.36	6.41	**93.59**
4	85	10.5	1.75	2.76	97.24
5	85	11.4	2.75	3.28	96.72
6	85	11.7	1.76	2.05	97.95
7	85	11.7	1.02	1.57	98.43
8	85	11.1	1.00	1.35	98.65
9	85	12.0	2.37	3.28	96.72
10	85	12.9	1.76	4.39	95.61
11	85	10.4	5.1	5.90	**94.10**
Minimum Filter Efficiency: 93.59%				**Maximum Filter Efficiency:** 98.65%	
Control 1	85	10.7	0.84	n/a	99.16
Control 2	85	10.1	0.83	n/a	99.17
Control 3*	85	11.2	3.90	4.17	95.83

*Controls 1 and 2 were tested for initial penetration only. Control 3 was loaded for 10 minutes.

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 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. Manikin Fit Evaluation

Static Advanced Medium Headform (Hanson Robotics)

Manikin Fit Factor of Decontaminated N95s				
Treated Sample #	**Result Normal Breathing 1**	**Result Deep Breathing**	**Result Normal Breathing 2**	**Overall Laboratory Fit Factor**
12	200+	200+	200+	200+
13	200+	147	200+	179
14	200+	200+	200+	200+
15	200+	178	200+	192
Control 4	200+	200+	200+	200+
Control 5	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 200% strain)		
Straps from Treated Sample #	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
1	4.456	4.112
2	4.662	3.766
3	4.487	3.869
Decontaminated Strap Average	4.535	3.916
Control 1	4.666	3.871
Control 2	4.828	3.596
Control Strap Average	4.747	3.734
% Difference ((Controls - Deconned) / Controls)	4.47%	-4.87%

Tensile Testing of Elastomeric Straps

Straps will be removed from 5 respirators as required for particulate filter efficiency testing. These straps include the top and bottom straps from 3 respirators that were subjected to the decontamination process and additional top and bottom straps from 2 control respirators that are new and have not undergone any decontamination process. The integrity of these elastomeric head straps will be assessed using an Instron 5943 tensile tester as follows.

1. Straps will be sectioned into 10-cm segments, with ~15 mm on each side to be clamped.
2. Straps will be inserted into the Instron and pulled at 1 cm/s until 200% strain (30 cm sample length) is reached.
3. This “pre-stretching” position will be held for 2-15 minutes or until the strap material reaches a stable state.
4. Straps will be returned to their original position for 45 minutes.
5. Straps will be pulled at 1 cm/s until reaching 150% strain (25 cm length) and held for 45 minutes.
6. The strain will then be reduced until the stress is zero, and the length in this zero-stress state will be the new sample length.
7. The stress at 200% strain of the new length will be measured and recorded.