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ASSESSMENT OF FILTER PENETRATION PERFORMANCE AND FIT FOR DECONTAMINATED N95 RESPIRATORS

NPPTL ASSESSMENT TO SUPPORT THE COVID-19 RESPONSE

National Personal Protective Technology Laboratory
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention

Contents

List of Acronyms 2

NPPTL Respirator Assessments in Response to COVID-19 3

Scope 3

Solicitation of Respirators 4

Handling of Received Products 4

Particulate Filter Efficiency Testing 5

Static Advanced Headform Fit Evaluation 5

- Headform Donning 6
- Headform Breathing 6
- Manakin Fit Factor 6

Tensile Testing of Elastomeric Straps 7

Sampling Strategy 7

Completion of Testing by Outside Test Laboratories 7

Dissemination of Results 8

List of Acronyms

CDC – Centers for Disease Control and Prevention

COVID-19 – Coronavirus Disease outbreak of 2019

DB – deep breathing exercise

FDA – US Food and Drug Administration

FF – fit factor

mFF – manakin fit factor

mFFO – manikin fit factor for overall exercises

NB1 – initial normal breathing exercise

NB2 – second normal breathing exercise

NIOSH – National Institute for Occupational Safety and Health

NPPTL – National Personal Protective Technology Laboratory

StAH – Static Advanced Headform

NPPTL Respirator Assessments in Response to COVID-19

The National Personal Protective Technology Laboratory (NPPTL) is conducting a series of respirator assessments in response to the COVID-19 pandemic, see Figure 1. These assessments include determining the filtration efficiency of non-NIOSH approved respirators and expired NIOSH-approved respirators from stockpiles. NIOSH will also begin sampling respirators and determining the fit and filtration efficiency following decontamination procedures. The assessment in this test plan applies only to the filtration efficiency and fit of decontaminated N95 respirators.

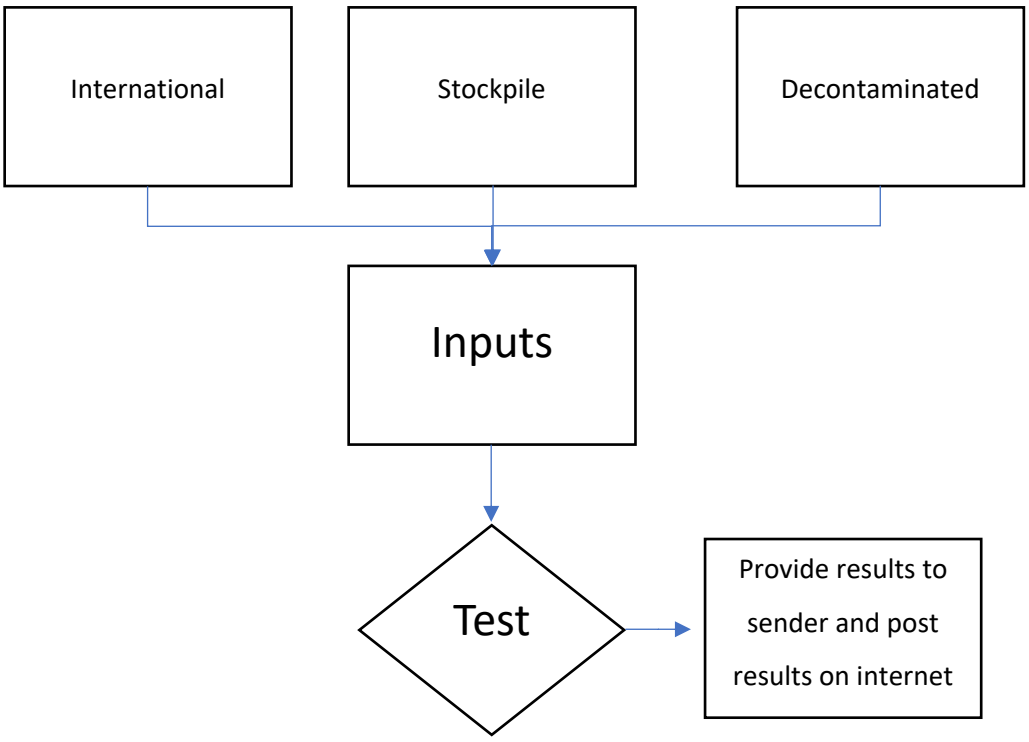

Figure 1: Diagram of NIOSH respirator assessments in response to COVID-19

Scope

This protocol establishes a method for assessing the particulate filter efficiency and change in static fit of N95 respirators following decontamination protocols. This assessment was developed as a means to quantify the filtration efficiency and fit of an N95 respirator that has been decontaminated. This assessment is not to determine the effectiveness of the decontamination procedure at killing pathogenic microorganisms. **Only new, unused respirators** that are subjected to a decontamination procedure will be included in this assessment. Only particulate filter efficiency and change in fit will be assessed as inhalation and exhalation resistance are not a

part of this assessment. This assessment provides useful information about the changes in filter efficiency and fit of respirators that may be used by healthcare workers in national emergency situations.

Solicitation of Respirators

The NPPTL has received several requests to assess the effects of decontamination on N95 performance. Upon request, NPPTL will perform testing of N95s that have undergone a decontamination procedure by an outside facility. No call for respirators or formal solicitation for these assessments will be published by NPPTL. Instead, companies who are currently performing decontamination and contact NPPTL wanting to know the effects of decontamination on their respirator performance will be included in this assessment. These companies will be asked to provide an overview of their decontamination procedure and asked to verify that respirators undergoing NIOSH testing were **new (unused and not exposed to any pathogenic microorganisms)** before undergoing the decontamination procedure and shipped to NIOSH.

Handling of Received Products

Once respirators to be evaluated are received by NPPTL, they will be assigned a unique ID for testing. This unique ID will consist of:

Make_Model_ModelCode_DeconType_DeconCycle_Sample#

Where,

Make – Make or brand or manufacturer of respirator

Model – Model of respirator (if available)

Model Code – Alphabetical code assigned by NPPTL if multiple versions or designs of the same model are received, linked to approval code

DeconType – Type of decontamination procedure applied to respirator

DeconCyle – Number of decontamination cycles applied to respirator

Sample Number – Number assigned by NPPTL to each respirator within test case

Photographs of respirators will also be taken and stored.

Particulate Filter Efficiency Testing

The maximum and minimum penetration value will be reported for the set of 10 respirators. If valves are present on the respirator, they will be sealed for testing. Each respirator will be tested on a TSI 8130 and/or 8130A Automated Filter Tester, set to the following parameters:

a. The flow rate will be set to 85.0 ± 4.0 Liters/Minute.
b. Aerosol concentration will not exceed 200 mg/m^3.
c. The particle size distribution will be 0.075 ± 0.020 micrometer with a geometric standard deviation not exceeding 1.86.
d. Each respirator will be tested for 10 minutes.
e. Maximum penetration will be recorded for each individual respirator

While some of the test parameters listed are consistent with NIOSH Standard Test Procedure TEB-APR-STP-0059 (STP-0059) [1], this modified test is different. 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. The values reported are only to provide an indication of filter efficiency following decontamination.

Static Advanced Headform Fit Evaluation

Static fit testing will be completed using a static advanced headform (StAH). A medium size, per the Principal Component Analysis Panel2, StAH (Hanson Robotics Inc., Plano, TX) will be used to assess the static fit of respirators. Depending on the size of the respirator received and the perception of fit on the medium sized headform, a large sized StAH (Lunar Studios, TX) may also be used. Overall manakin fit factor (mFFO) will be determined for 5 respirators that were subjected to decontamination procedures and an additional 2 control respirators that are new and were not decontaminated. This evaluation includes the assessment of mFFO using the below-described methodology.

The static advanced headform fit testing and tensile strength testing will be used to determine the anticipated changes in fit. The stress of the straps following the decontamination procedure will be compared to that of the control respirators that did not undergo the decontamination procedure. Therefore, the results of this testing will show any changes in tensile strength due to the decontamination procedure. Likewise, the change in the overall manikin fit factor will be reported.

[1] NIOSH Standard Test Procedure: https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf

Headform Donning

Respirators will be donned to the headform following the respirator manufacturers' guidance for correct headstrap placement and adjustment of the bendable noseclip (for models so equipped). Manikin fit factor evaluations are performed utilizing a "screening" method that was developed to quickly evaluate the seal of the respirator to the face of the StAH prior to beginning the actual fit factor evaluation. The screening method first involves donning the respirator onto the StAH and making adjustments to the noseclip and headstraps. Then, with the breathing machine operating at 11.2 lpm, the test operator observes a graphic display of real-time fit factors (FF) on the PortaCount® screen (real-time FF mode) where FFs are output approximately 1 per second. If the real-time output shows 10-consecutive FFs ≥ 100, then the test operator begins the actual fit factor evaluation. If not, the respirator is doffed, re-donned, adjusted, and reevaluated in real-time FF mode. Fit factor evaluations are started after the third attempt if fit criteria is not met after three attempts.

Headform Breathing

Respirator fit will be evaluated for the StAH under cyclic breathing conditions. The tube extending from the bottom of the StAH is connected to an inflatable (non-latex, powder-free) bladder inside an isolated, airtight, plastic cylinder. This configuration prevents any particles potentially generated by the simulator from entering the breathing zone of the StAH. A port on the cylinder is connected to a Series 1101 breathing simulator (Hans Rudolf, Inc., Shawnee, KS).

Two minute-volumes are used for manikin fit factor evaluation: normal breathing (14 breaths / min (bpm) x 800 ml tidal volume = 11.2 lpm) and deep breathing (12 bpm x 1700 ml tidal volume = 20.4 lpm). The use of only two exercises (normal and deep breathing) differs from the standard OSHA-accepted PortaCount® fit test which also includes dynamic movements and a speaking passage. Therefore, fit results from this assessment cannot be directly translated to using the standard OSHA-accepted test.

Manakin Fit Factor

Manikin fit factor (mFF) will be measured on the StAH using a PortaCount® Pro+ model 8038 Respirator Fit Tester (TSI, Inc., Shoreview, MN) operating in the N95-enabled mode. The PortaCount® utilizes condensation nuclei counting technology to enumerate individual particles and calculate a quantitative respirator mFF. The test agent used will be ambient room aerosol supplemented with generated sodium chloride aerosol. A non-commercial software will automate the fit factor data collection.

An individual fit factor evaluation includes three successive 86-sec exercises: an initial normal breathing exercise (NB1), a deep breathing exercise (DB), and then a second normal breathing exercise (NB2). Each 86-sec exercise consists of four PortaCount® actions: ambient purge (6 sec), ambient sample (15 sec), mask purge (15 sec), and mask sample (50 sec). Four mFFs are obtained for each test—one for each of the three exercises and an overall exercise (mFFO), calculated as the harmonic mean of the mFFs from the three individual exercises.

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 minutes.
4. Straps will be returned to their original position for 5 minutes and the new segment length will be measured after the 5 minutes.
5. Straps will be pulled at 1 cm/s until reaching 150% strain of the new length. This 150% strain position will be held for 30 seconds and the force at the end of the 30 seconds will be recorded.

Sampling Strategy

This assessment will use convenience sampling, a non-probability sampling technique whereby samples are drawn from the population based on their availability. All decontaminated respirators examined in this assessment will be provided to NIOSH from companies who contact NIOSH directly to conduct this testing.

Completion of Testing by Outside Test Laboratories

This assessment does not involve testing or services from outside test laboratories. The planned test procedure will be conducted by NIOSH staff at the NIOSH facility. NIOSH will not be conducting the decontamination procedures and cannot attest to the effectiveness of said procedure at eradicating pathogenic microorganisms.

Dissemination of Results

Testing results will be provided to the sender for each respirator evaluated. A table of results will also be posted on the NPPTL webpage. This table will include the respirator information, decontamination procedure, and resulting filtration, manikin fit factor, and tensile strength performance. This assessment does not include fit testing of people and only uses two exercises (normal and deep breathing). This method differs from the standard OSHA-accepted PortaCount® fit test which also includes dynamic movements and a speaking passage. 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 detriment in fit (if any) associated with the decontamination of respirators. NIOSH may post test results, at its discretion, from other laboratories that are testing similar products.