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ASSESSMENT OF FILTRATION EFFICIENCY AND MANIKIN FIT FOR DECONTAMINATED INTERNATIONAL 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

CDC – Centers for Disease Control and Prevention

COVID-19 – Coronavirus Disease 2019

DB – deep breathing exercise

FF – fit factor

mFF – manikin fit factor

mFF_O – 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

Scope

This protocol establishes a method for assessing the particulate filter efficiency and change in static headform fit of internationally approved (non-NIOSH approved) respirators following decontamination protocols. This assessment is not to determine the effectiveness of the decontamination procedure at killing pathogenic microorganisms. **Only unworn filtering facepiece respirators** that are subjected to a decontamination procedure will be included in this assessment. Only particulate filter efficiency and change in static headform fit will be assessed; 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

Upon request, NPPTL will perform testing of decontaminated internationally approved respirators (non-NIOSH approved) represented as meeting the classifications listed in Table 1. Interested parties will be asked to provide an overview of their decontamination procedure and asked to verify that respirators undergoing NIOSH testing were **unworn and not exposed to any biological microorganisms** before undergoing the decontamination procedure and shipped to NIOSH. **For this assessment of internationally approved respirators (non-NIOSH approved), only respirators meeting the approval requirements in Table 1 will be accepted for testing.**

Table 1: Classifications for non-NIOSH approved respirators that may be submitted for testing[1]

Country of Certification	Performance Standard	Acceptable Product Classification
Australia	AS/NZS 1716:2012	P2 P3
Brazil	ABNT/NBR 13698:2011	PFF2 PFF3
People's Republic of China	GB 2626-2006 GB 2626-2019 GB19083-2010	KN/KP95 KN/KP100
Europe	EN 149-2001	P2 P3
Japan	JMHLW-2000	DS/DL2 DS/DL3
Korea	KMOEL-2017-64	Special 1st
Mexico	NOM-116-2009	N95 R95 P95 N99 R99 P99 N100 R100 P100

[1] Products conforming to these standards are listed in the CDC Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies (accessed 9/24/2020).

Handling of Received Products

When samples are received by NPPTL, they will be logged in, numbered, and photographs will be taken. Laboratory photos of samples will be included in test reports. Any observations of physical damage to the samples will be noted.

Number of Samples Needed

Fifteen (15) treated samples and 5 control (untreated) samples are needed to complete the entire test plan (Table 2).

Table 2. Required Number of Samples for Testing

Test	Treated samples needed (n)	Controls Needed (n)
Particulate Filter Efficiency Test	10	3
Manikin Fit Test	5	2
	Total Treated = 15	**Total Controls = 5**

Particulate Filter Efficiency Testing

Filtration efficiency will be reported for a set of 10 decontaminated respirators. If valves are present on the respirator, they will be sealed for testing. The same filtration efficiency test method will be applied to a set of 3 new respirators (controls) that have not undergone decontamination. These respirators will serve as controls for comparison of filtration efficiency performance to the decontaminated samples.

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 count median diameter with a geometric standard deviation not exceeding 1.86.
d. Each respirator will be tested for 10 minutes.
e. Filtration efficiency correlating to the maximum penetration value over the 10 minute period 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) [2], 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 NIOSH-approved N95 respirators that were tested to STP-0059. The values reported are only to provide an indication of filter efficiency following decontamination.

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

Static Advanced Headform Fit Evaluation

Static fit testing will be completed using a static advanced headform (StAH). A medium size StAH (Hanson Robotics Inc., Plano, TX) (per the size classifications of the NIOSH Principal Component Analysis Panel) 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 size headform, a large sized StAH (Lunar Studios, TX) may alternatively be used. Overall manikin fit factor (mFF_O) will be determined for 5 respirators that were subjected to decontamination procedures and an additional 2 control respirators that were not decontaminated.

Overall manikin fit factor (mFF_O) 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 fit factors. The test agent used will be ambient room aerosol supplemented with generated sodium chloride aerosol. Commercial software from TSI, Inc. will automate the fit factor data collection.

NOTE: Because the fit of respirators approved to international standards other than NIOSH may be poor, the manikin fit will first be attempted on the two control samples. If a mFF_O ≥100 cannot be obtained on both of the control respirators, the manikin assessment will not be attempted on the treated samples.

Headform Donning

Respirators will be donned on the headform following the respirator manufacturer's 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 mFF_O evaluation. If not, the respirator is doffed, re-donned, adjusted, and reevaluated in real-time FF mode. If the screening procedure fails after three donning attempts, the actual mFF_O evaluations will be started after the third attempt.

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.

Manikin Fit Factor

An overall manikin fit factor (mFF_O) evaluation is derived from 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 manikin fit factors (mFFs) are obtained for each test—one for each of the three exercises, and the overall test result (mFF_O); the mFF_O is calculated as the harmonic mean of the three individual exercises mFFs.

The fit assessment does not include fit testing of people and only uses two types of exercises (normal and deep breathing) for the manikin fit testing. 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.

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 or institutions 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; the sender information (i.e., name of the group submitting the samples) will not be identified in the web posting. This posted results table will include the respirator information, decontamination procedure, and resulting filtration and manikin fit factor performance. NIOSH may post test results, at its discretion, from other laboratories that are testing similar products. **These test procedures are destructive to the samples; samples will be discarded after testing and will not be returned.**