MARCH 31, 2020

ASSESSMENT OF FILTER PENETRATION PERFORMANCE FOR NON-NIOSH APPROVED 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

FDA – US Food and Drug Administration

NIOSH – National Institute for Occupational Safety and Health

NPPTL – National Personal Protective Technology Laboratory

COVID-19 – Coronavirus Disease outbreak of 2019

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 of non-NIOSH approved respirators.

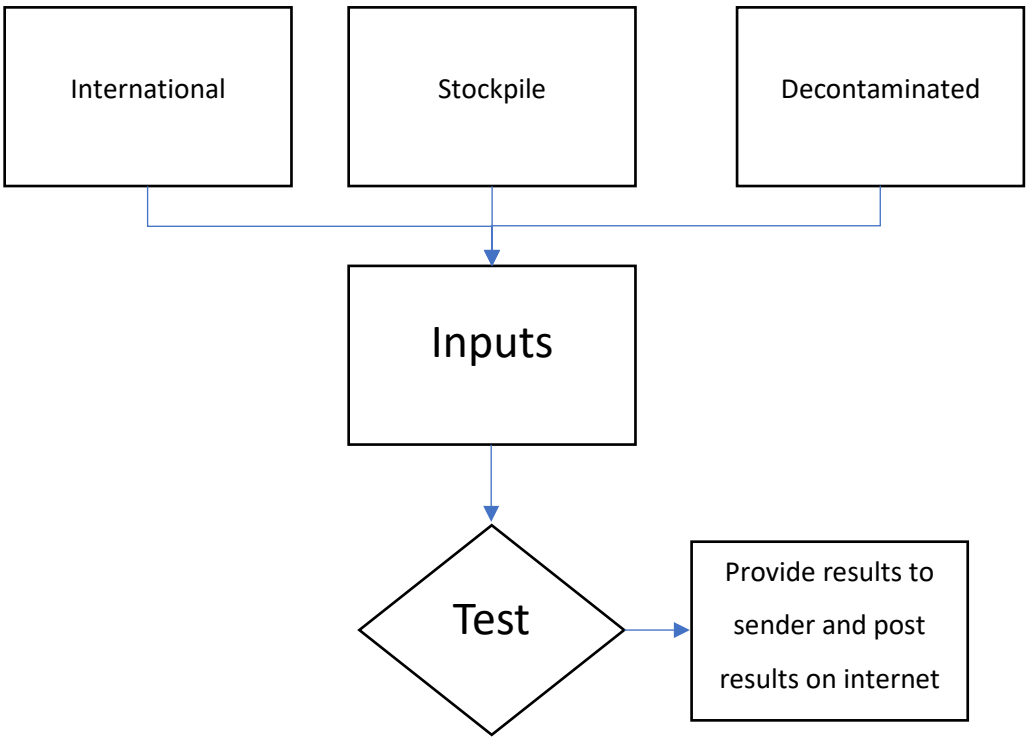

Figure 1: Diagram of NIOSH respirator assessments in response to COVID-19

Scope

This protocol establishes a method for assessing the particulate filter efficiency of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators. This assessment is not part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark. This assessment was developed as a means to efficiently quantify the filtration efficiency of a respirator approved by a foreign regulatory body based on a modified version of the NIOSH filter efficiency test (i.e. TEB-APR-STP-0059, Revision 3.2, December 13, 2019) to support

the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency will be assessed as inhalation and exhalation resistance and fit testing are not a part of this assessment.

Solicitation of Respirators

Respirators represented as meeting the classifications listed in Table 1 will be solicited from US users (or points of distribution to users) for assessment. Respirators will not be solicited nor received directly from manufacturers. Instead, the goal of this assessment is to determine the filtration performance, using a modified NIOSH test procedure to measure filter efficiency of those respirators actively being used by (and distributed to) US healthcare workers.

Table 1: Classifications for non-NIOSH approved respirators that will be included in NPPTL filtration efficiency[1] testing

Product Classifications	Jurisdiction	Performance Standard
P2, P3	Australia/New Zealand	AS/NZS 1716:2012
PFF2, PFF3	Brazil	ABNT/NBR 13698:2011
KN95, KP95, KN100, KP100	China	GB2626-2006 GB2626-2019
FFP2, FFP3	Europe	EN 149-2001
DS/DL2, DS/DL3	Japan	JMHLW-2000
Korea 1st class	Korea	KMOEL-2017-64
N95, P95, R95 N99, P99, R99 N100, P100, R100	Mexico	NOM-116-2009

The NPPTL has received several requests to assess the efficiency level of those products compared to NIOSH approved products. Responses to these requests will include the pertinent study details and a copy of the required submission form for filtration performance testing of non-NIOSH approved respirators (Appendix A).

[1] Products conforming to these standards are listed in the CDC Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies

This includes information helpful to identify the examined respirator, to determine if it is an approved respirator by a regulatory body included in Table 1, and to protect the safety of NPPTL staff from handling potentially contaminated respirators. Once NPPTL staff receive the form, it will be reviewed and approved before shipping instructions and a unique Sender ID is provided to the sender.

The response to inquiries for filtration testing of non-NIOSH approved respirators will read:

> On February 29, 2020, CDC published guidance Strategies for Optimizing the Supply of N95 Respirators. This guidance provides Crisis Alternate Strategies that includes the option: "Use of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators." The other countries listed in the guidance and their associated product classifications are shown below.

Product Classifications	**Jurisdiction**	**Performance Standard**
P2, P3	Australia/New Zealand	AS/NZS 1716:2012
PFF2, PFF3	Brazil	ABNT/NBR 13698:2011
KN95, KP95, KN100, KP100	China	GB2626-2006 GB2626-2019
FFP2, FFP3	Europe	EN 149-2001
DS/DL2, DS/DL3	Japan	JMHLW-2000
Korea 1st class	Korea	KMOEL-2017-64
N95, P95, R95 N99, P99, R99 N100, P100, R100	Mexico	NOM-116-2009

> While the above-listed product classifications have similar performance requirements to NIOSH-approved devices, CDC does not have knowledge about sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control. Due to the potential to have these non-NIOSH approved respirators used by US healthcare workers, NPPTL is currently undertaking a limited assessment to determine the product's particulate filtration performance in an abbreviated NIOSH test of these respirators. Respirators, meeting the requirements above, that are being used by (or distributed to) US healthcare workers are being solicited for assessment to determine their filtration performance compared to one aspect of the NIOSH performance requirements. This assessment is not

part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirators represented as certified by a foreign certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency will be assessed as inhalation and exhalation resistance and fit testing are not a part of this assessment.

If you are interested in having your respirators included in this testing, please complete and return the attached form.

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:

SenderID_Make_Model_ModelCode_LotNumber_Sample#

Where,

SenderID – unique ID provided to the sender by NPPTL

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

Lot Number –Lot Number assigned by manufacturer (if available)

Sample Number – Number assigned by NPPTL to each respirator within a lot

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), 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 and are not a confirmation that the product conforms with the requirements of the certification mark. This assessment provides useful information about the filter efficiency of respirators that may be used by healthcare workers in national emergency situations.

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 non-NIOSH approved respirators examined in this assessment will be provided to NIOSH from outside user groups who contact NIOSH directly to conduct this testing. Respirator manufacturers or authorized sales companies will not be solicited for inclusion in this assessment.

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.

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, photographs, and the minimum and maximum filtration efficiency for each set of 10 respirators. The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. As such, results will be presented with the below-listed caveats and qualifiers. NIOSH may post test results, at its discretion, from other laboratories that are testing similar products.

1. Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.

2. This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
3. This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.