JUNE 22, 2020

Assessment of filter penetration and pressure difference for non-NIOSH approved innovative filtering facepiece 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 outbreak of 2019

FDA – US Food and Drug Administration

NIOSH – National Institute for Occupational Safety and Health

NPPTL – National Personal Protective Technology Laboratory

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 and pressure difference of innovative non-NIOSH approved filtering facepiece respirators produced by novel commercially available equipment. Recently, several manufacturers produced N95 respirators using novel equipment and claimed equivalency to the performance of NIOSH approved N95 respirators. These are non-NIOSH certified respirators and their filtration performance is not available. To address this issue, the filtration efficiency and pressure difference will be measured using a TSI 8130 automated filtration tester and sodium chloride aerosol at NIOSH test conditions.

Non-NIOSH approved N95 respirator production using novel equipment

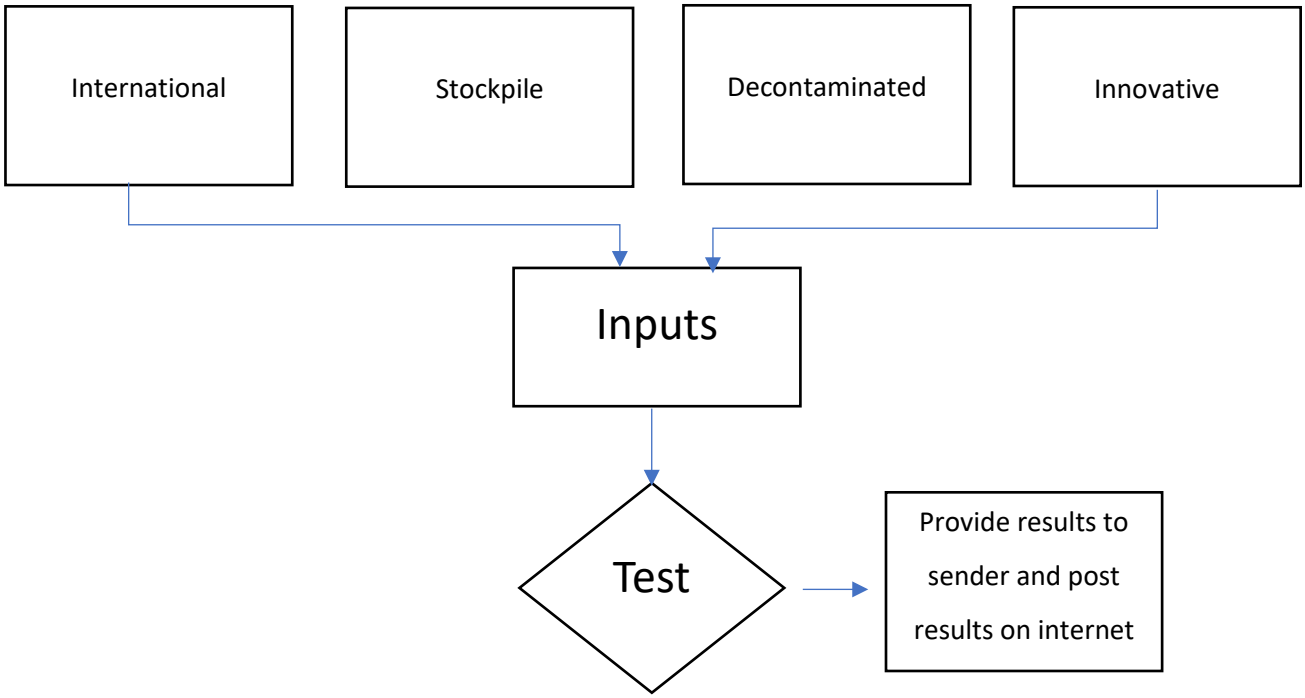

Figure 1: Diagram of NIOSH respirator assessments in response to COVID-19

Scope

This protocol assesses the particulate filter efficiency and pressure difference of innovative N95 respirators. **Only new, unused respirators** that are produced by novel commercial equipment. This assessment provides a comparison of the filtration performance of innovative respirators to NIOSH approved N95 filtering facepiece respirators. The innovative respirators may be fit tested and used by healthcare workers in crisis capacity during a national emergency situation provided NIOSH and FDA regulations permit.

Solicitation of Respirators

The NPPTL has received several requests to assess the filtration performance of non-NIOSH approved respirators produced using novel commercial equipment. A comparison of filtration performance of the non-NIOSH approved devices to NIOSH approved N95 respirators is not available. Upon request, NPPTL will perform testing the filtration efficiency and pressure difference at limited NIOSH test conditions. No call for respirators or formal solicitation for these assessments will be published by NPPTL. These companies/individuals will be asked to provide an overview of their product to include raw material and asked to verify that respirators undergoing NIOSH testing were **new (unused and not exposed to any pathogenic microorganisms)**.

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__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

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 filter efficiency at 1 minute and 5 minutes will be reported for the set of 5 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 using NaCl aerosol, 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 5 minutes.
e. Penetration at 1 minute and at 5 minutes will be recorded and filter efficiency will be calculated for each individual respirator.
f. Pressure difference at 1 minute and at 5 minutes will be recorded.

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 filtration performance.

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, filtration efficiency and pressure difference. NIOSH may post test results, at its discretion.

[1] NIOSH Standard Test Procedure: