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ASSESSMENT OF FILTER PENETRATION PERFORMANCE FOR RESPIRATORS BEYOND DESIGNATED SHELF LIFE AND STOCKPILED 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

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

PPE – Personal Protective Equipment

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 NIOSH-approved respirators from stockpiles that are beyond their designated shelf life. 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 expired NIOSH-approved N95 respirators.

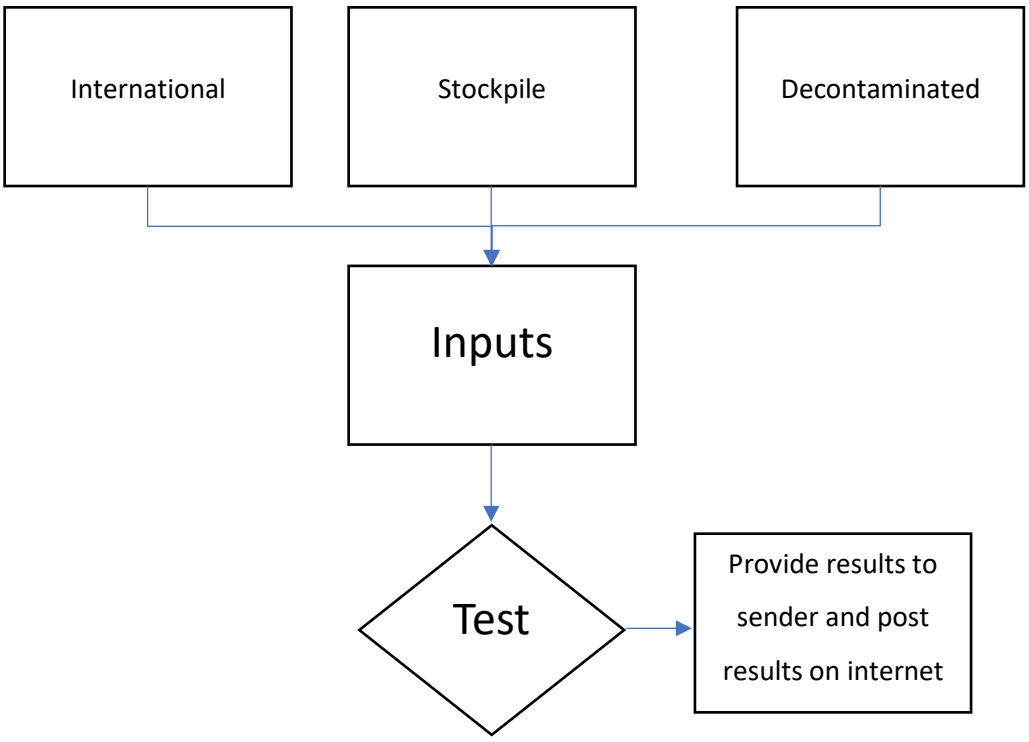

Figure 1: Diagram of NIOSH respirator assessments in response to COVID-19

Scope

This protocol establishes a method for assessing the particulate filter efficiency of N95 respirators that are stored in stockpiles and are beyond their designated shelf life. This assessment was developed as a means to quantify the filtration efficiency of a NIOSH-approved respirator that is beyond its manufacturer-supplied shelf life date or has been subjected to prolonged storage in a stockpile. This effort supports increasing 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 were previously found to have satisfactory performance in stockpiled and expired respirators[1].

Solicitation of Respirators

In 2017, NIOSH established a Personal Protective Equipment (PPE) Stockpile Partnership to inform the design and execution of studies to evaluate stockpiled air-purifying respirators. As part of this partnership, NPPTL obtained samples of N95 respirators and determined their inhalation and exhalation resistance and filtration performance. Since completing this examination, and due to the current respirator shortage associated with COVID-19, NPPTL has received several requests to assess the performance of expired and stockpiled respirators. Responses to these requests will include the pertinent study details and a copy of the required submission form for filtration performance testing of expired and stockpiled N95s (Appendix A). Once NPPTL staff receive the form, it will be reviewed and approved before shipping instructions are provided to the sender. Several models of N95s were examined as part of the NIOSH Stockpile Study. Respirators included in that study will not be evaluated in this assessment[1].

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_LotNumber_ExpDate_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 NIOSH approval number

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

ExpDate – Expiration date 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.

[1] Release of Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response: https://www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html

Particulate Filter Efficiency Testing

Particulate filter efficiency will be determined using NIOSH Standard Test Procedure TEB-APR-STP-0059[2] (STP-0059). All NIOSH-approved N95 respirators are approved using STP-0059. As such, this testing will allow NPPTL to assess the particulate filter efficiency of NIOSH-approved N95s that are beyond the manufacturer-supplied shelf life date or subjected to long-term storage conditions.

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 expired N95s examined in this assessment will be provided to NIOSH from outside user groups who contact NIOSH directly to conduct this testing of their stockpiled respirators.

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 a NIOSH facility.

Dissemination of Results

Testing results will be provided to the sender for each respirator evaluated. These results will also be posted on the NPPTL webpage. Results will include respirator information, photographs, and the filter penetration efficiency. Qualifying statements will be used to ensure the proper characterization of test results. NIOSH may post test results, at its discretion, from other laboratories that are testing similar products.

The following statement will be provided along with all available test results.

> NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators [NIOSH 1997]. NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs. The approval holder (i.e. the entity that is granted the approval from NIOSH) is responsible for understanding how their products' design or performance may be affected by various use or storage conditions and must provide instruction for establishing the proper use, storage, and maintenance procedures for their approved products, which may include designating a shelf life [NIOSH 2019]. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user

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

instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage. At this time, we do not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer- designated shelf life.

The results presented herein are for a subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

For an N95 with no manufacturer-designated shelf life, filtration efficiencies consistent with NIOSH STP-0059 requirements will read:

No failures for filtration performance were observed—i.e., the performance data suggests that these units would be protective so long as a proper fit is achieved. No shelf life was designated for this model by the approval holder. These findings pertain to XX units from a facility in XX and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

For an N95 with a manufacturer-designated shelf life, filtration efficiencies consistent with NIOSH STP-0059 requirements will read:

No failures for filtration performance were observed—i.e., the performance data suggests that these units would be protective so long as a proper fit is achieved. This model currently has an XX-year designated shelf life. Thus, these respirators tested are past their designated shelf life. These findings pertain to XX units from a facility in XX and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

For any N95 respirators that are not consistent with the filtration efficiencies of NIOSH STP-0059 requirements will read:

> Failures for filtration performance were observed – i.e., the performance data suggest that these units would not be protective at 95% efficiency. This model currently has an XX-year designated shelf life. Thus, these respirators tested are past their designated shelf life. These findings pertain to XX units from a facility in XX and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

APPENDIX A

Submission of Respirators Beyond Their Designated Shelf Life or Stockpiled NIOSH Approved Respirators for Filtration Efficiency Testing

If testing of multiple models of respirators is being requested, this form should be completed for each model.

PROPOSAL TO SHIP RESPIRATORS BEYOND DESIGNATED SHELF LIFE/STOCKPILED N95s FOR TESTING BY NIOSH/NPPTL Submit to: PPEConcerns@cdc.gov with subject: "Beyond Shelf Life/Stockpiled Respirator Testing"	
Sender Name and Contact Information	Name: Company: Phone: Email: Address:
Product Name/Manufacturer and Certification mark/number	
Model/Part Number	
Lot Number, if known	
Manufacturing Year/Expiration Date, if available	
Number of Respirators in Your Possession	
I certify that all respirators are new and have not been previously worn.	Sign and date