PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Performance of Stockpiled Air-Purifying Respirators, Facility Two of Ten: Inhalation and Exhalation Resistance and Filtration Efficiency Performance

National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
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NIOSH found that 301 of 301 N95 filtering facepiece respirators stockpiled at Facility Two that were 8-11 years old maintained their inhalation and exhalation resistance and filtration performance in accordance with NIOSH performance standards.

In the event of a national emergency, eighteen million U.S. healthcare workers may face high-consequence infectious disease exposures [NIOSH 2017]. Personal protective equipment (PPE), such as gowns, gloves, goggles, and respirators, is an important measure within the infection prevention hierarchy of controls. During public health emergencies, the sudden increase in PPE demand may exceed supplies for upwards of three months while manufacturers increase production [ASTHO 2013; Carias et al. 2015]; [Patel et al. 2017]. For example, during the 2009 H1N1 pandemic, local respirator shortages were reported and, during the 2016 Ebola outbreak and the first U.S. fatality, there was a 10-200 fold increase in PPE orders [DHHS 2012; NIOSH 2018]. To prepare for these shortages, large quantities of PPE are strategically stockpiled at hospital, local, state, and federal facilities [NIOSH 1997].

Due to the decision to stockpile PPE, stockpile personnel and decision makers have sought to understand if stockpiled PPE is still viable following long-term storage. NIOSH does not require approval holders (i.e. those granted the approval from NIOSH) to designate a shelf life for particulate-only air-purifying respirators (APR), although some choose to do so and may provide this information on product packaging or online. There is limited published data to understand the viability of respirators that have undergone long-term storage with or without a designated shelf life. Over the past decade, the Strategic National Stockpile (SNS) and state and local stockpile personnel asked NIOSH to evaluate the performance of stockpiled PPE as well as better understand storage conditions in U.S. stockpile facilities that store PPE.

In 2017, NIOSH established a PPE Stockpile Partnership consisting of 1) federal entities and stockpiles; 2) state, county, and city stockpiles; 3) hospital-related stockpile entities; and 4) a manufacturer trade association to inform the design and execution of an empirical study to evaluate stockpiled APRs. NIOSH obtained samples of PPE from geographically dispersed stockpiles with varying storage conditions.

This report details the inhalation/exhalation resistance and filtration performance of N95 filtering facepiece APRs collected from Facility Two of Ten. This facility is a state stockpile facility.

How NIOSH Evaluated Respirators and Storage Conditions

Description of Facility Two

- NIOSH researchers visited Facility Two in November 2017 (**Figure 1**). This facility was located within the U.S. Department of Health and Human Services Region 2, representing New York, New Jersey, Puerto Rico, and the Virgin Islands.

Assessment of Storage Conditions

- NIOSH, in conjunction with the PPE Partnership members, developed checklists to document site and packaging (i.e. pallet, case, and box) conditions that may impact respirator performance.
- NIOSH documented the following storage conditions: 1) the PPE packaging presence of dust, shrink-wrapping, chemicals, and moisture, 2) exposure to sunlight and direct light; 3) proximity to fans, windows, doors, and ventilation systems; 4) damage to pallet and product packaging; and 5) location of pallet on storage rack (e.g., top, bottom) and location of PPE product on pallet (e.g., top/not load-bearing, bottom/load-bearing).

Figure 1: NIOSH researchers documented storage practices at Facility Two such as location and type of lighting, pallet stacking practices, and conditions of the flooring, roofing, and exterior walls.

- NIOSH reviewed facility temperature and percent relative humidity (%RH) data provided by Facility Two stockpile personnel. This data was collected in 30-minute intervals from September 2013 to August 2016.

Collection of Respirator Samples

- NIOSH collected samples for three APR models stockpiled at Facility Two. Facility Two's inventory included APRs that are classified as N95 filtering facepiece respirators (FFRs). Samples were collected from two different manufacturing models[1]: 1) 3M 1860 (three different manufacturing years) and 2) Gerson 1730 (one manufacturing year) (**Table 1**).
- Upon reviewing the detailed APR inventories and storage location by lot within Facility Two, two different manufacturing lots for each model were identified and sampled within Facility Two. Two lots

[1] Based on the other nine collaborating stockpiles' inventories, these two models were sampled in order to compare performance within common respirator models when stored under disparate conditions.

were sampled to evaluate and attempt to account for inter-lot variation. Products were sampled and shipped to the NIOSH facility overnight to reduce exposure to non-climate-controlled conditions.

- Forty-three respirators were tested from each manufacturing lot for inhalation and exhalation resistance (n=3) and filtration performance testing (n=40)[2].

Selection of Control Respirators

- Control respirators of the same model as those sampled from the facility were purchased from the open market to be used as a comparison between stockpiled and new respirators.

Characteristics of Sampled Respirators

Table 1 provides a summary of the respirator models sampled from Facility Two.

Table 1. FFRs Sampled from Stockpile Facility Two

Model	Lot #	Year of Manufacture	Shelf Life on Packaging?	Respirator Age at Time of Testing[3]	Shelf Life Status at Time of Testing
3M 1860	Lot A	2006	No	11 years	Past 5-year shelf life [4]
3M 1860	Lot B	2006	No		
3M 1860	Lot A	2008	No	9 years	Past 5-year shelf life[4]
3M 1860	Lot B	2008	No		
3M 1860	Lot A	2009	No	8 years	Past 5-year shelf life[4]
3M 1860	Lot B	2009	No		
Gerson 1730	Lot A	2006	No	11 years	No shelf life designated
Gerson 1730	Lot B	2006	No		

Evaluation of Inhalation and Exhalation Resistance and Filtration Performance

- Twenty-three control respirators were tested for inhalation and exhalation resistance and filtration performance. The Gerson 1730 controls were manufactured in 2017 and the 3M 1860 controls were manufactured in 2018. NIOSH testing requirements state that a minimum of three respirator units must be tested for inhalation and exhalation resistance. The same three respirators can be used for both inhalation and exhalation resistance testing [NIOSH 2018].
- Inhalation and exhalation resistance and filtration performance of the stockpiled and control respirators were evaluated using the same Standard Test Procedures (STPs) NIOSH uses for approving respirators under 42 Code of Federal Regulations Part 84, "Approval of Respiratory Protective Devices" [NIOSH 2018] (**Table 2**).
- **Table 2** describes the method for evaluating the inhalation and exhalation resistance and filtration performance of sampled respirators and control respirators.

[2] NIOSH testing requirements state that a minimum of three respirator units must be tested for inhalation and exhalation resistance and a minimum of 20 must be tested for filtration efficiency [NIOSH 2018].
[3] Testing was completed in 2017.
[4] In 2013, 3M designated a five-year shelf life for the 3M 1860 model [3M 2018]. As of February 2020, this model still has a five-year shelf life.

Table 2. NIOSH Tests Conducted to Evaluate Inhalation and Exhalation Resistance and Filtration Performance.

NIOSH Standard Test Procedures (STPs)	Pass/Fail Criteria for APRs	Stockpiled Respirators Tested Per Manufacturing Lot	Control Respirators Tested
STP 3: Exhalation Resistance	<25 mm H_2O column @ 85 liters per minute (LPM)	3[5]	3[5]
STP 7: Inhalation Resistance	<35 mm H_2O column @ 85 LPM	3[5]	3[5]
STP 59: Particulate Filter Efficiency for N95	≤5.0% particulate penetration (≥95.0% filter efficiency)	40[6]	20

What NIOSH Found Through Inspection, Testing, and Evaluation

Storage Conditions

- Visual Inspections—Dust and damage to product packaging was limited or not observed at Facility Two; examples of the most amount of dust and damage to product packaging are shown in **Figures 2 and 3**. Of the 301 respirators visually inspected, twelve concerns were noted which involved respirator nose foam sticking to adjacent units for the 3M 1860 model (**Figure 4**).

Figure 2: Most amount of dust observed on product cases from Facility Two.

[5] NIOSH testing requirements state that a minimum of three respirator units must be tested for inhalation and exhalation resistance. The same three respirators can be used for both inhalation and exhalation resistance testing.
[6] An increased sample size was used for the stockpiled respirators as opposed to the control respirators to increase the precision of the performance estimates investigated.

Figure 3: Most amount of product case damage observed from Facility Two.

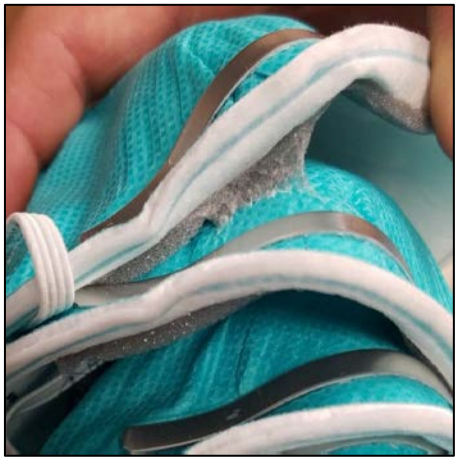
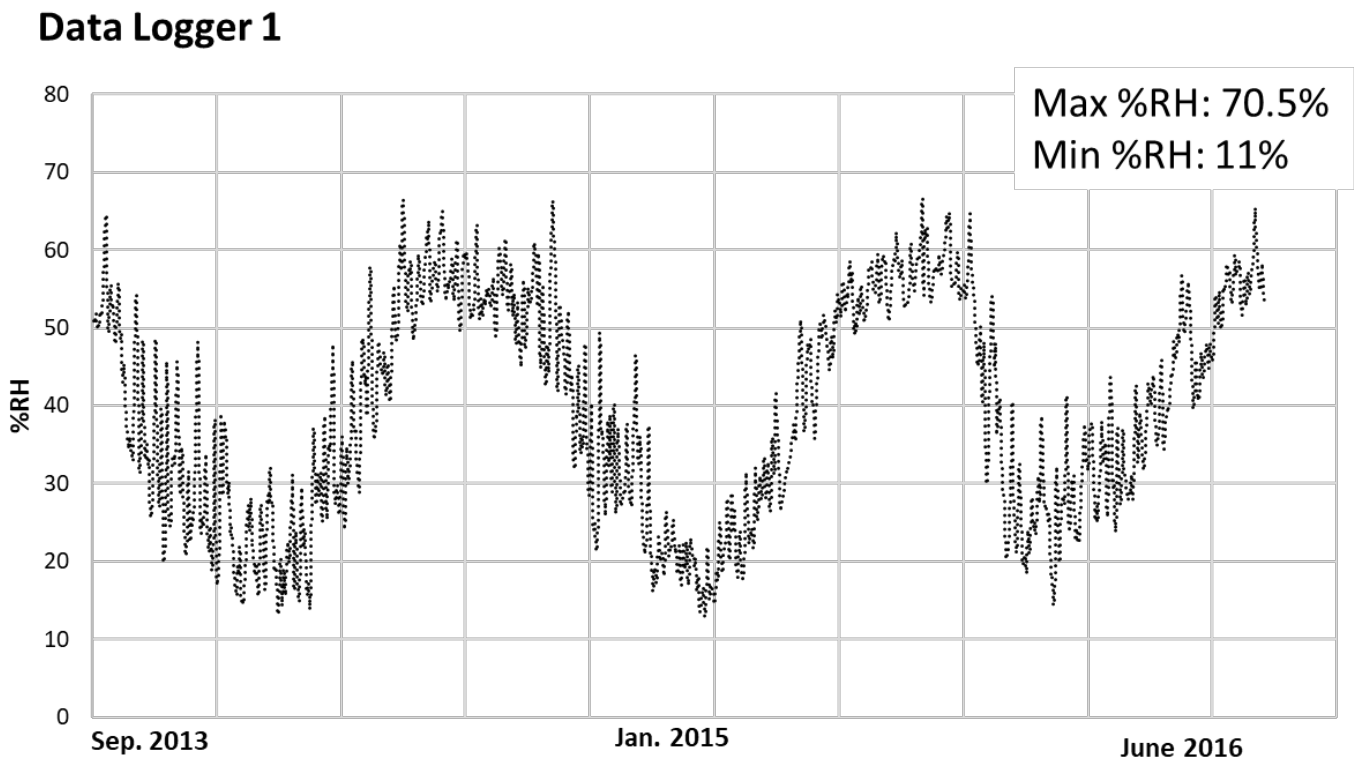


Figure 4: Most amount of product damage observed from Facility Two.

- Facility Two shared the warehouse space with another entity. On Facility Two's side, facility lights were off when not in use and no windows allowed sunlight to enter the facility. Stockpile personnel noted that although temperature and %RH are monitored, there is no air-conditioning, but fans exist and circulate air throughout the facility. No evidence of excess moisture or chemical spills that persisted beyond immediate mitigation were observed. Generally, the pallets were shrink wrapped around the four pallet sides but not across the top or bottom. Pallets were separated by metal racks, preventing weight/load applied to individual pallets.
- Percent RH (**Figure 5**) and Temperature (**Figure 6**)
    - **At the time of publication**, the recommended storage requirements for %RH and temperature are
        - 3M 1860: remain under 80 %RH; remain within -4°F to 86°F [3M 2017]
        - Gerson 1730: remain under 80 %RH; remain within -4°F to 95°F [Gerson 2019]
    - The average temperature between the 2013-2016 time period was 73.3°F. The average %RH between 2013-2016 was 40.4%; these averages are within the 3M and Gerson recommended temperature and %RH storage conditions.
    - No %RH or temperature data points deviated from the recommended storage conditions for the 3M 1860 or the Gerson 1730 respirator models.

- Some respirators from Facility Two were previously stored and deployed from a federal SNS facility. Although the current tracking process does not allow for retrieval of the historical location(s) and environmental conditions for these sampled products, subsequent discussions with SNS leadership suggest that SNS storage conditions met recommended conditions.



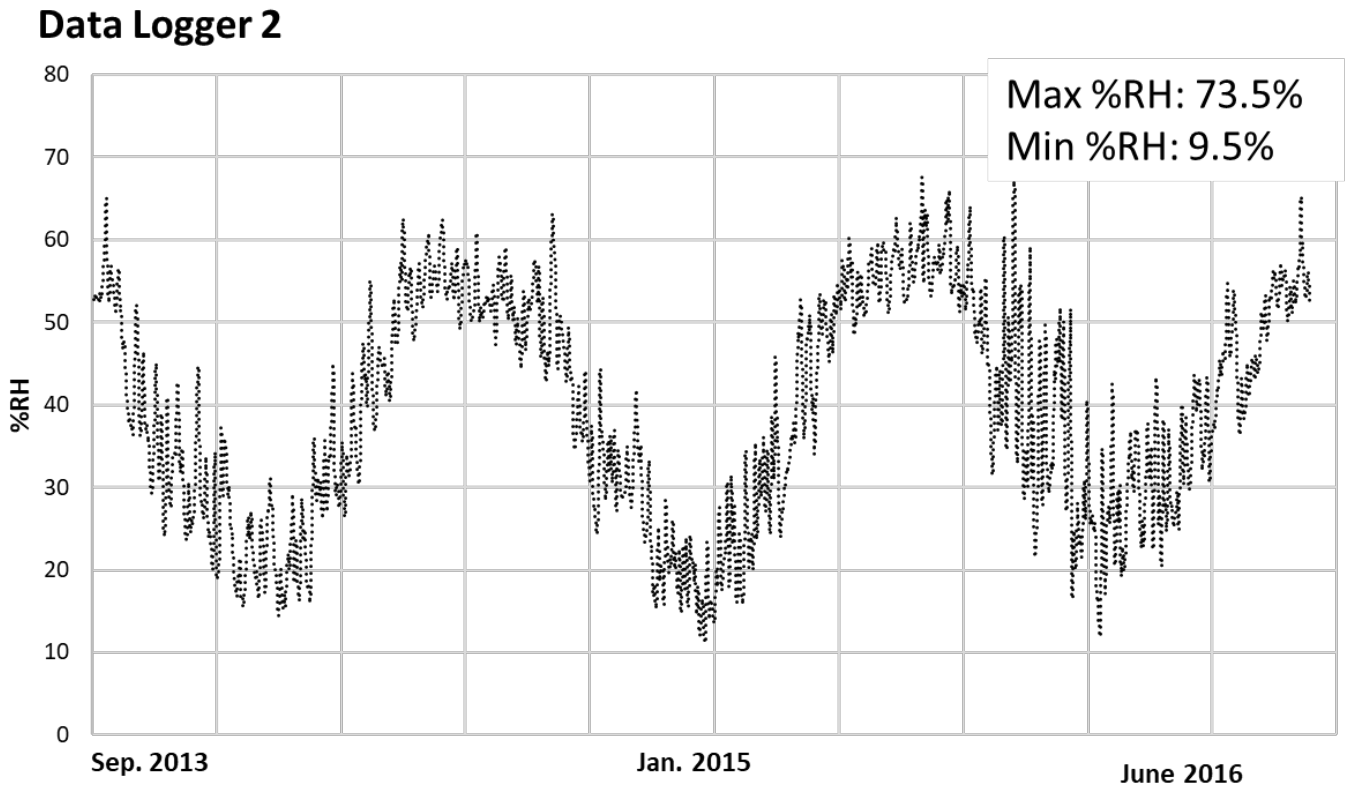
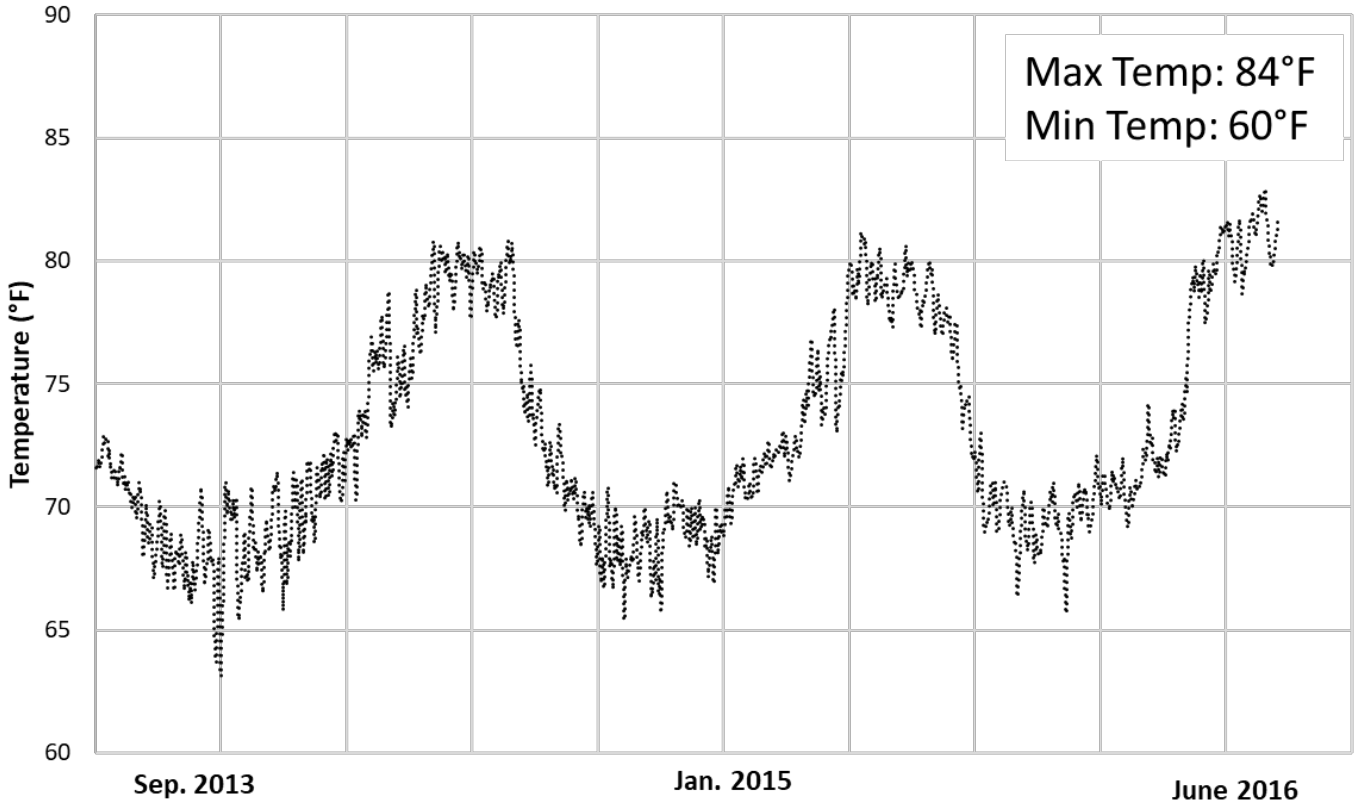


Figure 5: Percent Relative Humidity (% RH) from September 2013 – June 2016 for two data loggers stored at Facility Two. Data is plotted as a 50-point moving average for visualization purposes. Maximum and minimum temperatures reported are noted for each data logger.

Data Logger 1



Data Logger 2

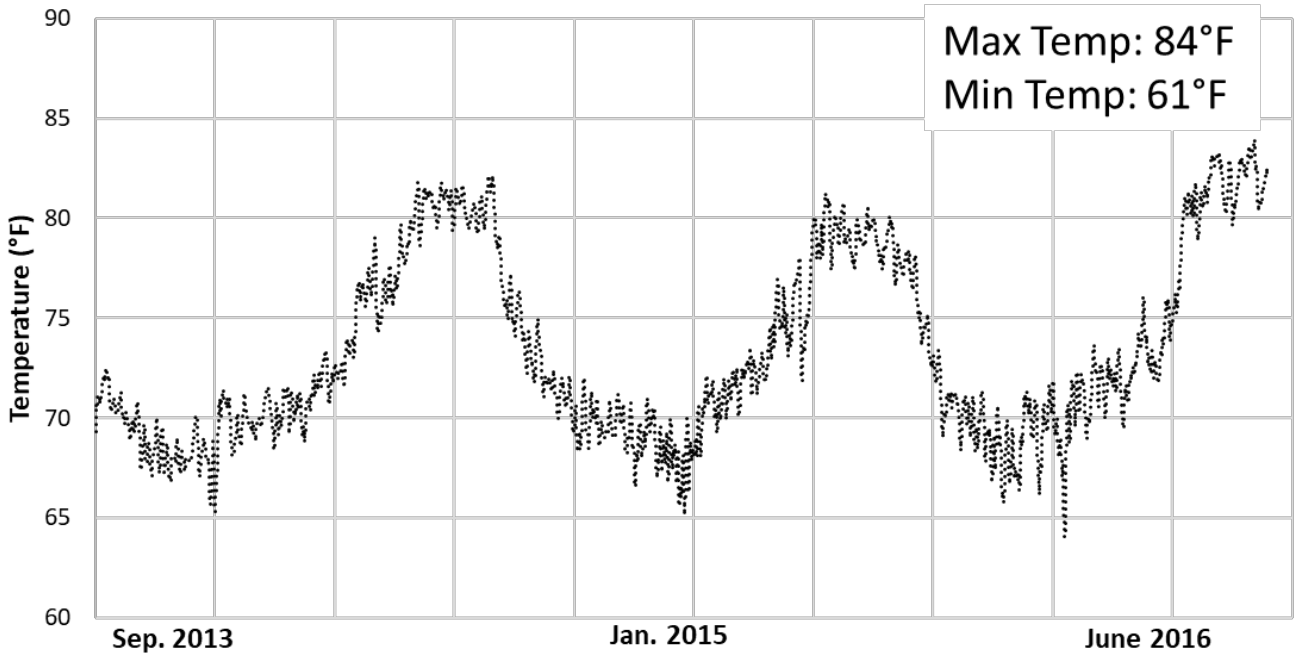


Figure 6: Temperatures from September 2013 – June 2016 for two data loggers stored at Facility Two. Data is plotted as a 50-point moving average for visualization purposes. Maximum and minimum temperatures reported are noted for each data logger.

Inhalation and Exhalation Resistance

- NIOSH evaluated the inhalation and exhalation resistance for a total of 21 stockpiled and 6 control respirators. **All stockpiled and control respirators from each model passed these tests (Figure 7).**
- Using an analysis of variance (ANOVA), **there were no statistically significant differences (defined as $\alpha \leq 0.05$)** between the FFR controls and FFR stockpiled respirators for inhalation and exhalation resistance when averaging across models.
- When comparing the individual respirator models to their respective controls through an ANOVA with adjusted, post-hoc multiple comparisons, the Gerson 1730 stockpiled 2008 Lot A was statistically significantly higher for both inhalation and exhalation resistance. The mean inhalation and exhalation resistance values are shown in **Figure 7**.
- For inhalation resistance, the individual stockpiled respirator with the highest resistance (10.40 mm H_2O) was below the NIOSH maximum limit for product approval (35 mm H_2O allowable maximum). For exhalation resistance, the individual stockpiled respirator with the highest resistance (9.63 mm H_2O) was below the NIOSH maximum limit for product approval (25 mm H_2O allowable maximum).

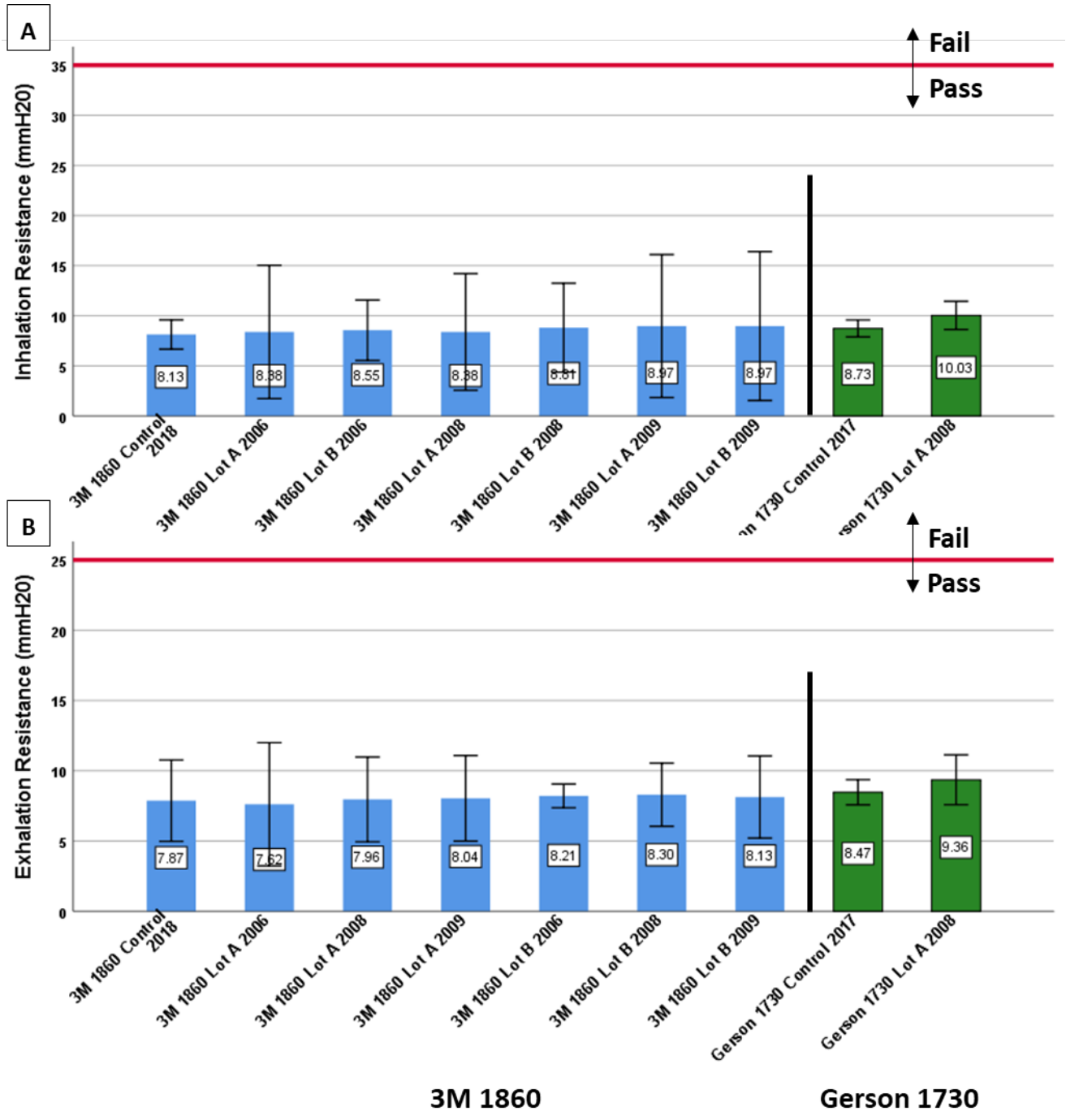


Figure 7: Control and stockpiled respirator inhalation (A) and exhalation (B) resistance data. N95 FFRs must have an inhalation resistance less than 35 mmH_2O and an exhalation resistance less than 25 mmH_2O. The pass/fail threshold for inhalation (A) and exhalation (B) resistance is shown by the red line. Error bars represent the 99% confidence interval and estimate the population parameters. This confidence interval suggests that 99% of any repeated samples tested and evaluated from this lot will have a mean between the upper and lower bounds.

Filtration Performance

- NIOSH evaluated the particulate penetration efficiency for 280 stockpiled respirators and 40 controls. **All stockpiled and control respirators from each model passed this test** (**Figure 8**).
- Using an analysis of variance (ANOVA), there were no statistically significant differences (defined as $\alpha \leq 0.05$) between the FFR controls and FFR stockpiled respirators for filtration when averaging across models.
- When comparing the individual respirator models to their respective controls through an ANOVA with adjusted, post-hoc multiple comparisons, the following statistically significant differences were detected: 1) 3M 1860 stockpiled 2006 Lot A had a higher penetration; 2) 3M 1860 stockpiled 2008 Lot A had a higher penetration; 3) 3M 1860 stockpiled 2008 Lot B had a lower penetration; 4) 3M 1860 stockpiled 2009 Lot B had a lower penetration; and 5) Gerson 1730 stockpiled 2008 Lot A had a higher penetration. The mean percent particle penetration for each lot of respirators tested is shown in **Figure 8**.
- None of the individual respirators tested exceeded the 5.0% maximum. The highest penetration for an individual stockpiled respirator was 2.82% and the highest penetration for an individual control respirator was 1.59%, both being below the NIOSH maximum limit for product approval.
- Additionally, the respirator shown in **Figure 4** is an example of one of 12 respirators where the nose foam stuck together. The highest maximum penetration when these units were tested was 1.61%, and, therefore, was not the stockpiled respirator associated with the highest penetration.

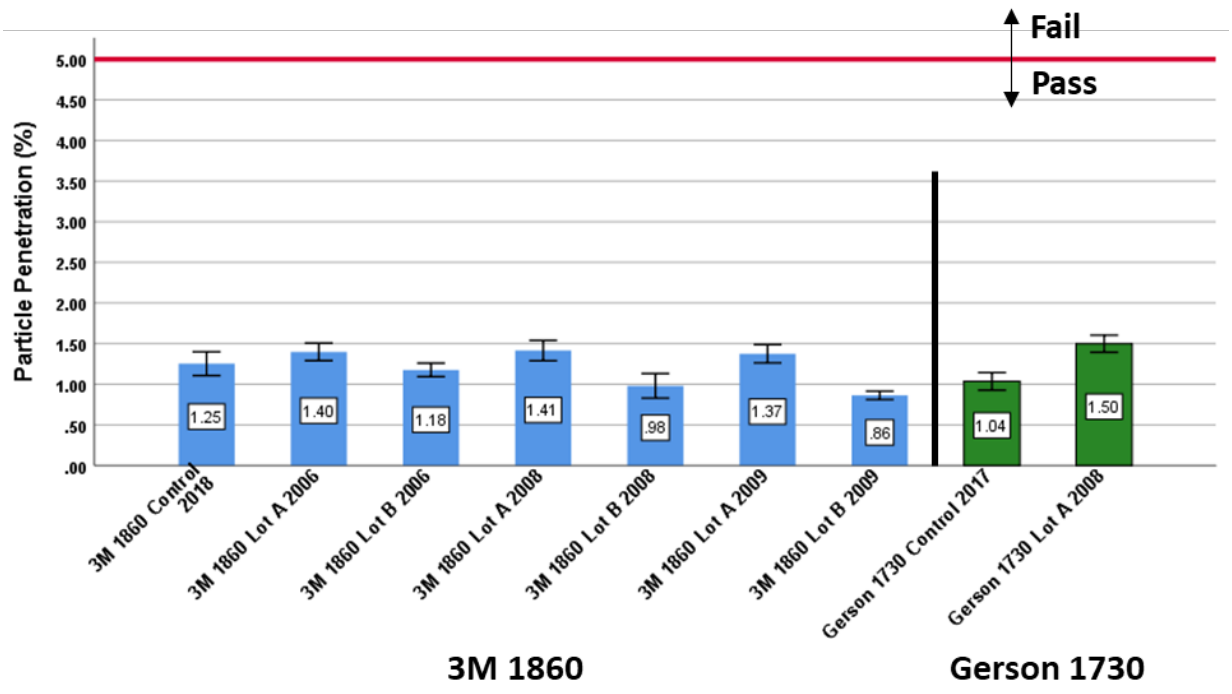


Figure 8: Control and stockpiled respirator particle filtration performance data. N95 FFRs must have a particle penetration of less than 5.0%. Error bars represent the 99% confidence interval and estimate the population parameters. This confidence interval suggests that 99% of any repeated samples tested and evaluated from this lot will have a mean between the upper and lower bounds.

CASE Findings

Findings for the Gerson 1730 Model:

No failures for inhalation resistance, exhalation resistance, or 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 Gerson 1730 units from Facility Two and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Findings for the 3M 1860 Model:

No failures for inhalation resistance, exhalation resistance, or 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 a five-year designated shelf life; the Appendix shows a 3M letter to end users with shelf life and recommended storage condition information [3M 2020]. Thus, these respirators tested are past their designated shelf life. These findings pertain to 3M units from Facility Two and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Stockpile Storage Conditions:

The data made available by Facility Two to the NIOSH research team suggests that both respirator models evaluated in this study were stored in an environment that was within the previously described recommendations for %RH and temperature. Stored under these conditions, NIOSH found that the 301 N95 FFRs evaluated in this study, which were 8-11 years old, maintained their inhalation and exhalation resistance and filtration performance (i.e., all respirators were below the NIOSH maximum limit as defined by 42 CFR Part 84).

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[7] (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 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

[7] An approval may be granted to a non-manufacturing entity.

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.

What Can Stockpile Personnel Do to Learn More about the Respirators in their Stockpile?

- Stockpile personnel should check the product information from the approval holder as well as the NIOSH Certified Equipment List to remain up-to-date on product storage conditions, shelf-life information, and NIOSH approval status. Check NIOSH's Certified Equipment List to verify the respirator model currently maintains its NIOSH approval at https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html
- Stockpile personnel should work with the approval holder(s) of the stockpiled products with specific questions regarding the use of expired product.
- Sign up for NPPTL's Listserv at https://www.cdc.gov/niosh/npptl/sub-NPPTL.html to receive email notifications relevant to PPE.

For more information related to personal protective equipment, visit the NIOSH NPPTL website https://www.cdc.gov/niosh/npptl/

Get More Information
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Monthly NIOSH eNews: cdc.gov/niosh/eNews

All photos courtesy of NIOSH NPPTL.

Disclaimer
The recommendations in this report are made based on the findings at the stockpile evaluated and may not be applicable to other stockpile facilities.

Suggested Citation

NIOSH [2020]. PPE CASE: Inhalation and Exhalation Resistance and Filtration Performance of Stockpiled Air-Purifying Respirators: Facility Two of Ten. By Greenawald, L., Moore, S., and Yorio, P. Pittsburgh, PA U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, NPPTL Report Number P2020-0102.

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Appendix [3M 2020]

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FAQ

Release 5, February 2020

Frequently Asked Questions: 3M Health Care Particulate Respirator and Surgical Masks Storage Conditions and Shelf Life

Why is 3M adding shelf life information for the 3M™ Health Care Particulate Respirator and Surgical Masks* 1804/1804S, 1860/1860S, 1870, 1870+?

The addition of shelf life information to our 3M NIOSH-approved respirators is a way to communicate to our customers the storage conditions and potential longevity of our respirators. Traditionally the life cycle of these respirators commonly used in health care workplace applications, from date of manufacture to use by the customer, has been short in duration as they are disposable. However, with the increased attention to respirator stockpiling, many customers have requested information on storage conditions and shelf life. We hope that by adding this information to the respirator packaging it will encourage our customers to employ good practices such as appropriate long term storage, rotation of stock and inventory management.

In the United States, per 29 CFR 1910.134, OSHA has required that respirators be stored in the original packaging and away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals. Canada's CSA Standard Z94.4 has a similar requirement.

*Models that are both NIOSH approved N95 filtering facepiece respirators and FDA cleared as a surgical mask.

What 3M Health Care Particulate Respirator and Surgical Masks have a shelf life?

The 3M Health Care Particulate Respirator and Surgical Mask models 1804/1804S, 1860/1860S, 1870, 1870+ have an established 5 year shelf life when respirators are stored in their original packaging within climatic conditions ranging from -4 °F (-20 °C) to +86 °F (+30 °C) and not exceeding 80% RH.

Why does the packaging for some 3M Health Care respirators have shelf life information and other respirator packaging does not?

The transition to updated packaging/labeling in relation to the storage conditions and shelf life has been initiated. However, for a period of time, you may see product packaging in the market place with and without storage condition and shelf life information included/incorporated.

How is the respirator's shelf life communicated?

The shelf life information is usually found on the side or bottom of the primary box. Storage conditions are included in the instructions for use (IFU). The shelf life for the health care NIOSH-approved respirators is in the form of a "use by" date such as "YYYY-MM-DD" (year-month-day) and should be located near the hourglass icon. This information is also located on the label of the shipper case or corrugated box. An explanation of the icons and additional information regarding shelf life and storage conditions can be found in the IFU provided with the respirator. Please refer to the respirator packaging as shelf life is specific to each model.

Here is an example of how storage conditions and shelf life will be depicted in the IFU and primary box respectively (this is an example only):

When stored in original packaging between temperatures from -4 °F (-20 °C) to +86 °F (+30 °C) and not exceeding 80% RH, the respirator may be used until the date specified on packaging located next to the "Use by Date" symbol.

 Use by Date

Here are some additional symbols that you will see in the updated instructions for use.

 Date of Manufacture

 Manufacturer's Lot Number relevant to the device bearing the symbol

 Manufacturer

What happens if storage conditions are not met?

3M's goal is to help our customers ensure that filtering facepiece respirators stored for extended periods of time will meet the performance requirements to which they were approved and function as intended. When establishing a shelf life, 3M takes into account the filter media as well as the component parts of the respirator such as the strap and any staples. Therefore, we are confident that the respirators will meet performance requirements when the identified conditions are met.

However, when respirators are maintained outside of the established storage conditions, 3M cannot ensure that the respirators will meet performance requirements. In this event, many different kinds of changes can occur to the respirator including cosmetic changes and degradation of components such as headbands, nose foam and noseclips. Examples of cosmetic changes include discoloration of materials. Examples of degradation include crumbling of nose foam or breaking of headbands.

It is always critical that the respirator be inspected and a user seal check be conducted by the wearer per the IFU. If the person wearing the respirator cannot achieve a proper seal the respirator should not be used.

How do we know when not to use the respirator?

First refer to the packaging for a "use by" date. 3M's recommendation is that respirators be disposed of after the stated use by date. Always inspect the respirator and conduct a user seal check before use per the IFU. If the person wearing the respirator cannot achieve a proper seal, then the respirator should not be used. Even for respirators within the stated shelf life, the respirator should be disposed of immediately upon observation of damaged or missing parts. For those respirators that have established shelf life but which packaging is not yet marked with a "use by" date, 3M recommends they no longer be used if 5 years has passed since the date of manufacture.

If the respirator is not marked with shelf life information, how can I determine the age of the respirator?

For respirators that are not currently labeled with shelf life information, the date of manufacture can be determined from the label or printed information located on the primary box as well as the shipper case or corrugated box. For assistance in interpreting the date of manufacture, please call 3M Health Care Helpline at 1-800-228-3957 if in the U.S. In Canada call 1-800-267-4414Release 5, February 2020. Other countries please contact your local 3M office.

Is it okay to exceed storage conditions and, if so, for how long?

It is recognized that recommended storage conditions may be exceeded for short periods of time during transportation. This has been accounted for in the shelf life determination. However, storage outside the recommended conditions should be avoided when possible.

Should the respirator be disposed of after the shelf life has expired?

3M's recommendation is that the respirator be disposed of after the stated use by date has expired.

Will 3M take back respirators that have reached the end of their stated shelf life?

No, 3M will not accept returns of respirators on the basis of shelf life.

Will all 3M respirators have the same shelf-life?

No, not all 3M respirators will have the same shelf life. In making shelf life determinations, 3M takes into account the filter media as well as the components of the respirator. Components vary from model to model. See the 3M Filtering Facepiece Shelf Life document for model specific information.

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3M PSD products are occupational use only.

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