PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Performance of Stockpiled Air-Purifying Respirators, Facility Six 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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March 1, 2020

NIOSH found that 387 of 387 N95 filtering facepiece respirators stockpiled at Facility Six that were 11-12 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 Six of Ten. This facility is a state stockpile facility.

How NIOSH Evaluated Respirators and Storage Conditions

Description of Facility Six

- NIOSH researchers visited Facility Six in April 2018 (**Figure 1**). This facility was located within the U.S. Department of Health and Human Services Region 10, representing Alaska, Idaho, Oregon, and Washington.

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 Six 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 Six stockpile personnel. This data was collected intermittently from January 2013 to November 2017. The data included temperatures taken at five different locations, which were averaged.

Collection of Respirator Samples

- Facility Six's inventory included APRs that are classified as N95 filtering facepiece respirators (FFRs). Samples were collected from four different manufacturing models[1]: 1) Kimberly Clark (KC) 46727; 2) KC 46827; 3) Moldex 2201; and 4) 3M 8000 (**Table 1**).
- Upon reviewing the detailed APR inventories and storage location by lot within Facility Six, two different manufacturing lots for each model were identified and sampled within Facility Six. Two lots were sampled to evaluate and attempt to account for inter-lot variation. More than two lots were sampled

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

from a model if conditions presented "worst-case scenario" conditions within the facility. 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 Six.

Table 1. FFRs Sampled from Stockpile Facility Six

Model	Lot #	Year of Manufacture	Shelf Life on Packaging?	Respirator Age at Time of Testing[3]	Shelf Life Status at Time of Testing
KC 46727	Lot A	2006	No	12 years	Past 5-year shelf life [4]
KC 46727	Lot A	2006	No		
KC 46827	Lot A	2007	No	11 years	Past 5-year shelf life[4]
KC 46827	Lot B	2007	No		
Moldex 2201	Lot A	2006	Yes - 2010	12 years	Past 9-year shelf life[5]
Moldex 2201	Lot B	2006	Yes - 2010		
3M 8000	Lot A	2006	No	12 years	Past 3-year shelf life[6]
3M 8000	Lot B	2006	No		
3M 8000	Lot C	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 KC 46827 and 46727 controls were manufactured in 2017, the Moldex 2201 controls were manufactured in 2018, and the 3M 8000 controls were manufactured in 2006[7]. 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**).

[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 2018.
[4] KC designated a five-year shelf life for this model [KC 2018]. As of February 2020, this model still has a five-year shelf life
[5] Moldex designated a nine-year shelf life for these models [Moldex 2015]. In 2006, the shelf life was designated as four years, but was changed in 2009 to nine years. As of February 2020, these models still have a nine-year shelf life.
[6] 3M designated a three-year shelf life for this model. This model is no longer produced or sold by 3M.
[7] 3M 8000 is no longer manufactured thus NIOSH was not able to purchase new units to be used as controls.

- **Table 2** describes the method for evaluating the inhalation and exhalation resistance and filtration performance of sampled respirators and control respirators.

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[8]	3[8]
STP 7: Inhalation Resistance	<35 mm H_2O column @ 85 LPM	3[8]	3[8]
STP 59: Particulate Filter Efficiency for N95	≤5.0% particulate penetration (≥95.0% filter efficiency)	40[9]	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 Six; examples of the most amount of dust is shown in **Figure 2**. No product boxes showed damage. Of the 387 respirators visually inspected, no concerns were noted.

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

- Temperature and %RH were controlled and intermittently monitored. Back-up generator existed in case of power outage. Facility lights were off when not in use. Ceiling fans continuously ran to circulate air.

[8] 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.
[9] 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.

No evidence of excess moisture or chemical spills that persisted beyond immediate mitigation were observed. Pallets were generally shrink wrapped around the four pallet sides and across the top. Generally, all pallets were separated by rack, reducing weight/load applied to a single pallet.

- Percent RH (**Figure 3**) and Temperature (**Figure 4**)
  - **At the time of publication**, the recommended storage requirements for %RH and temperature are
    - KC 46727 and 46827: remain under 60 %RH; remain within 68°F to 77°F [KC 2020]
    - Moldex 2201: no specific %RH recommendations; remain within 14°F and 122°F [Moldex 2019]
    - 3M 8000[7]: remain under 80 %RH; remain within -4°F to 86°F [3M 2017]
  - Temperature data was averaged across the five temperature collection locations. The average temperature between the 2013-2017 time period was 71.4°F. The average %RH between 2013-2017 was 34.0%; these averages are within KC, Moldex, and 3M's recommended temperature and %RH storage conditions.
  - For the KC models, 2.6% of data points were below 68°F and 0.3% were above 77°F. No temperature data points deviated from Moldex or 3M's recommended conditions. For %RH, no data points deviated from KC, 3M, or Moldex's recommended storage conditions.
  - Some respirators from Facility Six 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.

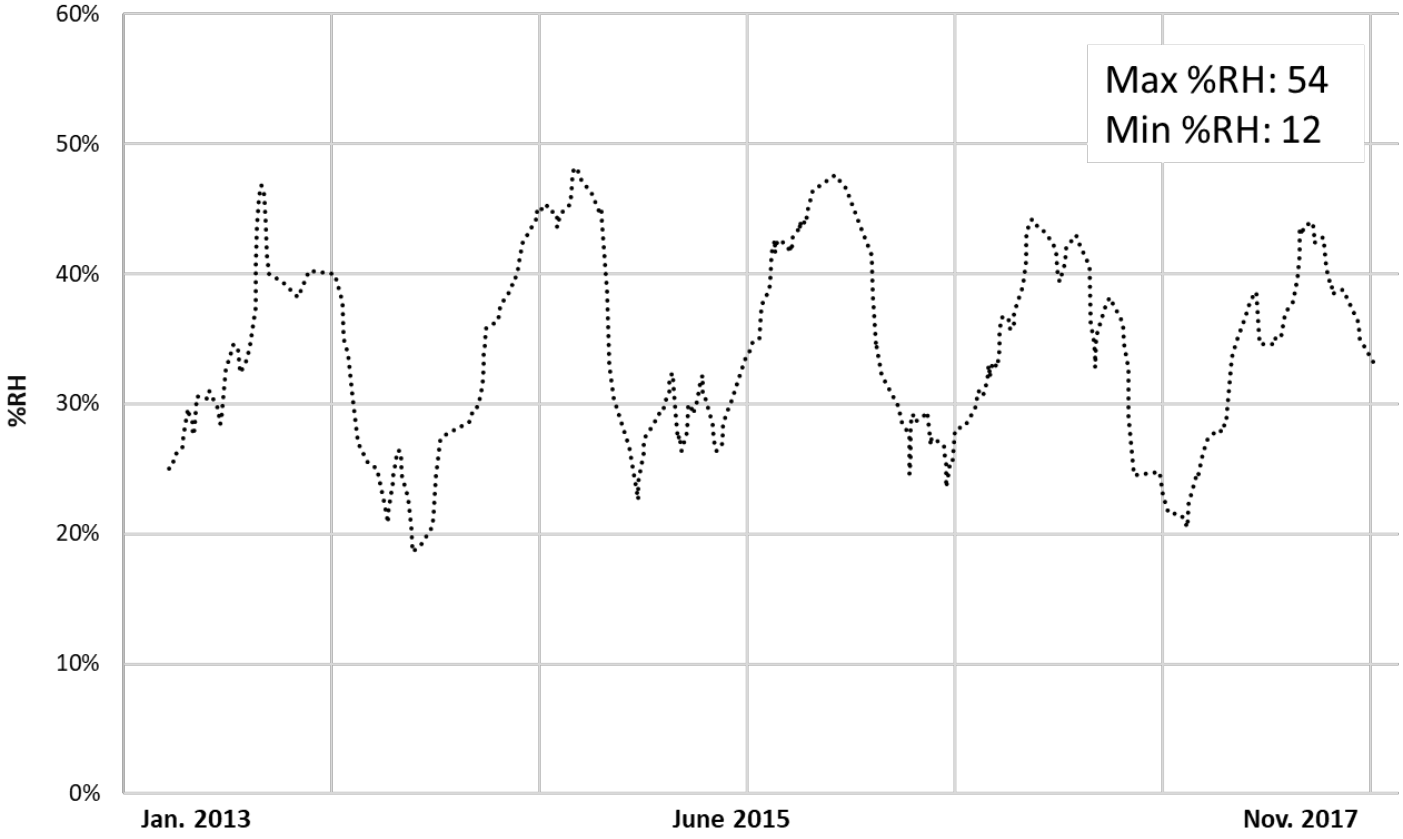

Figure 3: Percent Relative Humidity (% RH) from January 2013 – November 2017 taken at one location within Facility Six. Data is plotted as a 5-point moving average for visualization purposes. Maximum and minimum temperatures reported are noted for each data logger.

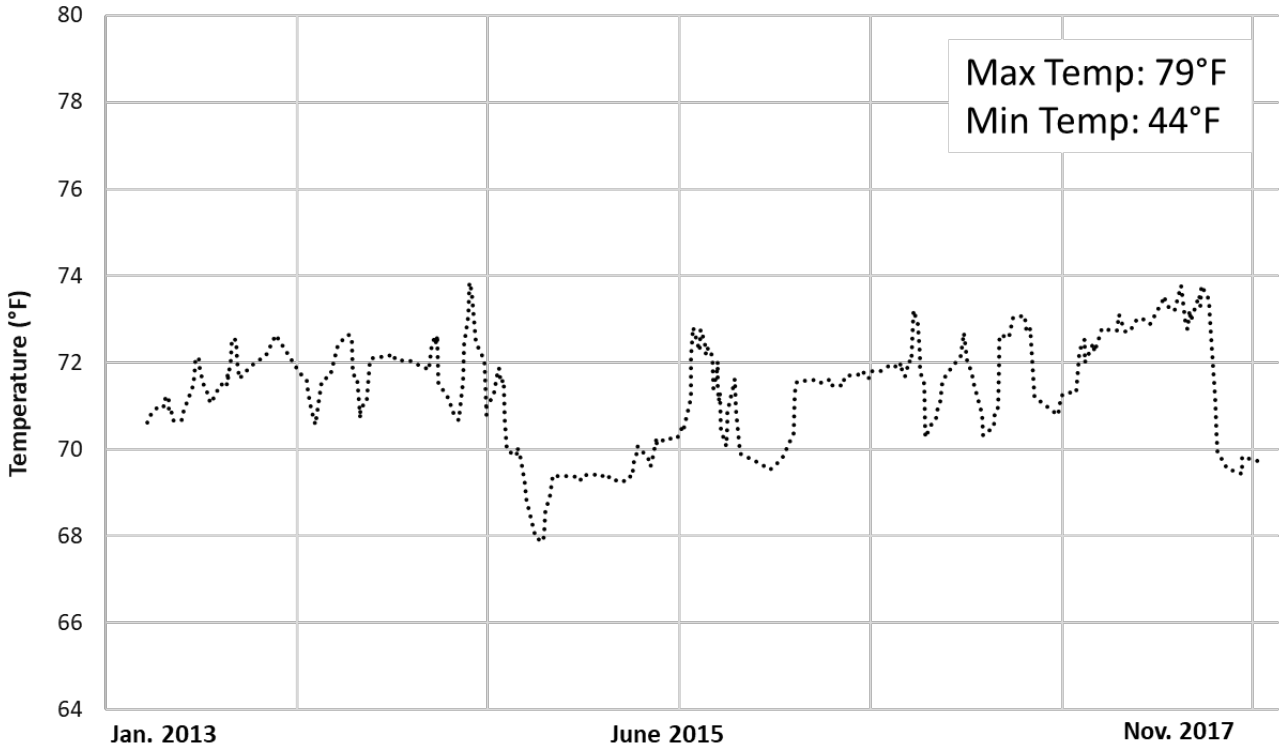

Figure 4: Temperatures from January 2013 – November 2017 taken at five locations within Facility Six. Data is plotted as a 5-point moving average for visualization purposes. Maximum and minimum temperatures reported are noted for each data logger.

Inhalation and Exhalation Resistance

- NIOSH evaluated the inhalation and exhalation resistance for a total of 27 stockpiled and 12 control respirators. **All stockpiled and control respirators from each model passed these tests (Figure 5).**
- 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 following statistically significant differences were found with respect to exhalation resistance: 1) 3M 8000 stockpiled 2006 Lots A and B were statistically significantly higher; 2) KC 46827 stockpiled 2007 Lot A was significantly lower; and 3) Moldex 2201 stockpiled 2006 Lot A was significantly higher. The following statistically significant differences were found with respect to inhalation resistance: 1) 3M 8000 stockpiled 2006 Lots A and B were statistically significantly higher; 2) KC 46827 stockpiled 2007 Lots A and B were significantly lower; and 3) Moldex 2201 stockpiled 2006 Lot A was statistically significantly higher.
- For inhalation resistance, the individual stockpiled respirator with the highest resistance (15.75 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 (14.22 mm H_2O) was below the NIOSH maximum limit for product approval (25 mm H_2O allowable maximum).

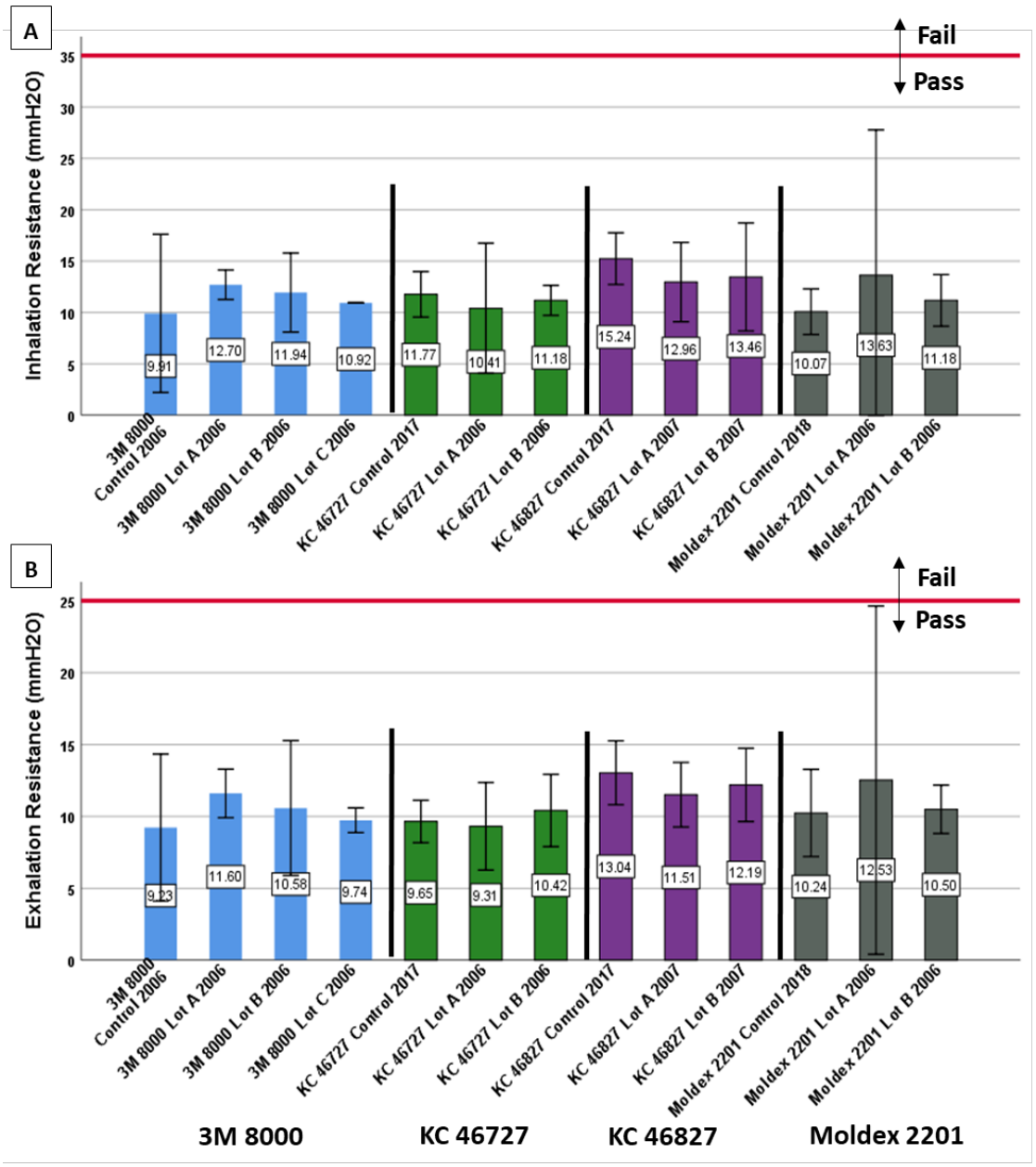

Figure 5: Control and stockpiled respirator inhalation (A) and exhalation (B) resistance data. N95 FFRs must have an inhalation resistance less than 35 mmH_2O and an exhalation resistance less than 25 mmH_2O. The pass/fail threshold for inhalation (A) and exhalation (B) resistance is shown by the red 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 360 stockpiled respirators and 80 controls.
- None of the individual stockpiled respirators tested exceeded the 5.0% maximum (**Figure 6**). The highest penetration for an individual stockpiled respirator was 4.82% (KC 46727) and the highest penetration for an individual control respirator was 4.93% (KC 46727).
- Using an analysis of variance (ANOVA), there was not a statistically significant difference (defined as $\alpha \leq 0.05$) between KC control and KC stockpiled respirators. 3M controls (mean percent penetration=2.45%, SD=0.36) displayed a significantly higher penetration when compared to 3M stockpiled respirators (mean percent penetration=1.75%, SD=0.67) when averaging across models; and Moldex controls (mean percent penetration=1.66%, SD=0.31) displayed a statistically significantly higher penetration when compared to Moldex stockpiled respirators (mean percent penetration=0.74%, SD=0.31) 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) each of the 3M 8000 stockpiled 2006 Lots had a lower penetration; 2) KC 46727 stockpiled 2006 Lot A had a lower penetration; 3) KC 46827 stockpiled 2007 Lot A had a higher penetration; and 4) both Moldex 2201 stockpiled 2006 Lots A and B had a lower penetration.

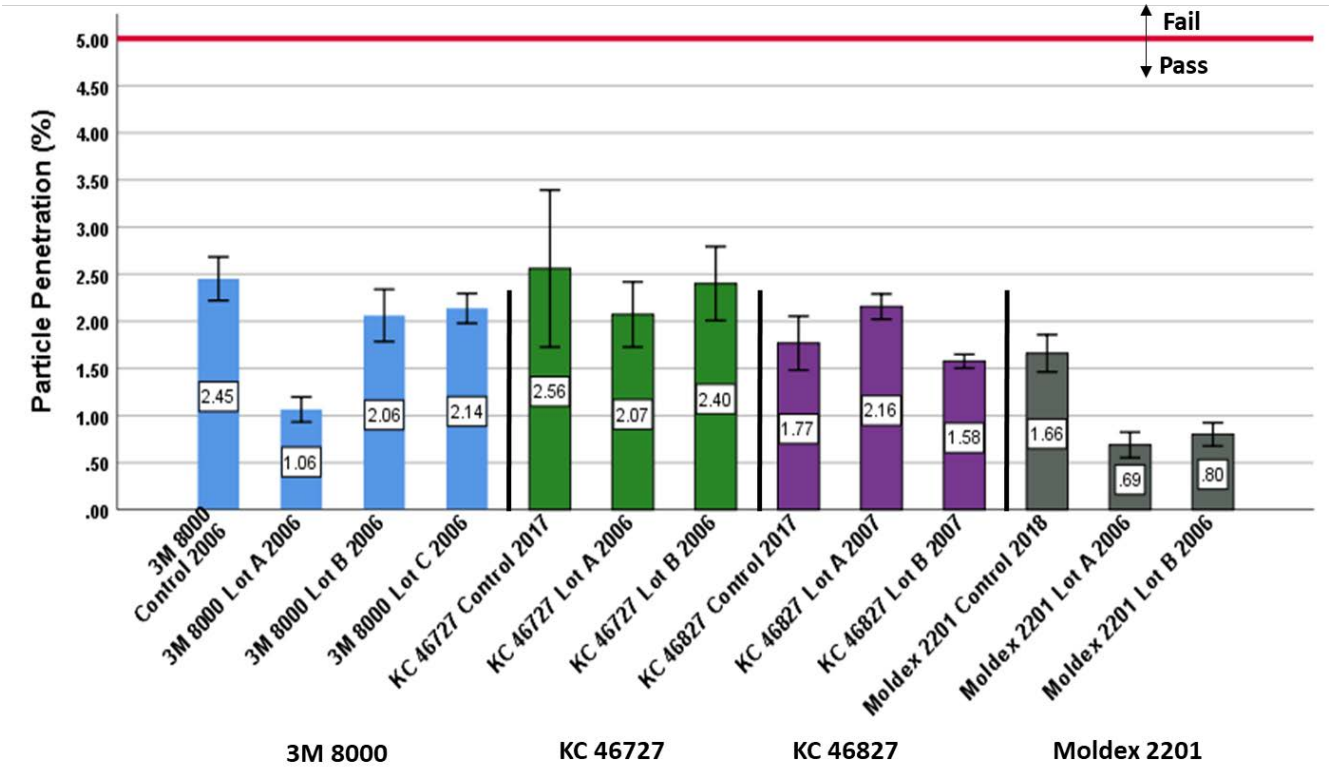

Figure 6: Control and stockpiled respirator particle filtration performance data. N95 FFRs must have a particle penetration of less than 5.0%. Error bars represent the 99% confidence interval and estimate the population parameters. This confidence interval suggests that 99% of any repeated samples tested and evaluated from this lot will have a mean between the upper and lower bounds.

CASE Findings

Findings for the KC 46727 and 46827 Models:

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 recommended shelf life; Appendix 1 shows a KC letter to end users with shelf life information, which states respirators past their shelf life should be discarded [KC 2018]. Thus, these respirators tested are past their recommended shelf life. These findings pertain to KC units from Facility Six and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Findings for the 3M 8000 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 is no longer produced and sold by 3M. Additionally, Appendix 2 shows two 3M letters to end users with shelf life and recommended storage condition information [3M 2018, 3M 2020]. Thus, all respirators tested are past their recommended shelf life. These findings pertain to 3M units from Facility Six and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Findings for the Moldex 2201 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 nine-year recommended shelf life; Appendix 3 shows a Moldex memo to customers and distributors with shelf life and recommended storage condition information [Moldex 2015]. Thus, all respirators tested are past their recommended shelf life. These findings pertain to Moldex units from Facility Six and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Stockpile Storage Conditions:

For the KC models, 2.9% of data points deviated from the previously described recommended conditions. No temperature data points deviated from Moldex or 3M's recommended conditions. For %RH, no data points deviated from KC, 3M, or Moldex's recommended storage conditions. Stored under these conditions, NIOSH found that 387 N95 FFRs evaluated in this study, which were 11-12 years old, maintained their inhalation and exhalation resistance and filtration performance (i.e. all sampled 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[10] (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.

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

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 designated shelf life.

NIOSH recommends users contact 3M regarding use of 3M model 8000 respirators.

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
Find NIOSH products and get answers to workplace safety and health questions:

1-800-CDC-INFO (1-800-232-4636) | TTY: 1-888-232-6348
CDC/NIOSH INFO: cdc.gov/info | cdc.gov/niosh
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.

Centers for Disease Control and Prevention
National Institute for Occupationa Safety and Health

Suggested Citation

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Appendix 1 [KC 2018]

Kimberly-Clark PROFESSIONAL*

Date: June 7, 2018

Subject: Kimberly-Clark* N95 Particulate Filter Respirator and Surgical Mask Shelf Life (Codes: 62355, 62126, 46827, 46727, 46867, and 46767)

Dear Valued KCP Customer,

Since 2014, all Kimberly-Clark* N95 Particulate Filter Respirator and Surgical Mask† packaging has included the storage conditions within the user instructions and the expiration date printed on each dispenser. If you have product in inventory produced prior to 2014 and without a printed expiration date, confirm that the product is within the recommended five year shelf life prior to using. Verify either through your purchase records or by contacting us with the printed lot number to determine the date of manufacture. We recommend disposing of any product that is beyond the established shelf life, has not been stored according to the user instructions, is damaged, does not provide a proper fit, or has missing parts.

For further information regarding the shelf life or interpreting the lot number to determine the expiration date, please contact us via the Kimberly-Clark Professional* Technical or Quality hotline at 888-346-4652, email kcpinfo@kcc.com

Thank you for your continued business and support of Kimberly-Clark Professional*.

†Kimberly-Clark* N95 Particulate Filter Respirator and Surgical Mask codes: 62355, 62126, 46827, 46727, 46867, and 46767

Appendix 2 [3M 2018], [3M 2020]

3M Personal Safety Division

St. Paul, MN 55144-1000

June, 2018

Dear Valued Customer:

Thank you for your inquiry regarding the shelf life of 3M filtering facepiece respirators. 3M is currently in the process of establishing a shelf life for various filtering facepiece respirators. The table below provides a list of models that currently have or will shortly have storage conditions and shelf life information communicated in either the User Instructions and/or packaging in the form of symbols, printed use by dates, etc. As some models were not introduced with storage conditions/ shelf life markings, the year listed indicates when these packaging updates were implemented for that particular model.

Table A. 3M Filtering Facepiece Respirators

Model	Years of Implementation on Package	Shelf Life from Date of Manufacture*
8110S	2016	5 years
8200 (AAD#07023)	2009	5 years
8210	2016	5 years
8210*Plus* (AAD#07048)	2016	5 years
8210V	2011	5 years
8211	2014	5 years
8212	2012	3 years
8214 (AAD#07187)	2012	3 years
8233	2018	5 years
8240	Future	5 years
8246	2017	3 years
8247 (AAD#07186)	2017	3 years
8271	Future	5 years
8293	2018	5 years
8510**	2010	5 years
8511 (AAD#07185)	2014	5 years
8512	2012	3 years
8514	2012	3 years
8515 (AAD#07189)	2012	2 years
8516	Future	3 years
8576	2017	3 years
8577	2017	3 years
9105, 9105S	2010	5 years
9210** (AAD#37021)**	2010	5 years
9211** (AAD#37022)**	2010	5 years
9210+ (AAD#37192)	2013	5 years
9211+ (AAD#37193)	2013	5 years
Medical		
1804, 1804S	2018	5 years
1860, 1860S	2013	5 years
1870**	2013	5 years
1870+	2013	5 years

* Please refer to respirator user instructions and packaging for specific storage conditions and use by date information.
**Discontinued.

IMPORTANT NOTE

OSHA requires that all respirators be stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and that they be stored to prevent deformation of the facepiece and exhalation valve. Always follow the product's User Instructions, including that respirators should always be inspected prior to use and discarded if damage to any component is observed.

Additional information, including updates regarding shelf life and storage conditions of 3M Filtering Facepiece Respirators can be found at www.3M.com/workersafety. The following resource documents are offered for your reference:

- Shelf Life FAQ Industrial Filtering Facepiece - Disposable Respirators
- Shelf Life FAQ Health Care Particulate Respirators and Surgical Mask

Please call 3M Personal Safety Division's Technical Service at 1-800-243-4630 if you have further questions. Thank you for using 3M products.

Sincerely,

3M Personal Safety Division (PSD)

3M Science. Applied to Life.™

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.

Personal Safety Division
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3M PSD products are occupational use only.

In United States of America
Technical Service: 1-800-243-4630
Customer Service: 1-800-328-1667
3M.com/workersafety
In Canada
Technical Service: 1-800-267-4414
Customer Service: 1-800-364-3577
3M.ca/Safety

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Appendix 3 [Moldex 2015]

MOLDEX
Ideas that wear well.

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TO: Moldex Customers & Distributors

FROM: Jeffrey S. Birkner, Ph.D., CIH
Vice President of Technical Services

RE: Use By/Expiration Dating for Moldex Respiratory Protection Products
Certified Under NIOSH/DHHS Schedules TC84A – Particulate Filter Respirators &
TC23C - Chemical Cartridge Respirators

DATE: Monday, June 22nd, 2015

All Moldex respiratory protection products have Use By (or) Expiration Dates on them.

These dates are placed on the product packaging as they are manufactured. This is intended to assist our customers who use and sell our products to deplete older inventory first, and to protect users where the performance of the product may have been affected by unknown or improper storage conditions.

We recommend that if you have any Moldex respirator or respirator related product that has an expired **"Use By Date"** or if the product packaging is not intact, that the product should NOT be sold or used.

If you have any additional questions or should you require further assistance, please call our Technical Service Department, at (800) 421-0668, ext. 512 or 550 or by e-mail us at tech@moldex.com.

Expiration Dating for Respirators, Filters, and Accessories

Product	Type	Expiration Date
Disposable Respirators	Any models with valve	Four Years
	N99, N100, R95, P95, P100 and OV and AG models	
	All other models, including new N95, series without carbon and without valve, and Healthcare N95/Surgical masks	Nine Years
Reusable Respirators	Spare Reusable Face Piece	Five Years
	Gasket Replacement Kit, Head Harness Kit, and Spare Exhale Valve Kit	
Filters	All Flat and Pleated Disk Filters	Four Years
Cartridges	P100 Filter Cartridge	
	Organic Vapors (OV)	
	OV/AG	
	Acid Gas (AG)	Five Years
	Ammonia/Methylamine	
	Formaldehyde	
	Multi Gas / Vapor	Three Years
Respirator & Cartridge and/or Filter Assemblies	Assembled Reusable Respirators with Cartridges Only	The same expiration date as the cartridge used to make the respirator assembly
	Assembled Reusable Respirators with Filter Cartridge, Flat or Pleated Disk Filters (standalone or in combination with cartridges)	Four Years
Fit Test Materials	Bitrex Fit Test Solutions	Five Years