

PPE CASE



Personal Protective Equipment Conformity Assessment Studies and Evaluations

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

*National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
Lee A. Greenawald, Susan M. Moore, Patrick L. Yorio
March 1, 2020*

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].

NIOSH found that 344 of 344 N95 filtering facepiece respirators stockpiled at Facility Eight that were 9-12 years old maintained their inhalation and exhalation resistance and filtration performance in accordance with NIOSH performance standards.

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 Eight of Ten. This facility is a regional stockpile facility.

How NIOSH Evaluated Respirators and Storage Conditions

Description of Facility Eight

- NIOSH researchers visited Facility Eight in November 2018 (**Figure 1**). This facility was located within the U.S. Department of Health and Human Services Region 8, representing Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.

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 Eight such as location and type of lighting, pallet stacking practices, and conditions of the flooring, roofing, and exterior walls.

- NIOSH collected facility temperature and percent relative humidity (%RH) data by placing one data logger in the facility. This data was collected in 60-minute intervals from December 2018 to July 2019.

Collection of Respirator Samples

- Facility Eight’s inventory included APRs that are classified as N95 filtering facepiece respirators (FFRs). Samples were collected from five different manufacturing models¹: 1) 3M 1860; 3M 8000; Kimberly Clark (KC) 46727; KC 46827; and Moldex 1512 (**Table 1**).
- Upon reviewing the detailed APR inventories and storage location by lot within Facility Eight, two different manufacturing lots for each model were identified and sampled within Facility Eight. Two lots were sampled to evaluate and attempt to account for inter-lot variation. Only one lot for the KC 46727 and KC 46827 were available for sampling. 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 Eight.

Table 1. FFRs Sampled from Stockpile Facility Eight

| 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 | 2007 | No | 11 years | Past 5-year shelf life ⁴ |
| 3M 1860 | Lot B | 2007 | No | | |
| 3M 8000 | Lot A | 2008 | No | 10 years | Past 3-year shelf life ⁴ |
| 3M 8000 | Lot B | 2008 | No | | |
| KC 46727 | Lot A | 2006 | No | 12 years | Past 5-year shelf life ⁵ |
| KC 46827 | Lot A | 2006 | No | | |
| Moldex 1512 | Lot A | 2009 | Yes-2018 | 9 years | Past 9-year shelf life ⁶ |
| Moldex 1512 | Lot B | 2009 | Yes-2018 | | |

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.

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 3M designated a five-year shelf life for the 3M 1860 model [3M 2018]. As of February 2020, the 3M 1860 model still has a five-year shelf life; the 3M 8000 has a three-year shelf life and is no longer produced or sold by 3M.

⁵ 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.

⁶ Moldex designated a nine-year shelf life for these models [Moldex 2015]. As of February 2020, these models still have a nine-year shelf life.

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 2006⁷. 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.

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 ₂ O column @ 85 liters per minute (LPM) | 3 ⁸ | 3 ⁸ |
| STP 7: Inhalation Resistance | <35 mm H ₂ O 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 |

⁷ 3M 8000 is no longer manufactured thus NIOSH was not able to purchase new units to be used as controls.

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.

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 Eight; examples of the most amount of dust and product case damage are shown in **Figures 2 and 3**. Three 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 Eight.



Figure 3: Most amount of damage observed on product cases from Facility Eight.

- Temperature was controlled by swamp coolers and heaters with minimum and maximum control on a thermostat. No %RH controls or monitoring existed. No back-up generators existed in case of power outage. Facility lights were off when not in use. 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; many products were not on pallets, but the product cases were shrink wrapped. Other products were not on pallets nor shrink wrapped. Generally, some pallets were separated by rack, and others were stacked two high causing some weight/load applied to a single pallet.

- Percent RH (**Figure 4**) and Temperature (**Figure 5**)
 - **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 1512: no specific %RH recommendations; remain within 14°F and 122°F [Moldex 2019]
 - 3M 1860: remain under 80 %RH; remain within -4°F to 86°F [3M 2017]
 - 3M 8000¹⁰: remain under 80 %RH; remain within -4°F to 86°F [3M 2017]
 - The average temperature between the 2018-2019 time period was 68.15°F. The average %RH between 2018-2019 was 72.8%; these averages are within KC, Moldex, and 3M's recommended temperature and %RH storage conditions.
 - For the KC models, 63.8% of data points were below 68°F and 7.9% were above 77°F. For the 3M models, 0.02% of temperature data points deviated from recommended conditions. No temperature data points deviated from Moldex's recommended conditions. For %RH, 2.9% of data points deviated for the KC models, where no data points deviated from 3M's or Moldex's recommended storage conditions.

¹⁰ This model is no longer produced and sold by 3M.

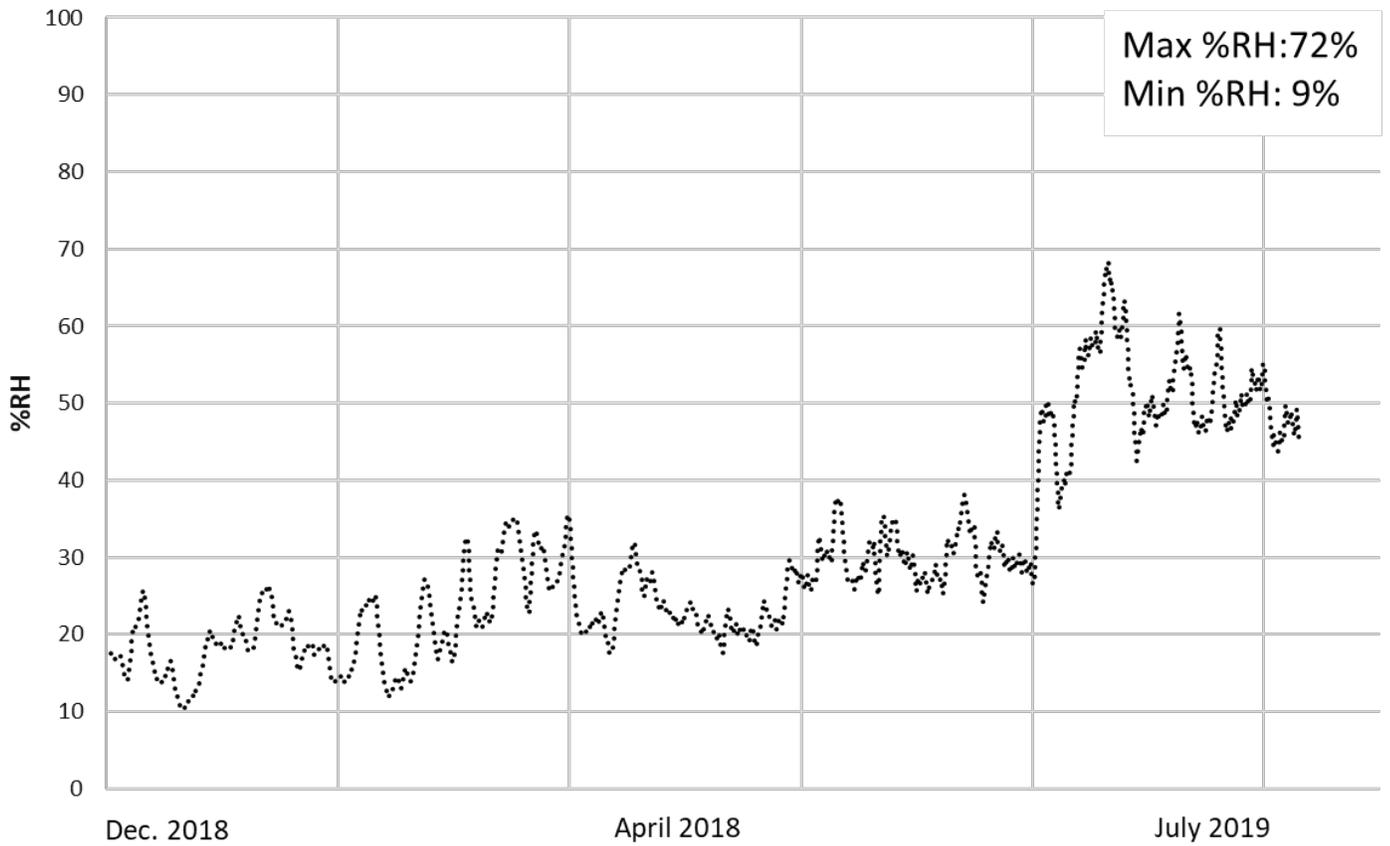
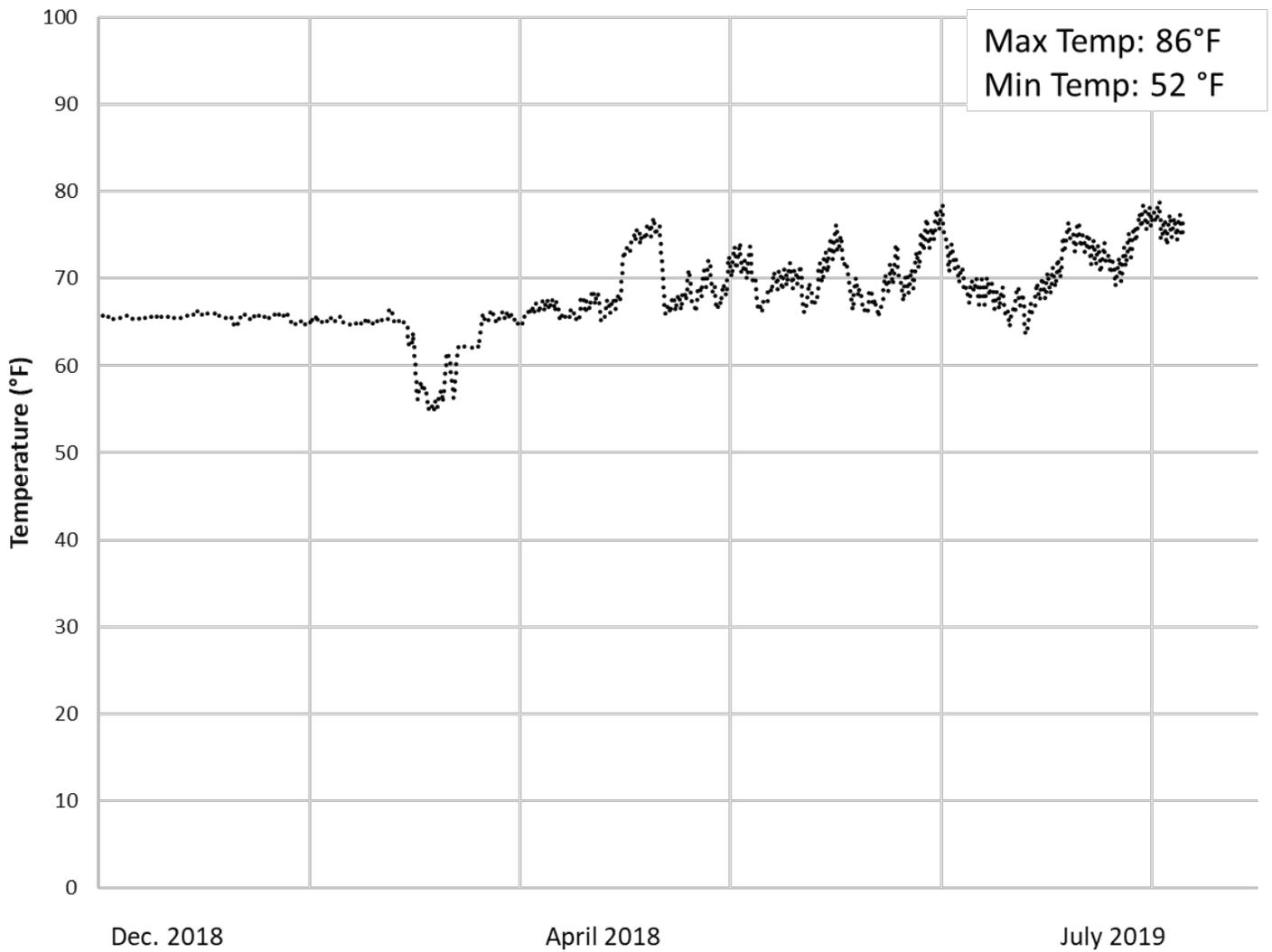


Figure 4: Percent Relative Humidity (% RH) from December 2018 – July 2019 for one data logger stored at Facility Eight. Data is plotted as a 20-point moving average for visualization purposes. Maximum and minimum temperatures reported are noted for each data logger.



Inhalation and Exhalation Resistance

- NIOSH evaluated the inhalation and exhalation resistance for a total of 24 stockpiled and 15 control respirators. **All stockpiled and control respirators from each model passed these tests (Figure 6).**
- 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 inhalation and exhalation resistance: 1) KC 46727 stockpiled 2006 Lot A was higher; and 2) KC 46827 stockpiled 2006 Lot A was lower.
- For inhalation resistance, the individual stockpiled respirator with the highest resistance (14.99 mm H₂O) was below the NIOSH maximum limit for product approval (35 mm H₂O allowable maximum). For exhalation resistance, the individual stockpiled respirator with the highest resistance (14.48 mm H₂O) was below the NIOSH maximum limit for product approval (25 mm H₂O allowable maximum).

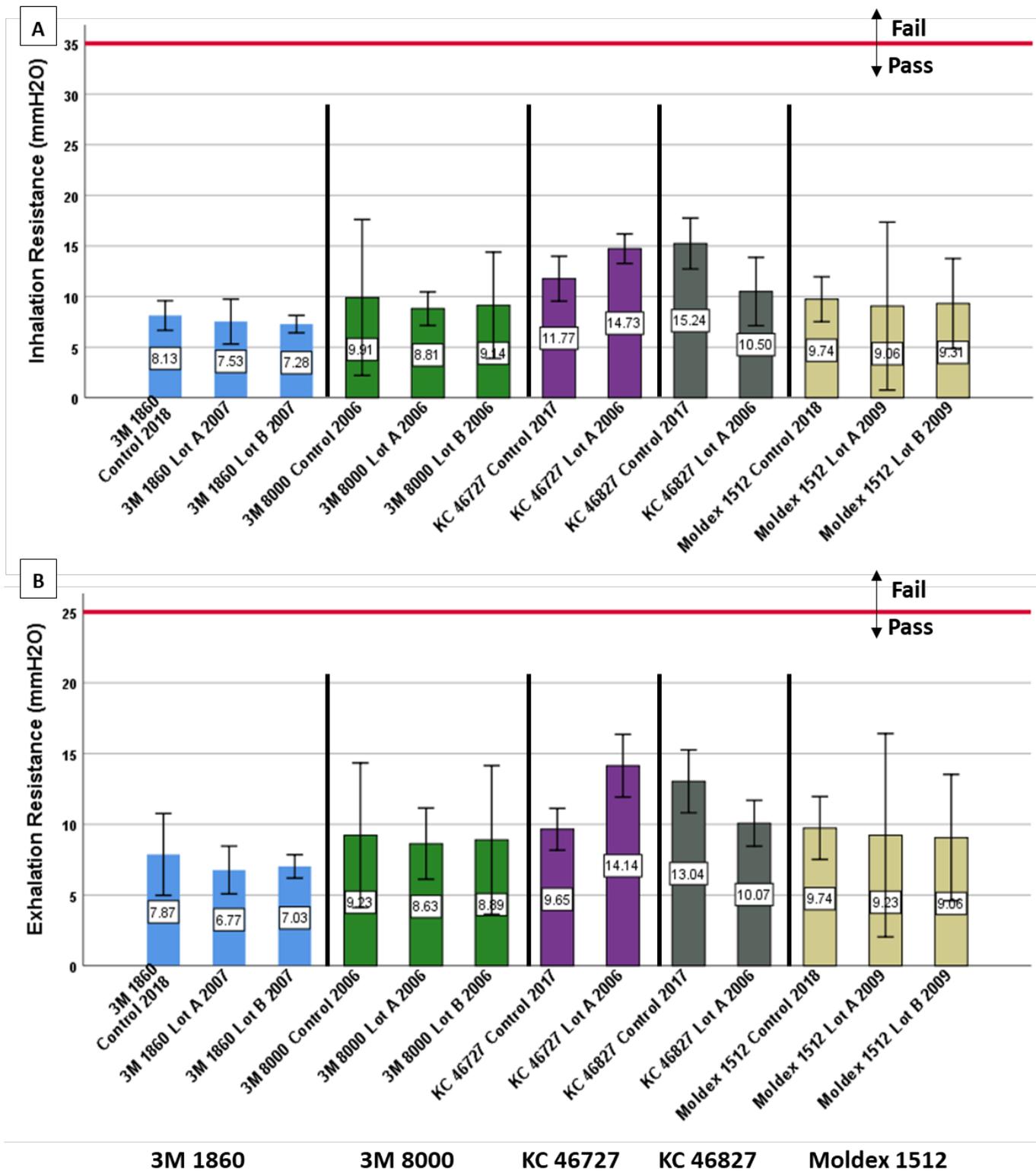


Figure 6: Control and stockpiled respirator inhalation (A) and exhalation (B) resistance data. N95 FFRs must have an inhalation resistance less than 35 mmH₂O and an exhalation resistance less than 25 mmH₂O. The pass/fail threshold for inhalation (A) and exhalation (B) resistance is shown by the red line. 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 320 stockpiled respirators and 100 controls (Figure 7).
- Using an analysis of variance (ANOVA), **there was no statistically significant difference (defined as $\alpha \leq 0.05$)** between the 3M and Moldex controls and the stockpiled respirators when averaging across models. There was a statistically significant difference between the KC controls (mean penetration=2.16, SD=1.04) and the KC stockpiled respirators (mean penetration=1.80, SD=0.54), $p=0.01$.
- When comparing the particle penetration for stockpiled respirator models to their respective controls through an ANOVA with adjusted, post-hoc multiple comparisons, the following statistically significant differences were detected: 1) both 3M 1860 stockpiled 2007 lots A and B were higher; 2) both 3M 8000 stockpiled 2006 lots A and B were lower; and 3) KC 46727 stockpiled 2006 Lot A was lower.
- None of the individual stockpiled respirators tested exceeded the 5.0% maximum. The highest penetration for an individual stockpiled respirator was 3.96% and the highest penetration for an individual control respirator was 4.93%.

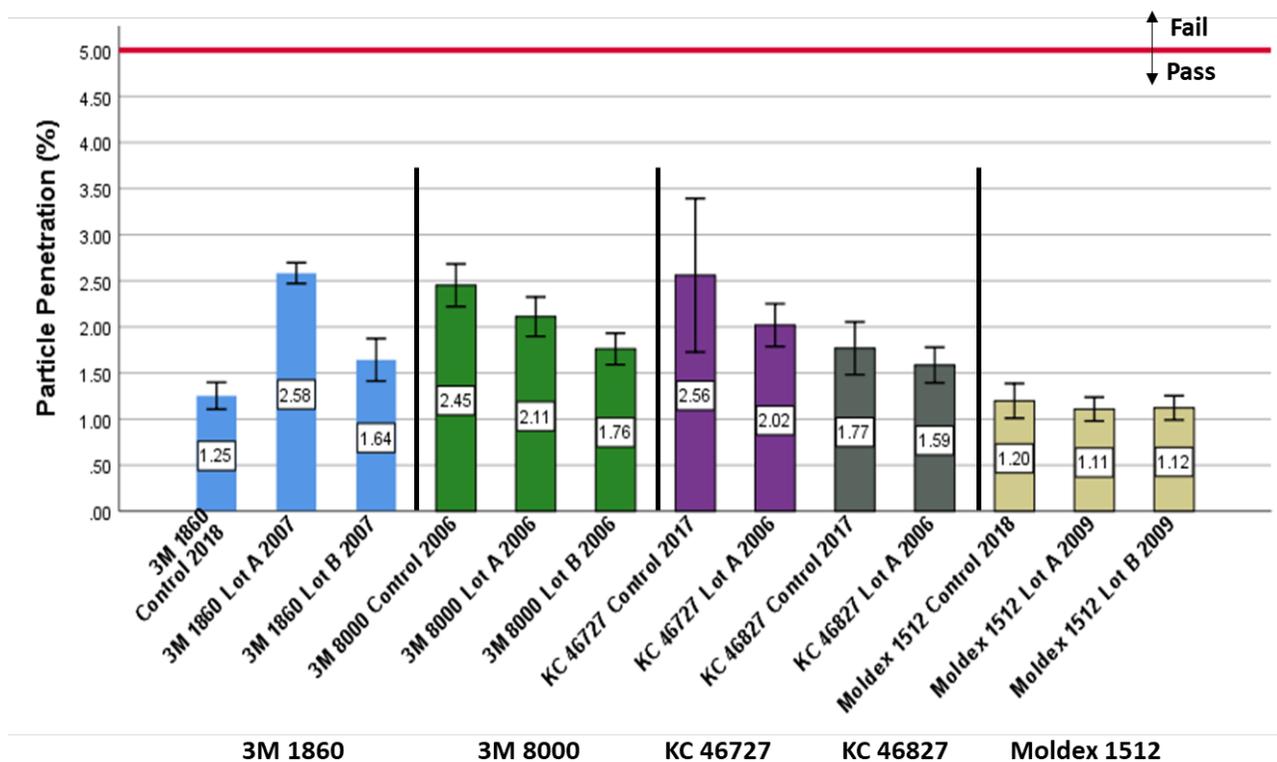


Figure 7: Control and stockpiled respirator particle filtration performance data. N95 FFRs must have a particle penetration of less than 5.0%. Error bars represent the 99% confidence interval and estimate the population parameters. This confidence interval suggests that 99% of any repeated samples tested 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. These models currently have 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 Eight 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 recommended shelf life; 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 Eight 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. 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 Eight and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

[Findings for the Moldex 1512 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 Eight and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

[Stockpile Storage Conditions:](#)

For the KC models, 71.7% of temperature data points deviated from the previously described recommended storage conditions. For the 3M models, 0.02% of temperature data points deviated from the previously described recommended conditions. No temperature data points deviated from Moldex's recommended conditions. For %RH, 2.9% of data points deviated for the KC models, where no data points deviated from 3M's or Moldex's recommended storage conditions. Stored under these conditions, NIOSH found that 384 N95 FFRs evaluated in this study, which were 9-12 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 holder¹¹ (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 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.

¹¹ An approval may be granted to a non-manufacturing entity.

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/) <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](https://www.cdc.gov/info) | [cdc.gov/niosh](https://www.cdc.gov/niosh)

Monthly NIOSH eNews: [cdc.gov/niosh/eNews](https://www.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.

Mention of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH). In addition, citations to websites external to NIOSH do not constitute NIOSH endorsement of the sponsoring organizations or their programs or products. Furthermore, NIOSH is not responsible for the content of these websites. All web addresses referenced in this document were accessible as of the publication date.



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

Suggested Citation

NIOSH [2020]. PPE CASE: Inhalation and Exhalation Resistance and Filtration Performance of Stockpiled Air-Purifying Respirators: Facility Eight 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 P2020-0108.

References

3M [2017]. Frequently Asked Questions: 3M Filtering Facepiece/Disposable Respirator Storage Conditions and Shelf Life. St. Paul, MN. <https://multimedia.3m.com/mws/media/10158530/faq-3m-filtering-facepiece-disposable-respirator-storage-conditions-and-shelf-life.pdf> [accessed February 27, 2020].

3M [2018]. 3M Personal Safety Division Letter. St. Paul, MN: The 3M Company. <https://multimedia.3m.com/mws/media/14303830/3m-filtering-facepiece-shelf-life-letter.pdf>.

3M [2020]. Frequently Asked Questions: 3M Health Care Particulate Respirator and Surgical Masks Storage Conditions and Shelf Life. St. Paul, MN. <http://multimedia.3m.com/mws/media/8692380/3m-health-care-particulate-respirator-and-surgical-masks-storage-conditions-and-shelf-life-faq.pdf>

ASTHO [2013]. Federal Emergency Preparedness Directives and Systems- Emergency Authority and Immunity Toolkit. Arlington, VA: Association of State and Territorial Health Officials. <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Authority-and-Immunity-Toolkit/Federal-Emergency-Preparedness-Directives-and-Systems-Fact-Sheet/>.

Carias C, Rainisch G, Shankar M, Adhikari BB, Swerdlow DL, Bower WA, Piliai SK, Meltzer MI, Koonin LM [2015]. Potential demand for respirators and surgical masks during a hypothetical influenza pandemic in the United States. *Clinical Infectious Diseases* 60 (1): S42-S51 <https://doi.org/10.1093/cid/civ141>.

DHHS [2012]. An HHS retrospective on the 2009 H1N1 influenza pandemic to advance all hazards preparedness. Washington D.C.: U.S. Department of Health and Human Services, <https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>.

KC [2018]. Kimberly Clark Letter to Customers (Appendix 1).

KC [2020]. Kimberly Clark representatives, email correspondence, February 25, 2020.

Moldex [2015] Moldex Memo to Customers and Distributors (Appendix 3).

Moldex [2019]. Moldex Customer Service Representative, email correspondence, October 31, 2019.

NIOSH [1997]. 42 CFR Part 84 respiratory protective devices. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, <https://www.cdc.gov/niosh/npptl/topics/respirators/pt84abs2.html>.

NIOSH [2017]. Workplace safety and health topics: healthcare workers. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, <https://www.cdc.gov/niosh/topics/healthcare/default.html>.

NIOSH [2018]. Standard respirator testing procedures. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, <https://www.cdc.gov/niosh/npptl/stps/apresp.html>.

NIOSH [2019]. NIOSH conformity assessment notice: NIOSH CA 2019-1012, NIOSH respirator approval contents and meaning. Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitynotice/CA-2019-1012.html>.

Patel A, D'Alessandro M, Ireland KJ, Burel WG, Wencil EB, Rasmussen SA [2017]. Personal protective equipment supply chain: lessons learned from recent public health emergency responses. *Health Security*. 15 (3): 244-252
<https://doi.org/10.1089/hs.2016.0129>.

Rottach DR, Lei Z [2017] Stockpiled N95 filtering facepiece respirator polyisoprene strap performance. *J Int Soc Respir Prot*. 34 (2): 69-80 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6198819/>.

Appendix 1 [KC 2018]



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

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 |
| 8210Plus (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.

3M Personal Safety Division

i 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)

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.

3M Personal Safety Division



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 1-800-267-4414. Release 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.

3M Personal Safety Division

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
3M Center, Building 235-2W-70
St. Paul, MN 55144-1000

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

© 3M 2020. All rights reserved.
3M is a trademark of 3M Company and
its affiliates.
Used under license in Canada.
All other trademarks are property
of their respective owners.
Please recycle.
Release 5, February 2020



Appendix 3 [Moldex 2015]



10111 WEST JEFFERSON BOULEVARD, CULVER CITY, CALIFORNIA 90232
 TELEPHONE 310-837-6500 FAX 310-837-9563 www.moldex.com

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 N99, N100, R95, P95, P100 and OV and AG models | Four Years |
| | 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) | |
| | Ammonia/Methylamine | Five Years |
| | Formaldehyde | Three Years |
| | Multi Gas / Vapor | |
| 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 |

THIS DOCUMENT CONTAINS INFORMATION PROPRIETARY TO MOLDEX-METRIC, INC. ANY REPRODUCTION, DISCLOSURE, OR USE OF THIS DOCUMENT IS EXPRESSLY PROHIBITED EXCEPT AS MOLDEX-METRIC, INC. MAY OTHERWISE AGREE IN WRITING.