

PPE CASE



Personal Protective Equipment Conformity Assessment Studies and Evaluations

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

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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 172 of 172 N95 filtering facepiece respirators stockpiled at Facility Nine that were 15 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 Nine of Ten. This facility is a regional stockpile facility.

How NIOSH Evaluated Respirators and Storage Conditions

Description of Facility Nine

- NIOSH researchers visited Facility Nine 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

- Respirators were stored in a trailer for at least seven years and were recently moved into a building basement (approximately in October 2018, one month prior to product sampling).
- 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 Nine 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 trailer. This data was collected in 60-minute intervals from November 2018 to August 2019.

Collection of Respirator Samples

- Facility Nine's inventory included APRs that are classified as N95 filtering facepiece respirators (FFRs). Samples were collected from two different manufacturing models¹: 1) Kimberly Clark (KC) 46727 and 2) KC 46827 (**Table 1**).

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.

- Upon reviewing the detailed APR inventories and storage location by lot within Facility Nine, two different manufacturing lots for each model were identified and sampled within Facility Nine. Two lots 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.
- Control respirators were purchased from the open market to be used as a comparison between stockpiled and new respirators.

Table 1. FFRs Sampled from Stockpile Facility Nine

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	2003	No	15 years	Past 5-year shelf life ⁴
KC 46727	Lot B	2003	No		
KC 46827	Lot A	2003	No	15 years	Past 5-year shelf life ⁴
KC 46827	Lot B	2003	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. 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 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.

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 ⁵	3 ⁵
STP 7: Inhalation Resistance	<35 mm H ₂ O 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 observed at Facility Nine. Many product cases and boxes were opened. Twelve product boxes showed damage due to crushing, mold, and/or dust. Examples of damage observed on product boxes are shown in **Figures 2A and B**. Of the 172 respirators visually inspected, 43 concerns were noted. An example of damage observed to the respirator is shown in **Figure 3**.

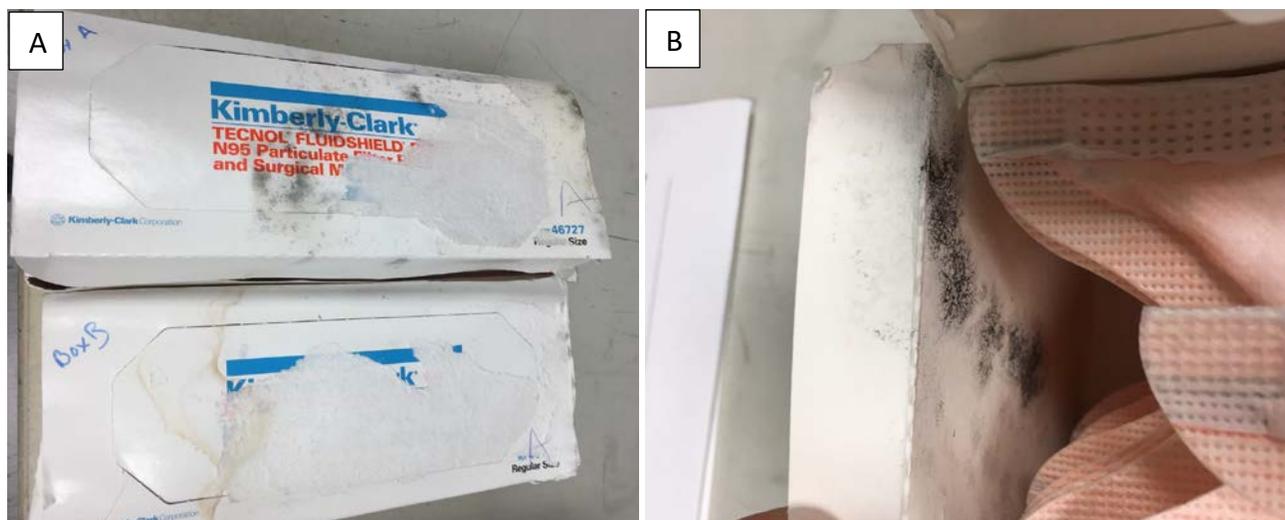


Figure 3: Most amount of damage observed on (A) and in (B) product boxes from Facility Nine.

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 damage observed to respirators from Facility Nine.

- Temperature and %RH were not controlled or monitored. Lights were off when not in use. No evidence of excess moisture or chemical spills that persisted beyond immediate mitigation were observed. Dust was limited. No air circulation existed. Trailer was always kept outside in direct sunlight. Products were not shrink-wrapped.
- Percent RH (**Figure 4**) and Temperature (**Figure 5**)
 - **At the time of publication**, the KC recommended storage requirements for %RH and temperature are to remain under 60 %RH and to remain within 68°F to 77°F [KC 2020].
 - The average temperature between the 2018-2019 time period was 52.3°F. The average %RH between 2018-2019 was 34.2%; this average temperature deviates from KC's recommended temperature storage condition but is within the recommended %RH storage condition.
 - 72.9% of temperature data points were below 68°F and 16.6% were above 77°F. For %RH, no data points deviated from KC's recommended conditions.

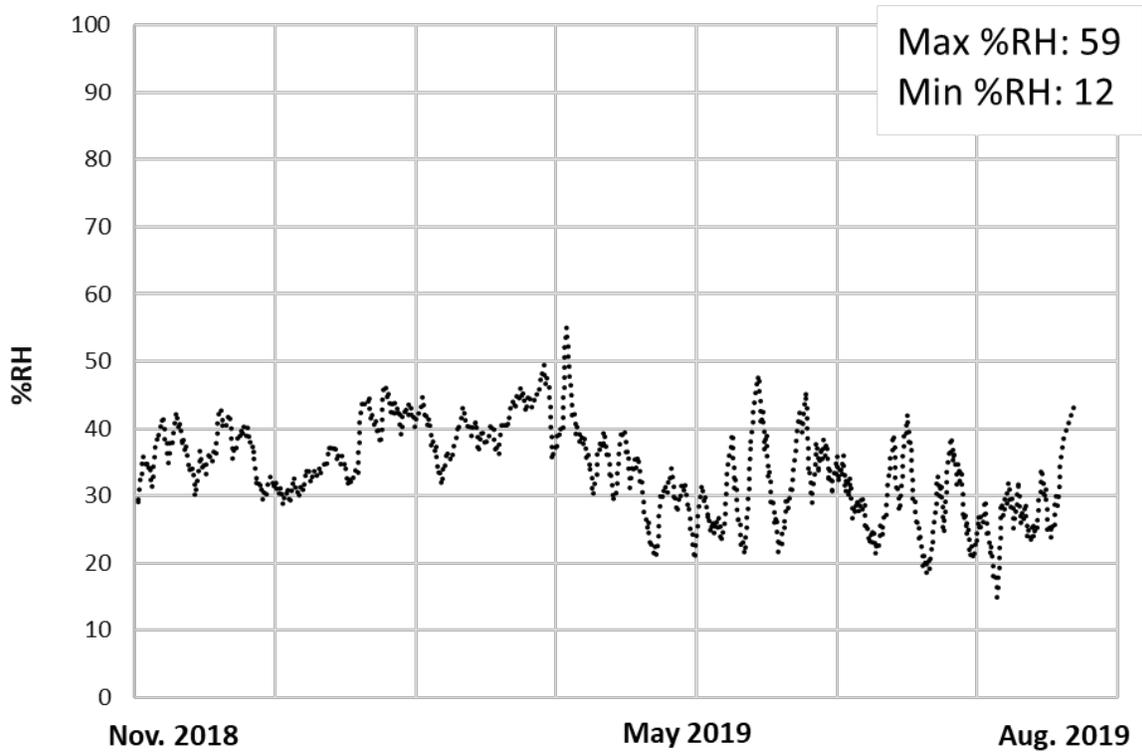


Figure 4: Percent Relative Humidity (% RH) from November 2018 – August 2019 for one data logger stored at Facility Nine. Data is plotted as a 20-point moving average for visualization purposes. Maximum and minimum temperatures reported are noted for each data logger.

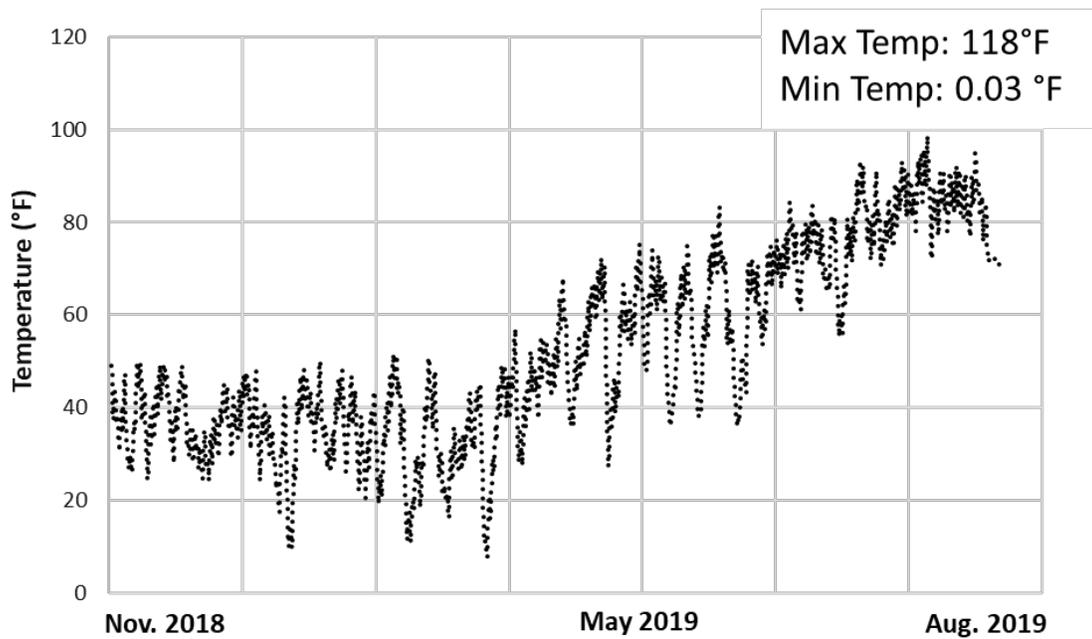


Figure 5: Temperatures from November 2018 – August 2019 for one data logger stored at Facility Nine. Data is plotted as a 20-point moving average for visualization purposes. Maximum and minimum temperatures reported are noted for each data logger.

Inhalation and Exhalation Resistance

- NIOSH evaluated the inhalation and exhalation resistance for a total of 12 stockpiled and 6 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) both of the KC 46727 stockpiled 2003 Lots A and B were lower; 2) KC 46827 stockpiled 2003 Lot A was lower; and 3) KC 46827 stockpiled 2003 Lot B was higher.
- For inhalation resistance, the individual stockpiled respirator with the highest resistance (17.27 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 (16.00 mm H₂O) was below the NIOSH maximum limit for product approval (25 mm H₂O allowable maximum).

Filtration Performance

- NIOSH evaluated the particulate penetration efficiency for 160 stockpiled respirators and 40 controls (Figure 7).
- None of the individual stockpiled respirators tested exceeded the 5.0% maximum. The highest penetration for an individual stockpiled respirator was 2.92% and the highest penetration for an individual control respirator was 4.93%.
- Using an analysis of variance (ANOVA), **there was no statistically significant difference (defined as $\alpha \leq 0.05$)** between the FFR controls and the FFR stockpiled respirators 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) both of the KC 46727 stockpiled 2003 Lots A and B had a lower penetration; and 2) KC 46827 stockpiled 2003 Lot B had a higher penetration.

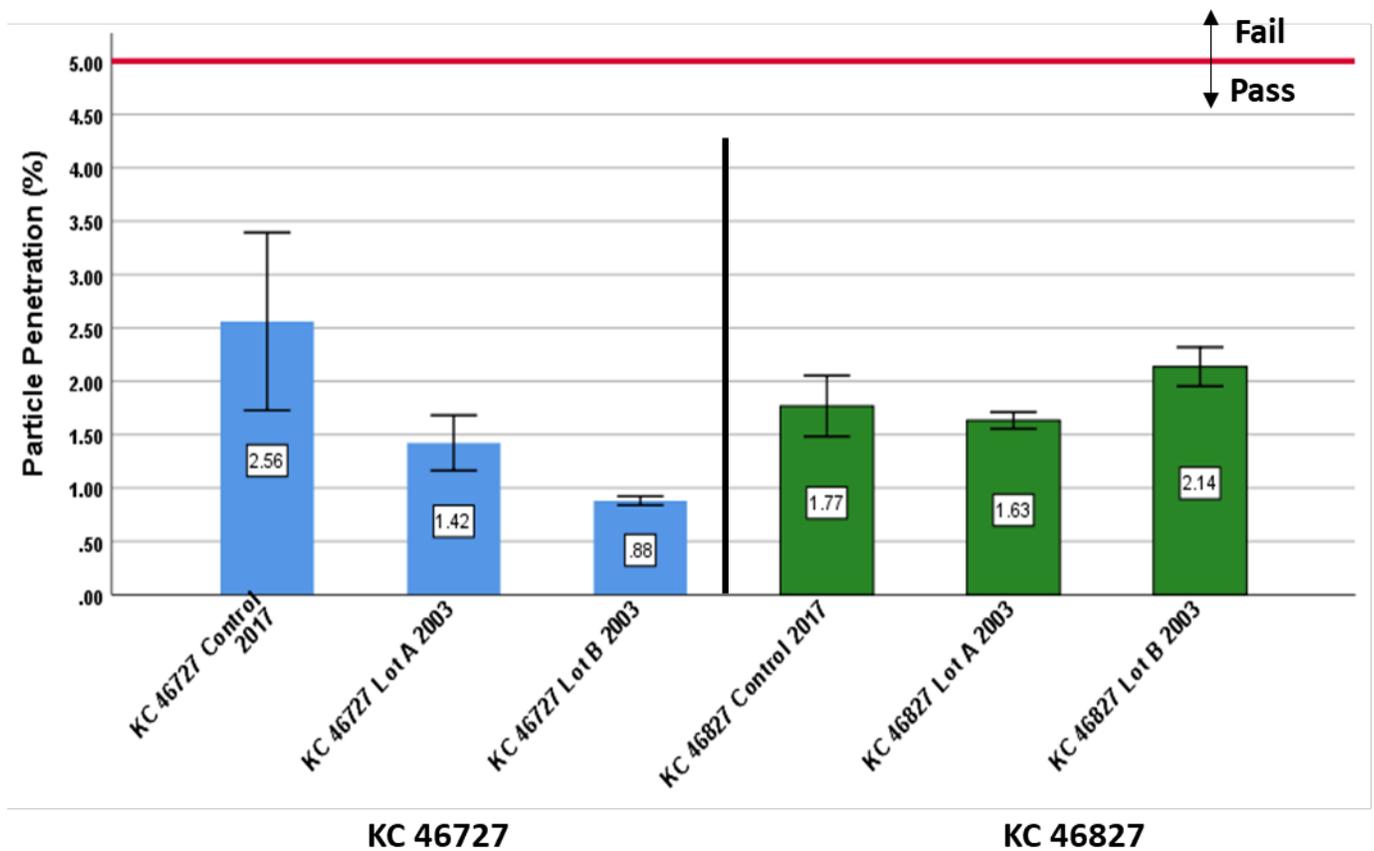


Figure 7: Control and stockpiled respirator particle filtration performance data. N95 FFRs must have a particle penetration of less than 5.0%. Error bars represent the 99% confidence interval and estimate the population parameters. This confidence interval suggests that 99% of any repeated samples tested 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 are based on units evaluated from Facility Nine and may not be applicable at other stockpile facilities and/or under different environmental storage conditions.

[Stockpile Storage Conditions:](#)

For the KC models, 89.5% of temperature data points deviated from the previously described recommended storage conditions. For %RH, no data points deviated from the previously described recommended conditions. Stored under these conditions, NIOSH found that 172 N95 FFRs evaluated in this study, which were 15 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 holder⁷ (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.

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

How Can You Learn More About the Respirators in Your 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.

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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