PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Inhalation and Exhalation Resistance and Filtration Performance of Stockpiled Air-Purifying Respirators: Overall Performance of Nearly 4,000 Respirators Sampled from Ten Stockpile Facilities

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This report details the results for inhalation and exhalation resistance and filtration performance from 3,971 APRs collected from ten U.S. stockpile facilities, including one federal stockpile, six state stockpiles, two regional stockpiles, and one county stockpile. Facility-specific reports can be found on NIOSH's PPE CASE Report website.

NIOSH found that 98% of the air-purifying respirators tested from ten stockpile facilities and manufactured between 2003-2013 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 surge demands, 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 sampled and tested nearly 4,000 respirators from ten geographically dispersed stockpiles with varying storage conditions.

How NIOSH Evaluated Respirators and Storage Conditions

Description of the Ten Facilities

- From 2017 to 2019, NIOSH researchers visited ten stockpile facilities, geographically dispersed across the U.S. These facilities included one federal stockpile, six state stockpiles, two regional stockpiles, and one county stockpile. These ten facilities represented the Department of Health and Human Services (HHS) Regions 1, 2, 4, 6, 8, 9, and 10 as shown in **Figure 1**.

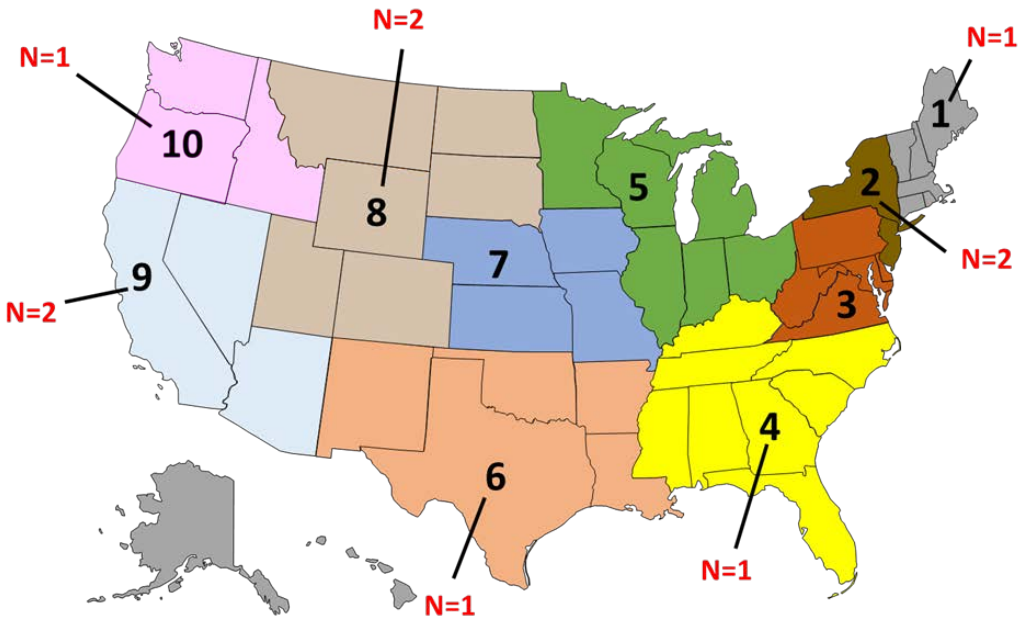

Figure 1. Figure shows locations of the ten collaborating stockpile facilities by the Department of Health and Human Services (HHS) national regions.

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. An example of a pallet, case, and box is shown in **Figure 2**.
- NIOSH documented site storage conditions, including the presence of: 1) dust, moisture, fans, windows, doors, and ventilations systems and 2) chemicals such as cleaning products, vermin traps, and pesticide treatment schedules—no indication of PPE product exposure was identified.
- NIOSH documented PPE pallet-specific storage conditions including: 1) the presence of dust, shrink-wrapping around the pallet, and moisture on the exterior packaging; 2) exposure to sunlight and direct light; 3) proximity to fans, windows, doors, and ventilation systems; 4) damage to shrink wrapping; and 5) location of pallet on storage rack (e.g., top, bottom).
- NIOSH documented PPE case-specific storage conditions including: 1) the presence of dust and moisture; 2) exposure to sunlight and direct light; 3) proximity to fans, windows, doors, and ventilation

systems; 4) damage to the case; and 5) location of case within the pallet (e.g., top/not load-bearing, bottom/load-bearing).

- For stockpiles where temperature and percent relative humidity (%RH) were monitored, NIOSH reviewed this data that was provided by the facility stockpile managers. Where these conditions were not monitored and therefore data was not available, NIOSH collected temperature and %RH data by placing data loggers in the facility, collecting temperature and %RH data for at least eight months, and in some facilities, up to one year (specifics provided in a later section).

Figure 2: Figure depicts the differences between the pallet, case, and box observed at one of the ten facilities

Collection of Respirator Samples

- Twelve different particulate APR models, manufactured between 2003 and 2013, were sampled from the ten facilities. These models were selected to ensure that commonly stockpiled models were included in the study. Of these twelve APR models, ten had shelf lives designated by the approval holder at the time of this report—of these ten, all sampled models exceeded their shelf lives. Eleven of these models were N95 filtering facepiece respirators (FFR), and one model was a P95 particulate filter to be used with an elastomeric half mask. Where possible, at least two production lots within a manufacturing year were sampled for each respirator model within a facility. Two lots were sampled to evaluate and attempt to account for possible inter-lot variation. More than two lots were sampled if there were unique circumstances of interest to explore (e.g., packaging showed visible damage or was in indirect or direct sunlight). One lot was sampled if there was only one available for sampling.
- Upon NIOSH researchers visiting each facility, products were sampled and shipped to the NIOSH facility overnight to reduce exposure to non-climate-controlled conditions during transport. The samples were tested at the NIOSH facility in accordance with NIOSH performance requirements.
- Forty-three respirators were tested from each manufacturing lot for inhalation and exhalation resistance (n=3) and filtration performance testing (n=40)[1].

Characteristics of Sampled Respirators

- **Table 1** provides a summary of the respirator models and quantity sampled from the ten facilities to test the inhalation and exhalation resistance and the filtration performance. The table also includes relevant storage condition and shelf life status information.
- NIOSH does not require approval holders to designate a shelf life, although some choose to do so. Additionally, many approval holders designated a shelf life after the models sampled from these stockpiles were manufactured.

[1] 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].

Table 1. Characteristics of the APRs Sampled from the Ten Collaborating Stockpile Facilities

Model (Range of Manufacturing Year[s] Range of the Sampled Lots)	NIOSH TC Approval Number	# of Lots Sampled	Total # of Respirators Tested	Total # of the Ten Collaborating Facilities Stockpiling this Model	Shelf Life Status at Time of Testing[2]	Recommended Storage Conditions[3]
3M 1860 (mfr. 2006 – 2011)	84A-0006	29	1,219[4]	8	Past 5-year shelf life	Remain under 80 %RH; remain within -4°F to 86°F
3M 1870 (mfr. 2010 – 2013)	84A-3844	5	215	3	Past 5-year shelf life	Remain under 80 %RH; remain within -4°F to 86°F
3M 8000[5] (mfr. 2006 – 2008)	84A-3981	9	387	4	Past 3-year shelf life	Remain under 80 %RH; remain within -4°F to 86°F
3M 8210 (mfr. 2006 and unknown[6])	84A-0007	6	258	3	Past 5-year shelf life	Remain under 80 %RH; remain within -4°F to 86°F
3M 9010 (mfr. 2006 – 2007)	84A-4243	6	258	3	Past 5-year shelf life	Remain under 80 %RH; remain within -4°F to 86°F
3M 2071 (mfr. 2006)	84A-1647	4	172	2	Past 5-year shelf life	Remain under 80 %RH; remain within -4°F to 86°F
Gerson 1730 (mfr. 2006)	84A-0160	5	215	3	No designated shelf life	Remain under 80 %RH; remain within -4°F to 95°F
Kimberly Clark 46727 (mfr. 2003 – 2007)	84A-0010	9	387	5	Past 5-year shelf life	Remain under 60 %RH; remain within 68°F to 77°F
Kimberly Clark 46827 (mfr. 2003 – 2007)	84A-0005	14	602	7	Past 5-year shelf life	Remain under 60 %RH; remain within 68°F to 77°F
Medline/Alpha ProTech NON27501 (mfr. 2008)	84A-0457	2	86	1	No designated shelf life	Avoid excessive moisture (water droplets or direct submersion in water)[7]; avoid prolonged extreme temperatures (< 60°F and >80°F)
Moldex 1512 (mfr. 2009)	84A-0013	2	86	1	Past 9-year shelf life	No specific %RH recommendations; remain with 14°F and 122°F
Moldex 2201N95 (mfr. 2006)	84A-2456	2	86	1	Past 9-year shelf life	No specific %RH recommendations; remain with 14°F and 122°F
	Total	**93 lots**	**3,971 respirators**			

[2] Testing was completed from 2017 – 2019. For shelf life information, refer to [3M 2018], [3M 2019], [3M 2020], [Kimberly Clark 2018], [Moldex 2015], [Alpha ProTech 2020]. Gerson does not designate a shelf life for the Gerson 1730 model.

[3] As of March 2020, these are the current storage recommendations made by the approval holder. Refer to [3M 2020], [Gerson 2019], [Kimberly Clark 2020], [Alpha ProTech 2019], [Moldex 2019].

[4] For one 3M 1860 lot, only 15 respirators were used for filtration testing, and no respirators were tested against inhalation/exhalation resistance. Remaining respirators were saved for other tests.

[5] The 3M 8000 model is no longer produced or sold by 3M.

[6] 3M was consulted and could not determine the manufacturing year for two lots sampled from Facility Ten and Facility Four.

[7] No specific %RH recommendations.

Selection of Control Respirators

- Control respirators of the same model as those sampled from the ten facilities were purchased from the open market, tested for inhalation/exhalation resistance and filtration performance, and the results were compared to the stockpiled respirators. One lot of each control model was purchased. New 3M 8000 respirators were not available to be purchased since this model is no longer produced or sold by 3M.
- Testing was completed from 2018 to 2019. The controls had the following manufacturing dates
    - 3M 1860 (size regular), 3M 2071, Moldex 2201 (size small), and Moldex 1512 (size medium): 2018
    - 3M 9010: purchased in 2018, approval holder could not verify manufacturing date
    - Kimberly Clark (KC) 46727 (size regular), KC 46827 (size small), Gerson 1730, and Medline/Alpha ProTech NON 27501: 2017
    - 3M 8210: 2015
    - 3M 1870: 2014
    - 3M 8000: 2006[8]

Evaluation of Inhalation and Exhalation Resistance and Filtration Performance

- 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**). Twenty-three control respirators were tested for inhalation and exhalation resistance (n=3) and filtration performance (n=20) per manufacturing lot. NIOSH testing requirements state that a minimum of three respirator units must be tested for inhalation and exhalation resistance and a minimum of 20 respirator units must be tested for filtration performance [NIOSH 2018]. For filtration performance, 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.

[8] The 3M 8000 model is no longer produced or sold by 3M and thus new respirators were unable to be purchased. An assumption is made that these respirators were stored within 3M's designated storage conditions.

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[9]	3[9]
STP 7: Inhalation Resistance	<35 mm H_2O column @ 85 LPM	3[9]	3[9]
STP 53: Liquid Particulate Filter Efficiency for P95[10]	≤5.0% particulate penetration (≥95.0% filter efficiency)	40[11]	20
STP 59: Particulate Filter Efficiency for N95	≤5.0% particulate penetration (≥95.0% filter efficiency)	40[11]	20
Total Number of N95 FFRs tested per lot		43	23
Total Number of P95 filters tested per lot		43	23

What NIOSH Found Through Inspection, Testing, and Evaluation

Storage Conditions

- Facility-specific findings—such as site and pallet storage conditions—can be found in the series of ten individual PPE CASE Reports [Greenawald *et al.* 2020].
- A brief synopsis of storage conditions found at each of the ten facilities is presented in **Table 3**.
- Temperature and % RH: Four facilities provided temperature and %RH records. For facilities without temperature and %RH records, NIOSH-provided a data logger to monitor temperature and %RH for at least eight months. Data points were collected from the following timeframes for each facility:
    - Facility One: 2 years 11 months (facility-generated data)
    - Facility Two: 2 years 11 months (facility-generated data)
    - Facility Three: 1 year 4 months (NIOSH data logger-generated data)
    - Facility Four: 1 year (NIOSH data logger-generated data)
    - Facility Five: 1 year (NIOSH data logger-generated data)
    - Facility Six: 3 years 10 months (facility-generated data)
    - Facility Seven: 1 year (NIOSH data logger-generated data)
    - Facility Eight: 8 months (NIOSH data logger-generated data)
    - Facility Nine: 9 months (NIOSH data logger-generated data)[12]
    - Facility Ten: 5 years (facility-generated data)

[9] 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.
[10] This STP was used for the P95 particulate filter.
[11] 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.
[12] Facility Nine stored products in a trailer that was outside year-round (the respirators were moved to the basement of a health department about one month prior to the NIOSH visit); mold was observed on and in these respirator boxes.

- **Figures 4** and **5** show the minimum, maximum, and average temperature and %RH, respectively, for each of the ten collaborating stockpiles across the specified timeframe. Facility-specific temperature and %RH data plots over time can be found in the series of ten PPE CASE reports [Greenawald *et al.* 2020].

Table 3: Summary of the Storage Characteristics at the Ten Stockpile Facilities

Stockpile Facility	Models	Storage Characteristics	Environmental Controls and Monitoring
1	3M 1860 Gerson 1730 Medline/APT	Lighting off when unoccupied; no evidence of excess moisture or chemical spills that; no windows allowing sunlight; pallets shrink wrapped on pallets sides but not top or bottom; some pallets stacked two-high on the top most rack, causing some weight to be applied to the bottom pallet	Temperature controlled; temperature and %RH monitored.
2	3M 1860 Gerson 1730	Warehouse shared with another entity; lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; pallets shrink wrapped on pallets sides but not top or bottom; pallets separated by metal rack.	Temperature controlled; temperature and %RH monitored.
3	3M 1860 KC 46727	Products stored outside of original case packaging and in plastic containers; products were not on pallets; lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; no dust was observed on the respirator boxes stored inside or on top of the containers. Some dust settled on the top-most layer of cases in the instances where no shrink wrap or heavy plastic was applied to the top of the pallet.	Temperature only recently controlled but not controlled for most of the products' storage life; temperature and %RH not monitored.
4	3M 1860 3M 1870 3M 2071 3M 8210 3M 9010 KC 46827	Lighting off when unoccupied; small ceiling vents allowed sunlight to enter facility; no evidence of excess moisture or chemical spills n; pallets shrink wrapped on pallets sides but not top or bottom; some pallets stacked two-high on the top most rack, causing some weight to be applied to the bottom pallet.	Temperature controlled; temperature and %RH not monitored.
5	3M 1860 3M 1870 3M 2071 3M 8210 3M 9010 KC 46827	Lighting off when unoccupied; ceiling skylights allowed sunlight to enter facility and shine on PPE pallets; no evidence of excess moisture or chemical spills; pallets shrink wrapped on pallets sides but not top or bottom; generally, all pallets stacked three (or more)-high, causing some weight to be applied to the bottom pallet.	No controls or monitoring.
6	3M 8000 KC 46727 KC 46827 Moldex 2201	Lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; ceiling fans circulated air; pallets shrink wrapped on pallets sides and the top; pallets separated by metal rack.	Temperature and %RH controlled; temperature and %RH intermittently monitored.
7	3M 1860 3M 1870 3M 8000 3M 9010 KC 46727 KC 46827	Lighting off when unoccupied; no evidence of chemical spills; evidence of mitigated moisture damage on facilities walls; some windows allowed indirect sunlight; pallets shrink wrapped on sides and a plastic covering was placed on the top; pallets separated by metal rack.	No controls or monitoring.
8	3M 1860 3M 8000 KC 46727 KC 46827 Moldex 1512	Lighting off when unoccupied; no evidence of excess moisture or chemical spills; pallets shrink wrapped on pallets sides and the top though many PPE products were not on pallets nor shrink wrapped; some pallets separated by metal rack and others stacked two-high, causing some weight to be applied to the bottom pallet.	Temperature controlled; temperature intermittently monitored.
9	KC 46727 KC 46827	Stockpile manager reported that products were stored in a trailer for at least seven years; trailer was stored outside at all times; PPE was stored outside of original case packaging; products were not on pallets; lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight	No controls or monitoring.
10	3M 1860 3M 8000 3M 8210 Gerson 1730 KC 46827	Lighting off when unoccupied; no evidence of excess moisture or chemical spills; no windows allowing sunlight; pallets shrink wrapped on sides but not top or bottom; pallets separated by metal rack.	Temperature controlled; temperature and %RH monitored.

- Respirator Box and Respirator Visual Inspections—Visual inspection concerns were recorded for factors that may affect respirator performance. These included crushing to the respirator box, damage to the respirator (including the nose bridge or straps), and/or the appearance of mold. Examples of visual inspection concerns for respirator boxes and individual respirators are provided in **Figure 3**. Overall, stockpiled respirators were sampled from 339 boxes; 36 boxes (10.6%) showed some level of damage (e.g., crushing, appearance of mold). Ninety-nine respirator visual inspection concerns were noted for 66 out of the 3,971 total respirator units individually inspected (i.e., 1.7% of the respirator units inspected included visual inspection concerns).

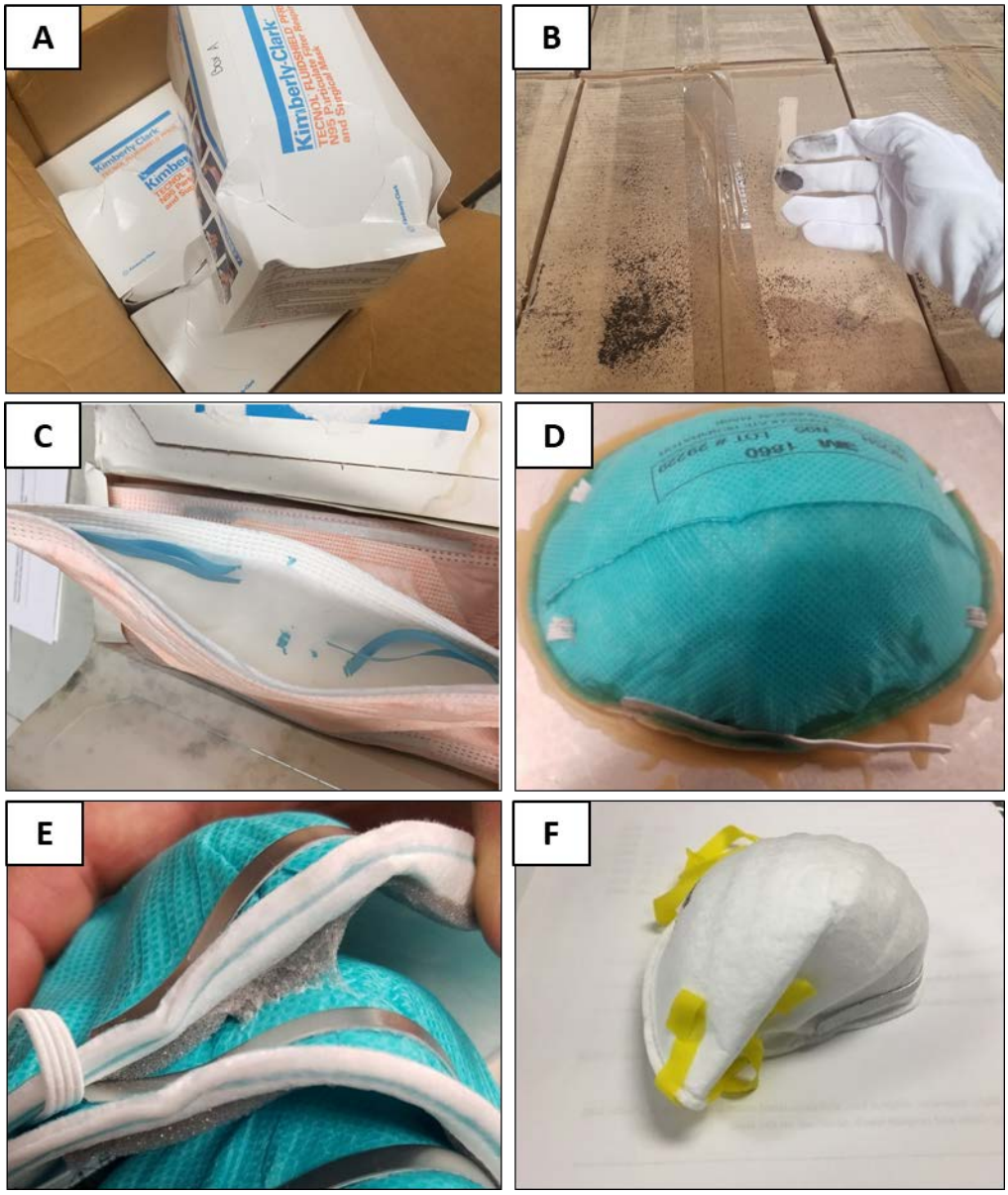

Figure 3: Examples of visual inspection concerns to the respirator box and individual respirator units including A) box damage; B) dust; C) strap damage to respirator and mold on respirator box; D) damage to respirator nose bridge (here, the respirator is fixed to test plate); E) damage to respirator nose foam; and F) crushing of the respirator unit itself.

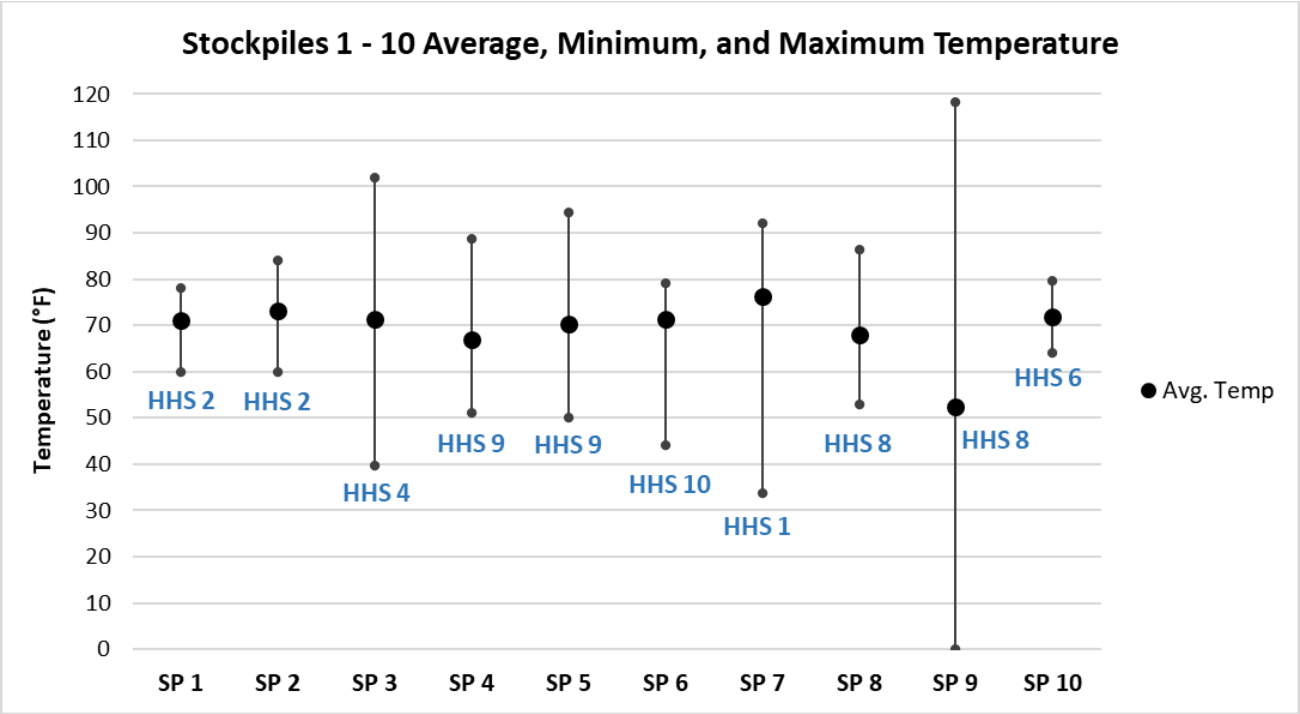

Figure 4: Average, minimum, and maximum temperature across all ten stockpile facilities visited in this study. HHS regions for each facility are also depicted; refer to Figure 1 for the HHS region locations.

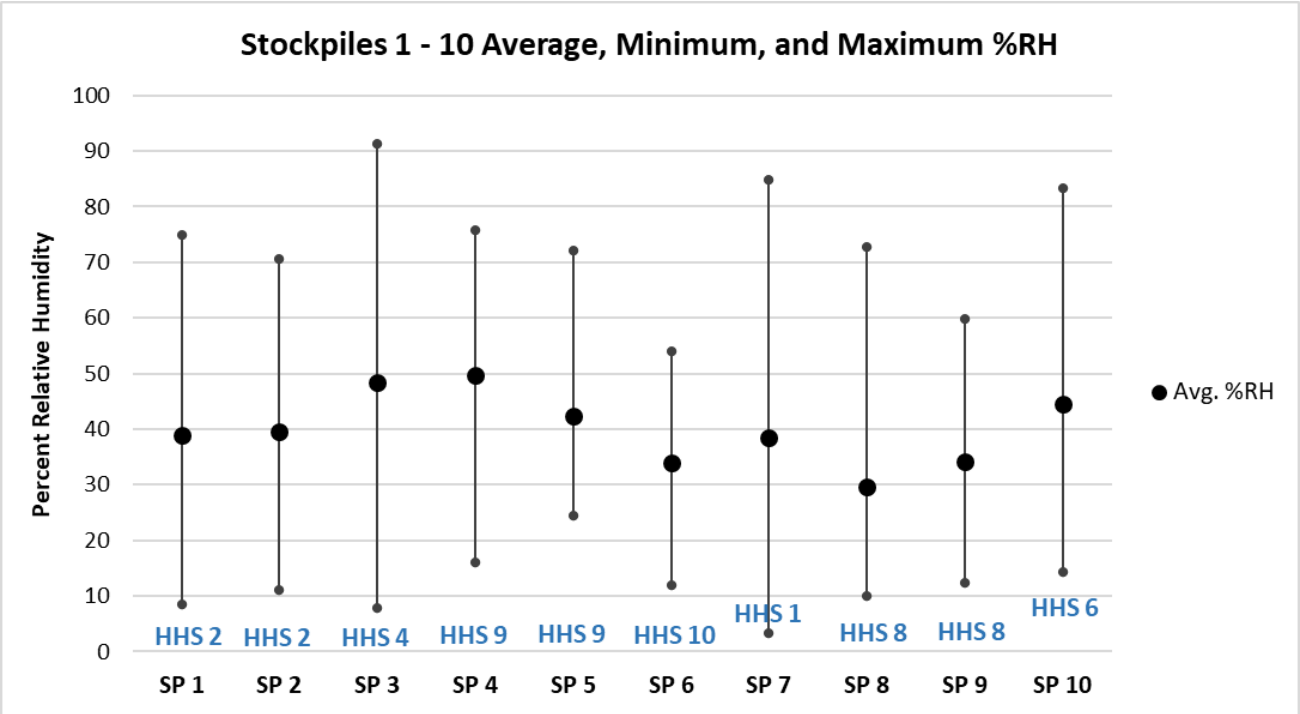

Figure 5: Average, minimum, and maximum %RH across all ten stockpile facilities visited in this study. HHS regions for each facility are also depicted; refer to Figure 1 for the HHS region locations.

Inhalation and Exhalation Resistance

- NIOSH evaluated the inhalation and exhalation resistance for a total of 276 stockpiled and 36 control respirators. **All stockpiled and control respirators from each model passed these tests.** The aggregated inhalation/exhalation resistance data for the 3M models can be seen in **Figure 6**; the aggregated inhalation/exhalation resistance data for the KC, Gerson, Moldex, and Medline/Alpha ProTech models can be seen in **Figure 7**.
- The 99% confidence interval for inhalation and exhalation resistance is shown in the figures. The upper bounds of each of the 99% confidence intervals are well within the NIOSH minimum performance requirements.

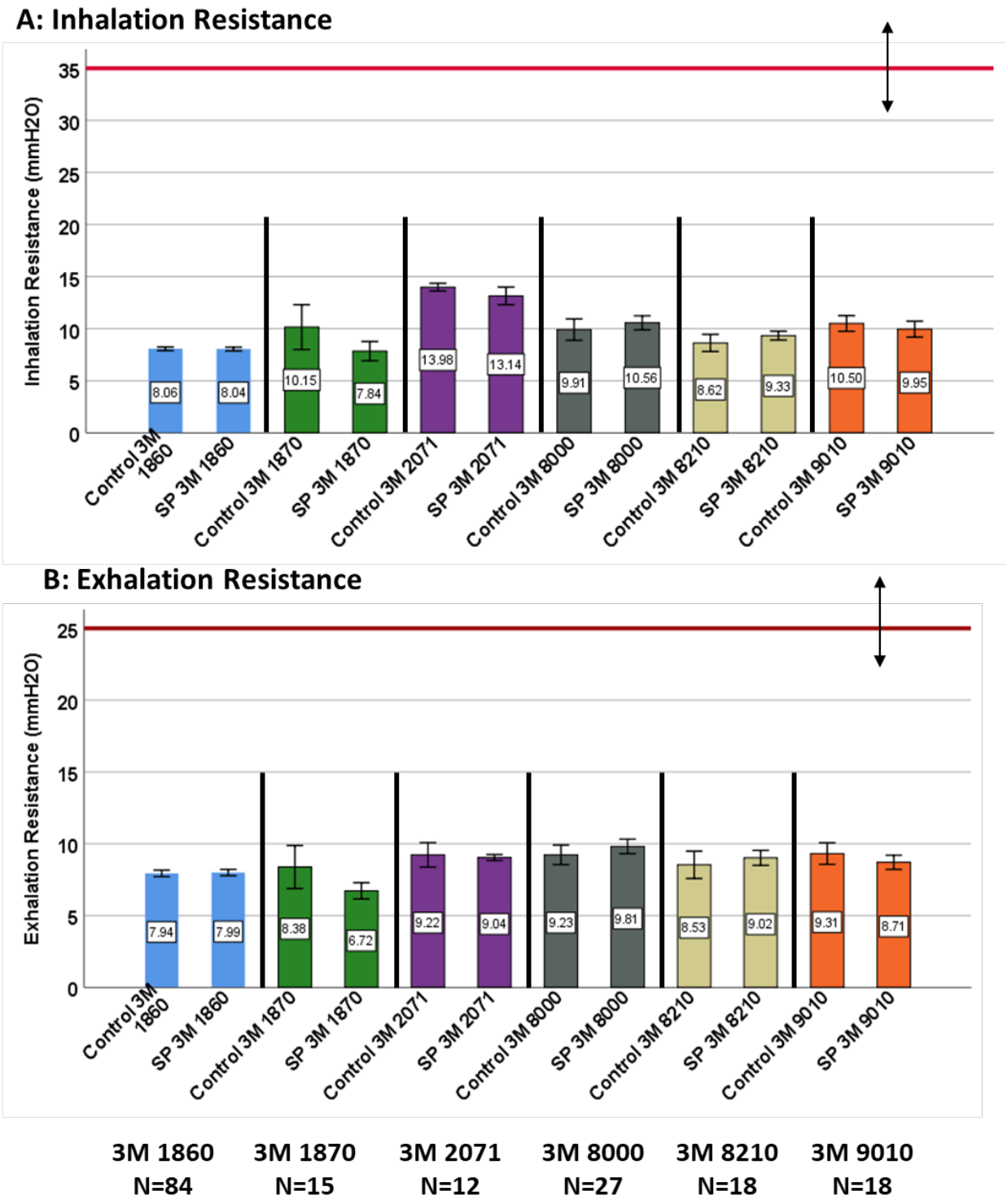

Figure 6: Mean control and stockpiled (SP) respirator inhalation (A) and exhalation (B) resistance data for the 3M 1860, 3M 1870, 3M 2071, 3M 8000, 3M 8210, and 3M 9010 models. APRs must have an inhalation resistance less than 35 mmH_2O and an exhalation resistance less than 25 mmH_2O. The pass/fail 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. The number of stockpiled units tested is shown under the model name.

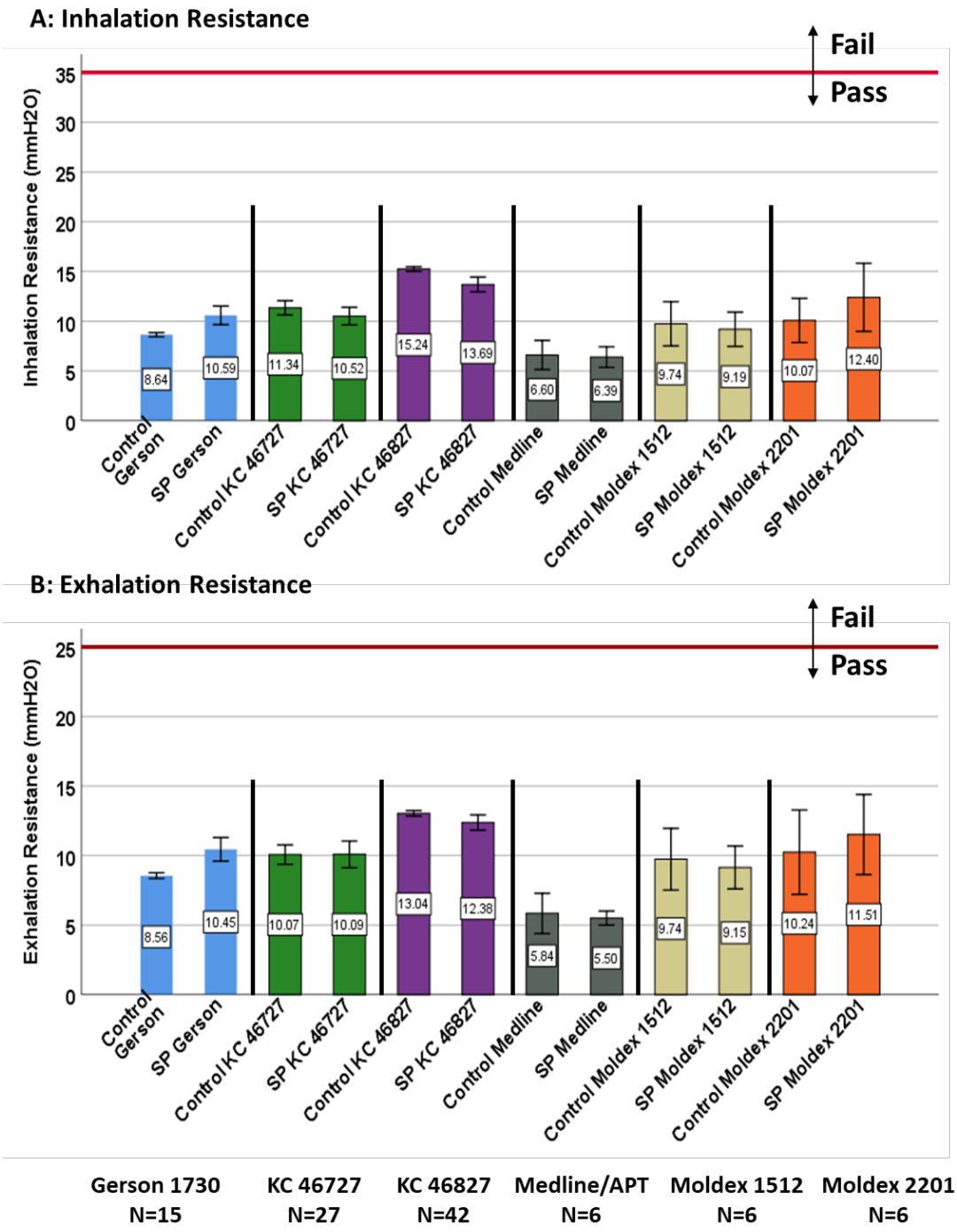

Figure 7: Mean control and stockpiled (SP) respirator inhalation (A) and exhalation (B) resistance data for the Gerson 1730, KC 46727, KC 46827, Medline/Alpha ProTech NON27501 (Medline/APT), Moldex 1512, and Moldex 2201 models. APRs must have an inhalation resistance less than 35 mmH_2O and an exhalation 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. The number of stockpiled units tested is shown under the model name.

Filtration Performance

- NIOSH evaluated the particulate penetration efficiency for 3,695 stockpiled respirators and 240 control respirators (i.e., 20 for each of the 12 respirator models). The aggregated filtration efficiency data for the 3M 1860, 3M 1870, 3M 8000, 3M 8210, and 3M 9010 models can be seen in **Figure 8**. The aggregated filtration efficiency data for the 3M 2071 model (the only P95 model in the study) can be seen in **Figure 9**. The aggregated filtration efficiency data for the Gerson 1730, KC 46727, KC 46827, Medline/Alpha ProTech, Moldex 1512, and Moldex 2201 models can be seen in **Figure 10**.
- Seventy-six N95 FFRs did not meet NIOSH performance standards, accounting for 2% of the total respirators tested to particulate N95 filtration performance. No liquid particulate (P95) filtration failures were observed.
- The respirators that failed came from three different stockpiles and three different N95 FFR models: 3M 1860, KC 46727, and KC 46827. In Facility Three, one 3M 1860 respirator failed from a lot manufactured in 2006, and one respirator failed from a lot that was manufactured in 2009. All other units tested from this facility passed. In Facility Four, 34 (42.5%) of the 80 KC 46827 units tested from two different lots (both manufactured in 2007) failed. In Facility Seven, all 40 (100%) of the KC 46727 respirators tested from one lot manufactured in 2007 failed. The other units tested from these facilities passed. These three models currently have a five-year designated shelf life.
- The 99% confidence interval for filtration performance is shown in the figures. The upper bounds of the 99% confidence intervals for all stockpiled respirators were no more than 60% of NIOSH's maximum permissible level of penetration.
- Lot-specific results can be found in the series of ten PPE CASE reports [Greenawald *et al.* 2020].
- The failing units were not associated with any respirator visual inspection concerns (i.e. no damage to the respirator, straps, or metal nose bridge was observed). One failing unit (the 3M 1860 unit from Facility Three) came from a box with slight crushing to the bottom.
- A summary of the visual inspection and overall pass/fail data for each stockpile is shown in **Table 4**. A footnote is included for those models that do not currently have a designated shelf life, which were the Gerson 1730 and the Alpha ProTech NON27501 [Appendix 1]; all other models currently have a designated shelf life. A summary of the respirator performance data for each stockpile is shown in **Table 5**
- **Figure 11** depicts the number of passing and failing units for each model sampled across the 10 facilities when considering only filtration performance. The failing units were not associated with visual inspection concerns to the respirator.

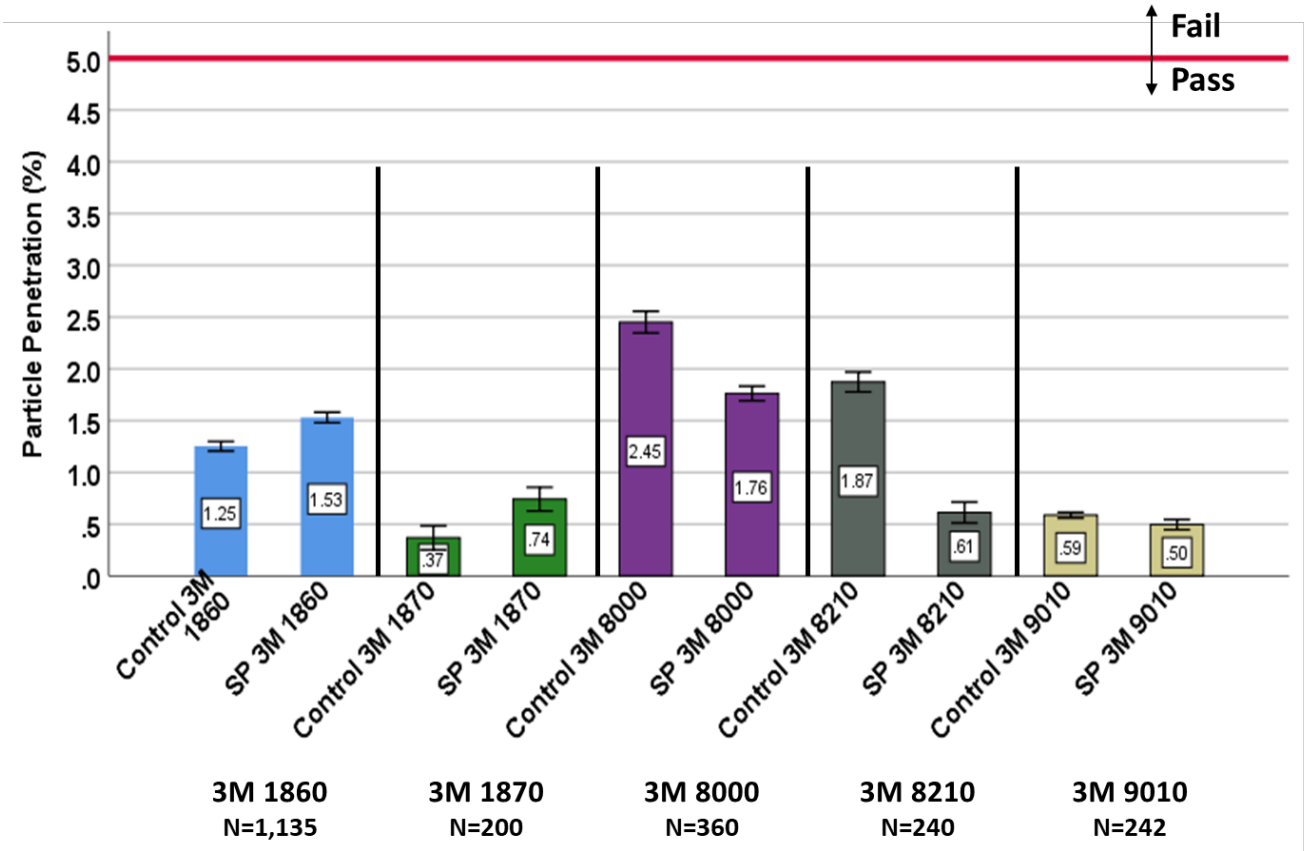

Figure 8: Mean **c**ontrol and stockpiled (SP) respirator particle filtration performance data for the 3M 1860, 3M 1870, 3M 8000, 3M 8210, and 3M 9010 models. N95 FFRs must have a particle penetration of less than 5.0%. Error bars represent the 99% confidence interval and estimate the population parameters. 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. The number of stockpiled units tested is shown under the model name.

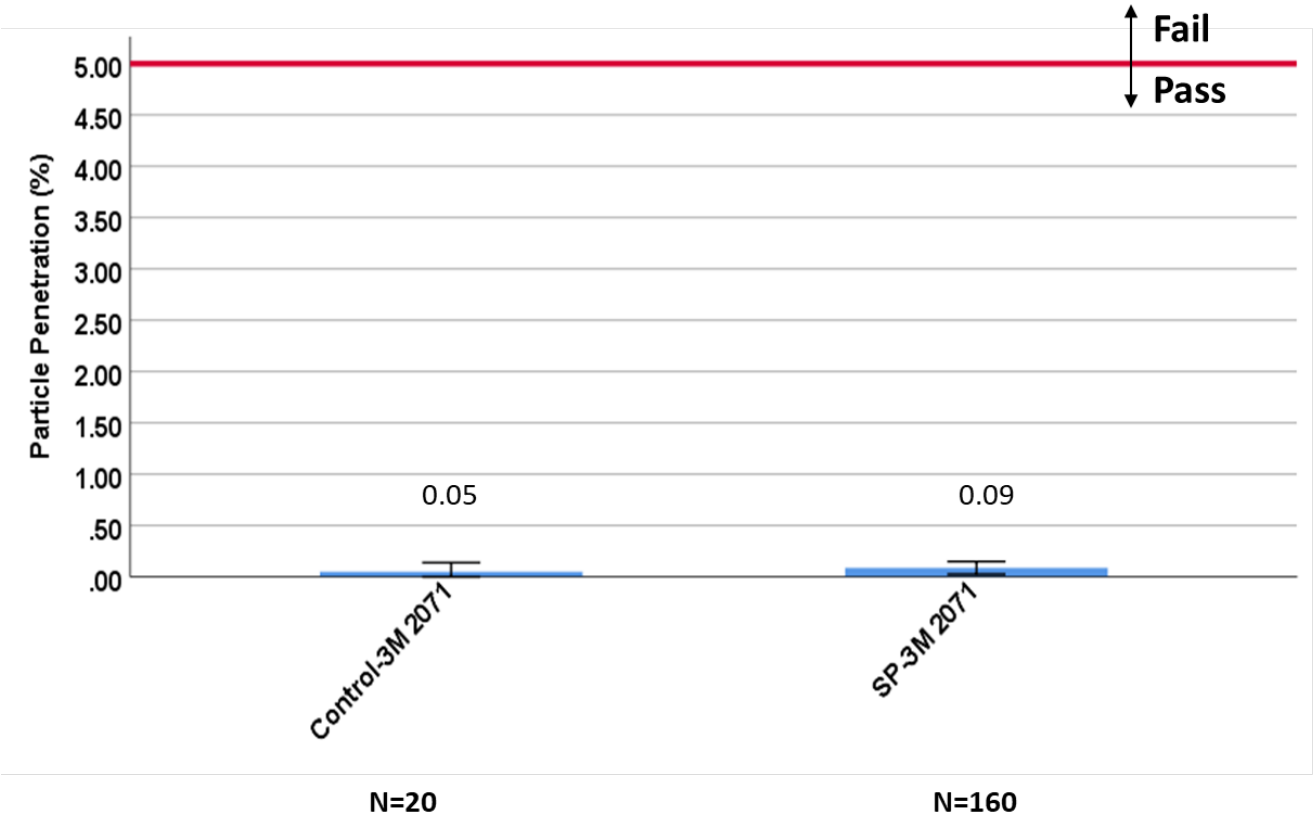

Figure 9: Mean **c**ontrol and stockpiled (SP) respirator particle filtration performance data for the 3M 2071 model. P95 filters must have a particle penetration of less than 5.0%. Error bars represent the 99% confidence interval and estimate the population parameters. This confidence interval suggests that 99% of any repeated samples tested and evaluated from this lot will have a mean between the upper and lower bounds. The number of units tested is shown under the model name.

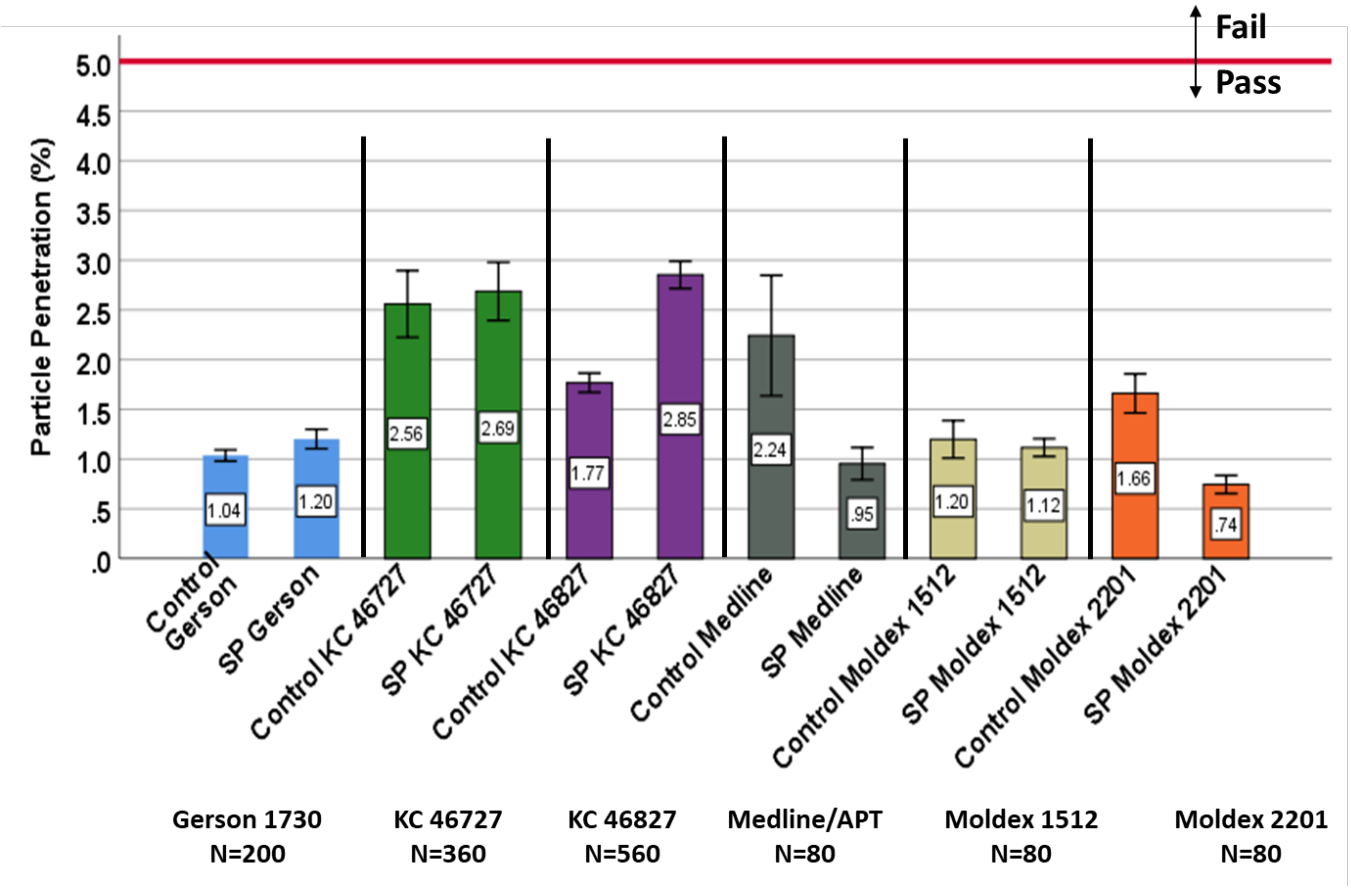

Figure 10: Mean control and stockpiled (SP) respirator particle filtration performance data for the Gerson 1730, KC 46727, KC 46827, Medline/Alpha ProTech NON27501 (Medline/APT), Moldex 1512, and Moldex 2201 models. N95 FFRs must have a particle penetration of less than 5.0%. Error bars represent the 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. The number of stockpiled units tested is shown under the model name.

Table 4: Summary of Visual Inspection Concerns and the Pass/Fail Data for Each Stockpile Facility; Asterisks Indicate Which Production Lot (Indicated by The Manufacturing Year) the Failing Units Came From

Stockpile Facility Model (Manufacturing Year of Sampled Lot[s])	Visual Inspection Concerns to Box or Respirator	% of Respirators with Visual Inspection Concerns to the Unit or the Box THAT STILL PASSED NIOSH Performance Requirements
Stockpile Facility One • Gerson 1730[13] (2006, 2006) • 3M 1860 (2008, 2008, 2009, 2009) • Alpha ProTech NON27501[13,14](2008, 2008)	1 respirator crushed, 3 boxes with slight damage to corner	100% Passed
Stockpile Facility Two • Gerson 1730[13] (2006) • 3M 1860 (2006, 2006, 2008, 2008, 2009, 2009)	12 respirators with nose foam concerns	100% Passed
Stockpile Facility Three • 3M 1860 (2006*, 2006, 2009*, 2009) • KC 46727 (2006, 2006)	5 boxes with slight crushing at the bottom; 1 nose foam concern	99.2% Passed 1 unit (2%) failed of the 50 units that were tested from the 5 boxes with slight crushing
Stockpile Facility Four • 3M 1860 (2006, 2010, 2010) • KC 46827 (2007, 2007*, 2007*) • 3M 1870 (2010, 2010) • 3M 8210 (2006, year not available)[15] • 3M 9010 (2006, 2006) • 3M 2071 (2006, 2006)	9 boxes with slight crushing near the bottom or sides	94.1% passed
Stockpile Facility Five • 3M 1860 (2007, 2007, 2010, 2010) • KC 46827 (2006, 2006) • 3M 1870 (2011, 2011) • 3M 8210 (2006, 2006) • 3M 9010 (2006, 2006) • 3M 2071 (2006, 2006)	0	100% Passed
Stockpile Facility Six • KC 46727 (2006, 2006) • KC 46827 (2007, 2007) • Moldex 2201 (2006, 2006) • 3M 8000 (2006, 2006, 2006)[16]	0	100% Passed
Stockpile Facility Seven • 3M 1860 (2007, 2007, 2010, 2010) • 3M 1870 (2013) • 3M 8000 (2008, 2008)[14] • KC 46727 (2006, 2007*) • KC 46827 (2006, 2007) • 3M 9010 (2007, 2007)	0	92.8% Passed
Stockpile Facility Eight • 3M 1860 (2007, 2007) • 3M 8000 (2006, 2006)[16] • KC 46727 (2006) • KC 46827 (2006) • Moldex 1512 (2009, 2009)	3 boxes with crushing to the right side and opened	100% Passed
Stockpile Facility Nine • KC 46727 (2003, 2003) • KC 46827 (2003, 2003)	12 boxes with crushing, mold concerns, and dust; 33 respirators had nose bridge damage, 43 respirators had mold concerns, 9 straps had damage	100% Passed
Stockpile Facility Ten • 3M 1860 (2006, 2006) • KC 46827 (2006, 2007) • 3M 8000 (2006, 2006)[16] • 3M 8210 (two lots sampled; years not available)[15] • Gerson 1730[13] (2006, 2006)	4 boxes with crushing to the top	100% Passed

[13] Model does not currently have a designated shelf life by the approval holder.

[14] The FFR model NON27501 has been manufactured by Alpha ProTech as a private label to Medline under TC-84A-0457.

[15] 3M was consulted and could not determine the manufacturing year of these two lots tested.

[16] The 3M 8000 is no longer produced or sold by 3M.

Table 5: Summary of the Respirator Performance for Units Sampled from the Ten Stockpiles; Asterisks Indicate Which Production Lot (Indicated by The Manufacturing Year) the Failing Units Came From

Stockpile Facility Model (Manufacturing Year of Sampled Lot[s])	**# of Respirators Tested to Inhalation and Exhalation Resistance (# of Failures)**	**# Respirators Tested to Particulate Filtration Efficiency (# of Failures)**
Stockpile Facility One • Gerson 1730[17] (2006, 2006) • 3M 1860 (2008, 2008, 2009, 2009) • Alpha ProTech NON27501[18](2008, 2008)	24 (0)	320 (0)
Stockpile Facility Two • Gerson 1730[11] (2006) • 3M 1860 (2006, 2006, 2008, 2008, 2009, 2009)	21 (0)	280 (0)
Stockpile Facility Three • 3M 1860 (2006*, 2006, 2009*, 2009) • Kimberly Clark (KC) 46727 (2006, 2006)	18 (0)	240 (2*)
Stockpile Facility Four • 3M 1860 (2006, 2010, 2010) • KC 46827 (2007, 2007*, 2007*) • 3M 1870 (2010, 2010) • 3M 8210 (2006, year not available)[19] • 3M 9010 (2006, 2006) • 3M 2071 (2006, 2006)	39 (0)	535 (34*)
Stockpile Facility Five • 3M 1860 (2007, 2007, 2010, 2010) • KC 46827 (2006, 2006) • 3M 1870 (2011, 2011) • 3M 8210 (2006, 2006) • 3M 9010 (2006, 2006) • 3M 2071 (2006, 2006)	42 (0)	560 (0)
Stockpile Facility Six • KC 46727 (2006, 2006) • KC 46827 (2007, 2007) • Moldex 2201 (2006, 2006) • 3M 8000 (2006, 2006, 2006)[20]	27 (0)	360 (0)
Stockpile Facility Seven • 3M 1860 (2007, 2007, 2010, 2010) • 3M 1870 (2013) • 3M 8000 (2008, 2008)[20] • KC 46727 (2006, 2007*) • KC 46827 (2006, 2007) • 3M 9010 (2007, 2007)	39 (0)	520 (40*)
Stockpile Facility Eight • 3M 1860 (2007, 2007) • 3M 8000 (2006, 2006)[20] • KC 46727 (2006) • KC 46827 (2006) • Moldex 1512 (2009, 2009)	24 (0)	320 (0)
Stockpile Facility Nine • KC 46727 (2003, 2003) • KC 46827 (2003, 2003)	12 (0)	160 (0)
Stockpile Facility Ten • 3M 1860 (2006, 2006) • KC 46827 (2006, 2007) • 3M 8000 (2006, 2006)[20] • 3M 8210 (two lots sampled; years not available)[19] • Gerson 1730[11] (2006, 2006)	30 (0)	400 (0)

[17] Model does not currently have a designated shelf life by the approval holder.

[18] The FFR model NON27501 has been manufactured by Alpha ProTech as a private label to Medline under TC-84A-0457.

[19] 3M was consulted and could not determine the manufacturing year of these two lots tested.

[20] The 3M 8000 is no longer produced or sold by 3M.

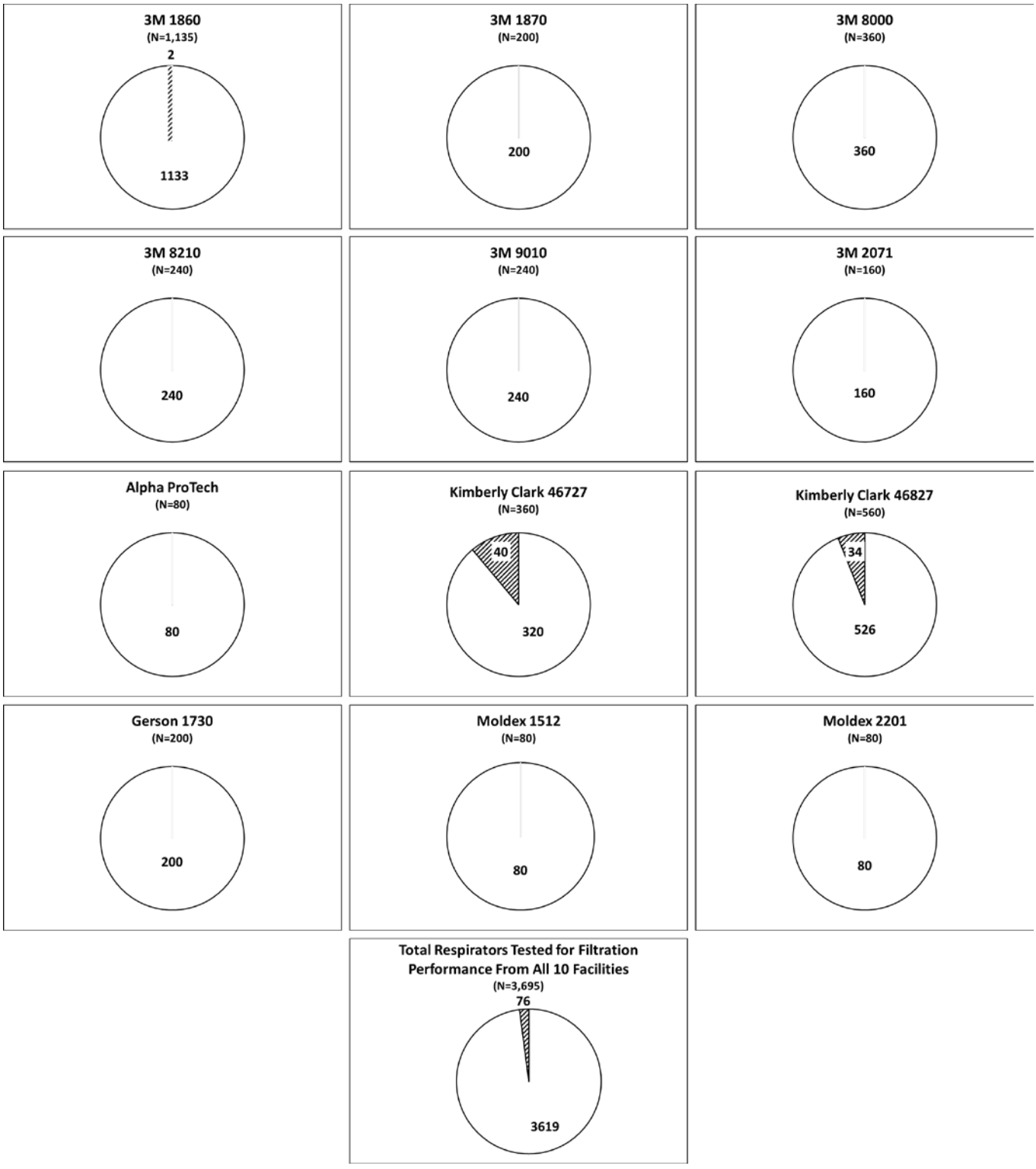

Figure 11: Summary of the stockpiled respirators tested for **filtration efficiency performance** from twelve APR models, as well as the total stockpiled respirators tested for **filtration efficiency performance** across the ten facilities. White represents the number of passing respirators and the black lines represents the number of failing respirators for each model.

CASE Findings

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[21] (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 primary application for the FFRs included in this study is to be a near-immediate use item that is both low-cost and single-use. The design and material selection for this primary application may not always align with secondary applications such as stockpiling where long-term product viability is required.

Findings for Respirator and Box Visual Inspections

- Overall, <2% of the total respirators visually inspected had visual inspection concerns, which included the respirators' nose foam sticking to adjacent respirators within the box, crushing, mold, and damage to straps. As seen in **Table 4**, no trends were observed between respirators with visual inspection concerns and performance—i.e. all 66 respirator units associated with visual inspection concerns met NIOSH's minimum performance requirements. Thirty-six boxes showed signs of damage, including crushing to the sides, mold, and signs of water damage.

Findings for Inhalation Resistance, Exhalation Resistance, and Filtration Performance

- NIOSH found that 3,895 out of the 3,971 APRs evaluated in this study maintained their inhalation and exhalation resistance and filtration performance (i.e., 98% of the sampled respirators were within the NIOSH performance limits as defined by 42 CFR Part 84).
- No failures were identified for the 276 stockpiled respirators tested against inhalation resistance or exhalation resistance.
- A total of 3,619 out of 3,695 (i.e., 98%) passed filtration performance across ten facilities with conditions that both met and deviated from recommended storage conditions. The upper bounds of each of the 99% confidence intervals for each test are well within the NIOSH minimum performance requirements. One of 3,695 respirators units (0.03%) that failed filtration performance from a box with damage. No failures were associated with respirators that) showed signs of damage to the unit itself. This one failing unit came from a box with damage (i.e., slight crushing to the bottom of the box). Thus, no trend/relationship was observed between filtration performance and visual inspection concerns of the box or respirator unit itself.
    - Filtration Performance Findings for the 3M Models
        - 3M 1860 – 1,135 units were tested from eight facilities. 99.99% of units passed.
        - 3M 1870 – 200 units were tested from three facilities. 100% of units passed.
        - 3M 8000 – 360 units were tested from four facilities. 100% of units passed.

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

        - 3M 8210 – 240 units were tested from three facilities. 100% of units passed.
        - 3M 9010 – 240 units were tested from three facilities. 100% of units passed.
        - 3M 2071 – 160 units were tested from two facilities. 100% of units passed.
    - Filtration Performance Findings for the Gerson Model
        - Gerson 1730 – 200 units were tested from three facilities. 100% of units passed.
    - Filtration Performance Findings for the Kimberly Clark Models
        - Kimberly Clark 46727 – 360 units were tested from five facilities. 89.66% of units passed.
        - Kimberly Clark 46827 – 560 units were tested from five facilities. 94.35% of units passed.
    - Filtration Performance Findings for the Medline/Alpha ProTech Model
        - Medline/Alpha ProTech NON27501 – 80 units were tested from one facility. 100% of units passed.
    - Filtration Performance Findings for the Moldex Models
        - Moldex 1512 – 80 units were tested from one facility. 100% of units passed.
        - Moldex 2201 – 80 units were tested from one facility. 100% of units passed.
- All stockpiled respirators tested that had a designated shelf life by the approval holder were past their shelf lives at the time of testing [Kimberly Clark 2018, Appendix 2]; [3M 2018, 3M 2020, Appendix 3]; [Moldex 2015, Appendix 4].
- Regarding the Kimberly Clark filtration failures, The Kimberly Clark 46727 model was stockpiled in five of the ten facilities, and the Kimberly Clark 46827 was stockpiled in seven of the ten facilities. The failing Kimberly Clark 46827 units were stockpiled in Facility Four, where 25 failures came from one production lot, and 9 failures came from a different production lot. Both lots were manufactured in 2007. A third Kimberly Clark 46827 lot, also manufactured in 2007, was sampled from Facility Four, where all units passed. The failing Kimberly Clark 46727 units came from Facility Seven, where all failures came from one production lot manufactured in 2007. A second Kimberly Clark 46827 lot, manufactured in 2006, was sampled from Facility Seven, where all units passed. All failing units were inspected, and no visual inspection concerns to the respirator or adherence to the test plate during testing were identified. In 2018, Kimberly Clark released a communication to end users reminding them of the five-year shelf life for these models and that units should be disposed of after they have reached their shelf life [Kimberly Clark 2018, Appendix 2]. The approval holder noted that the most likely cause of the test penetration failure was due to material changes over time and recommended that units beyond these models' five-year shelf life be disposed [Kimberly Clark 2018].
- Regarding the 3M 1860 filtration failures, these units were stockpiled in Facility Three, where one unit came from a production lot manufactured in 2006, and the other unit came from a production lot manufactured in 2009. All failing units were inspected, and no visual inspection concerns to the respirator or adherence to the test plate during testing were identified. These units were past the designated shelf life [3M 2018, 3M 2020, Appendix 3]. Two additional 3M 1860 lots were sampled from Facility Three, where all units passed.

The high replacement cost for large quantities of respirators (and other types of PPE) results in most stockpiles relying on federal resources during public health emergencies to replenish inventory. The temporal infrequency of large-scale public health emergencies suggests that shelf life issues will be an ongoing consideration for managing stockpiled respirators. While the results of this study significantly inform levels of protection that may be provided by respirators that have been stored for long periods in U.S. stockpiles, the results may not be applicable to other respirator models or stockpile facilities. Although the general trend observed in this study is that the majority of respirators evaluated would be protective across a variety of storage conditions, important variability was observed. For example, respirator units sampled from select production lots of a particular model demonstrated the ability to be protective while units from a different lot of the same model, stored in the same facility, are shown to not be protective. Furthermore, select models are demonstrated to be protective when sampled from one facility but not from another with similar conditions and years of storage.

At this time, NIOSH does not have enough information to definitively know the level of protection that may be provided by all 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.

However, based on the results of this study, on February 19, 2020 CDC/NIOSH issued guidance related to stockpiled FFRs: Release of Stockpiled N95 Filtering Facepiece Respirators beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response [CDC 2020a]. The summary of this guidance states:

- N95s that are past their manufacturer-designated shelf life are no longer considered NIOSH-approved, as all manufacturer-designated conditions of use must be met to maintain the NIOSH approval.
- In times of increased demand and decreased supply, consideration can be made to use the following N95s past their manufacturer-designated shelf life when responding to the 2019 novel coronavirus (COVID-19). These models that were tested in NIOSH's study continued to perform in accordance with NIOSH performance standards for filtration efficiency and inhalation/exhalation resistance:
    - 3M 1860
    - 3M 1870
    - 3M 8210
    - 3M 9010
    - 3M 8000
    - Gerson 1730
    - Medline/Alpha ProTech NON27501
    - Moldex 1512
    - Moldex 2201
- Although the preliminary information outlined from NIOSH's study suggests certain N95 models beyond their manufacturer-designated shelf life[22] will be protective, CDC/NIOSH recommends that N95s that have exceeded their manufacturer-designated shelf life should be used only as outlined in the Strategies for Optimizing the Supply of N95 Respirators [CDC 2020b].

[22] The Gerson 1730 and the Medline/Alpha Protech NON27501 models do not have a manufacturer-designated shelf life. All other models included in the study exceeded their manufacturer-designated shelf life.

Users provided any of these products 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 NIOSH approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the designated shelf life.

Stockpile personnel have reported needing uniform guidance related to inventory management for respirators that are past their shelf life designated by the approval holder. Ideally, stockpiles would continuously rotate products with local hospitals or other entities to ensure products are within their shelf life. However, the current reality is that facilities across the U.S. have respirators (and other types of PPE) stored that are over five years old, most exceeding their designated shelf life. One path forward is to develop and implement an economically sustainable stockpile quality assurance process where stockpiles from around the nation test and evaluate their respirator inventories with the results being shared with product manufactures to optimize shelf life designations. The quantitative testing should demonstrate conformance to NIOSH's minimum performance requirements. In addition to optimizing shelf life designations, NIOSH recommends a national stockpile maintenance approach to purchase, store, and deploy respirators (e.g., rotate inventory) to ensure respirator availability and product usage within these optimized shelf lives.

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 stockpiles 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.

Suggested Citation

NIOSH [2020]. PPE CASE: Inhalation and Exhalation Resistance and Filtration Performance of Stockpiled Air-Purifying Respirators: Overall Performance of Nearly 4,000 Respirators Sampled from Ten Stockpile Facilities. By Greenawald, L., Moore, S., and Yorio, P.L. 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 P2020-0111.

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Appendix 1 [Alpha ProTech 2020]

AlphaProTech

236 North 2200 West
Salt Lake, UT 84116
Office: 801-355-5816
Fax: 801-355-2534
www.alphaprotech.com

January 30, 2020

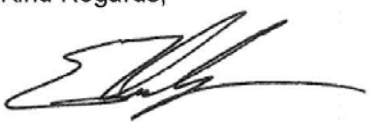
Shelf Life / Expiration Dating

This letter is in response to an inquiry on the requirement to label medical devices with an expiration date/shelf life. In accordance with the Food and Drug Administration (FDA) and guidance pertaining to this issue, shelf life dating solely for package integrity and sterility is not typically required. Expiration dating may be needed only if the device components contain a finite useful timeframe. Views in the industry see expiration dating as a safety factory and shelf life as a quality factor. While FDA interprets these items in a similar nature their view as to need of such date on packaging arises from the intended product make-up having limiting usefulness, degrading of components, or undesired package product interactions. With this being said, AlphaProTech (APT) does not include, as part of labeling, or related insert material, information pertaining to shelf life or expiration dates on their product lines due to the FDA guidance.

While APT's product lines do not specifically contain printed shelf life/expiration dates, defined testing on older products reveals these products continue to exceed the minimum requirements. Degradation of quality or safety on older product has not been seen in laboratory tests. Literature or labeling dealing with shelf life/expiration dating may be incorporated at a future date.

Please allow this memo to assist in clarifying any concerns you may have had about APT's exceptional products. If additional information or clarification on this subject is needed, please feel free to contact me.

Kind Regards,



Eric T. Llewelyn
V.P. Quality & Regulatory Affairs
Phone: (801) 355-5816
www.alphaprotech.com
AlphaProTech

Appendix 2 [Kimberly Clark 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 3 [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)

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
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

Appendix 4 [Moldex 2015]

MOLDEX
Ideas that wear well.

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	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