PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Evaluation of Fit and Strap Extension Performance of Stockpiled Filtering Facepiece Respirators from One U.S. Facility

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NIOSH evaluated 293 stockpiled N95 filtering facepiece respirators (FFR) from a single facility to determine if long-term storage (9-13 years) affected fit. Using human subjects, quantitative fit testing identified product- and lot-specific differences between the control and stockpiled respirators—substantial differences were detected for some products.

In the event of a national emergency, eighteen million U.S. healthcare workers may face exposure to high-consequence infectious disease [NIOSH 2017]. Personal protective equipment (PPE), such as gowns, gloves, goggles, and respirators, is an important control 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]. Recent outbreaks—even those that occurred without extensive impact on US operations (e.g., 2009 H1N1 pandemic, 2016 Ebola outbreak)—caused respirator shortages; when the first U.S. fatality was reported during the Ebola outbreak, the PPE orders increased 10-200 fold [CDC 2021; DHHS 2012; NIOSH 2018]. To prepare for these surge demands, emergency planners stockpile large quantities of PPE at federal and state levels to support local supplies [Patel et al. 2017]. At the onset of this study in 2017, these products had been stored for more than five or even ten years. NIOSH-approved N95 filtering facepiece respirators (FFRs) are commonly used particulate-only air-purifying respirators (APRs) by many healthcare facilities so they are a commonly stockpiled product. 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 (APRs), including FFRs. However, some approval holders have assigned a shelf life to the FFRs that they produce as indicated by product packaging or online reference materials. Additionally, NIOSH minimum performance requirements found within *Title 42, Code of Federal Regulations, Part 84* do not require an assessment of fit as part of the evaluation. However, under its Respiratory Protection Standard (29 CFR 1910.134), the Occupational Safety and Health Administration (OSHA) requires employers to fit test any workers using tight-fitting respirators, including FFRs, prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter [OSHA 2021]. OSHA also requires employers to ensure that workers using tight-fitting respirators perform a user seal check each time they put on the respirator [OSHA 2021].

Over the past decade, the Strategic National Stockpile (SNS) and state and local stockpile personnel asked NIOSH to evaluate the effect of stockpile conditions on the viability of respirators. To support this request, NIOSH collected samples of stockpiled N95 FFRs from ten geographically dispersed facilities with varying storage

conditions from 2017-2019. Approximately 4,000 FFRs were collected and tested in accordance with NIOSH performance requirements. The facility-specific reports can be found here.

This report details the fit testing performance of N95 FFRs collected from Facility Four which is one of the ten facilities visited. Facility Four is a state stockpile facility.

How NIOSH Evaluated Respirators and Storage Conditions

Description of Facility Four

- NIOSH researchers visited Facility Four in March 2018. This facility was located within the U.S. Department of Health and Human Services Region 9, representing Arizona, California, Hawaii, and Nevada. Respirators from Stockpile Four were chosen to evaluate for fit out of the ten stockpile facilities due to the various models of NIOSH-approved N95 FFRs that were available for sampling compared to some of the other facilities in this study.

Assessment of Storage Conditions

- For a full description of Facility Four storage conditions, refer to "Facility Four of Ten: Inhalation and Exhalation Resistance and Filtration Efficiency Performance" [Greenawald et al. 2020]. Briefly, temperature and percent relative humidity (%RH) data were obtained for one year prior to samples being collected and NIOSH documented the following storage conditions: 1) the presence of dust on PPE packaging, use of shrink-wrapping, potential for exposure to chemicals and moisture; 2) potential for 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).

Collection of Respirator Samples

- Samples were collected from five different manufacturing models[1]: 1) 3M 1860 (two manufacturing years); 2) 3M 1870; 3) 3M 8210; 4) 3M 9010; and 5) Kimberly Clark (KC) 46827 (**Table 1**).
- Detailed inventories and storage location by lot within Facility Four were reviewed. At a minimum, two manufacturing lots for each model were identified and sampled within Facility Four to consider inter-lot variation. For models with lots stored in a variety of conditions throughout the facility, one or two additional lots were sampled to reflect the range of storage conditions observed. Samples were collected from the stockpile and shipped to the NIOSH facility overnight to reduce exposure to non-climate-controlled conditions.
- A minimum of 25 respirators from each manufacturing lot were collected for fit testing.

Selection of Control Respirators

- Control respirators of the same model as those sampled from the facility were purchased from the open market and used for comparison to stockpiled respirators.
- The 3M 1860 controls were manufactured in 2018. The 3M 8210 controls were manufactured in 2015. The 3M 1870 controls were manufactured in 2014. The 3M 9010 controls were purchased in 2018, but

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

the researchers were not able to determine the manufacturing date from the product packaging. The KC 46827 controls were manufactured in 2017.

Characteristics of Sampled Respirators

- **Table 1** provides a summary of the respirator models sampled from Facility Four.

Table 1. FFRs Collected from Stockpile Facility Four

Model	Lot #	Year of Manufacture	Shelf Life on Packaging?	Respirator Age at Time of Testing[2]	Shelf Life Status at Time of Testing
3M 1860	Lot A	2010	No	9 years	Past 5-year shelf life[3]
3M 1860	Lot B	2010	No	9 years	Past 5-year shelf life[3]
3M 1860	Lot C[4]	2006	No	13 years	
3M 1870[5]	Lot A	2010	No	9 years	Past 5-year shelf life[3]
3M 1870[5]	Lot B	2010	No		
3M 8210	Lot A	2006	No	13 years	Past 5-year shelf life[3]
3M 8210	Lot B	2006	No		
3M 9010	Lot A	2006	No	13 years	Past 5-year shelf life[3]
3M 9010	Lot B	2006	No		
KC 46827	Lot A	2007	No	12 years	Past 5-year shelf life[6]
KC 46827	Lot B	2007	No		
KC 46827	Lot C	2007	No		

Evaluation of Fit

- The collected FFRs were quantitatively fit tested using the OSHA-accepted ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol specified in Appendix A of OSHA's Respiratory Protection standard (29 CFR 1910.134) [OSHA 2011] and human subjects[7] to assess if there was a difference in fit between the control and stockpiled respirators.
- Using face length and width, NIOSH's Bivariate panel (NIOSH Panel) [NPPTL 2019] was used to classify the test subjects into one of ten possible panel cells—i.e., face dimension categories. Test subject panel cell sizes from cell sizes 1 – 10 were used regardless of respirator model size (e.g., Small, Regular).
- An attempt was made to recruit test subjects that reflected a variety of facial dimensions (i.e., panel cells 1 – 10) for every lot tested. Therefore, each FFR model in Facility Four (i.e., 3M 1870, 3M 8210, 3M 9010, 3M 1860, and KC 46827) was tested using subjects with varying face shapes and sizes.
- Twenty-five volunteers were fit tested for the new (i.e., control) respirators from each model and the stockpiled respirators, where each test subject donned and fit tested with the same respirator four times. A successful user seal check was conducted prior to fit testing each respirator that was donned.

[2] Fit testing was completed in 2019.
[3] 3M designated a five-year shelf life for these models [3M 2018]. As of February 2021, these models still have a five-year shelf life.
[4] Only one lot of the 3M 1860 manufactured in 2006 was available for sampling.
[5] The 3M 1870 is no longer produced or sold by 3M and has been replaced by the 3M 1870+.
[6] KC designated a five-year shelf life for this model [Kimberly Clark 2018]. As of February 2021, this model still has a five-year shelf life.
[7] NIOSH IRB Protocol 18-NPPTL-01XP.

- A PortaCount® (Model: Pro+ Model 8038, TSI, Inc.) was used to perform fit testing and calculate individual and overall fit factors (FFs) according to OSHA's ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol [OSHA 2021]. The N95 Companion™ mode of the PortaCount® was used to eliminate the bias of particulate penetration through the filter media, and only include the particulate leakage at the seal. In N95 Companion™ mode, the PortaCount® measures only negatively charged 40-60 nm size particles, i.e., those shown to be efficiently captured by electrostatic filter media [Rengasamy et al 2012]. The PortaCount® limits the maximum achievable FF to 200.
- The objective was to fit test 25 respirators per lot, though minor deviations occurred due to subjects dropping out of the study or straps breaking. The analysis considered a FF $\geq$100 as a passing test since OSHA 29 CFR 1910.134 [OSHA 2021] requires a FF of 100 or greater during individual fit testing using the PortaCount®. Each subject performed the OSHA-accepted 8-exercise fit test,[8] where individual FF from each exercise (with the exclusion of the "grimace" exercise) were used to calculate an overall FF [OSHA 2011]. Doffing and re-donning was conducted between fit tests.
- Three metrics were used to assess fit:
    - **Mean overall FF**: Calculated for each model by using each of the subject's overall FF per donned respirator. The purpose of using this metric was to compare the continuous FF values between stockpiled lots and the controls without converting to pass/fail in relation to OSHA's passing value of 100. These FFs ranged from 0 – 200 and analyzing them in their continuous form communicates the average degree of fit observed for each lot. It also allows comparisons between lots with average FF scores below 100 but with important FF differences (e.g., an average FF close to 10 vs. an average FF of close to 100). In its continuous form, the FFs were analyzed using Analysis of Variance (ANOVA).
    - **Donning proportion passing rate:** Calculated by dividing the number of donnings out of total donnings that yielded an overall FF $\geq$100. Converting the continuous FF scores to pass/ fail (or 0s and 1s) provided the ability to conduct a z-test and analyze the difference of the percent of donnings that received a FF$\geq$100 between lots.
    - **Subject proportion passing rate:** Calculated by dividing the number of subjects that yielded an overall FF $\geq$100 on any one of their donnings. This provided the ability to conduct a z-test and analyze the differences of the percent of subjects that received a FF$\geq$100 between lots.

Evaluation of Strap Extension Performance

- To further explore factors that could influence fit of stockpiled respirators, the average strap extension (before and after adding a weight to the strap) of ten straps per manufacturing lot were compared to the controls of the same model. This evaluation was done to see if differences in strap characteristics for new and stockpiled respirators showed trends related to changes in fit (e.g., determine if looser straps could be associated with lower fit factors and thus poorer fit). Using a simplified test briefly described in Appendix 1, ten straps per manufacturing lot were compared to the controls to determine if the stockpiled straps were more or less stiff than the controls based on this simple test. Due to the nature of the materials used to construct straps, a full study of this type is resource- and time-intensive.

[8] These exercises included 1) normal breathing; deep breathing; breathing while moving their head from side to side; breathing while moving their head up and down; reciting the rainbow passage; bending over at the waist and reaching up and down; normal breathing; grimace; normal breathing. Grimace FF were not calculated or used for the overall FF.

[9] One test subject dropped out before completing the four donnings for Lot C, so a new test subject tested four donnings of the control and four donnings for Lot C.

Therefore, NIOSH used a simplified test protocol for this current study that was adapted from one of its previously published studies on respirator straps [Rottach and Lei 2017]. For each manufacturing lot, the average strap extension ratio of the stockpiled straps was then divided by the average strap extension ratio for its control straps to arrive at the normalized stockpile strap extension ratio, which was used to determine the difference in performance of stockpiled respirator straps.

What NIOSH Found Through Inspection, Testing, and Evaluation

Storage Conditions

- For a full description of Facility Four storage conditions, refer to "Facility Four of Ten: Inhalation and Exhalation Resistance and Filtration Efficiency Performance" [Greenawald et al 2020]. Briefly, these conditions were:
    - Dust and damage to product packaging was limited or not observed at Facility Four
    - Facility lights were off when the facility was not in use
    - Small ceiling vents allowed sunlight to enter the facility in specific locations on the top pallets
    - 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 but not across the top or bottom
    - With the exception of the top-most row, pallets were stacked two-high causing some weight/load to be applied to the bottom pallet.
    - Some deviation from manufacturer recommended temperature and percent relative humidity (%RH) conditions were noted (3M models: 0.02% of the temperature and 0% of the %RH data points; KC model: 66.4% of the temperature and 25.8% of %RH data points).

Observations during Donning

- Upon donning the respirators, nine KC 46827 respirators were not used since the straps were broken (in the middle of the strap) or broke (from the facepiece and in the middle of the strap) during subject donning. Five straps broke from Lot A, and four straps broke from Lot C. Test staff reported that these straps felt hardened/stiff to the touch prior to attempting to don. One 3M 1870 strap from Lot A broke during donning. These damaged straps affected the sample size of respirators tested, which is further explained in **Table 2**.

Fit Testing Subject Panel

- The distribution of test subjects for each model sampled from Facility Four as a function of the NIOSH panel cell size is shown in **Figure 1**. For each model, test subjects assigned to panel cells #1, #2, #4, #5, #7, and #8 were used. Subjects were sought but could not be identified for cells #3, #6, and #9.

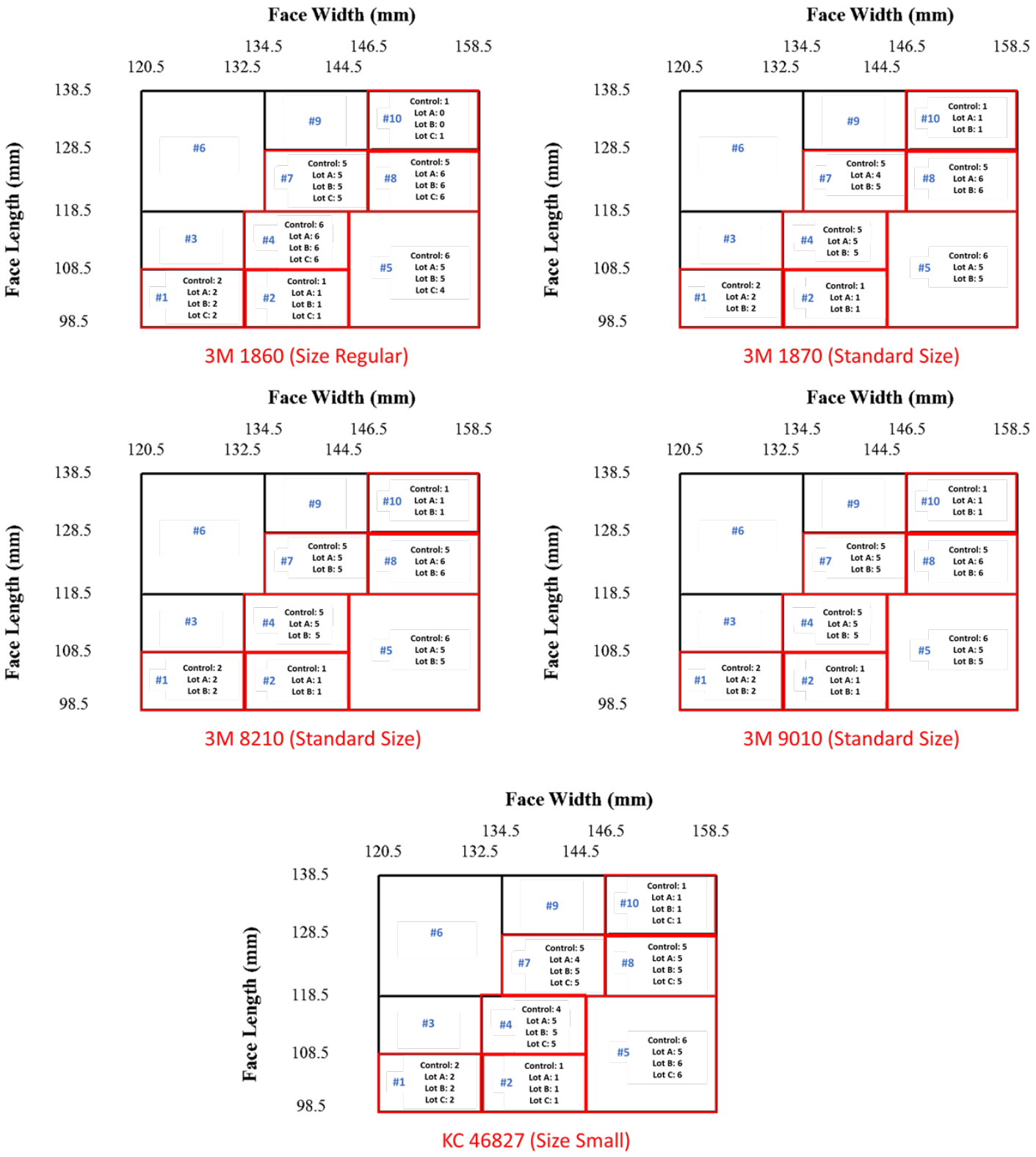

Figure 1: Distribution of test subjects by panel and model for Facility Four. Panel cell sizes are shown in blue, where the cell sizes used in this study are outlined in red. The model and model size are shown below each NIOSH Panel. Differing number of control and stockpile cell sizes were due to 1) test subjects exiting from the study and being replaced with new subjects of a different panel cell size; 2) same subject donning the same model across multiple lots; 3) as well as straps breaking.

Evaluation of Fit Using the Mean Overall FF

- It is important to note that fit testing is inherently variable due to many factors, including inter- and intra-subject variabilities [Da Roza et al. 1983; Zhuang et al. 2011, 2015]. Therefore, variability is not limited to fit testing aged FFRs, but is observed for new FFRs.
- In some instances, the mean overall FF for the control respirators was higher, indicating a better fit to the user, than the mean overall FF for the stockpiled respirators, and in other instances, stockpiled respirators had a higher FF than the controls. **Table 2** shows a summary of the fit testing results. Differences were assessed through analysis of variance (ANOVA) with post-hoc, Bonferroni adjusted comparisons. The p-values shown in red indicate a statistically significant difference was identified between the control and stockpiled model. **Figure 2** shows a summary of the overall FF for each model.
    - 3M 1860: No statistically significant differences were detected when comparing the control FF (mean [M]= 89.0, SD=66.8) to the mean overall FF when the three stockpiled lot data were aggregated (M=101.4, SD=71.5). When comparing each of the three individual stockpiled lots to the control, only one stockpiled lot (Lot C, manufactured in 2006) was statistically significantly different than the control, with a higher mean overall FF (M=112.5, SD=69.4).
    - 3M 1870: No statistically significant differences were detected when comparing the mean control overall FF (M=119.3, SD=70.0) to the average overall FF when the two stockpiled lots were aggregated (M=119.8, SD=73.6). When comparing each of the two individual stockpiled lots to the control, neither lot was statistically significantly different than the control.
    - 3M 8210: The mean control overall FF (M=127.1, SD=74.8) was statistically significantly higher than the mean overall stockpiled FF (M=96.3, SD=70.6), p=0.01. This difference was largely driven by Lot B. When comparing each of the two individual stockpiled lots to the control, Lot B was statistically significantly different than the control, with a lower mean overall FF (M=74.4, SD=62.1). Lot A (M=118.2, SD=72.1) was not statistically significantly different. Visual inspections of the product packaging or individual respirators did not provide insight on why Lot B had a lower FF than Lot A; boxes from both lots were stored outside of the original product cases.
    - 3M 9010: No statistically significant differences were detected when comparing the mean control overall FF (M=97.3, SD=73.3) to the mean overall FF when the two stockpiled lots were aggregated (M=106.7, SD=76.0). When comparing each of the two individual stockpiled lots to the control, neither Lot A nor Lot B was statistically significantly different than the control.
    - KC 46827: A statistically significant difference was detected when comparing the mean control overall FF (M=90.6, SD=72.3) to the mean overall FF when the three stockpiled lots were aggregated (M=19.0, SD=35.9). All three lots were statistically different than the control, with lower overall FF for each of the stockpiled lots.

Evaluation of Pass Rates: Proportion of Donnings and Proportion of Subjects

- Proportion of Donnings Passing (**Table 2, Columns 6 – 9**)
    - Analyses were conducted to determine if there was an overall statistically significant difference between the stockpiled and control FFRs in terms of donnings achieving a FF $\geq$100 across all models. The analyses showed statistical significances that were model specific.
    - Subjects donned the respirator four times, where FF varied among the different donnings. Overall, 248 (49%) of the 503 control donnings achieved a FF$\geq$100; 84 (67%) of the control respirators had an overall fit factor greater than or equal to 100. In contrast, for the stockpiled

donnings overall, 473 (41%) of the 1,165 donnings achieved a FF≥100; 160 (55%) of the 293 respirators achieved a FF≥100. When the controls of a specific model were compared to each stockpiled lot of the same model through a z-test, the following comparisons were observed:

- 3M 1870: no differences between each stockpiled lot and the control
- 3M 9010: no differences between each stockpiled lot and the control
- 3M 1860 Lot: a statistically significantly *higher* proportion of Lot C donnings passed compared to the control (60% of donnings passed vs. 40% for the control; $p<0.004$)
- 3M 8210 Lot B: a statistically significantly *lower* proportion of Lot B donnings passed compared to the control (26% of donnings passed vs. 65% for the control; $p<0.001$)
- KC 46827 Lots A, B, and C: a statistically significantly *lower* proportion of Lots A, B, and C donnings passed compared to the control (6%, 5%, and 6% of donnings passed the stockpiled lots, respectively, vs. 45% for the control)

- Proportion of Subjects Passing (**Table 2, Columns 10 – 13**)
  - Analyses were conducted to determine if there was an overall statistically significant difference between the stockpiled and control FFRs in terms of subjects achieving a FF ≥100 across all models. The analyses showed dependency between the 3M models and the KC models and thus the conclusions are model specific.
  - For each test subject, if one of any of the four donnings resulted in an overall FF ≥100, this was considered a pass. When the controls of a specific model were compared to each stockpiled lot of the same model, the following comparisons were observed:
    - 3M 1870: no differences between each stockpiled lot and the control.
    - 3M 9010: no differences between each stockpiled lot and the control.
    - 3M 1860: a statistically significantly *higher* proportion of Lot C subjects passed compared to the control (81% of the subjects passed vs. 58% for the control; $p<0.04$).
    - 3M 8210 Lot B: a statistically significant proportion of subjects had lower FFs for Lot B *when compared to* the control (32% of subjects passed the stockpiled lot vs. 76% for the control; $p<0.002$)
    - KC 46827 Lots A, B, and C: a statistically significant proportion of subjects fit Lots A, B, and C *worse* than the control (9%, 8%, and 9% of subjects passed the stockpiled lots, respectively, vs. 58% for the control).

Table 2: Summary of Facility Four Fit Testing Results

	Mean FF				Donning Proportion Passing				Subject Proportion Passing			
Model	**Control or Stockpiled Lot**	**Mean FF**	**Standard Error/ Standard Deviation**	**p- values (SP Lots Compared to the Control)**	**# of Donnings**	**# of Donnings that Passed (i.e. FF≥100)**	**Donning Pass Rate (%)**	**p-values (SP Lots Compared to the Control)**	**# of Subjects**	**# of Subjects that Passed**	**Subject Pass Rate (%)**	**p-values (SP Lots Compared to the Control)**
3M 1860	Control	88.96	6.57/66.78	-	103	41	39.8%	-	26[9]	15	57.7%	-
	Lot A 2010	96.11	7.07/70.69	0.75	100	46	46.0%	0.37	25	16	64.0%	0.63
	Lot B 2010	95.58	7.38/73.81	0.89	100	42	42.0%	0.75	25	17	68.0%	0.44
	Lot C 2006	112.48	6.80/69.36	0.15	100	60	60.0%	0.004	26	21	80.8%	0.04
3M 1870	Control	119.29	6.99/69.98	-	100	54	54.0%	-	25	20	80.0%	-
	Lot A	120.61	7.38/72.34	0.93	96[12]	61	63.5%	0.18	24[10]	19	79.2%	0.94
	Lot B	118.94	7.52/75.18	0.91	100	56	56.0%	0.78	25	20	80.0%	1.00
3M 8210	Control	127.13	7.48/74.77	-	100	65	65.0%	-	25	19	76.0%	-
	Lot A	118.20	7.21/72.10	0.49	100	63	63.0%	0.76	25	18	72.0%	0.76
	Lot B	74.44	6.21/62.06	<0.001	100	26	26.0%	<0.001	25	8	32.0%	0.002
3M 9010	Control	97.25	7.45/75.98	-	104[10]	45	43.3%	-	26[11]	16	61.5%	-
	Lot A	101.96	7.52/75.24	0.86	100	49	49.0%	0.41	25	17	65.4%	0.77
	Lot B	111.42	7.69/76.90	0.50	100	55	55.0%	0.10	25	18	72.0%	0.44
KC 46827	Control	90.64	7.38/72.28	-	96[12]	43	44.8%	-	24[11]	14	58.3%	-
	Lot A	17.97	3.73/34.43	<0.001	85[13]	5	5.9%	<0.001	22[12]	2	9.1%	<0.001
	Lot B	18.88	3.06/30.64	<0.001	100	5	5.0%	<0.001	25	2	8.0%	<0.001
	Lot C	20.05	4.55/42.69	<0.001	84[14]	5	5.7%	<0.001	21[13]	2	9.1%	<0.001

[9] One test subject dropped out before completing the four donnings for Lot C, so a new test subject tested four donnings of the control and four donnings for Lot C.
[10] One strap broke, 4 of these 4 donnings could not be completed.
[11] One subject dropped out before completing stockpiled Lots A and B, therefore, a new test subject donned the control and Lots A and B.
[12] One subject dropped out before completing the four donnings for the control.
[13] Four straps broke, 15 of these 16 donnings could not be completed; one complete donning was achieved for one of these respirators before the strap broke.
[14] Four straps broke, 16 of these 16 donnings could not be completed.

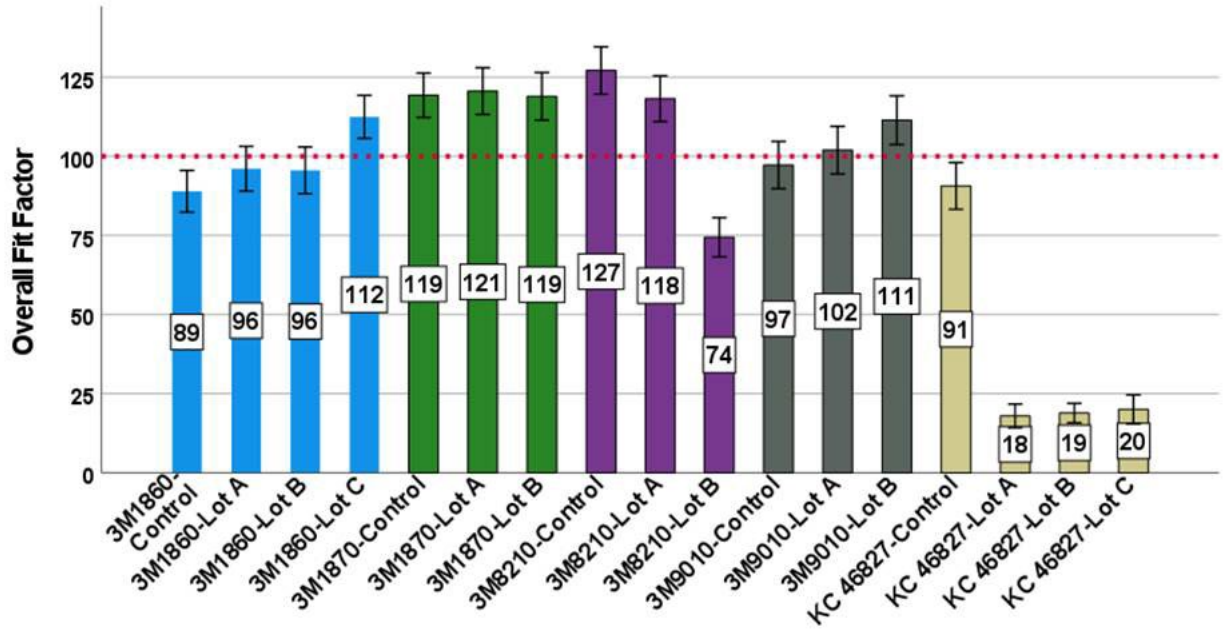

Figure 2: Summary of the Mean Overall Fit Factors for the Control and Stockpiled Respirators Tested. OSHA 29 CFR 1910.134 States that a FF $\geq$ 100 is a Pass (Depicted By the Red Dashed Line). Error Bars are Represented as the Standard Error of the Mean.

Evaluation of Strap Extension Performance

- Strap Performance
  - The average strap extension ratio for each manufacturing lot—normalized by the average strap extension ratio of the control straps—is shown in **Figure 3**. Because the force applied to both the stockpiled and control straps was consistent, the lower extension ratio for stockpiled respirator straps indicates that they were generally stiffer than their controls. The black line represents the strap extension ratios for the controls.
  - Differences were assessed through analysis of variance (ANOVA) with post-hoc, Bonferroni adjusted comparisons. The asterisks shown in **Figure 3** indicate a statistically significant difference was identified between the control and stockpiled lots.
    - 3M 1860: all three stockpiled lots were statistically significantly stiffer than the control lot.
    - 3M 1870: no stockpiled lots were statistically significantly different than the control lot.
    - 3M 8210: stockpiled Lot A was statistically significantly less stiff than the control lot. There were no visual concerns recorded that could be used to explain the difference between the two lots.
    - 3M 9010: no stockpiled lots were statistically significantly different than the control lot.
    - KC 46827: all three stockpiled lots were statistically significantly less stiff than the control lot.

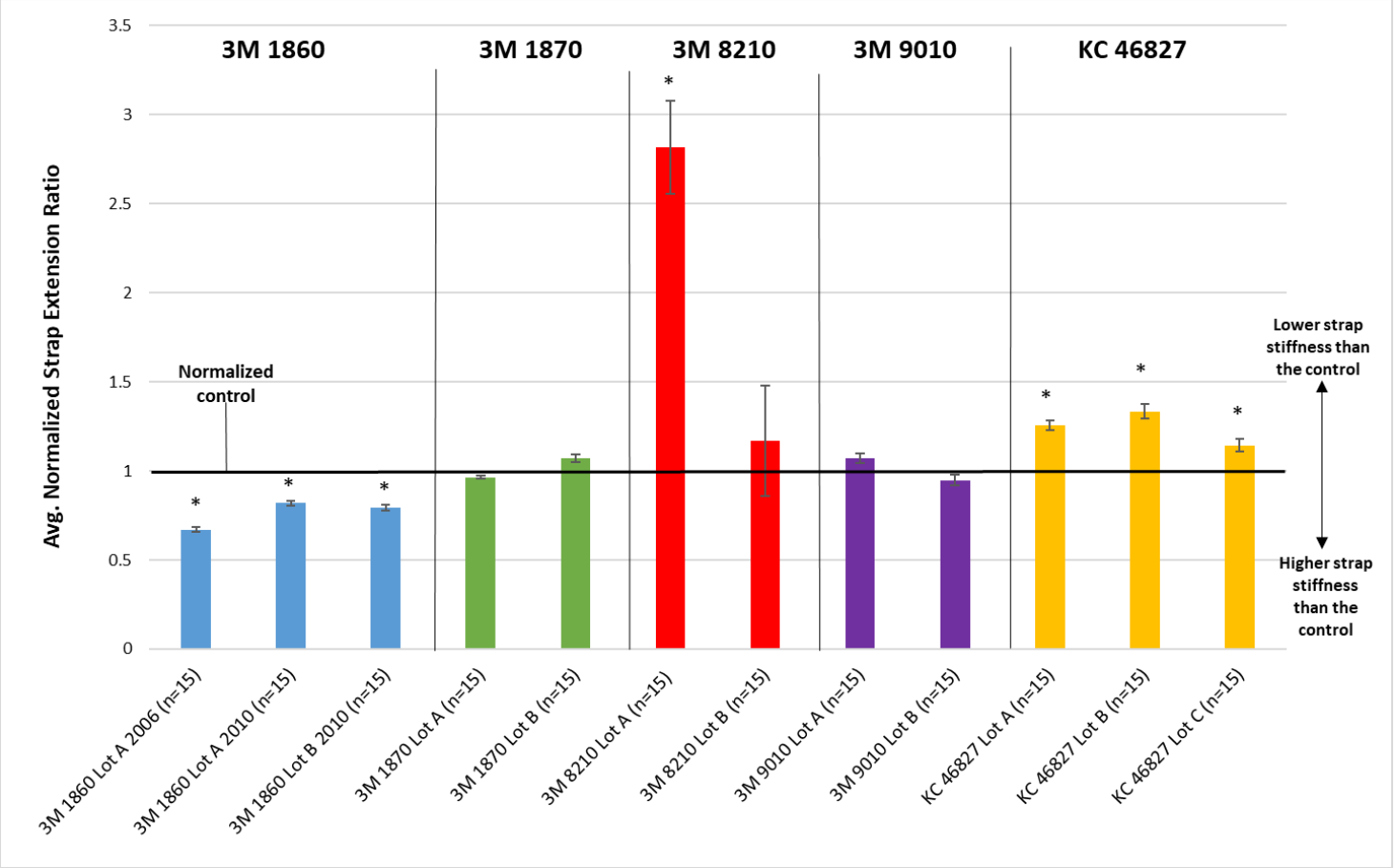

Figure 3: Average strap extension ratio, normalized by control strap performance shown by stockpiled manufacturing lot. Error bars represent the 95% confidence interval and estimate the population parameters. The asterisk (*) indicates that the stockpiled lot was found to be *statistically* significantly different from the control respirators of the same product model ($p<0.05$).

Limitations

This study design limits the generalizability of the results. Limitations include:

- Control samples were not the same lot/manufacturing year as those stockpiled samples.
- Test subject panel cell sizes from cell sizes 1 – 10 were used regardless of respirator model size
    - (e.g., Small, Regular). Subjects were sought but could not be identified for cells #3, #6, and #9.

CASE Findings

Findings for the 3M 1860 Model:

Fit Testing**: One of three stockpiled lot fit the test subjects better when compared with the control lot.**

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 Four and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Strap Testing: The straps from the three stockpiled lots were more stiff than the control lot.

Findings for the 3M 1870 Model:

Fit Testing: **The two stockpiled lots fit the test subjects similarly to the control lot.**

One strap broke during donning, possibly due to degradation of the strap material. 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, 2020]. Thus, all respirators tested are past their recommended shelf life. These findings pertain to 3M units from Facility Four and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Strap Testing: No statistically significant differences in strap stiffness were detected between the control lot and the stockpiled lots.

Findings for the 3M 8210 Model:

Fit Testing: **One of two stockpiled lots did not fit the test subjects as well as the control lot.**

No visual inspection concerns were identified. 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, 2020]. Thus, all respirators tested are past their recommended shelf life. These findings pertain to 3M units from Facility Four and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Strap Testing: Lot A straps were statistically significantly less stiff than the control, whereas Lot B straps were not statistically significantly different than the control lot.

Findings for the 3M 9010 Model:

Fit Testing: **The two stockpiled lots fit the test subjects similarly to the control lot.**

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, 2020]. Thus, all respirators tested are past their recommended shelf life. These findings pertain to 3M units from Facility Four and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

Strap Testing: No statistically significant differences in strap stiffness were detected between the control lot and the stockpiled lots.

Findings for the KC 46827 Model:

Fit Testing: The three stockpiled lots did not fit the test subjects as well as the control lot.

When fit testing, nine straps broke during donning, possibly due to degradation of the strap material. Five straps broke from Lot A, and four straps broke from Lot C. This model currently has a five-year shelf life; Appendix 3 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 Four and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

It's also important to consider findings from the aforementioned report, where NIOSH evaluated respirators from the same KC 46827 lots from Facility Four for breathing resistance and filtration performance [Greenawald et al 2020]. Thirty-four individual KC 46827 stockpiled respirators failed out of the 120 tested for filtration performance, where 25 of the 34 respirators failed filtration performance from Lot C, and 9 of the 34 respirators came from Lot B; both lots were manufactured in 2007.

Strap testing: The straps for all three stockpiled lots were statistically less stiff than the controls.

The described evaluations showed model-specific changes in fit and strap extension ratios. However, the findings cannot conclude whether the change in fit between control and stockpiled respirators was specifically affected by stockpiling conditions and/or long-term storage. At this time, sufficient information is not available to definitively know the change in fit of all respirators that 1) are stored for prolonged periods of time; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. It is also not clear why some stockpiled FFRs had better fit than those control FFRs; changes in strap extension (elasticity) or manufacturing conditions may be one variable. NIOSH recommends contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use or disposal of product if it is beyond the designated shelf life or questions regarding storage conditions. Users of respirators that have exceeded the designated shelf life or were stored outside of designated storage conditions should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of fit or filtration as those that have not exceeded the designated shelf life or storage conditions. While performing a visual inspection of each respirator unit may assist users in identifying possible material degradation, this degradation may not always be apparent—a user seal check must be performed with every donning.

It is not yet known how the strap testing results may impact the protectiveness of respirators. Intuitively, one might expect that changes in stiffness could impact respirator fit (e.g., looser straps may contribute to poorer fit); however, the magnitude of stiffness change to cause a change in fit is unknown. Previous studies have shown that strap length can vary by 10% within the same manufacturing lot [Rottach and Lei 2017]. This suggests that a substantial change in stiffness may be needed before fit (and protection) is affected. Thus, no assumptions on the effect of fit can be made at this time. However, some trends can be observed. The stockpiled straps that *generally* were less stiff than the controls (e.g., the three KC 46827 lots) had lower overall FF than those stockpiled straps that were stiffer than the controls (e.g., the three 3M 1860 lots). However, the 3M 8210 showed the opposite: Lot B overall FFs were lower than Lot A but had stiffer straps. Overall, storing respirators beyond the manufacturer-designated shelf life or outside of the recommended storage conditions as defined in the user's instructions can potentially impact the elasticity of the straps. Manufacturers may use this information for design considerations or for improved visual inspection procedures.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators [NIOSH 1997]. However, NIOSH does not assess face seal fit as part of the NIOSH approval of particulate-only APRs, including N95 FFRs. Additionally, NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs. The approval holder[15] (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 disseminate recommendations related to storage and shelf life through resources such as user and web notices. The FFRs tested in this study were generally not designed for long-term storage (e.g., over 5 years).

[15] 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 products that are beyond their manufacturer specified shelf life.
- 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
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Monthly NIOSH eNews: cdc.gov/niosh/eNews

All photos courtesy of NIOSH NPPTL.

Disclaimer
The findings 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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Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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Appendix 1 – Strap Testing Protocol

Six-centimeter (cm) sections were marked at the center followed by preconditioning each strap to account for strain softening effects. The strap was clamped in a test rig and a force of 2N was applied along the strap length, and the length of the marked section was measured. The strap was unclamped, and a final measurement was made of the unloaded length. The uniaxial strap extension was calculated from the loaded (i.e., 2N load applied) and unloaded lengths, per the formula below:

$$Strap\ Extension\ Ratio = \frac{Loaded\ Extension - Unloaded\ Extension}{Unloaded\ Extension}$$

Appendix 2 – [3M 2018], [3M 2020]

3M Personal Safety Division

St. Paul, MN 55144-1000

June, 2018

Dear Valued Customer:

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

Table A. 3M Filtering Facepiece Respirators

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

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

IMPORTANT NOTE

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

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

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

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

Sincerely,

3M Personal Safety Division (PSD)

3M Science. Applied to Life.™

FAQ

Release 5, February 2020

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

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

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

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

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

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

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

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

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

How is the respirator's shelf life communicated?

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

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

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

 Use by Date

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

 Date of Manufacture

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

 Manufacturer

What happens if storage conditions are not met?

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

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

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

How do we know when not to use the respirator?

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

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

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

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

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

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

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

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

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

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

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

Personal Safety Division
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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 3 – [Kimberly Clark 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