NPPTL COVID-19 Response: Beyond Shelf Life/Stockpiled Respirator Assessment

Manufacture: 3M

Model Tested: 3M 8511 Date Tested: April 7, 2020 Report Prepared: April 10, 2020

No failures for filtration performance were observed—i.e., the performance data suggests that these units would be protective so long as a proper fit is achieved. This model currently has a 5-year designated shelf life. Thus, these respirators tested are past their designated shelf life. These findings pertain to the 3M 8511 units from your facility in Washington, D.C., and may not be applicable to other stockpile facilities and/or under different environmental storage conditions.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators (42 CFR 84). NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs. The approval holder (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. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage.

Based on research conducted by NIOSH and this limited testing, NIOSH does not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer- designated shelf life.

The results provided in this letter are specific to the subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

These results will be added to the CDC guidance for <u>Stockpiled N95 Filtering Facepiece Respirators</u> <u>Beyond the Manufacturer-Designated Shelf Life</u>.

Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s



Test: TEB-APR-STP-0059

Manufacturer: 3M Item Tested: 8511

Expiration Date: None Specified (see note) **Manufacture Date:** 05/09

Respirator	Flow Rate Lpm	Initial Filter Resistance (mm H ₂ O)	Initial Penetration (%)	Maximum Penetration (%)	Filter Efficiency
1	85	6.5	0.841	2.07	95%
2	85	5.9	1.49	2.91	95%
3	85	6.5	1.36	2.07	95%
4	85	6.7	2.00	2.74	95%
5	85	6.9	0.922	2.18	95%
6	85	7.1	0.769	1.60	95%
7	85	6.7	1.20	2.08	95%
8	85	6.7	1.26	2.05	95%
9	85	7.0	0.864	1.56	95%
10	85	6.6	1.97	2.48	95%
11	85	6.6	0.714	1.86	95%
12	85	6.3	1.05	2.09	95%
13	85	7.0	1.17	2.22	95%
14	85	6.8	0.814	1.79	95%
15	85	6.7	0.958	1.57	95%
16	85	6.5	1.40	2.03	95%
17	85	6.6	1.16	1.77	95%
18	85	6.7	1.66	2.05	95%
19	85	6.7	0.894	1.69	95%
20	85	6.4	0.824	1.81	95%

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Note: The following links provide additional information regarding 3M products and shelf life.

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

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

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

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