Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

Considerations for Release of Stockpiled N95s Beyond the Manufacturer-Designated Shelf Life

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Summary

- 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 N95s listed above past their manufacturer-designated shelf life when responding to COVID-19.
- This preliminary information from the NIOSH study suggests certain N95 models beyond their manufacturer-designated shelf life[ii] will be protective. CDC 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*.
- Reports detailing the performance results of stockpiled respirators sampled from stockpile facilities are

Background

Some U.S. stockpiles include N95 filtering facepiece respirators (N95s) that have exceeded their manufacturer-designated shelf life. U.S. Government decision makers are considering whether these products should be released for use during the COVID-19 response. Information is provided below that may be used to inform these product release decisions. In times of respiratory protective device shortage, such as during the COVID-19 response, supplies must be managed so that protection against exposure is adequate.

Considerations to inform product release decisions

A study to evaluate stockpiled N95s from 10 geographically dispersed facilities with a range of storage conditions is underway by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH). This study includes data from 11 different N95 models. Ten reports detailing the performance results of respirators sampled from these 10 facilities are available on the NIOSH webpage. All N95 units evaluated in this study were manufactured between 2003 and 2013. Many have exceeded their manufacturer-designated shelf life. Testing was done in accordance with NIOSH performance standards for filtration efficiency and inhalation/exhalation resistance. Additional work to assess N95 fit testing is also included in the study, although a fit assessment is not a requirement for NIOSH approval of N95s.

Based on preliminary information gained in this study[i], many models have continued to perform in accordance with NIOSH performance standards. Accordingly, CDC/NIOSH believes the following products, despite being past their manufacturer-designated shelf life, should provide the expected level of protection to the user if the stockpile conditions have generally been in accordance with the manufacturer-recommended storage conditions and an OSHA-compliant respiratory protection program is used by employers. In alphabetical order, these models are:

- 3M 1855
- 3M 1860
- 3M 1870
- 3M 8210
- 3M 9010
- 3M 8000
- Gerson 1730
- Medline/Alpha Protech NON27501
- Moldex 1512
- Moldex 2201

available on the NIOSH webpage.

Firm conclusions cannot be drawn for stockpiled N95 models beyond those tested in this study; however, the 3M 1860S is a smaller version of the 3M 1860, constructed from the same materials, and is expected to perform in the same manner. The 3M 8000 is no longer produced; however, it should still be effective at protecting workers if the straps are intact and there are no visible signs of damage. While it performed favorably when evaluated against the NIOSH approval requirements, it is no longer supported by the manufacturer (i.e., user instructions, donning instructions, etc. are no longer available).

The Kimberly-Clark 46827 (size small) and Kimberly-Clark 46727 (size regular) may not provide the expected level of protection to the wearer when past their manufacturer-designated shelf life of 5 years. In June 2018, Kimberly Clark issued a letter to customers regarding these models, reminding them that they should be disposed of if beyond their shelf life, regardless of whether a shelf life is designated on the product label/packaging. It is important to note that the results of this study are for stockpiled N95s which have undergone long-term storage and have exceeded any manufacturer-designated shelf life. These results are not an indication of this product's performance when purchased new for (1) just-in-time use or (2) routine use.

CDC/NIOSH Recommendations

In times of increased demand and decreased supply, consideration can be given to use the N95s listed above past their manufacturer-designated shelf life when responding to COVID-19. Although this preliminary information from the NIOSH study suggests certain N95 models beyond their manufacturer-designated shelf life[ii] will be protective, CDC 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

The respirators exceeding their manufacturer-designated shelf life are only being released due to the potential urgent demand caused by the COVID-19 public health emergency. In the face of this emergency, the U.S. Government believes that the respirators beyond their manufacturer-designated shelf life should provide greater respiratory protection than surgical masks (i.e., medical masks) alone, improvised mouth and nose covers (e.g., bandanas), or no protection at all. Please note that surgical N95s are normally tested for fluid resistance and flammability. These requirements were not evaluated in this study. CDC does not recommend using N95s beyond the manufacturer-designated shelf life in surgical settings.

Prior to using these expired respirators, consideration should be given to acquiring other NIOSH-approved respirators including all types of filtering facepiece respirators, elastomeric respirators, or powered air purifying respirators as described in the Strategies for Optimizing the Supply of N95 Respirators. This recommendation is made because healthcare services are essential and must continue in the face of the COVID-19 outbreak. Users of N95s that have exceeded the manufacturer-designated shelf life should be notified before their use and the importance of inspection and user seal checks should be reemphasized.

Users should take the following precautionary measures prior to using the respirator in the workplace.

- Visually inspect the N95 to determine if its integrity has been compromised.
- Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit, and seal and therefore the effectiveness of the respirator.
    - **Recently, NIOSH received inquiries concerning the identification and replacement of damaged straps on large caches of NIOSH-approved N95 FFRs that have passed their designated shelf life.** Users should perform a visual inspection of each respirator prior to donning per the user instructions. Additional questions and concerns related to the condition of the respirator should be directed to the respirator manufacturer.

    - **Modifications to NIOSH-approved respirators should not be made as part of conventional operations.** In accordance with the NIOSH regulation, 42 CFR Part 84, Approval of Respiratory Protective Devices , **any changes that modify the NIOSH-approved design (e.g., replacing damaged straps), as approved by NIOSH, voids the NIOSH approval.** In this case, adding new straps may affect the fit or filtration performance of the respirator with potential to negatively impact the respiratory protection provided to the user.
    - **Only as a contingency or crisis capacity strategy option when no respirators are left**, other than those with damaged straps, can consideration be given to replacing the damaged straps and using these modified "respirators" as facemasks; these would then, NOT be NIOSH-approved N95 FFR. Follow CDC crisis capacity recommendations for prioritizing the use of respirators vs. facemasks by activity type.
- If the integrity of any part of the respirator is compromised, or if a successful user seal check cannot be performed, discard the respirator and try another respirator.
- Users should perform a user seal check immediately after they don each respirator and should not use a respirator on which they cannot perform a successful user seal check.

Footnote

(i) **Preliminary findings – NIOSH performance standards**

- The majority of respirator models tested continued to meet performance standards regardless of the facility from which they were sampled.
    - 3M 1860 (8 facilities), 3M 1870 (3 facilities), 3M 8210 (3 facilities), 3M 9010 (3 facilities), 3M 8000 (4 facilities), Gerson 1730 (3 facilities), Medline/Alpha Protech NON27501 (1 facility), Moldex 1512 (1 facility), and Moldex 2201 (1 facility).
- Thirty-four Kimberly-Clark 46827 units (6.1%) failed filtration performance out of 559 units tested. All failing units came from the same stockpile facility, while no failures were observed for the 6 other facilities stockpiling this product. For the stockpile with the failing units, three different production lots were tested—two of these three production lots had failing units. Twenty-five failing units came from one production lot while the remaining 9 came from a second lot; both were manufactured in 2007. The facility with all of the failing units had temperature controls but did not monitor the environment produced by these controls. The climate where this facility was located was mild and generally within the range of temperature and humidity appropriate for this product. Five other N95 models were also tested from this facility. Out of a total of 391 units tested from these five other models, no failures were observed.
- Forty Kimberly-Clark 46727 units (10.3%) failed filtration performance out of 387 units tested from 5 of the stockpile facilities. All of these failing units came from a single facility and a single production lot, which was manufactured in 2007. A second production lot, manufactured in 2006, was tested from this facility with no failures observed. This facility had no temperature or humidity controls or active monitoring in place. A total of 473 units were tested from 5 other models with no failures observed.
- Two 3M 1860 units (0.16%) failed filtration performance out of a total of 1,247 units tested from 8 of the stockpile facilities. Both failing units came from a single facility where another 170 units of the same model had no failures. The 2 units came from different production lots, manufactured in 2006 and 2009. This facility had no temperature or humidity controls or active monitoring in place for the majority of the units' storage time. Eighty-six units for a second respirator model also tested from this facility had no failures.

(ii) 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.

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