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Technical Bulletin

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Revision 3

# Respirators Beyond Their Shelf Life – Considerations

## Background

This is a general document that is not specific to any particular airborne contaminant, including viruses and bacteria, and that is intended for a sophisticated occupational audience.

During times of extremely high demand on available supplies of respirators, such as during disease outbreaks and other public health events, 3M is often asked whether respirators can be used beyond their shelf lives. During such times, it is especially important to take into consideration all guidance published by relevant government and non-government health authorities.

Most respirators have a limited shelf life, after which they are intended to be discarded. The longer a respirator is stored beyond its shelf life, or stored outside the recommended conditions, the less likely it is to perform at its full potential. It is important to note that shelf life and storage conditions are in place to help ensure that all respirator components – not only filter media but also headbands and nosefoam where applicable, which contribute to respirators' ability to seal effectively to the face – remain in good condition. Additionally, respirators that are beyond their shelf life may potentially no longer meet applicable requirements, such as the certification and/or approval requirements set by regulatory agencies.

For additional considerations in understanding shelf lives, these 3M resources may be helpful:

- 3M Blog Post: Why Do Disposable Respirators Have a Defined Shelf Life?
- 3M Filtering Facepiece/Disposable Respirator Storage Conditions and Shelf Life - FAQs
- 3M Healthcare Particulate Respirator and Surgical Masks Storage Conditions and Shelf Life - FAQs

## Relevant Guidelines

In early 2020, during the COVID-19 outbreak, the U.S. Centers for Disease Control and Prevention (CDC) published its guideline Strategies for Optimizing the Supply of N95 Respirators, in which CDC states the following about the use of respirators after the end of their shelf life: "In times of increased demand and decreased supply, consideration can be made to use N95 respirators past their intended shelf life. However, the potential exists that the respirator will not perform to the requirements for which it was certified. Over time, components such as the strap and material may degrade, which can affect the quality of the fit and seal. Prior to use of N95 respirators, the HCP [healthcare professional] should inspect the respirator and perform a seal check. Additionally, expired respirators may potentially no longer meet the certification requirements set by NIOSH."

CDC also published information regarding research NIOSH has performed on five stockpiled 3M respirator models that are past their shelf life. Release of Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response. Based on the research findings, CDC and NIOSH state that they believe the listed 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 employees." In the document linked above, CDC/NIOSH recommend thorough inspection procedures and conducting user seal checks before using those stockpiled respirators included in the study. Organizations who have been issued stockpiled respirators past their shelf lives should review the information published by CDC and NIOSH, to aid in decision-making regarding how to use those respirators.

In March 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of "FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles." These expired FFRs are for use in healthcare settings by healthcare personnel (HCP) during shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak. A complete list of EUAs on Personal Protective Equipment are available on the FDA website.In April 2020, the U.S. Occupational Safety & Health Administration (OSHA) published an Enforcement Memo – Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic. The guidance allows enforcement discretion for Compliance Safety and Health Officers to permit the use of respirators that are beyond the manufacturer's recommended shelf life, however the guidance is limited to the duration of the COVID-19 pandemic. This guidance applies in all industries, including workplaces in which:

- Healthcare personnel (HCP) are exposed to patients with suspected or confirmed coronavirus disease 2019 (COVID-19) and other sources of SARS-CoV-2 (the virus that causes COVID-19). Note: Expired N95s are not to be used for aerosol generating procedures on patients infected (or suspected to be infected) with SARS-CoV-2.
- Protection of workers exposed to other respiratory hazards is impacted by the shortage resulting from the response to the COVID-19 pandemic.

Employers must attempt to acquire needed respirators or use alternative options to extend supply. When expired respirators are used, employers must take specific actions when using expired respirators including:

- Notify employees of expired respirator use,
- Separate expired and non-expired respirators.
- Visually inspect the respirators prior to use.
- Seek assistance from the respirator manufacturer or independent lab regarding testing of stored respirators if utilizing expired N95s from a supply other than the U.S. Strategic National Stockpile. Note: 3M guidance as a manufacturer is to NOT use respiratory products beyond the expiration date.

Organizations considering the use of N95 respirators past their shelf lives should review the information published by the CDC, NIOSH, FDA and OSHA, to aid in decision-making regarding how to use those respirators.

## Can respirators that are beyond their stated shelf life be used for training?

Training activities are a way you can consider using a filtering facepiece respirator that is beyond its shelf life. Before using a respirator model, OSHA requires that wearers must be trained on correct donning techniques for that model, including headband placement, forming noseclips, and conducting user seal checks (fit checks). While wearers are learning these procedures, each wearer will use at least one respirator. If an organization has access to respirators that are past their shelf life and are the same model as those used by workers, CDC recommends using those respirators which are past their shelf life for training and preserve those respirators within their shelf life for use as respiratory protection.

## Can respirators that are beyond their stated shelf life be used for fit testing?

Respirators that are beyond their stated shelf life may be used for fit testing in certain circumstances. Organizations that wish to consider using these respirators for fit testing need to determine whether this is appropriate for their organization and the selected respirators. In determining whether this is appropriate, several important considerations should be evaluated, including the following:

- Fit testing should only ever be performed with respirators that have been stored according to the storage conditions specified on the packaging.

- Before use in fit testing, respirators should be visually inspected to confirm the respirators are not distorted or damaged in any way. This includes respirator headbands, nose clip, nose foam, shell and all other components.
- The amount of time that has elapsed between the stated shelf life date and the date of the fit test. Shorter periods will likely be viewed as more reasonable, while longer periods may be viewed as less reasonable. It is unlikely that fit testing with respirators that are more than one year beyond the stated shelf life will be viewed as reasonable.

If an organization experiences lower-than-expected fit test pass rates while fit testing using respirators that are beyond their stated shelf life, then the organization should consider discontinuing use of such respirators for fit testing and instead use respirators that are within their stated shelf life for their fit testing operations.

Organizations that choose to use respirators beyond their stated shelf life for fit testing should ensure that such respirators are kept separate from, and not confused with, the organizations' inventory of respirators within the stated shelf life.

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