NIOSH Respiratory Protective Device Information

NIOSH CA 2020-1028 May 2020

Information regarding damaged or degraded head straps on previously stockpiled NIOSH-approved filtering facepiece respirators



Document Number	Page 2 of 2
NIOSH CA 2020 - 1028	

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NIOSH is aware that many different NIOSH-approved filtering facepiece respirator (FFR) models were stockpiled for prolonged times and are now distributed for use during the COVID-19 response. These FFRs are made using different materials (e.g., filtering media and strap material), which may age or degrade over time and become damaged. Generally, FFRs are not designed for long-term storage, and many models may have shelf lives designated by the NIOSH approval holder. The shelf life information is generally found on the packaging or the approval holder's website.

Recently, NIOSH received multiple inquiries concerning the identification and replacement of damaged straps on large caches of NIOSH-approved N95 FFRs that have since 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 approval holder.

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 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, consideration can be given to replacing the damaged straps and using these modified "respirators" as facemasks (i.e., NOT as a NIOSH-approved N95 FFR). The CDC crisis capacity recommendations for prioritizing the use of respirators vs. facemasks by activity type should be followed.

Supplemental Information

CDC NIOSH posted guidance on <u>Stockpiled N95 Respirators</u> on March 6, 2020. As of March 28th 2020, the <u>FDA's emergency use authorization (EUA)</u> allows the use of NIOSH-approved FFR models in healthcare settings that have since passed the manufacturer's recommended shelf-life; however, if the product exhibits signs of damage, it should be discarded. The <u>FDA Emergency Use Authorizations website</u> should be checked for the most up-to-date information.

Users can find information about stockpiled FFRs tested in NIOSH's research study on <u>NIOSH's website</u>. Each FFR tested was visually inspected, where damage was <u>observed</u> for a number of straps for two particular models. All tested units with a designated shelf life were past the shelf life identified.