NIOSH Respiratory Protective Device Information

NIOSH CA 2021-1037 August 2021

Updated user instruction information regarding three NIOSH-approved filtering facepiece respirators TC-84A-9298, TC-84A-9308 and TC-84A-9315



Updated user instruction information regarding three NIOSH-approved filtering facepiece respirators TC-84A-9298, TC-84A-9308, and TC-84A-9315

The National Institute for Occupational Safety and Health (NIOSH) identified the following statement in the user instructions (UI) of three N95 approvals, recently issued to BNX Converting, LLC (BNX):

If you notice any air leakage, adjust the nosepiece and headbands until the leakage is corrected. Pull the headbands back, up, or, if necessary, **shorten them by knotting**". "Once corrected, repeat the seal check again". The instruction to shorten the headbands by knotting is not in agreement with the NIOSH Caution and Limitation N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.

NIOSH failed to identify this concern prior to issuing the approvals. As a result, a limited number of respirators were distributed with UIs that include this instruction. On July 16, 2021 the approval holder, BNX Converting LLC, was informed about the concern and took immediate action to remove the problematic statement from the UIs. This notice is intended to notify users who may have received the previous instructions that if they cannot achieve a fit, the respirator should not be modified in any way to achieve a satisfactory fit.

The affected BNX approvals are:

TC-84A-9298 (Model A96)

TC-84A-9308 (Model A96-2)

TC-84A-9315 (Models H95W / H95B).

NIOSH is updating checklists used during the approval application review process to ensure going forward that these types of mistakes are caught before approvals are issued.

REFERENCE

NIOSH Certified Equipment List, General Limitations, Schedule 84A, Non Powered Particulate Filter Respirators