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Respirator Users Notice

Subject: Use of Replacement and Spare Parts

The National Institute for Occupational Safety and Health (NIOSH) issues certificates of approval for specific and complete respirator assemblies after the respirator has been evaluated and found to comply with all the requirements of the NIOSH regulations at Title 42, *Code of Federal Regulations* (CFR) Part 84 (42 CFR Part 84). As part of this evaluation, NIOSH reviews the respirator manufacturer's quality control plan to determine if it is satisfactory. The respirator manufacturer¹ must address all the components of the respirator in its quality control plan, including those manufactured in-house and those obtained from suppliers. A respirator that includes any replacement or spare part that has not been inspected as part of the respirator manufacturer's quality control plan is in a configuration not evaluated by NIOSH, and is not NIOSH approved. Please consult the respirator manufacturer before purchasing and installing replacement or spare parts to ensure the NIOSH-approved configuration is maintained.

ADDITIONAL INFORMATION

This is an updated version of a previously-issued (November 6, 1984) Users Notice on the use of unapproved subassemblies. It is being reissued to clarify the interchangeability of respirator subassemblies and unapproved modifications to NIOSH certified (approved) respirators. In some cases even minor modifications to respirators may make significant changes in the performance of the respirator, even if the proposed replacement components or subassemblies (such as self contained breathing apparatus (SCBA) air cylinders or air supply hoses) meet the same component-specific industry safety and performance standards as those included in the NIOSH approval. Respirator manufacturers who modify certified respirators must test the modification to determine if the respirator continues to meet the minimum requirements of 42 CFR Part 84, and must submit the modifications to NIOSH. A user who modifies a certified respirator may not be able to determine whether a change will decrease respiratory protection. Several cases have been reported to NIOSH where unapproved modifications or use of an unapproved subassembly have resulted in respirator failures.

The NIOSH respirator certification regulation, 42 CFR Part 84, defines an approval as "a certificate or formal document issued by the Institute stating that an individual respirator or combination of respirators has met the minimum requirements of this part [84]." Approved is

¹ For the purposes of this notice, the term "respirator manufacturer" means the individual, partnership, company, corporation, association or other organization that holds the NIOSH-issued certificate of approval for a respirator.

defined to mean that the respirator conforms to the minimum requirements of the regulation. The minimum performance requirements include the applicable construction, performance, manufacturing system quality control and respiratory protection requirements set forth in 42 CFR Part 84. The regulation permits NIOSH to only approve complete respirator assemblies and prohibits the approval of respirator subassemblies such as SCBA air cylinders or supplied air respirator (SAR) air supply hoses. These requirements are intended to insure that one respirator manufacturer has overall control and responsibility for the integrity of the approved respirator. The respirator manufacturer has the responsibility to ensure that its replacement parts are “designed and constructed to ...maintain the effectiveness of the respirator.” 42 CFR 84.62(b).

NIOSH requires the respirator manufacturer to file a quality control plan to assure the quality of the respiratory protection provided by the respirator for which the approval is sought. 42 CFR 84.40. Once approved, that approved quality control plan becomes part of, and is incorporated into, the certificate of approval. Compliance with that plan is a condition of approval. 42 CFR 84.42(c). The issuance of the certificate licenses the respirator manufacturer to use the NIOSH approval label but also obligates that respirator manufacturer “to maintain the approved quality control sampling schedule and the acceptable quality level for each characteristic tested... ” 42 CFR 84.33(f).

Therefore, users of NIOSH approved respirators are cautioned against interchanging subassemblies or making unapproved modifications to their respirators. Respirators which have been modified by the interchanging of subassemblies or other deviations using parts not produced and distributed under the respirator manufacturer’s controlled system, no longer meet the definition of being approved as a NIOSH certified respirator and the use of the NIOSH approval label is not authorized for that unit.

Sincerely yours,

Heinz W. Ahlers
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