RECORD #146

TITLE: Updated Guidance on Fit Testing of Biopak 60-P Respirator Users

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

AUG 29 1984

MEMORANDUM FOR: Those on Attached List

FROM: LeMoine J. Cunningham, Chief
Section 2, Operating Reactor Programs Branch
Division of Quality Assurance, Safeguards,
and Inspection Programs
Office of Inspection and Enforcement

SUBJECT: UPDATED GUIDANCE ON FIT TESTING OF BIOPAK 60-P RESPIRATOR USERS

This letter provides updated guidance on fit testing of BioPak 60-P respirator users in response to inquiries from licensees and inspectors regarding implementation of previous guidance (memo to L.R. Greger, RIII, from L.J. Cunningham, IE August 8, 1983 - copy enclosed). Licensee and inspectors have inquired as to what constitutes an acceptable method for performing quantitative fitting of the wearers of this apparatus as required in footnote 1, to Appendix A of Part 20; specifically, is it acceptable to check the fit of the device (the face to facepiece sealing capability) by testing the user while the user is wearing just the facepiece equipped with a high efficiency filter supplied by the manufacturer of the device. Previous guidance stated that the wearer must don the entire unit for fit testing since it was felt that fitting the facepiece with a high efficiency filter that is capable of allowing no more than 0.03% leakage would preclude measurement of the required 0.02% leakage or less through the face to facepiece sealing area. However, the 0.03% leakage allowed for high efficiency filters is determined with a more penetrating aerosol (monodispersed) than used in fit testing. Therefore, it is possible to measure the 0.02% leakage accurately with the facepiece equipped with a high efficiency filter (0.02% leakage corresponds to a fit factor of 5000).

Requiring a fit factor of 5000 in the negative pressure air-purifying mode is too restrictive. This approach to fit testing allows no credit for protection provided by the positive pressure inside the facepiece generated by the device in its normal mode of operation. Positive pressure inside the facepiece can compensate for inward leakage of contaminants to some extent by ensuring air circulating through the device is leaked outward instead of leaking contaminants into the worker's breathing zone. However, in this device that protection is obtained at a large cost if the fit is poor and outward leakage is substantial because reduced service life results as outward leakage of air is made up from the small volume of oxygen carried by the user. The volume carried is sufficient to exchange the volume of carbon dioxide released in respiration with compressed oxygen. Carbon dioxide is removed from the circulating air by the sorbent scrubber.

A hard and fast number that delineates good from poorly fitting respirators is not available. In the opinions of many experts in the field of respiratory protection, 1000 seems to represent a reasonable number for distinguishing between good and poorly fitting respirators. It is recommended that licensees use this number as a guide for determining if an acceptable fit has been achieved with this device.

For those persons that are unable to attain a fit factor of 1000 with just the facepiece in negative pressure mode participation in emergency, potentially IDLH situations should be restricted. This person may experience drastically reduced service time which reduces emergency response capability as well as hindering escape from a potentially life threatening situation.

The intent of the previous guidance was not to verify proper functioning of the entire unit. The operability of the assembled unit is checked after maintenance and before each use. In addition, fit testing of workers wearing the assembled unit in the case of this apparatus was presenting other problems due to the low makeup volume and leakage detection interference from background water vapor droplets and particulates from the carbon dioxide scrubber system.

Based on the interference problem that has been reported and revaluation of the previous guidance it is now recommended that fit testing of wearers of the BioPak 60-P be performed with just the facepiece equipped with a high efficiency filter and that a factor of 1000 be considered an acceptable fit. A recommendation will be made to RES to update Appendix A to include the intent of this interpretation in the next rule change.

If you have any questions regarding this guidance please contact Lynnette Hendricks of my staff (492-9728) or Jim Wigginton, IE (492-4967).

LeMoine J. Cunningham, Chief
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and Inspection Programs
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Enclosure:
Memorandum L.R. Greger frm
L.J. Cunningham dtd. 8/8/84

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