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LETTER TO ALL MANUFACTURERS

Subject: Air-Purifying Fit Test Subject Selection

Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84) states the minimum facepiece fit requirements: 'Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes....' Compliance with this requirement is verified through the performance of an Isoamyl Acetate (IAA) fit test. In the late 1970's, an evaluation was done by the Los Alamos National Laboratory which determined that, for air-purifying respirators, this test should be performed using a panel of test subjects of various facial sizes as determined by this study. There are two panels, one for half facepiece and one for full facepiece respirators, both conventionally referred to as the LANL panel. Performing this test with the LANL panel of test subjects is done to insure that a respirator, fitted according to the manufacturer's User's Instructions and passing the manufacturer's prescribed user seal check, will protect as expected and maintain a proper fit. Although NIOSH is developing a new panel based on recent research, the LANL panels are currently still in use. Persons interested in the details of the measurements for selecting the face sizes for the LANL panel groups may contact the National Institute for Occupational Safety and Health National Personal Protective Technology Laboratories by phone at 412-386-4000 or email npptl@cdc.gov.

Over the years, several issues with test subject selection during testing have emerged and been interpreted differently. Therefore, the fit test policy for air-purifying respirators is being revised to clarify the requirements for this test. This test will now be performed as follows:

Group 1- Respirators submitted by the manufacturer where multiple facepiece sizes are used to insure that the respirator will fit a panel of test subjects of various facial sizes (i.e. -- not intended to fit a full panel consisting of sizes 1 through 10).

Facepiece sizes:

Small -- panel face sizes 1, 2, 3, 4; panel size 6 (1 or 2 for ea. size to total 6)

Medium -- panel face sizes 3, 4, 5, 6, 7, 8; panel size 6 (1 for ea. size to total 6)

Large -- panel face sizes 7, 8, 9, 10; panel size 6 (1 or 2 for ea. size to total 6)

Small/medium -- panel face sizes 1, 2, 3, 4, 5, 6; panel size 6 (1 for ea. size to total 6)

Medium/large -- face sizes- 5, 6, 7, 8, 9, 10; panel size 6 (1 for ea. size to total 6)

Criteria: Whenever less than a full panel (one of each size 1 thru 10) is used to evaluate a single size of any multiple size facepiece, no failures will be allowed. These respirators are designed to fit a specific facial size range (such as small) and are expected to fit all subjects of that size range. For overlapping panel face sizes (size 3, 4, 7 and 8) a subject need only pass wearing a respirator in one or the other size. Test subjects in the overlapping groups need not pass the test in both sizes; however, all panel face sizes for a specified respirator size must be accounted for during the test as follows:

1. The test subject will don the respirator and perform a user seal check per the manufacturer's User's Instructions. If the test subject cannot obtain a successful user seal check, he/she will not be sent into the chamber. Upon obtaining a successful user seal check, the subject will enter the chamber. Up to three different test subjects of a specified size will have the opportunity to obtain a successful user seal check before the project is denied. The test subjects of the specified size will be observed to try to insure that there is no unique characteristic of all three that would create an unfair disadvantage for the respirator. For example, three test subjects would not be chosen who all have a very shallow nose bridge.
2. The test subject must not detect the odor of IAA when they enter the chamber and perform the required exercises. If on initial entry into the IAA chamber, the subject immediately (before the required exercises begin) detects the odor of IAA, the subject will immediately exit the chamber, adjust the respirator, perform a second user seal check, and if successful, re-enter the chamber. If the subject again detects the odor of IAA, the respirator will be denied on the basis that the user seal check process is inadequate to determine fit or the respirator is unable to maintain a fit.

Group 2- Respirators submitted by the manufacturer where a single facepiece is intended to fit everyone (i.e.- intended to fit a full panel of sizes 1 through 10).

One Size Fits All -- panel face sizes 1 through 10 (1 for each size to total 10).

Criteria: A full panel of sizes 1 through 10 is used to evaluate a one size fits all respirator. All panel face sizes must be accounted for during the test as stated in items 1 and 2 above. One failure where the test subject detects the odor of IAA during the exercises will be permitted; however, an additional test using a different test subject of the same size must be performed with passing results. If two or more failures occur, the project will be denied.

For questions on this issue, please call the NIOSH Certification group at 412--386-4000.

Sincerely yours,



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