Miller, Diane M. (CDC/NIOSH/EID)

From: Dean.Shaw@MSANet.com
Sent: Thursday, August 30, 2007 8:53 AM
To: NIOSH Docket Office (CDC)
Subject: TIL ? Docket # 036 - MSA's Comments
Attachments: TIL - NIOSH 036 Docket Comments MSA.doc

Please see the attached MSWord file that contains MSA's comments related to the NIOSH TIL Program.

Thank you for your consideration,

Dean Shaw

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August 30, 2007

NIOSH Docket Office
Robert A. Taft Laboratories
TIL – NIOSH 036
4676 Columbia Parkway
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Re: NIOSH Proposed Total Inward Leakage Protocol (TIL)

MSA is taking this opportunity to provide our comments regarding the draft that NIOSH issued for a Total Inward Leakage Protocol. The draft that we refer to was presented at a public meeting held by NIOSH on June 26, 2007.

The administrative and regulatory changes that NIOSH has issued in the past have resulted in associated process changes within our organization. These process changes have been beneficial over time, and we anticipate that the current proposed changes will be just as beneficial if we provide complete consideration to how these changes may affect all aspects of the industry.

It is our opinion the new TIL protocol does not provide enough value or efficacy for the workplace wearer of respiratory protection products. Here are several reasons why:

1. Performing a certification fit test on test subjects in a panel does not eliminate the need for individual fit testing in the workplace. Certification fit testing does not assure a proper respiratory fit by all individual wearers. It is the responsibility of OSHA to enforce the laws associated with respiratory use, and fit testing in the workplace. It is important that employers understand that certification fit testing is not a replacement or substitution for individual workplace fit testing.
2. Manufacturers cannot predict within any degree of certainty that all users within a cell, will fit facepieces identified as appropriate for that cell. There has been has no published data to correlate specific cells within the panel grid to specific facepiece sizes.
3. The pass criteria value for the TIL is less than or equal to 5% for a minimum of 26 out of 35 test subjects. In relating this to a protection factor, the pass criterion becomes a PF of 20 for 75% of the subjects tested. The OSHA assigned protection factor (APF) requirement for half mask and filtering facepiece respirators is a minimum value of 10. OSHA requires that all workplace users of respirators be fit tested. If a quantitative fit testing method is used, as described in OSHA regulation 1910.134, a minimum fit factor value of 100 must be obtained before the half mask, or filtering facepiece, respirator can be used in service. Our customers expect this level respirator protection performance. A minimum fit factor score of 20 for 75% of

the subjects tested does not adequately represent the performance that is necessary to meet the minimum respiratory protection levels as defined by OSHA.

4. There is considerable variability in a number of the parameters of the test. The proposed fit test panel and test methods have a high inherent variability which has not been adequately identified, quantified and controlled to assure reproducible results.

Also, we recognize the importance of replacing the current Isoamyl Acetate Protocol (fit test) with a more consistent and predictable method of testing. We suggest that a Laboratory Respirator Protection Level (LRPL) program be considered for half mask and filter facepiece respirator products. The subject selection guidelines can include the new fit sizing criteria as defined in the TIL program. This new LRPL can include the series of exercises as defined in the OSHA standard 1910.134 along with the acceptable fit factor pass criteria of 100. When compared to the port-a-count method or Isoamyl Acetate method for fit testing the LRPL method of testing using corn oil aerosol would have less variation in the areas of particle size, mass, and distribution. This method of fit testing has been used for years by the US military and most recently by NIOSH for the CBRN APR and APER Standards.

Thank you for considering these comments, recommendations, and suggestions.

Sincerely,

Dean A Shaw

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