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NIOSH Docket Office
Robert A. Taft Laboratories
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4676 Columbia Parkway
Cincinnati, Ohio 45226

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Comments on the TIL Program for Half-mask Air Purifying Particulate Respirators

The International Safety Equipment Association (ISEA) is the leading organization representing manufacturers and suppliers of personal protective equipment and apparel. We offer the following comments in response to the information presented at the June 26, 2007 NIOSH public meeting on the TIL Program:

Summary

The proposed TIL certification procedure includes requirements which will not enhance the efficacy of respiratory protection products or increase worker protection, while increasing the regulatory burden for employers. The proposed fit test panel and test methods have high inherent variability which has not been adequately identified, quantified, and controlled to assure reproducible results. The very high variability and the questionable benefit of the TIL program indicate that NIOSH should not move forward on this project.

Program Issues

User Fit Testing

The TIL Program does not provide assurance that a particular respirator will fit a particular individual in the workplace. Fitting a respirator on each individual wearer in accordance with fit test procedures as outlined in applicable OSHA regulations (29 CFR 1910.134 for General Industry) is necessary for the respirator to perform as designed. Conducting a certification fit test on test subjects in a panel does not eliminate the need for individual fit testing and does not increase the probability that the respirator will fit individual wearers.

A TIL program, as part of respiratory product certification, is counterproductive because employers will believe that individual worksite fit testing is no longer necessary. In addition, under the NIOSH TIL proposal worksite fit testing procedures will be more complicated. The TIL Program will require that all employers acquire calipers, learn how to use them, measure facial dimensions of each wearer, determine the panel cells each respirator wearer fits into, and acquire respirators for those panel cells if they elect to select respirators in accordance with the information NIOSH may require manufacturers to place on packaging. The employer will also need to update the written Respiratory Protection Program to reflect all these changes. Neither the employer nor the respirator wearers will benefit from any of these new requirements.

Fit Test Panel

The new NIOSH face fit panel used in the proposed TIL certification omits some critical facial characteristics (for example, nose bridge height) that dramatically effect the ability of the respirator to pass the certification test.

Respirator manufacturers receive frequent calls from employers and unions who are trying to find respirators to fit unconventional faces. Because some facial dimensions such as face width and height are not determining factors for face fit, many respirators designed to fit these facial characteristics may be eliminated from the market.

As all critical facial characteristics are not included in the NIOSH panel grid, respirator 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 no published data to correlate specific cells within the panel grid to specific facepiece sizes. Thus manufacturers can not make claims regarding the faces their respirators fit.

By not including all the critical facial characteristics and dimensions, the NIOSH panel allows extreme variability and an individual respirator will show significantly different results within a panel cell when tested with different sets of subjects.

Procedure Variability

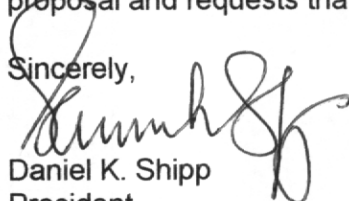
In addition to the within panel cell variability, there are many other sources of variability in the TIL procedure that NIOSH must address:

- 1) Operator variability (training and experience)
- 2) Stability of challenge concentration for PortaCount fit testing (lack of enclosures, number and types of generators, room size, etc.)
- 3) Interlab variability (NIOSH has indicated that testing will be done at different labs). NIOSH needs to add additional procedures for ensuring that the results obtained at one NIOSH testing facility are reproducible at other NIOSH facilities as well as at manufacturer laboratories.
- 4) Fit test subject variability (user experience, training, etc.)

Finally, there is no justification for selecting the pass/fail criterion $\leq 5\%$ TIL for half mask air purifying respirators and no data or information that suggests that this pass/fail criterion will increase worker protection. It is unacceptable to arbitrarily select a TIL cut-off value that will eliminate respirators that are providing effective protection to wearers and force the employer to go through the process of finding and fitting another respirator.

There are inherent problems with variability throughout the TIL proposal that make it unsuitable for a product certification test. NIOSH should withdraw the proposal until all variables are adequately addressed. ISEA encourages NIOSH to reconsider the TIL proposal and requests that it not become a product certification requirement.

Sincerely,


Daniel K. Shipp
President