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

From: Howard Cohen
Sent: Sunday, December 30, 2007 3:33 PM
To: NIOSH Docket Office (CDC)
Subject: 111 - NPPTL Facial Anthropometrics Research Roadmap

Dear Sirs:

I am writing to comment on the NPPTL action plan titled: *NPPTL Facial Anthropometrics Research Roadmap* authored by Ziqing Zhuang, Ph.D. and Ronald Shaffer, Ph.D..

NPPTL and Drs. Zhuang and Shaffer are to be complimented for the extensive and comprehensive responses to the IOM 2007 report titled: *Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users*. My comments are as follows:

1) One of the most important items that NPPTL can implement in the near term is to eliminate the use of subjective and limiting qualitative fit testing in their research and certification. In this regard, it is gratifying to read their action item:

Action Item 5-2: NPPTL will replace Isoamyl Acetate with quantitative measures for respirator fit-test certification.

2) Another key item is for NPPTL to begin to perform fit testing of filtering facepiece respirators as part of the certification criteria, just as they do for other respirators. OSHA and NIOSH have chosen to give the same assigned protection factor (APF) for filtering facepiece respirators, in their regulations and respirator decision logic documents respectively, as elastomeric half-facepiece respirators. However, there is evidence (research performed by NIOSH scientists) that some filtering facepiece respirators will not fit a wide range of faces, despite being offered in only a single size. It is gratifying to read NPPTL's action item:

Action Item 5-3: NPPTL will utilize the NPPTL panel for certifying filtering facepiece respirators.

3) An important recommendation contained in the IOM report was the impact of a new anthropometric test panel on the fitting characteristics of existing respirators. This is stated in the IOM report as:

Conclusion 4-3: The proposed NIOSH-sponsored Anthrotech face panel is likely to be more representative of the current U.S. workforce than the LANL panel, but information is not available to determine the extent to which the new panel provides a better fit for that workforce.
Recommendation 4-3: Perform Studies to Compare the Proposed Face Panel to the LANL Face Panel. NIOSH should perform a study in which it compares the range of quantitative fit provided for specified respirators on subjects representing the LANL face panel and subjects representing the proposed NIOSH-sponsored Anthrotech bivariate face panel.

It is troubling to read NPPTL's response:

Action Item 4-3: Such a comparison study is very difficult to conduct because of the large

intra- and inter-subject variability seen in fit test data. As described previously in the response to Recommendation 4-2, the new panels are representative of the facial sizes and shapes of workers today and an additional study designed specifically to address this recommendation is unnecessary.

This response questions the very basis of using a 25 member test panel for fit testing respirators in certification regulations and the on-going effort to establish a TIL regulation. If there is large intra and inter-subject variability, then the test panel would have to be adjusted to account for this, if the results of TIL testing are to be valid. Large test panels for each respirator being certified would be impractical. I would offer the following recommendation:

Recommendation: NPPTL should implement the following research plan or adjust existing plans accordingly:

Efforts be undertaken to eliminate the need for human test panels in respirator certification. Panels are difficult to construct and have inherent biases (same subjects are used over and over again and there is not sufficient racial and age balance). Studies should be undertaken using 3-D scanning (or other digital data) to determine key parameters in the shape of the face that affect the fitting of a respirator. Such parameters could be measured on a respirator (possibly attached to a manikin) submitted for certification to determine what range of faces that the device is likely to fit without the need for a panel of test subjects. A panel of test subjects might still be used to measure the comfort of the respirator; a key parameter as important as fit. However, it is likely that fewer subjects might be required for such subjective testing.

I hope that NPPTL and Drs. Zhuang and Shaffer find these comments to be useful. I commend NPPTL for undertaking their study with IOM and for their responses to the conclusions and recommendations contained in the IOM report.

Sincerely,

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