

February 21 , 2008

NIOSH Docket Office
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Re: NPPTL Facial Anthropometrics Research Roadmap-NIOSH Docket No. 111

ISEA member manufacturers of respiratory protection offer the following comments on the draft action plan intended to provide a long-term strategy for facial measurements and respirator fit research at NPPTL.

ISEA agrees that fit testing and characterizing populations that will wear respiratory protection are integral parts of using respiratory protection. We encourage NIOSH to develop a new anthropometric face fit panel that accounts for more current demographics than the dated Los Alamos National Laboratory panel. However, the current draft lacks specific details that are vital to respirator fit concepts. We believe that the current draft is a solid start but that it requires much more work to be adequate for implementation.

It is critical that efforts be focused on the most important aspects of respirator research so that limited resources can be utilized most effectively.

ISEA submits the following comments regarding the recommendations made by the National Academy of Science Institute of Medicine's report, *Assessment of the NIOSH Head-and-Face Anthropometric Survey* as well as the NPPTL facial anthropometrics research roadmap:

General Comment: The intent of updating the anthropometric fit test panel is to improve the fit of respirators for those who are required to wear them. To meet this intent, the critical facial dimensions that are the strongest predictors of fit should be identified and used to define the panel. The range for each critical facial dimension must be determined by the respirator user population, which may differ from that of the general US work force.

BLS statistics show the proportional growth of Hispanics in heavy manufacturing, which may have more respirator users than other workforce sectors. This may suggest that the demographics for respirator users may not be the same as that for the general US workforce. Consequently, one cannot conclude that moving from the LANL panel to the proposed NIOSH sponsored Anthrotech face panel may result in a better respirator fit.

For example, respirator manufacturers receive requests from respirator program managers to make respirators that fit very small faces. These requests suggest that if there is a move from the LANL panel to the NIOSH-sponsored Anthrotech Face Panel for certification purposes, the small faces will be even more under-represented in the new NIOSH panel and therefore will effectively decrease respirator fit for that sub-population.

Comments on IOM and NIOSH's responses to the IOM's conclusions:

IOM Conclusion 2-1: The NIOSH-sponsored Anthrotech report did not adequately address the potential impact of measurement error on the validity and quality of the anthropometric face dimension data.

ISEA Comment: NIOSH's response that "NPPTL will characterize the measurement error in future studies" does not address the extensive data that is the basis for the proposed NIOSH Anthrotech Face Panel. It is important for NIOSH reassess facial dimension data as this work is critical to the validity of the

proposed NIOSH Anthrotech Face Fit panel. This is particularly critical if it will be used in the future for the NIOSH TIL (Total Inward Leakage) project.

IOM Conclusion 3-1: The proposal and NIOSH-sponsored Anthrotech Report did not adequately define or represent an appropriate target population

ISEA Comment: It is critical for NIOSH to adequately define the target population and verify that the anthropometric test panel represents the target population. It is important for NIOSH to allocate resources to identify the demographic information for the respirator user population prior to performing further research.

IOM Conclusion 4-2: The proposed NIOSH-sponsored Anthrotech face panel selects larger-dimension faces at the expense of the smaller faces which are currently included in the LANL face panel, even though some of these small faces still make up a considerable proportion of the workforce.

ISEA Comment: NIOSH states that the NPPTL panel already covers more than 95% of the current U.S. workforce and that subsequent analysis validates its representativeness. However, the validation is for the entire US population, not necessarily for respirator wearers, which is a sub-set of the US population.

NIOSH comments in 3-1 that there is little demographic information on respirator users and therefore, it is unknown whether or not the new NPPTL panel adequately represents respirator wearers. We suggest that NIOSH go back and allocate resources to reevaluate this issue and determine if the new NPPTL panel is truly representative of respirator users. This is a particularly critical issue where the respirator use demographics may rapidly shift, such as from an industrial based user population to a healthcare based user population in the event of pandemic or a terrorist act.

IOM Conclusion 4-3: The proposed NIOSH-sponsored Anthrotech face panel is likely to be more representative of 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 the workforce.

ISEA Comment: IOM recommends that NIOSH conduct a study comparing the new NIOSH panels with the LANL panels. NIOSH states that such a comparison is difficult because of intra and inter-subject variability seen in fit test data.

This comment by NIOSH certainly calls into question the validity of using the new NIOSH panel instead of the LANL panel, especially for equipment certification or in new standards. Before changing the panel, it is critical to demonstrate that it will lead to improved fit for the target population, which means defining the variability.

IOM Conclusion 4-4: The present state of knowledge does not permit the committee to conclude with any degree of confidence that respirators that fit the proposed NIOSH-sponsored Anthrotech study face panel are likely to fit 95% of the population of workers who should be using respirators. Further, the committee was unable to determine a level of confidence or margin of error for the proposed face panel. However the proposed panel, based on newer data, appears to be more representative of the population than the 30-year-old data used in the LANL face panel.

ISEA Comments: ISEA does not believe that the proposed TIL program will result in ensuring good fitting respirators are on the market. NIOSH should delay the implementation of the TIL program until there is evidence that such a program will improve fit. There are issues that need to be resolved prior to implementing the TIL protocol. Failing to address these issues could severely disadvantage products already on the market.

IOM Conclusion 4-5: The ultimate utility of the data collected in the NIOSH-sponsored Anthrotech study is limited because the study did not include the collection of fit-testing data along with facial measurement.

ISEA Comments: We agree with IOM that contemporaneous data would have been much more useful than NIOSH's attempt to correlate fit and facial dimensions after the Anthrotech study was completed. This was a serious flaw in the Anthrotech study that should have been considered and accounted for prior to undertaking this study. The correlation of respirator fit and the appropriate facial dimensions must be determined and a new panel created (assuming it is different measurements than what is currently proposed) before the TIL project as proposed can proceed.

IOM Conclusion 4-6: Proper analysis of facial dimensions has not been performed for half face respirators; lip length and menton-sellion length may not be the most appropriate dimension to use when developing anthropometric face panels.

IOM Conclusion 4-7: The use of multiple features in the development of face panels is likely to be inherently better than the use of just facial height and width, but it is not yet well understood which features are directly relevant to fit and how they can best be combined.

ISEA Comments: We agree with IOM and have previously provided comments to NIOSH that many dimensions such as, but not limited to nasal bridge, height, nose breathe and nose protrusion are critical dimensions in formulating a fit test.

IOM Conclusion 5-1: The proposed NIOSH-sponsored Anthrotech face panel represents an improvement over the LANL face panel, and its application is likely to improve the availability of respirators that fit a broader segment of the workforce. However, the committee also found that this study could have been greatly improved. In addition, the NIOSH face panels require periodic update.

ISEA Comments: We agree with the IOM on these points.

IOM Conclusion 5-2: Qualitative fit testing is a subjective process and does not provide NIOSH certification personnel with a specific value to analyze leakage around the face piece:

ISEA Comment: A qualitative fit test will provide numerical data that can be analyzed.

IOM Conclusion 5-3: The failure to use anthropometric face panels for certification of filtering facepiece respirators may result in families of respirators that do not adequately fit some of the population of workers who should be using respirators.

ISEA Comments: The only way to ensure fit of all respirators is to fit test the respirator on the wearer.

IOM Conclusion 5-4: Manufactures (sic) of multiple-sized face pieces often have difficulty obtaining certification for each individually sized face piece.

ISEA Comments: IOM recommends that the certification requirements should be modified such that NIOSH encourage manufacturers to develop specific sizes designed to fit underrepresented anthropometric categories. Certification requirements should be modified to allow families of respirators (e.g. small, medium, and large) to be certified against a fit-test panel and not specify what portion of the panel each individual size respirator must fit. This assumes that the family adequately covers the entire panel. ISEA agrees with this recommendation with one caveat. We do not necessarily believe that every family of respirators must fit the entire population. If a product is designed for a particular population segment then that family of respirators may only address the identified population segment and should still be able to obtain certification. We believe that this was the intent of the IOM committee, but was not clearly stated.

General Comments to the NPPTL Facial Anthropometrics Research Roadmap

NIOSH's mission to do research is an important one. We believe that the health and safety of the worker is of highest importance. NIOSH must select research projects that will provide the greatest benefit.

ISEA Comments on NIOSH Docket 111

Careful consideration must be given to the types of research that NIOSH should conduct given limited critical resources.

NIOSH Proposal: NIOSH proposes to conduct a study to determine the rate at which respirator fit changes as a function of time for a representative sample of subjects wearing filtering face piece respirators. They will look at individuals for up to 36 months and attempt to determine how fit changes over time.

ISEA Comments: We do not see great value in this study. Given that respirator wearers are required to be fit tested at least annually, a study tracking change of fit on only 220 individuals over a three year period will not be useful.

There are many other variables and issues not addressed that can impact these results. One such variable that is ignored is the impact of training and experience. Training and experience (experience meaning people that wear respirators more than once every six months) has as much and perhaps more influence on obtaining a satisfactory fit than facial shape. If it is NIOSH's intent to investigate if fit testing is necessary on an annual basis, ISEA believes that the training accompanied with annual fit testing is an integral part of respirator use and should be continued regardless of the results of such a study.

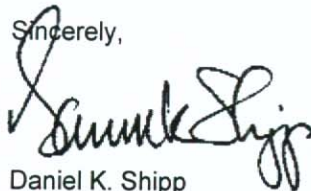
Finally, the respirator type chosen for the study may not be the most appropriate for this type of study. Some filtering facepiece respirators are probably affected less by facial changes than elastomerics as they are more rigid.

The user seal checks listed in the protocol are ones for elastomeric facepieces and not filtering facepieces. The protocol also discusses straightening the nose clip after use and before redonning ("returned to its unadjusted configuration before redonning") This is not practiced in use scenarios nor recommended by manufacturers.

If NIOSH intends to move forward with the TIL program NIOSH needs to do do extensive work in determining the most appropriate facial dimensions that determine respirator fit. NIOSH should devote resources to making sure that the statistical analyses of the anthropometric panels are adequate. We believe that the public would be better served in channeling resources in these directions rather than to determine how respirator fit changes over a three year period.

Thank you for your consideration.

Sincerely,



Daniel K. Shipp
President