December 3, 2009

Oral Comments of the International Safety Equipment Association (ISEA)
National Institute for Occupational Safety and Health (NIOSH)
Public Meeting on Notice of Proposed Rulemaking: Total Inward Leakage Requirements for Respirators, 42 CFR Part 84, RIN 0920-AA33

The International Safety Equipment Association (ISEA) is the leading trade association representing suppliers of safety equipment, including respiratory protection devices certified by NIOSH. We appreciate the opportunity to comment on the October 30, 2009 Notice of Proposed Rulemaking on Total Inward Leakage Requirements for Respirators. ISEA's comments represent the consensus view of the member manufacturers in our Respiratory Protection Group. Given the time constraints of assembling, reviewing and approving these comments, ISEA has formally requested an extension to the comment period for providing input to the official docket.

ISEA member companies believe that there are several areas that remain unresolved from the August 2007 comments that ISEA submitted to the criteria included in the October 2009 Federal Register notice.

Specifically, manufacturers have concerns with the proposed requirement in Section 84.175 (h)(1) that states that "The applicant shall specify in the user instructions the face size or sizes that the respirator is intended to fit; pursuant to this requirement, one respirator may be intended to fit all face sizes."

ISEA is not aware of any published data which statistically correlates facial measurements from bivariate grid dimensions to adequate fit of a respirator. A manufacturer cannot claim with any certainty that all users within a cell will fit facepieces appropriate for that cell. To require them to place facial grids on box panels may subject the manufacturer to potential liability issues as an end-user may view this information as an implicit warranty.

Related to this is the concern that users are expected to identify for themselves the size of respirator to be selected, having them rely on manufacturer's instructions and descriptions of applicable facial shapes and other pertinent characteristics.

ISEA members believe that this has the effect of creating worksite fit testing procedures that are more complicated, having an unintended consequence of *less* workplace fit testing. If they follow the TIL Program, employers will have to acquire calipers, receive training on their use, 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. Because of the complexity of these procedures and the questionable correlation of grid size to fit, employers will find it more difficult to comply with the required Respiratory Protection Program. Neither the employer nor the respirator wearers will benefit from any of these new requirements.

Additionally, with respect to testing and the use of the test panel, NIOSH states that "concerns …will be considered further in the development of testing procedures to be implemented under a final rule." Manufacturers stress the importance of having the final standard test procedure developed, validated and available for execution prior to its incorporation into regulatory text.

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Specific to this, ISEA members have identified several areas of the testing procedure that are either unclear or incorrect and need to be addressed before final implementation. We intend to elaborate on these items in our written comments.

Finally, ISEA believes that NIOSH should reconsider the proposed implementation scheme with respect to a three year “sell and ship” period for existing approvals. Clarification must be provided on how the agency will apply this to products already approved but manufactured during the three-year timeframe. It is also unclear if an existing device that fails the TIL test could be resubmitted after design tweaks under a request to modify the certification (TIL testing only) or if it would have to be resubmitted for full testing.

ISEA also believes that the implementation schedule may prove burdensome to NIOSH itself as the agency must ensure that it has all the necessary resources in place to accommodate modifications of existing approvals to include TIL testing. As the agency seeks to consider modifications during the specified time period, we are concerned that the volume of expected applications, without adequate resources, could jeopardize the continued availability of current protectors that may languish in the queue beyond the two years, but will also hinder the approval rate of new and unrelated products. ISEA intends to offer alternatives to the schedule in its written comments.

ISEA appreciates the opportunity to comment on the proposed total inward leakage requirements and will submit more detailed written comments to the NIOSH docket by the comment due date.