

## NIOSH Docket 237 - PPT Conformity Assessment NIOSH Responses to Comments Received

### Background:

In May 2011, the National Institute for Occupational Safety and Health (NIOSH) established Docket 237, Personal Protective Technologies (PPT) Conformity Assessment to provide an opportunity for interested parties to provide input to the NIOSH, National Personal Protective Technology Laboratory strategy to address the recommendations issued in November 2010 by the Institute of Medicine (IOM). The IOM report, *Certifying Personal Protective Technologies: Improving Worker Safety* identified the need for a consistent risk-based approach to PPT conformity assessment.

### Responses to comments:

NIOSH received six responses to its Docket Number 237, PPT Conformity Assessment representing comments from an anonymous private citizen, manufacturers, professional associations, and PPE consultant. The following organizations were represented: 3M, Kimberly-Clark Professional, International Safety Equipment Association (ISEA), International Association of Fire Fighters, and International Personal Protection (IPP), Inc. The following is a summary of the comment and NIOSH response.

**COMMENTERS:** Weber-3M, IAFF, and IPP

**COMMENTS:** Each states that NIOSH/NPPTL does not have sufficient resources with the appropriate level of expertise required to carry out the conformity assessment of non-respiratory PPE recommendation of the IOM report. For example, IAFF states: "NPPTL has not been fully funded nor have they demonstrated the level of expertise that is needed to understand a broader range of PPE for the protection of all workers, who depend on PPE to protect their health and safety."

**NIOSH RESPONSE:** It is agreed that at present staffing and funding levels, complete implementation of the IOM report recommendation that NIOSH develop and implement a comprehensive conformity assessment program (including third-party certification) for all PPE is not feasible. A replication of the staffing, funding and degree of expertise now utilized to support NIOSH's existing respirator approval program cannot be envisioned now or for the immediate future to expand its conformity assessment activities including certification to cover all non-respiratory PPE.

**COMMENTERS:** 3M, ISEA, Kimberly-Clark Professional, and IPP

**COMMENTS:** Each states that NIOSH/NPPTL should consider alternative approaches to that recommended in the IOM report.

**The following are examples of the comments:**

1) ISEA - "As NIOSH NPPTL develops a conformity assessment strategy, ISEA believes that it should consider alternative approaches such as the proposed ANSI/ISEA standard, in consultation with standards development and certification organizations within the U.S."

2) 3M - "NIOSH should restrict its activity to determining conformity perhaps as an audit or oversight-type process."; IPP states "... NIOSH NPPTL should investigate approaches for the review of product claims against standards."

3) Kline-Kimberly-Clark - "... if NIOSH's investigation shows that there is defective PPE coming from a few "bad actors" on the market, NIOSH should pursue alternative avenues to target those producers and products without applying the same expensive controls on the much larger, fully effective portion of the industry."

**NIOSH RESPONSE:** It is agreed that alternative approaches to that recommended in the IOM report be investigated, developed and analyzed throughout the strategy formulation process that NIOSH will undertake. These will include the development of national CA guidance, possible development of consensus standards for conformity assessment in cooperation with standards development organizations, as well as approaches defining NIOSH responsibilities as focused on audit/oversight functions. Such approaches will be developed with its broad range of stakeholders, including those suggesting that alternative processes be explored.

Issues related to off-shore manufacturing of PPE (IAFF and ISEA) and (2) fraudulent or counterfeit products (3M) will also be considered during the strategy development process.