

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

From: Cristine Fargo [cfargo@safetysafetyequipment.org]
Sent: Friday, July 01, 2011 11:35 AM
To: NIOSH Docket Office (CDC)
Subject: 237 - PPT Conformity Assessment
Attachments: isea comments niosh docket237 2011Jul01.pdf

Dear Docket Officer:

Attached please comments from the International Safety Equipment Association on the subject docket. Please let me know if you have any questions.

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July 1, 2011

NIOSH Docket Office
Robert A. Taft Laboratories, MS-C34
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Re: Docket NIOSH-237, Strategy to Address Recommendations Issued by the Institute of Medicine in November 2010 Report: Comments of the International Safety Equipment Association

The International Safety Equipment Association (ISEA), the association for personal protective technologies, appreciates the opportunity to provide input to NIOSH National Personal Protective Technology Laboratory (NPPTL) as it prepares a strategy to address the recommendations in the November 2010 report *Certifying Personal Protective Technologies: Improving Worker Safety* from the Institute of Medicine (IOM).

While there are numerous stakeholders to which this project will be important, the members of ISEA are key participants. These are the companies that design and make the personal protective clothing and equipment covered by the IOM report, participate in the development of product performance standards, test their products to the standards, and stand behind their products in the marketplace. They understand the purpose and importance of testing and conformity assessment and how information about conformity is communicated to the marketplace and the regulatory community, and they are the companies that will be most affected by decisions regarding certification of personal protective technologies.

ISEA is also thoroughly familiar with the study undertaken by the IOM committee and the resulting report and recommendations. We attended the public meetings of the committee, reviewed the report, and have discussed these recommendations at length within the association and with other stakeholders, and communicated our views in conversations with NIOSH staff members.

Personal Protective Technologies

In its report, the committee used the term "personal protective technologies," abbreviated "PPT" extensively. It defined PPT as "the specialized clothing or equipment worn by workers for protection against health and safety hazards, as well as the technical methods, processes techniques, tools, and materials that support their development, evaluation, and use." (IOM Report, p. 18) The committee regards personal protective equipment (PPE) as a subset of PPT, but its use of the term PPT almost always refers to what has traditionally been termed PPE. ISEA believes that PPT can be a useful term, especially as the technology of personal protection is advanced, and urges NIOSH NPPTL to provide a clear definition as part of its strategy. In this letter, we use the term PPE except where there is a specific reference to the IOM committee report.

The IOM Committee Report and the Realities of the Marketplace

As NIOSH NPPTL begins to develop a strategy to address the IOM recommendations, ISEA believes it should acknowledge the shortcomings of the committee's analysis. ISEA believes the report displays an academic indifference to the realities of the market and regulatory structure of workplace PPE in the United States. The committee examined NIOSH respirator certification, firefighter equipment under NFPA, FDA regulation of medical devices, Coast Guard supervision of personal flotation devices and certification of ballistic vests. It passed over the extensive product testing performed by companies, in their own labs or independent labs, on the products that make up the majority of PPE used in the workplace. Its conclusions appear to assume that a company that tests its own products is somehow less reliable than a company that has its products independently evaluated. It projects a risk-based framework for certification that leaves unanswered the question of how these judgments of risk would be

made. It projects an ideal world of risk-based testing and evaluation without evidence that worker health and safety would realize significant benefits from additional third-party certification. It is possible that the committee has arrived at a solution in search of a problem.

The committee report notes that "NIOSH does not have regulatory authority for non-respirator PPT and cannot require or enforce requirements for conformity assessment processes." (IOM Report, p.48) In fact, NIOSH does not have regulatory authority for any PPT, including respirators. NIOSH is authorized by legislation to set respirator standards and certification, but the *use* of these products is governed by other agencies responsible for workplace regulation. It is OSHA or MSHA, for example, that require the use of NIOSH-certified respirators. While NIOSH can control the approval process and use of its mark, it has no separate authority to demand the use of its certified products. This is a subtle distinction, but important to the understanding of the regulatory system that regulates PPE in the U.S.

OSHA regulations cite voluntary consensus standards for most types of PPE, and require that respiratory protection be NIOSH-certified. But OSHA specifically rejected proposals (from ISEA and others) that it require third-party certification of PPE when it published its 1994 revision to the PPE standards for general industry (29 CFR Part 1910, Subpart I). OSHA's discussion in the preamble to the revision cites several reasons for this decision:

First, while OSHA has recognized that third-party certification of PPE can increase confidence in and use of PPE, a requirement for such third-party certification will not add to the inherent safety of the PPE tested and certified.

... OSHA believes, given the limited benefit expected from third party certification, that it would be unreasonable to require that employers procure only PPE that has third party certification. Such a requirement would impose unnecessary burdens on PPE manufacturers who can establish by other means that their products comply with the pertinent OSHA standards. 59 FR 16348-16349

The agency felt that the revised Subpart I "provides other means to determine if PPE meets the pertinent standard," including requirements for hazard assessment, PPE selection and training.

In the 17 years since the publication of the revised Subpart I, there is no evidence that worker safety is jeopardized because third party certification is not required. Manufacturers in the United States continue to test their products to the standards cited in the OSHA standards and mark them as compliant, and employers and users accept this declaration. The system is based on a responsible manufacturing base, knowledgeable purchasers and a legal system that penalizes manufacturers when product failure contributes to injury.

At the same time, the marketplace has changed greatly in these years. Today there is more PPE being procured offshore and sold by companies who may not have a clear understanding of performance standards and requirements. Purchase decisions that were once made by experienced safety professionals may now be based on price alone, and PPE for which compliance with a standard is claimed may never have been tested.

The problem is that no one knows for sure. There are persistent reports of non-conforming PPE being sold in the U.S., as well as in Europe and other parts of the world. Yet the extent of this problem is largely unknown. The IOM committee did not address this issue, making reference only to the need for data on "PPT performance, use, failures and interface problems that could be harmful to workers." (IOM Report, p. 93)

Begin with Research

ISEA believes a first task for NIOSH NPPTL in responding to the committee's recommendations will be to conduct market research to determine whether there is a substantial volume of PPE in the marketplace that does not conform to required standards. This could be accomplished by purchasing PPE for which

compliance with a standard is claimed, and having it tested to that standard. The sample size would have to be large enough to produce a statistically significant result, but NIOSH NPPTL could select product categories based on reports of non-compliant products in the market.

At the same time, ISEA believes NIOSH NPPTL should undertake research to collect data on the efficacy of certified PPE and whether it offers superior protection to workers. The IOM committee cited no such research; indeed, in its discussion of the system of PPE conformity assessment in Europe, the committee acknowledges that it "did not identify any available data that compared worker safety before and after the conformity assessment requirements were implemented in the EU." (IOM Report, p.82)

Levels of Conformity Assessment

The IOM committee's recommendation calls for a "comprehensive risk-based framework for PPT conformity assessment." It believes that the U.S. should give priority to establishing a consistent scheme for conformity assessment of PPT products, categorizing products by risk (low, medium or high) to a worker's health and safety that could result from failure of the product. It also calls for greater market surveillance and communications, including online access to lists of certified equipment.

Recommendation 1 calls for the risk-based conformity assessment process, developed, implemented and supported by NIOSH in cooperation with other government agencies, certification organizations, manufacturers and end users. The committee states that NPPTL should take the lead to develop a framework for a tiered process:

- Low risk – manufacturer's declaration of conformity
- Medium risk – third-party testing and certification
- High risk – third-party testing and certification with government oversight and enforcement

This recommendation contrasts with the current system of conformity assessment in the US, where manufacturer testing and attestation is the rule. Exceptions are NIOSH-certified respirators, PPE that must be third-party certified to comply with specific standards, and PPE for which the manufacturer secures third-party certification on a voluntary basis. There is nothing in between, and no uniform evaluation of risk in the certification decision.

As NIOSH NPPTL develops its strategy to address this recommendation, ISEA urges the institute to be open to alternative approaches that are driven by data, responsive to marketplace and regulatory needs for assurance of conformity, and less disruptive than a massive expansion of third-party certification.

Consider Alternative Approaches

ISEA has studied PPE conformity assessment for a number of years. It set up the Safety Equipment Institute (SEI) 30 years ago as an independent voluntary third-party certification organization. There are third-party certification requirements in some ANSI/ISEA standards, covering classes of chemical protective clothing, background and retroreflective materials for high-visibility apparel, performance of emergency eyewash and showers, and respiratory protective smoke escape devices.

Today the association is pursuing an alternative approach: a voluntary standard for conformity assessment that could be used with any PPE product standard. The ISEA approach is also a three-tier system, but is more flexible than the approach recommended by the IOM committee. It embodies a separation of conformity assessment requirements from product standards. ISEA will keep NIOSH NPPTL informed of the progress of this activity and seek agency participation in the process. As NIOSH NPPTL develops its 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 in the U.S.

ISEA expects that NIOSH NPPTL will incorporate international standards and conformity assessment practice into its analysis, especially the Committee on Conformity Assessment of the International Organization for Standardization (ISO/CASCO). While the ISO documents do not necessarily reflect U.S. practice, and the U.S. standards community does not accept all the ISO conclusions, the "CASCO toolkit" is useful as a compilation of standards conformity guides and standards.

Comments on the NIOSH Proposed Timeline

NIOSH NPPTL has identified some activities it intends to address in its two-year strategy development. While all of these are valuable, ISEA reiterates its belief that the first task should be defining the need for changes to the conformity assessment system by collecting data on the extent of compliance or noncompliance with existing standards, and whether expanded certification would actually enhance the safety and health of workers who use PPE in the U.S.

1. Defining the standards to be included in the process;

NIOSH NPPTL should include all standards for personal protective equipment and technologies that may be used in the workplace. It should also identify those standards that require some kind of conformity assessment or certification, and those which are used in voluntary third-party certification programs.

2. Identifying the PPE on the market which complies with current standards;

As we stated previously, there is a difference between identifying the PPE on the market that is covered by certain standards and that which actually complies with the standards. ISEA urges to NIOSH to make compliance part of its initial research, to determine whether there is widespread noncompliance with required product standards.

3. Finalizing the conformity assessment terminology to be used in the effort;

NIOSH NPPTL should consult with standards development and conformity assessment organizations in the U.S. to ensure that its terminology is consistent and reflects U.S. practice. The analysis should also include terminology that may be used differently in the U.S. and internationally.

4. Defining low, medium, and high levels of risk;

A starting point for this analysis could be the categories of PPE identified by the European PPE Directive, noting that the directive is being revised and some of the categories will change in the near future.

5. Assessing available sources (e.g. surveillance data) to document the risks of the PPE not working properly and the risks of noncompliance;

ISEA believes the risks of PPE not working properly and the risks of noncompliance are well known. These risks are considered in the development of any PPE product standard. As stated earlier, NIOSH NPPTL should concentrate its initial research efforts on determining the extent of noncompliance with established product standards in the marketplace.

6. Defining the level of conformity assessment, including configuration management, required for each level of risk; and

The level of conformity assessment should be based on a realistic analysis of current practice in the United States, recognizing the unique aspects of the domestic standards and regulatory system.

7. Defining the types of PPE to be included in the framework to include those required by regulation, those desired by the user, and those that respond to specific health and safety needs in the marketplace.

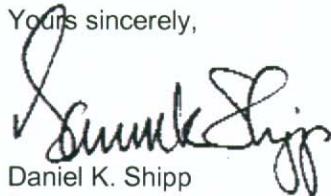
It is important for the NIOSH NPPTL analysis to ensure that it includes PPE required by any regulation, and identify standards for that PPE where they exist. For example, high-visibility apparel compliant with ANSI/ISEA 107 or ANSI/ISEA 207 is mandated by the Federal Highway Administration for workers in or near a highway right-of-way, but not specifically cited in OSHA regulations. On the other hand, OSHA requires employers to provide emergency eyewash and showers where workers are exposed to certain risks, and its inspectors look for equipment that complies with ANSI/ISEA Z358.1, even though the standard is not specifically cited in OSHA regulations. It would also be useful for this analysis to identify out of date or superseded standards that continue to persist in regulations, as a way of encouraging the responsible agencies to bring their regulations up to date.

Stakeholder Participation

ISEA encourages NIOSH NPPTL to involve the U.S. standards and conformity assessment community from the beginning of this project. This would involve outreach to the American National Standards Institute (ANSI) and its constituent standards development organizations, who can provide information on specific standards as well as accreditation requirements and perspective on international norms; standards developers such as ASTM International and the National Fire Protection Association (NFPA); government agencies involved in standards and product approval for the workplace; certification organizations and test laboratories, and manufacturers of personal protective technologies.

ISEA and its member companies look forward to active participation in this project.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Daniel K. Shipp". The signature is written in a cursive, flowing style with a large initial "D".

Daniel K. Shipp
President

