ISEA Voluntary Consensus Standard for PPE Conformity Assessment

BACKGROUND

ISEA began development of a voluntary consensus standard for PPE conformity assessment in 2010, at the direction of the ISEA Board. The Board had formed a CEO-level task force to address issues and concerns: The lack of a consistent system in the US for PPE conformity assessment; divergence of manufacturer views on the value and necessity of third-party certification; the proliferation in the marketplace of imported PPE that shows no evidence of having been tested, much less certified. The Board was also aware of the NIOSH-sponsored study of certification at the IOM, and growing government interest.

ISEA members design, manufacture and sell products in a number of markets around the world. They understand the testing and certification requirements in Europe and other regions, as well as the markets in the US that demand independent certification. ISEA was the founder of the Safety Equipment Institute, the leading independent PPE certification body. When the task force met, their conclusion was that the market would be best served by a separate standard for conformity assessment that could be used in conjunction with product performance standards for a wide variety of PPE. Accordingly, in May 2010 ISEA notified ANSI of its intent to develop a standard with the following scope:

> *This standard establishes criteria for conformity assessment of safety and personal protective equipment which is sold with claims of compliance with product-performance standards. Specific provisions are described for:*
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> - *qualification performance testing data collection and maintenance,*
> - *periodic verification,*
> - *substantiation of processes to maintain manufacturing quality,*
> - *roles and responsibilities of suppliers, testing organizations, and certification organizations who participate in the process.*
>
> *This standard does not address fines, penalties, or government enforcement of activity covered in criminal code such as fraud and counterfeiting, or other material consequences resulting from failure to maintain conformance.*

The standard was approved by the American National Standards Institute (ANSI) on February 5, 2014, given the designation ANSI/ISEA 125-2014.

ANSI/ISEA 125 is designed to provide a standardized conformity assessment system that can be used by suppliers, specifiers, users and regulators. As a stand-alone document it can be applied as a uniform reference across a range of product categories. It is intended as a resource that can be referenced by end user purchasers of products, who may include compliance to this standard as a requirement of a purchase contract with a supplier; by regulatory authorities having jurisdiction over workplace safety and health; or by product standard development committees to define their conformity assessment requirements for a particular product performance standard.

ANSI/ISEA 125 provides the option to select a method of conformity assessment that provides a suitable level of assurance of conformity for any product or application. It is not the intent of the standard to prescribe the appropriate method or level for any product category. This is a decision that is made by the supplier, the end use purchaser who references standards, by a regulatory body with authority over the use of PPE or by the product standards committee whose members are closest to the product category and the product's application.

The standard has three methods of conformity assessment:

Level 1	Level 2	Level 3
Supplier testing	Supplier testing, ISO 17025-accredited lab	Independent third-party testing and certification
Quality management system tied to manufacture of the specified product	ISO 9001 registered quality management system tied to manufacture of the specified product	Quality management system as determined by the third-party certifier
Supplier declaration of conformity	Supplier declaration of conformity	Third-party mark, certification

All three levels require testing to a specified product standard, recordkeeping, verification of ongoing compliance, corrective action system, preventive action process, product recalls.

Under level 1, a supplier will perform the required product testing in-house or have it done in an outside lab, and supply a declaration of conformity. The supplier will also maintain quality management, recordkeeping, corrective action system and other system requirements. Level 2 would add a requirement that the product be tested in a lab – either in-house or independent – that is accredited to ISO 17025, and that the company or the source supplier be ISO 9001 registered. Level 3 is third-party certification, with the understanding that an accredited certification body will set its own requirements for testing, quality management and other pieces of the system, and apply its mark to a certified product.

PROCESS

The ISEA standard was drafted by a task group from the association's Standards Planning and Policy Committee. This group, which includes a test lab as well as manufacturers, worked for over a year to produce a document that was submitted to an international group of users and experts for an informal peer review in mid-2012. The draft was revised based on comments received, and submitted to a general review within ISEA and final committee ballot. The draft was approved by the ISEA Board in February 2013, clearing the way for the standard to begin the ANSI consensus review process.

ISEA submitted the standard to a consensus group selected to provide expertise in the subject matter and a balance of interests, and supplied it for public review at the same time. Comments received were analyzed, responses were provided to commenters, and a revised draft was prepared for a second round of consensus review. The standard achieved consensus in the second round, and was approved by ANSI in February 2014.

For more information, contact ISEA director of member and technical services Cristine Fargo (cfargo@safetyequipment.org) at 703-525-1695.

International Safety Equipment Association
1901 N Moore St.
Arlington, VA 22209 USA
www.safetyequipment.org

OUTLINE OF ANSI/ISEA 125-2014

1. Scope

2. Normative References

3. Definitions

4. Application

This section establishes that the standard may be applied to the manufacture of PPE; that it may be cited as part of a contract for purchase of PPE; that it may be referenced in product standards; or that it may be used as a basis for regulations specifying a level of conformity assessment.

5. Conformity

This section establishes that products for which conformity is claimed must meet all the requirements of the specified product performance standard, and the supplier shall meet all the requirements of the applicable section of ISEA 125.

6, 7, 8. Requirements

There are three sections, one for each level of conformity assessment. Each section contains specific requirements for:

- Quality management system
- Conformance testing
- Corrective and preventive action (including complaints, safety alerts and product recall systems)
- Recordkeeping
- Declaration of conformity

The requirements for level 3 (section 8) also include accreditation of the third-party certifier.

9. Marking

Provides a format for indicating, on the product label or literature, the conformity assessment level being claimed (optional).

Appendix A: Required Elements of Conformity Assessment Systems

This appendix summarizes the standard requirements in table form.

Appendix B. Guidance on Application of Conformity Assessment

This appendix provides guidance for selecting an appropriate method of conformity assessment, considering risks, hazards, PPE capabilities and limitations and other factors.

Appendix C: Supplier's Declaration of Conformity

This appendix provides a format for a supplier's declaration of conformity (levels 1 and 2), including information about the supplier, applicable standards, product and model, and test facility and conformity assessment level. The SDOC is to be signed by an authorized company representative.