



ANSI/ISEA

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American National Standard for Conformity Assessment of Safety and Personal Protective Equipment

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**American National Standard for
Conformity Assessment of Safety and
Personal Protective Equipment**

Secretariat
International Safety Equipment Association

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American National Standard

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Foreword (This Foreword is not part of American National Standard ANSI/ISEA 125-2014)

Conformity assessment is defined as the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. For safety and personal protective equipment (PPE), the specified requirements are found in product standards, along with test methods, sampling procedures, and labeling and marking requirements. Conformity assessment includes testing, evaluation of test data to determine conformity, declaration of conformity, and accreditation of laboratories, certification bodies and quality management systems.

In the United States, there are multiple approaches to PPE conformity assessment. Respiratory protection PPE is subject to federal regulations requiring government testing and certification. Some product standards include specific conformity assessment requirements, including in some cases independent third-party certification. Most PPE is tested and evaluated by the supplier to requirements of voluntary product standards, and the supplier attests to the product's conformance to the standard by marking or labeling. Federal regulations require that employers provide PPE that meets minimum performance requirements, but in most cases do not specify any type of conformity assessment.

ANSI/ISEA 125-2014 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.

As part of their benchmark research, the developers of the standard studied conformity assessment models in use around the world. These models include comprehensive national requirements for standards, testing and certification; the multinational European system based on product performance requirements established in legislation, and the decentralized system in the US.

ANSI/ISEA 125-2014 provides three levels of conformity assessment. For each level, there are requirements for initial and ongoing testing, quality management, corrective and preventive action, recordkeeping and declaration of conformity. Where standards are specified for these processes, accreditation requirements are included. The standard 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 beyond the scope of this standard to prescribe the appropriate level of conformity assessment for any product category, hazard or work environment. This is a decision that is made by the end use purchaser who references standards, by a regulatory agency 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. Guidance for selecting the appropriate level is included in an appendix.

Suggestions for the improvement of this standard are welcome. They should be sent to the ISEA, 1901 N. Moore Street, Suite 808, Arlington, VA 22209; e-mail standards@safetyequipment.org.

This standard was developed and drafted by the ISEA Standards Policy and Planning Committee (SPPC), whose members are knowledgeable and experienced in the development and implementation of PPE product standards and conformity assessment in the United States and around the world. Members of the drafting committee included representatives of 3M Company, Capital Safety, Encon Safety Products, ERB Industries, Gateway Safety, Honeywell Safety Products, ICS Laboratories, Kimberly-Clark Professional, Lakeland Industries, MSA and OccuNomix International.

This standard was processed and approved using consensus procedures prescribed by the American National Standards Institute. The following organizations were contacted prior to the approval of this standard. Inclusion in this list does not necessarily imply that the organization concurred with the submittal of the proposed standard to ANSI.

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1. Scope

1.1 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:

- 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.

A summary of the provisions of the standard is presented in table form in appendix A.

1.2 This standard does not attempt to assign a level of conformity assessment to any product, hazard, or work environment. Guidance in making a determination of an appropriate conformity assessment level is found in appendix B.

1.3 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.

2. Normative References

ISO 9001:2008, *Quality management systems – Requirements*,

ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO/IEC 17021:2011, *Conformity assessment – requirements for bodies providing audit and certification of management systems*

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC 17065:2012, *Conformity assessment – Requirements for bodies certifying products, processes and service*

3. Definitions

3.1 accreditation. Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. The body or person deemed competent through this process is **accredited**.

3.2 attestation. Issue of a statement, based on a decision following review, that fulfillment of specified requirements has been demonstrated.

3.3 certification. A system whereby a **certification organization** (3.4) determines that a **supplier** (3.14) has demonstrated the ability to produce a product that complies with the requirements of a specified **product performance standard** (3.12), authorizes the supplier to use a label on products that comply with the requirements of a specified standard, and establishes and conducts a surveillance program to provide confidence in the continued conformity of certified products with the requirements of a specified standard.

3.4 certification organization. An **independent third-party** (3.9) organization that determines product **conformance** (3.6) with the requirements of a specified standard with a labeling/listing/surveillance program.

3.5 compliance. A judgment based on evidence that a supplier meets the requirements of a standard or regulation.

3.6 conformance. A judgment based on evidence that a product or service meets the requirements of a specified standard.

3.7 conformity assessment. Demonstration that specified requirements