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125-2014

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

ANSI/ISEA 125-2014

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

Secretariat
International Safety Equipment Association

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American National Standards Institute, Inc.

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

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

relating to a product, process, system, person or body are fulfilled.

3.8 cosmetic variation. A change in the appearance of the product.

3.9 independent third party. An entity unaffiliated with another through common or shared ownership, governance, management or operating control, and having no ability to materially guide or influence the decisions or actions of the other party.

3.10 quality management system. A set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved.

3.11 personal protective equipment. Equipment worn or used to minimize or mitigate the effects of exposure to hazards encountered by people doing work, designed and manufactured in conformance to requirements in **product performance standards** (3.12).

3.12 product performance standard. A document, that provides rules, guidelines or characteristics for a product or process for common and repeated use. A product performance standard may be established by consensus and approved by a recognized body, or established by a government entity.

3.13 safety alert. A notice regarding a safety issue with a product, providing guidance for user actions to address the issue.

3.14 supplier. The business entity that claims **conformance** (3.6) of a product's performance with a **standard** (3.12), sells it as conforming, and issues a **supplier's declaration of conformity** (3.15). This may be the manufacturer, distributor, importer or assembler.

3.15 supplier's declaration of conformity. Signed documentation provided by a **supplier** (3.14) that indicates the supplier's **attestation** (3.2) that a product conforms to the requirements of an applicable **product performance standard** (3.12) for which claims are made.

4. Application

4.1 This standard may be applied to a broad range of safety and personal protective equipment.

4.2 Purchasers, specifiers and users of safety and personal protective equipment may include conformity assessment to performance standards, conducted in compliance with this standard, as a requirement of a purchase contract with a supplier.

4.3 Product standard development committees may make reference to this standard to define their conformity assessment requirements for a particular product performance standard.

4.4 Regulators and authorities having jurisdiction over the selection and use of safety and personal protective equipment may use this standard as a basis for specifying an appropriate method of conformity assessment for a particular product or system.

5. Compliance

5.1 A supplier shall use a conformity assessment system that complies with this standard to demonstrate that a product conforms to the requirements of a product performance standard to which the supplier is claiming conformance.

5.2 A product for which Level 1 conformity is claimed shall meet all the requirements of the product performance standard to which the supplier is claiming conformance, and the supplier shall meet all the requirements in Section 6 of ANSI/ISEA 125-2014.

5.3 A product for which Level 2 conformity is claimed shall meet all the requirements of the product performance standard to which the supplier is claiming conformance, and the supplier shall meet all the requirements in Section 7 of ANSI/ISEA 125-2014. A product meeting the requirements for Level 2 conformity shall be deemed additionally to meet Level 1.

5.4 A product for which Level 3 conformity is claimed shall be certified as meeting all the requirements of the product performance standard to which the supplier is claiming

conformance, and the supplier and certification organization shall meet all the requirements in Section 8 of ANSI/ISEA 125-2014. A product meeting the requirements for Level 3 conformity shall be deemed additionally to meet Level 1 and Level 2.

6. Requirements for Level 1

6.1 Quality Management System

The supplier shall maintain a quality management system whose scope includes the manufacture of the specified product. The quality management system shall provide initial and ongoing assurance that the product meets the specified product performance standard to which claims of conformance are made.

6.2 Conformance Testing

6.2.1 Tests shall be conducted as defined in the product performance standard, including test procedures and standards incorporated by reference therein.

6.2.2 Selection of the test facility shall be determined by the supplier.

6.2.3 The supplier shall be responsible for determining whether product form, fit or function with respect to the underlying product performance standard is affected by a product revision, change in raw materials, change in manufacturing processes, change in supplier, or cosmetic variation and if product conformity re-evaluation for any element of the product performance standard is needed.

6.2.4 Products shall be tested in accordance with this section at an interval not longer than every five years.

6.3 Corrective and Preventive Action

6.3.1 The supplier shall establish and maintain a written corrective action and preventive action process that addresses nonconformities in the product performance specified in the product performance standard, and user complaints.

6.3.2 The supplier shall establish and maintain a written product recall and safety alert system.

6.4 Recordkeeping

The supplier shall establish and follow a record retention policy that identifies records needed to establish evidence of conformity, including complaints, safety alerts and product recalls. The documented procedure should establish controls needed for the identification, storage, protection, retrieval, retention and disposition of records, including those maintained electronically.

6.5 Supplier's Declaration of Conformity (See Appendix C)

The supplier shall develop a declaration of conformity that shall be available for examination upon request from a customer, user or relevant authority. Equivalent electronic documents shall be permitted. The declaration of conformity shall, at a minimum:

- a) be written in English;
- b) list the supplier name and address;
- c) include a product model number or other identification details;
- d) list the product performance standard or standards (designation and year) to which conformance is claimed;
- e) indicate that ANSI/ISEA 125-201x conformity assessment Level 1 was followed;
- f) reference the test report (title, number, date, etc.) that serves as the basis of determining conformity;
- g) include a statement of attestation, and
- h) be dated, written on supplier letterhead and signed by an authorized representative. The name and title of the authorized representative shall also be printed.

7. Requirements for Level 2

7.1 Quality Management System

7.1.1 Either the supplier of the finished product or the manufacturer that provides the finished product shall be registered to ISO 9001.

7.1.2 The ISO 9001 registrar shall be accredited to ISO/IEC 17021 by an accreditation body that is a signatory to the International Accreditation Forum (IAF) MLA for management systems, and operates in accordance with ISO/IEC 17011.

7.1.3 The quality management system's scope shall include the manufacture of the specified product. The quality management system shall provide initial and ongoing assurance that the product meets the specified product performance standard to which claims of conformance are made.

7.2 Conformance Testing

7.2.1 Tests shall be conducted as defined in the specified product performance standard, including test procedures and standards incorporated by reference therein.

7.2.2 Initial (type) testing shall be conducted either at an in-house test facility or at an independent third-party test facility, as determined by the supplier. The test facility shall be accredited to ISO/IEC 17025 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC). The scope of accreditation shall include the product performance standard applicable to the product tested.

7.2.3 The supplier shall be responsible for determining whether product form, fit or function with respect to the underlying product performance standard is affected by a product revision, change in raw materials, change in manufacturing processes, change in supplier, or cosmetic variation and if product conformity re-evaluation for any element of the product performance standard is needed.

7.2.4 Products shall be tested in accordance with this section at an interval not longer than every five years.

7.3 Corrective and Preventive Action

7.3.1 The supplier shall establish and maintain a written corrective action and preventive action process that addresses nonconformities in the product performance specified in the product performance standard, and user complaints.

7.3.2 The supplier shall establish and maintain a written product recall and safety alert system.

7.4 Recordkeeping

The supplier shall establish and follow a record retention policy that identifies records needed to establish evidence of conformity, including complaints, safety alerts and product recalls. The documented procedure should establish controls needed for the identification, storage, protection, retrieval, retention and disposition of records, including those maintained electronically.

7.5 Supplier's Declaration of Conformity (See Appendix C)

The supplier shall develop a declaration of conformity that shall be available for examination upon request from a customer, user or relevant authority. Equivalent electronic documents shall be permitted. The declaration of conformity shall, at a minimum:

- a) be written in English;
- b) list the supplier name and address;
- c) include a product model number or other identification details;
- d) list the product performance standard or standards (designation and year) to which conformance is claimed;
- e) indicate that ANSI/ISEA 125-201x conformity assessment Level 2 was followed;
- f) indicate whether the ISO 17025 testing facility is (1) an independent third-party or (2) in-house, defined as owned or partially owned by an entity within the supplier's corporate structure, or within the manufacturing stream for the

applicable product, including subcontractors and subsuppliers;

- g) reference the test report (title, number, date, etc.) that serves as the basis of determining conformity;
- h) include a statement of attestation; and
- i) be dated, written on supplier letterhead and signed by an authorized representative. The name and title of the authorized representative shall also be printed.

8. Requirements for Level 3

8.1 Quality Management System

The supplier shall maintain a quality management system that is acceptable to the third-party certification organization. The quality management system shall provide initial and ongoing assurance that the product meets the specified product performance standard to which claims of conformance are made.

8.2 Conformance Testing

8.2.1 Tests shall be conducted as defined in the specified product performance standard, including test procedures and standards incorporated by reference therein.

8.2.2 Testing shall be conducted by the third-party certification organization or at an independent, third-party test facility as directed by the certification organization. The test facility shall be accredited to ISO/IEC 17025 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC). The scope of the test facility shall include the product performance standard applicable to the product tested.

8.2.3 The third-party certification organization meeting the requirements of section 8.6 shall be responsible for determining whether product form, fit or function with respect to the underlying product performance standard is affected by a product revision, change in raw materials, change in manufacturing processes, change in supplier, or cosmetic variance, and if product conformity re-evaluation for any element of the product performance standard is needed.

8.2.4 The third-party certification organization shall be responsible for determining the interval at which products shall be tested in accordance with this section. In no case shall the interval be longer than every five years.

8.3 Corrective and Preventive Action

8.3.1 The supplier shall establish and maintain a written corrective action and preventive action process that addresses nonconformities in the product performance specified in the product performance standard, and user complaints.

8.3.2 The supplier shall establish and maintain a written product recall and safety alert system.

8.4 Recordkeeping

The supplier shall establish and follow a record retention policy that identifies records needed to establish evidence of conformity, including complaints, safety alerts and product recalls. The documented procedure should establish controls needed for the identification, storage, protection, retrieval, retention and disposition of records, including those maintained electronically. .

8.5 Declaration of Conformity

8.5.1 A certificate of conformity shall be issued by the certification organization and the supplier shall make such certificate available for examination upon request from a customer, user or relevant authority. Equivalent electronic documents shall be permitted.

8.5.2 The supplier shall apply the certification organization's conformance mark to the product.

8.6 Requirements for Third-Party Certification Organization

8.6.1 The certification organization shall be accredited for personal protective equipment to ISO/IEC 17065. Such accreditation shall be issued by an accreditation body that is a signatory to the International Accreditation Forum (IAF) MLA and operates in accordance with ISO/IEC 17011. The scope of the accreditation shall include the product to be certified.

8.6.2 The certification organization's name and label shall be registered and legally defended.

9. Marking

9.1 The ANSI/ISEA 125-2014 method by which a supplier attests conformity to a product performance standard may be identified in writing on a label permanently affixed to the product, on the product itself, or within product literature or on product packaging.

9.2 The text shall be of the form "Conformity to (product performance standard) has been assessed per ANSI/ISEA 125-2014 Level (1, 2, or 3)." The text shall be legibly printed in English.

Appendix A (informative). Required Elements of Conformity Assessment Systems

	Level 1	Level 2	Level 3
Quality management system	Scope includes manufacture of specified product. Must provide initial and ongoing assurance of conformity (6.1)	Supplier or OEM must be registered to ISO 9001. Scope includes manufacture of specified product. Must provide initial and ongoing assurance of conformity (7.1)	As determined by the 3 rd party certification organization. Must provide initial and ongoing assurance of conformity (8.1)
Test facility criteria	As determined by the supplier (6.2.2)	In-house or independent third-party, as determined by the supplier; ISO/IEC 17025 accreditation required (7.2.2)	As directed by the certification organization; ISO/IEC 17025 accreditation required (8.2.2)
Retesting determined by whom?	Supplier (6.2.3)	Supplier (7.2.3)	3 rd party certification organization (8.2.3)
Testing interval	At least every 5 years (6.2.4)	At least every 5 years (7.2.4)	As determined by the certification organization; at least every 5 years (8.2.4)
Corrective and preventive action	Supplier to establish and maintain written program (6.3.1)	Supplier to establish and maintain written program (7.3.1)	Supplier to establish and maintain written program (8.3.1)
Product recalls/safety alerts	Supplier to establish and maintain written program (6.3.2)	Supplier to establish and maintain written program (7.3.2)	Supplier to establish and maintain written program (8.3.2)
Recordkeeping	Record retention policy (6.4)	Record retention policy (7.4)	Record retention policy (8.4)
Declaration of conformity	Supplier (6.5, appendix C)	Supplier (7.5, appendix C)	3 rd party certification organization issues certificate and supplier applies certification mark to product (8.5)

Appendix B (informative). Guidance on Application of Conformity Assessment Methods

Risk, Hazards, and Conformity Assessment – General Discussion

Conformity assessment is the process of demonstrating that a product meets the requirements of a performance standard. The level of rigor required to demonstrate conformity should be based on the potential safety and health consequence of using a product that does not meet a stated performance standard. Standards development organizations, regulatory authorities, or users selecting a conformity assessment level for PPE should primarily consider the risk of using non-conforming PPE including the severity of the injury or illness that may occur if the PPE does not provide the protection specified by the standard and the likelihood that such an injury or illness will occur. In addition, the level of conformity assessment should consider the complexity of selecting and using the appropriate PPE.

Assigning PPE to a Category

Three categories of PPE are described below as a framework within which a user of this standard may specify a conformity assessment level for a given type of PPE. The categories are, roughly, low-medium-high with respect to the level of rigor that is required to demonstrate conformance.

Establishing a PPE category is based on the following general assumptions:

- Risks and hazards are contemplated based on reasonably expected outcomes, not imaginable best- or worst-case scenarios.
- The seriousness of an injury is evaluated on an objective basis and includes consideration of where the injury fits in the entire spectrum of workplace injuries. Any injury, regardless of severity, is inherently considered more serious or grave to the person injured. However, highly individualized and subjective outlooks regarding potential injury or illness should be avoided in establishing a PPE category.
- The user is wearing and using the PPE properly. Scenarios related to user misuse such as wearing spectacles down on the nose or tying high visibility apparel around the waist, should not be considered.
- The PPE was properly selected for the hazard and is appropriate for the reasonably expected outcomes and events within the environment.
- The PPE is maintained and inspected according to the manufacturer's instructions.
- The PPE-related "cause" of an injury is limited solely to incidents in which:
 - The PPE does not perform as specified because of a nonconformance in the PPE that is not detectable to the user, or
 - The magnitude of the hazard or event does not exceed the performance ability of the PPE per the performance standard.

This standard does not attempt to assign a risk/complexity level (or conformity assessment level) to particular types of PPE. The following description of levels provides guidance on PPE categories based on the concepts in the European PPE Directive 89/686. It is intended to assist the user, selector or safety professional in making a reasoned assignment of conformity assessment level based on a particular situation.

Level 1

Level 1 PPE can be used effectively where injury to the user is likely to be superficial and require only standard first aid or routine medical attention on a one-time basis. Level 1 PPE is further defined by the users on their own, being able to assess and choose the level of protection required for their working sit-

uation and environment. PPE that may fit into this level are those intended to protect from the physical agents of mechanical, ergonomic, acoustic or thermal nature. For example: mechanical effects that may result in superficial or non-life threatening injuries; cleaning agents that have reversible effects; minor impact and vibrations that do not affect vital areas of the body or working.

Level 2

Level 2 PPE is intended to protect against dangers that may cause grave and irreversible injury or illness and for which the user is unlikely to be able to spot a defective condition in time to avoid injury or illness. Use of Level 2 PPE requires professional judgment and assistance in selection, use and training. This level may include PPE to protect against mechanical and acoustic hazards.

Level 3

Level 3 PPE is intended to protect against mortal danger or against dangers that may cause grave and irreversible injury or illness and for which the user is unlikely to be able to spot a defective condition in time to avoid such mortal or grave injury or illness. Use of Level 3 PPE requires professional judgment and assistance in selection, use and training and is reserved for truly life-threatening situations or those for which permanently debilitating outcomes can reasonably be expected. The user is cautioned to avoid using Level 3 for lesser harms or personal and subjective outcomes. This level may include PPE to protect against toxic gases, severe electrical shock, high-intensity optical radiation, drowning and other life-threatening hazards.

Appendix C (informative). Example of Supplier's Declaration of Conformity

Declaration of Conformity
In accordance with ANSI/ISEA 125-2014

Declaration No.
Supplier name and address:
Product information (name, model number, part number or other information as applicable):

Supplier declares that the product listed above is in conformity with the requirements of the following standard(s):

Standard(s) to which product was tested and for which conformity is claimed. Include designation and year of standard(s):

ANSI/ISEA 125-2014 conformity assessment method: <input type="checkbox"/> Level 1 <input type="checkbox"/> Level 2
For Level 2, information about the ISO 17025-accredited facility in which the product was tested: <input type="checkbox"/> The test facility is an independent third party <input type="checkbox"/> The test facility is owned or partially owned by an entity within supplier's corporate structure, or within the manufacturing stream for this product, including subcontractors and sub-suppliers.
Test report reference (title, number, date):

Authorized Signature

Name (printed) _____

Title (printed) _____

Date _____