INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION

The Catalyst for Safety Worldwide

ANSI / ISEA 125-2021

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

ANSI/ISEA 125-2021
Revision of ANSI/ISEA 125-2014

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

Secretariat
International Safety Equipment Association

Approved June 17, 2021
American National Standards Institute, Inc.

American National Standard

Approval of an American National Standard requires verification by ANSI that the requirements for due process, consensus and other criteria for approval have been met by the standards developer. Consensus is established when, in the judgment of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered and that a concerted effort be made toward their resolution. The use of American National Standards is completely voluntary; their existence does not in any respect preclude anyone, whether he/she has approved the standards or not, from manufacturing, marketing, purchasing or using products, processes or procedures not conforming to the standards. The American National Standards Institute does not develop standards and will in no circumstance give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretation should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

CAUTION NOTICE: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

Published by

International Safety Equipment Association
1101 Wilson Boulevard, Suite 1425, Arlington, Virginia 22209

Printed in the United States of America

Foreword (This Foreword is not part of American National Standard ANSI/ISEA 125-2021)

ANSI/ISEA 125-2021 continues to describe three levels of conformity assessment approaches that can be used to demonstrate that specified requirements for safety and personal protective equipment (PPE) are fulfilled. For each level, there are requirements for initial and ongoing testing, quality management, corrective and preventive action, recordkeeping and declaration of conformity.

This updated version addresses improvements and introduces greater flexibility in an effort to promote wider voluntary adoption. To this end, ANSI/ISEA 125 Level 2 requirements have been revised to create two alternate paths compliance. The prior edition required *both* ISO 9000 quality management system registration *and* use of an ISO 17025 accredited laboratory for product type testing. This revision requires only one of these two methods of external engagement. The selection of which path to use is solely at the discretion of the supplier seeking to meet Level 2. In choosing to use an ISO 17025 accredited laboratory for Level 2, a supplier is obligated to maintain a quality management system. ISO 9001 represents an appropriate framework toward constructing a quality management system, though it is stressed that ISO 9001 registration is not a requirement for achieving Level 2 compliance when selecting the accredited laboratory approach.

ANSI/ISEA Level 3 requirements have been revised to allow use of third-party certification on individual materials and components of a finished device. While such had not been specifically prohibited in the previous version, this revision clarifies the option, recognizing that many devices include a single material or component that is protective against much more serious hazards than other components. It will also help abate concerns among specifiers that designating an entire device as Level 3 because of a single component will result in undue burdens as all other components and variations are also subjected to third-party requirements. Appendix C has been added to discuss the considerations for requiring third-party certification at the component level.

Appendix B is expanded to give the user a broader view of the role that risk plays in selecting a conformity assessment practice, along with a framework for considering the level of user risk. It is intended to provide more meaningful guidance to specifiers who may not have deep experience in selecting conformity assessment levels. It continues to be beyond the scope of this standard to prescribe the appropriate level of conformity assessment for any product category, hazard or work environment.

Suggestions for the improvement of this standard are welcome. They should be sent to the ISEA, 1101 Wilson Boulevard, Suite 1425, Arlington, VA 22209; e-mail standards@safetyequipment.org.

This standard was developed and drafted by a working group of 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, ArcWear, Bullard, Carhartt, DuPont Personal Protection, Kimberly-Clark Professional, and MSA Safety.

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.

Association of Hazard Materials Professionals
GKN Aerospace
International Safety Equipment Association
International Personnel Protection Inc.
National Institute for Occupational Safety and Health
National Institute of Standards and Technology
Oak Ridge National Laboratory
Safety Equipment Institute

Contents

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 9001:2015, *Quality management systems – Requirements,*

ISO/IEC 17011:2017, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

ISO/IEC 17021:2015, *Conformity assessment – requirements for bodies providing audit and certification of management systems*

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC17065:2012, *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 (3.15) has demonstrated the ability to produce a product that conforms with the requirements of a specified product performance standard (3.12), authorizes the supplier to use a label on products that conform 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 conformance testing. A measurement to confirm that an example of the finished PPE article demonstrates that it meets or exceeds the performance threshold(s) specified in the cited standard.

3.8 conformity assessment. Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

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 subcontractor. Any entity at any level in the stream of commerce that provides any component, material, chemical or other item that becomes part of the finished product.

3.15 supplier. The business entity that claims conformance (3.6) of a product's performance with a standard, sells it as conforming, and issues a supplier's declaration of conformity (3.16). This may be the manufacturer, distributor, importer, subcontracto ror assembler.

3.16 supplier's declaration of conformity. Signed documentation provided by a supplier (3.15) 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.

3.17 type test. One or more tests performed on an item to approve a material, construction, model or design to determine if it is capable of meeting the requirements of a product standard.

NOTE: For purposes of this standard, type tests include initial testing and subsequent tests made at calendar intervals as required in Sections 6.1.4 and 7.1.4, as well as testing needed after changes as described in Sections 6.1.3 and 7.1.3.

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 or, where applicable as described below, a component 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 125-2021.

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 125-2021. 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 125-2021.

A supplier may also claim Level 3 conformity for certain components as described in Section 8 and Appendix C. 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 Conformance Testing

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

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

6.1.3 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, which may include a change in raw materials, change in manufacturing processes, design or supplier and if product conformity re-evaluation for any element of the product performance standard is needed.

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

6.2 Quality Management System

The supplier shall maintain a quality management system whose scope includes the manufacture of the specified product in conformance with specified standards. 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.

6.3 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.

6.4 Corrective and Preventive Action

6.4.1 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.

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

6.5 Supplier’s Declaration of Conformity (See Appendix D)

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 125-2021 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

To meet Level 2 requirements, the supplier shall incorporate one or more of the following approaches for third-party oversight as chosen solely by the supplier who provides the Declaration of Conformity

OPTION A: Performing the testing required to demonstrate conformance as described in section 7.1 to the claimed standard in an internal laboratory with ISO/IEC 17025 third-party accreditation.

OPTION B: Performing the testing required to demonstrate conformance as described in Section 7.1 to the claimed standard in an external (third party) laboratory with ISO/IEC 17025 accreditation.

OPTION C: Obtaining ISO 9001 certification for the quality management system that is supporting the conformance claims for the PPE as described in section 7.2

The type(s) of third party oversight to achieve Level 2 conformity assessment and described in sections 7.1 and/or 7.2, and the specific approach shall be reported on the Supplier's Declaration of Conformity (Appendix D) as described in 7.5.

NOTE: Sections 7.3, 7.4 and 7.5 are all mandatory for Level 2 compliance regardless of which option A, B, or C us used. The supplier then chooses between Sections 7.1 and 7.2 to complete the requirement.

NOTE: Regardless of which option is selected, the resulting representation is Level 2. Any alphanumeric designation (such as Level 2A, 2B or 2C) is discouraged as this standard does not distinguish between these options for purposes in a rank-order manner.

7.1* Conformance Testing - Pathways for Options A and B, above

A manufacturer or supplier of PPE who optionally chooses to conform to ANSI/ISEA 125 Level 2 by performing testing in an ISO/IEC 17025 accredited test facility is required to meet all items in this Section 7.1, along with Sections 7.3, 7.4 and 7.5

7.1.1 Quality Management System

The supplier shall maintain a quality management system whose scope includes the manufacture of the specified product in conformance with specified standards. 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.

7.1.2 ISO 17025 Conformance Testing

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

7.1.2.2 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 third-party 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.

7.1.2.3 Conformity shall be re-evaluated if, as determined by the supplier, conformance to applicable product performance standard is affected by a product revision, which may include a change in raw materials, manufacturing processes, design or supplier and if product conformity re-evaluation for any element of the product performance standard is needed.

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

7.1.2.5 Products subjected to standard conformance testing by an ISO/IEC 17025 accredited testing facility shall be designated as

conforming to ANSI/ISEA 125 Level 2 conformity assessment.

7.2* Quality Management System - Pathway for Option C, above

A manufacturer or supplier of PPE who optionally chooses to conform to ANSI/ISEA 125 Level 2 by registering his or the product manufacturing's quality management system with ISO 9000 is required to meet all items in this this Section 7.2, along with Sections 7.3, 7.4 and 7.5.

7.2.1 Conformance Testing

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

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

7.2.1.3 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.

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

7.2.2 ISO 9000 Registered Quality Management System

7.2.2.1 Either the manufacturer of the finished product or the supplier that provides the finished product shall be registered to ISO 9001 or any industry-specific quality management system that has the ISO 9001, including registration, as base requirements.

NOTE: Examples of industry-specific, ISO 9001-based quality management system standards include, but are not limited to ISO 13485 for medical-device manufacturing and AS9100 for aerospace manufacturing. The term ISO 900x as used in this standard shall be understood to include all progeny QMS standards based on ISO 9001.

7.2.2.2 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.

7.2.2.3 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.

7.2.2.4 Products manufactured under a certified ISO 9001 quality management system shall be designated as conforming to ANSI/ISEA 125 Level 2 conformity assessment.

7.3 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.

7.4 Corrective and Preventive Action

7.4.1 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.

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

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

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 125-2021 conformity assessment Level 2 was followed;

f) indicate whether Level 2 conformity was obtained by (1) type testing performed by an in-house ISO 17025 accredited facility that is within the stream of commerce for the product, including supplier, subcontractor, or subsupplier laboratories (section 7.1.2), or (2) type testing performed by an independent, third party ISO 17025 accredited facility (section 7.1.2), or (3) manufacture in a facility or contracted by a supplier with a QMS registered to ISO 9001 (Section 7.22);

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

Level 3 may be applied to a complete product or an individual component or material if the risk analysis of Appendix B indicates that a particular component or material carries the appropriate risk, on its own, suitable for Level 3 assessment. However, such application of Level 3 has complications that are not present for device-level application of Level 3 assessment. The user is cautioned to read Appendix C carefully for process and considerations for requiring Level 3 assessment of a component. Only Level 3 may be applied at the component level. Assigning individual components to Level 1 or Level 2 is not allowed.

8.1 Requirements for Third-Party Certification Organization

8.1.1 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.

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

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 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, which may include a change in raw materials, manufacturing processes, design or supplier 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 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.

8.4 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 Corrective and Preventive Action

8.5.1 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.

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

8.6 Declaration of Conformity

8.6.1 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.

8.6.2 The supplier shall apply the certification organization's conformance mark according to the certification body's requirements.

9. Marking

9.1 The ANSI/ISEA 125-2021 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. Equivalent electronic or digital means of communication shall be permitted.

9.2 The text shall be of the form "Conformity to (product performance standard) has been assessed per ANSI/ISEA 125-2021 Level (1, 2, or 3)."

The text shall be legibly printed in English.

9.2.1 Marking on the product may utilize an abbreviated version "ISEA L(1,2 or 3); however, at least one additional means of identification, per Section 9.1 shall be provided that includes the text as stated in Section 9.2.

9.2.2 A complete product shall only be labeled as complying with Level 3 of this standard if the entire product, as an entire product, has been third-party certified. Where components of a complete product are third-party certified, they shall bear the markings required of the certification organization for the specific component, and the label for the complete product under this section shall indicate compliance to either Level 1 or Level 2.

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

	Level 1	Level 2 Option A	Level 2 Option B	Level 2 Option C	Level 3
Test facility criteria	As determined by the supplier (6.1.2)	In-house; ISO/IEC 17025 accreditation required (7.1.2.2)	Independent third-party; ISO/IEC 17025 accreditation required (7.1.2.2)	As determined by the supplier (7.2.1.2)	As directed by the certification organization; (8.2.2)
Retesting determined by whom?	Supplier (6.1.3)	Supplier (7.1.2.3)	Supplier (7.1.2.3)	Supplier (7.2.1.3)	3rd party certification organization (8.2.3)
Testing interval	At least every 5 years (6.1.4)	At least every 5 years (7.1.2.4)	At least every 5 years (7.1.2.4)	At least every 5 years (7.2.1.4)	As determined by the certification organization; at least every 5 years (8.2.4)
Quality management system	Scope includes manufacture of specified product. Must provide initial and ongoing assurance of conformity (6.2)	Scope includes manufacture of specified product. Must provide initial and ongoing assurance of conformity (7.1.1)	Scope includes manufacture of specified product. Must provide initial and ongoing assurance of conformity (7.1.1)	Supplier or OEM must be registered to ISO 9001. Scope includes manufacture of specified product. Must provide initial and ongoing assurance of conformity (7.2.2.2)**	As determined by the 3rd party certification organization. Must provide initial and ongoing assurance of conformity (8.3)
Recordkeeping	Record retention policy (6.3)	Record retention policy (7.3)	Record retention policy (7.3)	Record retention policy (7.3)	Record retention policy (8.4)
Corrective and preventive action	Supplier to establish and maintain written program (6.4.1)	Supplier to establish and maintain written program (7.4.1)	Supplier to establish and maintain written program (7.4.1)	Supplier to establish and maintain written program (7.4.1)	Supplier to establish and maintain written program (8.5.1)
Product recalls/safety alerts	Supplier to establish and maintain written program (6.4.2)	Supplier to establish and maintain written program (7.4.2)	Supplier to establish and maintain written program (7.4.2)	Supplier to establish and maintain written program (7.4.2)	Supplier to establish and maintain written program (8.5.2)
Declaration of conformity	Supplier (6.5, appendix D)	Supplier (7.5, appendix D)	Supplier (7.5, appendix D)	Supplier (7.5, appendix D)	3rd party certification organization issues certificate and supplier applies certification mark according to certification body requirements (8.6)
**For Level 2, Option C, any industry-specific quality management system that has ISO 9001, including registration, as its base requirement, is acceptable.					

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

Introduction

The user guide for the Conformity Assessment for PPE is a reference guide to help evaluate the appropriate level of conformity assessment for a given PPE category. This guide is intended to give general direction based on three levels of risk hazards that a worker might face in a typical work environment. This guide does not certify products or look at each individual worker doing the specific task but gives a general guideline based on generalized workplace and workplace hazards one might face. The level of risk should be determined by self-assessment based on each individual work application.

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.

Assessing Risk

Conformity assessment means the product does what it says it will do – it protects in the way that it says it will protect according to the standard applied to that product by the manufacturer. Deciding which level of conformity should be applied to a product should not be taken lightly. What is to be considered is the outcome should the product not protect the way it is intended to. For instance, would the injury that results be life-interrupting, life-altering, or life-ending? These are 3 very different outcomes, even though the person who suffers the injury may consider it catastrophic at the time regardless of the level.

- **Life Interrupting:** *Injuries that are minor and interrupt the lifestyle of the victim but do not have a lasting effect. An example is a minor cut or scrape that requires the victim to go to the doctor but no long-term issue.*
- **Life Altering:** *Injuries that are serious enough that they result in some form of permanent disability, long-term health problems and/or reduction in the victim's life expectance. These injuries have a major impact on the victim's lifestyle. An example is loss of limb, eyesight, hearing, etc.*
- **Life Ending:** *Injuries that result in death.*

Assigning PPE to a Category

The three categories of PPE outlined in ANSI/ISEA 125 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, as well as the potential outcome should the PPE not perform to its required level of protection.

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. Again, life-interrupting, life-altering, or life-ending are broad ways to view the spectrum of potential workplace injuries.

- 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, used, 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, meaning the appropriate level of protection was chosen initially for the potential hazard.

As a helpful contrast to the risk factors discussed in this Appendix, below are examples of reasons that are generally not considered appropriate for assigning a Conformity Assessment level to a type of PPE:

1. To match what is perceived to be current practice in the industry.
2. To match the practices of any individual making the specification. Most manufacturers consider their internal practices to be the best balance of all considerations – that's why the practice was implemented. Specifiers should resist the temptation to use their internal practices as a benchmark for establishing a wider requirement. Consideration of risk should be objective.
3. As a means to gain a competitive advantage over others in the market, to help drive perceived "cheaters" from the marketplace, or to otherwise create a market enforcement scheme. Note that Level 3 third-party certification programs frequently include some level of commercial market enforcement, but Level 3 should be selected based on risk and not the desire to leverage these enforcement practices against some segment of the industry or other manufacturers. [Note that *any* manufacturer may seek a competitive advantage by obtaining third-party certification on his products. This is not the same as attempting to impose the requirements on others for competitive reasons.]
4. To give any particular product performance standard "more credibility" to any industry cohort such as US regulators, global regulators, or any users in any region

The same framework used for PPE should be applied when evaluating the risk of injury as it relates to ANSI/ISEA compliant components. Please see Appendix C for an overview of component compliance to this standard.

This standard does not attempt to assign a risk/complexity level (or conformity assessment level) to 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 or life interrupting and requires only minor first aid or short term medical treatment. 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 situation 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 . While Level 1 PPE is described as minor, or life interrupting event, to the injured person it may represent more than “life interrupting” especially if time off work or potentially reduced wages, and/or doctors’ visits, etc. are involved that personally interrupts their lives.

Level 2

Level 2 PPE is intended to protect against life altering 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. A Level 2 is life altering and could include a loss of a limb, vision, digits, etc. which depending on the work at hand could have significant impact on an individual lifestyle as it pertains to work and home life. Assessment of a Level 2 injury should take into consideration the present condition of the user who may be impacted by an injury and be cumulative when necessary. For example, the loss of a limb will impact a user who already has a significant injury or illness more severely than someone who does not.

Level 3

Level 3 PPE is intended to protect against mortal danger and for which the user is unlikely to be able to spot a defective condition in time to avoid such an occurance. 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. Level 3 is the most catastrophic and injuries are considered life ending. Persons wearing Level 3 PPE are performing some of the most dangerous jobs. For example, consider emergency responders that are running into a fire while others are running out of the fire. This type of job could need a Level 3 certified product to protect the wearer from mortal injuries.

Appendix C (informative). Considerations for Requiring Certification of Individual Components

There may be situations for which the preferred Conformity Assessment scheme involves certifying certain critical components but not the entire device. Certification of components does not grant or imply certification of the final device or product. This appendix details some of the issues that a specifier must consider before publishing a standard that includes a requirement for component certification under Section 8.

Note that in this discussion, the term “component” is understood to include subassemblies and individual materials.

Requiring third-party certification (Level 3) of components - the case for certifying critical components only

When evaluating a device for a component that might merit Level 3 Conformity Assessment methods, the specifier should consider the following factors:

- Whether the finished PPE device includes a single component for which the risk to user safety, if defective, is much greater than for other components.

- Whether a defect in the component is reasonably foreseeable to have life-ending consequences as described in Appendix B

- Availability of other protective mechanisms – does the component represent the only or near-only means of protecting a user from the hazard?

- Is the defective condition detectable by the user? Can a user avoid using the PPE with the defective critical condition by mere observation and obviousness of the defective condition?

Considerations for requiring third party-certification of components – availability of infrastructure

Certification of a device or component necessarily requires that there are accredited certification organizations who are willing and able to provide such certification.

Specifiers are strongly encouraged to discuss any proposed requirement to certify a component well in advance of any publication of a standard or other need for certified components in the field. It is critical to involve at least one certification organizations in any discussions of establishing a requirement for third-party certification of components for the following reasons:

- Certification organizations must review proposals before committing to create a scheme to certify new products or components. They may consider anything from internal capability to the business case before agreeing create the program. They may need to get approval for the program from legal counsel and internal executives.

- Once a certification organization decides to create a certification program, they must also have time for such preparatory activities as acquiring equipment, training employees, and making any necessary adjustments to accreditation scopes.

- See the next section for more detail on what a specifier might expect when considering creating a requirement for component certification.

Any certification organizations may decline to create a program for a component that they believe is a poor candidate for component certification.

Structural and process considerations

Most items in this section will be decided by the certification organization, but it may help standards authors to understand the issues, conflicts and problems that may arise in establishing a certification program for components.

General Structural Considerations

In cases where there is no existing certification available for a given component, the exact interplay between creating a requirement and creating a program can be unclear. Both sides – the specifier considering making the requirement and the certification organization that would create the certification program – will likely need to be acting in concert and in parallel.

The entity desiring to specify component certification should approach one or more certification organization prior to publishing a component certification requirement.

The certification organization would then review the request for the new component certification program and seek internal input such as a risk evaluation, legal input, and the business case creating the program. A decision as to whether to create a program to create the proposed component certification would follow.

- Standards authors should again be cautioned not to publish a component certification requirement without first assuring that there is at least one, preferably more, certification organization who would create the certification program for it.

The certification organization could apprise the specifier of the work needed and timing to create the program. This could vary depending on:

- The boundaries that the certification organizations places on the program within the stream of commerce for the component. Most certifiers would limit oversight activities to the facility manufacturing the component, disclaiming any responsibility once the component has left the component manufacturer's facility. However, some certification organizations may want to establish controls beyond this point to include investigations of adverse field events, market surveillance, etc.

- Whether and how the component certification fits with the certifier's current Scope of Accreditation. That is, if the certification organizations already certifies the assembly or similar products, the new program should fit within the Scope of Accreditation. If the product and testing would be new to the certification organizations, the Scope of Accreditation may need to be revised to accommodate the program.

- The certification organizations will also need to have the equipment and technical expertise to perform effective oversight of the component manufacturers. Although performance testing can be outsourced to an accredited lab, the certifier may need to provide subject-matter training to employees before offering the certification.

- It is helpful for the specifier to think of the structural needs in terms of tiered timing. The process would be fastest if the product standard is within the current Scope of Accreditation, medium-fast if the exact standard is not in scope but other PPE is in scope, and longest if the certification organizations is new to PPE.

- Once a certification organization approves a program, logistics such as equipment and expertise procurement, establishing contracts with any subcontracted service providers, and establishing a marking schemed (see below) may take time beyond that required to investigate the opportunity and obtaining the appropriate Scope of Accreditation.

Considerations for Drafting Component Requirements Suitable for Isolated Certification

When considering adding component certification into a program, it is recommended to bring certification organizations to standards development discussions to ensure that the specifications are robust enough for certification organizations to adopt programs for component certification.

- For an ISO 17065 accredited certification organization to consider adopting a component certification program, a workable specification is one of the most important necessities. A workable specification should include, but is not limited to, the following:

    Test methods and requirements for the component must be clearly outlined and isolated to the component as a self-contained, individual product. A separate section specifically addressing the component is generally preferred, but not always required.

    Generally, the component requirements may not mandate the use of any mating connection during the testing process, as downstream changes may affect performance and certification status of the component. Specifications with clauses such as “must be tested as a complete device” or that require use of mating parts as test fixtures would not be good candidates for component certification programs; in such cases where certification is desired, final product certification may be a more suitable option.

    Discussion: In granting certification to components or to final products, ISO 17065 certification organizations use discretion on both external and internal requirements for use of their certification mark. This may include the way the certification organization views a component’s requirements relative to downstream operations, testing in assembly, and risk of use in the field. Individual certification organizations may make exceptions to the above guidelines in some cases and should always be consulted for evaluation of specific scenarios.

- Requirements for components should reflect the state of the component as it will be shipped to the assembling or final entity.

Considerations related to component markings

Any certification mark applied to a component would need guidelines and practices in place to assure that the mark is not mistakenly interpreted as applying to the entire device. Various certification organizations may take different approaches, such as:

- Creating a modified mark for use on the component.

- Requiring, if any sort of mark is used, clear and even specific language on the product, packaging or collateral stating that the mark applies to the component only and not the complete device.

- Prohibiting any mark on the component, limiting the certification mark to the packaging of the component only. In these cases, the packaging would be discarded by the final device assembler, and the internal records of the final assembling manufacturer would suffice for meeting a component-certification requirement.

Specifiers should be prepared to accept that the product end user may not be able to see a component mark either directly or after disassembly. This is contrary to the common requirement that marks indicating full-device certification must be visible and legible. Although a specifier may request a visible mark, this will ultimately be the sole decision of the certification organization.

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

Declaration of Conformity
In accordance with ANSI/ISEA 125-2021

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 125-2021 conformity assessment method: ❑ Level 1 ❑ Level 2
For Level 2, third-party oversight is demonstrated by one or more of the following, as indicated: ❑ The ISO/IEC 17025 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. ❑ The ISO/IEC 17025 test facility is an independent third party. ❑ The quality management system of the manufacturer or supplier of the product is ISO 9001 registered.
Test report reference (title, number, date):

Authorized Signature

_____

Name (printed) _____

Title (printed) _____

Date _____