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Standard Guide for Conformity Assessment of Personal Protective Clothing and Equipment[1]

This standard is issued under the fixed designation F3050; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide describes options for conformity assessment (CA) requirements relating to personal protective clothing and equipment (hereafter referred to as "PPE"). This guidance can optionally be used to define conformity assessment requirements in a PPE specification standard or in a companion ASTM conformity assessment Standard Practice document[2] associated with the PPE specification standard. It is understood that the former approach is not consistent with ISO Directive, Part 2, Section 6.7.

1.2 This guide is not intended to require additional conformity assessment requirements to any PPE specification standard or to the integral components of the PPE.

1.3 This guide defines conformity assessment principles and requirement options consistent with U.S. HHS NIOSH National Framework for Personal Protective Equipment – Conformity Assessment Infrastructure as a means to manage the risks to wearers to defined hazards from nonconforming PPE.

1.4 This guide identifies potential hazard and risk assessment outcomes for which a conformity assessment scheme (commonly referred to as a "program") can be developed to manage assessed risks.

1.5 It is not the intent of this guide to prescribe any particular model of conformity assessment requirements for PPE or its integral components.

1.6 The requirements and activities in a given conformity assessment scheme should be determined by a conformity assessment scheme owner or can be defined by the PPE specification standard writers, and should be based, at a minimum, on the criteria contained in Section 6 of this guide.

1.7 This guide is not intended to supersede any federal, state, or local laws or regulations.

1.8 This guide offers an organized collection of information or a series of options and does not recommend a specific course of action. This document cannot replace education or experience and should be used in conjunction with professional judgment. Not all aspects of this guide may be applicable in all PPE circumstances. This ASTM guide is not intended to represent or replace the standard of care by which the adequacy of a given professional service must be judged, nor should this document be applied without consideration of a project's many unique aspects. The word "standard" in the title of this document means only that the document has been approved through the ASTM consensus process.

1.9 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

D123 Terminology Relating to Textiles

F1494 Terminology Relating to Protective Clothing

F2669 Performance Specification for Protective Clothing Worn by Operators Applying Pesticides

F2962 Practice for Conformity Assessment of Protective Clothing Worn by Operators Applying Pesticides

2.2 *Federal Regulations:*[4]

CFR Title 21, Part 7, Subpart C Recall Procedures

2.3 *ISO Standards:*[5]

ISO 9001:2015 Quality Management Systems – Requirements

ISO/IEC 17000:2004 Conformity Assessment – Vocabulary and General Principles

[1] This guide is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.50 on Certification and PPE Interoperability.

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[2] Practice F2962 establishes the conformity assessment requirements for Specification F2669. This is an example for having conformity assessment requirements in a PPE practice document related to a PPE specification standard.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, http://www.access.gpo.gov.

[5] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

ISO/IEC 17011:2004 General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories
ISO/IEC 17065:2012 Requirements for Bodies Certifying Products, Processes, and Services
ISO/IEC 17067:2013 Fundamentals of Product Certification and Guidelines for Product Certification Schemes
ISO/IEC TR 17026:2015 Example of a Certification Scheme for Tangible Products

3. Terminology

3.1 *Definitions:*

3.1.1 *accreditation, n*—third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. **ISO/IEC 17000**

3.1.2 *audit, n*—systematic, independent, documented process for getting records, statements of fact, or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. **ISO/IEC 17000**

3.1.3 *certification, n*—a system whereby a third party independent organization determines that a supplier has demonstrated the ability to make a product that complies with the requirements of the specification, authorizes the supplier to use a label on products that comply with the requirements of the specification, and conducts a follow-up surveillance program to verify the methods the supplier uses to determine conformance with the requirements of the specification. **F1494**

3.1.4 *certification body, n*—third-party conformity assessment body operating certification schemes and attesting to the conformity of products.

3.1.4.1 *Discussion*—A certification body can be nongovernmental or governmental (with or without regulatory authority), and can also be known as "certification organizations."

3.1.5 *certified product, n*—product that has successfully been tested and found to conform by an appropriately accredited certification body.

3.1.6 *certified product listing, n*—a publicly accessible listing of certified products.

3.1.7 *conformity assessment, n*—demonstration that specified requirements relating to a product, process, system, person, or body have been fulfilled. **ISO/IEC 17000**

3.1.8 *conformity assessment scheme, n*—the specified conformity assessment program's rules, procedures, and requirements applied to completely assembled PPE, or individual components, or subassemblies where required by a specification. **Adapted from ISO/IEC 17067**

3.1.9 *conformity assessment scheme owner, n*—a person or organization that has authority and responsibility for developing and maintaining the conformity assessment scheme. **Adapted from ISO/IEC 17067**

3.1.10 *evaluation, n*—determination of the significance or condition by careful appraisal and study.

3.1.11 *inspection, n*—examination of a product, product design, service, process, or manufacturing facility and determination of conformity with specific or (on the basis of professional judgment) general requirements. **Adapted from ISO/IEC 17000**

3.1.12 *labeled, n*—equipment or materials to which has been attached a label, symbol, or other identifying mark of an organization that is acceptable to the authority having jurisdiction and concerned with product evaluation, that maintains periodic inspection of production of labeled equipment or materials, and by whose labeling the personal protective equipment indicates conformance with designated specifications.

3.1.13 *listed, n*—equipment, materials, or services included in a list published by an organization that is acceptable to the authority having jurisdiction and concerned with evaluation of products or services, that maintains periodic inspection of production of listed equipment or materials or periodic evaluation of services, and whose listing states that either the equipment, material, or service meets appropriate designated end-product specifications or has been tested and found suitable for a specified purpose.

3.1.14 *mark of conformity, n*—legally registered certification mark applied by or issued under the procedures of a third-party certification system for a product, process, or service that is in conformity with specific standards or other technical specifications.

3.1.15 *PPE, n*—completely assembled personal protective clothing and equipment whose purpose is to provide a wearer personal protection from defined hazards.

3.1.16 *quality assurance, n*—all the planned and systematic activities implemented within the quality management system that can be demonstrated to provide evidence that a product or service will fulfill claimed requirements with a verifiable and high degree of confidence.

3.1.17 *registration, n*—the term (now retired) for the declaration by an accredited certification body that an organization has demonstrated conformance with ISO 9001. A certification (current term) is issued as the declaration of conformity to ISO 9001.

3.1.18 *sample, n*—(*1*) a portion of a lot of material which is taken for testing or for record purposes; (*2*) a group of specimens used, or observations made, which provide information that can be used for making statistical inferences about the population from which they were drawn. **D123**

3.1.19 *scheme owner, n*—see *conformity assessment scheme owner*.

3.1.20 *specimen, n*—a specific portion of a material or a laboratory sample upon which a test is performed or which is selected for that purpose. **D123**

3.1.21 *supplier declaration of conformity (SDOC), n*—the procedure by which a first party or supplier conveys assurance that the object of conformity fulfills specified requirements.

3.1.22 *supplier, n*—the entity that directs and controls the following: conformant product design, conformant product

manufacturing, conformant product quality assurance; or the entity that assumes the liability for the conformant product or provides the warranty for the conformant product.

3.1.23 *surveillance, n*—sampling, inspection, tests, or other measures used on a periodic basis to determine the continued conformance of products that are being made by the supplier to the requirements of the specification, or to assess the effectiveness of the conformity assessment scheme.

3.1.24 *user, n*—person or organization who makes use of the PPE; for example, one involved in selecting or maintaining the personal protective clothing and equipment for wearer protection from a defined hazard.

3.1.25 *wearer, n*—the person who wears the personal protective clothing and equipment.

3.2 For definitions of other personal protective product-related terms used in this guide, refer to Terminology F1494.

4. Summary of Guide

4.1 This guide is structured to identify conformity assessment considerations and optional requirements related to personal protective clothing and equipment.

5. Significance and Use

5.1 Writers of PPE specifications produce requirements to mitigate defined personal safety and health hazards.

5.2 The users and wearers of PPE expect that these products will perform in conformance with stated specifications to help to mitigate personal hazard(s).

5.3 Conformity assessment requirements are a means to provide confidence that PPE conform to specifications.

5.3.1 Conformity assessment requirements should be defined to address the confidence needed to ensure the PPE will provide protection for the identified hazard. (See Annex A1 for a discussion on how standards should address hazards and risks through performance and other requirements that provide adequate protection.)

5.3.2 Conformity assessment requirements are a means to manage the risks of nonconforming PPE and can serve as a balance of cost effectiveness and risk of injury or illness of a nonconforming product.

6. Conformity Assessment – Requirements as Related to Risk

6.1 Conformity assessment is defined as the demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled.

6.1.1 Conformity assessment can include sampling and testing, inspection, supplier's declaration, certification, surveillance, and quality and environmental system assessment and registration. It can also include accreditation that indicates competence by the provider from a third party.

6.1.2 This guide identifies options for conformity assessment consistent with the U.S. HHS NIOSH National Framework for Personal Protective Equipment – A Conformity Assessment Infrastructure as a means to manage the defined hazards and risk to wearers of a nonconforming PPE.

6.1.3 The requirements' rigor and scheme participant independence of the conformity assessment activities can vary from a supplier declaration of conformity (SDOC), to third-party independent testing, certification, and other conformity assessment requirements.

6.1.4 This guide further identifies hazards and risks for which a conformity assessment scheme can be developed.

6.2 Conformity assessment requirements should be tailored to meet the needs of product suppliers, users, and regulatory bodies.

6.2.1 PPE specification requirements should clearly define hazards for which the requirements are written to ensure conforming products provide adequate protection.

6.2.2 The risk associated with nonconformance should in part determine decisions relative to the conformity requirements' rigor and participant independence needed in a conformity assessment scheme.

6.2.3 Writers of CA requirements can use risk assessment methods and data to the extent that such are available; they also apply professional judgment and experience. Examples of safety and health considerations for assessing hazards and risks are indicated below:

High Hazard/Risk Considerations:

(1) Severity – Life threatening or serious injuries or illnesses are irreversible.

(2) Detectability – Nonconformance cannot be detected prior to use following supplier instructions for inspection, evaluation, or other suitable means.

(3) Medical attention – Required to care of critical injury or serious illness.

(4) Hospitalization – Required.

(5) Lost wages or time off work – Occurs.

(6) Probability of occurrence – High.

Medium Hazard/Risk Considerations:

(1) Severity – Serious injury or illness is reversible.

(2) Detectability – Nonconformance is not likely detected prior to use following supplier instructions for inspection, evaluation, or other suitable and reliable means.

(3) Medical attention – Required, including first aid.

(4) Hospitalization – May be required.

(5) Lost wages or days off work – May occur.

(6) Probability of occurrence – Medium.

Low Hazard/Risk Considerations:

(1) Severity – Injury or illness is not serious; may include discomfort, minor skin irritations or abrasions, etc.

(2) Detectability – Nonconformance is detected prior to use following supplier instructions for inspection, evaluation, or other suitable means.

(3) Medical attention – Not required.

(4) Hospitalization – Not required.

(5) Lost wages or days off work – Does not occur.

(6) Probability of occurrence – Low.

7. Conformity Assessment – Administrative Issues

7.1 The conformity assessment scheme is a means for managing hazards and risks associated with a nonconforming product. This requires participation by the conformity assessment stakeholders.

7.2 Conformity assessment stakeholders can include other organizations such as suppliers, purchasers, certification bodies, testing laboratories, regulatory bodies, trade associations, labor associations, etc.

7.3 Standards-writing groups are encouraged to engage in a thorough and thoughtful discussion of the advantages and disadvantages of independence and robustness of conformity assessment activities required to meet the hazard/risk assessed. Conformity assessment activities with greater independence and requirements' robustness can sometimes have unintended negative consequences, including being time consuming and expensive, and may not deliver proportional benefits to the user community. Conversely, conformity assessment activities with less independence and robustness, while cost effective, are reliant on claims from the manufacturer and may not be robust enough to serve stakeholder needs. (See Annex A2 for questions that can inform this discussion.)

7.4 The scheme owner is the person or organization with authority to develop and maintain a specific conformity assessment scheme. A scheme owner defines, operates, and monitors scheme performance and effectiveness, and adjusts the requirements of the scheme. For additional guidance refer to ISO/IEC 17067.

7.5 A conformity assessment scheme owner selects PPE specifications to which a product should conform to ensure that a product provides adequate protection for the defined hazard.

7.6 When conformity assessment requirements are defined in a PPE practice or specification, a scheme owner may be identified. Organizations serving as scheme owners may include certification bodies, regulatory bodies, trade associations, labor associations, suppliers, etc.

7.7 As a guide, the following considerations are helpful when identifying conformity assessment requirements and the conformity assessment scheme:

(1) Indicate the roles of various conformity assessment bodies that may have a role within the conformity assessment scheme.

(2) A contract or formal agreement may bind scheme participants to the requirements of the scheme.

(3) Identify and determine the contents of the conformity assessment scheme.

(4) A conformity assessment scheme may contain some of the following elements (source is ISO/IEC 17067 with modifications):[6]

(a) Scope of the conformity assessment scheme, including the type of product(s) covered,

(b) All requirements against which the product(s) are evaluated, including reference to standards or other normative documents,

(c) Selection of the activities appropriate to the purpose and the scope of the conformity assessment scheme,

(d) Requirements associated with the operation of a quality management system and product quality control for ongoing production of product(s),

(e) Requirements for conformity assessment bodies including accreditation (for example, testing laboratories, inspection bodies, product certification bodies, bodies auditing manufacturers' management systems),

Note: The use of accredited conformity assessment bodies can allow for the acceptance of test data or recognition of current certifications by conformity assessment bodies from other appropriate accredited conformity assessment bodies meeting all requirements.

(f) Methods and procedures to be used by the conformity assessment bodies and other organizations involved in the conformity assessment to ensure the integrity and consistency of the outcome of the conformity assessment processes,

(g) Information to be supplied to the various bodies in the scheme,

(h) Content of the statement of conformity (for example, certificate) which unambiguously identifies the product to which it applies,

(i) Conditions under which the statement of conformity or marks of conformity are used, the ownership, use, and control of the marks,

(j) Resources required for the operation of the conformity assessment scheme, including impartiality and competence of the personnel (internal and external), the evaluation resources, and the use of subcontractors,

(k) Determination (evaluation) and surveillance stages to be reported and used by the various conformity assessment bodies and by the scheme owner,

(l) Surveillance procedures,

(m) Procedures for how nonconformities with the scheme requirements, including product requirements, are to be dealt with and resolved,

(n) Criteria for access by conformity assessment bodies to the conformity assessment scheme and for the access of clients to the scheme,

(o) Content, conditions, and responsibility for publication of the directory of products by various bodies and the scheme owner,

(p) Content of various contracts including the rights, responsibilities, and liabilities of the various parties within the scheme such as between scheme owner, clients, and conformity assessment bodies,

(q) General conditions for granting, maintaining, continuing, extending the scope of, reducing the scope of, suspending, and withdrawing conformity declarations, including requirements for discontinuation of advertising and return of conformity documents and any other action if the declaration is suspended, withdrawn, or terminated,

(r) Requirements for complaints records are to be verified if such verification is part of the scheme,

(s) Rights and obligations for public declarations, and

[6]

(t) Requirements for retention of records by scheme owner and conformity assessment bodies.

8. Conformity Assessment – Activities and Requirements

8.1 This guide identifies conformity assessment activities with robustness and independence relative to the hazards and risk assessment considerations specified in Section 6.

8.2 Establishment of overall risk is often not an exact exercise. Risk is commonly considered to include the dual factors of likelihood of an event and seriousness of the consequences of the event. For PPE wearers subsequent outcome, such as the resultant health condition and resultant loss of work, are obvious factors.

8.2.1 A consideration is whether the nonconformity is detectable by the wearer prior to or during use, such that mitigation of hazard risk can be decreased. The hazard/risk categories used in this guide categorize these aspects of risk and associated hazard types.

8.3 Unrelated factors that can be addressed by training or closer supervision, such as a wearer improperly wearing the device, using the wrong device for the hazard, using a poorly fitting device, or not maintaining the device are not considered when establishing the overall hazard risk. Furthermore, the exercise should be based on reasonably expected outcomes for typical use as defined by supplier use instructions.

8.4 The following activities may be considered when developing a conformity assessment scheme: testing/inspection, attestation, surveillance, quality assurance, and use of marks.

8.5 For each activity, robustness and independence need to be determined that are suitable for the risk and other factors. See Annex A2 for considerations of other factors.

8.5.1 Aspects of robustness and independence include: accreditation and registration, use of third-party independence, surveillance, marking/branding, and other activities.

8.5.2 Testing laboratories, inspection bodies, and certification bodies should be accredited if a formal demonstration of competence to carry out specific conformity assessment tasks is needed.

8.5.3 Testing laboratories and inspection bodies must be independent of the supplier if independence is needed.

8.6 Table A2.1, Conformity Assessment Example Models (see Annex A2), provides a general association of assessed hazard/risk with conformity assessment variation of independence and robustness. Examples of detailed conformity assessment requirements relevant to each model are also contained in Annex A3. Other governmental regulations or national or international consensus standards (for example, ANSI/ISEA 125) may also be used to associate conformity assessment activities to meet the assessed hazard/risk.

9. Keywords

9.1 certification; conformity assessment; hazard; personal protective clothing and equipment; PPE; quality assurance; risk; supplier declaration; third-party testing

ANNEXES

(Mandatory Information)

A1. ADDRESSING HAZARDS THROUGH STANDARDS

A1.1 The NIOSH National Framework for PPE – Conformity Assessment Infrastructure[7] provides recommendations and guidance for effective demonstration and attestation that PPE conforming to requirements provide adequate protection by addressing hazards and risks.

A1.2 The requirements, as expressed in standards, identify the protection to which PPE must conform to sufficiently address the exposure to the hazard. They provide the link between identified hazards and activities of conformity. Typically, this is done in a standard through a simple statement, which connects identified hazards with a measurable protection requirement. The conformity assessment scheme owner should understand whether the end product PPE specifications are adequate in addressing specific hazards to define effective conformity assessment program activities. The example below shows how a standard addresses hazards and associated protection requirements.

ASTM Specification F1818 for Foot Protection for Chain Saw Users identifies the HAZARD from which conforming products are intended to protect by stating that "the objective of this specification is to prescribe […] criteria for footwear and foot protective devices, worn by chain saw operators, which are intended to reduce foot injuries caused by contact with a running power chain saw." The standard identifies the PROTECTION REQUIREMENTS necessary to in part mitigate the risk to this hazard. Requirements include areas of protection for:

•Height: "The chain saw cut resistance area of the upper test cut zone shall extend downward from a minimum height of 178 mm (7 in.)," and

•Toe area thickness and width: "Toe boxes at least 1.6 mm (0.60 in.)."

It also specifies performance requirements; such as:

•"The footwear shall demonstrate a minimum CS50 (the mean velocity at which cut through occurs) of 13.9 m/s (2750 fpm)," or

•"There shall be no cut through at 1.5 seconds when tested in accordance with Test Method F1458."

[7] The NIOSH National Framework for PPE – Conformity Assessment Infrastructure provides guidance that can be appropriately tailored and universally applied to all PPE that protects from a variety of risks regardless of the hazard, type, or environment. The Framework report defines a process that contains five steps that link the elements of the well-developed public health hierarchy of controls with those of CA. The report describes the foundational principles of CA to enable program owners to define the independence and rigor of CA requirements based on risk to workers from a nonconforming product. The Framework is supported by a checklist that provides guidance to allow prospective CA scheme owners to evaluate and then define an approach specific to their workplace needs.

A2. CONSIDERATIONS FOR DETERMINING CONFORMITY ASSESSMENT ACTIVITIES AND REQUIREMENTS

A2.1 In addition to the hazard/risk considerations discussed in 6.2.3, Table A2.1 provides descriptions of example conformity assessment models. Standards-writing groups are encouraged to engage in a thorough and thoughtful discussion of the advantages and disadvantages of independence and robustness of conformity assessment processes required to meet hazard/risk assessed. Conformity assessment activities with greater independence and robustness can sometimes have unintended negative consequences, including being time consuming and expensive, and may not deliver proportional benefits to the user community. Conversely, conformity assessment activities with less independence and robustness, while cost effective, are reliant on claims from the manufacturer and may not be robust enough to serve an industry's specific needs.

A2.2 The discussion should include a range of topics such as the following:

(1) Are there issues with nonconformity of current products in the field? Have these issues jeopardized wearer safety?

(2) What would be the costs or burdens to producers and users of any imposed conformity assessment scheme?

(3) Does the market of interest currently demand greater conformity assessment, including fully certified products?

(4) How would the various conformity assessment schemes benefit users? Do these benefits include improved safety? Are there benefits to users besides safety?

(5) How well would the current state of the industry, including the maturity of product design, manufacturing processes, and testing experience, support conformity assessment schemes based on a manufacturer's self-declaration? How well has manufacturing self-declaration worked up to now where it is currently allowed and widely used, and can similar performance of self-declaration techniques be reasonably expected going forward?

(6) How might requirements for greater independence and robustness of conformity assessment activities affect the availability of a variety of sizes, fits, and styles of product?

TABLE A2.1 Conformity Assessment Example Models

Conformity Activity	Example Models Increased confidence requires increased cost and resources			
Attestation	Supplier Supplier establishes requirements	Supplier SDOC meets ISO/IEC 17050, Parts 1 & 2	Certification Body (CB) CB is accredited to ISO/IEC 17065	Certification Body (CB) CB is accredited to ISO/IEC 17065
Testing & Inspection	*Independence* Supplier establishes *Robustness* Supplier establishes requirements	*Independence* Supplier establishes *Robustness* Testing Laboratory (TL) is accredited to ISO/IEC 17025	*Independence* CB establishes independence *Robustness* TL is accredited to ISO/IEC 17025	*Independence* Third party only *Robustness* TL is accredited to ISO/IEC 17025
Quality Management System (QMS)	Supplier maintains a QMS with appropriate scope	Supplier maintains a QMS with ISO 9001 certification with appropriate scope	Supplier maintains a QMS with ISO 9001 certification with appropriate scope; and additional CB requirements	Supplier maintains a QMS with ISO 9001 certification with appropriate scope; and additional CB requirements
Ongoing Conformity	Supplier monitors conformity and ensures product changes result in retesting or inspection	Supplier monitors conformity and ensures product changes result in retesting or inspection	CB establishes surveillance requirements	CB establishes surveillance requirements
Model Examples	A	B	C	D

(7) Will increased independence and robustness of conformity assessment curb the distribution of fraudulently labeled goods? If so, who will police the market?

(8) Can the current testing or certification infrastructure (or both), including the existence and availability of equipment and trained personnel both in commercial labs and within manufacturing organizations, support a contemplated conformity assessment scheme?

(9) Does the relevant performance standard provide guidance on how to properly label certified products? If not, can the standard be revised within a reasonable time to accommodate labeling for appropriate conformity assessment independence and robustness?

A3. GUIDANCE TO RELATE RISK TO CONFORMITY ASSESSMENT ACTIVITIES

NOTE A3.1—This Annex contains examples of conformity assessment requirements that may be used by standards writers to express conformity assessment requirements related to a specification standard. The example requirements of each model may be used in part or in total. As examples, these conformity assessment requirements use the terms SHALL, SHOULD and MAY. The use of SHALL does not denote a mandatory requirement in this guide; rather it indicates that if the example requirement is used in relation to a specification standard, this guide recommends that it be a mandatory requirement.

A3.1 Conformity Assessment – Models of Conformity – Model A Requirements (See Table A2.1)

A3.1.1 *General:*

A3.1.1.1 The supplier declaration of conformity (SDOC) is written as a declarative statement and clearly states that the product conforms to the complete specification unless the specification allows for claims of a subset of requirements. The supplier shall meet the requirements of A3.1, including all subsections.

A3.1.1.2 The supplier shall not claim conformity with portions or segments of the requirements of any PPE specification unless explicitly allowed by the PPE specification.

A3.1.1.2.1 The ASTM name or the name or identification of the PPE specification shall not be used in any supplier statements about their respective product(s) when conformity is to only portions of the specification unless explicitly allowed by the PPE specification.

A3.1.1.2.2 Component suppliers may claim conformity with portions or segments of the requirements of a PPE specification provided the component requirements are clearly defined with the PPE specification and the PPE specifications permits such claims.

A3.1.1.3 The supplier shall be responsible for issuing, maintaining and withdrawing a declaration of conformity.

A3.1.1.4 All items that are part of the declaration of conformity and are labeled as being conformant with a PPE specification or components conformant with applicable portions or segments of the PPE specification shall meet or exceed all applicable requirements in the PPE specification.

A3.1.2 *Supplier Declaration of Conformity (SDOC):*

A3.1.2.1 The supplier shall supply the following information in the declaration of conformity:

(1) Unique identification number of the declaration of conformity,

(2) Name and address of the issuer (supplier) of the declaration of conformity,

(3) Identification (model name or part number) of the item of the declaration of conformity,

(4) Statement of conformity,

(5) Identification of the PPE specification number, title, and edition,

(6) Test dates for all performance tests,

(7) Date of issue of the declaration of conformity, and

(8) Signature, name, and function of the person making the declaration.

A3.1.2.2 The supplier shall supply the following additional information if applicable:

(1) Name and address of any testing laboratories or certification bodies involved,

(2) References to relevant test reports and the date of such reports, and

(3) Additional information regarding certifications or registrations that have been obtained.

A3.1.3 *Testing/Inspection Facility and Criteria:*

A3.1.3.1 For declarations of conformity, the supplier shall conduct or have conducted on their behalf both inspection and testing as specified in this section.

A3.1.3.2 All inspections, conditioning, and testing for declaration of conformity shall be conducted by the supplier or on behalf of the supplier in a testing laboratory.

A3.1.3.3 The supplier shall be permitted to utilize conditioning and testing results conducted by a product or component supplier for declarations of conformity.

A3.1.3.4 Sampling for testing and inspection shall be established by the supplier to ensure confidence that the end product complies to the specification, unless such sampling is specified therein.

NOTE A3.2—It is the responsibility of the supplier to determine sampling requirements based on production volume.

A3.1.3.5 Inspection shall include a review of the user information required in the User Information section of the PPE specification to ensure that the information has been developed and is available.

A3.1.3.6 Inspection for determining conformity with the design requirements specified in the Design Requirements of the PPE specification shall be performed on whole or complete products.

A3.1.3.7 Testing to determine product conformity with the performance requirements specified in the Performance Requirements section of the PPE specification shall be conducted in accordance with the specified testing requirements of the test methods identified in the PPE specification.

A3.1.3.7.1 Testing shall be performed on samples with specimens representative of materials and components used in the construction of the item.

A3.1.3.7.2 Sample materials cut from a representative product shall be permitted to be used for evaluation.

A3.1.3.8 The supplier shall test only products or product components that are the same in every respect as the actual final product or product component.

A3.1.3.9 No modifications, pretreatment, conditioning, or other such special processes of the product or any product component prior to the product's evaluation and testing shall be permitted unless specified in the test methods of the PPE specification.

A3.1.3.10 No substitution, repair, or modification, other than as specifically permitted herein, of any product or any product component during testing shall be permitted.

A3.1.3.11 Test specimens that have been conditioned and tested for one method shall not be reconditioned and tested for another test method unless specifically permitted in the test method.

A3.1.4 *Quality Management System:*

A3.1.4.1 The supplier shall maintain a quality management system with a scope that includes the manufacture of the product to which conformity is affirmed. The quality management system shall ensure initial and ongoing conformity to the PPE specification to which attestation of conformity is made.

A3.1.5 *Record Retention:*

A3.1.5.1 The supplier shall maintain or cause to be maintained by subcontractors all design, performance, inspection, and test data used for the declaration of conformity. The supplier shall provide test data upon request to the purchaser or authority having jurisdiction.

A3.1.5.2 The supplier shall keep or cause to be maintained by the subcontractor all required technical documentation for the minimum period required by the conformity assessment scheme owner or specified in the PPE specification after the last of the personal protective equipment has been manufactured.

A3.1.6 *Ongoing Conformity:*

A3.1.6.1 The supplier shall establish and maintain a corrective and preventive action plan.

A3.1.6.2 The supplier shall evaluate any changes affecting the form, fit, or function of the product to determine its continued conformity to the PPE specification.

A3.1.6.3 Any change in the design, construction, or material of a product shall necessitate new inspection and testing to verify conformity to all applicable requirements of the PPE specification. This validation shall be conducted before labeling the modified product as being conformant with the PPE specification.

A3.1.6.4 Any revision to the PPE specification to which the product was evaluated shall necessitate new inspection and testing to verify conformity to all applicable requirements of the PPE specification. This validation shall be conducted before labeling the modified product as being conformant with the PPE specification. The time frame for revalidation and relabeling may be specified by the conformity assessment scheme owner or specified in the PPE specification.

A3.1.7 *Recalls and Safety Alerts:*

A3.1.7.1 The supplier shall have in place a documented product recall process as part of its quality management system to be used in the event that the personal protective equipment supplier decides, or is required by the certification body, to issue a product recall.

A3.1.8 *Mark/Logo:*

A3.1.8.1 All conformant items shall have a product label that meets the requirements specified in the PPE specification.

A3.1.8.2 The supplier's name and address shall be attached to the product label, shall be part of the product label, or shall be immediately adjacent to the product label.

A3.1.8.3 Inspection shall include a review of all product labels to ensure that all required label attachments, conformance statements, and other product information are at least as specified for the item in the Labeling Requirements section of the PPE specification.

A3.1.8.4 Inspection shall include an evaluation of any symbols and pictorial representations used on product labels or in user information, as permitted by the PPE specification, to ensure that the symbols are clearly explained in the product's user information package.

A3.2 Conformity Assessment – Models of Conformity – Model B Requirements (see Table A2.1)

A3.2.1 *General:*

A3.2.1.1 The process of supplier declaration with a certified quality management system for products as being conformant with a PPE specification shall meet the requirements of A3.2, Model B Requirements, and each of the A3.2 subsections.

A3.2.1.2 The supplier declaration of conformity is written as a declarative statement and clearly states that the product conforms to the complete specification unless the specification allows for claims of a subset of requirements.

A3.2.1.3 Component suppliers may claim conformity with portions or segments of the requirements of a PPE specification provided the component requirements are clearly defined with the PPE specification and the PPE specifications permits such claims.

A3.2.1.4 The supplier shall be responsible for issuing, maintaining, and withdrawing a declaration of conformity.

A3.2.1.5 All items that are part of the declaration of conformity and are labeled as being conformant with a PPE specification, or components conformant with applicable portions or segments of the PPE specification shall meet or exceed all applicable requirements in the PPE specification.

A3.2.1.6 The supplier declaration of conformity shall be of complete items as required by the individual PPE specification unless the specification allows for claims of a subset of requirements.

A3.2.1.7 The ASTM name or the name or identification of the PPE specification shall not be used in any statements about their respective product(s) when conformity is to only portions of the specification unless explicitly allowed by the PPE specification.

A3.2.2 *Attestation of Conformity – SDOC with Requirements of ISO/IEC 17050:*

A3.2.2.1 The supplier shall attest to the conformity of the product to the requirements of the PPE specification by issuing a supplier declaration of conformity.

A3.2.2.2 The supplier declaration of conformity shall be conformant to ISO/IEC 17050-1 and ISO/IEC 17050-2 and include the following information:

(1) Unique identification number of the declaration of conformity,

(2) The name and address of the issuer of the declaration of conformity,

(3) The identification (model name or part number) of the item of the declaration of conformity,

(4) The statement of conformity,

(5) The identification of the PPE specification number, title, and edition,

(6) The date of issue of the declaration of conformity,

(7) The signature, name, and function of the person making the declaration,

(8) The name and address of the testing laboratory(ies),

(9) The name of any certification bodies involved,

(10) References to relevant test reports and the date of such reports, and

(11) Additional information regarding certifications or registrations that have been obtained.

A3.2.3 *Testing/Inspection Facility and Criteria:*

A3.2.3.1 For declarations of conformity, the supplier shall conduct or have conducted on their behalf both inspection and testing as specified in this section.

A3.2.3.2 All inspections, conditioning, and testing for declarations of conformity shall be conducted by the supplier or on behalf of the supplier in a testing laboratory. The testing laboratory shall be accredited to ISO/IEC 17025 by an accreditation body that is a signatory to the ILAC. The scope of accreditation shall include the test being conducted or the product performance standard applicable to the product being tested.

A3.2.3.3 The supplier shall be permitted to utilize conditioning and testing results conducted by a product or component supplier, provided the laboratory generating results meets the requirements of A3.2.3.2.

A3.2.3.4 Sampling for testing and inspection shall be established by the supplier to ensure confidence that the end product complies to the specification, unless such sampling is specified therein.

A3.2.3.5 Inspection shall include an evaluation of any symbols and pictorial representations where required on product labels or in user information.

A3.2.3.6 Inspection shall include a review of the user information required in the User Information section of the PPE specification to ensure that the information has been developed and is available.

A3.2.3.7 Inspection for determining conformity with the design requirements specified in the Design Requirements of the PPE specification shall be performed on whole or complete products.

A3.2.3.8 Testing to determine product conformity with the performance requirements specified in the Performance Requirements section of the PPE specification shall be conducted in accordance with the specified testing requirements of the Test Methods section of the PPE specification.

A3.2.3.8.1 Testing shall be performed on specimens representative of material and components used in the construction of the item, as listed in the declaration of conformity.

A3.2.3.8.2 Sample material cut from a representative product shall be permitted to be used for evaluation.

A3.2.3.9 The supplier shall test or have tested only products or product components that are the same in every respect as the actual final product or product component.

A3.2.3.10 No modifications, pretreatment, conditioning, or other such special processes of the product or any product

component prior to the product's evaluation shall be permitted unless specified in the test method of the PPE specification.

A3.2.3.11 No substitution, repair, or modification of any product or any product component shall be permitted during testing, unless specifically authorized by the PPE specification.

A3.2.3.12 Test specimens that have been conditioned and tested for one method shall not be reconditioned and tested for another test method unless specifically permitted in the test method.

A3.2.4 *Quality Management System:*

A3.2.4.1 The supplier shall be certified to ISO 9001 (with respect to manufacturing personal protective equipment) by a registrar that is accredited as conforming to ISO/IEC 17021 by an accreditation body that is a signatory in good standing to IAF multilateral agreement for QMS (quality management system).

A3.2.4.2 The supplier quality management system shall include policies and procedures for declarations of conformity as specified in this guide.

A3.2.5 *Record Retention:*

A3.2.5.1 The supplier shall maintain or cause to be maintained by subcontractors all design, performance, inspection and test data used for the declaration of conformity for the minimum period required by the conformity assessment scheme owner or specified in the PPE specification after the last of the personal protective equipment has been manufactured.

A3.2.5.2 The supplier shall keep technical documentation or cause to be maintained by subcontractors for a minimum period specified by the scheme owner or in the PPE specification.

A3.2.6 *Ongoing Conformity:*

A3.2.6.1 The supplier shall establish and maintain a corrective and preventive action plan.

A3.2.6.2 The supplier shall evaluate any changes affecting the form, fit, or function of the product to determine its continued conformity to the PPE specification.

A3.2.6.3 Any change in the design, construction, or material of a product shall necessitate new inspection and testing to verify conformity to all applicable requirements of the PPE specification. This validation shall be conducted before labeling the modified product as being conformant with the PPE specification.

A3.2.6.4 Any revision to the PPE specification to which the product was evaluated shall necessitate new inspection and testing to verify conformity to all applicable requirements of the PPE specification. This validation shall be conducted before declaring the modified product as conforming to the PPE specification. The time frame for revalidation and relabeling may be specified by the conformity assessment scheme owner or specified in the PPE specification.

A3.2.7 *Recalls and Safety Alerts:*

A3.2.7.1 The supplier shall have in place a documented product recall process as part of its quality management system to be used in the event that the supplier decides, or is required by the certification body, to issue a product recall. The product recall process shall satisfy the certification body.

A3.2.8 *Mark/Logo:*

A3.2.8.1 All conformant items shall have a product label that meets the requirements specified in the PPE specification.

A3.2.8.2 The supplier's name and address shall be attached to the product label, or shall be immediately adjacent to the product label.

A3.3 Conformity Assessment – Models of Conformity – Model C Requirements (see Table A2.1)

A3.3.1 *General:*

A3.3.1.1 The process of certification for items as being conformant with a PPE specification shall meet the requirements of A3.3 Model C Requirements and all subsections of A3.3. The supplier shall use a laboratory that meets the independence requirements for the testing laboratory as defined by the certification body (that is, the certification body determines the policy for accepting test results from a first-party (supplier) or third-party testing laboratory).

A3.3.2 *Attestation of Conformity – Certification by an Accredited Certification Body:*

A3.3.2.1 All products that are labeled as being compliant with a PPE specification shall meet or exceed all applicable requirements specified in the PPE specification and shall be certified.

A3.3.2.2 The certification body shall be accredited for the scope of personal protective equipment in accordance with ISO/IEC 17065. The accreditation shall be issued by an accreditation body that is accredited as conforming to ISO/IEC 17011 and is a signatory to the International Accreditation Forum Multilateral Agreement (IAF MLA).

A3.3.2.3 The certification body shall have a program for initial determination of conformance of product models.

A3.3.2.4 At a minimum, the program shall include inspection, audit, and testing as required by the PPE specification, including the following:

(1) Labeling and marking as specified in the PPE specification,

(2) The supplier's applicable manufacturing facilities, and

(3) The supplier's management systems as specified in A3.3.4 and related procedures, records, and documentation.

A3.3.3 *Testing/Inspection Facility and Criteria:*

A3.3.3.1 For both initial determinations of conformance and surveillance, the certification body shall direct how inspection, audit, and testing shall be conducted as specified in this section or otherwise. The certification body shall require all inspections, conditioning, and testing for declaration of conformity to be conducted by a laboratory accredited to ISO/IEC 17025 by an accreditation body that is a signatory to the ILAC. The scope of accreditation shall include the test being conducted or the product performance standard applicable to the product being tested.

A3.3.3.2 The supplier shall use a laboratory that meets the independence requirements for the testing laboratory as defined by the certification body (that is, the certification body determines the policy for accepting test results from a first-party (supplier) or third-party testing laboratory).

A3.3.3.3 The certification body shall require the supplier to establish and maintain a quality assurance program that meets the requirements of the certification body.

A3.3.3.4 Inspection shall include:

(1) Review of applicable form and fit requirements under the PPE specification,

(2) Review of required product labels, and

(3) Review of any manufacturing facilities.

A3.3.3.5 Audit shall include a review of the following:

(1) Applicable form and fit requirements under the PPE specification,

(2) Required user information and technical data package where applicable,

(3) Personal protective equipment supplier's management systems as specified in A3.3.4 and related procedures, records, and documentation.

A3.3.3.6 The certification body shall not use conditioned specimens or test results provided by a supplier.

A3.3.4 *Quality Management System:*

A3.3.4.1 The supplier shall be certified to ISO 9001 (with respect to manufacturing personal protective equipment) by a certification body that is accredited as conforming to ISO/IEC 17021 by an accreditation body that is a signatory to the IAF MLA.

A3.3.5 *Record Retention:*

A3.3.5.1 The supplier shall maintain or cause to be maintained by the subcontractors at least the following records for the minimum period required by the conformity assessment scheme owner or specified in the PPE specification after the last of the personal protective equipment has been manufactured:

(1) Information provided by the certification body relating to the personal protective equipment or a particular product or model,

(2) Information prepared in response to the certification body's certification program-related activities,

(3) Returns and complaints related to certified products and actions taken in response, and

(4) Documentation related to certified product recall.

A3.3.6 *Ongoing Conformity:*

A3.3.6.1 The certification body shall have a surveillance program for conformant models, which after initial certification establishes the criteria for continued conformance/certification. All certified/conformant models shall undergo surveillance.

A3.3.6.2 At a minimum, the surveillance program shall include the following:

(1) Inspection of conformant products and audit of manufacturer's records annually, and

(2) Testing, either directly or by confirmation of supplier-performed testing, to the performance requirements for conformant product models as required by the PPE specification.

A3.3.6.3 The certification body shall use products from the supplier's production line or inventory, or from the open market, for surveillance inspection and surveillance testing.

A3.3.6.4 The supplier shall promptly notify the certification body in writing whenever the supplier determines that a certified product could be nonconformant, be unfit for the intended purpose, have failed in use, or involve a safety issue. The supplier shall provide information about its review to assist the certification body with its investigation.

A3.3.6.5 The supplier shall submit to the certification body any proposed change(s) to a conformant product model and related documentation prior to implementation of a change. The certification body shall evaluate the change(s) and impact to the product model and determine (*1*) which tests are required to be performed, if any, to demonstrate continued conformance, or (*2*) if the change is so significant that the change will result in a new product model.

A3.3.7 *Recalls and Safety Alerts:*

A3.3.7.1 The supplier shall have in place a documented product recall process as part of its quality management system to be used in the event that the supplier decides, or is required by the certification body, to issue a product recall. The product recall process shall satisfy the certification body.

NOTE A3.3—For further information and guidance on recall programs, see CFR Title 21, Part 7, Subpart C.

A3.3.7.2 The supplier shall notify the certification body of any safety alert or certified product recall not initiated by the certification body as soon as the decision to issue the same has been made.

A3.3.7.3 If the investigation reveals the certified product to be nonconformant, to be unfit for the intended purpose, to have failed in use, or to involve a safety issue, and action is indicated, the certification body shall take at minimum one or more of the following actions:

(1) Require the supplier to issue a safety alert, when, in the opinion of the certification body, such an alert is necessary or advisable to inform users or the public,

(2) Require the supplier to issue a product recall, when, in the opinion of the certification body, such a recall is necessary or advisable to protect users or the public,

(3) Suspend or withdraw the model certification,

(4) Remove the product from its certified product listing or annotate its certified product listing entry, as appropriate, to explain the action(s), and

(5) Take other action(s) as appropriate.

A3.3.8 *Mark/Logo:*

A3.3.8.1 The supplier shall not use a mark of conformity or reference to the certification body on any product other than a certified product.

A3.3.8.2 A certification body mark of conformity shall be part of, attached to, or immediately adjacent to a product label that otherwise satisfies the requirements for labeling in the PPE specification.

A3.3.8.3 The certification body mark of conformity shall be legibly printed.

A3.4 Conformity Assessment – Models of Conformity – Model D Requirements (see Table A2.1)

A3.4.1 *General:*

A3.4.1.1 The process of certification for items as being conformant with a PPE specification shall meet the requirements of Model D. The supplier shall use a laboratory that is independent to the supplier (that is, considered a third-party laboratory).

A3.4.2 *Attestation of Conformity – Certification by an Accredited Certification Body:*

A3.4.2.1 All products that are labeled as being conformant with a PPE specification shall meet or exceed all applicable requirements specified in the PPE specification and shall be certified.

A3.4.2.2 The certification body shall be accredited for the scope of personal protective equipment in accordance with ISO/IEC 17065. The accreditation shall be issued by an accreditation body that is accredited as conforming to ISO/IEC 17011 and is a signatory to the International Accreditation Forum Multilateral Agreement (IAF MLA).

A3.4.2.3 The certification body shall have a program for initial determination of conformance of product models.

A3.4.2.4 At a minimum, the program shall include inspection, audit, and testing as required by the PPE specification, including the following:

(1) Labeling and marking as specified in the PPE specification,

(2) The supplier's applicable manufacturing facilities, and

(3) The supplier's management systems as specified in A3.4.4 and related procedures, records, and documentation.

A3.4.3 *Testing/Inspection Facility and Criteria:*

A3.4.3.1 For both initial determinations of conformance and surveillance, the certification body shall direct how inspection, audit, and testing shall be conducted as specified in this section or otherwise. All inspections, conditioning, and testing for declarations of conformity shall be conducted by an independent testing laboratory. The testing laboratory shall be accredited to ISO/IEC 17025 by an accreditation body that is a signatory to the ILAC. The scope of accreditation shall include the test being conducted or the product performance standard applicable to the product being tested.

A3.4.3.2 The certification body shall require the supplier to establish and maintain a quality assurance program that meets the requirements of the certification body.

A3.4.3.3 Inspection shall include:

(1) Review of applicable form and fit requirements under the PPE specification,

(2) Review of required product labels, and

(3) Review of any manufacturing facilities.

A3.4.3.4 Audit shall include a review of the following:

(1) Applicable form and fit requirements under the PPE specification,

(2) Required user information and technical data package where applicable, and

(3) Personal protective equipment supplier's management systems as specified in A3.4.4 and related procedures, records, and documentation,

A3.4.3.5 The certification body shall not use conditioned specimens or test results provided by a supplier.

A3.4.4 *Quality Management System:*

A3.4.4.1 The supplier shall be certified to ISO 9001 (with respect to manufacturing personal protective equipment) by a certification body that is accredited as conforming to ISO/IEC 17021 by an accreditation body that is a signatory to the IAF MLA.

A3.4.5 *Record Retention:*

A3.4.5.1 The supplier shall maintain or cause to be maintained by the subcontractors at least the following records for the minimum period required by the conformity assessment scheme owner or specified in the PPE specification after the last of the personal protective equipment has been manufactured:

(1) Information provided by the certification body relating to the personal protective equipment or a particular product or model,

(2) Information prepared in response to the certification body's certification program-related activities,

(3) Returns and complaints related to certified products and actions taken in response, and

(4) Documentation related to certified product recall.

A3.4.6 *Ongoing Conformity:*

A3.4.6.1 The certification body shall have a surveillance program for conformant models, which after initial certification establishes the criteria for continued conformance/certification. All certified/conformant models shall undergo surveillance.

A3.4.6.2 At a minimum, the surveillance program shall include the following:

(1) Inspection of conformant products and audit of manufacturer's records annually, and

(2) Testing, either directly or by confirmation of supplier-performed testing, to the performance requirements for conformant product models as required by the PPE specification.

A3.4.6.3 The certification body shall use products from the supplier's production line or inventory, or from the open market, for surveillance inspection and surveillance testing.

A3.4.6.4 The supplier shall promptly notify the certification body in writing whenever the supplier determines that a certified product could be nonconformant, be unfit for the intended purpose, have failed in use, or involve a safety issue. The supplier shall provide information about its review to assist the certification body with its investigation.

A3.4.6.5 The supplier shall submit to the certification body any proposed change(s) to a conformant product model and related documentation prior to implementation of a change. The certification body shall evaluate the change(s) and impact to the product model and determine (*1*) which tests are required to be performed, if any, to demonstrate continued conformance, or (*2*) if the change is so significant that the change will result in a new product model.

A3.4.7 *Recalls and Safety Alerts:*

A3.4.7.1 The supplier shall have in place a documented product recall process as part of its quality management system to be used in the event that the supplier decides, or is required

by the certification body, to issue a product recall. The product recall process shall satisfy the certification body.

NOTE A3.4—For further information and guidance on recall programs, see CFR Title 21, Part 7, Subpart C.

A3.4.7.2 The supplier shall notify the certification body of any safety alert or certified product recall not initiated by the certification body, as soon as the decision to issue the same has been made.

A3.4.7.3 If the investigation reveals the certified product to be nonconformant, to be unfit for the intended purpose, to have failed in use, or to involve a safety issue, and action is indicated, the certification body shall take at minimum one or more of the following actions:

(1) Require the supplier to issue a safety alert, when, in the opinion of the certification body, such an alert is necessary or advisable to inform users or the public,

(2) Require the supplier to issue a product recall, when, in the opinion of the certification body, such a recall is necessary or advisable to protect users or the public,

(3) Suspend or withdraw the model certification,

(4) Remove the product from its certified product listing or annotate its certified product listing entry, as appropriate, to explain the action(s), and

(5) Take other action(s) as appropriate.

A3.4.8 *Mark/Logo:*

A3.4.8.1 The supplier shall not use a mark of conformity or reference to the certification body on any product other than a certified product.

A3.4.8.2 A certification body mark of conformity shall be part of, attached to, or immediately adjacent to a product label that otherwise satisfies the requirements for labeling in the PPE specification.

A3.4.8.3 The certification body mark of conformity shall be legibly printed.