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Designation: ~~F3050 – 22~~ F3050 – 22a

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.

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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.

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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

[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 PPE Conformity Assessment, Interoperability and Compatibility.

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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.

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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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.10 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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 (Withdrawn 2019)[4]

2.2 *Federal Regulations:*[5]

CFR Title 21, Part 7, Subpart C Recall Procedures

2.3 *ISO Standards:*[6]

ISO 9001:2015 Quality Management Systems – Requirements
ISO/IEC 17000:2004 Conformity Assessment – Vocabulary and General Principles
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

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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**

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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 non-governmental 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] 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] The last approved version of this historical standard is referenced on www.astm.org.
[5] Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, http://www.access.gpo.gov.
[6] 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.

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.

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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.

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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, 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.

3.1.22 *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.

3.1.23 *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 mitigate personal hazard(s).

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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.)

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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.

5.4 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.

5.4.1 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.

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

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

6. Conformity Assessment – Requirements as Related to Risk

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

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

6.1.2 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.

6.1.3 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:~~in Table 1.

~~*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.~~

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7. Conformity Assessment Schemes

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7.1 Conformity assessment schemes are a way to manage hazards and risks associated with a nonconforming product.

TABLE 1 Examples of Safety and Health Considerations for Assessing Hazards and Risks[A]

Considerations	Hazard/Risk Level				
	Low	Low/Medium	Medium	Medium/High	High
Severity	Injury or illness is not serious but may include discomfort, skin irritations or abrasions, etc.	Injury or illness is not serious but may include discomfort, skin irritations or abrasions, etc.	Serious injury is reversible	Serious injuries that are not life threatening but may not be reversible	Life threatening; serious injuries; illness is irreversible
Detectability	Nonconformance can be detected prior to use when following supplier instructions for inspection, evaluation, or other suitable means	Nonconformance may be detected prior to use when following supplier instructions for inspection, evaluation, or other suitable means	Nonconformance is not likely detectable prior to use when following supplier instructions for inspection, evaluation, or other suitable means	Nonconformance is not detectable prior to use when following supplier instructions for inspection, evaluation, or other suitable means	Nonconformance is not detectable prior to use when following supplier instructions for inspection, evaluation, or other suitable means
Medical Attention	Not required	Not required, but first aid may be necessary	Required, including first aid	Required	Required
Hospitalization	Not required	Not required	May be required	Required	Required
Lost Wages or Time Off Work	Does not occur	May occur, but limited	May occur, but limited	May occur	Occurs
Probability of Occurrence	Low	Low/Medium	Medium	Medium/High	High

[A] The severity considerations outlined in this table refer to acute hazards/risks only.

7.1.1 Conformity assessment scheme owners will define, operate, and monitor scheme performance and effectiveness, and adjust the requirements of the scheme. They will also select PPE specifications to which a product should conform to ensure that a product provides adequate protection for the defined hazard. For additional guidance, refer to ISO/IEC 17067.

7.2 Additional conformity assessment stakeholders can include other organizations such as suppliers, purchasers, certification bodies, testing laboratories, regulatory bodies, trade associations, labor associations, standards-writing groups, 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 in order to provide proportional benefits to the effort and cost associated. (See Annex A2 for questions that can inform this discussion.)

7.4 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.

7.5 As a guide for developing a scheme, the following considerations are helpful when identifying conformity assessment requirements:

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

(2) A conformity assessment scheme may contain some of the following elements (source is ISO/IEC 17067 with modifications):[7]

(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 conformity assessment scheme,

(d) Requirements associated with 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.

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(f) Methods and procedures to be used by the conformity assessment bodies and other organizations involved in the conformity assessment scheme that 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,

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(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

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

8. Conformity Assessment Scheme Activities

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 outcomes such as the resultant health condition and resultant loss of work are obvious factors.

8.2.1 One consideration to make 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 improper wearing of 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 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.

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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[8] 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

[8] 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.

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."

A2. CONSIDERATIONS FOR DETERMINING CONFORMITY ASSESSMENT ACTIVITIES AND REQUIREMENTS

A2.1 In addition to the hazard/risk considerations discussed in ~~6.1.3~~Table 1, Table A2.1 provides descriptions of example conformity assessment ~~models.~~ models and how they can be applied based on the hazards/risks assessed. 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.

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A2.2 ~~The~~ When deciding on a CA program, 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?

(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?

TABLE A2.1 Conformity Assessment Example Models

~~Conformity Activity~~	~~Example Models~~ ~~Increased confidence requires increased cost and resources~~				
Conformity Activity	Example Conformity Assessment (CA) Models (Increased confidence requires increased cost and resources)				
CA Model Designation	A	A1	B	C	D
Associated Risk/Hazard	Low	Low/Medium	Medium	Medium/High	High
~~Attestation~~ Attestation	~~Supplier~~ Supplier	~~Supplier~~ Supplier	~~Certification Body (CB)~~ Supplier	~~Certification Body (CB)~~ Certification body (CB)	Certification body (CB)
Attester Qualifications	Supplier establishes requirements	Supplier establishes requirements	SDOC meets ISO/IEC 17050, Parts 1 & 2	CB is accredited to ISO/IEC 17065	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~~	
Testing and Inspection	*Independence* Supplier establishes *Robustness* Supplier establishes	*Independence* Supplier establishes *Robustness* Testing Laboratory (TL) is accredited to ISO/IEC 17025	*Independence* Supplier establishes *Robustness* TL is accredited to ISO/IEC 17025	*Independence* CB establishes *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~~	
Quality Management System (QMS)	Supplier maintains a QMS with appropriate scope	Supplier maintains a QMS with appropriate scope	Supplier maintains a QMS with ISO 9001 accreditation and appropriate scope	Supplier maintains a QMS with ISO 9001 accreditation and appropriate scope; additional CB requirements	Supplier maintains a QMS with ISO 9001 accreditation and appropriate scope; 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~~	
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	Supplier monitors conformity and ensures product changes result in retesting or inspection	CB establishes surveillance	CB establishes surveillance
~~Model Examples~~	~~A~~	~~B~~	~~C~~	~~D~~	

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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 specification 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.

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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.

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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.

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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.

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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.