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Standard Guide for Conformity Assessment of Personal Protective Clothing and Equipment¹

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 document² 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 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.

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, 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

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.

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

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 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.

3.1.6 *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

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>.