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Standard Practice for Conformity Assessment of Metal Detectors Used in Safety and Security[1]

This standard is issued under the fixed designation F3356; 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 specification establishes the conformity assessment requirements for security systems and equipment. The design and testing requirements for a product's conformity assessment are specified in the applicable ASTM performance standards developed by the ASTM F12 Committee on Security Systems and Equipment.

1.2 Conformity assessment requirements ensure the consistent application of the ASTM performance standards and establishes requirements of the certification body's accreditation process and operation of certification programs.

1.3 Certification bodies, to acquire or maintain accreditation, shall meet and continue to meet the requirements established by this specification, including any matter incorporated by reference.

1.4 *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.*

1.5 *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:*[2]

F3020 Performance Specifications and Test Methods for Hand-Worn Metal Detectors Used in Safety and Security

F3278 Performance Specifications and Test Methods for Hand-Held Metal Detectors Used in Safety and Security

2.2 *ISO Standards:*[3]

ISO 9001:2008 Quality management systems – Requirements

ISO 9001:2015 Quality management systems – Requirements

ISO/IEC 17000 Conformity assessment – Vocabulary and general principles

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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.

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

[1] This practice is under the jurisdiction of ASTM Committee F12 on Security Systems and Equipment and is the direct responsibility of Subcommittee F12.60 on Controlled Access Security, Search, and Screening Equipment.

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[2] 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.

[3] 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.

3.1.5 *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 *complaint, n*—expression of dissatisfaction, other than an appeal, from any source.

3.1.8 *compliance/compliant, n*—the condition of a model meeting or exceeding all applicable requirements of the specified standard as determined pursuant and subject to this specification.

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

3.1.10 *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

3.1.11 *manufacturer, n*—a commercial enterprise engaged in fabricating a product.

3.1.12 *mark of conformity*—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.

3.1.13 *model, n*—the manufacturer's design, with unique specifications and characteristics, of a particular item.

3.1.14 *product, n*—one unit of a particular model.

3.1.15 *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.

3.1.16 *safety alert, n*—notification to users or the public of an actual or potential safety issue with a specific product(s) or model(s), including identification of the product(s) or model(s); a description of the concern, its ramifications, and how it was identified; recommended actions to be taken; or other relevant information, or combinations thereof.

3.1.17 *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.

3.1.18 *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.

3.1.19 *suspension, n*—temporary invalidation.

3.1.20 *withdrawal, n*—revocation or cancellation.

4. Certification Program for Standard F3278 and Standard F3020

4.1 *General Requirements:*

4.1.1 Each product model shall be certified in accordance with Standard F3020 for hand-worn metal detectors or Standard F3278 for hand-held metal detectors. Product models that are labeled as certified to either of those specifications shall meet all applicable requirements of that specification.

4.1.2 Suppliers shall not claim compliance with any part of the requirements of the applicable ASTM performance standard and shall not use the name or identification of either of those specifications in any statements regarding their respective products unless the product is certified to that specification.

4.1.3 Each compliant product model that has been certified and has entered the stream of commerce shall maintain its certification status throughout its shelf life.

4.1.4 A compliant product model shall have a product label that meets the requirements specified in the applicable ASTM performance standard and 4.4.

4.1.5 All certification shall be performed by a certification body that is independent of any supplier and meets the requirements specified in 4.2, in accordance with ISO/IEC 17065.

4.1.6 Certification bodies shall have a scope of accreditation to include this specification and the applicable ASTM performance standard. The accreditation shall be issued by an accreditation body that is a signatory to the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA).

4.1.7 The certification body shall use a testing laboratory that is independent of any supplier and is accredited to ISO/IEC 17025 for the scope of this specification by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

4.1.7.1 The certification body may use more than one testing laboratory for completion of all the required tests. However, the format of the data presented by the testing laboratory shall conform to the format given herein to facilitate accurate and consistent evaluation and comparison of the model tested.

4.1.8 The certification body shall have a program for initial determination of conformance of product models. At a minimum, the program shall include inspection, audit, and testing as required by the specification, including the following:

(1) Inspection of labeling and marking as specified in the applicable ASTM performance standard and 4.4,

(2) Visiting the supplier's applicable manufacturing facilities, and

(3) Auditing the supplier's management systems and related procedures, records, and documentation.

4.1.8.1 For surveillance audits where the manufacturer holds an ISO 9001:2008 or ISO 9001:2015 registration, the certification body shall perform a defined audit, which includes a limited review of the manufacturer's or supplier's Quality Management System. The audit shall include, at a minimum, a review of the ISO Certificate, the last two (2) audit reports issued by the ISO Registrar / Certification Body and corrective action close out report.

4.2 *Certification Body:*

4.2.1 For both initial determination of compliance and surveillance, the certification body shall conduct inspection, audit, and testing as specified in this section or as otherwise noted in this specification.

4.2.2 The certification body will accept, in their conformity assessment program, certification from other ISO 17065 accredited certification bodies for requirements in the ASTM standard that are described in other standards, which include: electromagnetic compatibility, environmental tolerance, and safety.

4.2.3 The certification body shall refuse to certify products that do not comply with all applicable requirements of this specification.

4.2.4 The contractual provisions between the certification body and the supplier shall specify that certification is contingent on compliance with all applicable requirements of this specification. There shall be no conditional, temporary, or partial certifications. Suppliers shall not be authorized to use any label or reference to the certification body on products that are not manufactured in compliance with all applicable requirements of this specification.

4.2.5 The certification body and the supplier shall identify each model for certification and the variants (if any) within each model.

4.2.6 The certification body shall require the supplier to establish and maintain a quality assurance program to include production inspection and testing that at least meets the requirements specified in 4.3. The certification body shall audit the supplier's quality assurance program to ensure that the quality assurance program provides continued product compliance with this specification.

4.2.7 The certification body shall conduct a surveillance quality audit and inspection program of the manufacturing facilities of the certified product with at least one visit per twelve-month period. As part of the annual quality audit and inspection program, the certification body shall select samples at random from the supplier's production line, the supplier's in-house stock, or the open market. These samples shall be inspected and tested by the certification body per 4.3 to verify the product's continued compliance. The number of samples submitted for initial certification testing shall be three. Each of these samples may not be tested for each and every requirement in the ASTM performance standard but all the requirements in the ASTM performance shall be tested using this set of three samples.

4.2.8 The certification body shall require the supplier to have a product recall system as part of the supplier's quality assurance program.

4.2.9 The certification body's name and label shall be registered and legally defendable.

4.3 *Inspection and Testing:*

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.

4.3.2 The inspection by the certification body shall determine compliance with the requirements specified in the applicable ASTM performance standard.

4.3.3 Product models that are identical to the product(s) that will be offered for sale shall be inspected and tested for certification in accordance with the applicable ASTM performance standard and shall meet the performance requirements of those specifications.

4.3.4 After initial certification to the applicable ASTM performance standard, product models from production shall be inspected and tested annually and shall meet the applicable performance requirements as specified in Annex A1 and Annex A2.

4.3.5 Any change in the design, construction, or material of a certified product model shall be reported to the certification body to determine what inspection and testing shall be conducted to verify compliance to all applicable requirements of this specification.

4.3.6 For inspection and testing for certification, the certification body shall accept from the supplier only product models that are identical in every respect to the final product or component. The certification body shall not permit the substitution, repair, or modification of any product model during testing.

4.4 *Certification Mark/Logo:*

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

4.4.2 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 as specified in the applicable ASTM performance standard.

4.4.3 The certification body mark of conformity shall be legibly printed.

4.5 *Certified Model Listing:*

4.5.1 The certification body shall maintain a certified product model listing of applicable models, including a web-based listing.

4.6 *Reports of Noncompliance, Lack of Fitness for Intended Purpose, Failure in Use, or Safety Issues:*

4.6.1 The certification body shall establish procedures for dealing with reports (or indications) from any source, including surveillance, that certified products are noncompliant, are unfit for the intended purpose, have failed in use, or involve a safety issue.

4.6.2 When a report is received by the certification body, the credibility of the report shall be investigated.

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

4.6.4 The certification body shall require the supplier to notify it of any safety alert or certified product recall not