Designation: E3215 – 19

Standard Practice for Certification of Less Lethal Aerosol Devices Used by Law Enforcement, Corrections, and Other Public Safety Officers[1]

This standard is issued under the fixed designation E3215; 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 practice establishes the certification requirements for less lethal aerosol devices used by law enforcement, corrections officers, and other public safety officers.

1.1.1 This practice is intended to be used by certification bodies and by purchasers and suppliers in the procurement of less lethal aerosol devices that meet Specification E3187/E3187M.

1.1.2 The performance, testing, labeling, documentation, and reporting requirements for certification are specified in Specification E3187/E3187M.

1.2 *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.*

1.3 *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]

E3108 Practice for Conformity Assessment of Protective Gloves Worn by Law Enforcement and Corrections Officers

E3187/E3187M Specification for Less Lethal Aerosol Devices Used by Law Enforcement, Corrections, and Other Public Safety Officers

2.2 *Other Standards:*

ISO 9000 Quality management systems – Fundamentals and vocabulary[3]

ISO 9001 Quality management systems – Requirements[3]

ISO/IEC 17000 Conformity assessment – Vocabulary and general principles[3]

ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies[3]

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories[3]

ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services[3]

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. **Practice E3108**

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

[1] This practice is under the jurisdiction of ASTM Committee E54 on Homeland Security Applications and is the direct responsibility of Subcommittee E54.08 on Operational 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.

3.1.4.1 *Discussion*—A certification body can be non-governmental or governmental (with or without regulatory authority), and can also be known as a certification organization.

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

3.1.6 *certified model listing, n*—a publicly accessible listing of certified models.

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

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

3.1.9 *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

3.1.10 *listed, adj*—included in a publicly accessible list published by an accredited certification body.

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

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

3.1.13 *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.

3.1.14 *surveillance, n*—systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

3.1.15 *third-party, adj*—independent of the person or organization that provides the product and of the user interests in that object.

3.1.16 *third-party certification, n*—conformity assessment activity that is performed by a person or body that is independent of the person or organization that provides the object and of user interests in that object.

4. General

4.1 Each product model shall be certified in accordance with Specification E3187/E3187M. Product models that are labeled as certified to Specification E3187/E3187M shall meet all applicable requirements of Specification E3187/E3187M. The certification program shall meet at least the criteria specified in Section 5 of this practice.

4.2 Suppliers shall not claim compliance with any part of the requirements of Specification E3187/E3187M and shall not use the name or identification of Specification E3187/E3187M in any statements regarding their respective products unless the product is certified to Specification E3187/E3187M.

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

4.4 A compliant product model shall have a product label that meets the requirements specified in Specification E3187/E3187M and Section 8 of this practice.

4.5 All certification shall be performed by a certification body that is independent of any supplier and meets the requirements specified in Specification E3187/E3187M, in accordance with ISO/IEC 17065.

4.6 Certification bodies shall have a scope of accreditation to include Specification E3187/E3187M. The accreditation shall be issued by an accreditation body that is a signatory to the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA).

4.7 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 Specification E3187/E3187M by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

4.8 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 Specification E3187/E3187M, including the following:

4.8.1 Inspection of labeling and marking as specified in Specification E3187/E3187M,

4.8.2 Visiting the supplier's applicable manufacturing facilities,

4.8.3 Auditing the supplier's management systems and related procedures, records, and documentation, and

4.8.4 Audit/inspection of all testing laboratory procedures utilized by the supplier to conduct OC spray, CS spray, and OC-CS blended spray batch testing.

5. Certification Program

5.1 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 Specification E3187/E3187M.

5.2 The certification body shall refuse to certify products that do not comply with all applicable requirements of Specification E3187/E3187M.

5.3 The contractual provisions between the certification body and the supplier shall specify that certification is contingent on compliance with all applicable requirements of Specification E3187/E3187M. 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 Specification E3187/E3187M.

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

5.5 The certification body shall require the supplier to establish and maintain a quality assurance program, registered to ISO 9001, to include production inspection and testing that at least meets the requirements specified in Section 6 of this

practice. The certification body shall audit the supplier's quality assurance program to ensure that the quality assurance program provides continued product compliance with Specification E3187/E3187M.

5.6 The certification body shall conduct a surveillance quality audit and inspection program of the manufacturing facilities of the certified products with at least one visit per twelve-month period. As part of the annual quality audit and inspection program, the certification body shall select 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 to verify the product's continued compliance.

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

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

6. Inspection, Audit, and Testing

6.1 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. (See Appendix X1 for a checklist of items assessed during this process.)

6.1.1 The inspection is of the product.

6.1.2 The audit is of the supplier's quality system.

6.2 The inspection by the certification body shall determine compliance with the requirements specified in Specification E3187/E3187M.

6.3 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 Specification E3187/E3187M and shall meet the requirements of Specification E3187/E3187M.

6.4 Any change in the design, construction, or material of a certified model shall necessitate new inspection and testing to verify compliance to all applicable requirements of Specification E3187/E3187M that the certification body determines can be affected by such change. Inspection and testing shall be conducted before labeling the modified product as compliant with Specification E3187/E3187M.

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

7. Surveillance Requirements

7.1 The certification body shall have a surveillance program for certified models to determine continued compliance, after initial certification, and all such models shall undergo surveillance and shall meet all the applicable performance requirements of Specification E3187/E3187M.

7.2 At a minimum, the surveillance program shall include the following:

7.2.1 Inspection and audit as specified in Section 6 of this practice, on a frequency of at least once per year; and

7.2.2 Annual testing to the performance requirements of Specification E3187/E3187M.

7.3 The certification body shall use products from the open market for surveillance inspection and surveillance testing.

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

8. Certification Mark/Logo

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.

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 Specification E3187/E3187M.

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

9. Certified Model Listing

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

10. Reports of Noncompliance, Lack of Fitness for Intended Purpose, Failure in Use, or Safety Issues

10.1 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.

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

10.3 The certification body shall require the supplier to promptly 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 and to assist the certification body with its investigation.

10.3.1 The certification body shall require the supplier to notify it 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.

10.4 If the investigation reveals the certified product to be noncompliant, 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, with prompt notice to the applicable government agency, shall take at minimum one or more of the following actions: