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An American National Standard

Standard Guide for Laboratory Monitors[1]

This standard is issued under the fixed designation E2335; 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.

INTRODUCTION

This guide is for use by laboratory monitors who observe interlaboratory testing performed by participating organizations that validate the legitimacy of test methods and also establish a base of data from which precision and bias statements are to be written. Interlaboratory testing is done to determine the validity of a test standard. Such testing requires diligence by adhering to the protocol established for performing the test in order to minimize variability which often exists between laboratories. Because laboratories differ in size, organization, management, personnel, facilities and environment there is always a potential for introducing variability in test results.

Laboratory monitors confirm that the participating facilities adhere to the test protocol as closely as possible, thereby improving the chances of a successful interlaboratory study. The laboratory monitor observes and assesses but does not perform the functions of an auditor or trainer; the laboratory monitor does not provide accreditation of a laboratory. Laboratory monitors should demonstrate expertise in both the content and the intent of the test method. The laboratory monitor is responsible to render a report to the appointing subcommittee. It is incumbent upon the laboratory monitor to maintain objectivity when working with participating laboratories.

Full-scale product fire tests are expensive, especially full-scale tests of bedding and home furnishings. The development of this standard is intended to ensure that the precision and bias developed for E05 standards demonstrates a high level of statistical validity.

This guide does not contain procedures for analysis of the test data obtained from an interlaboratory study. The user is directed to Practice E691, if the laboratory study includes six laboratories or more, and to Practice E2653 if the number of laboratories in the interlaboratory study is at least three, but less than six.

Using a laboratory monitor as part of an interlaboratory test program is optional. However, if a monitor is used, all of the laboratories in the project are to be included.

1. Scope

1.1 This guide provides a general outline, for use by a laboratory monitor, to assess the qualifications of a laboratory that has requested to participate in a specific ASTM interlaboratory test.

1.2 The preliminary assessment is based on observations made before initiation of any interlaboratory tests.

1.3 The subcommittee, which appoints the laboratory monitor, specifies the minimum requirements that an organization should meet to qualify as a participant for the interlaboratory test. If a laboratory qualification test (pretest) is to be included, see details in Section 13.

1.4 This fire standard can not be used to provide quantitative measures.

1.5 *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] This guide is under the jurisdiction of ASTM Committee E05 on Fire Standards and is the direct responsibility of Subcommittee E05.31 on Terminology and Services / Functions.

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1.6 *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]

E176 Terminology of Fire Standards

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

E1537 Test Method for Fire Testing of Upholstered Furniture

E1822 Test Method for Fire Testing of Stacked Chairs

E2653 Practice for Conducting an Interlaboratory Study to Determine Precision Estimates for a Fire Test Method with Fewer Than Six Participating Laboratories

2.2 *ISO Standards:*

ISO 13943 Fire Safety-Vocabulary[3]

ISO/IEC 17025 :2005 General Requirements for the Competence of Testing and Calibration Laboratories[3]

2.3 *Other Standard:*

A2LA R101 -General Requirements: Accreditation of ISO/IEC 17025 Laboratories (December 2016)[4]

3. Terminology

3.1 For definitions of terms used in this guide and associated with fire issues refer to the terminology contained in Terminology E176 and ISO 13943. In case of conflict, the definition given in Terminology E176 shall prevail.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *laboratory monitor, n*—a representative of a subcommittee who is appointed to determine if the qualifications, equipment, personnel, and level of skill at a test facility meet the criteria necessary to participate in an interlaboratory test protocol.

4. Significance and Use

4.1 These guidelines are intended to enable a laboratory monitor to perform onsite assessments of laboratory facilities. Accepted facilities will then participate in an interlaboratory test protocol to establish precision and bias for a particular ASTM standard.

4.2 This assessment is intended to determine that all of the participants have the necessary equipment, an understanding of the test method, and the minimum level of skill necessary to gather data that are to be used to establish precision and bias for the particular standard.

4.3 This guide is not intended to be used as a tool to qualify or accredit laboratories to perform any tests. Refer to ISO/IEC 17025 and to the A2LA R101 Document for further guidance on accreditation requirements.

5. Qualifications of a Laboratory Monitor

5.1 The laboratory monitor should demonstrate a level of expertise about the test method for which the interlaboratory test will be done.

5.2 Technical understanding of the test method is imperative in order to understand the principles of the measurements to be made during the test procedure.

5.3 The laboratory monitor should demonstrate objectivity. This includes not deriving any profit, commissions, or dividends from any commercial entity that performs the same or similar type of test evaluations.

6. Responsibilities of a Laboratory Monitor

6.1 Develop a checklist specific to the subject test method.

6.1.1 This checklist is to serve as a guide for the inspection of the laboratory during the initial qualification phase.

6.2 The laboratory monitor performs an inspection of the test laboratories to determine if the equipment conforms with that required to perform the test method, and if adequate training of the operators has been done.

6.3 Verify that the data acquisition system used by the laboratory is compatible with the data to be acquired; and that analysis of the data will provide results that are reliable and comparable to data obtained from other participants.

6.4 Following completion of every laboratory inspection, an assessment report, based on the Checklist described in Section 7, shall be completed and forwarded, with recommendations, to the sponsoring ASTM Subcommittee.

7. Checklist

7.1 The laboratory monitor's checklist is to be made available to participating laboratories, in advance of the preliminary assessment visit so that a self-evaluation is an option for the participating laboratory.

7.1.1 The checklist is a one-time, test specific document used as a guide by the laboratory monitor in assessing the following:

7.1.1.1 Management of the laboratory,

7.1.1.2 Test operator skill level,

7.1.1.3 Condition and calibration of the laboratory facilities and equipment,

7.1.1.4 Environmental conditions and facilities for conditioning specimens,

7.1.1.5 Handling and storage of the test materials and any reference materials, and

7.1.1.6 Appropriate handling of data to ensure that the validity of the data is not compromised.

7.2 Each test method and associated interlaboratory test requires development of a specific checklist. See Appendix X1 for an example of a checklist used in an ASTM E5.15 Interlaboratory Study.

[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), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland.

[4] Available from American Association for Laboratory Accreditation, 5202 Presidents Court, Suite 220, Frederick, MD 21703; www.a21a.org.

8. Management, Supervisor, and Operators

8.1 The environment established by management of the laboratory is expected to demonstrate support for the objectives of the interlaboratory test. The following demonstrate this type of support:

8.1.1 Have managerial staff that understands the purpose of the test, are supportive of the testing, and also have the authority and resources needed to see that the interlaboratory test is conducted as agreed, and in accordance with the established timetable.

8.1.2 Specify and document the responsibility, authority, and interrelations of all personnel who manage, perform or verify work affecting the quality of tests (chain of management).

8.1.3 Provide supervision by persons who have a functional knowledge of the test method, the apparatus, the objective of the test and the assessment of the results.

8.1.4 Have a quality system describing its commitment to good laboratory practices and quality of testing.

8.1.5 Have procedures for control and maintenance of documentation.

8.1.6 Have supervisors and personnel involved in testing who are trained and capable of performing the test.

8.1.7 Have sufficient personnel for backups.

8.1.8 Practice laboratory safety and good housekeeping.

9. Laboratory Physical Facilities and Environment

9.1 Laboratory facilities shall demonstrate adherence to recognized laboratory protocols and procedures. See documents referenced in Section 2 for guidance.

9.2 Laboratory accommodations, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of the test and safety of operators.

9.3 The environment in which testing is undertaken shall not invalidate the results or adversely affect the required accuracy of measurements.

9.4 The laboratory is to have facilities for the effective monitoring, control and recording of environmental conditions as specified in the test method.

9.5 There shall be effective separation between neighboring areas when the activities therein are incompatible.

9.6 Access to and use of all areas affecting the quality of testing shall be defined and controlled.

10. Laboratory Equipment and Reference Materials

10.1 Equipment shall meet the specifications of the test method.

10.2 Equipment shall be properly maintained with documentation, as appropriate.

10.3 Each item of equipment shall have calibration records, as appropriate.

10.4 Reference materials, if available, shall meet standards specified for the test.

10.5 Reference materials are to be properly stored and conditioned.

11. Test Materials

11.1 The laboratory system for identifying the items to be tested shall ensure that there is no confusion regarding the identity of such items at any time.

11.2 Upon receipt, the condition of the test items, including any abnormalities or departures from standard conditions as prescribed in the test method, are to be recorded.

11.3 The laboratory shall have procedures and appropriate facilities to avoid deterioration or damage to test items, during storage, prior to test specimen preparation and testing.

11.4 Where items have to be stored, or conditioned under specific environmental conditions, these conditions are to be maintained, monitored and recorded.

11.5 There shall be a procedure for receipt, retention and safe disposal of test items. Confidentiality of the sources of test items is to be maintained.

12. Records

12.1 The laboratory shall have a system for:

12.1.1 Maintaining clear and concise records.

12.1.2 If test results are to be transmitted by telephone, facsimile, email, or other electronic/electromagnetic means (for example, CD or DVD), follow a documented procedure that ensures the quality of the transmission.

13. Observation of Laboratory Qualification Testing (Pretest)

13.1 Verify the test specimen preparation protocol is followed, that is, randomization of samples and test specimen preparation.

13.2 Verify the test protocol is being followed in performing the test.

13.3 Document observations and report findings to the managing Subcommittee or Task Group. Recommend whether the laboratory is adequately qualified to proceed with the interlaboratory test program.