



# Standard Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data<sup>1</sup>

This standard is issued under the fixed designation E1323; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide covers key elements of an evaluation of a laboratory's measurement practices and the statistical analysis of the resulting data. This guide addresses an evaluation that covers a broad range of in-house quality measurements, some of which may be directly related to accreditation requirements.

1.2 This guide describes the documentation needed to verify the operation of the practices, and what parts of the data, to test and interpret to verify the quality of data being generated by the laboratory.

1.3 This guide does not specify or provide guidance for the establishment or assessment of a quality program.

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

E178 Practice for Dealing With Outlying Observations

E456 Terminology Relating to Quality and Statistics

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

E1169 Practice for Conducting Ruggedness Tests

E2554 Practice for Estimating and Monitoring the Uncertainty of Test Results of a Test Method in a Single Laboratory Using a Control Sample Program

E2587 Practice for Use of Control Charts in Statistical Process Control

### 2.2 ISO Standard:

ISO 9000–9001 Quality Management and Quality Assurance Standards<sup>3</sup>

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories<sup>3</sup>

<sup>1</sup> This guide is under the jurisdiction of ASTM Committee E11 on Quality and Statistics and is the direct responsibility of Subcommittee E11.20 on Test Method Evaluation and Quality Control.

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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>3</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

### 2.3 Other Standard:

ILAC/ISO Laboratory Accreditation Principles and Practice—Collected Reports 1979–1983<sup>4</sup>

## 3. Terminology

3.1 Terms are defined in Terminology E456.

## 4. Significance and Use

4.1 This guide is intended to provide guidance for an assessor to evaluate measurement practices of laboratories, the protocol for statistically analyzing the resulting data from these practices, and the statistical results from these practices.

4.2 This guide is generic in the sense that it covers the entire range of in-house quality measurement practices found in a testing laboratory, but the results of the described evaluation may be used by accrediting agencies if their requirements can be satisfied through the laboratory's existing quality data.

4.3 It is not the intent of this guide to serve as sole criterion for evaluating and accrediting laboratories. It is not intended to cover the important generic guidelines for evaluating the laboratory's quality program, which are contained in ISO/IEC 17025 and other equivalent standards.

## 5. Purpose of Evaluating Measurement Practices and the Statistical Analysis of the Resulting Data

5.1 Data generated from the measurement practices of a laboratory are evaluated to determine its capability to obtain accurate and precise data, and to determine if the laboratory correctly and efficiently analyzes and reacts to its own data.

## 6. Documentation of Measurement Practices and the Statistical Protocol for Analyzing the Resulting Data

### 6.1 Documentation Relative to Calibration:

6.1.1 The material to be measured should be documented together with its source, expiration or shelf-life date, the accuracy and its source, and any preparations or conditions required which are specific to this material before it can be utilized as a calibration material. Any additional components,

<sup>4</sup> ILAC/ISO Laboratory Accreditation-Principles and Practice-Collected Reports 1979–1983. American Association for Laboratory Accreditation, 656 Quince Orchard Rd. #704 Gaithersburg, MD 20878.