



Standard Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data¹

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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 provides an overview of the documentation needed for verification and monitoring of the practices used in the laboratory for measurement. In addition, it guides the user in verifying that the extent of documentation and the quality of statistical evaluations performed on the data being generated is sufficient. The user is advised to fully document all work covered by the scope of this guide as a general principle of laboratory practice and for audit purposes, whether internal or external.

1.3 This guide is not designed to be exhaustive for all aspects of work realized under its scope. The user is encouraged to thoroughly realize (achieve in practice) the principles set forth in this guide, consulting other relevant standards and industry documents when appropriate.

2. Referenced Documents

2.1 ASTM Standards:²

- E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods
- 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 Using Control Chart Techniques

¹ 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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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.

E2587 Practice for Use of Control Charts in Statistical Process Control

E2655 Guide for Reporting Uncertainty of Test Results and Use of the Term Measurement Uncertainty in ASTM Test Methods

3. Terminology

3.1 Terms are defined in Terminology E456.

4. Significance and Use

4.1 This guide is intended to provide guidance for laboratory quality managers, accrediting bodies and assessors in evaluating the measurement practices of a laboratory, 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, and the results of the described evaluation may be used by accrediting agencies for assessment purposes to determine whether their requirements can be satisfied through the laboratory's existing quality data program.

4.3 It is not the intent of this guide to serve as sole criterion for evaluating and accrediting laboratories. Evaluation of measurement practices is only one aspect in a comprehensive quality program.

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 bias and precision performance, 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 any preparations or conditions required which are specific to this material before it can be utilized as a calibration material. Any additional components, reagents, or