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An American National Standard

Standard Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data[1]

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 (ε) 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~~ provides an overview of the documentation needed ~~to verify the operation of the practices, and what parts of the data, to test and interpret to verify~~ 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 ~~by the laboratory.~~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 ~~does not specify or provide guidance for the establishment or assessment of a quality program.~~ 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
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

~~2.2 *ISO Standard:*~~

~~ISO 9000–9001 Quality Management and Quality Assurance Standards~~[3]
~~ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories~~[3]

~~2.3 *Other Standard:*~~

~~ILAC/ISO Laboratory Accreditation Principles and Practice—Collected Reports 1979–1983~~[4]

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~~ laboratory quality managers, accrediting bodies and assessors in evaluating the measurement practices of ~~laboratories,~~ a laboratory, the protocol for statistically analyzing the resulting data from these practices, and the statistical results from these practices.

[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.

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~~and the results of the described evaluation may be used by accrediting agencies ~~if~~ for assessment purposes to determine whether their requirements can be satisfied through the laboratory's existing quality ~~data.~~data program.

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.~~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 ~~capability to obtain accurate and precise data,~~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 its source, and~~ 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 physical sources used along with this material, which could potentially alter the reliability of the material, should also be documented.

6.1.2 The identification of the equipment used, together with the date and operator responsible for the run, and any preparations involved with the calibration run should be documented.

6.1.3 The type of data representation to be used, including the exact number of data points to be used in the computation of an average, standard deviation, or range, as well as how and when these data points are to be generated should be documented. This requires information regarding testing of replicates, duplicates, or single runs tested on one day, a series of days, or a specific time interval to be clearly stated for each set of data.

6.1.4 The mathematical formula for obtaining control limits, the frequency of computing new limits together with rules of acceptability of the new limits, should be documented whenever control limits are applied to a chart.

6.1.5 The corrective action taken whenever data points indicate that an out of control condition exists, or whenever trend analysis indicates a change or shift in the instrument response should be recorded.

6.1.6 A table of actual measured values for each calibration or calibration check, the corresponding reference value, and the corresponding date should be documented.

6.2 *Documentation Relative to Method Precision:*

6.2.1 The precision of each test method used in the laboratory should be determined using Practice E691 or other equivalent standards.

6.2.2 The reference of the specific method being followed for each set of data, as well as any changes to the method should be documented. If a method has not been published, then the laboratory should prepare a detailed procedure.

6.2.3 The type of run (duplicate, replicate, single) used to generate the data points, including specific directions on how to prepare and test a duplicate or replicate specimen, should be documented.

6.2.4 The time interval for testing, or a date for each data point if a time interval is not practical, should be documented.

6.2.5 Directions on how to statistically compare the laboratory results of precision with a known statement of precision for that method should be documented. These directions should include the specific statistical test, the number of data points used for the test and the acceptable level of precision, be it known either from other studies on this specific method or as a limit determined by the laboratory itself.

6.2.6 The method for determining if outliers exist should be according to Practice E178 or other equivalent standards.

6.2.6.1 The method should be documented, stating when it is acceptable to ignore such data points when computing control limits.

6.2.6.2 Outliers, which were not used in the computation of control limits, should be documented.

6.2.7 The precision of each test method used in the laboratory should be documented.

6.2.8 The precision of a test method should be documented in the test report for that method.

6.3 *Documentation Relative to Instrument or Method Bias:*

6.3.1 The method for determining if bias exists and the frequency for continued checks on the instrument or method having a bias should be documented, including any adjustments made to the test data as a result of the bias determined from these ~~measurements.~~measurements (see Practice E177).

6.3.2 A table of actual values and the corresponding dates should be documented for each instrument and method used in the laboratory.

6.3.3 The bias of an instrument or method should be documented in the test report for that instrument or method.

6.4 *Documentation Relative to Operator Precision and Bias:*

6.4.1 The material, methods, and equipment used to determine levels of operator precision and bias should be documented.