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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 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.

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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

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to 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.

[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.

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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 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 (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.

6.4.2 The source of stated bias of the material, the current precision and bias of the equipment, and the current precision and bias of the method should be documented, together with the exact computations used to determine the single or group operator precision, bias, or both.

6.4.3 The number of data points generated per operator for this comparison test as well as the protocol design should be documented.

6.4.4 The limits of acceptability for both operator bias and operator precision should be documented.

6.4.5 The records should show the frequency of obtaining operator bias and operator precision as well as the corrective action taken whenever an operator fails to meet the limits of acceptability.

6.4.6 A table of actual measured values, the corresponding reference values, and corresponding dates for each operator should be documented.

6.5 *Documentation Relative to Uncertainty:*

6.5.1 The uncertainty of results for each test method used in the laboratory should be determined according to Practice E2554 or Guide E2655 or other equivalent standards.

6.5.2 The actual measured values and the corresponding date used in the calculation of uncertainty should be documented.

6.5.3 The uncertainty of each test method used in the laboratory should be documented.

6.5.4 The uncertainty of a test method should be documented in the test report for that method.

6.6 *Documentation Relative to Ruggedness:*

6.6.1 The ruggedness of each test method used in the laboratory should be determined according to Practice E1169 or other equivalent standards.

6.6.2 The factors used in the ruggedness study, their magnitude, statistical significance and date of the study should be documented.

6.6.3 The experimental design, factor settings and actual measured values for each experimental run should be documented.

6.6.4 The statistically significant ruggedness factors should be documented for each test method used in the laboratory.

6.6.5 The factor settings for each statistically significant factor in a method should be documented in the test report for that method.

7. Evaluation of the Laboratory's Measurement Practices and of the Statistical Analysis from the Resulting Data

7.1 1 A general overview of the laboratory's documentation of measurement practices and the statistical analysis of the data should be made, verifying that all practices cited are actually in use and the rules stated by the laboratory for the generation and use of the data are followed.

7.2 A walk-through of the laboratory to verify the location of all data representation charts should be made. Discussions with laboratory personnel to verify their knowledge of the measurement practices also should be made.

7.3 The choice of representation of the data, as well as the generation of control chart limits, should be reviewed to determine if appropriate models have been used for each type of population. For further information, see Practice E2587.

7.4 Each piece of equipment used in the laboratory to generate a test result should be calibrated on a periodic basis. The raw data from the calibration records should be compared to the status indicated for that piece of equipment. Every raw data point outside of control limits or outside of specification limits should have a corresponding documented corrective action which resulted in restoring the equipment to normal operation (status of in calibration) or resulted in a recommendation for further work (status of out of calibration). Dates and results from the raw data should agree with the status shown on that piece of equipment.

7.5 All charts should be viewed for trend analysis. Checks of trends or shifts should be documented, including the interpretation of those found to be beyond acceptance limits by laboratory personnel as well as the corrective action taken. This information does not have to be on the chart itself, but it should be documented somewhere by the laboratory and available for review upon request by the assessor.

7.6 All data calculations for any kind of limits, be it for accuracy or precision of equipment, precision or bias of methods, or bias or precision of an operator, should be reviewed to determine if the appropriate type of chart has been used and the optimum number of data points have been used.

7.7 Spot checks of the raw data should also be made to verify that no data point is being disregarded unless an outlier test has indicated that the data point can be omitted from the calculation of control limits. The outlier is still documented as a check and listed in the table of data with corresponding dates.

7.8 Raw data checks should also be made to verify the frequency of testing for calibration. For example, a measurement practice that requires a replicate be tested on 1 of every 10 specimens received, should show, through raw data, that the appropriate number of replicate tests were performed, reported, and transferred to the corresponding chart.

8. Use of the Evaluation by Accrediting Bodies

8.1 An accrediting body may use the evaluation to determine the methods of monitoring the quality control of the laboratory, such as the extent and frequency of future on-site visits to the laboratory, review of the data from the measurement practices, and review of the data from proficiency testing programs to verify the laboratory's continued state of statistical control.

9. Keywords

9.1 accreditation; laboratory accreditation; laboratory measurement practices; statistical analysis

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