



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

This standard is issued under the fixed designation E 1323; 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.

^{ε1} NOTE—Section 9 on Keywords was added editorially July 1994.

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 what to look for as documentation in order to verify the operation of the practices, and what parts of the data to test and interpret in order 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.

NOTE 1—Generic guidelines dealing with elements of a quality program may be found in ANSI, A1, A3, Q1, Q2, Z34.1; ISO9000–9004; and ILAC/ISO Collected Reports 1979–1983.²

2. Referenced Documents

2.1 ASTM Standards:

E 548 Practice for Preparation of Criteria for Use in the Evaluation of Testing Laboratories and Inspection Bodies³
E 994 Guide for Laboratory Accreditation Systems³
E 1187 Terminology Relating to Laboratory Accreditation³

2.2 ANSI Standards:

ANSI/ASQC A1 Definitions, Symbols, Formulas and Tables for Control Charts⁴
ANSI/ASQC A3 Quality Systems Terminology⁴
ANSI/ASQC Q1 Generic Guidelines for Auditing of Quality Systems⁴
ANSI/ASQC Q2 Quality Management and Quality System Elements for Laboratories—Guidelines⁴
ANSI Z34.1 American National Standard for

Certification—Third Party Certification Program⁴

2.3 ISO Standard:

ISO 9000–9004 Quality Management and Quality Assurance Standards³

2.4 Other Standard:

ILAC/ISO Laboratory Accreditation—Principles and Practice—Collected Reports 1979–1983⁴

3. Terminology

3.1 Terms are defined in Terminology E 1187.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *duplicate*—a separate specimen, taken from the same source as the first specimen, tested at the same time and in the same manner as the first specimen. Duplicates can provide pooled precision data for a homogeneous specimen, the test method, and the test equipment.

3.2.2 *out of control*—the condition that exists when a data point falls outside the control limits and when retesting and further evaluation indicates that a problem exists in analyst performance, the method, equipment, standardization, or calibration.

3.2.3 *replicate analysis*—the same specimen tested again, usually at a different time. Replicate data can be used to provide pooled precision of the test method, equipment, and operator, providing the specimen is homogeneous in nature.

4. Significance and Use

4.1 This guide is intended to provide guidance for an assessor to evaluate measurement practices of laboratories, their protocol for statistically analyzing the resulting data from these practices, and their 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 can be found in Practice E 548 and Guide E 994.

¹ This guide is under the jurisdiction of ASTM Committee E-36 on Criteria for the Evaluation of Testing and Inspection Agencies and is the direct responsibility of Subcommittee E36.60 on Laboratory Accreditation Operations.

Current edition approved Dec. 29, 1989. Published February 1990.

² ILAC/ISO Laboratory Accreditation-Principles and Practice-Collected Reports 1979–1983. American Association for Laboratory Accreditation, 656 Quince Orchard Rd. #704 Gaithersburg, MD 20878

³ *Annual Book of ASTM Standards*, Vol 14.02.

⁴ Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

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 is evaluated to determine its capability to obtain accurate and precise data and to determine if the laboratory correctly and efficiently analyzes and reacts to their own data.

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

6.1 The following documentation shall contain the information necessary for someone to carry out the same steps involved in generating, charting, and reporting the data.

6.1.1 Documentation Relative to Calibration:

6.1.1.1 The material to be measured must 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, reagents, or physical sources used along with this material which could potentially alter the reliability of the material must also be documented.

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

6.1.1.3 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 must 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.

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

6.1.1.5 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 must be recorded.

6.1.1.6 A table of actual values for each calibration or calibration check and the corresponding date must be kept.

6.1.2 Documentation Relative to Method Precision and Bias:

6.1.2.1 The reference of the specific method being followed for each set of data, as well as any changes to the method must be documented. If a method has not been published, then the laboratory is responsible for preparing a detailed procedure.

6.1.2.2 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, must be recorded.

6.1.2.3 The time interval for testing, or a date for each data point if a time interval is not practical, must be noted.

6.1.2.4 Directions on how to statistically compare the laboratory results of precision with a known statement of precision for that method must be clearly documented. These directions

must 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.

6.1.2.5 The method for determining if outliers exist must also be documented, stating when it is acceptable to ignore such data points when computing control limits.

6.1.2.6 The method for determining if bias exists and the frequency for continued checks on the instrument or method having a bias must be recorded, including any adjustments made to test data as a result of the bias determined from these measurements.

6.1.2.7 A table of actual values and the corresponding dates must be kept.

6.1.3 Documentation Relative to Operator Precision and Accuracy:

6.1.3.1 The material, methods, and equipment used to determine levels of precision and accuracy of operators must be documented.

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

6.1.3.3 The number of data points generated per operator for this comparison test as well as the type (duplicate, replicate or single) and description of the type of runs being made. It must be clearly stated which runs are related to the accuracy and which are related to precision.

6.1.3.4 The limits of acceptability for both operator accuracy and operator precision must be noted.

6.1.3.5 The records must show the frequency of obtaining operator accuracy and precision as well as the corrective action taken whenever an operator fails to meet the limits of acceptability.

6.1.3.6 A table of actual values and corresponding dates for each operator must also be documented.

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

7.1 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 that 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 must be made as well as general discussions with laboratory personnel to verify their knowledge of the measurement practices.

7.3 The choice of representation of the data, as well as the generation of control chart limits must be reviewed to determine if appropriate models have been used for each type of population. For further information, see *ASTM STP 15D*.⁵

7.4 The raw data from the calibration records must be compared to status indicated for that piece of equipment. Every

⁵ *Manual on Presentation of Data and Control Chart Analysis, ASTM STP15 D, ASTM, 1982.*