



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 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

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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.