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An American National Standard

Standard Guide for Proficiency Testing by Interlaboratory Comparisons[1]

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ϵ^1 NOTE—Annex A3 was deleted editorially in March 1998.

INTRODUCTION

Proficiency testing is the use of interlaboratory test comparisons to determine the performance of individual laboratories for specific tests and to monitor the consistency and comparability of a laboratory's test data.

Interlaboratory test comparisons are conducted for a number of other purposes including:

(*1*) Check the consistency and comparability of data for individual testing personnel;

(*2*) Assist in maintaining the calibration of instrumentation;

(*3*) Establish the effectiveness and comparability of new test methods;

(*4*) Achieve commercial improvement;

(*5*) Assist in determining reasons for interlaboratory differences;

(*6*) Determine the precision of a test method—often known as interlaboratory studies (see Practice E 691E 691), collaborative trials, or round-robins; and

(*7*) Assign values to certified reference materials (CRMs).

Participation in proficiency testing programs provides laboratories with an objective means of assessing and demonstrating the reliability of the data they are producing. Although there are several types of proficiency testing programs, they all share the common feature of the comparison of test results obtained by two or more laboratories.

One of the main uses of proficiency testing programs is to assess laboratories' ability to perform tests competently. It thus supplements laboratories' own internal quality control procedures by providing an additional external evaluation of their testing capability. These activities also complement the technique of on-site laboratory assessment by technical specialists usually used by laboratory accrediting bodies. Confidence that a testing or calibration laboratory consistently obtains reliable results is of major importance to users of laboratory services. Users seeking such an assurance may undertake their own evaluation or may use the evaluation of other bodies.

Bodies assessing the technical competence of testing laboratories normally require or expect satisfactory participation in proficiency testing as evidence of a laboratory's ability to produce reliable test results, except where proficiency testing is inappropriate. However, it is emphasized that a major distinction exists between:

(*1*) The evaluation of the competence of a laboratory by the assessment of its total operation against pre-determined requirements, and

(*2*) The examination of the results of a laboratory's participation in proficiency testing which may only be considered as giving information about the technical competence of the testing laboratory at a single point of time under the specific conditions of the test for tests involved in a particular proficiency testing program.

1. Scope

1.1 While there are a number of uses for interlaboratory tests, and variations in their design and implementation, it is still possible to specify the essential principles that need to be considered when organizing such tests. Part A of this guide

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defines those principles and describes the factors that should be taken into account in the organization and conduct of proficiency testing programs.

1.2 This guide also covers how laboratory accrediting bodies, which assess technical competence of testing laboratories, should select and use proficiency testing programs (refer to Part B).

1.3 Part A of the guide is intended for use by various parties, such as accrediting bodies, regulatory authorities and clients of laboratory services which have a need to assess the technical competence of laboratories. It is also useful for laboratories in self-evaluation, but recognizes that proficiency testing is only one mechanism that can contribute to establishing equivalent confidence among users of different testing laboratories.

1.4 It is currently a condition of some accreditation bodies that laboratories participate regularly in "approved" proficiency testing programs. Therefore, it is essential that program operators comply with principles for conduct of professionally managed proficiency programs, both in terms of technical requirements and quality management (see Annex A1 and Annex A2).

1.5 The methods of operation within different proficiency testing organizations are not expected to be identical and this guide does not give specific operational details for interlaboratory test comparisons. It does, however, cover both measurement comparison and testing programs in which large numbers of laboratories (over 20) or small groups of laboratories (1 to 20) are tested. Therefore, the contents of this guide are intended only as a framework to be modified appropriately for particular situations.

1.6 A list of some relevant references is given in Appendix X1.

2. Referenced Documents

2.1 *ASTM Standards:*

E 178 Practice for Dealing with Outlying Observations[2]

E 456 Terminology Relating to Quality and Statistics[2]

E 548 Guide for General Criteria Used for Evaluating Laboratory Competence[2]

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[2]

E 1187 Terminology Relating to Laboratory Accreditation[2]

2.2 *ANSI Standard:*[3]

ANSI/ISO/ASQC Q9000 Series: Quality Management and Quality Assurance Standards

2.3 *ISO Standards:*

ISO/IEC Guide 2, General Terms and Their Definitions Concerning Standardization and Related Activities[3]

ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories[3]

ISO Guide 30, Terms and Definitions Used in Connection with Reference Materials[3]

3. Terminology

3.1 *Definitions*—For formal definitions related to laboratory accreditation, Terminology E 1187E 1187 applies. For formal definitions related to quality and statistics, Terminology E 456E 456 applies. In addition, the following terms and their definitions are provided for ease of reference.

3.1.1 *accuracy*—the closeness of agreement between a test result and an accepted reference value (Terminology E 456E 456 without the note).

3.1.2 *bias*—the difference between the population mean of the test results and an accepted reference value (Terminology E 456E 456 without the discussion).

3.1.3 *certified reference material (CRM)*—a reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure that establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence (ISO Guide 30 without the notes).

3.1.4 *precision*—the closeness of agreement between test results obtained under prescribed conditions (Terminology E 456E 456 without the three notes).

3.1.5 *proficiency testing (laboratory)*—determination of laboratory testing performance by means of interlaboratory comparisons (ISO/IEC Guide 2).

3.1.6 *reference material*—a material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials (ISO Guide 30 without the note).

3.1.7 *repeatability*—the closeness of agreement between test results obtained under repeatability conditions (that is, conditions under which test results are obtained with the same test method in the same laboratory by the same operator with the same equipment in the shortest practical period of time using test units or test specimens taken at random from a single quantity of material that is as nearly homogeneous as possible (Terminology E 456E 456 without the notes).

3.1.8 *reproducibility*—the closeness of agreement between test results obtained under reproducibility conditions (that is, conditions under which test results are obtained with the same test method on identical material in different laboratories (Terminology E 456E 456 without the notes).

3.1.9 *test*—technical operation that consists of determination of one or more characteristics of a given product, process or service according to a specified procedure (ISO/IEC Guide 2).

3.1.10 *trueness*—the closeness of agreement between the population mean of the measurements or test results and an accepted reference value (Terminology E 456E 456 without the note).

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *accepted reference value*—a value that serves as an agreed-upon reference for comparison and which is derived as: (*1*) a theoretical or established value, based on scientific principles, (*2*) an assigned value, based on experimental work of some national or international organization, and (*3*) a

[2] *Annual Book of ASTM Standards*, Vol 14.02.

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.