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Standard Guide for Proficiency Testing by Interlaboratory Comparisons[1]

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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 E691), 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 defines those principles and describes the factors that should be

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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:*[2]

E178 Practice for Dealing With Outlying Observations

E456 Terminology Relating to Quality and Statistics

E548 Guide for General Criteria Used for Evaluating Laboratory Competence[3]

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

E1187 Terminology Relating to Conformity Assessment[3]

2.2 *ANSI Standard:*[4]

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[4]

ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories[4]

ISO Guide 30, Terms and Definitions Used in Connection with Reference Materials[4]

3. Terminology

3.1 *Definitions*—For formal definitions related to laboratory accreditation, Terminology E1187 applies. For formal definitions related to quality and statistics, Terminology E456 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 E456 without the note).

3.1.2 *bias*—the difference between the population mean of the test results and an accepted reference value (Terminology E456 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 E456 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 E456 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 E456 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 E456 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] 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.

[3] Withdrawn. The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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consensus value, based on collaborative experimental work under the auspices of a scientific or engineering group.

3.2.2 *Discussion*—When the accepted reference value is the theoretical value, it is sometimes referred to as the "true" value. (This is a small variation from the definition in Terminology E456.)

3.2.3 *assigned value*—estimate of the true value used in the assessment of proficiency (also referred to as assigned reference value).

3.2.4 *coordinator*—person or body that coordinates all the activities associated with a proficiency program.

3.2.5 *internal quality control (IQC)*—the set of procedures undertaken by a laboratory for continuous monitoring of operations and results in order to decide whether the results are reliable enough to be released; IQC primarily monitors the batch-to-batch accuracy of results on quality control materials, and precision on independent replicate analyses of test materials.

3.2.6 *outlier*—an observation that appears to deviate markedly from the other observations of the sample (also referred to as extreme result, outlying or doubtful observation, or aberrant value) (see Practice E178).

3.2.7 *quality assurance system*—the sum total of a laboratory's activities aimed at achieving the required standard of analysis.

3.2.8 *reference laboratory*—laboratory that establishes the accepted reference value or assigned value.

3.2.9 *test item*—material(s) or artifact(s) presented to the participating laboratory for the purpose of proficiency testing.

3.2.10 *testing laboratory*—laboratory that performs tests (including calibration) (also referred to as "participating laboratory" or just "laboratory").

4. Significance and Use

4.1 The previous edition of this guide (E1301 – 89) covered the development and operation of laboratory proficiency testing programs with limited, if any, emphasis on the use of the outcomes of proficiency testing by accreditation bodies.

4.2 This revised version is now intended to provide guidance in three areas:

4.2.1 The introduction to this guide distinguishes between use of interlaboratory tests for proficiency testing and for other purposes.

4.2.2 Part A of this guide provides guidance on the development and operation of interlaboratory tests for use in proficiency testing programs.

4.2.3 Part B of this guide provides guidance on the selection and use of proficiency testing programs by laboratory accreditation bodies.

4.3 Annex A1 through Annex A2 provide statistical guidance on treatment of data from proficiency testing programs and a guide to the documentation of the quality assurance system of proficiency testing programs.

4.4 While the emphasis of Part A of the guide is on operation of interlaboratory tests for proficiency testing, most of the principles and guidance given are applicable to operation of interlaboratory tests for other purposes.

4.5 While many laboratory accreditation bodies operate their own proficiency testing programs, a significant number also use proficiency testing programs or other forms of interlaboratory tests operated by other bodies. The purpose of Part B of this guide is to provide harmonized principles for selection of suitable interlaboratory test programs for use as proficiency testing programs by laboratory accreditation bodies.

4.6 Part B of this guide is intended:

4.6.1 To establish principles for the selection of proficiency testing programs for use in laboratory accreditation programs; and

4.6.2 To assist in harmonizing the use of results of proficiency testing programs by laboratory accreditation bodies.

4.7 As results from proficiency testing programs may be used in accreditation decisions, it is important that both the accrediting bodies and participating laboratories have confidence in the design and operation of the programs.

4.8 It is also important for participating laboratories and laboratory accreditation assessors to have a clear understanding of the accrediting bodies' policies for participation in such programs; the criteria they use for judging successful performance in proficiency testing programs; and their policies and procedures for following up any unsatisfactory results from a proficiency test.

4.9 It should be recognized that laboratory accrediting bodies and their assessors may take into account the suitability of test data produced from other activities apart from proficiency testing programs. This includes results of laboratories' own internal quality control procedures with control samples, comparison with split-sample data from other laboratories, performance of one-time audit tests with certified reference materials, and so on. The use of data from these sources by laboratory accrediting bodies is not covered by this guide. However, the principles set out in this guide, regarding follow-up of unsatisfactory performance, could also apply to these activities.

Part A: DEVELOPMENT AND OPERATION OF PROFICIENCY TESTING PROGRAMS

5. Types of Proficiency Testing

5.1 Proficiency testing techniques vary depending on the nature of the item or material under test, the test method in use and the number of testing laboratories participating. They possess the common feature of comparison of test results obtained by one testing laboratory with those obtained by one or more other testing laboratories. In some programs, one of the participating laboratories may have a controlling, coordinating, or reference function. Paragraphs 5.2-5.4 describe the major types of proficiency testing programs.

5.2 *Measurement Comparison Programs*— Measurement comparison programs involve the item (measurement artifact) to be tested or calibrated being circulated successively from one participating laboratory to the next. Features of such programs usually are:

5.2.1 The item will often be periodically returned to a central laboratory acting as the reference laboratory for calibration, testing or inspection before being passed on to the next successive participating laboratory in order to minimize

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whether any changes have taken place to the item or its assigned reference values.

5.2.2 Programs involving sequential participation take time (in some cases years) to complete. This causes a number of difficulties such as ensuring the stability of the item, the strict monitoring of its circulation and the time allowed for testing by individual participants, and the need to supply feedback on individual performance to laboratories during the program rather than waiting until it finishes. In addition, it may be difficult to compare results on a group basis as there may be relatively few laboratories whose measurement capabilities closely match each other.

5.2.3 The individual measurement results are compared with the reference values established by the reference laboratory. The coordinator may have to take into account the claimed measurement uncertainty of each participating laboratory.

5.2.4 Examples of items (measurement artifacts) used in this type of proficiency testing include reference standards, such as resistors, gauges and instruments.

5.3 *Interlaboratory Testing Programs*— Interlaboratory testing programs involve randomly selected subsamples from a source of material being distributed simultaneously to participating testing laboratories for concurrent testing. Usual features of such programs include:

5.3.1 Subsamples provided to each participant must be sufficiently homogeneous so that any results later identified as extreme cannot be attributed to significant sample variability.

5.3.2 Testing results are returned to the coordinator and analyzed against an assigned value (best estimate of the "true value") to give an indication of the performance of the individual laboratories and the group as a whole.

5.3.3 This is the type commonly used by accreditation bodies and other organizations when they conduct programs in the testing field as opposed to the measurement/calibration field.

5.3.4 Examples of samples used in this type of proficiency testing include food, bodily fluids, water, soils, and other environmental material. In some cases, separate portions of previously established certified reference materials are circulated.

5.4 *Split Sample Testing Programs*— These programs involve samples of a product or a material being divided into two or more parts with each participating laboratory testing one part of each sample.

5.4.1 These programs differ from the type of proficiency testing described in 5.3, as there is usually limited control of, or preliminary data on, the homogeneity of the sample being divided.

5.4.2 This technique is sometimes used by clients of laboratory services, including regulatory authorities.

5.4.3 This type of program often needs retention of sufficient material for possible further analysis conducted by additional laboratories in order to resolve any perceived differences among the limited number of laboratories initially involved.

5.4.4 There may be statistical limitations on analysis of data provided by the laboratories, due to the small number involved, often only two laboratories.

6. Organization and Design

6.1 *Framework*:

6.1.1 The design stage of any proficiency program requires the input of technical experts, statistician(s), and a program coordinator to ensure its success and smooth operation.

6.1.2 The coordinator in consultation with these other personnel should develop a program appropriate to the particular proficiency test. A plan should be agreed upon and documented (see Annex A2) before the start of the program and typically should include the following information:

6.1.2.1 The name and the address of the organization conducting the proficiency program;

6.1.2.2 The name and address of the coordinator and other personnel involved in the design and operation of the proficiency program;

6.1.2.3 The nature and the purpose of the proficiency program;

6.1.2.4 A procedure for the manner in which the participants are selected;

6.1.2.5 The name and address of the laboratory or laboratories performing various parts of the program, such as sampling, sample processing, homogeneity testing and stability testing, and also a list of the potential participating laboratories;

6.1.2.6 The nature of the test item(s) and test(s) selected, as well as a short description of the considerations underlying these choices;

6.1.2.7 A description of the manner in which the test items are obtained, processed, checked and transported;

6.1.2.8 A description of the information that is supplied to participants in the prenotification phase and of the time schedule for the various phases of the proficiency testing (refer to Section 8);

6.1.2.9 The expected initial and final date of the proficiency program including the date(s) for the testing to be carried out by the participants;

6.1.2.10 Details of methods or procedures which participants should use to perform the tests;

6.1.2.11 The basis for the selected statistical model and any outlier tests to be used;

6.1.2.12 The techniques for evaluating laboratory performance;

6.1.2.13 A description of the extent to which the test results, and the conclusions that will be based on the outcome of the proficiency test, are to be made public.

6.2 *Personnel*:

6.2.1 The personnel involved in providing the program should have adequate qualifications and experience in the design, implementation, and reporting of interlaboratory tests and include appropriate technical, statistical and administrative skills.

6.2.2 The operation of particular interlaboratory test comparisons may also require the guidance of persons with detailed technical knowledge and experience of the test methods and procedures involved. To this end, the coordinator may need to

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