



GUIDE 43-1

Proficiency testing by interlaboratory comparisons —

Part 1: Development and operation of proficiency testing schemes

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Contents

Page

1	Scope	1
2	References.....	1
3	Definitions	2
4	Types of proficiency testing.....	3
4.1	General.....	3
4.2	Measurement comparison schemes	3
4.3	Interlaboratory testing schemes	4
4.4	Split-sample testing schemes	4
4.5	Qualitative schemes	5
4.6	Known-value schemes	5
4.7	Partial-process schemes	5
5	Organization and design.....	5
5.1	Framework.....	5
5.2	Staff.....	6
5.3	Data-processing equipment	6
5.4	Statistical design	6
5.5	Test item preparation	6
5.6	Test item management.....	7
5.7	Choice of method/procedure	7
5.8	Evolution of proficiency testing schemes	7
6	Operation and reporting	8
6.1	Coordination and documentation	8
6.2	Instructions	8
6.3	Packaging and transportation.....	8
6.4	Data analysis and records	8
6.5	Scheme reports.....	8

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6.6	Evaluation of performance	9
6.7	Communication with participants	9
7	Confidentiality/ethical considerations	10
7.1	Confidentiality of records	10
7.2	Collusion and falsification of results	10
Annexes		
A	Examples of statistical methods for treatment of proficiency test data	11
B	Quality management of proficiency testing schemes	15
C	Bibliography	16

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

ISO/IEC Guide 43-1 was prepared by ISO/CASCO Ad Hoc Group for Revision of ISO/IEC Guide 43. A draft was circulated to CASCO members and IEC National Committees for comments. A final draft has subsequently been approved by ISO/CASCO and by IEC Council for publication as an ISO/IEC Guide.

Parts 1 and 2 of ISO/IEC Guide 43 cancel and replace the first edition (ISO/IEC Guide 43:1984).

ISO/IEC Guide 43:1984 covered guidance on development and operation of laboratory proficiency testing with limited emphasis on the use of the outcomes of proficiency testing by accreditation bodies. It is now intended to provide guidance in three areas, namely:

- a) to distinguish between use of interlaboratory comparisons for proficiency testing and for other purposes;
- b) the development and operation of interlaboratory comparisons for use in proficiency testing schemes; and
- c) the selection and use of proficiency testing schemes by laboratory accreditation bodies.

ISO/IEC Guide 43 consists of the following parts, under the general title *Proficiency testing by interlaboratory comparisons*:

- *Part 1: Development and operation of proficiency testing schemes*
- *Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*

Annexes to this part of ISO/IEC Guide 43 provide statistical guidance on treatment of data from proficiency testing schemes and guidelines on documentation (Quality Manual) for the operation of proficiency testing schemes.

Introduction

Interlaboratory comparisons are conducted for a number of purposes and may be used by participating laboratories and other parties.

Interlaboratory comparisons may be used, for example, to:

- a) determine the performance of individual laboratories for specific tests or measurements and to monitor laboratories' continuing performance;
- b) identify problems in laboratories and initiate remedial actions which may be related to, for example, individual staff performance or calibration of instrumentation;
- c) establish the effectiveness and comparability of new test or measurement methods and similarly to monitor established methods;
- d) provide additional confidence to laboratory clients;
- e) identify interlaboratory differences;
- f) determine the performance characteristics of a method — often known as collaborative trials;
- g) assign values to reference materials (RMs) and assess their suitability for use in specific test or measurement procedures.

Proficiency testing is the use of interlaboratory comparisons for purpose a); i.e. the determination of laboratory testing or measurement performance. However, the operation of proficiency testing schemes may often also provide information for the other purposes listed above.

Participation in proficiency testing schemes 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 schemes (see clause 4), most share the common feature of the comparison of test and measurement results obtained by two or more laboratories.

One of the main uses of proficiency testing schemes is to assess laboratories' ability to perform tests competently. This may include assessment by laboratories themselves, by their clients, or by other parties such as accreditation or regulatory bodies. It thus supplements laboratories' own internal quality control procedures by providing an additional external measure of their testing capability. These activities also complement the technique of on-site laboratory assessment by technical specialists (usually used by laboratory accreditation 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 of results or may use the evaluation of other bodies.

While the emphasis of this part of ISO/IEC Guide 43 is on operation of interlaboratory comparisons for proficiency testing, most of the principles and guidance given are applicable to operation of interlaboratory comparisons for other purposes.

While many laboratory accreditation bodies operate their own proficiency testing schemes, a significant number also use proficiency testing schemes or other forms of interlaboratory comparisons operated by other bodies. The purpose of part 2 of ISO/IEC Guide 43 is to provide harmonized principles for the selection of suitable interlaboratory comparisons for use as proficiency testing schemes by laboratory accreditation bodies.

Most bodies assessing the technical competence of laboratories require or expect satisfactory performance in proficiency testing schemes as significant evidence of a laboratory's ability to produce reliable results (except where proficiency testing is inappropriate).

However, it is emphasized that a major distinction exists between:

- a) the evaluation of the competence of a laboratory by the assessment of its total operation against predetermined requirements; and
- b) 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 (or tests) involved in a particular proficiency testing scheme.

In preparing this Guide, reference was made to a number of guidance documents relevant to proficiency testing produced by ILAC; ISO (TC 69); ISO/REMCO; IUPAC; AOAC; ASTM; and WECC and WELAC (now combined as EAL).

Proficiency testing by interlaboratory comparisons —

Part 1: Development and operation of proficiency testing schemes

1 Scope

While there are a number of uses of interlaboratory comparisons, and variations in their design and implementation, it is still possible to specify the essential principles that need to be considered when organizing such comparisons. This part of ISO/IEC Guide 43 defines those principles and describes the factors which should be taken into account in the organization and conduct of proficiency testing schemes.

Part 2 of ISO/IEC Guide 43 describes how laboratory accreditation bodies, who assess technical competence of laboratories, should select and use proficiency testing schemes.

This part of ISO/IEC Guide 43 is intended for use by proficiency testing operators and users such as participant laboratories, accreditation bodies, regulatory authorities and clients of laboratory services who have a need to assess the technical competence of laboratories. It is particularly useful for laboratories in self-evaluation, but recognizes that proficiency testing is only one mechanism which can contribute to the establishment of mutual confidence between users of different testing laboratories.

It is currently a condition of some accreditation bodies that laboratories participate regularly in proficiency testing schemes that they have accepted as fit for purpose. Therefore, it is essential that operators of such schemes comply with principles for conduct of professionally managed proficiency schemes, both in terms of technical requirements, statistical procedures (see examples in annex A), and in quality management (see guidance in annex B).

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 comparisons. The contents of this Guide are intended only as a framework to be modified appropriately for particular situations,

including schemes with either small or large numbers of participants.

This Guide is not intended to cover a technique often used by organizations to evaluate a single laboratory's performance through submissions of certified reference materials or other well-characterized test items.

A bibliography is given in annex C.

2 References

ISO 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*.

ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*.

ISO 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*.

ISO 5725-4:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 4: Basic methods for the determination of the trueness of a standard measurement method*.

ISO 9000 Quality Management Compendium, 1994.

ISO/IEC Guide 2:1996, *General terms and their definitions concerning standardization and related activities*.

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories*.

ISO/IEC Guide 43-2:1997, *Proficiency testing by interlaboratory comparisons — Part 2: Selection and use of*

proficiency testing schemes by laboratory accreditation bodies.

Guide to the Expression of Uncertainty in Measurement: 1993, issued by BIPM; IEC; IFCC; ISO; IUPAC; IUPAP; OIML.

International vocabulary of basic and general terms in metrology: 1993, issued by BIPM; IEC; IFCC; ISO; IUPAC; IUPAP; OIML. [VIM:1993]

The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories. *Journal of AOAC International*, **76**, No. 4, 1993, pp. 926-940.

Evaluation of Matrix Effects: Proposed Guideline, NCCLS Document EP-14P. National Committee for Clinical Laboratory Standards, Villanova, PA, 1994.

3 Definitions

For the purposes of this Guide, the following definitions apply. Some definitions are taken from other ISO Guides and International Standards, as shown.

3.1 test

technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure

[ISO/IEC Guide 2]

3.2 testing laboratory

laboratory that performs tests

NOTE — The term "testing laboratory" can be used in the sense of a legal entity, a technical entity or both.

[ISO/IEC Guide 2]

3.3 test item

material or artefact presented to the participating laboratory for the purpose of proficiency testing

3.4 test method

specified technical procedure for performing a test

[ISO/IEC Guide 2]

3.5 test result

the value of a characteristic obtained by completely carrying out a specified measurement method

[ISO 5725-1]

3.6 (laboratory) proficiency testing

determination of laboratory testing performance by means of interlaboratory comparisons

[ISO/IEC Guide 2]

NOTE — For the purposes of this Guide, the term laboratory proficiency testing is taken in its widest sense and includes, for example:

- Qualitative schemes — for example where laboratories are required to identify a component of a test item.
- Data transformation exercises — for example where laboratories are furnished with sets of data and are required to manipulate the data to provide further information.
- Single item testing — where one item is sent to a number of laboratories sequentially and returned to the organizer at intervals.
- One-off exercises — where laboratories are provided with a test item on a single occasion.
- Continuous schemes — where laboratories are provided with test items at regular intervals on a continuing basis.
- Sampling — for example where individuals or organizations are required to take samples for subsequent analysis.

3.7 interlaboratory comparisons

organization, performance and evaluation of tests on the same or similar test items by two or more laboratories in accordance with predetermined conditions

NOTE — In some circumstances, one of the laboratories involved in the intercomparison may be the laboratory which provided the assigned value for the test item.

3.8 reference material (RM)

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 the materials

[VIM:1993, 6.13]