



## GUIDE 43-1

**Proficiency testing by  
interlaboratory comparisons —**

**Part 1:  
Development and operation of  
proficiency testing schemes**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO/IEC Guide 43-1:1997](#)

<https://standards.iteh.ai/catalog/standards/sist/94891b07-54a0-42f2-8bed-f5dc21cd1c00/iso-iec-guide-43-1-1997>

<b>Contents</b>	<b>Page</b>
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

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

ISO/IEC Guide 43-1:1997

<https://standards.iteh.ai/catalog/standards/sist/94891b07-54a0-42f2-8bed-f5dc21cd1c00/iso-iec-guide-43-1-1997>

© ISO/IEC 1997

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization  
Case postale 56 • CH-1211 Genève 20 • Switzerland  
Internet central@iso.ch  
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

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
<b>Annexes</b>		
A	Examples of statistical methods for treatment of proficiency test data.....	11
B	Quality management of proficiency testing schemes .....	15
C	Bibliography.....	16

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO/IEC Guide 43-1:1997](https://standards.iteh.ai/catalog/standards/sist/94891b07-54a0-42f2-8bed-f5dc21cd1c00/iso-iec-guide-43-1-1997)

<https://standards.iteh.ai/catalog/standards/sist/94891b07-54a0-42f2-8bed-f5dc21cd1c00/iso-iec-guide-43-1-1997>

## 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;  
<https://standards.iteh.ai/catalog/standards/sist/018911b07-54-0-42/2-83115dc2-d159-4690-b03c-331997>  
[ISO/IEC Guide 43-1:1997](https://standards.iteh.ai/catalog/standards/sist/018911b07-54-0-42/2-83115dc2-d159-4690-b03c-331997)
- 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).

<https://standards.iteh.ai/catalog/standards/sist/94891b07-54a0-42f2-8bed-f5dc21cd1c00/iso-iec-guide-43-1-1997>

# 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:

- a) Qualitative schemes — for example where laboratories are required to identify a component of a test item.
- b) Data transformation exercises — for example where laboratories are furnished with sets of data and are required to manipulate the data to provide further information.
- c) Single item testing — where one item is sent to a number of laboratories sequentially and returned to the organizer at intervals.
- d) One-off exercises — where laboratories are provided with a test item on a single occasion.
- e) Continuous schemes — where laboratories are provided with test items at regular intervals on a continuing basis.
- f) 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]



**3.9****certified reference material (CRM)**

reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its 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

[VIM:1993, 6.14]

**3.10****reference laboratory**

laboratory that provides reference values on a test item

NOTE — For example, a National Calibration Laboratory.

**3.11****assigned value**

value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose

[see VIM:1993, 1.20 and notes 1 and 2]

**3.12****traceability**

property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

[VIM:1993, 6.10]

**3.13****coordinator**

organization (or person) with responsibility for coordinating all of the activities involved in the operation of a proficiency testing scheme

**3.14****trueness**

closeness of agreement between the average value obtained from a large series of test results and an accepted reference value

[ISO 3534-1]

**3.15****precision**

closeness of agreement between independent test results obtained under prescribed (stipulated) conditions

[ISO 3534-1]

**3.16****outlier**

member of a set of values which is inconsistent with the other members of that set

[ISO 5725-1]

**3.17****extreme results**

outliers and other values which are grossly inconsistent with other members of the data set

NOTE — These results can have a profound influence on summary statistics such as the mean and standard deviation.

**3.18****robust statistical techniques**

techniques to minimize the influence that extreme results can have on estimates of the mean and standard deviation

NOTE — These techniques assign less weight to extreme results, rather than eliminate them from a data set.

**3.19****uncertainty of measurement**

parameter associated with the results of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

[VIM:1993, 3.9]

**4 Types of proficiency testing****4.1 General**

Proficiency testing techniques vary depending on the nature of the test item, the method in use and the number of laboratories participating. Most possess the common feature of comparison of results obtained by one laboratory with those obtained by one or more other laboratories. In some schemes, one of the participating laboratories may have a controlling, coordinating, or reference function.

The following are common types of proficiency testing schemes.

**4.2 Measurement comparison schemes**

Measurement comparison schemes involve the test item to be measured or calibrated being circulated successively from one participating laboratory to the

next. Features of such schemes usually are as follows.

- a) Assigned values for the test item are provided by a Reference Laboratory, which might be a country's highest authority for the measurement concerned. It may be necessary for the test item to be checked at specific stages during the conduct of the proficiency test. This is to ensure that there are no significant changes in the assigned value throughout the course of the proficiency test.
- b) Schemes 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 measurement by individual participants; and the need to supply feedback on individual performance to laboratories during the scheme's implementation, 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.
- c) The individual measurement results are compared with the reference values established by the Reference Laboratory. The coordinator should take into account the claimed measurement uncertainty of each participating laboratory.
- d) Examples of items (measurement artefacts) used in this type of proficiency testing include reference standards (e.g. resistors, gauges and instruments).

### 4.3 Interlaboratory testing schemes

Interlaboratory testing schemes involve randomly selected sub-samples from a source of material being distributed simultaneously to participating testing laboratories for concurrent testing. Occasionally, this technique is also used for interlaboratory measurement schemes. After completion of the testing, the results are returned to the coordinating body, and compared with the assigned value(s) to give an indication of the performance of the individual laboratories and the group as a whole.

Examples of test items used in this type of proficiency testing include food, body fluids, water, soils and other environmental material. In some cases, separate portions of previously established (certified) reference materials are circulated.

It is essential that the batch of test items provided to participants in each round be sufficiently homogeneous so that any results later identified as extreme are not attributed to any significant test item variability. (See 5.6.2 and A.4 in annex A.)

Interlaboratory testing type schemes are commonly used by accreditation bodies, regulatory bodies and other organizations when they utilize schemes in the testing field.

One common interlaboratory test scheme is the "split-level" design where similar (but not identical) levels of measurand are included in two separate test items. This design is used to estimate laboratory precision at a specific level of a measurand. It avoids problems associated with replicate measurements on the same test item, or with inclusion of two identical test items in the same proficiency test round.

### 4.4 Split-sample testing schemes

One special form of proficiency testing which is often used by clients of laboratories, including some regulatory bodies, is the technique of split-sample testing. (This technique should not be confused with split-level schemes which are discussed in 4.3.)

Typically, split-sample testing involves comparisons of the data produced by small groups of laboratories (often only two laboratories) which are being evaluated as potential, or continuing, suppliers of testing services.

Similar intercomparisons are regularly conducted in commercial transactions when samples representing a traded commodity are split between a laboratory representing the supplier and another laboratory representing the purchaser. An additional sample is normally retained for a third-party laboratory to test if arbitration is needed on any significant differences between the results produced by the supplier's and the purchaser's laboratories.

Split-sample testing schemes 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. They differ from the type of proficiency testing described in 4.3, as there is usually a very limited number of participating laboratories (often two). Uses for this type of scheme include identifying poor precision, describing consistent bias and verifying the effectiveness of corrective actions.

Such schemes often need retention of sufficient material to resolve any perceived differences between the limited number of laboratories involved by further analysis by additional laboratories.

A similar technique of split-sample testing is also used in the monitoring of clinical and environmental laboratories. Typically, these schemes involve the results from several split samples over a wide concentration interval being compared between an individual laboratory and one or more other laboratories. Under such schemes, one of the laboratories may be considered to operate at a higher metrological level (i.e. lower level of uncertainty) due to the use of reference methodology and more advanced equipment, etc. Its results are considered to be the reference values in such intercomparisons and it may act as an advisory or mentor laboratory to the other laboratories comparing split-sample data with it.

#### 4.5 Qualitative schemes

Evaluation of laboratory testing performance will not always involve interlaboratory comparisons. [See a) in note to 3.6.] For example, some schemes are designed to evaluate the capabilities of laboratories to characterize specific entities (e.g. type of asbestos, identity of a specific pathogenic organism, etc.).

Such schemes may involve the special preparation of test items with addition of the subject component by the scheme coordinator. As such, the schemes are "qualitative" in nature, and do not need the involvement of multiple laboratories or interlaboratory comparisons to evaluate a laboratory's testing performance.

#### 4.6 Known-value schemes

Other special types of proficiency testing schemes may involve the preparation of test items with known amounts of the measurand under test. It is then possible to evaluate the capability of an individual laboratory to test the item and provide numerical results for comparison with the assigned value. Once again, such proficiency schemes do not need the involvement of multiple laboratories.

#### 4.7 Partial-process schemes

Special types of proficiency testing involve the evaluation of laboratories' abilities to perform parts of the overall testing or measurement process. For example, some existing proficiency schemes evaluate laboratories' abilities to transform and report a given set of data (rather than conduct the actual test or measurement) or to take and prepare samples or specimens in accordance with a specification.

## 5 Organization and design

### 5.1 Framework

**5.1.1** The design stage of any proficiency testing scheme requires the input of technical experts, statisticians and a scheme coordinator to ensure its success and smooth operation.

**5.1.2** The coordinator, in consultation with these other personnel, should develop a scheme appropriate to the particular proficiency test. A proficiency test scheme should be designed to avoid any confusion about its objectives. A plan should be agreed upon and documented (see annex B) before the start of the scheme and typically would include the following information:

- a) the name and the address of the organization conducting the proficiency scheme;
- b) the name and address of the coordinator and other personnel involved in the design and operation of the proficiency scheme;
- c) the nature and the purpose of the proficiency scheme;
- d) a procedure for the manner in which the participants are selected, where appropriate, or criteria which need to be met before participation is allowed;
- e) the name and address of the laboratory or laboratories performing (parts of) the scheme (e.g. sampling, sample processing, homogeneity testing and assigning values), and the number of expected participants;
- f) the nature of the test item(s) and test(s) selected, as well as a short description of the considerations underlying these choices;
- g) a description of the manner in which the test items are obtained, processed, checked and transported;
- h) a description of the information that is supplied to participants in this notification phase and of the time schedule for the various phases of the proficiency testing;
- i) the expected initial and target dates or deadlines of the proficiency scheme including the date(s) for the testing to be carried out by the participants;
- j) for on-going schemes, the frequency at which test items are distributed;