



GUIDE 43-2

Proficiency testing by interlaboratory comparisons —

Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies

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Printed in Switzerland

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 43-2 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 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*

Introduction

Part 1 of ISO/IEC Guide 43 provides guidance on the development and operation of interlaboratory comparisons for use in proficiency testing schemes.

This part of ISO/IEC Guide 43 is intended to provide a harmonized model for selection and use of proficiency testing schemes. This will facilitate national and international harmonization and thus acceptance of test data from accredited laboratories in various locations.

Proficiency testing schemes may be operated either by laboratory accreditation bodies or by other organizations. As the results of laboratories' performance in proficiency testing schemes are used in judging their technical competence, it is critical that the proficiency testing schemes used by accreditation bodies be operated competently, effectively and fairly.

The objective of laboratory accreditation is to provide an independent recognition that a laboratory is competent to perform specific tests, measurements, calibrations or sampling. The procedures used to determine competence include assessment of laboratories' specific capabilities by independent technical assessors who judge both technical competence and the compliance of the laboratories with appropriate technical and quality systems criteria such as those described in ISO/IEC Guide 25.

Most laboratory accreditation bodies complement their on-site assessments with various forms of practical testing, to judge whether a laboratory's data are comparable to either reference data or to data provided by a laboratory or laboratories already determined to be competent in the relevant tests or measurements.

Some of the practical testing or audit testing may be of an *ad hoc* nature involving a single laboratory, such as through submission of a certified reference material or a reference calibration artefact to a single laboratory. This part of ISO/IEC Guide 43 is not intended to cover this technique to evaluate a single laboratory's performance.

Proficiency testing by interlaboratory comparisons

Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies

1 Scope

The objectives of this part of ISO/IEC Guide 43 are:

- a) to establish principles for the selection of proficiency testing schemes for use in laboratory accreditation programmes; and
- b) to assist in harmonizing the use of results of proficiency testing schemes by laboratory accreditation bodies.

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

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

It should be recognized, however, that laboratory accreditation bodies and their assessors may take into account the suitability of test data produced from other activities apart from proficiency testing schemes. This includes results of laboratories' own internal quality control procedures with control samples, comparison with split-sample data from other laboratories, performance of audit tests with certified reference materials, etc. The use of data from these sources by laboratory accreditation bodies is not covered by this part of ISO/IEC Guide 43. However, the principles set out in this part of ISO/IEC Guide 43, regarding follow-up of unsatisfactory performance, could also apply to these activities.

2 References

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

ISO/IEC Guide 43-1:1997, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*.

3 Definitions

For the purposes of this part of ISO/IEC Guide 43, the definitions given in ISO/IEC Guide 43-1 apply.

4 Selection of proficiency testing schemes

4.1 To assist in the evaluation of competence of laboratories for laboratory accreditation purposes, accreditation bodies should use proficiency testing schemes complying with the guidelines described in ISO/IEC Guide 43-1.

4.2 If the proficiency testing scheme is operated by a laboratory accreditation body, it should periodically audit and review its own scheme(s) for compliance with ISO/IEC Guide 43-1.

4.3 If the proficiency testing scheme used by a laboratory accreditation body is operated by another organization, the laboratory accreditation body should seek documentary evidence that the sub-contracted scheme(s) comply with ISO/IEC Guide 43-1 before recognizing the scheme. Compliance should be confirmed by audit.

4.4 In selecting a proficiency testing scheme, the following factors should be considered by the laboratory accreditation body:

- a) the tests, measurements or calibrations involved should match the types of tests, measurements or calibrations performed by the applicant or accredited laboratories proposed for participation;
- b) with the agreement of their accredited laboratories, the accreditation body should have access to accredited participants' results, together with details of the scheme's design, procedures for establishment of assigned values, instructions to participants, statistical treatment of data and the final report from each selected proficiency test;
- c) the frequency at which the scheme is run;
- d) the suitability of the organizational logistics for the scheme, such as timing, location, sample stability considerations, distribution arrangements, etc., relevant to the group of accredited laboratories proposed for the scheme;
- e) the availability of acceptance criteria for the participating laboratories (i.e. for judging successful performance in the proficiency test);
- f) the costs of the selected schemes;
- g) the scheme's policy on maintaining participants' confidentiality;
- h) the timescale for reporting of results; and
- i) confidence in the suitability of test materials, measurement artefacts, etc. used by the scheme for characteristics such as homogeneity, stability and, where appropriate, traceability to national or international standards.

NOTE — Some proficiency testing schemes may offer tests which are not an exact match for the tests performed by an accredited laboratory (for example, the use of a different national standard for the same determination) but it may still be technically justified to include the laboratories in the scheme if the treatment of the data allows for consideration of any significant differences in test methodology or other factors.

4.5 The selection of a specific proficiency testing scheme by a laboratory accreditation body should be authorized by, and supervised by, suitably qualified personnel of the accreditation body.

5 Policies on participation in proficiency testing schemes

5.1 Laboratory accreditation bodies should document their policies for participation in proficiency testing schemes by accredited and applicant laboratories. Such documented policies should be publicly available to laboratories and other interested parties.

5.2 Issues which should be addressed in participation policies include:

- a) whether participation is mandatory or voluntary for specific proficiency testing schemes;
- b) the frequency at which laboratories are expected or invited to participate in proficiency testing schemes;
- c) the criteria used by the laboratory accreditation body to judge successful or unsatisfactory performance in a specific scheme;
- d) whether laboratories may be required to participate in follow-up schemes if performance is judged to be unsatisfactory in a specific scheme;
- e) how the results of proficiency testing will be used in accreditation decisions; and
- f) details of the laboratory accreditation body's policy on preserving participants' confidentiality.

NOTES

1) In some cases, laboratory accreditation bodies may have policies which require mandatory participation in a minimum number of approved proficiency testing schemes and accept voluntary participation in any additional schemes which may be available.

2) The designs of proficiency testing schemes vary depending on the technologies involved and the acceptance criteria may also vary from scheme to scheme. In many cases, acceptance data will be derived from the results obtained during conduct of a specific scheme and thus will not be available to laboratories in advance. In such cases, the laboratory accreditation bodies should provide participating laboratories with details of the principles on which acceptance criteria will be based.

6 Use of results by laboratory accreditation bodies

6.1 The results from proficiency testing schemes are useful for both participating laboratories and accreditation bodies. There are, however, limitations

on the use of such results to determine competence. Successful performance in a specific scheme may represent evidence of competence for that exercise but may not reflect ongoing competence. Similarly, unsuccessful performance in a specific scheme may reflect a random departure from a laboratory's normal state of competence. It is for these reasons that proficiency testing alone should not be used by laboratory accreditation bodies in their accreditation processes.

6.2 If a laboratory submits a result or results which fall outside acceptance criteria for a specific scheme, a laboratory accreditation body should have procedures for acting on such results.

6.3 Such procedures should include early reporting to the laboratory of its results with an invitation for the laboratory to investigate and comment on its performance.

NOTE — Some proficiency testing schemes take considerable time to complete, particularly where participants are sequentially provided with the same test item to test, measure or calibrate. In such cases, it is desirable that laboratories be provided with interim reports on their performance, and particularly if their reported results are unsatisfactory. This will allow investigation and any subsequent corrective action to be taken quickly without awaiting publication of a final report from the scheme.

6.4 For laboratories reporting unsatisfactory results, the laboratory accreditation body should have policies to:

- a) have the laboratory investigate and comment on its performance within an agreed time-frame;
- b) where necessary, have the laboratory undertake any subsequent proficiency test which may be available, to confirm that any corrective actions taken by the laboratory are effective; and
- c) where necessary, have on-site evaluation of the laboratory by appropriate technical assessors to confirm that corrective actions are effective.

6.5 The laboratory accreditation body should advise participating laboratories of the possible outcomes of unsatisfactory performance in a proficiency testing scheme. These may range from continuing accreditation subject to successful attention to cor-

rective actions within agreed time-frames, temporary suspension of accreditation for the relevant tests (subject to corrective action), through to withdrawal of accreditation for the relevant tests. Normally, the options selected by a laboratory accreditation body will depend on the history of performance of the laboratory over time and from the most recent on-site assessments.

6.6 The laboratory accreditation body should have procedures to ensure that the records of performance of laboratories in proficiency testing schemes are maintained (in accreditation files or records) for the participating laboratories and are made available to technical assessors for on-site assessments.

6.7 Laboratory accreditation bodies should have policies for feedback from accredited laboratories of action taken from results of proficiency testing schemes, particularly for unsatisfactory performance.

7 Action and feedback by laboratories

7.1 Accredited laboratories should be required to maintain their own records of performance in proficiency testing, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective or preventative actions.

7.2 The laboratories should draw their own conclusions about their performance from an evaluation of the organization and design of the proficiency test. The information that should be taken into consideration includes:

- a) the origin and character of test samples;
- b) the test methods used and, where possible, the assignment of the results to particular methods;
- c) the organization of the proficiency test (e.g. the statistical model, the number of replicates, the parameter to be measured, the manner of execution);
- d) the criteria used by the organizing body to evaluate the participants' performance.



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Ref. No.: ISO/IEC GUIDE 43-2:1997(E)

ICS 03.120.20

Descriptors: certification, quality assurance systems,
laboratory accreditation, laboratories, testing laboratories,
estimation, performance.

Price based on 3 pages