



PURPOSE

This document has been developed by a joint EA-EUROLAB-EURACHEM Group to provide information on how to use Proficiency Testing in order to provide practical guidance for an effective and harmonised application of the relevant European standards. It was approved by the EA General Assembly in April 2001.

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Authorship

The publication has been written by the EA-EUROLAB-EURACHEM Proficiency Testing Working Group. It replaces the former EA-03/04 **Welac Criteria for Proficiency Testing in Accreditation-Edition 1**.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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1 OBJECTIVE

- 1.1 The objective of this document is to ensure a consistent good practice for Accreditation Bodies (ABs) and laboratories in the cost-effective use of proficiency testing in accreditation.

2 SCOPE AND FIELD OF APPLICATION

- 2.1 This document covers the activities of testing laboratories, and not calibration laboratories.
- 2.2 This document is to help and unify accreditation bodies and testing laboratories understanding concerning the use of proficiency testing in accreditation.
- 2.3 The document provides guidance in the use of different types of proficiency testing to support evidence of testing laboratories' competence within their scope of accreditation.

3 INTRODUCTION

- 3.1 A demonstration of competence has to be given by a laboratory during an accreditation assessment in accordance with ISO/IEC 17025:1999¹ and EN 45003:1995.
- 3.2 Proficiency testing as defined in ISO/IEC Guide 43: 1997, Part 1 [1] is seen as one powerful tool to help a laboratory to demonstrate such competence to an accreditation body or other third party. It is clear that the primary aim of proficiency testing has a significant educational element.
Proficiency testing also enables laboratories to monitor their tests over time. Longer-term trends can therefore be identified, and any necessary corrective action considered.
- 3.3 It is important to issue a common understanding on the use of proficiency testing for the bodies concerned with accreditation.
- 3.4 An improvement and maintenance of the quality in the laboratory can be also achieved by regular participation in interlaboratory comparisons used for other purposes but modified for the purposes of proficiency testing. The results obtained in such interlaboratory comparisons, however, should be interpreted with caution (see section 6.3.c). As such they may also become tools for demonstrating the competence of laboratories, i.e. as proficiency testing in accreditation procedures. They have therefore been included explicitly in this document, although up to now there has been no common policy for the effective use of this kind of interlaboratory comparison in the accreditation context.

¹ EN45001:1989 is still applicable in some cases

- 3.5** Proficiency testing should be carefully and competently planned, prepared, carried out, interpreted and documented. Interpretation should be carried out with particular care when used in accreditation procedures. Competent PT scheme providers should comply with ISO/IEC Guide 43:1997, Part 1 [1] and the ILAC G13:2000 [5]. However, in less demanding situations, it is also possible to use less extensive requirements as long as they are technically sound and agreed between the accreditation body, assessor and laboratory.
- 3.6** It is also important that the cost-effective aspects and fitness-for-purpose of the use of proficiency testing are taken into account.
- 3.7** It is important that the accreditation bodies ensure that the persons involved in the accreditation process have an appropriate level of understanding of proficiency testing. The primary aim of proficiency testing is to provide a quality assurance tool for individual laboratories to enable them to compare their performance with similar laboratories, to take any necessary remedial action, and to facilitate improvement.
- 3.8** There are many models used for the operation of proficiency testing schemes throughout Europe. Many of these, although varying widely, represent good practice as defined by ISO/IEC Guide 43:1997 Part 1 [1].
- 3.9** There are moves by a number of European countries for accreditation bodies to accredit proficiency testing scheme providers according, for example, to ILAC G13:2000 [5].

4 DEFINITIONS

Note: Only direct quotations from standards and other normative references are written in italic.

4.1 (Laboratory) proficiency testing

“Determination of laboratory testing performance by means of interlaboratory comparisons.

Note - For the purpose of this Guide, the term laboratory proficiency testing is taken in its widest sense and includes, for example:

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

ISO/IEC Guide 43:1997 [1]§3.6

4.2 Interlaboratory comparisons

“Organisation, performance and evaluation of test on the same or similar test items by two or more laboratories in accordance with pre-determined 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.”

ISO/IEC Guide 43:1997 [1]§3.7

Additional remarks for the purpose of this position paper:

4.2.1 The International Standard ISO 5725 Part 1 to 6 [3] generally defines interlaboratory comparisons for a certain minimum number of participants. Interlaboratory comparisons without the statistical limitations imposed by the number of participants have also proved to be cost-effective and accessible for some laboratories. Such interlaboratory comparisons may be carried out by means of the same method in different laboratories (e.g. the client: supplier-relationship), or in the same laboratory. These two procedures are generally characterised by the fact that performance scores or ratings exist for specific data from test items and that they are carried out regularly.

4.2.2 Interlaboratory comparisons can be primarily designed for purposes other than proficiency testing:

a) the validation of methods

For validation of methods, interlaboratory comparisons are used as a means for determining the key performance characteristics such as reproducibility, comparability, robustness, measurement uncertainty etc. as defined in ISO 5725 B1 1-6 [3].

Note: The result from such comparison exercises can be used to determine laboratory competence by reference to the performance criteria. Performance characteristics of test methods such as the confidence intervals under comparable conditions, limiting values or robust mean are useful targets in such interlaboratory comparisons.

b) the characterisation of reference materials

For the characterisation of matrix-type certified reference materials, mainly in chemistry and related disciplines, results from interlaboratory comparisons may be used to assign the certified value and to estimate the uncertainty of this value.

c) the self-assessment of a laboratory's performance in a test

When a laboratory reviews its quality management system, interlaboratory comparisons are one of the tools used to evaluate the laboratory's performance.

4.3 Bilateral proficiency test(ing)

(Sometimes called "**Check Sample Test**")

Laboratory receives a test item with accurately determined characteristics, which are to be tested in the frame of an accreditation procedure. The test item is given either by the assessor or provided by a third party.

4.4 Blind test item

Sample with undisclosed characteristics to be tested by the laboratory, whose competence in a specific field is to be assessed. This sample is not identified as a sample for proficiency testing.

5 REQUIREMENTS

5.1 According to the EN 45003:1995, section 6.8.1:

"Laboratories shall be encouraged by the accreditation bodies to participate in proficiency testing or other interlaboratory comparisons".

5.2 According to the EN 45001:1989, section 6.2.d (Note: This is not in ISO/IEC 17025:1999):

"Co-operation with bodies granting accreditation. The testing laboratory shall afford the body granting accreditation and its representative such reasonable co-operation as is necessary, to enable the body granting accreditation to monitor compliance with these requirements and other criteria. This co-operation shall include:

...d) participation in any appropriate program of proficiency testing or comparison testing that the body granting accreditation may reasonably deem to be necessary"

5.3 According to the ISO/IEC 17025:1999, section 5.9:

"The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

...b) participation in interlaboratory comparison or proficiency testing programmes;...."

5.4 According to the EN 45003:1995, section 6.8.3:

"Accredited laboratories shall participate in proficiency testing or other interlaboratory comparisons as required by the accreditation body. Their performance in such tests shall meet the requirements of the accreditation body"

5.5 According to ISO/IEC Guide 43:1997, Part 2, section 6.5:

"If the results of the participation in the required proficiency testing are unsatisfactory the granting of maintenance of accreditation shall be considered. However, an accreditation shall not be granted or maintained only on the basis of results of proficiency testing"

5.6 According to ISO/IEC Guide 43:1997, Part 2, section 7.1:

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

6 PROFICIENCY TESTING IN ACCREDITATION

6.1 The performance of accredited laboratories in proficiency testing is one of many tools that should all be used in accreditation procedures by accreditation bodies

6.2 Possible types of proficiency testing in accreditation are:

- a) Bilateral proficiency testing (see Section 4.3)
- b) Proficiency testing schemes
- c) Interlaboratory comparisons designed primarily for other purposes: it should be emphasised that results of interlaboratory comparisons, although gained originally for other purposes, may be used for the assessment of the laboratory's competence to carry out specific test methods, if the acceptability criteria are correctly and adequately defined

Note 1: The results of the participating laboratories in such interlaboratory comparisons should be taken into account by the accreditation bodies, as they demonstrate the competence of the laboratory to carry out the test method of interest, although it may not be the one they normally use

Note 2: While such programs may be used as a quality assurance tool, together with other quality assurance tools, to demonstrate competence, it is not clear that they can be used to demonstrate incompetence, especially when requiring the use of new methods or any activity that is not part of routine operation

6.3 There is significant added value to accredited laboratories, or those seeking accreditation, from participation in appropriate proficiency testing schemes. Appropriate and cost-effective use of PT scheme results by accreditation bodies may reduce the cost to laboratories of accreditation. Therefore, the perceived extra cost to a laboratory of PT scheme participation may result in an overall cost-saving in respect of quality assurance measures, including accreditation.

6.4 Participating in proficiency testing schemes can be a part of a contract between the laboratory and the customer, e.g. an authority, and in this case mandatory for the laboratory. If, in these cases, the consequences of participation are part of the contract and are publicly available, then accreditation bodies should take into account such prescriptions when reviewing these proficiency testing results during an assessment. The accreditation body should not interfere with any contracts between laboratories and their customers.

For practical Guidelines for assessors in use of all types of proficiency testing in accreditation see Annex 1.

7 ACTIONS

In order to meet the requirements of ISO/IEC 17025 and the EN 45000 series, and in order to create the necessary transparency and confidence in the technical competence of the accreditation bodies and the accredited laboratories in the environment of the EA Multilateral Agreement, the following actions are strongly recommended:

7.1 Actions for Accreditation Bodies and Assessors

- 7.1.1 Collection and provision of general information about appropriate PT schemes (e.g. from EPTIS) [4].
- 7.1.2 Promotion of the benefits of participation in proficiency testing, and how performance is used to help assess the competence of laboratories
- 7.1.3 Supporting of organisation or arrangement of proficiency tests, wherever possible and useful in the most cost-effective manner
- 7.1.4 The accreditation body should judge the appropriateness of proficiency tests in which the laboratory participates, which will be taken into account in the accreditation. Where the accreditation body recommends participation in any particular PT scheme, for its accredited laboratories, it should satisfy itself of the competence of the organisation providing the proficiency test
- 7.1.5 Ensuring that assessors have the following competences:
- a) have demonstrable competence in interpretation of the assigned value and acceptability criteria in all types of proficiency testing in order to afford a critical evaluation of quantitative and qualitative results of laboratories
 - b) have relevant knowledge about standards and Guidelines on the organisation, performance and evaluation of interlaboratory comparisons, as e. g. ISO/IEC Guide 43:1997 [1], ISO 5725 B1.1-6 [3]
 - c) have competence in the use of different types of proficiency testing for accreditation purposes appropriate to the work of the laboratory being assessed and in basic principles for proficiency testing
- 7.1.6 Establishment of criteria for the acceptance of proficiency testing results, where necessary
- 7.1.7 Check that laboratories have a written procedure in the Quality Manual (QM) or in laboratory instructions covering participation in proficiency testing, including how the performance in proficiency testing is used to demonstrate the laboratory's competence and procedures followed in the event of unsatisfactory performance
- 7.1.8 Establishment of a policy for keeping records related to proficiency testing by the accreditation body and by accredited laboratories
- 7.1.9 The use of results in all types of proficiency testing by accreditation bodies should be performed in accordance to the flow chart in Annex 2 of this document and ISO/IEC Guide 43:1997. Part 2, Section 6 [2]

7.2 Actions for Laboratories

- 7.2.1 Appropriate participation in proficiency testing, both in bilateral proficiency testing and interlaboratory comparisons, covering the scope of the laboratory's accreditation, in an useful and cost-effective manner. The laboratory should satisfy itself of the competence of the providers of PT schemes in which they voluntarily participate

- 7.2.2** The laboratory policy for participation in proficiency tests as a form of external quality control should be adequately described in the Quality Manual or in other operational documents of the laboratory. This particularly concerns planning, performance/operation, evaluation, corrective action, documentation and its storage
- 7.2.3** The laboratory should be prepared to justify non-participation in readily available proficiency testing schemes, where one or more appropriate schemes exist

8 REFERENCES

- [1] ISO/IEC Guide 43:1997, Part 1: "Development and Operation of Proficiency Testing Schemes" (2nd Edition, 1997)
- [2] ISO/IEC Guide 43:1997, Part 2: "Selection and Use of Proficiency Testing Schemes by Laboratory
- [3] ISO 5725, B1.1-6, Accuracy (Trueness and Precision) of Measurement Methods and Results, February 1996
- [4] EPTIS 1998, <http://www.eptis.bam.de>; "European Proficiency Testing Information System", European Commission Project SMT-CT-8002
- [5] ILAC G13:2000- Guidelines for Requirements for Competence of Providers of Proficiency Testing Schemes, ILAC, Sydney, January 2000

ANNEX 1: GUIDELINES FOR THE ASSESSMENT

1 GENERAL RECOMMENDATIONS

- 1.1** A review of the performance of laboratories in proficiency testing provides a basis for improving the quality of testing, where and as required
- 1.2** The participation of laboratories in proficiency testing is particularly recommended where there are doubts regarding the technical competence of the laboratory even after taking into account the laboratory's own quality system. Internal as well as external quality measures are to be considered, e.g.:
- a) calibration of measuring devices,
 - b) use of quality control charts,
 - c) performance of duplicate/multiple determinations,
 - d) use of standard addition methods,
 - e) regular use of certified reference materials, where appropriate or use of purchasable or in-house calibration and control materials,
 - f) introduction of "blind" test materials into the laboratory (e.g. by the Quality Manager)
 - g) all kinds of proficiency tests already carried out on the laboratory's own initiative
- 1.3** Additional proficiency tests may be required, if:
- a) due to changes of personnel, there are doubts regarding the technical competence of the laboratory
 - b) from an assessment point of view, the external quality measures taken for the test methods/types of tests applied in the scope of accreditation are not sufficient, regarding, e.g.:
 - the number of proficiency tests performed in specific cases
 - the application of the test method to another matrix as formerly described
 - the extension of the scope of accreditation
 - the performance of insufficiently validated and documented in-house methods
 - the use of procedural steps deviating from the test standard
 - c) the results of the proficiency tests submitted by the laboratory are unsatisfactory as defined by the acceptability criteria
 - d) the conclusions drawn and the necessary corrective actions of the laboratory have not been carried out or documented, or are not sufficient
 - e) assistance in detecting systematic errors in the laboratory is needed
- and if the laboratory has no other means to provide evidence of its technical competence and quality of measurement

1.4 Documentation

The results achieved in proficiency tests should be adequately documented in the laboratories before they can be considered as part of an accreditation procedure (see 7.1.8)

1.5 The period for keeping the records of proficiency testing results and other documentation should be in compliance with the policy of the accreditation body (see 7.1.8), or as agreed

2 **DETERMINATION OF ACCEPTABILITY CRITERIA, BASED ON THE EVALUATION OF THE PROFICIENCY TEST**

2.1 **General**

Generally the assessment team should use the criteria stated by the organiser of the proficiency testing scheme

2.1.1 **Criteria used by the accreditation body**

The criteria defined by the accreditation body (for instance, in the responsible sectoral committees) should be taken over by the assessors, who apply them to evaluate the performance of the laboratories in the particular testing area. This guarantees that the overall treatment of the laboratories applying for accreditation or being accredited is consistent

2.1.2 **Criteria used by regulatory authorities**

- a) If the laboratory is active in the concerned mandatory area, the assessment team should use the criteria set by the regulatory authority
- b) If the laboratory is not active in the mandatory area, but is taking part in the proficiency testing scheme for purposes of internal quality assurance, then the assessment team should use the criteria defined for the intended use by the laboratory, after checking the ability of the laboratory to set criteria

Note: The criteria set by the authority or customer should normally have precedence over the criteria given by the accreditation body

2.2 **Assessment of results in proficiency testing schemes**

2.2.1 The procedure for establishing both the assigned value and its uncertainty should be clearly stated in the scheme documentation (protocol) as defined in ISO/IEC Guide 43 [1]

2.2.2 For providers of PT schemes, the procedures, organisation, performance and evaluation are usually defined between the organiser and the laboratories on the basis of respective standards and/or regulations. Therefore the assessment team should consider, in particular, that the requirements of the test, as defined by the organiser, have been fulfilled

2.2.3 For the participation in PT schemes, the check can be done on the basis of the documents provided by the organiser

2.2.4 For the interpretation of the results where guidance is needed, the assessment team is recommended to speak to the organiser

2.3 Assessment of results in interlaboratory comparisons designed for purposes other than proficiency testing

2.3.1 This type of interlaboratory comparison can be planned and carried out among the laboratories themselves, or among the laboratories of one organisation. The results of such interlaboratory comparisons are mostly available in a shorter time than commercial ones and are often cheaper. Furthermore, they have the advantage that they can be applied to the specific problems of laboratories

2.3.2 A precondition for the recognition of interlaboratory comparisons is that the provider of the intercomparison should clearly state in their programmes the assigned values according to ISO/IEC Guide 43:1997- A.1.1 [1]

2.3.3 For interlaboratory comparisons, which are organised or carried out by the laboratories themselves, an additional examination of the proper choice of the selected methods should be made by the assessment team. In certain cases, the acceptability criteria used for the evaluation of the intercomparison and defined by the laboratories should also be checked by the assessment team.

2.3.4 If the laboratory is able to state the uncertainties of its results on the basis of its own experience with the test method, and if the laboratory uses this knowledge to determine the evaluation criteria for the interlaboratory comparison, then the assessment team should accept and use these criteria. A precondition is that the laboratory organising the interlaboratory comparisons defines the assigned values, which are agreed with the participating laboratories

2.3.5 Special case:

If the organiser of interlaboratory comparisons does not provide any criteria for acceptance of results (e.g. interlaboratory comparisons for validation of procedures and certification of reference substances), then the assessment team, in agreement with the laboratory under evaluation, should define - according to his technical knowledge - their own acceptance limits or they may take over the acceptability criteria of the laboratory defined by itself on the basis of their own experience

2.4 Protocol for performing a bilateral proficiency test

2.4.1 Upon agreement with the accreditation body and, if possible, the laboratory, the assessment may include a bilateral proficiency test, where a number of different scenarios can occur:

- a) The assessment team has access to the appropriate test material, and hands it over to the laboratory after proper announcement
- b) The assessment team does not have a sufficiently characterised test material. In this case the assessment team can subcontract a competent organisation to provide the test material to the laboratory cost-effectively

2.4.2 In both cases the following procedures should be agreed with the laboratory:

- a) Type and number of test materials: the material should be unambiguously and unequivocally characterised concerning its homogeneity and stability, (e.g. a test material taken from interlaboratory comparisons or certified reference materials with undisclosed properties)
- b) The test methods to be used, the parameters (which have assigned values) to be determined, and the acceptability criteria to be used for the evaluation by the assessment team
- c) The dates for delivering the test material (e. g. by hand or by mail), for carrying out the tests and for reporting the results to the assessment team
- d) Reporting the results as a test report, which conforms with standards, where appropriate. Furthermore, it should be guaranteed that the raw data leading to the test results are also provided, in order to detect possible errors in the calculation more easily
- e) When not included in the normal accreditation fees, the estimate for the bilateral proficiency test's costs should be made known to the laboratory prior to carrying it out. These costs should be roughly the same as those of comparable commercial PT schemes.
- f) The acceptability criteria for the test should be agreed before the commencement of the test
- g) The conditions under which the bilateral proficiency test needs to be repeated as a consequence of insufficient results. A repeat of the bilateral proficiency test carried out under the same conditions with the same or a comparable test item has proved to be a satisfactory procedure

2.4.3 The test items used for a bilateral proficiency test should fulfil the following requirements:

- a) They should have been produced and characterised by competent laboratories
- b) The assigned values including the uncertainties for the parameters to be determined should exist
- c) These assigned values should only be determined by recognised and competent laboratories, which have carried out, and demonstrated expertise in the respective test method for a long time in the testing field concerned
- d) The laboratory supplying the assigned values has to prove its competence by participation in appropriate interlaboratory comparisons

3 GENERAL USE OF PROFICIENCY TESTS FOR THE ASSESSMENT OF LABORATORIES

3.1 A precondition is that the quality and extent of the accompanying documentation allow for a correct evaluation of the proficiency testing already carried out

3.2 Depending on the type of proficiency testing carried out, different major points play a key role in the evaluation. The major points are:

- 3.2.1** Before or during the assessment, the assessment team should obtain a survey on the participation of the laboratory in proficiency tests. A respective list of proficiency tests should always be part of the documentation of the laboratory's accreditation or surveillance procedure
- 3.2.2** Such a list should contain:
- a) date of proficiency tests already carried out
 - b) organiser (where applicable)
 - c) test materials/ measured quantities/parameters
 - d) matrices
 - e) acceptability criteria
 - f) results (satisfactory/questionable/unsatisfactory)
 - g) corrective actions, where applicable
- 3.3** If the laboratory submits a greater number of proficiency tests, then the assessment team should limit its assessment to a sufficient number chosen in a representative way. From the survey on proficiency tests and considering the above mentioned main points, proficiency tests that are to be checked on-site are to be selected by the assessment team
- 3.4** It is of great importance for proof of the laboratory's competence that general conclusions have been drawn by the laboratory from the participation in proficiency tests concerning their work and, if necessary, where corrective actions have been taken. An assessment team can gain significant information about a laboratory's competence by studying the actions taken following unsatisfactory performance in a proficiency test
- 3.5** In any case, if there are doubts concerning the competence, the assessment team should find out - in agreement with the laboratory - whether interlaboratory comparisons with other laboratories or the participation in existing interlaboratory comparison schemes or even a bilateral proficiency test should be performed. The extent, selected type, the way of performing and evaluating the proficiency tests should be explained to the laboratory by the assessment team
- 3.6** If the laboratory did not have satisfactory results in the proficiency test, the accreditation procedures defined for such cases should be followed (See ISO/Guide 43:1997, Part 2, Chapter 6 and Annex 2)
- 3.7** The assessment team should, where appropriate, conduct an audit of the results in any type of proficiency testing to be satisfied that these results are an honest representation of the laboratory's work

ANNEX 2: PROCEDURE FOR THE ASSESSMENT OF LABORATORIES BY ACCREDITATION BODIES USING PROFICIENCY TESTING (FLOWCHART)

