



**PROFICIENCY TESTING: GUIDELINES ON THE LEVEL OF
PARTICIPATION AND EVALUATION OF PERFORMANCES IN
PROFICIENCY TESTING ACTIVITIES IN THE CONTEXT OF
ACCREDITATION ASSESSMENTS**

The only valid versions of the documents of the BELAC management system are those available from the BELAC website (www.belac.be).

English translation for information only.

French and Dutch version remain the authoritative documents.

Date of implementation: 20.06.2022

HISTORY OF THE DOCUMENT

Revision and date of approval	Reason for revision	Type of revision
0 CC 19.12.2006	First document	Not applicable
1 CC written procedure with end date 17.01.2011	Replacement of reference to Guide ISO 43 by the standard NBN EN ISO/IEC 17043:2010 Extension of application area to all types of laboratories and inspection bodies performing tests. Revision of guidelines concerning frequency of participation. Addition of the concept « measurement audit » as part of the accreditation assessment.	Full document Section 1 Section 4.3.2 Section 4.4.1
2 CC 26.04.2022	Full revision, partly in connection with the publication of EA 4/18 G: 2021	Complete document

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1 OBJECTIVES AND NORMATIVE REFERENCES

Interlaboratory comparisons, including proficiency tests, are an integral part of a laboratory's monitoring of the validity of its results (EN ISO/IEC 17025 §7.7.2 ; EN ISO 15189 §5.6.3).

In the context of this document, the term 'laboratory' covers all organizations that perform testing, calibration or sampling. This document therefore applies to:

- Testing laboratories, accredited according to EN ISO/IEC 17025;
- Calibration laboratories, accredited according to EN ISO/IEC 17025;
- Medical laboratories, accredited according to EN ISO 15189;
- Any other accredited body that carries out its own sampling, testing or critical calibration as part of its activities that may have an influence on the outcome of the conformity assessment (e.g. inspection bodies, product certification bodies, reference materials producers, proficiency test providers).

The purpose of this document is to identify the BELAC requirements concerning the participation of laboratories in proficiency testing. The document further determines the criteria for evaluation of performance in the context of proficiency testing.

This document refers to and is in compliance with:

- standard EN ISO/IEC 17011;
- standard EN ISO/IEC 17025;
- standard EN ISO 15189
- relevant EA en ILAC guidelines (cfr. websites www.european-accreditation.org and www.ilac.org) and in particular EA 4/18 G:2021 and ILAC P9.

2 RECIPIENTS

With follow-up of modifications:

- Coordination Commission
- Accreditation Board
- Secretariat
- Assessors
- Accredited bodies

Without follow-up of modifications

- Any external request

3 DEFINITIONS

Note: Extracts taken directly from standards and other normative documents are reproduced in italic in the original language (English).

3.1 Proficiency Testing (PT)

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

NOTE 1 For the purposes of this International Standard, the term “proficiency testing” is taken in its widest sense and includes, but is not limited to:

- a) quantitative scheme – where the objective is to quantify one or more measurands of the proficiency test item;*
- b) qualitative scheme – where the objective is to identify or describe one or more characteristics of the proficiency test item;*
- c) sequential scheme – where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;*
- d) simultaneous scheme – where proficiency test items are distributed for concurrent testing or measurement within a defined time period;*
- e) single occasion exercise – where proficiency test items are provided on a single occasion;*
- f) continuous scheme – where proficiency test items are provided at regular intervals;*
- g) sampling – where samples are taken for subsequent analysis; and*
- h) data transformation and interpretation – where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).*

NOTE 2 Some providers of proficiency testing in the medical area use the term “External Quality Assessment (EQA)” for their proficiency testing schemes, or for their broader programmes, or both.

(EN ISO/IEC 17043 clause 3.7)

3.2 Interlaboratory comparisons

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

(EN ISO/IEC 17043 clause 3.4)

3.3 Measurement Audit /Bilateral proficiency testing

Laboratories receive a test or calibration item with accurately determined characteristics, which is to be tested or calibrated in the context of an accreditation process. The test or calibration item is given either by the assessor or provided by a third party.

4 GENERAL POLICY AND PRACTICAL ASPECTS REGARDING PARTICIPATION IN PROFICIENCY TESTING.

4.1 General

Proficiency testing is a means by which laboratories can monitor their technical competence (EN ISO/IEC 17025 §7.7.2, EN ISO 15189 § 5.6.3). In addition, proficiency test results can also form part of a validation or verification file.

The following interlaboratory comparisons can also be considered as proficiency testing, provided that the points of attention mentioned are taken into account:

- Interlaboratory comparisons used for purposes other than the evaluation of the performance of participants (e.g. validation of methods or characterization of reference materials). However, the results obtained in such interlaboratory comparisons should be interpreted with caution;
- Interlaboratory comparisons, organized between a number of laboratories (as a one-off or continuous exercise), are also considered as proficiency testing. In such cases, it is appropriate to consider as much as possible the applicable requirements of EN ISO/IEC 17043 and EA-4/21 INF (when there are less than 8 participants), in particular if the results and performance evaluation are used as a tool to check and demonstrate the validity of their results.

For the accreditation bodies, the evaluation of the participation in interlaboratory comparisons, and in particular proficiency testing, as an independent demonstration of the technical competence of a laboratory, is an essential part of the assessments as it can confirm the value of a granted accreditation. This aspect also plays a major role in the acceptance of the results at national and international level through mutual recognition.

The analysis of performance during participation in proficiency testing must be considered as a means of evaluating and possibly improving technical competence and does not have the primary purpose of serving as an instrument to decide whether or not to maintain the accredited status.

In order to ensure the credibility of the accreditation concept, persistent poor performance in proficiency testing may give rise to sanctions. In addition, it may also indicate operational issues with the laboratory's management system (e.g. nonconformity management and corrective actions).

In specific sectors where no or no appropriate proficiency testing is available, the laboratory should use alternative resources to demonstrate its technical competence. These include for example:

- The regular use of (certified) reference materials;
- Repeating a test using a different or the same method;
- Interlaboratory comparisons.

The general requirements concerning the policy on participation in proficiency testing also apply to laboratories using alternative means.

4.2 Terms for participation in proficiency testing

4.2.1 Proficiency testing selection: general provisions

A high level of technical competence is required of the proficiency testing provider with regard to the planning, preparation, execution, interpretation and documentation of the results of proficiency testing.

BELAC gives the laboratory the free choice of the proficiency testing provider. This provider is considered to be a service supplier (EN ISO/IEC 17025 clause 6.6). The selection should be based on the evaluation of the suitability of proposed services with regard to the needs of the laboratory. Previous experience of the laboratory with the proficiency testing provider can serve as the basis for the selection.

In general, the evaluation of the suitability of a proficiency testing provider should include the following elements:

- Competence of the proficiency testing provider: this can be proven by accreditation according to the standard EN ISO/IEC 17043. If the laboratory relies on an provider that is not accredited, the laboratory is required to perform and document its own evaluation.
- Measurement processes/methods, parameters/properties, matrices/products and measurement ranges should, as far as possible, correspond with the routine activities of the laboratory;
- Frequency: should allow to meet the laboratory's needs ;
- Statistical result analysis: the protocol used should be clearly defined.

In many cases it will be difficult – if not impossible – to select a proficiency testing that covers all of the above mentioned criteria for all of the activities covered by the accreditation. A compromise will be necessary and it is the laboratory's task to justify its choices while ensuring adequate coverage of activities covered by accreditation (price / efficiency ratio). See also under §4.3.2.

BELAC recommends laboratories to consult the EPTIS database (European PT Information System – www.eptis.bam.de) to, whenever necessary, identify the appropriate proficiency testing for their activities.

4.2.2 Proficiency testing selection: additional provisions

BELAC can require laboratories to participate in specific proficiency testing, on their own costs, in case elements indicate that there is need to do so; ; in this case BELAC will preferentially select an provider whose management conforms to the requirements of the standard EN ISO/IEC 17043.

Arguments that might lead to such initiatives are: the absence of proficiency testing in a certain sector or special problems discovered during the assessment of laboratories in a specific sector.

In some sectors, participation in specific proficiency testing is mandatory in the context of the contract with the customer, and in particular within the framework of recognitions by the authority.

In the context of the international mutual recognitions by EA and ILAC, international proficiency testing programs are regularly organized. The purpose is to ensure mutual trust on an international level. The accredited laboratories invited by BELAC to participate in these tests are required to participate in these tests, but they cannot request any compensation for the services provided.

4.3 Responsibilities of the laboratory concerning the participation in proficiency testing.

4.3.1 Documentation

The laboratory shall, for the activities covered by the accreditation scope, maintain an updated overview of the results of proficiency testing in which it participated, or in case of lack of proficiency testing, of other initiatives taken to ensure the validity of the test results. This document shall be made available to BELAC in preparation of each assessment.

4.3.2 Degree and frequency of participation in proficiency testing in relation to the accreditation scope

Ideally, a laboratory would participate in a specific proficiency testing for each measurement process or method, for each characteristic or parameter and for each product or matrix included in its accreditation scope. It is recognized that this is not feasible both logistically and economically. For this reason, laboratories themselves are expected to identify technical fields of competence within their accreditation scope. Each field of competence consists of one or more activities (measurement processes/methods, parameters/properties and matrices/products) for which the same level of technical competence is assumed and for which it can therefore be assumed that the result of a proficiency testing for an activity from this set can be directly correlated with the other activities in the same set.

A field of competence can therefore include several measurement processes/methods, parameters/properties and matrices/products as long as the equivalence between the combined measurement processes/methods, parameters/properties and matrices/products can be justified by the laboratory. Different technical competences can usually be identified by the need for different training and qualification and use of different equipment, knowledge or experience.

The laboratory must determine the extent and frequency of its participation in proficiency testing for the different fields of competence in its accreditation scope and record it in a schedule based on a risk analysis. This analysis must take into account at least the following elements:

- other quality assurance measures used by the laboratory to ensure the validity of the results, in particular those capable of revealing, quantifying and monitoring any bias;
- the number of tests performed (at possibly different concentration levels), calibrations or samples taken;
- the number of involved operators and the staff turnover;
- the education level and general experience of the personnel;

- the availability or not of sources of traceability (national standards, certified reference materials);
- the level of complexity and robustness of the measurement method/technique used;
- the known stability/instability of the method/measurement technique used;
- the level of criticality of the result, taking into account its final use;
- changes in specifications when declarations of conformity are reported;
- the general risks and opportunities associated with the laboratory activities;
- the scope of the validation/verification.

In document EA 4/18 §6 some case studies are elaborated (purely by way of illustration) to show how a laboratory can work out the extent and frequency of participation in proficiency testing.

The laboratory re-evaluates the established schedule and the choice of the extent and frequency of participation in proficiency tests whenever deemed necessary, and at least in the event of significant changes in the way the laboratory or the laboratory activities are organized.

Poor performance in proficiency testing or other quality assurance activities may also be a reason for a review of the extent and frequency of participation in proficiency testing.

BELAC can, for a specific sector, impose a higher participation frequency or specific implementation provisions.

An accreditation for one or several tests/calibrations can only be provided if the performance level of the laboratory can be proven by its results in proficiency testing or, in the absence of these proficiency tests, by other means as mentioned above.

If proficiency testing is available, the laboratory should be able to justify why it did not participate.

4.3.3 Statistical evaluation of the results

The statistical result evaluation is a key element to estimate the laboratories performance.

Investigation concerning consistency between the performance of the laboratory (in terms of accuracy and reliability) and the uncertainty reported by the laboratory is of great importance to decide if corrective actions have to be taken and to determine the characteristics of these actions.

4.3.4 Corrective actions

In the case of unsatisfactory results the laboratory should investigate the causes and possible consequences and if necessary take appropriate actions. These actions should involve feedback to test reports or calibration certificates that could be influenced and which have already been send to customers. The actions should also comprise some technical corrective and preventive measures that guaranty that the quality and validity of the future test results will satisfy the costumer's demands and expectations.

As long as the laboratory cannot prove its test/sampling/calibration competence, either through proficiency testing or through any other means available to the laboratory, it is not allowed to issue results under accreditation as in that case the accreditation requirements are not met. The provisions of BELAC 2-001 also apply, in particular with regard to informing the customer about carrying out activities outside accreditation. If this situation continues, the laboratory must inform BELAC.

4.4 BELAC responsibilities in the evaluation by BELAC of the results of participation in proficiency testing.

4.4.1 Evaluation during accreditation assessments

During each assessment the BELAC assessors are required to check the performance in proficiency testing and to evaluate the efficiency of corrective actions and preventive measures.

The assessor shall specifically focus on the following items:

- the suitability of the risk-based approach for determining the extent and frequency of participation in proficiency testing in the different fields of competence as defined by the laboratory;
- the choice and competence of the proficiency testing provider;
- the examination of raw data;
- the operating conditions, which must be identical as much as possible to those of the routine tests;
- the analysis of the results by the laboratory;
- the consistency with the measurement uncertainty as determined by the laboratory;
- the extent of the observed deviation in relation to the customers' expectations;
- any corrective actions taken, including those related to test reports already sent to customers, in the event of poor performance in proficiency testing;
- the complexity of the test.

The findings of the assessor shall be mentioned in the assessment report.

Where appropriate and in particular in calibration activities, the assessor can ask for a bilateral test/calibration (measurement audit) to be performed as part of the assessment activities.

4.4.2 Communication of results of proficiency testing to BELAC.

The BELAC secretariat investigates the results of the proficiency testing in which BELAC accredited laboratories participated in case they are presented to BELAC for example by competent authorities or international organizations. In case of apparently unsatisfactory performance, BELAC contacts the concerned laboratory and the involved technical assessors. An additional assessment will be organized if necessary.

4.4.3 Taking into account the proficiency testing results in a certain technical sector

Repeated and collective unsatisfactory performance of BELAC accredited laboratories in a certain sector should result in a thorough discussion in the Accreditation Bureau with respect to the need for general corrective measures; this can include additional training of BELAC assessors active in this specified sector.

4.5 Sanctions within the context of evaluation of the results of proficiency testing

An unsatisfactory performance without effective corrective actions or repeated (consecutive or not) poor performances in proficiency testing, will result in a sanction.

When, for a particular laboratory, problems arise in multiple technical sectors, the accreditations status can be questioned for all tests within the scope.

This is because globally unsatisfactory results in proficiency testing can indicate an ineffective management system, which must guarantee the quality and validity of the results as the basic aim of the accreditation concept.
