



# **THE ACCREDITATION SCOPE GRANTED TO A PROFICIENCY TESTING PROVIDER: GUIDELINES FOR ITS DESCRIPTION AND EVALUATION**

**THIS PROCEDURE COMPLEMENTS DOCUMENT BELAC 2-002:**

**“Accreditation certificate and corresponding scope of accreditation: general  
guidelines for the formulation and evaluation”**

The general provisions documented in this procedure may be in turn complemented with the specific provisions of a document of the BELAC series 2-405, whenever this is relevant for a specific conformity assessment activity.

The only valid versions of the documents of the BELAC management system are those available from the internet website ([www.belac.fgov.be](http://www.belac.fgov.be))

English translation for information only.  
Versions in French and Dutch remain the authoritative documents.

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## HISTORY OF THE DOCUMENT

Revision and date of approval	Reason(s) for revision	Scope of the revision
0 CC 20.04.2017	New document	
1 CC 01.12.2022	Following the revision of ILAC G18:12/2021 and the withdrawal of EA 2/18	Complete document

# **ACCREDITATION SCOPE GRANTED TO A PROFICIENCY TESTING PROVIDER:**

## **GENERAL GUIDELINES FOR ITS DEFINITION AND EVALUATION**

### **1. PURPOSE AND NORMATIVE REFERENCES**

**This document complements document BELAC 2-002 “Accreditation certificate and corresponding scope of accreditation: general guidelines for the formulation and evaluation” and consequently has to be read and applied together with BELAC 2-002.**

This document provides more specific guidelines for the definition and assessment of a scope for an accreditation granted to a proficiency testing provider.

The provisions of this document explicitly refer to the corresponding clauses and paragraphs of document BELAC 2-002.

This document refers to and complies with the relevant sections of:

- the legal provisions governing the functioning of BELAC;
- standard NBN EN ISO/IEC 17011 and the EA and ILAC guidelines, in particular document ILAC G18;
- the guidelines for the implementation of the accreditation procedure (documents BELAC 3-11 and 3-12);
- the general guidelines for the accreditation of multi-sites bodies (BELAC 1-04).

### **2. RECIPIENTS OF THIS DOCUMENT**

- The members of the Coordination Commission
- The members of the Accreditation Board
- The Accreditation Secretariat
- The assessors
- The accredited bodies

### **3. SPECIFIC PROVISIONS APPLICABLE TO PROFICIENCY TESTING PROVIDERS (PTPs) (COMPLEMENT TO BELAC 2-002 § 3 DEFINITIONS)**

In addition to the definitions contained in the ISO/IEC 17043 standard, the following definitions apply:

#### **Product or matrix or artifact**

Type of sample, product, artifact, reference material, device, material, measurement standard, data set, or other information used for proficiency testing (PT item).

#### **Parameter or property**

Characteristic/feature/quantity (of a PT item) that is determined in proficiency testing and to which a value ('assigned value') has been assigned.

*Note: The concept of value also includes qualitative data (e.g. identity or ordinal data)*

## 4. SPECIFIC PROVISIONS APPLICABLE TO PROFICIENCY TESTING PROVIDERS (COMPLEMENT TO BELAC 2-002 §4: GENERAL PROVISIONS)

### 4.1 Accreditation certificate and accreditation scope: concept and rules for presentation

#### 4.1.1 Presentation of the accreditation certificate

No additional guidelines

#### 4.1.2 Presentation of the accreditation scope

Any type of proficiency testing covered by the proficiency testing provider's accreditation shall be unambiguously specified in the accreditation scope. The level of detail used will depend on whether it is a fixed scope or a flexible scope and the degree of flexibility granted by BELAC after a thorough evaluation of the experience and competence of the proficiency testing provider.

BELAC is aware of the importance of proficiency testing for laboratory activities and of the fact that a certain degree of flexibility in the accreditation scope is essential to meet the needs of the laboratories and will always take this into account during its audits. . The degree of detail of the accreditation scope will depend on the level of flexibility that BELAC can allow after a thorough evaluation of the capabilities, experience and competence of the proficiency testing provider. The provisions for the description of an accreditation scope for a proficiency testing provider are described in § 4.1.2.1 (for a fixed accreditation scope) and § 4.1.2.2 (for a flexible accreditation scope).

The accreditation scope can consist of a fixed and a flexible part.

##### **4.1.2.1 Presentation of a fixed accreditation scope**

- a) A fixed accreditation scope is in particular appropriate for proficiency testing of a repetitive nature (e.g. annually recurring proficiency tests or PT schemes). If a proficiency testing provider has little experience or can only demonstrate limited competence during an audit, the scope will also be limited to a fixed accreditation scope.

The formulation in this case will consist of a detailed list of the types of proficiency tests, well defined with regard to product/material/artifact and parameter/property, for which compliance with the accreditation requirements has been established. In other words, the accreditation scope reflects the specific proficiency tests for which compliance with the applicable requirements could be established during an assessment in terms of their organization.

b) In line with the requirements of ISO/IEC 17011 §7.8.3 e), at least the following elements are specified for each line in the fixed scope (i.e. for each individual proficiency test or PT scheme):

- Unique identification of the proficiency testing (PT scheme): name, number or other clear and unique identification of the PT scheme;
- product/matrix/artifact that is the subject of the proficiency testing (PT scheme);
- parameter/property determined in the proficiency test;

Where deemed necessary by BELAC, the range and uncertainty associated with the assigned (quantitative) values or the nature of the proficiency test (qualitative, quantitative or interpretative) will also be specified.

c) Prior to each assessment, a proficiency test provider will also be required to provide, per line in the accreditation scope, additional information regarding:

- the number of PT rounds performed in the past year (or date of the last PT round if no PT round was organized in the past year)
- the type of PT scheme
- the procedure for determining the assigned value
- activities that are outsourced and to whom they are outsourced

A change or extension of a fixed scope is only possible after evaluation and approval by BELAC: a formal application will have to be submitted to BELAC for this.

Examples of presentation of a fixed accreditation scope:

- In the calibration field:

Identification code PT scheme	Product/matrix/artifact	Parameter/ property	Measurement range
TEMP.01	Liquid in glass thermometers	Temperature	0-50 °C

- In the testing field :

Identification-code PT scheme	Product/matrix/artifact	Parameter/property
MILKINC	Milk	Fat content

- In the medical testing field:

Identification code PT scheme	Product/matrix/artifact	Parameter/property
S_OES	Serum	Oestradiol

#### 4.1.2.2 Presentation of a flexible accreditation scope

- When a proficiency testing provider can demonstrate during an assessment sufficient experience and competence to operate a certain range of PT schemes within the same technical domain (e.g. Microbiology – edibles), this competence is best reflected in a flexible accreditation scope.
- In a flexible accreditation scope of proficiency testing providers, flexibility can only apply at product/matrix/artifact level and/or parameter/property level.

In concrete terms, this means that in the accreditation scope groups of PT schemes, in terms of:

- groups of products/matrices/artifacts or
- groups of parameters/properties or
- a combination of groups of products/matrices/artifacts and groups of parameters/properties

are defined, rather than individual PT schemes (with a well-defined, detailed description of product/matrix/artifact and parameter/property) as is the case in a fixed accreditation scope.

The groups must be formulated in such a way that no confusion is possible about the concrete products/matrices/artifacts and/or concrete parameters/properties that can be covered by the groups concerned, nor about their extent and scope.

For example, a proficiency testing provider can, without having to request an extension of the accreditation scope from BELAC, operate various PT schemes, which fall under the heading of groups of products/matrices/artifacts and/or groups of parameters/properties such as defined in the accreditation scope. This

also makes it possible, for example, to respond quickly and flexibly to customer requests for non-routine PT schemes.

The degree of competence and experience of a proficiency testing provider in the organization of proficiency tests and the extent of his knowledge about:

- the products/matrices/artifacts,
- the parameters/properties,
- the analytical methods used for the characterization and possibly the determination of stability and homogeneity of the PT items,
- the methods of analysis used by the participants in the proficiency tests,
- the (statistical) methods used to evaluate the performance of the participants,

are the key factors in determining the range of flexibility in an accreditation scope.

- c) Activities that fall under a flexible scope are designated as such in the accreditation scope. A clause/disclaimer always explicitly refers to the available and current list of PT schemes that have been organized within the extent of the flexible scope, as described under d).
- d) For each line in the flexible accreditation scope, which reflects a group of PT schemes for which the provider has demonstrated his experience and competence, the provider maintains an up-to-date and detailed list of the individual PT schemes that have been produced under the heading of this group of PT schemes.

A PT scheme can only be included in the detailed list after formal approval by the management and after all necessary steps have been taken to demonstrate that the concrete process for executing the PT scheme is under control and leads to a reliable evaluation of the performance of the participants,.

The detailed list contains at least the following information:

- in the case of flexibility at the product/matrix/artifact level: specification of the specific, well-defined products/matrices/artifacts that are offered under accreditation as a PT item, with a clear link to the group of products/matrices/artifacts (as stated in the BELAC scope) under which these fall.
- in the case of flexibility at the parameter/property level: specification of the specific, well-defined parameters/properties that are offered in PT schemes, with a clear link to the group of parameters/properties (as stated in the BELAC scope) under which they fall. It must also be clear whether these are qualitative or quantitative parameters/properties.
- per listed PT scheme:

- the type of PT scheme
- the procedure for determining the assigned value
- the identification of the sub-processes that are outsourced (such as the production & processing of PT items, assessment of homogeneity and/or stability, characterization, storage, distribution);
- date as of which the PT scheme is operated under accreditation;
- where deemed necessary by BELAC: additional specifications such as the range and uncertainty of the assigned values.

In any case, the information about which concrete and specific PT schemes (falling under the heading of the flexible scope) are covered by the accreditation must be transparent and accurate.

The detailed list shall be made available upon request from BELAC or any other interested party. In any case, this list is provided to BELAC by the proficiency testing provider prior to each assessment.

- e) A flexible scope will not allow, without the intervention of BELAC, to extend the activities:
- to a new accreditation application, which falls under a new accreditation standard;
  - to PT schemes belonging to a completely new competence domain;
  - to another activity centre.

Examples of presentation of a flexible accreditation scope:

- In the calibration field :

General code	Product/matrix/artifact	Parameter/property
FLEX_T01	Liquid in glass thermometers	Temperature (*)

*(\*)The proficiency testing provider maintains, for the benefit of each applicant, an updated and detailed list of the specific PT schemes (in terms of specific products/matrices/artifacts and specific parameters/properties) that are operated under accreditation (in accordance with the provisions of BELAC 2-109).*

General code	Product/matrix/artifact	Parameter/property
FLEX_T02	All types of measurement instruments for temperature (*)	Temperature (*)

*(\*) The proficiency testing provider maintains, for the benefit of each applicant, an updated and detailed list of the specific PT schemes (in terms of specific products/matrices/artifacts and specific parameters/properties) that are operated under accreditation (in accordance with the provisions of BELAC 2-109).*

- In the testing field:

General code	Product/matrix/artifact	Parameter/property
MILK_FLEX01	Milk	Nutritional properties(*)

(\*) The proficiency testing provider maintains, for the benefit of each applicant, an updated and detailed list of the specific PT schemes (in terms of specific products/matrices/artifacts and specific parameters/properties) that are operated under accreditation (in accordance with the provisions of BELAC 2-109).

General code	Product/matrix/artifact	Parameter/property
MILK_FLEX02	Foodstuffs of animal origin (*)	Nutritional properties (*)

(\*) The proficiency testing provider maintains, for the benefit of each applicant, an updated and detailed list of the specific PT schemes (in terms of specific products/matrices/artifacts and specific parameters/properties) that are operated under accreditation (in accordance with the provisions of BELAC 2-109).

- In the medical testing field:

General code	Product/matrix/artifact	Parameter/property
FLEX_HOR	Serum	Hormones (*)

(\*) The proficiency testing provider maintains, for the benefit of each applicant, an updated and detailed list of the specific PT schemes (in terms of specific products/matrices/artifacts and specific parameters/properties) that are operated under accreditation (in accordance with the provisions of BELAC 2-109).

## **4.2 Organization of assessments in the case of a fixed accreditation scope**

### **4.2.1 General procedure for evaluation**

- a) The purpose of an assessment is to assess the competence of a proficiency testing provider, in particular with regard to the organization of the specific PT schemes as included in the accreditation scope.

In addition to an assessment of the implementation of the requirements of ISO/IEC 17043, a check against the requirements of ISO/IEC 17025 will also be performed with regard to the tests performed as part of the process (to determine homogeneity and stability and /or to characterize the PT items). Where these tests are performed in-house, the proficiency testing provider may also choose to apply for a separate accreditation to ISO/IEC 17025 for these tests. This ISO/IEC 17025 accreditation can be considered sufficient to meet the relevant requirements of ISO/IEC 17043 regarding the testing activities.

- b) The evaluation shall be based on a balanced combination of:
- review of procedures and working instructions;

- review of records;
- interviews of personnel.
- witnessing of specific activities related to the organization of proficiency testing insofar as these are carried out by the provider himself, such as preparation, packaging, characterization, storage, transport and distribution of PT items, the performance of tests in the context of homogeneity and/or stability studies and/or characterization of the PT item;
- if there are no PT activities in progress at the time of the assessment, specific activities can also be demonstrated (simulation) but this cannot systematically replace the activities actually performed, where all influences are taken into account.
- assessment of a full PT round, from planning/design to reporting the results for at least 1 specific PT scheme that falls under the accreditation scope.

During the assessment, specific attention will also be given to:

- knowledge and competence of the personnel involved in the organization of proficiency tests (including with regard to the products/matrices/artifacts and the parameters/properties that are the subject of the PT Schemes that the provider offers under accreditation, the methods of analysis used for the characterization and possibly the determination of stability and homogeneity of the PT items, the analysis methods used by the participants in the proficiency tests, the (statistical) methods used to evaluate the performance of the participants);
  - competence management of the subcontractors called upon for specific tasks in the process (where applicable);
  - the management and supervision of the outsourced activities (where applicable)
  - methods used for the (statistical) evaluation of the results of participants in proficiency tests;
  - communication and information exchange with participants in proficiency tests.
- c) In an initial assessment, the assessment will consist of:
- an evaluation of the process for one or more PT schemes, exemplary for the full accreditation scope presented;
  - witnessing of the realization of specific activities (insofar as these are carried out by the organizer itself) in the organization of a proficiency test.
- d) In the assessments which are subsequently organized within an accreditation cycle, the assessment will consist of:
- evaluation of the process for one or more PT schemes, exemplary for one or more specific competence domains in the accreditation scope;
  - at least once in a cycle: witnessing of the realization of specific activities (insofar as these are carried out by the organizer itself) in the organization of a proficiency test.

The competence domains that will be covered for each assessment are recorded in the assessment program that is drawn up prior to each cycle, taking into account, among other things, the complexity and volume of activities.

This program can be modified if necessary, taking into account, for example, changes in the volume of activities, the activity centres, personnel, organization but also the results of each BELAC audit.

BELAC will in any case ensure that all competence domains within an accreditation scope are covered during a complete accreditation cycle.

- e) If the proficiency testing provider is active in several activity centres, the provisions applicable to multi-site bodies (BELAC 1-04) are taken into account in the assessment program.

#### 4.2.2 Maintaining a fixed accreditation scope

No additional guidelines.

#### 4.2.3 "Dormant" activities

No additional guidelines.

#### 4.2.4 Extension of a fixed accreditation scope

- a) In order to respond to the wishes of his customers, the provider may at any time submit a formal application to BELAC to:
- modify or extend the proficiency tests as included in the accreditation scope. Based on the proposed changes, BELAC will decide whether an evaluation (documentary or on-site) is necessary; In case of limited changes, with a close link to activities already under accreditation, BELAC may also grant an administrative adaptation of the scope, without prior evaluation. In that case, special attention will be paid to these activities during the next scheduled assessment
  - extend an accreditation scope with completely new specific proficiency tests;
  - to extend or replace an accreditation scope with a flexible accreditation scope (see further under §4.3.4).
- b) In each of the aforementioned cases, the proficiency testing provider will submit a proposal to BELAC for the formulation of the new activities or the to be changed activities, based on the accreditation scope applicable at that time (a copy of which can be requested at any time from the BELAC file manager).

In addition, information regarding the number of PT rounds performed on an annual basis, the type of PT schedule, the procedure for determining the assigned value and the activities that are outsourced will be submitted to BELAC.

#### 4.2.5 Sanctions in case of non-compliance with the accreditation requirements

No additional guidelines.

### 4.3 Organization of assessments in case of a flexible accreditation scope

#### 4.3.1 Requirements applicable to conformity assessment bodies that apply for a flexible scope

- a) When applying for a flexible scope, a proficiency testing provider must be able to provide evidence of:
- sufficient experience in the organization of proficiency tests;
  - adequate knowledge of:
    - o the products/matrices/artifacts, the parameters/properties and the analysis methods used (in the context of stability and homogeneity studies and characterization of PT items);
    - o data analysis and (statistical) evaluation of the performance of participants in proficiency tests.

During the audit, specific attention will be given to the above points and it will also be verified that the general functioning of the proficiency testing provider is based on a high-performance management system, which must guarantee a consistent, high-quality and reliable performance evaluation of participating laboratories.

- b) In view of the specific context in which proficiency testing providers operate and the importance of some flexibility in their operation in order to be able to respond quickly to demands from laboratories that rely on proficiency testing to substantiate the reliability of their results, an accreditation application with a flexible accreditation scope may already be submitted from the initial audit.
- c) When applying for a flexible scope, the proficiency testing provider shall provide, for each group of PT schemes (in terms of group of products/matrices/artifacts and/or group of parameters/properties), at least the following:
- A documented process for managing applications for the organization of new, previously unorganized PT schemes, which fall under the heading of proficiency testing (expressed in terms of a group of products/matrices/artifacts and/or a group of parameters /properties) included in the flexible scope. In this process, the elements to be taken into account and the steps to be taken with such applications must be defined.

The various responsibilities regarding the management of the activities that fall under the flexible scope must also be included.

- A formulation proposal for a flexible accreditation scope, in which the degree of flexibility should reflect the demonstrable competence and experience, the available resources, and the needs of the proficiency testing provider as well as those of his customers. This proposal will be evaluated during the assessment and may or may not be confirmed depending on the findings of the assessment team.
- A proposal for a detailed list of specific proficiency tests that fall under the heading of the proficiency tests as included in the flexible scope on the basis of which the proficiency testing provider is able to demonstrate his knowledge and experience in the organization of proficiency tests in the domain concerned, as included in the flexible scope submitted for accreditation.

#### 4.3.2 Assessment modalities

In addition to the provisions as included under §4.2.1 of this document, which also remain applicable for flexible accreditation scopes, each assessment of a proficiency testing provider who has a flexible accreditation scope, will also give specific attention to:

- the detailed list and in particular the PT schemes that have been added since the previous audit and fall within the extent of the flexible scope;
- the general organizational aspects related to the organization of new PT schemes that fall within the extent of the flexible scope, including the possible impact on impartiality and the identification of risks;
- the qualifications, experience and continuous training of key personnel involved in the activities that fall under the flexible scope;
- presence of suitable (technical) procedures to organize high-quality and reliable PT schemes within the extent of the scope;
- effectiveness of the management system in supporting a consistent organization of high quality and reliable PT schemes;
- records related to validations, verifications and quality assurance checks where relevant.

#### 4.3.3 "Dormant" activities

No additional guidelines

#### 4.3.4 Extension of an accreditation with a flexible scope

In order to take into account the wishes of his customers, a proficiency testing provider may at any time submit an application to BELAC to extend the accreditation scope with one or more groups of products/matrices/artifacts and/or groups of parameters/properties.

Each extension application must contain sufficient information about the activities for which the extension is requested (see also under §4.2.4) and will be examined by BELAC which, depending on the application and the history of the file, will at least organize a documentary audit and, where appropriate, an on-site audit.

#### 4.3.5 Sanctions in case of non-compliance with the accreditation requirements

No additional guidelines

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