



THE ACCREDITATION SCOPE OF A PRODUCER OF REFERENCE MATERIALS: GUIDELINES FOR FORMULATION AND EVALUATION

**THIS DOCUMENT COMPLEMENTS DOCUMENT BELAC 2-002:
“ACCREDITATION CERTIFICATE AND CORRESPONDING SCOPE OF
ACCREDITATION: GENERAL GUIDELINES FOR FORMULATION AND
EVALUATION”.**

Whenever it is relevant to a particular conformity assessment activity, the general principles described in this procedure are supplemented with specific provisions in a document from the series BELAC 2-405.

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

English translation for information only.

Versions in French and Dutch remain the authoritative documents.

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1 OBJECTIVES AND NORMATIVE REFERENCES

This document complements the document BELAC 2-002 «Accreditation certificate and corresponding scope of accreditation: general guide-lines for formulation and evaluation» and must therefore always be read and applied together with BELAC 2-002.

This document provides more specific guidelines for the definition and evaluation of an accreditation scope assigned to a producer of reference materials.

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

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

- the legal provisions governing the functioning of BELAC;
- the EN ISO/IEC 17011 standard and the EA and ILAC guidance documents, in particular document EA-2/15;
- ISO guide 30, ISO guide 31, ISO guide 35;
- the provisions for the implementation of the accreditation procedure (documents BELAC 3-11 et 3-12);
- the general provisions of the document BELAC 2-002 on the formulation of the accreditation scope and its evaluation;
- the general provisions for the accreditation of multi-sites bodies (BELAC 1-04).

2 RECIPIENTS

With follow-up of revisions:

- The members of the Coordination Committees
- The members of the Accreditation Board
- The accreditation secretariat
- The assessors
- The accredited calibration laboratories and applicants for accreditation

Without follow-up of revisions

- Any external request

3 SPECIFIC PROVISIONS APPLICABLE TO PRODUCERS OF REFERENCE MATERIALS (SUPPLEMENT TO BELAC 2-002 § 3: DEFINITIONS)

The following definitions complement those already included in ISO 17034, ISO Guide 30 and §3 of BELAC 2-002:

Product or matrix or artefact

Type of matter/material/substance presented as reference material

Parameter or property

Characteristic/feature of a reference material for which one or more (reference) values have been determined

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

4 SPECIFIC PROVISIONS APPLICABLE TO PRODUCERS OF REFERENCE MATERIALS (SUPPLEMENT TO BELAC 2-002 § 4: SPECIFIC 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

Each type of reference material that falls under the accreditation of the producer of reference materials must be unambiguously specified in the accreditation scope. The level of detail used will depend on whether it concerns a fixed scope or a flexible scope and the degree of flexibility assigned by BELAC after a thorough evaluation of the experience and competence of the producer of the reference material.

BELAC is aware of the importance of reference materials in laboratory activities and confirms that a certain degree of flexibility in the accreditation scope is essential to meet the needs of the laboratories. Therefore, BELAC will always take this into account during its assessments.

The provisions for the description of an accreditation scope of a producer of reference materials 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 of the accreditation 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 recommended for reference materials whose production process has a repetitive character and hardly changes, if at all. Also when the producer of reference materials has only little experience or can only demonstrate limited competence during an assessment, the scope will be limited to a fixed accreditation scope.

The formulation of the scope in this case will consist of a detailed list of types of reference materials, precisely defined with respect to product/matrix/artifact and parameter/property.

In other words, the accreditation scope indicates the specific reference materials for which conformity with the applicable requirements with regard to their production could be established during an assessment.

- b) In line with the requirements of ISO/IEC 17011 §7.8.3 f), at least the following elements are specified for each line in a fixed scope:
- type of reference material (certified reference material, reference material or both);
 - matrix, product or artifact;
 - characterized parameter or property;
 - approach used to assign the values of the characterized parameter.

Where deemed necessary by BELAC, the range and uncertainty of the assigned (quantitative) values will also be specified in order to clearly indicate the extent of the competence of the producer of reference materials, as determined during an assessment.

- c) Prior to each assessment, a producer of reference materials will also need to provide additional information for each reference material mentioned in the accreditation scope, with regard to :
- number of productions (production rounds) in the past year (or date of the last production if no reference material was produced in the past year);
 - activities that are outsourced and to whom they are outsourced.

- d) Changing or extending a fixed accreditation scope is only possible after evaluation and approval by BELAC: a formal application with this regard must therefore be submitted to BELAC.

Example of presentation of a fixed accreditation scope:

Product/ Matrix/ Artefact	Characteristic/ Property	Type of reference material (certified reference material, reference material or both)	Approach/procedure for characterization
Drinking water	Lead content	Certified reference material (CRM)	Characterization of an operationally defined measurand with the help of a network of competent laboratories

4.1.2.2 Presentation of a “flexible ” accreditation scope

- a) When a producer of reference materials can demonstrate sufficient experience and competence to produce a certain range of reference materials during an assessment, this competence can be reflected in a flexible accreditation scope.
- b) In a flexible accreditation scope of reference material producers, flexibility can only be applied at the level of product/matrix/artifact and/or the level of parameter/property. This means that in a flexible accreditation scope, groups of reference materials, 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 instead of individual reference materials (with definite 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 range.

As such, a producer of reference materials can – without having to apply for an extension of the accreditation scope to BELAC – produce a variety of reference materials that fall under the heading of the groups of products/matrices/artifacts and/or groups of parameters/properties as defined in the accreditation scope. This allows a producer of reference materials to respond quickly and flexibly to requests from customers for non-routine reference materials.

The degree of competence and experience of the producer of reference materials and his range of knowledge regarding the products/matrices/artifacts, the parameters/properties and the analysis methods used (for stability and homogeneity studies and characterization of the reference material) and the end-uses of the reference materials are key factors in determining the range of flexibility in an accreditation scope.

- c) Activities that fall under a flexible scope are indicated as such in the accreditation scope. A clause/disclaimer will also explicitly refer to the available and up-to-date list of reference materials that were produced within the range of the flexible scope, as described under d).
- d) For each activity in the flexible accreditation scope, which reflects a group of reference materials for which the producer has been able to demonstrate his experience and competence, the producer maintains an up-to-date and detailed list of the individual reference materials that have been produced within the range of this group of reference materials.

The inclusion of reference materials in the detailed list is only permitted after formal approval by the management and after all necessary steps have been taken to demonstrate that the production process is under control and leads to reliable reference materials.

The detailed list contains at least the following information:

- in the case of flexibility at the level of product/matrix/artifact: specification of the concrete, well-defined products/matrices/artifacts that are produced under accreditation, with a clear link to the group of products/matrices/artifacts (as stated in the BELAC scope) into which these reference materials fall.
- with flexibility at the level of parameter/property: specification of the concrete, well-defined parameters/properties for which reference materials are offered under accreditation, with a clear link to the group of parameters/properties (as stated in the BELAC scope) into which these reference materials fall. It must also be clear whether it concerns qualitative or quantitative parameters/properties.
- per listed reference material:
 - o identification of the sub-processes that are outsourced (such as production & processing, assessment of homogeneity, assessment of stability, characterization, storage, distribution);
 - o the characterization procedure used;
 - o identification of type of reference material (CRM or RM);
 - o date since when the reference material is produced under accreditation;

- where deemed necessary by BELAC: additional specifications such as, for example, the range and uncertainty of the assigned values.

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

The detailed list must be made available on request of BELAC or any other interested party. In any case, this list is provided to BELAC by the producer of reference materials in preparation of each assessment.

- e) A flexible scope will not allow to extend the activities:
- towards a new accreditation application, which falls under a new accreditation standard;
 - to any reference materials that belong to a completely new competence domain or to any reference materials for which a different characterization strategy is used than the one(s) covered under the flexible scope;
 - to another activity centre;
 - without the intervention of BELAC.

Example of presentation of a flexible accreditation scope:

Product/ Matrix/ Artefact	Characteristic/ Property	Type of reference material (certified reference material, reference material or both)	Approach/procedure for characterization
Water	Metal content	Certified reference material (CRM)	Characterization of an operationally defined measurand with the help of a network of competent laboratories

A detailed list of the reference materials covered under accreditation, including the characterization approach for these reference materials is maintained by, and available upon request from, the reference material producer.

4.2 Organisation of assessments in case of a fixed scope

4.2.1 General procedure for evaluation

- a) The purpose of an assessment is to evaluate the competence of a producer of reference materials, in particular with regard to the production of the specific reference materials as included in the accreditation scope.

In addition to an evaluation of the fulfilment of the requirements of ISO 17034, an assessment against the requirements of ISO/IEC 17025 will also be carried out with regard to the tests that are carried out as part of the production process (to determine homogeneity and stability and/or to characterize the candidate reference material).

When these tests are carried out in-house, the producer of reference materials can also choose to request a separate accreditation according to ISO/IEC 17025 for these tests. This ISO/IEC 17025 accreditation can be considered sufficient to meet the relevant requirements of ISO 17034 with regard to the testing activities.

- b) The evaluation will be based on a balanced distribution of:
- examination of procedures and instructions;
 - review of registrations;
 - interviews with the staff;
 - observation of specific activities related to the production of reference material such as preparation, identification, packaging, storage, transport, distribution of reference materials and the realization of tests in the context of homogeneity and/or stability studies and characterization of the reference material, whereby attention will also be paid to the different approaches and statistical methods that can be used by the producer of reference materials.
- If no reference material is produced at the time of the assessment, specific activities can also be demonstrated (simulation), but this cannot systematically replace the activities actually carried out, taking all influences into account.
- assessment of a complete production process, from planning to distribution and stability control for at least 1 specific reference material that falls under the accreditation scope.

During the assessment, special consideration shall be given to the competence management of the personnel involved in the production of reference materials as well as of the subcontractors called upon for specific tasks in the production process. The management and supervision of the outsourced activities is also a particular point of attention during the assessment.

- c) An initial assessment will consist of:
- evaluation of the production process of one or more produced reference materials, exemplary for the complete accreditation scope as submitted to BELAC;
 - observation of the realization of specific activities in the production process.
- d) The assessments, subsequently organized within an accreditation cycle, will consist of:
- evaluation of the production process of one or more produced reference materials, exemplary for a specific competence domain in the accreditation scope;

- at least once on an accreditation cycle: observation of the realization of specific activities in the production process.

The competence domains that will be covered per assessment are laid down in an assessment program that is drawn up prior to each cycle. This takes into account, among other things, the complexity and volume of activities.

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

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

- e) If the producer of reference materials is active in several activity centres, the assessment program takes into account the provisions applicable to multi-site organizations (BELAC 1-04).

4.2.2 Maintaining a fixed accreditation scope

No additional guidelines

4.2.3 "Dormant" activities

No additional guidelines

4.2.4 Extension of the fixed accreditation scope

- a) To meet the expectations of its customers, the producer of reference materials may introduce at any moment an application for extension of the accreditation scope in order to:
 - adapt or extend the types of reference materials as included in the accreditation scope. Based on the proposed changes, BELAC will investigate whether an evaluation (documentary or on-site) is required; In case of limited adaptations, which are closely related to the activities already accredited, BELAC may consider an administrative adjustment of the accreditation scope without a prior evaluation. In that case, these activities will be a point of attention during the next assessment;
 - extend an accreditation scope with completely new types of reference materials;
 - extend or replace an accreditation scope with a flexible accreditation scope (see also §4.3.4).

- b) In each of the aforementioned cases, the producer of reference materials will submit a proposal for the formulation of the new activities or the activities to be changed to BELAC, based on the accreditation scope applicable at that time (a copy of which can be requested from the BELAC file manager at any time).

In addition, the information on the number of productions on an annual basis and on the activities that are outsourced will also be submitted to BELAC.

4.2.5 Sanctions in case of failure to comply with the accreditation conditions

No additional guidelines

4.3 Organisation of assessments in case of a flexible scope

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

- a) When applying for a flexible scope, a producer of reference materials must provide evidence of:
- sufficient experience in the production of reference materials;
 - adequate knowledge of:
 - o the products/matrices/artefacts, the parameters/properties and the analysis methods used (in relation to stability and homogeneity studies and characterization of the reference material);
 - o the end-uses of the reference materials.

During the assessment, particular consideration shall be given to the abovementioned points. The assessment team will also evaluate whether the general functioning of the organization is based on a performant management system, which ensures the consistent production of high-quality reference materials in terms of stability, homogeneity and characterized parameters or properties.

- b) Given the specific context in which producers of reference materials operate and the importance of some flexibility in their operation, to be able to respond quickly to demands from laboratories, which rely on reference materials to substantiate the reliability of their results, an application for a flexible accreditation scope can be submitted during the initial assessment.
- c) When applying for a flexible scope, the producer of reference materials has to submit at least the following documents for each group of reference materials (in terms of group of products/matrices/artifacts and/or group of parameters/properties) applied for:

- A documented process for the management of customer requests for the production of new reference material, which has been produced before but which belongs to the group of products/matrices/artifacts and/or group of parameters/properties included in the flexible scope. In this process, the elements to be taken into account and the steps to be carried out for such applications must be recorded.
- A proposed wording for a flexible accreditation scope, where the degree of flexibility should reflect its demonstrable competence and experience, its available resources, and its needs as well as those of its customers. This proposal will be evaluated during the assessment and may or may not be confirmed depending on the findings of the assessment team.

4.3.2 Assessment provisions

The provisions, as included in §4.2.1 of this document, also continue to apply for evaluation of a flexible scope. In addition, particular attention will also be paid to:

- the detailed list and in particular the reference materials that have been added since previous assessment;
- the general organizational aspects related to the introduction of productions of new reference materials that fall within the range of the flexible scope, including the possible consequences for the impartiality and identification of risks;
- the qualifications, experience and continuous training of key personnel involved;
- presence of suitable (technical) procedures to produce high-quality reference materials within the range of the scope;
- effectiveness of the management system in supporting a consistent production of quality reference materials;
- records regarding validations, verifications and quality assurance checks where relevant.

4.3.3 “Dormant” activities

No additional guidelines

4.3.4 Extension of the accreditation scope with a flexible scope

In response to customer demands, a producer of reference materials may apply for an extension of the accreditation scope with one or more groups of products/matrices/artifacts and/or groups of parameters/properties.

Each application for an extension of the accreditation scope will contain sufficient information about the activities for which extension is sought (see also 4.2.4 – last paragraph) and shall be investigated by BELAC. Depending on the nature of the application, BELAC will consider whether a documentary or an on site assessment is required.

4.3.5 Sanctions in case of failure to comply with the accreditation conditions

No additional guidelines
