



ACCREDITATION CERTIFICATE AND CORRESPONDING SCOPE OF ACCREDITATION

General guidelines for formulation and evaluation

The provisions in this document are supplemented by specific rules of implementation for:

- the different types of conformity assessment bodies:

BELAC 2-101:	Testing laboratories
BELAC 2-109:	Proficiency Testing Providers
BELAC 2-110:	Calibration laboratories
BELAC 2-111:	Reference material producers

- specific conformity assessment activities :

BELAC documents 2-405 – NAME ACTIVITY

The only valid versions of the documents of the BELAC management system are those available from the internet website (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) of revision	Extent of the revision
0 CC written procedure 17.01.2011	New document Extension of the concepts, previously included in document BELAC 2-101, to all accreditation sectors	Full document
1 Secretariat 29.10.2012	Extension of the scope of the document to the accreditation of validation and verification bodies Reference to the existence of BELAC documents series 2-405 in case of specific accreditation requirements for a specific conformity assessment activity	Cover page Point 4.1.1 Cover page
2 Secretariat 20.06.2014	Updating the reference to complementary documents Update of the reference standards for the accreditation Precising that drafting complementary sectoral guidelines is an option and not a requirement	Cover page Point 4.1.1 Point 4.1.2
3 CC 19.04.2018	Update of the reference to accreditation standards Modification of the maximum period for sleeping activities	Point 4.1.1 Point 4.2.3
4 CC 29.06.2020	Update of definitions Implementation of the provisions of EA-2/15-2019 "requirements for the Accreditation of Flexible Scopes" Change of the concept of "issue date and validity date" of accreditation certificates and scopes with a validity period and a version number. dates	Point 3 Full document Points 4.1.1, 4.1.2
5 Secretariat 05.09.2022	Addition of reference to BELAC 2-111 Addition of the VV certificate Clarifications management detailed list	Cover page Point 4.1.1 Point 4.3.1.2
6 CC 01.12.2022	Mention and management of version numbers and release dates Clarifications management dormant activities	Point 4.1.2.1 Point 4.2.3 and 4.3.3
7 CC written procedure 25.09.2023	Section on listing and management of version numbers and release dates has been deleted from point 4.1.2.1 and reworked and included under 4.1.2 and 4.3.1.2. For changes, BELAC is informed via the additional columns in the 'working version of the scope' or via the detailed list Adjustments to the 'dormant activities' section	Point 4.1.2.1, 4.1.2 and 4.3.1.2 Point 4.2.3

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ACCREDITATION CERTIFICATE AND CORRESPONDING SCOPE OF ACCREDITATION

General guidelines for formulation and evaluation

1. INTRODUCTION AND NORMATIVE REFERENCES

This document aims to set guidelines for drawing up an accreditation certificate as well as for the formulation and evaluation of the accreditation scope, granted to a conformity assessment body.

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

- the legal provisions governing the functioning of BELAC;
- the ISO/IEC 17011 standard and the relevant guidances of EA, ILAC and IAF;
- the provisions for the implementation of the accreditation procedure (documents BELAC 3-11 et 3-12).

The provisions in this document are supplemented by specific rules of implementation for the different types of conformity assessment bodies.

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. DEFINITIONS

3.1. Accreditation scheme

Type of conformity assessment activity falling under a specific accreditation standard

3.2. Accreditation scope

List of specific conformity assessment activities, which are covered by an accreditation scheme

3.3. Fixed accreditation scope

Accreditation scope expressed as a fixed and detailed list of conformity assessment activities the body is accredited for.

3.4. Flexible accreditation scope

Scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body (ISO/IEC 17011:2017)

3.5. Name of the conformity assessment body

Name of the registered (legal) entity of the conformity assessment body as mentioned in the Crossroads Bank for Enterprises of the FPS Economy. The name may be complemented with an abbreviation and/or a trade name provided these data are mentioned in the Crossroads Bank for Enterprises.

3.6. Juridical form of the conformity assessment body

The juridical form defines the legally binding rules (statute) applicable to the body.

3.7. Main activity site of a conformity assessment body

Location where conformity assessment activities are performed and activities performed in secondary sites, if relevant, are managed and coordinated. The address of the main activity site may be different from that of the legal entity.

3.8. Secondary activity site of a conformity assessment body

Location whose address is different from that of the legal entity or of the main activity site and where conformity assessment activities are performed under the responsibility of the accredited body.

3.9. Establishment Unit

Activity site a mentioned in the Crossroad Bank for Enterprises in relation with concerned body, where conformity assessment bodies are performed under the responsibility of the accredited body.

3.10. Activity sites

The activity sites include the main activity site (when different from the legal entity) and the secondary site(s) and shall be registered as establishment unit

4. GENERAL PROVISIONS

4.1. Principles and rules for drawing up the accreditation certificate and scope of accreditation

4.1.1. The accreditation certificate

When an accreditation is granted, an accreditation certificate is issued. This certificate acts as a formal proof of competence, independence and impartiality of a conformity assessment body to carry out specific conformity assessment activities.

The certificate, that will be signed by the Chairman of the Accreditation Board, is prepared using a template model and will state the following:

- a unique identification code, composed of a reference to the file number, followed by a reference to the relevant accreditation standard, as follows:
 - CAL referring to calibration laboratories (EN ISO/IEC 17025);
 - TEST referring to testing laboratories (EN ISO/IEC 17025);
 - MED referring to medical laboratories (EN ISO 15189);
 - INSP referring to inspection bodies (EN ISO/IEC 17020);
 - QMS referring to certification bodies for quality management systems (EN ISO/IEC 17021-1);
 - EMS referring to certification bodies for environmental management systems (EN ISO/IEC 17021-1);
 - EMAS referring to environmental verifier (EN ISO/IEC 17021-1:2015 and Regulation (EC) No 1221/2009);
 - PROD referring to certification bodies for products (EN ISO/IEC 17065);
 - PERS referring to certification bodies for persons (EN ISO/IEC 17024);
 - PT referring to organizers of proficiency testing (EN ISO/IEC 17043);
 - RM referring to producer of reference materials (EN ISO 17034);
 - GHG referring to the validation and verification bodies (EN ISO 14065) (Note: these certificates are valid until transition to VV by 31 December 2023 at the latest);
 - VV referring to validation and verification bodies (ISO/IEC 17029).

- specifically for the environmental verification bodies (EMAS): a unique identification code of type BE-V-0xyz where xyz refers to the file number;
- the name, juridical form and address of the legal entity of the accredited body.
- reference to the relevant accreditation standard;
- reference to the scope to which the accreditation applies. This list constitutes an integral part of the certificate;
- a version number and the validity period of the certificate.

In case an accreditation is granted to a conformity assessment body with regard to activities that relate to different types of conformity assessment, an accreditation certificate for each accreditation standard will be issued.

The certificate is delivered:

- in the language of the file, which will be considered as the legal version;
- in each of the two other national languages as well as in English (making explicit reference to the legal version). These versions of the certificate can be used by accredited bodies in dealing with foreign stakeholders.

4.1.2. The accreditation scope

The conformity assessment activities, covered by an accreditation, are specified in an accreditation scope that is an annex to the certificate.

The description of the competence of the accredited body must be sufficiently clear and unambiguous to exclude any misinterpretation. In that way, the scope can serve as a transparent and credible reference to ascertain the competence of the accredited body for its customers, for other interested parties and for the market in general.

The annex that details the accreditation scope contains:

- a front page mentioning the following:
 - a reference to the identification code of the certificate to which the accreditation scope belongs;
 - the name, the juridical form and the address of the legal entity of the accredited body;
 - wherever relevant, the identification of or the restriction to one or more activity sites. When the body is part of a larger entity, the entity to which the accreditation applies will be clearly indicated;
 - a validity period with an end of validity date which is always identical to the one mentioned on the certificate; the starting date of the validity period may be different from that of the certificate considering that the accreditation scope needs to be revised by each modification, extension or reduction;
 - a version number.
- the description of the accredited activities and, whenever relevant, the identification of the activity site(s) where they are performed.

General guidelines/instructions for a standardized presentation of an accreditation scope for each type of conformity assessment activity or, if applicable, for specific activity sectors may be described in separate BELAC documents. The items needed to allow a clear, transparent and harmonized description of the accredited conformity assessment activities for this sector, will be indicated.

The conformity assessment bodies themselves make a proposal of formulation for the accreditation scope based on the template BELAC 6-213. The formulation will be verified by the assessment team members and, if necessary, will be modified in consultation with the conformity assessment body. BELAC will assist to ensure harmonization of the scope formulation. The final approval of the accreditation scope forms an integral part of the accreditation decision; the final version of the scope falls under the responsibility and control of the BELAC Secretariat. The accreditation scope is normally only issued in the language of the file. The accredited body may submit at any time other language versions to the Accreditation Secretariat for review and validation.

In the scope of accreditation, the activities are in principle described without mentioning version numbers or release dates of the applicable documents such as normative documents, schemes, methods, etc. except in the case of a legal obligation, a scheme requirement or specific sectoral requirements as included in documents of the BELAC 2-405 series.

When no version or only a major version is mentioned in the scope of accreditation, it is assumed that the accreditation applies to the most recent (minor) version of the method/scheme/normative document.

An accreditation for an outdated or expired version can only be issued/maintained providing a thorough argumentation for this. In that case, the version(s) or release dates are specifically mentioned in the accreditation scope. If this working method is not practicable, it will be made clear in another appropriate way (e.g. via a disclaimer) that outdated or expired version(s) will be applied under accreditation: this will always be done in consultation with the BELAC secretariat.

When a normative document, scheme, method, etc. mentioned in the accreditation scope is revised, an accredited body is expected to switch to the most current version within a reasonable period of time (and latest before the imposed deadline if applicable) and to keep the necessary records.

During a transition period, activities can also still be carried out according to the previously applicable version.

Changeovers to new versions of a normative document, scheme, method, etc. mentioned in the accreditation scope, which also lead to a change of the scope, must be reported immediately to BELAC. BELAC will then determine whether an additional evaluation is required and will take the necessary actions to implement adjustments to the scope.

BELAC must be informed of changes to new versions of a normative document, scheme, method, etc. mentioned in the accreditation scope, that do not lead to an adjustment of the scope, via the additional columns in the 'working version of the scope' and this on the moment of the next assessment request.

The registrations (gap and impact analysis of the change(s), implementation plan, etc.) and measures regarding the switch to the new version will be discussed during this assessment.

To meet the demands and needs of the accredited bodies and their customers, BELAC offers the possibility to choose between different types of formulation, i.e a fixed scope, a flexible scope or a combination of both:

4.1.2.1. a “**fixed**” accreditation scope:

The “**fixed**” scope lists specific, clearly described activities for which compliance with the accreditation requirements has formally been confirmed during an assessment.

Amendments and/or extensions of the activities as listed in a fixed scope always require an intervention by the accreditation body. Only after completing an evaluation procedure and final approval of the proposed modifications and/or extensions by the accreditation body, the accreditation scope can be updated.

4.1.2.2. a “**flexible**” accreditation scope

The “**flexible**” scope lists defined groups of activities for which a conformity assessment body has already demonstrated that a design/development process is in place to implement new activities (covered by the flexible scope but not yet performed).

The design/development process shall include provisions that aim to:

- fix the minimum input elements;
- develop the new conformity assessment activity;
- validate the conformity with respect to the requirements;
- check the conformity with respect to the requirements after implementation.

Granting a flexible accreditation scope shall reflect the competence of the body not only with respect to the technical activities but also in terms of management of the flexibility.

In this case, a conformity assessment body is allowed to modify its activities and/or to add new activities within the boundaries of its flexible scope without prior approval of BELAC. The requirements to be met are described in section 4.3.1.

An accreditation with flexible scope allows the accredited conformity assessment body to rapidly respond to demands from customers (especially in those sectors where these demands are little repetitive or subject to constant change) or to urgent situations.

An accreditation with flexible scope does not mean that the accredited body has a higher level of competence than one with a fixed scope.

A flexible scope will not allow to:

- extend the scope to a new type of conformity assessment, falling under a new accreditation standard;
- extend the scope with a new activity falling under a new general competence;
- without the intervention of BELAC;
- extend the scope to another site of activity.

A conformity assessment body, who wants to apply for a "flexible" scope, must meet the specific requirements as described in section 4.3.1.

4.1.2.3. an accreditation scope with a "fixed" part and a "flexible" part

An accreditation scope may consist of a combination of both a "fixed" and a "flexible" part. The same provisions as described for a "fixed" or "flexible" scope apply here.

4.2. Organisation of assessments in case of a "fixed" scope

4.2.1. General procedure for evaluation

During an assessment, the team members will pay special attention to the presence of the technical competence for carrying out the specific activities falling under accreditation or for which accreditation is sought. A representative sample of these activities will be taken and subject to evaluation, both in terms of organizational and documentary aspects as in terms of specific implementation provisions.

Based on the number and/or nature of the non-conformities raised during the assessment, although related to specific assessed activities, serious doubts could be raised about the general technical competence and operability of the quality management system. Consequently, compliance with the accreditation requirements can no longer be assured for the activities which were not assessed in detail. In that case, the Accreditation Board can demand for (a) supplementary assessment(s) or can refuse the accreditation partly or as a whole.

4.2.2. Maintenance of the "fixed" scope

During the surveillance and renewal assessments, the team members will verify if the technical competence is maintained for all activities included in the accreditation scope. All areas of technical competences shall however, be assessed during an accreditation cycle.

4.2.3. "Dormant" activities

Accredited bodies may be faced with the situation that specific accredited activities are no longer performed during certain periods, for example due to the absence of customers or requests for those specific activities. Such infrequently performed activities pose a challenge in terms of maintaining and permanently demonstrating competence.

These activities are called "dormant" one year after the last performance of the activity (i.e when the activity has not been performed since one year). However, an activity does not have to be regarded as dormant if it can be demonstrated on the basis of a risk-based analysis that resources and competences are maintained through other activities (e.g. other similar accredited activities that require the same resources and competences, participation in proficiency tests, implementation of a simulation of the activity...).

Starting from the date on which the activity is considered dormant, it can, in principle, remain dormant in the scope for a maximum of 2 years. As a result, an activity can

remain "inactive" in the scope for a total of 3 years, counting from the date of its last execution.

BELAC allows for the maintenance of dormant activities in the accreditation scope, as well as the resumption of their execution, provided that the conditions below are met. Once an activity is considered dormant, it is necessary:

- having a documented procedure for the administrative management of the "dormant" activities;
- keeping available human and material resources required for the performance of the activities and for the follow-up of standards, regulations and other relevant documents regarding these activities, so that the activities can be restarted at any time and after taking the necessary measures (to guarantee that reliable results will be obtained), when a customer presents itself or an application comes in;
- defining measures (based on a risk analysis) that must be taken in the event that the activities are resumed in order to guarantee that the implementation remains under control. The results of this risk analysis and the measures to be taken should be reviewed on a regular basis to ensure that they remain relevant, taking into account the evolution of the activities and operational context;
- informing BELAC prior to each assessment about which activities have become dormant since the last audit, including the date of last execution.

During the surveillance and renewal assessments, the team members will pay special attention to the procedures for the management of the dormant activities and, if applicable, for the reactivation of these activities.

4.2.4. Extension of the accreditation scope with a fixed scope

To meet the technological progress or the expectations of customers, the conformity assessment body may request BELAC:

- to modify its currently accredited methods or to enlarge the currently accredited activity domain;
- to supplement its current accreditation with new specific activities;
- to replace or complete its current accreditation by an accreditation with a flexible scope.

The application for extension will contain sufficient information on the activities for which extension or adaptation of the scope is sought and shall be investigated by BELAC. BELAC will, depending on the nature of the file, consider whether an evaluation (documentary or on site) is required. In case of limited modifications, with close link to activities already under accreditation, BELAC may also grant an administrative extension/modification of the scope, without a prior evaluation. During the next scheduled renewal or surveillance assessment, special attention will be paid to these activities.

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

In case of non-compliance with the accreditation conditions, and depending on the nature of the non-conformities, the Accreditation Board decides on the suspension or withdrawal of one or more specific activities in the scope or of the accreditation scope as a whole.

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 body applying for a flexible scope has to provide evidence of sufficient experience in a sufficiently wide range of activities (to be determined according to the type of conformity assessment) and of a performant quality management system. This normally implies that a conformity assessment body can only apply for a flexible scope for a general competence if it is already accredited with a fixed scope within the same general competence. Deviation from this rule may be based upon properly documented and well-founded arguments.

In addition, the accreditation with a flexible scope is subject to the following additional requirements (see points 4.3.1.1 to 4.3.1.3).

4.3.1.1. Implementation and management of an accreditation with flexible scope

Before applying for an accreditation with a flexible scope, the body shall

- develop, document and implement a transparent and structured process of design/development leading to a “go/no go” decision that allows for the management of the activities covered by the flexible scope;
- define the boundaries of the flexibility with respect to its competence and resources as well as its expectations and those of its customers.

This process shall define the elements to be considered and the steps necessary for the management of a request to perform a new activity within the boundaries of an accreditation with a flexible scope:

- the management approval for the development of the new activity within the boundaries of the flexible scope;
- the availability of all resources and means necessary to perform the requested activity;
- the documentation of the instructions for the performance of the activity, including the steps for validation of the conformity with respect to the requirements and check that the conformity has been achieved;
- the availability of qualified personnel for the development, the validation, the verification, the approval, the performance and the supervision of the activity;
- the definition of the responsibilities for all tasks dealing with the management of the flexible scope.

In case the design and development process results in a “no go” decision, a detailed rootcause analysis shall be performed and corrective measures will be decided. These shall include:

- information of the customer that it will not be possible to issue a report/certificate during the period of investigation and implementation of corrective actions and the reasons for this;

- a revision of the concerned procedure/method where needed (e.g in case of technical problems) in order to solve the identified problem and to avoid its recurrence;
- considering a redefinition of the boundaries of the flexibility, where relevant; in this case the body is required to contact BELAC and the formulation of the flexible scope may need to be updated.

4.3.1.2. List of activities

- The conformity assessment body shall have a list of specific activities carried out under accreditation and covered by the flexible scope. This list shall be publically available and is referred to in the BELAC scope.
- This list includes for each activity (as a minimum) the same information as required to describe a fixed scope. It shall be made available to BELAC and any other interested party upon request and shall be communicated to BELAC in any case, prior to every renewal or surveillance assessment. Significant changes to normative documents, schemes, methods,...mentioned in the detailed list must also be traceable.
- The inclusion of a new activity in the list is allowed only after all necessary steps, showing that the activity is under control and leads to reliable results, have been completed and approved by the management of the conformity assessment body.
- Information on which activities are covered by the accreditation and which are not must be transparent and accurate. On basis of this detailed list it must therefore undeniably be shown from which moment the specific application is carried out under accreditation; the basis on which this decision was made must also be fully traceable.

4.3.1.3. Contract review and information of the customers

The body shall develop, document and implement a contract review process applicable to a request for an activity within the boundaries of the flexible scope but not yet previously performed (not yet included in the detailed list).

The contract review process shall also ensure that:

- the customer is informed that the effective implementation of this new activity and the subsequent release of a certificate or report may only happen after the different steps of the design/development process will have been completed;
- the list of activities has formally been updated;
- the consequences in terms of delay and price are clearly communicated.

4.3.2. Provisions for evaluation

When reviewing an application to move from a fixed to a flexible scope, BELAC considers the risks associated with the activities. The following aspects are taken into account:

- the degree of understanding of the body in the rules and procedures for implementing and managing a flexible scope;
- the level of performance and stability of the body's management system;
- the complexity of the conformity assessment activities;

- the extent of flexibility to be given to the body;
- the reputational risks for BELAC, the body and the market;
- the stability of the body's technical personnel responsible for the activities relating to flexible scope;
- the level of knowledge of the body for the related activities;
- the stakeholder/regulatory expectations;
- the planned frequency of use of the flexible scope;
- the extent of controls proposed by the CAB for managing a flexible scope;
- the location and geographical risks.

The same aspects will be considered when designing the assessment program.

During each assessment, the evaluation will particularly concern the following:

- the new/modified activities performed within the boundaries of the flexible scope (since the previous assessment);
- the organizational aspects that need to be managed by the conformity assessment body when introducing new or modified activities, including the possible impact on the impartiality and the identification of risks;
- qualifications, experience and continuous training of personnel (and in particular the technical manager and general management positions) related to the sector of concerned activities;
- the performance of the equipment;
- the presence of appropriate technical procedures and any required legal documents;
- the performance of the quality management system;
- the records of validations/verifications including where relevant the quality control records;
- the level of compliance with the accreditation requirements as stated in the conclusions of previous assessments (and especially for managing the technical aspects);
- the procedures for monitoring less frequent activities.

The selection and evaluation of the most representative activities will be the responsibility of the assessment team. Based hereupon, the team will formulate a well founded recommendation on whether to grant or maintain the accreditation. The basic criteria for the selection of activities include:

- the level of technical complexity of the activity;
- the severity of the consequences in case of poor performance;
- the frequency with which the activity is performed.

The assessment will include a review of actual cases for which the body has implemented a flexible scope.

With the actual selection and global evaluation of the assessed activities, BELAC should be able to decide on the competence of a conformity assessment body to introduce new activities or to modify existing methods under accreditation.

4.3.3. "Dormant" activities

Also for activities included in the detailed list belonging to a flexible scope, the provisions of 4.2.3 must be complied with in the case of dormant activities.

4.3.4. Extension of the accreditation scope with a flexible scope

In response to technological advances or customer demands, the conformity assessment body can request for an extension of the flexible scope with one or more other groups of activities.

The application for extension will contain sufficient information about the activities for which extension is sought and shall be investigated by BELAC. Depending on the nature of the file, BELAC will consider whether a documentary or on site assessment is required.

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

In case of non-compliance with the accreditation conditions related to the accreditation with a flexible scope, and depending on the number and/or the nature of the non-conformities, the Accreditation Board can decide on the suspension or withdrawal of one or more specific groups of activities in the scope or of the accreditation scope as a whole. The maintenance of the accreditation with a fixed scope could be considered.

If during an assessment it is found that unauthorized reference to accreditation has been made for activities covered by the flexible scope, the conformity assessment body shall rectify this as soon as possible towards all customers involved and revoke all concerned reports or certificates that were released under accreditation.
