



PROCEDURES AND PROVISIONS FOR THE ACCREDITATION OF MULTI-SITE CONFORMITY ASSESSMENT BODIES

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

Date of implementation : 16.12.2022

HISTORY OF THE DOCUMENT

Revision and date of approval	Motivation of the revision	Scope of the revision
0 CC 16.03.2012.	New document	
1 CC 22.01.2015	Integration of the provisions of clauses 7.5.7 of the document ILAC/IAF A5: 11/2013 Integration of the provisions of EA-2/13 S1(2013) Integration of the provisions of IAF MD 12:2013	Point 3.2.2 and new appendix 1 Point 3.3.1 and 3.3.2 and new appendix 2 Point 4.2
2 CC 20.04.2017	Definition of key activities in the case of assessment of Laboratories, Proficiency Testing Providers and Producers of Reference Materials	Appendix 1
3 secr 24.05.2018	Adaptation of appendix 1: supplementing the interpretation of the concept of key activities for the evaluation of laboratories (TEST + CAL + MED)	Appendix 1
4 CC 01.12.2022	Full revision of the text taking into account EA 2/13 M:2019 and the withdrawal of ILAC/IAF A5. The most important modifications are: - The concept of "critical location" is no longer used, but the term "activity sites" is used by analogy with the definitions in BELAC 2-002. - The concept of responsibility and coordination from the 'head office' is replaced by responsibility and coordination from the 'legal entity' - The assessment program is developed on the basis of a risk analysis	Complete text The amendments do not entail any significant changes to BELAC's policy and working methods

PROCEDURES AND PROVISIONS FOR THE ACCREDITATION OF MULTI-SITE CONFORMITY ASSESSMENT BODIES

1. AIM OF THE DOCUMENT AND REFERENCES TO NORMATIVE DOCUMENTS

This document aims to define the procedures and provisions for the accreditation of conformity assessments bodies that operate from different locations, in Belgium or abroad.

This document refers to and complies with the relevant sections of the standard ISO/IEC 17011 and the relevant requirements of EA, ILAC and IAF.

In case the conformity assessment body operates from (a) site(s) located outside Belgium, in addition the provisions regarding cross border activities and cooperation with other accreditation bodies (BELAC 1-05) apply.

2. RECIPIENTS

- The members of the Coordination Commission
- The members of the Accreditation Board
- The Accreditation Secretariat
- The assessors
- The (candidate) accredited bodies.

3. GENERAL CONDITIONS FOR MULTI-SITE ACCREDITATION

3.1. Types of bodies eligible for accreditation under the multi-site regime

3.1.1 The multi-site accreditation is meant only for use by bodies operating from different activity sites within the same organisation (see definition under appendix), and where the activities performed fall under the responsibility of a single legal entity.

3.1.2 If the activity sites also have their own legal entity, these entities are expected to be part of the organization to which the accreditation is granted (see appendix). The responsibility of the accredited legal entity has to be demonstrated on the basis of contractual or other legal arrangements between the accredited legal entity and the activity sites and through internal procedures that further specify these relationships in terms of management and responsibilities.

In case different bodies having their own legal identity share their means and resources but maintain their own responsibility for the activities they perform, the concept of multi-site accreditation is not applicable.

3.1.3 Multisite accreditation can apply to all kinds of activity sites such as subsidiaries, divisions, agencies, offices, etc. regardless of their legal personality and is valid for all kinds of conformity assessment bodies, as long as they carry out well-defined and relevant activities within the scope of the multisite accreditation.

3.1.4 If certain activity sites are located abroad, the provisions on cross-border activities and on cooperation with other accreditation bodies also apply (BELAC 1-05).

3.2. Conditions for accreditation as multi-site body

3.3.1 The BELAC certificate and the associated accreditation scope shall mention only one legal entity. This legal entity holds the multi-site accreditation and holds the final responsibility for the accredited activities, including any activity performed in the different activity sites that form part of the scope of accreditation (see also appendix).

3.3.2 All activity sites to be included under the accreditation operate under the same management and the same global management system (see also appendix). The accredited legal entity has the means to influence and control the activities of the activity sites. The entity has to demonstrate that such influence and control is in place and properly working. Holding the final responsibility for activities performed by the activity sites implies that the legal entity takes over the operational, financial and legal responsibility.

3.3.3 The activity sites do not offer accredited services to the market under their own name or logo or under their own legal entity within the multi-site accreditation. They may only offer conformity assessment activities under the accreditation on behalf of the accredited conformity assessment body, i.e. the accredited legal entity.

The certificates and reports issued under the multi-site accreditation contain the name and address of the accredited legal entity. However, these certificates and reports may make reference to the contact details of the activity site issuing the certificate or report in question. The certificates or reports issued shall not create any confusion as to the conformity assessment body that holds the accreditation.

When these conditions are not met in all aspects, multi-site accreditation cannot be granted.

4. SPECIFIC PROVISIONS FOR THE OF ACCREDITATION OF MULTI-SITE BODIES

4.1. Application and review of the application

4.1.1 BELAC requires the applicants for multi-site accreditation to identify the different activity sites that should be covered by the accreditation and their legal relationship with the legal entity. In addition, it is also the responsibility of the applicant to clearly indicate which conformity assessment activities are carried out in which activity sites or from which activity sites they are organised.

In addition to activity sites, where conformity assessment activities are carried out or from which they are organised, a body may also have establishment units, where support activities take place . Such activities are not conformity assessment activities as such, but can constitute an important supporting part of the conformity assessment process and can have a significant impact on the outcome of the conformity assessment. Such information must also be clarified by the applicant with the application.

4.1.2 BELAC will consider all this information in its contract review as this has an influence on the organization of the assessment and the later drafting of the accreditation scope.

It should be emphasized that sometimes BELAC can only obtain an accurate picture after an on-site evaluation has taken place. This may result in additional evaluation activities that are required before a final decision on the multi-site accreditation can be made.

4.1.3 When accepting an application for multi-site accreditation, BELAC will make sure that the applicant is made aware of and accepts the related specific requirements and conditions.

4.2. Assessment program

In principle, all activity sites will be covered during the initial assessment. On the basis of a risk analysis and well-founded substantiation, BELAC can decide to limit this evaluation to a sample of locations.

An adjustment of the assessment schedule (during the assessment) may be necessary to verify that compliance with the requirements is assured at all locations, both on a technical and organizational level. On the basis of a risk analysis, BELAC will determine which other establishment units (where support activities are carried out) should possibly also be included in the initial assessment.

The assessment program on the cycle with regard to the various locations is elaborated and, where necessary, updated, taking into account:

- the risks associated with the activities carried out in the different activity sites ;
- the equivalence of activities carried out in the different activity sites (in terms of type of activities, type of equipment, personnel, etc.) ;
- the way in which the body has organized its activities, including with regard to the degree of control of the activity sites by the multisite organisation ;
- the results of (the) previous assessment(s), in particular with regard to the management and supervision of the activity sites by the legal entity.

All activity sites where conformity assessment activities are carried out or from which they are managed will in principle be evaluated for organizational and technical aspects at least once per accreditation cycle.

When drawing up the assessment program for an accreditation cycle, the establishment units where support activities are carried out are also taken into account. The risks associated with these activities and the impact they have on the result of the conformity assessment are also taken into account.

The extension of the accreditation scope to a new activity site is in principle the subject of a full evaluation of this location. On the basis of a risk analysis and well-founded substantiation, BELAC can decide to limit this evaluation.

Serious deficiencies in the functioning of the new activity site or in the control of this location by the legal entity may result in the reconsideration of the accreditation status of the entire organization by BELAC.

4.3. Accreditation documents

4.3.1 In case of a multi-site accreditation, the accredited body receives only one accreditation number and one certificate and scope per accreditation field. The

certificate mentions the name and address of the legal entity responsible for the accreditation.

4.3.2 The technical appendix to the certificate (or accreditation scope) mentions :

- the name and address of the legal entity ;
- the address of the different activity sites where conformity assessment activities are carried out and that operate under the accreditation of the multi-site body ;
- the activities performed by each activity site.

4.4. Suspension or reduction of accreditation

In case of a decision to suspend or reduce the scope of one activity site, or in case of a withdrawal of the accreditation for all activities performed at one activity site, BELAC will automatically consider the potential implications for the accredited organisation as a whole. This may result in other activity sites- or even the whole organisation - being affected by the decision. In this regard particular consideration shall be given to the requirements on the accredited body for controlling activities and for taking responsibility for performed activities.

Appendix : Interpretation of the terminology used in this document (appendix EA 2/13)

1. Same organization

Definition :

Group of legal entities, composed of multiple locations connected with the (accredited) legal entity on the basis of contractual or equivalent legal relationships, operating under the same commercial name and logo.

Assessment focus :

- Contractual agreements or documentation of legal relationships between entity and the activity sites
- Registration of the commercial name and logo
- Marketing material
- Issued reports and/or certificates

2. Same management

Definition :

*Set of persons or organisational entities (e.g. CEO, Board of Directors) of the **same organization** taking overall **responsibility for the accredited activities**.*

Assessment focus :

- Organisation charts linked to named individuals ;
- Reporting lines from the activity sites to the legal entity ;
- Descriptions of authorities and responsibilities of persons ;
 - approving policies and instructions for conformity assessment activities ;
 - approving authorities and responsibilities of personnel involved in conformity assessment activities ;
 - authorising certificates and reports.
- Names of persons in the legal entity to which authorities and responsibilities are assigned to control and monitor activities performed at the activity sites, including decisions concerning resource management etc.
- Evidence of monitoring of the central controls within the conformity assessment body of each activity in every aspect (managerial, financial and operational). (Note that the sole performance of internal audits is not considered sufficient for taking responsibility for accredited activities.) Evidence of monitoring may be written instructions and records produced and maintained.
- Evidence of effective communication within the organisation. Special care should be taken where there is not a single language of communication within the organisation used by all members of the management in a position to influence the quality of the accredited services.

3. Same quality management system

Definition :

*Set of linked rules and procedures defined by **same management** to allow it to take **responsibility for accredited activities**.*

Comments to definition :

In order for the quality management system to be considered as the same it shall be designed to provide the same outcome of accredited activities regardless of where the activities are carried out or by whom. The policies governing conformity assessment activities shall be the same throughout the organisation. To provide consistency of results:

- The *same management* is to define in the *same quality management system* any sub-sets of alternative rules and procedures, used e.g. by different activity sites or throughout different geographical regions.
- All activities defined by the *same quality management system* are covered by an internal audit program managed and approved by the *same management*, and the outcome of individual audits, including decisions on corrective actions, is channelled through affected management at all levels as the situation warrants.
- All activities of the *same quality management system* are subject to a management review by the *same management*. The outcome of the management review, including any decisions, is channelled through affected management at all levels as the situation warrants. The *same management* has the authority and legal means to enforce corrective and preventive actions.

Assessment focus :

- Management system structure.
- Rules for approval of policies and instructions.
- Implementation of policies.
- Application of requirements for competence, procedures for qualification and monitoring of personnel involved in conformity assessment activities.
- Internal audit program. Documentation of internal audits. Communication of corrective actions. Lack of same or similar non-conformances recurring throughout the organization.
- Procedure for management review. Documentation of management reviews. Communication and implementation of decisions. Lack of similar problems recurring throughout the organization.

4. Responsibility for accredited activities

Definition :

Responsibility for the performance and outcome of accredited activities.

Comments to definition :

In order to take responsibility for accredited activities the head office shall have full operational control over these activities. To this end, the head office shall have appropriate technical competence and the resources to assure control over the full scope of accreditation.

To take responsibility for the outcome of accredited activities is to take responsibility for:

- the competence and resources used,
- the rules and procedures applied,
- the consistency obtained and quality achieved through the application of these rules and procedures,
- the impartiality displayed applying these rules and procedures, and
- the contents of issued reports and/or certificates.

The responsibility is to be upheld;

- towards the customer,
- towards authorities,
- towards the public, and
- in court.

Assessment focus :

- harmonising conformity assessment outcomes through :
 - common or equivalent procedures ;
 - common or equivalent competence, training, qualification and monitoring requirements ;
 - supervising conformity assessment activities, e.g. by means of :
 - internal audits ;
 - participation in proficiency testing schemes ;
 - monitoring activities ;
 - the checking of data, calculations, analyses and reports or certificates.
 - documentation of communication with authorities ;
 - handling of complaints and appeals, both at the level of the registered legal entity and at the level of the activity sites ;
 - handling of impartiality issues, both at the level of the registered legal entity and at the level of the activity sites ;
 - handling of media coverage, both at the level of the registered legal entity and at the level of the activity sites ;
 - handling of legal cases, both at the level of the registered legal entity and at the level of the activity sites.
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