



## **CROSS BORDER ACCREDITATION AND COOPERATION WITH ACCREDITATION BODIES MEMBERS OF EA**

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

English translation for information only.

French and Dutch version remain the authoritative documents.

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## HISTORY OF THE DOCUMENT

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1 CC 19.04.2018	<ul style="list-style-type: none"> <li>- Update of the reference to the relevant IAF document (IAF MD 12 instead of IAF GD 3)</li> <li>- Consequences of a refusal by a CAB in case of subcontracting part of the assessment to a foreign accreditation body (cross border policy)</li> </ul>	Point 1  Point 5
1 CC 02.12.2021	<ul style="list-style-type: none"> <li>- Update due to the new version of EA 2/13</li> </ul>	Full revision

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# CROSS BORDER ACCREDITATION AND COOPERATION WITH ACCREDITATION BODIES MEMBERS OF EA

## 1 OBJECTIVES AND NORMATIVE REFERENCES

This document describes the policy and procedures for cross border accreditation and cooperation between BELAC and EA members, when operating in the EA region.

It includes and complements the general policies documented in the BELAC management manual (BELAC 1-01).

This document refers to and complies with the relevant sections of the European Regulation 765/2008/EC, the provisions of the Royal Decree setting up BELAC as the Belgian accreditation body (BELAC 0-05) and the requirements of EA (EA-2/13) and IAF MD 12.

For the implementation of the provisions of this document in case of accreditation of multi-sites conformity assessment bodies with sites located outside Belgium, see also document BELAC 1-04.

## 2 RECIPIENTS

With follow-up of modifications:

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

Without follow-up of modifications

- Any external request

### 3 GENERAL

In order to avoid multiple accreditation, to enhance acceptance and recognition of accreditation certificates and to carry out effective monitoring of accredited conformity assessment bodies, conformity assessment bodies (CABs) should request - according to Regulation 765/2008/EC - accreditation by the national accreditation body of the country in which they are established. Nevertheless, it is necessary to ensure that a conformity assessment body is able to request accreditation in another country in the event that there is no national accreditation body in its own country or where the national accreditation body is not competent to provide the accreditation services requested.

In addition, CABs are allowed to carry out conformity assessment activities in another country than where they are established.

When a national accreditation body provides accreditation services in another country it has to ensure it has the necessary competence to conduct the accreditation, taking into account factors such as language local laws and regulations, culture etc... in addition to the normal technical competence requirements. The preferred approach to ensure access to relevant competence is to use resources of the accreditation body (AB) from the country where the activities are performed as much as possible.

Implementing the regulation 765/2008/EC and the EA policy on cross border accreditation (EA-2/13), BELAC:

- offers its services by priority to companies established on the Belgian territory and operating under a Belgian legal entity;
- does not compete with other ABs who are members of EA;
- does not promote or market its services in the country of another AB in the EA region.

Cross border accreditation refers to any accreditation activity that a national AB performs outside its national borders.

This document deals with the following types of cross border activities:

- 1) BELAC accredited bodies established outside Belgium (point 4.1);
- 2) BELAC accredited bodies established in Belgium, operating from locations outside Belgium (point 4.2);
- 3) BELAC accredited bodies established and operating from a location in Belgium, performing conformity assessment activities outside Belgium (point 4.3);
- 4) Bodies accredited by a foreign accreditation body performing conformity assessment activities on the Belgian territory (point 7).

## 4 BELAC ACCREDITATION OF CONFORMITY ASSESSMENT BODIES OPERATING OUTSIDE BELGIUM

### 4.1 BELAC accredited bodies established outside Belgium

#### 4.1.1 Conditions for acceptance of applications

BELAC may accept an application for accreditation from a conformity assessment body established in a foreign country provided one of the following conditions are complied with:

- there is no local AB or the local AB is under development and is not yet fully operational;
- the local AB is an EA member but not a signatory of the relevant MLA or lacks the available competence for the conformity assessment activities for which accreditation is sought;
- the local AB is an EA member signatory of the relevant EA-MLA but requests BELAC, with due motivation, to handle the case;
- the local AB is an EA member, however, the applicant especially requests for a BELAC accreditation in order to fulfil specific expectations of the Belgian or European market.

#### 4.1.2 Acceptance of applications

Before accepting an application from a foreign conformity assessment body, BELAC:

- will enquire whether the applicant has considered to apply with their local AB and why the application is put to BELAC. Where relevant, the advantages of applying to the local accreditation body and the equivalence demonstrated through the international multilateral arrangements will be pointed out;
- will inform the local accreditation body of its intentions and keep the local AB informed of its actions;
- will take all necessary steps to cooperate as much as possible with the local AB;
- will confirm with the local AB that one of the conditions under 4.1.1 applies;
- will check through a comprehensive application review whether BELAC has the necessary competence to conduct the accreditation, taking into account factors such as language local laws and regulations, culture etc... in addition to the normal technical competence requirements.

BELAC reserves the right to reject applications related to the following situations:

- the application has been rejected or the accreditation has been withdrawn by the local AB;

- the body applies for accreditation of a type of activity (e.g. a sector scheme) that is not considered as an accreditable activity by the local body and that is not yet part of the BELAC scope of activities;
- the applicant has no justification to apply specifically to BELAC and the application is in the framework of a general tender.

#### 4.1.3 Change of conditions

If BELAC has granted accreditations in another country in the EA region due to the lack of available competence of the local AB to accredit the requested activity or due to the fact that the local AB is not a signatory of the relevant EA MLA, conformity assessment bodies (CABs) shall be informed of the fact that they will have to transfer their accreditation to the local AB as soon as these conditions change.

BELAC shall not initiate a new accreditation cycle or extend the accreditation after the local AB enters the MLA, except on motivated request of the local AB.

At each re-assessment, BELAC will confirm that previously accepted justifications and conditions for providing cross border accreditation still apply. The records of these justifications will be retained.

#### **4.2 BELAC accredited bodies established in Belgium, operating from locations outside Belgium**

Where a CAB legally established in Belgium also operates in locations in other countries, it may seek an accreditation to cover the activities for all of its locations, with BELAC. The principles of multisite accreditation are described in BELAC 1-04.

The principles of multiple location cross border accreditation require the CAB and the locations included within the scope of accreditation to abide by the following:

- 1) The CAB shall fully cooperate with the local ABs involved;
- 2) Individual locations cannot reject the participation of the local AB in the assessment, reassessment and monitoring processes.

The assessment programme is developed by BELAC in accordance with its usual assessment procedures taking into account the risk associated with the activities and the market conditions in the locations. The review of the risk shall be undertaken with input from the local AB(s) utilising their knowledge and expertise of their respective markets and regulations. Specific considerations to take into account when establishing the approach and degree of sampling required include, but are not limited to:

- Different local regulations;
- Knowledge of the local market;

- Volume of work carried out by the CAB at different locations;
- Impact of the CAB activities conducted under the BELAC accreditation on the local market e.g. the proportion of the market share held by the CAB;
- History of assessment results of the conformity assessment activity and/or location;
- Level of control and monitoring demonstrated by the CAB for each given location;
- Whether or not the local office holds accreditation from the local AB for the same or different scope and/or utilises the same or different conformity assessment processes and/or operated the same or different management system;
- Where location holds accreditation by the local AB, the cycle/frequency of the local AB assessment shall be utilised as far as possible.

When BELAC accredits a CAB established in Belgium for a foreign national regulation, BELAC shall ensure, in cooperation with the local AB of the country issuing the regulation, that it has access to the necessary expertise and information concerning that regulation.

#### **4.3 BELAC accredited bodies established in Belgium, performing conformity assessment activities outside Belgium**

Where a CAB legally established and operating from a location in Belgium performs conformity assessment activities in other countries, the cooperation principles between ABs of the cross border policy also apply and BELAC will subcontract witnessing activities to the local AB.

The assessment programme is developed by BELAC in accordance with its usual assessment procedures taking into account the risk associated with the activities and the market conditions in the other countries.

## **5 COOPERATION OF THE CAB WITH THE LOCAL AB**

BELAC informs the CAB of its intention to outsource part of the assessments to (a) local AB('s) and of the related practical provisions. Refusal by the CAB to cooperate with the local AB('s) involved, could result in withdrawal of accreditation of the concerned activities in the accreditation scope.

BELAC and the local AB can share information with each other concerning the CAB even if the local AB does not perform the assessment.



## **6 COOPERATION PROCEDURE BETWEEN ACCREDITATION BODIES**

It is essential that BELAC has the cooperation of the local AB in order to determine the approach for the assessment of the CAB. BELAC commits itself to make and respond to all requests and announce at an early stage any difficulties it foresees or encounters.

For existing accredited activities BELAC shall provide sufficient information to the local AB concerning the anticipated assessment requirements over the accreditation cycle.

BELAC shall also inform the local AB of its needs in the coming calendar year at the latest three months before the beginning of the calendar year. At this stage, the exact scope of the assessment may not be clear but such early information is essential to allow the local AB to have input to the planning and for resource planning by the local AB.

The scope of the assessment shall be reported to the local AB at the latest three months before the due date of the assessment. For additional requests e.g. ad-hoc assessments or extensions to scope, BELAC shall notify the local AB as soon as the request is known and BELAC shall work together with the local AB to manage and, wherever possible, meet the CAB's expectations in a timely manner.

The cooperation between the local AB and BELAC takes the form of a formal agreement.

BELAC shall specify the scope of the requested assessment in such detail that the risk for misunderstanding is minimised. BELAC shall provide the local AB with all information needed to ensure effective assessment within the agreed time frame according to the agreement signed. BELAC shall inform the local AB of the outcome of the accreditation decision when it is made.

When a local AB agrees to undertake assessments on behalf of BELAC, BELAC will give instructions in relation to communications with the CAB and the scope of the requested assessment. The local AB may use its own accreditation assessment procedures, systems and reports and shall not be required to use the assessment procedures, systems or reports of BELAC. The report has, in any case, to contain sufficient information about the findings and supporting evidence to ensure that a sound decision can be taken by BELAC.

The language to be used during the assessment and in reports shall be agreed between BELAC and the local AB involved and the CAB in advance of the assessment. English is used when French or Dutch are not appropriate.

In advance of any assessment BELAC shall provide the local AB with at least the following:

- Report of the last assessment of the location identified as holding the management control; including the details of nonconformities and actions arising;
- Up-to-date information about the CAB including details of how it is organised and managed and how the conformity assessment activities carried out at/from its locations are controlled;
- Any specific additional requirements or activities to be particularly assessed by the local AB;
- Any requirements from regulators which may have an impact on the activities of the location when accreditation is being granted for the purposes of notification;
- Full scope of the activities which can be performed by the local location under the CAB's accreditation;
- Detailed description of the scope to be assessed, including any sector schemes;
- Assessment plan, including witnessing for the location over the full accreditation cycle;
- Assessment programme for all of the CAB's activities, including witnessing, if necessary.

BELAC asks the local AB to provide BELAC with at least the following:

- Assessment results in accordance with the timescales specified in the agreement between BELAC and the local AB;
- Assessment report within the time frame stated in the agreement between the BELAC and the local AB;
- Statement on recommendations regarding the closure of any findings if these are to be reviewed by the local AB according to the agreement. (Note that corrective actions may have been provided directly to BELAC e.g. where the location passed the responsibility to another location e.g. its main office).

If the local AB is not taking part in the performance of the assessment, BELAC keeps the full responsibility for the organisation of the assessment, but BELAC shall give the opportunity to the local AB to observe that assessment.

In the exceptional case where BELAC has not been able to establish cooperation with the local AB, BELAC will keep records of the reason why it has not been able to cooperate.

## 7 ACTIVITIES OF BELAC AS A SUBCONTRACTOR

On request of a foreign AB signatory to the EA, ILAC or IAF multilateral agreements, BELAC may act as a subcontractor to perform all or part of the assessment of a conformity assessment body accredited abroad and operating in Belgium, provided that all the following conditions are complied with:

- a specific arrangement or a framework agreement, with clear identification of the respective rights and obligations of BELAC and the foreign AB, is in place;
- the activity to be evaluated is part of the scope of activities of BELAC;
- the evaluation will be performed according to the procedures of BELAC;
- the request for cooperation has been notified to BELAC at least 3 months before the beginning of the calendar year. The scope of the assessment shall be reported to BELAC at the latest three months before the due date of the assessment;
- BELAC has received the necessary information to allow for a proper organisation of the evaluation; the scope of the requested assessment will be specified in such detail that the risk of misunderstanding is minimised;
- BELAC has assessors who are available in the given period.

BELAC will evaluate if the specified conditions are met and will inform the foreign AB if it accepts to act as a subcontractor. Alternatively, BELAC and the foreign AB can agree that the foreign AB may carry out (part of) the assessment on Belgian territory.

In advance of any assessment BELAC asks to be provided by the foreign AB with at least the following:

- Report of the last assessment of the location identified as holding the management control; including the details of nonconformities and actions arising;
- Up-to-date information about the CAB including details of how it is organised and managed and how the conformity assessment activities carried out at/from its locations are controlled;
- Any specific additional requirements or activities to be particularly assessed by the BELAC;
- Any requirements from regulators which may have an impact on the activities of the location when accreditation is being granted for the purposes of notification;
- Full scope of the activities which can be performed by the local location under the CAB's accreditation;
- Detailed description of the scope to be assessed, including any sector schemes;
- Assessment plan, including witnessing for the location over the full accreditation cycle;

- Assessment programme for all of the CAB's activities, including witnessing, if necessary.

## **8 INFORMATION EXCHANGE**

BELAC shall notify the local AB of any decision to suspend or terminate accreditation for an activity performed in the local AB's country. Equally BELAC asks the local AB to notify BELAC of any decision to suspend or terminate accreditation for an activity that takes place at a location that holds local accreditation granted by the local AB. It is important that this information is communicated immediately after the decision has been taken to allow BELAC and the local AB to consider if the suspension/termination affects the accreditations.

BELAC and the local AB shall exchange any valid and relevant information, such as outcomes of assessments, complaints, market feedback etc, concerning the individual locations where they are both involved.

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