



## **RULES GOVERNING THE NOTIFICATION TO BELAC AND THE MANAGEMENT BY BELAC OF SIGNIFICANT CHANGES BY ACCREDITED BODIES**

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English translation for information only.

French and Dutch version remain the authoritative documents.

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# RULES GOVERNING THE NOTIFICATION TO BELAC AND THE MANAGEMENT BY BELAC OF SIGNIFICANT CHANGES BY ACCREDITED BODIES

## 1 OBJECTIVES AND NORMATIVE REFERENCES

This document aims to specify

- the general principles relating to the obligation for accredited bodies to notify BELAC of any significant organizational, administrative, legal or technical change likely to have an impact on maintaining the status of accredited body;
- (without the list being exhaustive) the main situations encountered for which the notification obligation applies;
- the actions to be taken by the accredited body;
- how BELAC intends to manage notifications of changes and the consequences for the accredited body.

This document does not cover requests for modification or extension of the scope of accreditation (including to one or more new activity sites), the management of which is determined by the provisions of point 5.1 of the BELAC 3-11 document.

The provisions in this document apply to all accredited bodies.

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

- the standard EN ISO/IEC 17011:2017 in particular point 4.2 i);
- the Royal Decree of January 31, 2006 amended by the Royal Decree of February 7, 2014 establishing BELAC and more particularly Article 9, 4 °;
- the BELAC 3-06 document and more particularly point 6 indent 8.

## 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 RULES

BELAC accredited bodies are required to inform BELAC without delay of any significant organizational, administrative, legal or technical change that may affect their ability to meet the accreditation requirements, and in particular, without this list being limitative, modifications of:

- the articles of association of the organization or property (see also points 4 and 7 of this document);
- the address of the head office, the main operating site and the ancillary sites where the activities are carried out (see also point 5 of this document);
- holders of key functions (see also point 6 of this document);
- subcontracting.

It may be necessary to combine these changes and in this case, all the provisions applicable to individual situations must be taken into account.

The information must:

- specify the date planned for the implementation of the change;
- be sent to BELAC ([belacdossiers@economie.fgov.be](mailto:belacdossiers@economie.fgov.be)) sufficiently in advance to allow BELAC to analyze the situation and take the necessary measures without risk of interruption of accreditation; BELAC cannot be held responsible for an interruption of accreditation in the event of late or incomplete notification from the body concerned;
- be accompanied by the relevant supporting documents depending on the type of change (*see points 4 to 7 of this document*).

Any notification of modification is formally registered by BELAC, which informs the body concerned of the follow-up measures that will apply.

Any change requiring an adaptation of an accreditation certificate and/or of the scope of accreditation must be the subject of a formal decision by BELAC that also determines the validity period of the new documents.

### 4 MODIFICATION OF THE ARTICLES OF ASSOCIATION AND/OR OWNERSHIP OF THE BODY

The following situations (possibly in combination) must be notified to BELAC.

#### **4.1 Change in the name of the accredited body**

In this case, the change relates only to the name of the accredited body, without changing the legal form, ownership, activities (whether or not covered by accreditation) and the general functioning of the body.

The accredited body is required to send the following information to BELAC, at the latest 1 month before the presumed date of the name change:

- the act (or the draft act) amending the articles of association, including the new name of the body;
- a declaration confirming that the name change has no impact on the legal form, ownership, impartiality, activities (whether or not covered by accreditation) and the general functioning of the body;
- the actions planned to adapt the means of communication and documentation of the management system and, if necessary, to inform customers.

The date on which the amendment of the articles of association of the body has been registered by the Crossroads Bank for Enterprises will be notified to BELAC as soon as available.

After evaluation of the information provided, BELAC will adapt the accreditation documents, with effect from the date of the modification of the articles of association of the body and without adaptation of the expiry date of the accreditation. The accreditation number is kept and the change has no impact on the planning of surveillance assessments.

Should the information be sent less than 1 month before the probable date of the name change, BELAC will handle the file, but there is a possibility of an interruption of accreditation.

#### **4.2 Change of legal form**

In this case, the modification relates only to the legal form of the accredited body.

The organization shall provide the following information to BELAC, at the latest 3 months before the expected date of the change of legal form:

- the act (or the draft act) amending the articles of association which includes the new legal form of the body as it has (or will be) registered in the Crossroads Bank for Enterprises;
- an analysis of the impact of the change of legal form on the ownership, impartiality, activities (covered or not by accreditation), the personnel and the general functioning of the body;

- the actions planned to adapt the means of communication and documentation of the management system and, if necessary, to inform customers.

Should the information be sent less than 3 months before the probable date of the change of legal form, BELAC will handle the file but there is a possibility of an interruption of accreditation.

The date on which the amendment of the articles of association of the body has been registered by the Crossroads Bank for Enterprises will be notified to BELAC as soon as available.

BELAC assesses the information provided and decides on the possibility of a simple administrative adaptation or the need to organize a documentary assessment or an assessment with an on-site visit.

In the event of a positive assessment, BELAC shall adapt the accreditation documents, with effect from the date of amendment of the body's articles of association and without adaptation of the expiry date of the accreditation. The accreditation number is kept and the change has no impact on the schedule of surveillance assessments.

In the event of a negative assessment, BELAC may have to consider measures up to the withdrawal of accreditation.

#### **4.3 Transfer of an accreditation granted to body A to body B**

The provisions below also include cases of merger between 2 conformity assessment bodies, acquisition of a subsidiary or transfer under the control of a group.

In this case, the institution legally responsible for the accredited activities is designated as body B.

It should be noted that:

- the takeover of the activities of an accredited body A by a non-accredited body B is not considered as a transfer of accreditation but as a normal initial accreditation;
- bodies A and B are required to take the necessary steps to inform their customers.

##### **4.3.1 With regard to body A**

Body A must notify BELAC of its intention to transfer its activities to body B.

The total transfer of accredited activities implies the withdrawal of the accreditation delivered to body A; the provisions in point 5.2 of BELAC 3-11 apply.

A partial transfer of accredited activities implies an adaptation of the scope of accreditation of body A; the provisions in point 5.2 of BELAC 3-11 apply.

#### 4.3.2 With regard to body B

Two situations can arise:

##### 4.3.2.1 Body B does not hold an accreditation for the relevant type of conformity assessment

Body B must submit an accreditation application for the type of accreditation concerned. As soon as body B is able to demonstrate that it is able to perform, in accordance with the accreditation requirements, the activities for which accreditation is requested, an initial assessment will be organized as soon as possible. Body B informs BELAC of the terms of transfer with regard to the impact on:

- compliance with the requirements of impartiality;
- the provisions of the management system;
- resources in personnel, equipment and premises;
- the conformity assessment methods.

These elements can be taken into account during the initial assessment of body B.

In case of a positive decision for the accreditation of body B for the type of accreditation concerned, the decision date of the Board sets the start of the accreditation cycle. If body B is already accredited for other accreditation sectors, accreditation for the new sector follows the existing accreditation cycle.

In the case of certification bodies, the arrangements for the reissue of certificates issued by body A must take into account the requirements of the IAF MD 2 document.

##### 4.3.2.2 Body B holds an accreditation for the relevant type of conformity assessment

Body B should apply for accreditation for conformity assessment activities initially carried out under accreditation by body A and which are not yet included in its scope of accreditation. An extension assessment will be organized as soon as possible.

Body B shall provide the following information to BELAC:

- the address of the new site(s) involved, as it was (or will be) communicated to the Crossroads Bank for Enterprises;
- an analysis of the potential impact of the transfer of the activities initially covered by the accreditation of body A with regard to:
  - o compliance with the requirements of impartiality;

- the provisions of the management system;
- resources in personnel, equipment and premises;
- the conformity assessment methods;
- the actions planned to maintain the level of performance of the activities to be included in the scope of accreditation and the compliance of the management system with accreditation requirements, in particular to adapt the documentation and train staff if necessary;
- the planned schedule for the transfer and the date from which body B intends to carry out the transferred activities under its own responsibility;
- in the case of certification bodies, the provisions for the reissue of certificates issued by body A, taking into account the requirements of the IAF MD 2 document.

BELAC takes this information into account in determining the form and content of the extension assessment to be carried out.

Any application for extension of the accreditation scope linked to a transfer of activities must be the subject of a formal decision by the BELAC Board.

In the event of a positive decision for all or part of the extension of the accreditation scope of body B, the new activities will be included in the scope of accreditation of body B with the decision date as issue date.

## **5 ADDRESS CHANGE OF THE HEAD OFFICE, OF THE MAIN OPERATING SITE AND OF THE RELATED SITES**

The following names apply:

- Head office: address as mentioned in the Crossroads Bank for Enterprises for the body concerned.
- Site of activity: place of activity as mentioned in the Crossroads Bank for Enterprises in relation to the body concerned, geographically identifiable by an address, where at least one activity of the company is carried out or from which it is exercised.
- Main operating site: address (possibly different from that of the head office) where conformity assessment activities are carried out and from which the management of the activities of any ancillary sites is coordinated.
- Ancillary site: address different from that of the head office or the main operating site, at which conformity assessment activities are carried out under the responsibility of the accredited body.

The main operating site (if different from the body's head office) and the ancillary site(s) must be registered as site(s) of activity.

The following situations (possibly in combination) must be notified to BELAC:

- transfer of the head office;
- change of address of the main operating site;
- change of address of one or more ancillary sites.

The body shall send the following information to BELAC, at the latest 3 months before the expected relocation:

- the new address of the head office and/or site(s) concerned, as it was (or will be) registered in the Crossroads Bank for Enterprises;
- an analysis of the potential impact of the relocation(s) on the activities covered by the accreditation;
- the actions planned to maintain the performance level of the activities within the concerned scope and the compliance of the management system with the accreditation requirements and in particular to inform customers, adapt documentation, train personnel if necessary. In the particular case of testing and calibration laboratories and medical biology laboratories, the plan will also aim to (see details in Annex 1):
  - o maintain the integrity of the moved samples and products
  - o ensure the transport, installation of the equipment and check it before use;
  - o comment on the acceptability of the new ambient conditions
- the planning of relocation operations and whether or not the body considers a period of total or partial cessation of activities.

Should the information be sent less than 3 months before the presumed date of the change of legal form, BELAC will handle the file but there is a possibility of an interruption of accreditation..

The above information will be regularly updated if necessary. The actual dates of the relocation and the resumption of activities under accreditation will be communicated as soon as fixed and an evaluation report of the measures taken (for example in the form of a targeted internal assessment report) will be provided.

In all cases of relocation and taking into account the information provided and the risk on the validity of the accredited services, BELAC is responsible for deciding:

- whether the accreditation documents can be directly adapted to authorize the resumption of activities under accreditation;
- whether a documentary and/or on-site assessment is necessary shortly after resuming activities in the new facilities before the new accreditation documents are issued and the body is authorized to resume its activities under accreditation.

## **6 MODIFICATIONS IN KEY POSITION HOLDERS**

By key position is meant more specifically, taking into account the internal organization of the body, the management function(s), technical responsibility and monitoring of the management system.

As soon as a replacement (temporary or permanent) becomes effective, the body shall provide the following information to BELAC:

- an analysis of the possible impact of the replacement(s) on the activities covered by the accreditation;
- demonstrating the competence of the person(s) concerned in relation to the function to be performed;
- the training plan that led to formalize the person in his position.

Given the risk on the validity of accredited services, BELAC is responsible for deciding whether an on-site assessment of the information provided is required or whether it can be integrated in the next regular assessment.

## **7 CHANGES TO CONTACT DETAILS**

Even in the absence of modifications as mentioned in points 4, 5 and 6, any accredited body is required to communicate without delay to BELAC (via [belacdossiers@economie.fgov.be](mailto:belacdossiers@economie.fgov.be)) the changes of telephone numbers, e-mail and internet addresses as well as the names of contact persons, in order to allow BELAC to maintain effective communication and update its databases.

## **8 CESSATION OF ACTIVITIES**

Any type of cessation of activities other than that linked to a transfer of activities (see point 4.3) must be notified to BELAC at least 1 month before the effective date in order to allow adaptation of the accreditation documents and the closure of the file, including the financial aspects.

## ANNEX 1 GUIDELINES FOR RELOCATING A LABORATORY (INFORMATIVE)

In the event of a relocation of all or part of a laboratory, BELAC asks to be informed of the changes that will take place.

Without being exhaustive, the guidelines below provide an overview of the information that is expected from the laboratory for the different stages of the process of the relocation.

1. Prior to the relocation, the following information will be provided to BELAC as soon as it is available:
  - What?
    - The entire laboratory or a specific department
    - The accredited activities concerned
    - The equipment involved
    - ...
  - When?
    - Expected date of relocation
    - Concrete program for the relocation (who does what and when?)
    - Possible period of cessation of activities
    - ...
  - Where?
    - New address(es) and related administrative changes
    - Description of the new premises and their assignment, if possible including a plan
    - Access to new premises control procedures
    - ...
  - Who?
    - Possible changes in the allocation of personnel in charge of accredited activities
    - Names of the persons in charge designated for the coordination of the various moving activities (ex: transfer and calibration of equipment – informing and contacting BELAC, customers and suppliers, etc.)
    - ...
  - How?
    - Based on a risk analysis, identification and planning of the measures to be taken during and after the relocation to guarantee the reliability of the results (e.g. possible outsourcing of activities during the relocation, putting equipment back into service, validation of environmental

conditions, confirmation/adaptation of the criteria for accepting results, carrying out an internal assessment after the relocation, etc.)

- ...

2. During the relocating period:

BELAC shall be immediately informed of any significant modification to the program planned for the move.

3. After the relocation and prior to resuming activities under accreditation, the following information will be provided to BELAC:

- An overview of the controls carried out to ensure, on the basis of previously defined criteria, the reliability of the results obtained in the new location. The raw data must be available and can possibly be requested by BELAC beforehand or during an assessment.
- Were additional internal assessments performed and/or planned?
- Any significant problems encountered when resuming activities in the new location.
- The need or not to make significant changes to the analysis or calibration methods, to the provisions of the management system or to the scope of accreditation.