



POLICY AND PROVISIONS FOR COOPERATION BETWEEN BELAC AND THE COMPETENT (REGULATORY) AUTHORITIES

The only valid versions of the documents of the BELAC management system are those available from the internet website.

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

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HISTORY OF THE DOCUMENT

Revision and date of approval	Reason for revision	Scope of the revision
0 CC 16.03.2012	New document	.
1 CC 22.01.2015	Handling of complementary accreditation requirements during BELAC assessments on request of regulatory authorities.	Point 6.1.2

POLICY AND PROVISIONS FOR COOPERATION BETWEEN BELAC AND THE COMPETENT (REGULATORY) AUTHORITIES

1. PURPOSE OF THE DOCUMENT AND REFERENCE TO STANDARDS

Since the start of its activities, BELAC has considered the cooperation with the different parties involved in the accreditation framework as an essential achievement for its operation. In this respect, the cooperation with the regulatory authorities (also called competent authorities) plays a prominent role and should aim to fulfil the expectations of both parties.

With the provisions of the Decision EC 768/2008 and of the Regulations EC 764/2008 and 765/2008) the European Commission and the Council have reinforced the role of accreditation as a tool of choice to facilitate the free circulation of goods and services and to implement an efficient market regulation ; the texts confirm the importance of cooperation between the national accreditation bodies and the national regulatory authorities.

It is aimed, through an efficient cooperation, to ensure that the regulatory authorities gain a better understanding of the functioning of BELAC and of its level of performance ; confidence in the services provided by the accredited bodies will therefore become a fact. It is also necessary to provide evidence that the specific requirements of the regulated sectors are well understood and taken into account by the accreditation process.

Moreover, BELAC is required to cover a broad range of conformity assessment activities, including complex regulated matters in constantly evolving technical sectors. Having access to expertise is a must and BELAC should not undermine the expertise available by the regulatory authorities.

This document aims to define the general policy principles for the cooperation between BELAC and the competent authorities as well as the respective rights and duties of both parties and the practical provisions for implementation.

The document refers to and complies with:

- the requirements of Regulation 765/2008 EC ;
- the legal provisions for the operation of BELAC ;
- the concerned clauses of the standard EN ISO/IEC 17011 ;
- the relevant EA recommendations;
- the rules of order of the BELAC organs.

1.1. RECIPIENTS

With follow-up of revisions:

Members of the National Council for Accreditation
Members of the Coordination Commission
Members of the Accreditation Board
Accreditation Secretariat

Without follow-up of revisions:

Any external request

2. RECIPIENTS

With follow-up of revisions:

Members of the Coordination Commission
Members of the Accreditation Board
Accreditation Secretariat
The accredited bodies
The assessors

Without follow-up of revisions:

Any external request

3. CONCEPTS AND DEFINITIONS

3.1. Competent authority

The Royal Decree of 31 January 2006 creating BELAC includes the following definition of a competent authority : « an authority in charge of either notifying or proposing for notification to the EU or recognising (conformity assessment) organisations », according to legal provisions ».

Depending on the diversity of its sectors of competence, one authority (e.g. a federal department) may feel the need to identify different competent authorities within its services.

Each authority is responsible to notify to BELAC the competent that depend of its jurisdiction.

3.2. BELAC organs

The BELAC organs consist of the Coordination Commission and the Accreditation Board.

4. THE PARTICIPATION OF THE COMPETENT AUTHORITIES IN THE BELAC ORGANS

4.1. Designation of the representatives of the competent authorities in the Coordination Commission

Competent authorities	BELAC
<p>4.1.1 Each competent authority intending to take part in the activities of BELAC may propose a representative to the Minister of Economy through its governing authority.</p> <p>The members are proposed on the basis of their competence in the accreditation and conformity assessment matters.</p> <p>A deputy may be appointed for each representative.</p> <p>The same rule applies in case of replacement of a member.</p>	<p>As soon as the BELAC secretariat has received confirmation of the approval of appointment by the Minister of Economy, the membership is confirmed, with voting right.</p> <p>The secretariat updates the list of members and the member is invited to communicate all necessary administrative data.</p> <p>At least once a year, the amendments to the composition of the Commission are formally registered through a Ministerial Decree.</p>
<p>4.1.2 Each member who is no longer able to fulfil his function informs the competent authority and BELAC.</p>	<p>BELAC takes the necessary initiatives with the competent authority in order to allow for the replacement.</p> <p>In order to ensure the continuity of the cooperation and except in case of express request of the resigning member, the member</p>

	keeps in charge until a new member has been appointed.
4.1.3 The representative and his/her deputy provide for an effective interaction.	
4.1.4 The authorities in charge of competent authorities that do not decide to formally designate representatives for the Coordination Commission are invited to appoint a contact person.	<p>Once a year, BELAC reminds the authorities that are not represented in the BELAC organs of the possibility :</p> <ul style="list-style-type: none"> - to designate competent authorities and representatives or contact persons; - to be informed about the BELAC activities through the BELAC website. <p>Depending on the specific needs, the contact persons may be invited to take part as experts in dedicated activities of the Commission or of working groups.</p>

4.2. Designation of the representatives of the competent authorities in the Accreditation Board

Competent authorities	BELAC
<p>4.2.1 The concerned authorities propose a representative and a deputy to the BELAC secretariat, through their representatives in the Coordination Commission.</p> <p>The designation is based on the following criteria : impartiality, technical competence with regard to accreditation and field experience for a specific accreditation sector.</p> <p>The same rule applies in case of replacement of a member.</p>	<p>As soon as the BELAC secretariat has received a proposal of designation, the secretariat, acting by delegation of the Coordination Commission, updates the list of members ; the member is invited to fill in a form with administrative data and a commitment for confidentiality. The status of member with voting right is effective as soon as the notification has been registered. The designations are formally ratified by each plenary session of the Commission.</p>
<p>4.2.2 4.1.2 Each member who is no longer able to fulfil his function informs BELAC and the representative of the competent authority in the Coordination Commission</p>	<p>BELAC takes the necessary initiatives to provide for a replacement .</p> <p>In order to ensure the continuity of the cooperation and except in case of express request of the resigning member, the member keeps in charge until a new member has been appointed.</p>
4.2.3 The representative and his/her deputy provide for an effective interaction..	
4.2.4 Each representative of a competent authority is responsible to inform the Board about the specific aspects in his/her sector but as member of the Board, he/she also required to take an effective part in all decision processes	

5. THE PARTICIPATION OF THE COMPETENT AUTHORITIES IN THE ACCREDITATION ASSESSMENTS

Competent authorities	BELAC
<p>5.1 The competent authorities that are represented in the Accreditation Board are invited to take part as observers in the accreditation assessments in their respective sector of competence, when the accreditation is a prerequisite for an agreement or notification by the authority.</p> <p>The competent authorities are therefore requested to inform the agreed or notified bodies (or candidate bodies) that</p> <ul style="list-style-type: none"> - they are required to inform BELAC when the application for accreditation is related to an agreement or a notification ; - they have to accept the presence of a representative during the accreditation assessment ; the instance will also mention the consequences in case of refusal. 	<p>The applicant body identifies via the application form all agreements or notifications that have already been granted or or are applied for, when the accreditation is a prerequisite.</p> <p>Through the endorsement of the quotation, the applicant formally accepts the presence of one or more representatives of the concerned competent authorities during the assessment, as well as the transmission to these persons of information about the assessment</p> <p>BELAC keeps the right to check the comprehensiveness and correctness of the information, in cooperation with the concerned competent authorities.</p> <p>In parallel to the composition of the assessment team, BELAC interacts with the concerned competent authorities through their representatives in the Accreditation Board. The representative appoints the person who will take part in the assessment. When this person is not the member of the Board, he/she will be required to respect all deontological rules applicable to a Board member.</p>
<p>5.2 The role and limits of responsibility of a representative of a competent authority who take part in an accreditation assessment are documented in BELAC 3-11.</p> <p>The participation of a competent authority as observer during an accreditation assessment does not limit the right of this authority to perform all audits and controls that may be made necessary according to the agreement or notification requirements.</p>	<p>BELAC provides the persons who will take part in assessments with all the necessary practical information (documents, dates...) , in timely manner.</p>

6. THE EXCHANGE OF INFORMATION BETWEEN BELAC AND THE COMPETENT AUTHORITIES.

6.1. Exchange of information with regard to the regulatory stipulations that are in force in a specific sector and that need to be taken into account during an accreditation assessment

Competent authorities	BELAC
<p>6.1.1 The representatives of the competent authorities in the Coordination Commission and the Accreditation Board commit themselves to provide BELAC with the list of the regulated sectors that fall under their jurisdiction and where accreditation is a prerequisite, as well as the relevant legal documents.</p> <p>The authorities commit themselves to update these lists at least once a year, with mention of the revisions and new projects in progress.</p>	<p>BELAC makes available to the assessment teams the lists of legal documents to be considered during the assessments. BELAC is not responsible for the content and update of the lists.</p> <p>Whenever necessary, BELAC identifies and documents, in cooperation with the authority and for each sector of activity:</p> <ul style="list-style-type: none"> - the requirements <u>supplementary</u> to the accreditation requirements to be included in the BELAC assessment; - the formulation of the accreditation schedules.
<p>6.1.2 Each competent authority is entitled, per regulation,</p> <ul style="list-style-type: none"> - to identify complementary specific requirements, applicable to the conformity assessment bodies, on condition that they can be explicitly related to the general accreditation requirements; - to require BELAC to include the evaluation of these supplementary requirements in the BELAC assessments; - to propose a standard formulation for the accreditation schedules. 	<p>BELAC ensures that the assessment teams are properly informed and the assessments are organised accordingly.</p> <p>All non-compliances with respect to the complementary requirements are classified as formal non-conformities</p> <p>BELAC takes into account the proposals of formulation of accreditation schedule provided the general BELAC policies can be respected.</p>

6.2. Exchange of information with regard to the preparation of new regulatory stipulations, when they include reference to conformity assessment and accreditation

Competent authorities	BELAC
<p>6.2.1 In order to facilitate the implementation of the regulatory stipulations that include reference to conformity assessment and accreditation, the competent authorities ensure that the proposed provisions do not contradict the legal and normative provisions on accreditation. To this aim, the competent authorities are invited to contact BELAC as soon as a process of preparation of a new text or revision of an</p>	<p>BELAC provides an advice, limited to the parts of the text with direct link to accreditation.</p> <p>This advice is purely informative; it is not binding for the concerned competent authority and does not engage the responsibility of the Department of Economy.</p>

existing text is started.	
6.2.2 The authorities commit themselves to inform BELAC on the state of progress of the new regulations that are in development. Early communication of the date of implementation as well as the provisions for transition is especially important.	For each new regulation that intends to refer to accreditation, BELAC evaluates whether an extension of its own scope is necessary as part of the implementation of the regulation.

6.3. Exchange of information with regard to specific information pertaining to an accreditation file

Competent authorities	BELAC
<p>6.3.1 The representative of a competent authority who has been appointed as member of the Board has access to the information present in the accreditation file, and in particular the assessment reports.</p> <p>Each time accreditation is a prerequisite for an agreement or a notification, the member of the Board is allowed to transmit the relevant information to the authority in charge of the agreement or the notification. The deontology rules of the authority will be respected.</p>	<p>The BELAC policy on exchange of information with the competent authorities is communicated to the accredited or applicant bodies through the BELAC document 3-06.</p>
<p>6.3.2 The personnel of the competent authorities who act as assessor or expert is required to comply with the BELAC relevant deontological rules, in particular with respect to the confidentiality of information. Derogations may be applicable in specific cases (see BELAC 3-05 point 6.2.2). The same provisions apply for the representatives of the competent authorities who take part in assessments as observers.</p>	
<p>6.3.3 The competent authority is invited to inform BELAC about all potential breaches of compliance with the accreditation requirements by an accredited body. In particular, any suspension or withdrawal of an agreement or notification will be communicated.</p>	<p>Depending on the nature and seriousness of the facts, BELAC takes the necessary measures for supervision (request for information, complementary assessment.) and, when justified, decides on sanctions. The competent authority is involved in the evaluation of the case.</p>
<p>6.3.4</p>	<p>BELAC informs the competent authority of the non-compliances identified during an assessment and of the related decisions through the participation of the authority in the assessment or the meetings of the Accreditation Board. When necessary or desirable, further contacts with the competent authority may be organised.</p> <p>In case of relevant information communicated to BELAC outside the framework of an accreditation assessment, BELAC informs the</p>

	representative of the authority in the Accreditation Board.
<p>6.3.5 The competent authority communicates to BELAC any information on an agreed or notified body that may be relevant for the accreditation process of this body (e.g: results of participation in proficiency testing exercises organised by the authority).</p> <p>The competent authority insures that this provision is included in its contractual documents with the body.</p>	

6.4. Communication with respect to the mutual recognition agreements where BELAC is signatory.

Competent authorities	BELAC
<p>6.4.1 In order to promote the confidence in the mechanisms of peer evaluation (EA peer review), the competent authorities are invited to delegate representatives and to take part as observers in the BELAC peer evaluations.</p>	<p>BELAC informs the competent authorities of the results of the EA and FALB peer reviews and of the status of signatory of the mutual recognition agreements.</p>