



# *BELAC*

## *Management Manual*

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

<b>Revision/ Date of approval</b>	<b>Reason for the revision</b>	<b>Scope of the revision</b>
0 draft CC 28.11.2002	Merger of BKO, BELTEST and BELCERT quality systems	Full revision following merger of documents but without significant amendment of basic principles
0 CC 05.06.2003	Update of format and lay-out Amendments after findings during EA peer review	Full document
1 Secr. 31.01.2004	Update of format and lay-out New structure of FPS Economy	Full document § 3.3.5
2 Secr. 16.12.2005	<ul style="list-style-type: none"> <li>- reference to ISO 17011</li> <li>- systematic change of “quality system” by “management system”</li> <li>- introduction of the concept of measurable quality indicators</li> <li>- introduction of the concept of continuous improvement and preventive actions</li> <li>- new tel/fax of BELAC</li> <li>- new structure of the General Direction Quality and Safety</li> </ul>	<ul style="list-style-type: none"> <li>§ 1.1 – § 3.1.2</li> <li>full document</li> <li>§ 4.1 § 4.6.2</li> <li>§ 4.1</li> <li>page 4</li> <li>§ 3.2.2 – 3.2.3 – 3.3.5.1/2/4/5</li> </ul>
3 CC 18.05.2006	Revision following the implementation of the BELAC R.D.	Full document
4 CC 07.12.2007	<ul style="list-style-type: none"> <li>- new name of the Division and organogram</li> <li>- Cross frontier policy</li> </ul>	<ul style="list-style-type: none"> <li>§ 3.2.2 en § 3.3.5</li> <li>§ 2.2.2</li> </ul>
5 CC written ballot 17.01.2011	<ul style="list-style-type: none"> <li>- General revision of the document in order to facilitate the reading</li> <li>- Revision of chapters 1,2,3 following the implementation of the EC Regulation 765/2008: structure and content</li> <li>- Revision of the point dealing with the independence, impartiality and objectivity of BELAC;</li> <li>- Limitation of the text to general policy principles with respect to <ul style="list-style-type: none"> <li>- the management of the documents of the management system (details are included in BELAC 3-01);</li> <li>- the management of records (details are transferred to BELAC 3-13)</li> <li>- the organisation of the permanent secretariat (details transferred to BELAC 3-02)</li> <li>- the internal audit (details included in BELAC 3-04)</li> </ul> </li> <li>- Revision of the provisions for the transfer of an accreditation</li> <li>- Revision of the provisions for sanctions in case of non-respect of the accreditation requirements.</li> </ul>	<ul style="list-style-type: none"> <li>Full document</li> <li>Chapters 1,2,3</li> <li>Point 5.2</li> <li>Point 6.2</li> <li>Point 6.3</li> <li>Point 5.3.5</li> <li>Point 6.4.3</li> <li>Point 7.4.5</li> <li>Point 7.5</li> </ul>
6 CC 12.05.2011	<ul style="list-style-type: none"> <li>- Organisational chart</li> <li>- Concept of related administrative bodies</li> <li>- Reference to the FPS Economy website for information on the position of BELAC within the FPS Economy.</li> <li>- Points to be considered during the management review.</li> </ul>	<ul style="list-style-type: none"> <li>Point 5.1</li> <li>Point 5.2</li> <li>Point 5.3.5.1</li> <li>Point 6.6.2</li> </ul>

7 Secretariat 29.10.2012	<p>Extension of the BELAC scope to the accreditation of validation and verification bodies according to ISO 14065:</p> <ul style="list-style-type: none"> <li>- List of BELAC activities</li> <li>- Organisation of the BELAC secretariat</li> <li>- Accreditation requirements</li> <li>- Editorial amendment (Use of the more general terminology “conformity assessment bodies”)</li> </ul> <p>Cooperation between BELAC and the regulatory authorities</p>	<p>Point 4.1 Point 5.3.5.3 Points 7.2, 7.2.1, 7.2.2 Point 8.2.2 first indent</p> <p>New chapter 10</p>
8 CC 22.01.2015	<p>Revision of the structure of the document in order to ensure a closer link with the standard NBN EN ISO/IEC 17011</p> <p>Update of the reference to the legal documents : Code of Economical Law instead of Law on Accreditation, Revision of Royal Decree creating BELAC</p> <p>Further detailing of the BELAC quality policy</p> <p>Mention of the monitoring task of the National Council on behalf of the Belgian State, according to EC Regulation 765/2008</p> <p>Update of the provisions related to international activities</p> <p>Revision of the accreditation costs – introduction of yearly fee</p> <p>Update of the references to standards</p> <p>Intercomparisons and proficiency testing</p> <p>Reference to the status of BELAC as signatory of the EA, ILAC and IAF MLA’s</p>	<p>Full document</p> <p>Point 3.1</p> <p>Point 2.3</p> <p>Point 3.2.2.1</p> <p>Point 4.4.3</p> <p>Point 4.5.2</p> <p>Point 7.2.1</p> <p>Point 7.2.3</p> <p>Point 8.2.2</p>
9 Secretariat (*) 01.09.2017	<p>Update of reference to standards</p> <p>Mention of the EMAS agreement and reference to FALB</p> <p>Functionnal organigram of BELAC</p> <p>Internal audit (withdrawal of the concepts of “quality actions” and “ performance indicators”)</p> <p>Update internal organization of the BELAC secretariat</p> <p>Concept of assessment program for an accreditation cycle – content of a renewal assessment</p> <p>Publication of decisions of withdrawal and suspension Communication</p> <p>Reference to multilateral agreements of EA, ILAC and IAF</p> <p>(*) Considering that the Coordination Commission has approved the underlying documents dealing with these issues, these amendments in BELAC 1-01 are approved under the responsibility of the BELAC secretariat.</p>	<p>Points 4.4.1, 7.2.1</p> <p>Points 1.1, 3.1, 7.2.2</p> <p>Point 4.1</p> <p>Point 5.4.1</p> <p>Point 6.1.3</p> <p>Points 7.3.3.4, 7.3.3.5</p> <p>Points 7.4.2, 7.4.3</p> <p>Point 8.2.2.2</p>

10 CC 07.11.2019	Comprehensive revision following implementation of ISO/IEC 17011:2017	
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# ***Chapter 1.    General***

## **1.1.    PURPOSE OF THE BELAC MANAGEMENT MANUAL AND REFERENCE TO STANDARDS**

The aim of this management manual is:

- to define the goals and policies of BELAC;
- to describe the fundamentals for its operation;
- to document the objectives and essential elements of its management system.

The operation and the management system of BELAC, as described in this manual, are based on the European and national legal provisions regarding accreditation, the requirements of the international standard EN ISO/IEC 17011:2017 and the relevant EA /ILAC/IAF/FALB guidelines.

This manual, along with the procedures and instructions therein mentioned, forms the basis for the participation of BELAC in multilateral agreement with analogous accreditation bodies in and outside the EU.

The management manual is meant as

- a promotion and information tool which, as such, may be distributed to third parties without restriction.
- a practical tool for the use of BELAC organs to whom a global and coherent vision of its policy and means is proposed.

Associated documents:

- Document 6-001 presents a comprehensive list of documents belonging to the BELAC management system documentation.
- Document 6-003 presents a correspondence table between the provisions of the management manual and of the underlying procedures with the requirements of the EC Regulation 765/2008, those of the EN ISO/IEC 17011:2017 standard and the EA/ILAC/IAF/FALB guidelines.

## **1.2.    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

## ***Chapter 2.     The Belgian accreditation structure***

### **2.1. THE ROLE OF ACCREDITATION**

The current economic structures are subject to a dynamic evolution stirred by liberalisation and internationalisation of trade. Technical barriers based on local regulations and standards are eliminated through harmonisation and trade agreements, in order to allow for competition.

The concept of conformity assessment is increasingly referred to as a central tool when free circulation of goods and services is to be achieved and harmonised.

In such a framework it is essential to boost confidence of the economic actors with regard to reports and certificates issued by laboratories, inspection bodies and certification bodies, so that these may be regarded as technical passports for a product or service.

Accreditation allows accredited conformity assessment bodies that seek for a reliable and third-party recognition of their technical competence to promote their know-how.

Accreditation does not only aim at facilitating commercial exchanges and export but should also be seen as an instrument for public authorities, whose role in the economic process is evolving.

The legal provisions, especially that coming from the European Commission, emphasise the role of "self-regulation" (or deregulation) in trade through anticipating measures before bringing goods on the market.

These measures provide for the intervention of specifically appointed bodies (notified bodies) whose technical ability is recognised by an official authority and which act on its behalf for the control of goods before they are brought to the market.

Post-market control, with a view to protect the welfare of the population and the integrity of the environment, remains indeed the responsibility of the public authorities. In this area as well, in order to be consistent with measures of pre-market control, the accreditation of bodies involved in the attestation of conformity is the pre-eminent instrument for the authorities in charge of control.

The role of accreditation was confirmed and even emphasized through the publication, in August 2008, of the Decision 768/2008 EC (\*) and of Regulations 764/2008 EC (\*\*\*) modified by the Regulation EU 2019/515 (\*\*\*\*) and 765/2008 EC (\*\*\*\*\*) amended by the Regulations EU /2019/1020 (\*\*\*\*\*)

(\*) DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

(\*\*) REGULATION (EC) No 764/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

(\*\*\*) REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

(\*\*\*\*) REGULATION (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008

(\*\*\*\*\*) REGULATION (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

Confidence in calibration or test reports, inspection certificates or certification of a product, a

process or a person will be increased when these documents are issued by bodies whose impartiality and technical competence prove to comply with objective and internationally recognised standards.

## **2.2. THE DEVELOPMENT OF ACCREDITATION IN BELGIUM**

In 1990, Belgian trade and industry have turned to the government so that an accreditation structure would be made available; the structure was expected to offer all the guarantees of an independent and indisputable body, relying on a specific legal basis and covering all aspects of conformity assessment.

It is in response to this expectation that, at the initiative of the Ministry of Economy and in cooperation with the different regulatory authorities at the national, regional and community level, a structure for accreditation supported by legislation was created. This structure has been the subject of several modifications in order to accommodate the needs of the final users of accreditation and the evolution of the European context.

From 1992 to 2006, 3 distinct accreditation bodies have been respectively responsible for the accreditation of calibration laboratories (BKO), testing laboratories and inspection bodies (BELTEST) and certification bodies (BELCERT). Their policies and operation were however very similar.

In order to offer a better service to the concerned parties and to provide a better answer to their expectations, an evolution towards a single accreditation body was felt necessary and in 2006, BKO; BELTEST and BELCERT merged into a single body for the accreditation of conformity assessment bodies called **BELAC**.

## **2.3. THE BELAC GENERAL POLICY**

### **2.3.1. BELAC: a mission**

*"To contribute to create the conditions for a competitive, sustainable and balanced market for goods and services in Belgium, by providing accreditation as a tool for the recognition of competence of conformity assessment bodies for products and services"*

BELAC has been formally appointed as the sole Belgian accreditation body in compliance with Regulation EC 765/2008 . BELAC operates under the auspices of the Belgian State and the Minister of Economy has final responsibility for the management and supervision.

The requirements of Regulation EC 765/2008 form the basis for the operation. The management of BELAC shall therefore be compliant in particular with the requirements of the EN ISO/IEC 17011 standard and the associated harmonised standards relevant for the accreditation of conformity assessment bodies.

### **2.3.2. BELAC: a vision**

*« To develop and maintain accreditation as a tool in all interested technological sectors, with specific attention for supporting innovation.*

For BELAC, the level of performance is the degree to which the accreditation structure fulfils the expectations of all concerned parties and in particular the regulatory authorities, the accredited conformity assessment bodies and their customers.

BELAC therefore aims to deliver high level expert services in order to build up credibility and to foster confidence in the accredited organisms and the conformity attests they issue.

The conformity assessment market in Belgium is rather restricted considering the size of the country but covers a broad and diversified range of activities, considering the level of economical development and the expectations of the Belgian society. In such conditions, maintaining the level of performance of the accreditation body is a constant challenge, that BELAC is committed to address.

### **2.3.3. BELAC: the values that support its policies**

The following elements are regarded as key issues of the BELAC policies:

- *The independence and impartiality of the accreditation body and the transparency of the management and of the decision-making process*

The BELAC structure as well as its ways of functioning is fixed by legal stipulations that provide for its autonomy for decision. In particular,

- the participation of all interested parties in the design and approval of policies and general procedures is ensured;
- the responsibility for accreditation decisions is by a college of experts in matters related to conformity assessment.

- *The development and continuous update of competence at all levels of operation of the accreditation processes and in particular the technical expertise with regard to conformity assessment matters*

The BELAC structure organises and encourages exchanges of information with the national regulatory authorities, the international relevant organisations, the economical and industrial partners, the scientific community and the accredited bodies themselves. These communication channels are tools that need to be activated and maintained in the most effective way.

Assessors are the most important instrument of the system. They have to provide evidence of the level of competence of the accredited bodies and their performance conditions to a large extent the value of an accreditation and its acceptance by the market. A strict follow-up of performance and further training on a regular basis are of utmost importance.

- *A customer driven operation*

BELAC takes into account the interest of all parties concerned with conformity assessment matters and strives for a continuous improvement of its level of service.

- *A functioning based on an efficient and continuously evolving management system*

The management system will follow and adapt itself to the expectations of the users and to the requirements of international standards that are applicable to accreditation bodies.

BELAC rests on the following tools to define the driving forces of its management system and to achieve and maintain the requested level of performance :

- a risk-based approach and the implementation of measures to eliminate or minimize them;
- the input of the assessors, of the accredited bodies and of the stakeholders;
- the results of internal audits, treatment of complaints and other information;
- the annual management review.

- *A service designed to follow and anticipate the needs of the accredited bodies and of their customers*

The BELAC structure allows for cooperation with the associations of accredited bodies as well as with the different regulatory authorities and economical actors. BELAC therefore strives to contribute to the discussions on the role of conformity assessment when activities are being developed in new technological areas.

- *The participation of BELAC in mutual recognition agreements between accreditation bodies*

The legal provisions for accreditation in Belgium include the recognition of the benefits of the multilateral agreements between accreditation bodies in which BELAC is required to take part. Moreover, BELAC commits itself to promote the recognition of the conformity assessment certificates issued by accreditation bodies signatories to such agreements.

BELAC is member and participates actively in the activities of EA (European Co-operation for Accreditation), as the body appointed to ensure the coordination of accreditation activities in Europe in compliance with article 14 of The EC Regulation 765/2008, as well as in the activities of ILAC (International Laboratory Accreditation Co-operation), IAF (International Accreditation Forum) and FALB ( Forum of Accreditation and Licensing Bodies).

Information on the BELAC status as signatory to the EA MLA, ILAC MRA, IAF MLA and FALB recognitions are published can be retrieved from the BELAC webpage.

BELAC commits itself to respect the specific requirements related to its obligations as signatory of the international multilateral agreements and considers this as an essential element for its operation.

- *The promotion of accreditation and of services delivered by the accredited bodies*

*“tested/inspected/certified once – accepted everywhere”*

## **Chapter 3.      Legal basis and organisation of accreditation in Belgium**

### **3.1.    THE LEGAL BASIS**

#### *Main associated documents:*

- BELAC 0-03    Code of Economic Law (especially but not limited to book VIII – title 2),*
- BELAC 0-02    Royal Decree creating the national accreditation Council*
- BELAC 0-05    Royal Decree creating BELAC*
- BELAC 0-08    Cooperation agreement between the Federal State, the Flemish Region, the Walloon Region and the Brussels Capital Region with respect to the implementation of the EMAS scheme*

Accreditation in Belgium is organised on the basis of the following legal provisions:

- the Code of Economic Law, especially but not limited to book VIII – title 2, on accreditation of conformity assessment bodies

The legal provisions on accreditation

- create a general structure for accreditation of conformity assessment bodies in compliance with the provisions of the EC Regulation 765/2008 and see in particular for the setting up of a unique non for profit governmental accreditation body;
  - require compliance with the relevant European and international standards;
  - attribute to the FPS Economy the final responsibility for the administrative management of the accreditation structure;
  - set up a National Council for Accreditation with representation of all concerned parties as an advisory body to the Minister of Economy; the Council is responsible for the supervision of the functioning of accreditation.
- the Royal Decree of January 24, 1991, setting up the National Council for Accreditation (see also under point 3.2.2):
  - the Royal Decree of January 31, 2006, modified by the Royal Decree of February 7, 2014, setting up the accreditation body BELAC:

The Royal Decree includes provisions with regard to:

- requirements to be complied with by conformity assessment bodies that apply for accreditation;
- requirements for the functioning of BELAC (management - accreditation process – financing )
- the obligation for BELAC to take part in mutual recognition agreements between accreditation bodies, and the consequences for the Belgian State, with respect to acceptance of documents issued by conformity assessment bodies with reference to accreditation granted by bodies equivalent with BELAC.

The legal basis includes also several complementary Royal and Ministerial Decrees.

Since its creation, the Belgian accreditation structure intends to reflect the visions and expectations of all interested parties with regard to accreditation. It operates according to a model of consensus that also strictly satisfies the normative and legal requirements.

- Cooperation agreement between the Federal State, the Flemish Region, the Walloon Region and the Brussels Capital Region with respect to the implementation of the EMAS Scheme (Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC ).

This agreement includes delegation for the accreditation and supervision of the Belgian environmental verifiers to BELAC, the Belgian national accreditation body notified by the Belgian State in compliance with article 4 of the EC Regulation 765/2008 setting out the requirements for accreditation. As a consequence, BELAC is required to be member of FALB Forum of Accreditation and Licensing Bodies).

The legal basis also includes complementary royal and ministerial decrees.

Since its creation, the Belgian accreditation structure has been aiming to reflect the views and expectations of all parties with interest in accreditation matters. It is a model based on consensus, operating on strict normative and legal grounds.

## **3.2. THE ORGANISATION OF THE BELGIAN ACCREDITATION STRUCTURE**

### **3.2.1. General organisation**

The Belgian accreditation structure is placed under the final responsibility of the Minister of Economy.

It includes

- an administrative support provided by the FPS Economy and more particularly the general Direction Quality and Safety, that cares for the necessary material aspects for the operation of accreditation (personnel, premises, IT infrastructure, finances and accounting);
- the National Council for Accreditation as a discussion forum for all concerned parties; while not formally belonging to the Belgian Accreditation Body BELAC, the Council acts through the remittance of advices to the Minister of Economy (see also under 3.2.2)
- the BELAC accreditation body itself (see also under chapter 4) that includes different organs ( the BELAC Co-ordination Commission, the Board of Appeals, the Accreditation Board and the BELAC secretariat).

### **3.2.2. The National Accreditation Council**

#### *Main associated documents:*

<i>BELAC 0-02</i>	<i>Royal Decree creating the national accreditation Council</i>
<i>Ministerial Decrees</i>	<i>appointing the members of the Council</i>
<i>CNR 1</i>	<i>Rules of order</i>
<i>CNR 1 INFO</i>	<i>List of the members of the Council</i>

#### **3.2.2.1 Tasks and responsibilities**

The Council's task is:

- to co-ordinate the coherent and transparent application of the principles and procedures concerning accreditation;
- to evaluate the annual report of activities of the national accreditation body and to bring advice to the Minister; the Council is responsible, on behalf of the Belgian State, of the monitoring of the operation of the national accreditation according to article 9 point 2 of the EC Regulation 765/2008
- to ensure the collection, distribution and publishing of information related to activities in this area;
- to ensure that all interested parties are involved in the activities concerning accreditation;
- to provide advice dealing with all aspects regarding accreditation.

The Council operates through the delivery of advices to the Minister of Economy. A statement issued by the Council is mandatory in case of significant amendment of legal provisions with relation to the operation of the accreditation body set up according to the Code of economic law.

#### **3.2.2.2 Composition**

The Council is composed of about 50 members who are the representatives of federal, regional and community authorities, of industry, of trade unions, of consumers and of the accredited bodies.

In this composition, care is taken to ensure that no group of interest dominates.

The representatives are presented by the relevant authorities and appointed by the Minister of Economy.

#### **3.2.2.3 Functioning**

The holding of meetings is described in the rules of order.

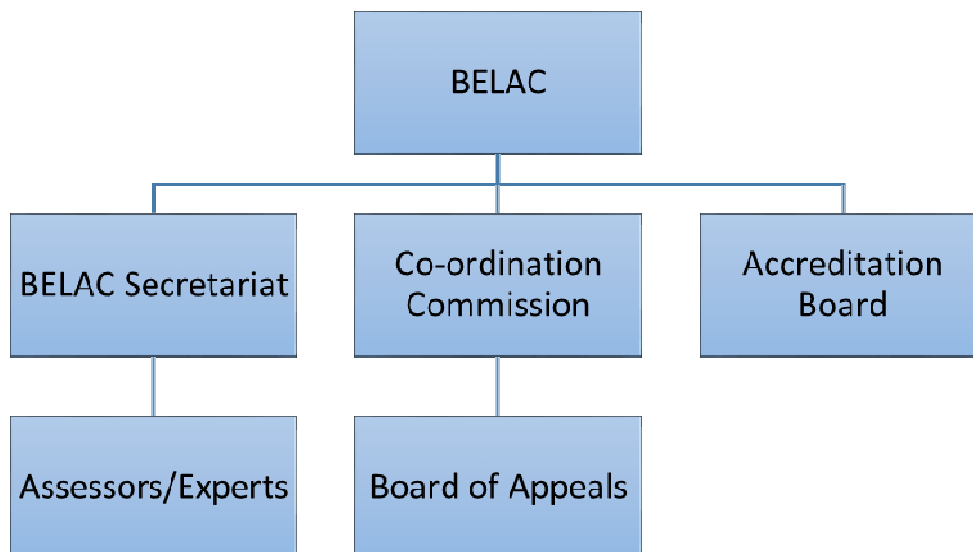


## Chapter 4. General organisation

### 4.1. FUNCTIONAL ORGANIGRAM

The Royal Decree governing BELAC attributes to the Minister of Economy the final responsibility for the management of BELAC, but provides for a functional delegation of responsibilities and decision-making competence through various management bodies, i.e.:

- a Coordination Commission (see also under 4.3.1), responsible for the definition of general management policies and procedures and for the follow-up of appeals and complaints through the Board of Appeals (see also under 4.3.3);
- an Accreditation Board (see also under 4.3.2), responsible mainly for the follow-up of individual accreditation files.
- a permanent secretariat, which is part of the Quality and Safety General Direction, Division “Quality and Innovation ” - (see also under 6.1), in charge of the general management of BELAC and in particular:
  - the daily operation of BELAC and of the accreditation files;
  - the relations with the Board, the Co-ordination Commission and the Board of Appeals;
  - external relations with all concerned parties.



## **4.2. ROLE, RESPONSIBILITIES AND OPERATION OF THE BELAC ORGANS**

### **4.2.1. The Co-ordination Commission**

*Main associated documents:*

<i>BELAC 0-05</i>	<i>Royal Decree creating BELAC</i>
<i>BELAC 0-07</i>	<i>Ministerial Decree appointing the members of the Co-ordination Commission</i>
<i>BELAC 3-08</i>	<i>Rules of order of the Co-ordination Commission</i>
<i>BELAC 6-015</i>	<i>List of the members of the Co-ordination Commission</i>

#### **4.2.1.1 Role and responsibilities**

The Co-ordination Commission is responsible for the general management of BELAC. Its composition provides opportunity for an effective involvement of all interested parties.

The Co-ordination Commission is particularly responsible for:

- maintaining the impartiality of BELAC activities;
- developing, approving and ensuring a transparent and consistent implementation of the general BELAC policies as well as the principles and provisions for its operation;
- approving the accreditation programs to be included in the scope of BELAC activities;
- approving the guidelines for the implementation of the general criteria for accreditation ;
- supervising the financial aspects as well as the availability in human and material resources;
- ratifying the participation of BELAC in international multilateral agreements or any other co-operation contracts;
- setting up an Accreditation Board with decision competence on accreditation;
- evaluating the BELAC activities on a yearly basis and approving the management review.

#### **4.2.1.2 Composition**

The BELAC Co-ordination Commission is composed of representatives from all involved authorities, industry, consumers and trade unions, as well as accredited bodies. This composition aims to provide for a balanced representation of all parties having interest in conformity assessment and accreditation.

The members are appointed based on their competence with respect to accreditation and conformity assessment. They are appointed by the Minister for Economy upon recommendation by the parties involved.

With a view to achieve full transparency and efficiency of the working of the Commission, as well as consistency with the other organs within the whole accreditation structure, the Chairman of the National Council and of the Accreditation Board are also appointed as members of the Commission.

#### **4.2.1.3 Functioning and decision-making**

The meetings are held according to the rules of order, which specify the voting procedure.

#### **4.2.2. The Board of Appeals**

*Main associated documents:*

*BELAC 0-05  
BELAC 3-04*

*Royal Decree creating BELAC  
Handling of dysfunctions*

#### **4.2.2.1 Role and responsibilities**

A Board of Appeal is established by the Coordination Commission with the task of investigating and giving advice on:

- appeals regarding the decisions of the Accreditation Board on a whole or partial denial, suspension or withdrawal of an accreditation;
- complaints expressed by an accredited body, a regulatory authority or any interested person on the implementation of the accreditation procedures or the reference to the status of accredited body or the functioning of an accredited body.

#### **4.2.2.2 Composition**

The composition of the Board of Appeal aims to provide, depending on the file subject to examination, a technically grounded and impartial decision.

The Board is composed of

- a Chairman belonging to the FPS Economy, with an appropriate knowledge of legal matters;
- the Chairman of the Coordination Commission and 2 members appointed by the Chairman;
- two assessors who are not involved in the case to be investigated.

The Board can call for experts

#### **4.2.2.3 Functioning and decision-making process**

Provisions for lodging appeals and complaints, as well as investigating the individual cases are specified in the legal provisions and in the documents of the BELAC management system.

The decisions of the Board of Appeal are notified to the interested parties and to the Coordination Commission and the Accreditation Board for implementation, within the limits of their respective responsibilities.

### **4.2.3. The Accreditation Board**

#### *Main associated documents:*

<i>BELAC 0-05</i>	<i>Royal Decree creating BELAC</i>
<i>BELAC 3-09</i>	<i>Rules of order of the Accreditation Board</i>
<i>BELAC 6-016</i>	<i>List of the members of the Accreditation Board</i>
<i>BELAC 6-316</i>	<i>Competence of the BELAC Board's members</i>

#### **4.2.3.1 Role and responsibilities**

The Board is the executive organ of the accreditation body. The Board is responsible for decision-making in the accreditation procedure and supervises the follow-up of accredited bodies.

#### **4.2.3.2 Composition**

The Board is composed of representatives of the regulatory authorities that rely on accreditation within the remits of a specific legislation.

Industry, consumers and trade unions may appoint representatives in the capacity of observers. Accredited bodies are not represented in the Board in order to avoid impartiality risks.

Ensuring reliability and confidence in accreditation decisions (which implies ensuring the competence of the Board's members) is an essential element of the BELAC policy. With this aim, the members are appointed based on the following criteria: impartiality, personal experience in the operation of conformity assessment bodies, knowledge of accreditation requirements and technical competence with respect to specific accreditation programs. The competence sectors of each member of the Board are documented and regularly updated.

#### **4.2.3.3 Functioning**

The meetings are held according to documented rules of order that specify the voting procedure.

Depending on the type of decision, the Board operates

- during plenary meetings or through correspondence consultation where all members are involved;
- based on the advice of at least one of the Board's members appointed as reviewer and delegation of decision to the Board's Chair.

The members are bound to documented rules of confidentiality on matters related to the accreditation processes.

#### **4.2.4. Permanent secretariat**

##### *Mains associated documents:*

*BELAC 0-05                      Royal Decree creating BELAC*  
*BELAC 5-07                      Organisation and operation of the BELAC secretariat - Tasks and responsibilities of the members*

##### **4.2.4.1 Relation with the Federal Public Service for Economy, SME's, Independent Professions and Energy (FPS Economy)**

The permanent secretariat function is in charge of the daily management of the accreditation body in compliance with the aims, policies and working procedures of BELAC.

The BELAC permanent secretariat is administratively placed under the Quality and Innovation division of the Quality and Safety General Direction of the FPS Economy which is responsible for material aspects (personnel, premises, office and IT means) As a service of the Quality and Safety Administration, the secretariat and its staff are bounded to the rules here linked

*For more information on the position of the BELAC secretariat within the FPS Economy : see [www.economie.fgov.be/](http://www.economie.fgov.be/) à propos du SPF Economie/ Structure / Organigramme / E6*

##### **4.2.4.2 Role and responsibilities**

The role and responsibilities of the secretariat are described in the various legal provisions and include mainly:

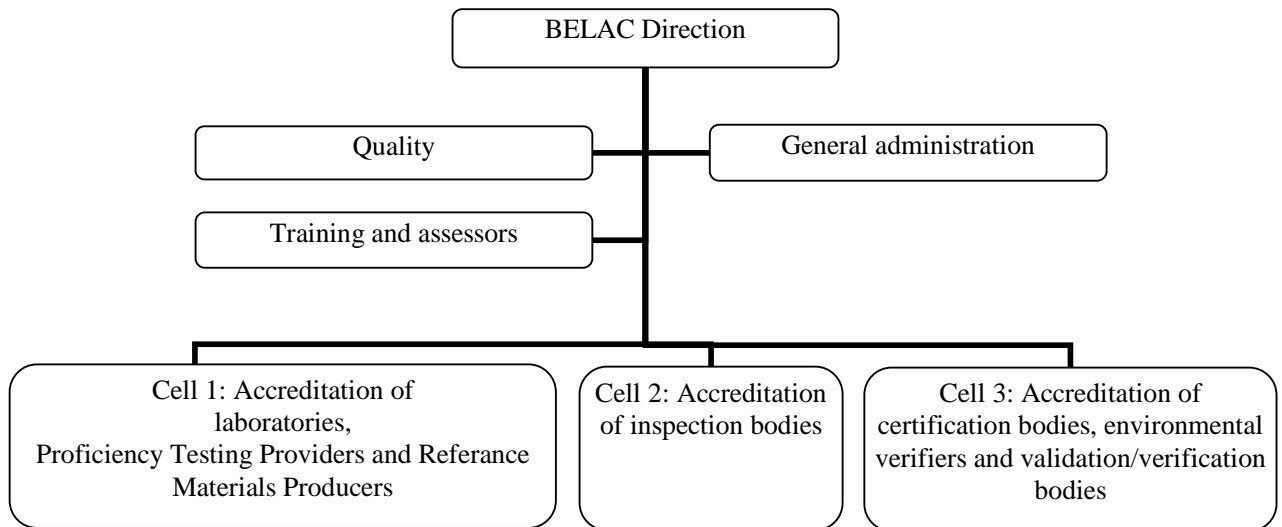
- the management of the individual accreditation cases;
- the management of assessors and experts;
- the follow-up of the working of the BELAC organs and the implementation of the decisions;
- the management of the external relations at the national and international levels including the supervision of the participations in mutual recognitions between accreditation bodies;
- the follow-up of the national and international evolutions in accreditation and the development of accreditation activities in new sectors of economy and technology;
- the implementation of the management system including the development and implementation of the business plan with respect to the development of the system.

The staff of the secretariat is appointed by the FPS Economy and is authorised to perform other activities with no direct link with accreditation provided they are compatible with their obligations within BELAC.

##### **4.2.4.3 Organisation**

The Direction is responsible for the general supervision of the accreditation activities and for the proper functioning of the secretariat, as well as for the relations between BELAC and third parties, at the national and international levels.

The following organigram describes the internal structure of the secretariat:



Function descriptions are available for the main functions with description of the profile for the function and of the main tasks and responsibilities.

BELAC organises initial and continued training of the secretariat staff. For each member staff, an individual file is regularly updated and includes amongst others their specific tasks and responsibilities.

### **4.3. INDEPENDENCE AND IMPARTIALITY**

#### *Main associated documents:*

*BELAC 1-02 BELAC general policy and means for the implementation of the ISO/IEC 17011:2017 requirements on the identification and management of risks related to its operation.*

BELAC is organised such as to ensure the independence and impartiality of its operation at all levels of management and decision. A detailed analysis of the risks that may endanger its independence and impartiality has been performed and mechanisms have been set up in order to eliminate or control them. The results are approved at the highest level of management and are systematically reconsidered as part of the management review.

The following measures ensure that the risks in terms of independence and impartiality are

under control:

- BELAC is an accreditation body ruled by the public authority but has an independent position with regard to its relations with accredited bodies and their clients.

However, considering that BELAC is placed under the responsibility of the Belgian State and has no specific legal identity, all entities of the Belgian administration are formally to be considered as related bodies especially if they perform conformity assessment activities.

The independence of the accreditation process with respect to the related administrative bodies that perform conformity assessment activities is ensured through a functional separation.

No administrative entity outside BELAC belonging to the General Administration Quality and Safety is entitled to take part in the decision making process with respect to the accreditation procedure.

- A particular aspect of the legislation governing BELAC is the cooperative character of the provisions for the implementation of the accreditation procedure, in which all interested parties are involved:

- the federal, regional and community authorities;
- industry;
- trade unions;
- consumers
- accredited bodies.

This cooperative approach is demonstrated by stipulations such as:

- the different BELAC organs are evenly composed of representatives from the interested parties;
- the participation of the regulatory authorities for the implementation of accreditation in regulated sectors is provided for.

Through the participation of all interested parties without any one of these parties being dominant, transparency as well as independence is ensured.

- BELAC policies and procedures exclude any form of discrimination and the services of BELAC are open to any applicant, provided the applicant formally accepts to comply with all accreditation requirements as fixed by the legal framework of BELAC.
- BELAC does not offer any type of conformity assessment activity that can be the subject of an accreditation. An effective separation of responsibilities with respect to the services of the FPS Economy that provide conformity assessment activities is in place.
- Except for general information concerning the accreditation requirements and the procedures of BELAC, BELAC is prohibited from giving consultancy or offering services liable to compromise the objectivity of the decision process.

## **4.4. FINANCIAL MANAGEMENT**

### *Main associated documents:*

<i>BELAC 0-03</i>	<i>Code of Economic Law</i>
<i>BELAC 0-05</i>	<i>Royal Decree creating BELAC</i>
<i>BELAC 7-01</i>	<i>BELAC: general information and practical provisions.</i>

### **4.4.1. Basis**

The financial management of BELAC is arranged on the basis of

- legal stipulations: administrative management (secretariat staff salaries, office space, material...) and promotion of the Belgian accreditation structure are provided for by the FPS Economy;
- the regulations creating the Belgian accreditation structure which provide for the payment of assessment costs by the accredited bodies.

### **4.4.2. Funding with regard to the accreditation procedure**

#### **4.4.2.1 Application fee**

Each application for an accreditation is subject to the payment of a non-refundable fee fixed by the legal stipulations.

#### **4.4.2.2 Assessment costs**

The services of the assessors are charged at an hourly rate fixed by the legal stipulations plus travelling costs.

The services of the assessors include document review, the assessment visit and writing of the report.

#### **4.4.2.3 Annual fee**

Every accredited body is required to pay an annual fee per accredited type of conformity assessment activity.

The fee is payable from the calendar year following that of obtaining the accreditation.

### **4.4.3. The Accreditation Fund**

#### **4.4.3.1 Income and expenses**

The management of the income and expenses arising from the implementation of the accreditation procedure is arranged via the Accreditation Fund.

The type of possible income and expenses are recorded in legal stipulations.

Fees charged to the accredited bodies are the largest source of income, while payment by the Fund to the assessors and salary costs of some BELAC secretariat staff represent the largest expenditure.



The administrative rules of the Accounting Service of the FPS Economy apply to the expenditures.

A member of the Accreditation Service is appointed as « ordinary accountant » and is responsible for income.

A member of the Accounting Division of the Administration for general Affairs of FPS Economy is appointed as « extraordinary accountant » and is responsible for expenditures.

#### ***4.4.3.2 Control of the management of the BELAC Fund***

The secretariat is responsible for the control of the financial aspects and reports once a year to the Co-ordination Commission. A final supervision is exerted by the High Financial Court (Cour des Comptes / Rekenhof)

## **Chapter 5. SCOPE OF ACTIVITIES AND ACCREDITATION REQUIREMENTS**

*Main associated documents:*

*BELAC 0-06 Ministerial Decree fixing the list of accreditation criteria*

*BELAC 1-03 Activities of BELAC: description and criteria for selection*

BELAC is not entitled to perform other activities than the accreditation of conformity assessments bodies in compliance with the requirements of EN ISO/IEC 17011.

BELAC does not subcontract any of its accreditation activities except in case of (partial) assessment to be performed outside Belgium ( see under 5.1.3) but BELAC is allowed to perform joint assessments with other accreditation bodies as part of international agreements.

### **5.1. ACCREDITATION PROGRAMS**

#### **5.1.1. Scope of activities**

BELAC may cover all potential fields of conformity assessment activities and all technical domains, in both the regulated and non-regulated sectors.

However, accreditation can only be granted on the basis of accreditation requirements that are defined in normative documents accepted at the international level and that aim to provide confidence in the bodies that comply with these requirements. The Minister of Economy, following advice of the national Council for Accreditation and Certification, publishes the list of the normative documents that fix the accreditation requirements.

In practice, the activities of BELAC cover the activities of the following types of bodies:

- the calibration laboratories;
- the testing laboratories;
- the medical laboratories including the activities of Point of Care Testing
- the inspection bodies;
- the certification bodies for management systems;
- the certification bodies for products;
- the certification bodies for personnel;
- the proficiency testing organizers;
- the producers of reference materials;
- the greenhouse gases validation and verification bodies;
- the environmental verifiers according to the EC Regulation CE n° 1221/2009 (EMAS III).

The technical sectors that can be covered by an accreditation are defined according to documented criteria.

#### **5.1.2. Extension of the BELAC scope**

The extension of the scope of activities of BELAC to a new accreditation field (i.e. an

accreditation standard not yet operated by BELAC) will only be proposed based on a risk-analysis documented in a feasibility study prepared by the BELAC secretariat; the interest expressed by the concerned sector, the expectations of the stakeholders, the position of the regulatory authorities when relevant, the situation at the international level, the availability of assessors and the need to develop specific documents or instructions are considered.

The extension is subject to a positive advice of the National Accreditation Council and the endorsement by the Minister of Economy and publication as Ministerial Decree.

A similar approach is used in case of extension of the scope of activities of BELAC to significantly new technical activities or schemes within an already active accreditation field; the feasibility study is only submitted for endorsement by the Co-ordination Commission .

### **5.1.3. International activities (Cross Frontier Policy)**

#### *Main associated documents:*

*BELAC 1-04: Procedures and provisions for the accreditation of multi-site conformity assessment bodies*

*BELAC 1-05: Procedures and provisions for cross frontier accreditation and cooperation with accreditation bodies members of EA, ILAC and IAF*

#### **5.1.3.1 Accreditation of companies whose main activity site is located outside Belgium**

BELAC

- offers its services by priority to companies established on the Belgian territory;
- does not engage in any marketing of its services outside the Belgian territory;
- operates in compliance with the international provisions and obligations that are binding for the accreditation bodies signatories to the mutual recognition agreements.

BELAC may exceptionally accept applications for accreditation originating from

- European countries in case the national accreditation body is in a development phase or is not signatory to the EA, ILAC or IAF multilateral agreements or declares it has not the possibility to handle the case
- non-European countries, provided the application can be considered as an action within the framework of the international co-operation activities of the Belgian State,.

#### **5.1.3.2 Assessment of activities performed outside Belgium by BELAC accredited bodies**

Activities performed outside Belgium by BELAC accredited bodies and managed through the main operation office or critical sites established abroad will be covered by the BELAC accreditation only in case these activities have been the subject of a specific evaluation.

With this respect, BELAC implements the rules decided at the international level that fix the respective obligations of the accreditation bodies that are signatories of the multilateral agreements, especially in the case of multi-site accreditation.

#### **5.1.3.3 Activities of BELAC as a subcontractor**

On request of a foreign accreditation body signatory to the multilateral agreements, BELAC can act as a subcontractor to perform all or part of the assessment of a conformity assessment body accredited abroad and operating Belgium.

## **5.2. THE ACCREDITATION REQUIREMENTS**

### **Main associated documents:**

*BELAC 0-06: Ministerial Decree fixing the list of the accreditation requirements*

*BELAC 1-03: BELAC activities: description and selection criteria*

*Documents of the series 2 for the implementation of the accreditation standards*

*Documents of the series 2-405-xxx for the accreditation of specific conformity assessment activities*

### **5.2.1. References to standards**

Conformity assessment bodies are evaluated and accredited with reference to the international accreditation standards as approved within the framework of the EU Regulation 765/2008.

### **5.2.2. Complementary and guidance documents**

Depending on the type and technical sector for the conformity assessment activity, the requirements of an accreditation standard may need to be complemented with :

- Guidelines issued at the international level (EA, ILAC, IAF, FALB) : based on the classification by EA, ILAC, IAF or FALB some of those guidelines may have a mandatory character and are considered as complementary requirements.
- Requirements applicable to a specific conformity assessment activity and made mandatory by a regulating authority or by a scheme owner, provided these complementary requirements comply with the general BELAC policy as expressed in document BELAC 1-03.

The Coordination Commission may further clarify and specify the accreditation requirements. Consultation with all interested parties is the rule.

One will note in particular the complementary requirements with respect to traceability (BELAC 2-003) , participation in proficiency testing for calibration, testing and medical laboratories (BELAC 2-106) as well as the documents of the series BELAC 2-405 with the specific requirement for the accreditation according to national or international legislation.

All complementary and guidance documents are made publically available, in particular to the bodies concerned and to members of the evaluation teams.

## **Chapter 6. Human resources**

### **6.1. GENERAL POLICY**

BELAC commits itself to ensure that all personnel involved in the management of the accreditation body and the operation of the accreditation processes maintains a level of competence, knowledge and skills appropriate for the function and the associated responsibilities. For each relevant function and based on the associated risks, BELAC has documented :

- a detailed description of the function;
- the applicable deontological rules in particular with respect to confidentiality and impartiality;
- the knowledge requirements;
- the provisions for initial and continued training;
- the provisions for the supervision of the level of competence.

With personnel associated with BELAC activities is meant:

- the staff of the BELAC permanent secretariat ( see under 4.2.4);
- the assessors and experts ( see under 6.2);
- the persons with decision-making capacity and in particular the members of the Co-ordination Commission ( see under 4.2.1) and of the Accreditation Board (see under 4.2.3).

### **6.2. ASSESSORS AND EXPERTS**

*Main associated documents:*

***BELAC 3-05: Provisions for the co-operation with BELAC assessors and experts***

For carrying out the evaluations BELAC calls upon external assessors who are staff of the BELAC permanent secretariat or to external assessors or experts belonging to public or private bodies or having independent consultancy activities . BELAC can also call upon recognized assessors from accreditation bodies signatories to the EA, ILAC or IAF multilateral agreements.

Each assessor or expert is appointed by the BELAC secretariat for the duration of the assessment and is required to sign a formal acceptance document by which he/she

- accepts to respect
  - the limits of the assignment entrusted to him/her;
  - the working instructions of BELAC;
  - the confidentiality of any document or information relating to the evaluation;
- declares his/her ability to act freely and impartially;
- accepts the financial conditions proposed by BELAC.

The risks in terms of impartiality due to the professional activity of each assessor or expert (especially in case of recourse to consultants) are evaluated on an individual basis.

Any person will be recognised and maintained as a BELAC assessor if he/she

- has the necessary professional experience to carry out an evaluation of the compliance of a specific type of conformity assessment body with the accreditation requirements;
- has received the specific training in their role as assessor (lead or technical) run by BELAC or an equivalent body, including participation in at least two evaluation assignments;
- is considered to be competent as an assessor and have officially been registered on the lists of lead and/or technical assessors;
- complies with the deontological rules and ongoing training requirements as specified by BELAC;
- undergoes regular performance evaluation during assessments on the field.

The requirements on education and professional experience as well as deontological rules are applicable to experts too.

## **Chapter 7. The accreditation process**

### **7.1. GENERAL PRINCIPLES**

#### *Main associated documents:*

<i>BELAC 0-05</i>	<i>Royal Decree creating BELAC</i>
<i>BELAC 3-11</i>	<i>The accreditation procedure: general provision for implementation</i>
<i>BELAC 3-12</i>	<i>The accreditation procedure: specific provisions</i>
<i>BELAC 2-002</i>	<i>Certificat d'accréditation et domaine d'application d'une accréditation: Lignes directrices générales pour la formulation et l'évaluation</i>

- An accreditation can only be granted after an assessment performed by one or more assessors or experts and aiming to establish the conformity with the accreditation requirements for the related sector; the assessment includes the organisational aspects and the technical competence. The risks related to the complexity of the activities subject to accreditation and the characteristics of the applicant's organization are taken into account to fix the composition of the assessment team and its duration.
- The Accreditation Board is responsible for all decisions on accreditation. Depending on the type of decision, the Board operates
  - during plenary meetings or through correspondence consultation where all members are involved;
  - based on the positive advice of at least one of the Board's members appointed as reviewer and delegation of decision to the Board's Chair (so-called "simplified decision-making process").
- BELAC accreditations are granted per type of conformity assessment body for an accreditation schedule that details the concerned conformity assessment activities. Each accreditation has a maximum validity of 3 years in case of initial accreditation and 5 years starting from the 2d accreditation cycle.
- Accreditation may only be maintained when the organisation
  - keeps complying with the accreditation requirements and respects the surveillance programme;
  - fulfils its financial obligations towards BELAC;
  - requests the Board for renewal of the accreditation at least nine months before the expiry of its validity ;
  - has met the specific obligations indicated to it at the time of the accreditation.

In case one or more of the above-mentioned conditions are no longer met, the Accreditation Board may decide on sanctions against the accredited body ( see under point 7.4.3)

BELAC differentiates between the following types of assessments ( see under 7.2 and 7.3 for details) :

- the initial assessment ( following a pre-assessment if required);
- the surveillance assessment
- the renewal assessment;
- the assessment for extension of the accreditation schedule.

Any assessment process involves successive steps described under points 7.2 and 7.3.

## **7.2. The initial assessment**

### **7.2.1. The administrative step**

#### **7.2.1.1 Submitting an application for accreditation**

- Information of the applicant

Upon request to the secretariat, any organisation wishing to apply for accreditation receives: the relevant information on the BELAC system, the accreditation process and accreditation requirements, the financial aspects and the way to access to the documentation through the BELAC homepage and in particular, a standard application form.

- Submitting the application

All accreditation applications shall be submitted to the BELAC secretariat by using the standard form and shall be accompanied by the documents listed in the application form, as well as evidence of payment of the application fees.

All information is handled confidentially.

In case the applicant does not provide the requested documentation and cannot give any justification or provides false information or conceals information, BELAC rejects the application

- Application review

The secretariat is responsible for the review of the application. This review aims to check whether BELAC has the necessary competence and resources to handle the application . If it is not the case, the applicant is informed without delay.

#### **7.2.1.2 Organizing the accreditation assessment**

- Composition of the assessment team, duration of the assessment and quotation

The assessors are appointed by the secretariat for the duration of the assessment.

The assessors and experts are appointed taking in consideration the type and specificities of the application and according to their impartiality and competence; the specific competence requirements defined in regulatory or normative sector documents are taken into account.

If the application relates in total or in part to one or more regulated sectors, the competent authority(ies) is(are) informed of the composition of the assessment team and is(are) invited to attend the assessment as observer.

A member of the Accreditation Board or of the secretariat may be appointed as coordinator to accompany the assessment team in order to facilitate the communication between the concerned parties.



The duration of the assessment is fixed in order to allow for a proper evaluation of the functioning of the body and of its technical ability to perform the activities for which accreditation has been applied; it covers the preparation, on-site evaluation and reporting phases..

A quotation is prepared taking into account the proposed composition of the assessment team and duration of the assessment.

The quotation covers only the assessment activities as planned on the basis of the information available in the application form; it may need to be complemented in case this information was incorrect or not comprehensive enough or in case further investigation is deemed necessary.

- Notification to the applicant

The quotation is submitted to the application, for approval.

The applicant may object one or more of the proposed assessors or experts based on a reasoned opinion presented to the secretariat. It may only be submitted twice and within the framework of the examined application.

- Notification to the assessment team

A formal assignment is sent to the assessment team, together with the documents necessary for the preparation of the assessment; the members are required to confirm the absence of conflict of interest and to accept or refuse the proposed assignment.

- The assessment plan

The assessment program is drafted in advance of the visit on place, in cooperation between the team and the file manager and communicated to the body under evaluation. The plan mentions the relevant accreditation requirements and the distribution of tasks for all team members.

The initial assessment includes a comprehensive review (or elements) of the organisation of the conformity assessment body and its technical competence. In all cases, the initial assessment includes witnessing of actual activities performed by the conformity assessment body.

### **7.2.2. The assessment visit**

A preparatory meeting between members of the evaluation team may take place before the assessment visit.

The assessment visit consists of

- an introductory meeting, to recall the context, requirements and procedure for the accreditation;
- an analysis of the management system documentation and an evaluation of the implementation of the documented provisions, including witnessing of activities , in order to evaluate compliance with the accreditation requirements;
- the identification and categorisation of any non conformity;

- a final meeting during which the assessment team informs the applicant of its findings. Non conformities are categorised in function of their degree of seriousness; minimum conditions for clearance, including timing, are fixed for each category of nonconformity.
- 

### **7.2.3. The evaluation report**

The lead assessor is responsible for drafting the final evaluation report that needs to reflect the views and observations of all members of the team. To this respect, the report shall include, besides administrative information relating to the applicant:

- a summary of the evaluation of all points outlined in the accreditation requirements; are considered both organisational aspects and technical issues related to the scope of application;
- details of non conformities together with the corrective actions taken by the applicant and the extent to which this is adequate;
- a description of the technical activity for which accreditation is to be considered.

Specific templates for the assessment report for all accreditation programs are available.

The report is for use

- by the secretariat; a file manager having the specific competence for the evaluation of the report but has not been involved in the accreditation process is appointed as internal reviewer;
- by the Board as a basis for its decision; 2 members of the Board ( with at least one having the specific competence for the evaluation of the report ) not involved in the accreditation process are appointed as external reviewers;
- by the applicant to get knowledge with the elements on which the accreditation decision is based and to allow them to submit any comments;
- by members of the evaluation team in the event of a further visit.

### **7.2.4. The decision-making process and granting of accreditation**

The Accreditation Board's decision is made on ground of the assessment report, the recommendations of the reviewers and the complementary information provided by the applicant, if relevant .

Granting accreditation is subject to a positive decision from the Accreditation Board, stating the conformity assessment body's compliance with the accreditation requirements. Decisions are made during plenary sessions or by correspondance and all members are involved.

If, after examination of the assessment report, the Board decides to recommend the granting of the accreditation, the secretariat formalises the accreditation recommendation which includes a draft of the certificate including a description of the scope of the accreditation; the format is defined per accreditation program and depending on the technical sector.

The Board's Chair (or the Vice-Chair in case of absence) confirms the decision by signing the accreditation documents.

If the Board decides against accreditation, the Chair informs the applicant who may then decide to drop the application, to continue it (in which case further evaluation will be necessary), or to lodge an appeal.

The accreditation is granted for a maximum period of 3 years, except if the Board decides for a shorter period. The accreditation covers only the activities described in the accreditation schedule.

#### **7.2.5. The assessment program and the supervision of the accredited body**

After the initial assessment, the program for the supervision of the accredited body is defined for the coming accreditation cycle; it includes surveillance assessments and ends up with a renewal assessment.

The assessment program is designed as to ensure a representative sampling of the list of accredited activities; the normative, regulatory or contractual requirements relevant for each type of conformity assessment activity are taken into account.

### **7.3. The specific aspects of the various assessment visits**

The general provisions for the organisation of an assessment visit as described in case of an initial assessment are applicable.

#### **7.3.1. Pre-assessment**

- Objectives

The applicant may request for the performance (only once) of a pre-assessment before going to the initial assessment.

The objective of a pre-assessment is to determine whether, by means of a limited evaluation of compliance with the accreditation requirements both in terms of documentation and effective implementation, the applicant is in a position to undergo an initial assessment with a reasonable chance of success. Performing a pre-assessment may in no case lead to consultancy.

- Implementation

The pre-assessment involves the examination of documentation and an assessment visit, limited to the main offices, with a team, consisting usually only of the coordinator and a lead assessor; a report is prepared.

The report has only an indicative value. The applicant is invited to take the comments into account but is not required to report on actions before going to the initial assessment.

#### **7.3.2. Initial assessment**

See under 7.2

### **7.3.3. Extension assessment**

- Objectives

The accreditation certificate covers only the activities as described in the accreditation scope. Accredited bodies are allowed to widen the accreditation scope to activities close to those already covered by the accreditation, on condition that specific requirements are complied with (accreditation with flexible scope) .

For all other types of extension of the accreditation scope, a formal application is necessary and an evaluation appropriate to the nature of the concerned extension will be organised.

The accredited body can apply for an extension of scope at any moment during the validity period of the certificate.

Granting an extension of the accreditation scope does not result in any modification of the validity date of the certificate neither in the surveillance program but the description of the accreditation scope is updated.

- Implementation

The extension assessment involves an examination of documentation and, each time necessary, an assessment visit at the main offices and at places where the activities are performed. Depending on the specific nature of the extension request, the assessment team will consist of a coordinator, a lead assessor and/or one or more technical assessors or experts.

A request for extension may be submitted at any time during the period of validity of the certificate.

The so-called “simplified decision-making process” is used except when the application for extension relates to a substantial modification of the nature of the accredited activities, which means there is an impact on the competence of the accredited body, or if the results of the extension assessment leads to question the possibility to maintain the accreditation.

### **7.3.4. Surveillance assessment**

- Objectives

Surveillance refers to all activities carried out by BELAC at any time between the initial assessment and the reassessment or between two reassessments, with the aim of ensuring that accredited organisations comply on a day-to-day basis with the accreditation requirements.

- Implementation

Surveillance involves assessments undertaken at intervals specified by the Accreditation Board , with evaluation at the main offices of the accredited body and at the places where activities are performed:

- during the first cycle of accreditation (limited to 3 years), surveillance visits are normally organised on a yearly basis.
- starting with the second accreditation cycle (with duration of 5 years in principle) 3

surveillance visits are organised between 2 re-assessments. The maximum period of time between 2 surveillance visits is 24 months.

- a deviation from the above-mentioned principles is possible if duly motivated and documented in order to accommodate specific situations of an accredited body.

#### Surveillance

- can be complemented by enquiries, questionnaires, requests for documents or other requests for information;
- may require complementary visits not foreseen in the standard programme.

Surveillance is generally less thorough than the initial assessment or the reassessment, but the evaluation must nevertheless cover both elements of the management system and of the technical activities.

All elements of the management system shall be evaluated at least once within an accreditation cycle.

Sample evaluation of the activities covered by the accreditation shall encompass all fields of technical competence concerned within an accreditation cycle .

The so-called “simplified decision-making process” (see under 7.1) is used except if the results of the assessment may lead to question the possibility to maintain the accreditation.

#### **7.3.5. Re-assessment**

- Objectives

Re-assessment refers to the re-evaluation carried out by BELAC at the end of each accreditation cycle. The aim is to check whether an accredited body continues to comply with the accreditation requirements in all the activities covered by the certificate.

Based on the results of a re-assessment , a decision will be made to re-issue the accreditation after 3 years in case of first accreditation cycle and after 5 years for the following cycles.

- Implementation

Re-assessment involves an examination of documentation and an evaluation at the organisation’s main offices and at places where activities are performed.

The program of a re-assessment is similar to an initial assessment but the information gained through the previous assessments is taken into account.

The content of the re-assessment plan is fixed based on the following guidelines:

- all elements of the management system need to be evaluated;
- the selection of technical activities to be evaluated takes into account the content of the surveillance assessments during the preceding cycle.

Reassessment results in the issuance of a new certificate and the updating of the scope.

The decision to renew or not the accreditation is taken by the Accreditation Board during a plenary meeting or by means of a correspondence voting where all members are involved.

## **7.4. Modifying the status of an accredited body**

### **7.4.1. Cancellation**

An accredited body may, at any time, definitively cancel its accreditation, for either all or part of its accreditation scope.

The decision to cancel

- doesn't affect the surveillance programme, nor affects the period of validity of the certificate in the event of a partial cancellation;
- doesn't relieve the accredited organisation of its other obligations towards BELAC incurred during the accreditation period.
- is formalised by a removal from the list of accredited organisations, in case of total cancellation in case of partial cancellation or an update of the accreditation scope .

A request for temporarily cancellation takes the form of a voluntary suspension (see under 7.4.3.2)

### **7.4.2. Transfer of an accreditation**

The Accreditation Board, after having either examined the relevant documents or instructed further evaluation, may accept the transfer of an accreditation, particularly in case of transfer of activities to another legal entity or where there has been a change in the legal identity of an accredited body. A transfer with maintenance of the accreditation number is authorized only when there is evidence of continuity in the management policy, functioning of the body and accredited activities.

### **7.4.3. Sanctions in case accreditation requirements are no longer met: warning, suspension, withdrawal**

*Main associated documents:*

*BELAC 0-05  
BELAC 3-11*

*Royal Decree creating BELAC  
The accreditation procedure: general provision for implementation*

When the accreditation requirements are no longer fully met , the Accreditation Board decides on a sanction proportionate to the criticality of the situation.

The sanction consists of one of the following options: warning, total or partial suspension, total or partial withdrawal.

#### **7.4.3.1 Warning**

A warning can include conditions such as a request to transmit complementary information or to accept a complementary assessment.

#### **7.4.3.2 Suspension**

Suspension means that a temporary ban prevents the organisation from referring, within all or part of its accreditation scope, to its status as an accredited organisation and from issuing reports or certificates covered by the accreditation.

It applies to those cases where exceptional circumstances temporarily prevent the body from complying with the accreditation requirements, but where a return to normal circumstances can be expected. As a rule, the maximum period of a suspension should not exceed 6 months.

#### Suspension

- temporarily interrupts the surveillance programme but the period of validity of the certificate is not affected;
- doesn't relieve the accredited organisation of its other obligations towards BELAC incurred during the accreditation period;
- will be referred to in the list of accredited organisations, on the BELAC web site and on the accreditation scope of the accredited body.

The request for suspension can be introduced by the body itself; it is then examined by the Accreditation Board which may consider that the specific conditions for a suspension have not been met; in this case the Board may recommend a total or partial withdrawal.

A suspension can also be decided by the Board itself, in which case the body is reminded of the possibility to lodge an appeal.

Any lifting of a suspension will be subject to an appropriate evaluation under the responsibility of the Accreditation Board.

#### ***7.4.3.3 Withdrawal***

The withdrawal of accreditation is decided by the Accreditation Board

- in cases of serious or repeated non compliance with the accreditation conditions; the withdrawal may be total or partial when it concerns a part of the accredited organisation's technical competence.
- in case of evidence of fraudulent behaviour or in case the body deliberately provides false information or conceals information.

A total withdrawal implies:

- a breaking of the co-operation agreement between BELAC and the accredited organisation;
- the return to BELAC of the accreditation certificate;
- the removal from the list of accredited bodies and the BELAC web site;
- in case of a certification body, the obligation to provide information on certified suppliers that are affected by the withdrawal.

## ***Chapter 8.     The BELAC Management system***

### **8.1.   GENERAL GUIDELINES**

The activities of BELAC are covered by a management system which takes into account all requirements laid down by legal stipulations and the international standards for the management of accreditation bodies.

The management system aims at achieving, maintaining and improving the level of performance of BELAC as accreditation body.

The implementation of the management system is based on and controlled through:

- the recourse to an appropriate quality documentation;
- the registration and archiving of documents specific to the implementation of accreditation procedures and to the general management of BELAC;
- the follow-up of internal non-conformities as well as complains and appeals, disputes or observations ;
- the identification of opportunities for improvement in relation with the identification of potential risks;
- the implementation of documented provisions through the internal audit
- the follow-up of complains and appeals, disputes or observations including implementation of corrective actions and review of their efficiency;
- the performance of a management review.

The quality manager is in charge of the follow-up and implementation of the management system.

### **8.2.   MANAGEMENT SYSTEM DOCUMENTATION**

*Main associated documents:*

<i>BELAC 3-01</i>	<i>Management of the BELAC quality documentation</i>
<i>BELAC 6-001</i>	<i>List of the documents pertaining to the management system</i>

#### **8.2.1.   Structure of quality documentation**

##### **8.2.1.1   Elements**

The policies and the management system of BELAC are documented in a management manual which refers to documents detailing the legal and regulatory grounds, the requirements and procedure for accreditation, as well as the means pursued by BELAC to ensure the level of its services.

The following measures are in force in order to ensure the effective implementation of the documented provisions:

- the distribution of documents under controlled regime to all persons concerned with a specific activity; the distribution includes the members of the BELAC organs and of the secretariat, the accredited or applicant bodies, the assessors and experts.



- the organisation, each time relevant and per type of interest group, of training sessions aiming to provide information on the documents;
- the development of standards forms or letters aiming to a standardised implementation of the accreditation procedure, each time relevant.

### **8.2.1.2 The management manual**

The management manual is limited to a presentation of the general policies and objectives pursued by BELAC and an outline of its organisation. It aims to be

- a promotion and information tool which, as such, may be distributed to third parties without restriction;
- a practical tool for use by the BELAC organs, offering a global and coherent vision of the policies being implemented.

### **8.2.1.3 Associated documents**

The documents relating to the management manual are divided into various series depending on their content:

- legal documents and references to standards;
- documents detailing the accreditation requirements and the procedures directly linked to the rights and obligations of bodies that have either been accredited or have applied for accreditation.
- procedural documents directly applicable to BELAC and, where appropriate, to its assessors, with relation to the management of the accreditation body and the implementation of accreditation procedures.
- instructions detailing provisions for the implementation of procedures by the secretariat, assessors and third parties.

Except when otherwise explicitly stated, provisions mentioned in these documents have a mandatory character.

- lists, databases and standard forms resulting from the implementation of procedures.
- information documents drawn up by BELAC as part of the promotion of the system and guideline documents issued by external organisations, both national and international.

## **8.2.2. Document Control**

Documented provisions are in force for the control of the management documentation; they cover in particular the rules for presentation, preparation and approval, distribution and archiving.

### **8.3. REGISTRATIONS**

*Main associated documents:*

*BELAC 3-13 Management of BELAC registrations*

#### **8.3.1. Nature of registrations**

The documents dealing with the implementation of the accreditation procedure are considered to be registered documents and are not included as elements of the quality documentation. Examples of such registered documents include

- individual files of bodies applying for accreditation;
- individual files of the assessors/experts, members of the BELAC permanent secretariat and members of the decision-making committees' files;
- documents relating to the meetings of the BELAC organs;
- monitoring activities as part of the management system .

#### **8.3.2. Control of registered documents**

Specific instructions are in force for the control of registered documents; they cover in particular the requirements with respect to distribution, confidentiality and archiving.

### **8.4. HANDLING OF DYSFUNCTIONS**

*Main associated documents:*

*BELAC 3-04 Handling of dysfunctions*

It is the policy of BELAC to pay due attention to the analysis of all kind of dysfunctions in its operation , as an essential element with a view to answer customer needs and to improve the efficiency of the management system.

With the word dysfunction is meant, depending on the nature and the potential consequences of the facts:

- formal complaints and appeals ;
  - disputes with accredited bodies, assessors or users of the system:  
these concern mainly conflicts with regard to cases raised without request for formal handling by the Board of Appeal.
- observations :  
these are mainly punctual errors and defects in the operation identified by the secretariat itself or raised orally or in writing by third parties or members of the BELAC organs.

Formal complaints and appeals are handled by the Board of Appeals.  
Disputes and observations are handled by the secretariat.

In case the analysis of a dysfunction reveals a non-conformity in the operation of BELAC, corrections and corrective actions are identified based on a root-cause and extent analysis.

The quality manager is responsible for coordination and follow-up of all types of dysfunctions.

## **8.5. IDENTIFICATION OF RISKS AND OPPORTUNITIES FOR IMPROVEMENT**

*Main associated documents:*

*BELAC 1-02 BELAC general policy and means for the implementation of the ISO/IEC 17011:2017 requirements on the identification and management of risks related to its operation.*

As a basis to design and develop its operational processes, BELAC identifies the different risks that may negatively affect its level of performance. Measures are set in place in order to eliminate or minimize these risks and to strive for continuous improvement.

BELAC has documented and regularly updates under the supervision of the Co-ordination Commission a list of potentials risks related to all elements of the operation of BELAC; the level of impact and probability of occurrence of each risk as well as the measures aiming to control it are documented.

The risk-based approach is implemented in particular with respect to the following issues:

- the obligation for BELAC to act in an impartial and non-discriminatory manner in all of its activities;
- the management of human, material and financial resources;
- the development of new accreditation programs;
- the obligation to maintain an appropriate level of competence for all functions involved in the accreditation process;
- the obligation to ensure that all accredited activities are evaluated during an accreditation cycle.

Situations not being at risk but showing opportunity for improvement are taken into account.

## **8.6. INTERNAL AUDIT**

*Main associated documents:*

*BELAC 3-03 Internal audit*

At least once a year (possibly in the form of successive partial evaluations), BELAC undergoes an internal audit of all its activities in order

- to ascertain that all elements of its management system are systematically implemented and kept adapted to the evolution of the needs ;
- to check the adequacy of the provisions of the management system with relation to the BELAC aims and in particular the compliance to the requirements of international standards and relevant guidelines.

Complementary to the regular evaluations, it may from time to time be necessary to undertake a total or partial evaluation, for example:

- in the case where a serious or repeated non compliance has been detected during the regular checks of management activities;
- following a complaint or appeal that casts doubt on the adequacy or efficiency of the management system provisions;
- during the 6 months following a significant modification in either the management system, the accreditation requirements or the accreditation procedure.

The practical provisions for the internal audit are documented.

## **8.7. MANAGEMENT REVIEW**

### **8.7.1. Aims**

Once a year the management of BELAC undertakes a review of the management system in order to check if its operation

- enables the quality objectives to be achieved;
- guarantees compliance with the requirements of international standards for the management of accreditation bodies;
- needs to be modified in line with new developments in the context of its operation.

### **8.7.2. Implementation**

The quality manager is responsible to prepare the review of the system which includes as input elements, in compliance with the requirements of clause 9.8 of the standard ISO/IEC 17011:2017:

- a) evolution of activities ( nature and volume) as well as of human, material and financial means;
- b) results of internal and external audits;
- c) participation in international activities;
- d) safeguarding impartiality;
- e) feedback from interested parties;
- f) new areas of accreditation;
- g) trends in nonconformities;
- h) status of corrective actions;
- i) the status of actions to address risks and opportunities;
- j) follow-up actions from earlier management reviews;
- k) fulfilment of objectives;
- l) changes that could affect the management system;
- m) analysis of complaints and appeals.

The output elements of the management review identify the actions related to

- a) improvement of the management system and its processes;
- b) improvement of services and accreditation process in conformity with the relevant standards and expectations of interested parties;
- c) need for resources;

d) defining or redefining policies, goals and objectives.

### **8.7.3. Responsibilities**

The management review of BELAC is under the responsibility of the Direction of BELAC. The report is presented to the Coordination Commission for approval and then submitted to the National Council; the Council may bring advice to the Minister of Economy as part of the supervision of the BELAC operation by the Belgian State.

## **Chapter 9. Cooperation between BELAC and the accredited bodies**

### **9.1. RECIPROCAL RIGHTS AND DUTIES BETWEEN BELAC AND ACCREDITED ORGANISMS**

#### *Main associated documents*

#### *BELAC 3-06 Guidelines for the co-operation between BELAC and the accredited bodies*

Granting an accreditation creates a cooperation relationship between BELAC and the accredited organisms; this involves for both parties mutual rights and duties as described hereafter.

Towards BELAC is the accredited body committed to:

- comply on a continuous basis with the accreditation requirements;
- offer to BELAC the necessary cooperation with regard to the assessment activities;
- keep BELAC informed of all information regarding its organisation likely to affect the accreditation granted;
- avoid to make any statement relevant to its accreditation which may reasonably be considered as misleading;
- not use its accreditation in such a manner as to bring BELAC into disrepute.

Towards the accredited bodies is BELAC committed to:

- handle with strict confidentiality all information and documents related to an accreditation case;
- perform the accreditation procedure in accordance to the relevant legal and regulatory provisions as well as the quality system procedures;
- provide them with the necessary elements related to their accreditation statute (certificate, symbol);
- to examine all observations, complaints or appeals issued by an accredited body;
- to publish on a regular basis a directory of accredited bodies;
- to keep accredited bodies informed of revisions of accreditation requirements or procedures;
- to give them the opportunity to participate to the activities of the BELAC organs;
- to promote the use of services of accredited organisms, both nationally and internationally.

## **9.2. REFERENCE TO ACCREDITATION**

### **9.2.1. Reference to the BELAC accreditation**

#### *Main associated documents:*

*BELAC 2-001      Rules with respect to the reference to accreditation and use of the BELAC symbol.*

#### **9.2.1.1 By accredited bodies**

- Aims

BELAC recommends accredited bodies to refer to their accreditation status on calibration, testing and inspection reports and on certificates, they issue, as well as on documents with a more general character.

By that means, accredited bodies may provide evidence that their technical competence has been third-party evaluated and recognised compliant to international requirements.

Only those documents bearing reference to the accreditation status provide evidence of compliance to accreditation requirements; they can enjoy wide acceptance nationally and internationally through a network of formal mutual recognition agreements amongst accreditation bodies.

- Conditions for use of reference to accreditation

Reference to accreditation may take the form of the BELAC symbol or an appropriate sentence.

The accredited body needs to comply with the specific instructions issued by BELAC that aim to prevent any confusion with respect to activities being covered or not by accreditation.

In particular, all reference to accreditation needs to provide, the identification number of the accreditation granted, and the relevant accreditation standard(s).

In case of misuse, the Accreditation Bureau is entitled to take the necessary measures, either on an internal basis (warning, limitation/withdrawal of the right of use of the symbol, proposal of withdrawal of the accreditation) or, when necessary, by bringing the case to the Court.

- Rules for use of the BELAC symbol

The symbol of BELAC has been officially registered with the BENELUX Office of Trademarks, including their graphical characteristics; its use is therefore protected.

Specific rules and conditions for the use of the symbol are in place and need be complied with.

### **9.2.1.2 By users of accredited services**

BELAC encourages users of accredited services to mention that their orders have been placed by bodies whose technical competence has been third-party evaluated and complies with international requirements.

Are concerned: companies holding certification by an accredited certification body, clients of accredited laboratories and inspection bodies.

Specific rules are in force in order to prevent any type of abuse. Accredited bodies are responsible to keep their clients informed.

## **9.2.2. Reference to the status of BELAC as signatory of the EA, ILAC and IAF multilateral agreements**

### **9.2.2.1 By BELAC**

BELAC is allowed, in all communication with third parties, to make reference to its status of signatory to the mutual recognitions of EA, ILAC and IAF.

The BELAC stationary paper as well as all accreditation certificates issued by BELAC include the following statement in conjunction with the BELAC symbol: “ Signatory to EA, ILAC and IAF Multilateral Agreements”

### **9.2.2.2 By BELAC accredited bodies**

BELAC accredited bodies are allowed, in conjunction with the reference to their BELAC accreditation and on a voluntary basis, to refer to the BELAC status of signatory of the multilateral agreements of EA, ILAC and IAF . Specific rules are in force in order to prevent any type of abuse.

## **9.3. DIRECTORY OF ACCREDITED BODIES**

### ***Main associated documents:***

#### ***BELAC 6-021: List of BELAC accredited bodies***

BELAC keeps updated a directory of accredited bodies showing under each entry:

- the field of accreditation, through mention of the accreditation standard;
- the number of the certificate;
- the name and address of the body and the name of a contact person;
- a brief description, in the form of keywords, of the accreditation schedule.

The lists are made available to the public via the BELAC website ([www.BELAC.fgov.be](http://www.BELAC.fgov.be))

The website offers the possibility, by means of search system,

- to access the detailed accreditation schedules ;
- to identify accredited bodies able to provide a specific service under accreditation regime.



## **Chapter 10. Cooperation between BELAC and the regulatory authorities**

### ***Main associated documents:***

***BELAC 3-07: Policy and provisions for the cooperation between BELAC and the regulatory authorities.***

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.

The main routes for cooperation include the possibility for the different regulatory authorities

- to take an active part in the management of BELAC through their representation in the different management committees (National Accreditation Council, Coordination Commission, Accreditation Board, technical workgroups .....);
- to take part as observer in the BELAC assessments;
- to act as BELAC assessor or expert when the general competence requirements are complied with.