



## **PROCEDURE AND CRITERIA FOR A CONFORMITY ASSESSMENT SCHEME EVALUATION ACCORDING TO EA-1/22**

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## HISTORY OF THE DOCUMENT

Revision	Motivation of the revision	Scope of the revision
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## TABLE OF CONTENTS

1	AIM AND SCOPE OF THE DOCUMENT AND REFERENCE TO STANDARDS.....	4
2	RECIPIENTS.....	4
3	DEFINITIONS AND ABBREVIATIONS.....	5
3.1	Conformity Assessment Scheme (CAS).....	5
3.2	Conformity Assessment System.....	5
3.3	Conformity Assessment Body (CAB).....	5
3.4	Scheme Owner (SO).....	5
3.5	(National) Accreditation Body (NAB).....	5
3.6	Home Accreditation Body (hAB).....	5
4	REQUIREMENTS FOR SCHEME OWNERS AND CONFORMITY ASSESSMENT SCHEMES.....	6
4.1	Requirements for scheme owners (EA 1/22: §3.1).....	6
4.2	Requirements for conformity assessment schemes (EA 1/22: §3.2).....	6
4.3	Additional BELAC Requirements.....	6
5	INITIAL EVALUATION OF A CONFORMITY ASSESSMENT SCHEME.....	7
5.1	Application for a CAS Evaluation to achieve international recognition.....	7
5.2	Evaluation.....	9
5.3	EA Review and decision.....	9
6	CHANGES OF A CAS.....	9

# PROCEDURE AND CRITERIA FOR A CONFORMITY ASSESSMENT SCHEME EVALUATION ACCORDING TO EA-1/22

## 1 AIM AND SCOPE OF THE DOCUMENT AND REFERENCE TO STANDARDS

This document aims to define the provisions for the evaluation of a new conformity assessment scheme for which an application was submitted to BELAC to be internationally recognized according to the provisions of the European Cooperation for Accreditation (EA).

This document refers to and is in accordance with the relevant parts of:

- EN ISO/IEC 17011:2017, more specifically § 4.6.3 (*The accreditation body shall have a policy and documented procedures to determine the suitability of the conformity assessment schemes and standards for accreditation purposes*);
- document EA-1/22: *EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members*;
- Royal Decree of January 31, 2006 Creating the BELAC system for the accreditation of conformity assessment bodies

Whenever “conformity assessment scheme (CAS) evaluation” is used within this document this is to be understood as the CAS evaluation according to EA-1/22 with the aim of international recognition.

## 2 RECIPIENTS

With follow-up of modifications:

- Coordination Commission
- BELAC Secretariat

Without follow-up of modifications:

- Any external request

### 3 DEFINITIONS AND ABBREVIATIONS

The definitions of EN ISO/IEC 17000 (*Conformity assessment – Vocabulary and general principles*) and EA-1/22 apply to the terms used in this document

EA: European co-operation for Accreditation

ILAC: International Laboratory Accreditation

IAF: International Accreditation Forum

#### 3.1 Conformity Assessment Scheme (CAS)

A documented and publicly available set of requirements which establishes:

- the object of conformity assessment;
- the specified requirements against which conformity is to be assessed;
- the mechanism by which conformity is determined;
- any requirements placed on CABs by the SO, if applicable;
- any specific applications or interpretations of ISO/IEC 17011, if applicable.

#### 3.2 Conformity Assessment System

Set of rules and procedures for the management of similar or related conformity assessment schemes

#### 3.3 Conformity Assessment Body (CAB)

Body that performs conformity assessment activities, excluding accreditation

#### 3.4 Scheme Owner (SO)

Person or organization responsible for the development and maintenance of a conformity assessment system or conformity assessment scheme

#### 3.5 (National) Accreditation Body (NAB)

Authoritative body that performs accreditation

#### 3.6 Home Accreditation Body (hAB)

The NAB which takes the lead for evaluating an international CAS operated in more than one EA member country. The hAB will normally but not necessarily be the NAB from the country where the SO is legally established

## **4 REQUIREMENTS FOR SCHEME OWNERS AND CONFORMITY ASSESSMENT SCHEMES**

### **4.1 Requirements for scheme owners (EA 1/22: §3.1)**

- The SO shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its activities;
- The SO has the authority to establish and change the requirements of the CAS;
- The SO shall have the mandate to cooperate with BELAC. The SO shall have a mechanism to provide for feedback from BELAC on the operation of the CAS;
- The SO shall be able to demonstrate that there is a need in the market for the CAS;
- The SO shall commit to accept results from CABs accredited by any EA MLA signatory (for the relevant scope) which follow the CAS requirements
- The SO shall demonstrate that the CAS has been validated
- The SO shall restrict the use of the CAS to accredited CABs with which an agreement has been entered into. Such an agreement must guarantee at least that the CABs will use the CAS as it is without any limitations and without any additions. A transition arrangement should clarify how the transition from non-accredited conformity assessment will be managed and how new CABs may start using the CAS.
- The SO shall be responsible for keeping BELAC and CABs informed of any relevant information and developments relating to the CAS, including in particular any proposed changes in requirements.
- The SO shall be prepared to pay for the costs of the evaluation of its CAS by BELAC.
- By signing the declaration in the application form, the SO commits in writing to comply with the BELAC evaluation procedure

### **4.2 Requirements for conformity assessment schemes (EA 1/22: §3.2)**

- The conformity assessment process described or chosen by the SO shall fall within the scope of one of the EA MLA Level 3 standards and shall fall within the BELAC-scope of the EA MLA (<https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signatories/>)
- Scheme specific requirements placed on CABs by the SO shall not contradict, or exclude, any of the requirements included in the relevant EA MLA Level 3 standard;
- If a CAS places scheme specific requirements on NABs, they shall not contradict or exclude any of the requirements in ISO/IEC 17011, EU Regulation (EC) 765/2008 and, where applicable, EA mandatory documents and IAF or ILAC documents endorsed by EA as mandatory;
- CASs in the voluntary sector shall neither contradict, nor simply be the fulfilment of applicable, legal requirements

### **4.3 Additional BELAC Requirements**

- The resulting evaluation report and any BELAC 'acceptance' of the CAS for accredited conformity assessment purposes relates only to the specific CAS (including version status) subject to the evaluation;

- The responsibility for maintaining the CAS remains with the SO and, to maintain BELAC 'acceptance' status of the CAS whenever the CAS content changes further BELAC evaluation will be required (and incur costs);
- The responsibility for notifying CABs of the BELAC 'acceptance' status and all other relevant aspects of the CAS remains with the SO
- No CAB will be assessed or accredited for a scope to include the CAS under evaluation until the evaluation process is completed and the CAS has achieved 'acceptance' status

## 5 INITIAL EVALUATION OF A CONFORMITY ASSESSMENT SCHEME

### 5.1 Application for a CAS Evaluation to achieve international recognition

Each scheme owner intending to submit an application for a conformity assessment scheme evaluation and which contacts the BELAC secretariat, will receive documentation providing details on the evaluation procedure, the financial aspects, the application form (including the annex to be completed by the scheme owner) and the way to access the main documents via the homepage of BELAC.

#### 5.1.1 *Submission of application*

The application of a scheme evaluation shall be initiated by the scheme owner. By submitting the application form, the SO commits itself to respect the BELAC conformity assessment scheme evaluation procedure and especially to provide all the requested information, to pay the fees regardless of the result / outcome of the assessment and to follow all the obligations of the follow-up programme for the maintenance of the conformity assessment scheme.

The scheme owner will include a proposal for the accreditation scope in the application for CAS review.

An application for a CAS review is only fully registered once:

- The completed application form has been submitted to the secretariat,
- The documentation as specified in the application form has been supplied;

#### 5.1.2 *Application review*

The Secretariat will acknowledge receipt of the application to the applicant. The secretariat, referring to the various pieces of documentation submitted with the application, will review the information to determine whether to proceed with the application.

In the event that the applicant's file appears to contain serious gaps, the secretariat will contact the applicant in order to collect additional information. If the issues cannot be clarified, the secretariat may declare that the application is not receivable.

The review by the Secretariat will ensure that:

- a) The means are available to perform the evaluation activity;
- b) The Secretariat has the competence and capability to perform the evaluation.

- c) The topic of the conformity assessment scheme under evaluation is within the current working scope of BELAC (as detailed in BELAC 6-017 “Detailed list of the BELAC activities”)
- d) EA has not already nominated a hAB for the specific CAS (information available on the EA Intranet)
- e) There is a need for the CAS on the market in which BELAC operates (CABs expressing an interest to be accredited for the CAS under evaluation)

When the Secretariat declines to undertake the evaluation, it will inform the applicant of its decision and provide justification for its decision.

### 5.1.3 Evaluation quotation

When the Secretariat has accepted the application, an evaluation quotation will be composed by the File Manager handling the evaluation dossier.

The amount of the evaluation fee is depending on the type and the volume of the evaluation. The hourly rate on which the evaluation fee is based, is set to 100 euro (KB Belac 31/01/2006; Art. 13 §4). This rate is linked to the consumer price index of December 2001 and are adjusted annually on January 1 according to the variations of that index. (KB Belac 31/01/2006; Art. 13 §6).

The duration of an initial evaluation of a conformity assessment scheme for international use is set to a minimum of 20 hours. For the determination of the duration of the evaluation, the following elements will be taken into account (non-exclusive list):

- Number of scheme-documents (+);
- Relation to legal applications / norms (+);
- Relation to existing evaluated conformity assessment schemes (-);
- Scope/subscope (+);
- Previous evaluations (version changes, repeated requests) (-);
- Complexity of the activities (+).

When the secretariat requires the expertise of technical assessors for the scheme evaluation, they will be included on the quotation.

The secretariat will notify the applicant of the quotation and will request its approval within 15 working days. If no agreement can be reached on the quotation, the evaluation process will be terminated.

### 5.1.4 EA registration of CAS in process

Once acceptance of the quotation has been received by the secretariat, BELAC will notify the EA Secretariat that it has been approached by the SO and intends to perform the initial evaluation as the hAB. (document EA 1/22, 4.2.2.a; Step 2)

The EA Secretariat will inform all EA members that a new CAS is under evaluation and will identify the hAB and will record this information on the EA Intranet.



## 5.2 Evaluation

The evaluation will be performed according to the procedure and criteria documented in EA 1/22. The evaluation will allow BELAC to ensure that the requirements for the scheme owner, the requirements for the CAS and the additional BELAC requirements are fulfilled.

When important gaps are found between the information provided by the scheme owner and the requirements, these will be discussed between the BELAC secretariat and the scheme owner. The SO will be responsible to resolve all matters or to provide justification on the reasons for not doing so.

In the case the evaluation requires adjustments to the conformity assessment scheme by the SO, this can result in additional hours of evaluation. This amount will be determined taking into account the number and the complexity of the remarks/adjustments. The applicant will be informed of the need for extra hours and a new quotation will be provided.

### 5.2.1 Notification of the evaluation report to EA

Upon BELAC approval of the CAS, the outcome will be reported to the EA Secretariat, along with all supporting documentation.

## 5.3 EA Review and decision

*No additions to the provisions of EA 1/22*

If and when necessary during the commenting period, BELAC shall contact NABs and SO to resolve any issues with regards to the CAS evaluation. BELAC will provide input to the task force assembled by the EA HCC to discuss and decide with regards to the provided comments.

## 6 CHANGES OF A CAS

*The provisions of EA 1/22 apply.*

Based on the information provided the BELAC secretariat will provide a quotation for the evaluation of the revision of the CAS taking into account the principles as described in 5.1.3 of this document.

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