



**REPUBLICAN UNITARY ENTERPRISE  
«BELARUSIAN STATE CENTRE FOR ACCREDITATION»**

**Documented procedure of management system  
DP SM 4.6-01-2019  
(EA-1/22 A:2016, MOD)**

**PROCEDURE AND CRITERIA FOR THE EVALUATION OF  
CONFORMITY ASSESSMENT SCHEMES BY EA  
ACCREDITATION BODY MEMBERS**

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Approved	Order dated 04.06.2019 №40/1
Entered into force	c 20.06.2019
Issue	01
Amendment	
Copy	CONTROL
Instead of	

**Minsk, 2019**

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## 1 SCOPE

**1.1** The present documented procedure (hereinafter – the procedure) is the BSCA management system document and is developed to implement clause 4.6.3 of the BSCA Quality Manual as well as clause 4.6.3 of GOST ISO/IEC 17011, EA-1/22 A. The procedure sets the criteria and the order of determination whether the conformity assessment scheme fits for purpose.

**1.2** The requirements of the present procedure is mandatory for application by BSCA personnel including applicants for accreditation and accredited bodies.

## 2 REFERENCES

The present procedure uses the references to the following documents:

GOST ISO/IEC 17000 (ISO/IEC 17000, IDT) Conformity assessment. vocabulary and general principles

GOST ISO/IEC 17007 (ISO/IEC 17007, IDT) Conformity assessment. Guidance for drafting normative documents suitable for use for conformity assessment

GOST ISO/IEC 17011 (ISO/IEC 17011, IDT) Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies

GOST ISO/IEC 17024 (ISO/IEC 17024, IDT) Conformity assessment. General requirements for bodies operating certification of persons

GOST ISO/IEC 17067 (ISO/IEC 17067, IDT) Conformity assessment. Fundamentals of product certification and guidelines for product certification schemes

PK CM Quality Manual of the State Enterprise “BSCA”

EA-1/06 A-AB EA multilateral agreement - Criteria for signing - Policy and procedures for development

EA-1/22 A EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members

*Note: When using this procedure the current versions of the referenced documents should be used. If the reference documents are replaced (modified), then the modified documents should be used. If reference documents are canceled without replacement, the provisions of the procedure in which references are given to them are applied in the part that does not affect these references.*

## 3 TERMS AND DEFINITIONS

The following terms and their definitions are used in this procedure.

**3.1 Conformity assessment scheme:** A documented and publicly available set of requirements that establishes the following:

- object of conformity assessment, i.e. product, process, service, system, person to whom the conformity assessment scheme is applicable;
- requirements for conformity assessment;
- mechanism by which compliance is determined, i.e. testing, inspection or audit and any other supplementary activities to ensure compliance;
- any requirements set by the scheme owners with respect to conformity assessment bodies, as well as their interpretation or application if appropriate;
- any specific interpretation or application of the GOST ISO/IEC 17011 if appropriate.

**3.2 International conformity assessment scheme:** Scheme under which conformity assessment bodies operate, legally established in more than one EA Member State.

**3.3 Scheme owner:** The organization which established the conformity assessment scheme and which is responsible for development the conformity assessment scheme. Scheme owners can be standardization bodies, conformity assessment bodies, organizations that use the services provided by conformity assessment bodies, organizations that produce or buy products that are

subject of conformity assessment activities, manufacturers or their associations that have established their own assessment schemes. National accreditation bodies may not be scheme owners.

**3.4 Scheme owner recognition of a conformity assessment body:** Scheme owner recognition means that the scheme owner accepts certificates and reports issued by a CAB for the purposes of confirming that a test or calibration result, a product, a process, a service, a system, or a person meets the requirements of its conformity assessment scheme. As a result, the CAB can perform conformity assessment activities covered by the conformity assessment scheme or may have the right to use the scheme owner's mark. The nature and scope of recognition may vary between conformity assessment scheme and scheme owners. There may also be differences in how it is made known to the market.

**3.5 Scheme specific requirements for the CABs:** specific requirements on the CABs laid down by the scheme owner.

**3.6 Scheme specific requirements for NABs:** Additional applications of any GOST ISO/IEC 17011 requirements for a particular conformity assessment scheme established by the scheme owner (for example, specific competence criteria for assessors, assessment criteria, specific details in the assessment reports, etc.).

**3.7 Home Accreditation Body (hAB):** The local NAB which takes the lead for evaluating a conformity assessment scheme operated in more than one EA member country. The hAB will normally but not necessarily be the NAB from the country where the scheme owner is legally established. The hAB must be, in those cases where the conformity assessment scheme is to be implemented in several countries, a signatory to an EA MLA Accreditation Activity appropriate to the conformity assessment scheme.

*Note. References to the EA MLA and EA MLA signatories are also applicable to EA Bilateral Agreements and their signatories.*

**3.8 Acceptance of a conformity assessment scheme (by an EA member):** Confirmation by a NAB of the suitability of the standard to be used to accredit CABs participating in the conformity assessment scheme and fulfilment of the requirements included in chapter 7 of this document.

Note: EA members' acceptance of a given conformity assessment scheme does not mean a judgment on the market value or usefulness of the technical requirements of the conformity assessment scheme. The responsibility for the technical robustness and market acceptance of the conformity assessment scheme lies entirely with the scheme owner.

**3.9 Acceptance of a CAS (by EA):** Commitment by NABs to accredit CABs participating in the conformity assessment scheme according to the standard and conditions established by the home AB.

Note 1: EA acceptance of a given conformity assessment scheme does not mean a judgment on the market value or usefulness of the technical requirements of the conformity assessment scheme. The responsibility for the technical robustness and market acceptance of the conformity assessment scheme lies entirely with the scheme owner.

Note 2: The acceptance of a conformity assessment scheme by EA does not place an obligation on NABs to offer accreditation of conformity assessment activities in accordance with the conformity assessment scheme.

## 4 Abbreviations

The following notations and abbreviations are used in this documented procedure:

BSCA,	Republican Unitary Enterprise «Belarusian State Centre for
accreditation body	Accreditation»

SO	Conformity assessment scheme owner
OAL 1	Accreditation department №1;
OAL 2	Accreditation department №2;
OAOS	Department for certification bodies accreditation;
CAB	Conformity assessment body;
OORA	Department of accreditation activity management;
Scheme	Conformity assessment scheme;
CASCO	ISO committee on conformity assessment;
EA	European co-operation for Accreditation;
EA MLA	EA Multilateral Agreement;
IAF	International Accreditation Forum;
IDT	Identical degree of compliance with the international standard (identity in technical content and structure);
ILAC	International Laboratory Accreditation Cooperation;
ISO	International Organization for Standardization;
MOD	Modified degree of compliance with the international standard (modification of the technical content and structure).

## 5 RESPONSIBILITY

5.1 BSCA holds responsibility for evaluation of conformity assessment scheme in accordance with GOST ISO/IEC 17011 (chapter 4.6), EA-1/22 A and the present procedure.

## 6 POLICY

BSCA scope of activity can be extended if there is a need to ensure: compliance with international accreditation practices, harmonization of accreditation requirements, development of new types of accreditation activities, including establishment of new conformity assessment schemes.

When implementing the new conformity assessment scheme BSCA follows the requirements of EA-1/22 A and this documented procedure.

BSCA policy regarding the procedure and criteria for evaluating conformity assessment schemes defines the requirements for the process of evaluating schemes and is aimed at establishing consistent relationship between BSCA, conformity assessment scheme owners, relevant accredited bodies and stakeholders.

## 7 REQUIREMENTS TO THE CONFORMITY ASSESSMENT SCHEME OWNER

**7.1** When evaluating CAS BSCA cooperated with the SO under the following conditions:

7.1.1 The SO shall be a legal entity;

7.1.2 The SO has the authority to establish and change the requirements of the CAS;

7.1.3 The SO shall cooperate with BSCA;

7.1.4 The SO shall be able to demonstrate social or economic need for the CAS. Such need may include a request to demonstrate that the object of conformity assessment complies with the established requirements, to strengthen confidence in the objects of conformity assessment, improve quality and trade facilitation, and may include government initiatives and legislative changes. The SO shall provide evidence of social or economic need for the scheme received from interested parties, for example, industry associations, consumers, etc.;

7.1.5 The conformity assessment process described or chosen by the SO shall fall within the scope of one of the EA MLA Level 3 standards.

Scheme specific requirements placed on CABs by the SO shall not contradict, or exclude, any of the requirements included in the EA MLA Level 3 standard;

7.1.6 If a CAS places additional requirements on NABs, they shall not contradict or exclude any of the requirements GOST ISO/IEC 17011 and applicable EA, IAF, ILAC mandatory documents. Any additional requirements shall be set forth in a separate document in order to clearly identify such requirements;

7.1.7 The CAS requirements relating to the mandatory sector of technical regulation shall not contradict the requirements of the legislation in this field, nor should they be merely the fulfillment of the requirements of the legislation;

7.1.8 The SO shall commit to accept results from CABs accredited by any EA MLA signatory (for the relevant scope).

7.1.9 The SO shall demonstrate that the CAS has been validated. The validation shall be documented and include:

- A description of the purpose and the requirements of the CAS;
- An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the CAS;
- description of the methods that are necessary to determine whether the requirements are met, analysis of the appropriateness of the described methods;
- Determination of conformity assessment activities, including the definition of the standard containing the basic requirements for CABs, analysis of the appropriateness of the selected conformity assessment activity

7.1.10 The SO shall conclude an agreement with accredited CABs. Such an agreement must guarantee at least that the CABs will use the CAS as it is, without any limitations and without any additions. If the CAB is not accredited, the SO shall develop an agreement containing the obligations of the parties to transfer to accredited activities.

7.1.11 The SO shall be responsible for informing BSCA and affected accreditation bodies – signatories of EA MLA as well as CABs in relation to the scheme;

7.1.12 The SO shall be prepared to pay for the costs of the evaluation of its CAS by the EA member;

**7.2** In order to ensure the adoption of the scheme by BSCA, the SO shall develop the scheme in compliance with the criteria given in Appendix 1 which include relevant standards and guidelines of ISO/CASCO.

## **8 CONFORMITY ASSESSMENT SCHEME EVALUATIONS**

### **8.1 CAS Evaluation**

#### **8.1.1 General**

8.1.1.1 BSCA evaluates the appropriateness of the CAS under the following conditions:

- the SO has defined the most suitable standard which is to be applied to assess competence of CABs participating in the scheme. Chose of the standard shall depend on the type of conformity assessment activity or the content of the declaration of conformity;
- both CAS and SO comply with the requirements of the present procedure.

8.1.1.2. BSCA acceptance of a given CAS does not mean a judgment on the market value or usefulness of the CAS. The responsibility for the technical robustness and market acceptance of the CAS lies entirely with the SO. However BSCA commits to ensure that the process undertaken for ensuring the technical robustness and market acceptability of the CAS by the SO was suitable and thorough.

8.1.1.3 Once BSCA has decided that a CAS is considered appropriate as an EA MLA Level 4 CAS (documents containing additional criteria to level 3 standards) and accredits CABs for that CAS – thus BSCA declares that the CAS is covered by the MLA (see clause 7.2 in EA 1/06).

### **8.1.2 Process**

8.1.2.1 Before evaluating a CAS for the purposes of accrediting CABs working within the CAS, BSCA ensures that EA has not already nominated a hAB for that CAS (information on nominated hABs is available on the EA intranet). If a hAB has already been nominated then BSCA does not undertake any assessment but follows the directions given by the hAB.

8.1.2.2 If no hAB has been nominated by EA to evaluate the CAS the SO shall use the form Φ 4.6-01 in order submit to BSCA the required information in written. Before he evaluation the SO informs BSCA in written on the intention to operate the CAS in more than one EA country and, if so, whether the SO agrees to follow the evaluation process described in paragraph 8.2.

If the owner of a scheme operating in several countries decides not to follow the process described in paragraph 8.2 of this procedure, BSCA informs the SO in writing that other ABs EA members will not be obliged to follow the decisions of the BSCA in relation to the scheme, and, therefore, the SO will be obliged to interact individually with each EA AB in which the scheme operates, and will be obliged to accept any potential differences in approaches that may occur in these bodies.

If the initial intention is for a CAS to only be operated in the Republic of Belarus, BSCA shall informs the SO that the CAS will be evaluated at the national level only and when extending the scheme to an international level the SO should follow the process described in paragraph 8.2 of this procedure. In case of extension of the scheme to an international level the original decisions of BSCA in relation to the CAS can be challenged and modified by other EA ABs.

BSCA retains all records relating to evaluation of the scheme, including documented grounds for the evaluation and decision-making.

## **8.2 EA common approach to the evaluation of a multinational CAS**

### **8.2.1 General**

If the SO informs BSCA in writing of its obligation to follow the process described in this section, BSCA also commits to follow this process.

### **8.2.2 Process**

#### **8.2.2.1 Initial evaluation**

8.2.2.1.1 Before starting an evaluation of a multinational CAS, BSCA shall receive notification from the SO in writing:

- that it is aware of the fact that until the evaluation is finished the SO will work with BSCA without contacts with other EA NABs. Interaction between the SO and any other EA NAB about the particular CAS is not allowed.

- whether the CAS includes additional requirements to GOST ISO/IEC 17011, and/or, where applicable, EA, IAF and ILAC mandatory documents. If it does then written confirmation is also required that the SO is aware of the fact that those additional requirements will need to be endorsed by the EA GA before the evaluation process by the NAB starts;;

- that it agrees to follow the evaluation procedure described in this chapter.

8.2.2.1.2 Once this notification has been received, BSA informs the EA Secretariat that it has been approached by the SO and intends to perform the initial evaluation.



8.2.2.1.3 The EA Secretariat informs all EA members that a new CAS is under evaluation and identifies BSCA as the hAB. Records of this will be kept in the EA intranet. During this step, neither BSCA nor other NABs do not offer accreditation to CABs in relation to this CAS.

8.2.2.1.4 Once BSCA has performed the initial evaluation of a CAS to be operated in several EA member countries, it then reports the outcome of the evaluation to the EA Secretariat. This outcome must include:

- confirmation by BSCA that the CAS fulfils, or not, the requirements of EA-1/22 A, using a report based on the template Φ 4.6-01;
- identification of the standard to be used to accredit CABs, including a justification for why the standard has been chosen;
- the documentation (or a link to the documentation) of the CAS (in English).

8.2.2.1.5 The EA Secretariat shall circulate the CAS documents and BSCA evaluation report to NABs for a 30 day comment period

8.2.2.1.6 Until the commenting stage has been finalised, it is not recommended to start assessment activities related to the CAS under evaluation. If there is a need to start the assessment before the end of the commenting period BSCA informs the SO that any decision on the CAS may be challenged by other NAB members and that this may result in changes to the assessment process. If there is no need to start accreditation before the commenting stage is finalised, accreditation cannot be granted before the CAS has been accepted.

8.2.2.1.7 Once the comment period has finished, if no adverse comments have been received, then BSCA conclusions are confirmed by the EA Secretariat which also informs this to all other EA NABs. BSCA then makes the information on the new level 4 accreditation service offered publicly accessible on its website.

8.2.2.1.8 The result obtained after the commenting period is over shall also be published within the Members-Only area of the EA Intranet where a list is maintained by the EA Secretariat of CAS evaluated according to EA-1/22. These results are made publicly available on BSCA website since BSCA holds the responsibility as contact point for the CAS.

8.2.2.1.9 If any negative comments have been received then the EA Secretariat reports these to BSCA. BSCA gets in touch with commenting NABs to reach a consensus. If consensus is not reached the matter shall be escalated to the EA HHC for discussion and decision involving, if and when necessary, a task force comprising BSCA, NABs having provided the comments, other NABs volunteering and the SO.

### **8.2.2.2 Subsequent actions**

8.2.2.2.1 Once the conclusions of BSCA to accept the CAS for accreditation have been confirmed and published on the EA intranet, any other NAB can perform accreditation to that CAS to the CAS having previously informed BSCA and made relevant information publicly available on their website.

8.2.2.2.2 Any questions to the SO regarding the CAS shall be raised via BSCA.

8.2.2.2.3 If national CAS develops into an international CAS it may occur that a new active NAB has strong objections to the initial decisions on the CAS, then it shall contact BSCA for clarification. If it still does not agree, it will contact the EA Secretariat which shall inform all NABs asking for agreement to initiate the full process described in paragraph 8.2.2. In these cases, BSCA accrediting the CAB at national level will be appointed the hAB and is thus responsible for full evaluation of the CAS.

8.2.2.2.4 BSCA leads the analysis of proposed changes to the CAS involving all active EA NABs. BSCA keeps records of the comments, feedback and suggestions received from other active EA NABs.



8.2.2.2.5 Any conflicts between BSCA and any active NABs in a specific CAS shall be referred to the EA HHC for discussion and decision involving a task force and a voting process as above if and when necessary.

8.2.2.2.6 The process is illustrated in the flowchart on the next page.

## 9 FORMS TO APPLY

Φ 4.6-01 Analysis of conformity assessment scheme

## 10 MANAGEMENT OF RECORDS

For information on management of records in this procedure see Table 1.

**Table 1 Management of records**

Title, type* or records	Place for records retain	Responsibility for update of records form/keeping records	Place for records form retain	Term for records retain
Analysis of conformity assessment scheme (paper mean)	w:/OAJ 1 w:/OAJ 2 w:/OAO C	OORA/OAL 1 OORA/OAL 2 OORA/OAOS	IPS Standart/ Our documents/ DP SM 4.6-01/ Forms/Φ 4.6-01	on a continuous basis

## Annex 1

### Guidance for the scheme owner on development of conformity assessment scheme

1 SOs should follow ISO/IEC 17007 as a general guide when designing normative documents for conformity assessment, with a particular focus on:

- principles in chapter 4;
- guidance on designing normative documents which lay down requirements to objects of conformity assessment as described in chapter 5;
- guidance on designing normative documents which lay down requirements to conformity assessment systems as described in clause 6.

2 When designing products certification scheme or when there is a need for inspection certification scheme or management system or schemes which includes testing or calibration activities the SO should follow GOST ISO/IEC 17067 with a particular focus on requirements in clause 6 “Designing and operation of products certification scheme”.

3 When designing persons certification scheme the SO should follow GOST ISO/IEC 17024 with a particular focus on requirements in clause 8 “Certification schemes”.

4 When developing a CAS the SO should stick to functional approach to conformity assessment which outlines the framework for considering basic functions of conformity assessment and their interrelations.

Functional approach identifies elements which shall be included into a CAS. Table 1 provides elements for different types of activity;

Table 1

Conformity assessment form	CAS elements
Calibration and testing (including medical tests)	The application area (object, matrix, scope)
	Calibration and test methods
	Performance characteristics of methods
	Requirements applicable to laboratories, supplementary to international standards for laboratories, for example ISO/IEC 17025 or ISO 15189
	Requirements against which the object is to be tested or calibrated. These requirements may be international standards, or legal requirements, or standards set out within the sector or specifications of a group of manufacturers
	Specific requirements concerning e.g. internal and/or external quality control procedures and/or performance characteristics, if any

Conformity assessment form	CAS elements
Inspection	The application area (object, matrix, scope)
	Inspection methods, if relevant, including any examinations which need to be performed as part of the conformity assessment activity
	Requirements applicable to inspection bodies, supplementary to ISO/IEC 17020
	Requirements against which the object of inspection is to be judged. These requirements may be international standards, or legal requirements, or standards set out within the sector or specifications of a group of manufacturers
Certification	Объект сертификации, например, система менеджмента, продукция, услуга, процесс, персонал The object of certification, e.g. management systems, products, services and processes, persons
	Requirements against which the object of certification shall be assessed and certified. These requirements may be international standards, or standards or specifications set out within the sector or specifications of a group of manufacturers
	Description of the certification system
	Requirements applicable to certification bodies, supplementary to the international standards for certification bodies

Specific guidance on validation of certification schemes is provided in Table 2.

Table 2

CAS elements	Information needed for validation
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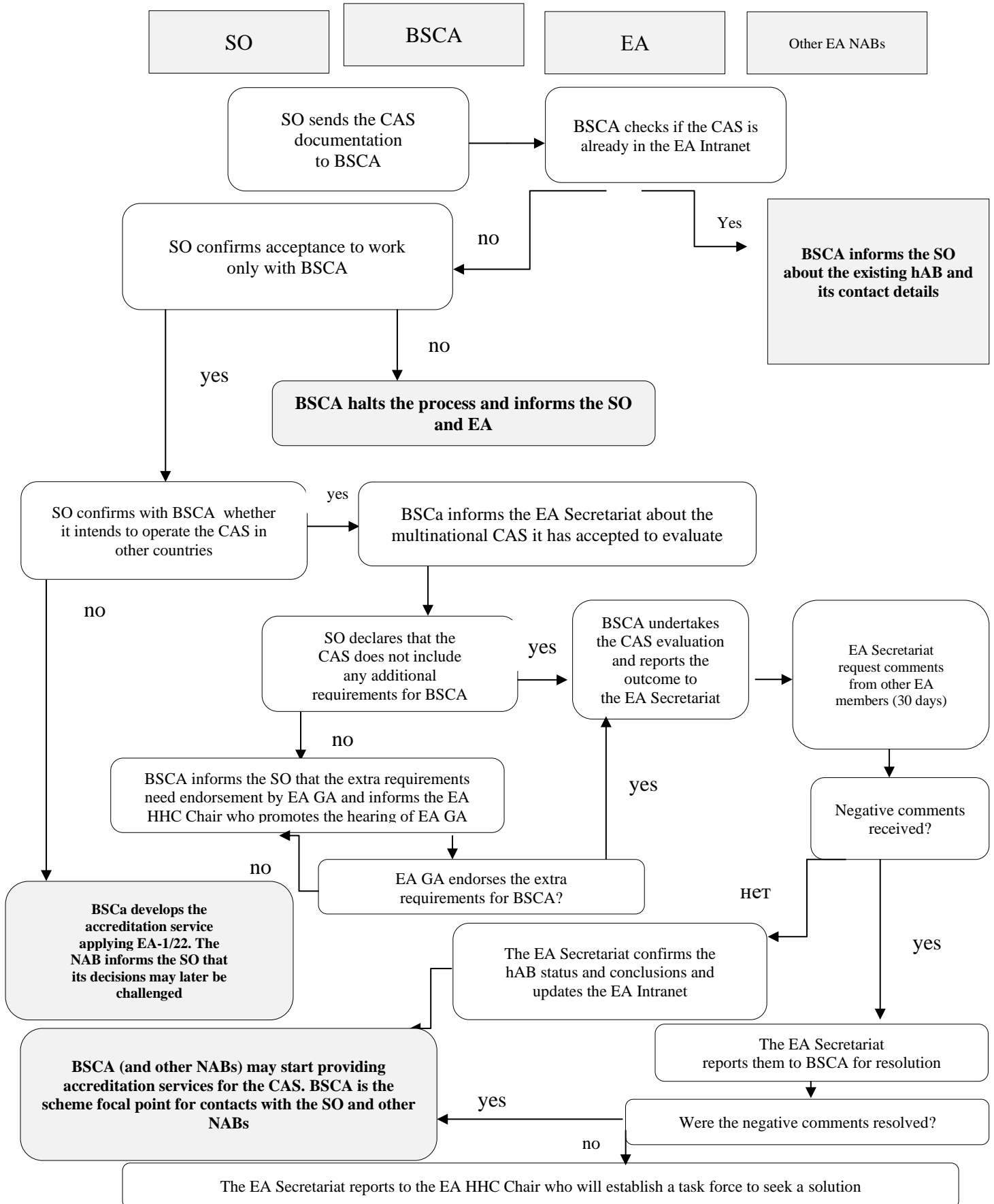
Object	What is the object of certification?
	Which (group of) products/services/processes/systems/competencies does the conformity assessment scheme cover?
	What aspect of the product/service/process/ system / competency does the statement of conformity relate to?
Certificate	What is the conformity statement which appears on certificates?
	What are the validity conditions of the certificate or the statement of conformity?
	How is the applicable certification system stated or referred to?
Certification mark	How is the significance of the certification mark communicated to the market?
	Is there any significant risk of the certification mark being misinterpreted or misused?

CAS elements	Information needed for validation
Requirements to certification process	Identify the scheme documents where the requirements are stated
	How is it demonstrated that the requirements are possible to evaluate?
	Identify legal requirements
	Does the scheme only contain legal requirements?
	How is compliance with legal requirements determined?
	Are there documents explaining or interpreting the requirements?
	Have the documents explaining or interpreting the requirements been published? Who is the author of the interpretation document(s)?
Certification system	Which is the evaluation method used in order to determine conformity?
	How do you demonstrate that your method is suitable for supporting the conformity statement?
	Which method do you rely on to monitor that the certificate holder continues to comply with requirements?
	How do you demonstrate the suitability of your method in order to monitor that the certificate holder continues to comply with requirements?
Conditions	Which criteria are required for granting, maintaining, expanding, reducing, extending, suspending or revoking certification?
	Is the definition of nonconformity in line with the competence standards for CABs and/or IAF guidance?
	What rights and obligations are stipulated for the SO, certification bodies and the applicants?
	What records are kept demonstrating continued compliance

	with the requirements?
	Describe a process of registration of complaints by certificate holders
Procedures	Are the certification procedures described and where? Provide reference to the document
	Has the suitability of the procedures been demonstrated?

<b>CAS elements</b>	<b>Information needed for validation</b>
Expertise	What are the competency requirements for certification auditors?
	What are the competency requirements for decision-makers?
	What are the competency requirements for other staff members involved in the certification process?
	How has it been substantiated that the competency requirements are appropriate?
Public awareness	Where are the scheme documents published?
	Are they made public?
	Does the SO have any market surveillance, for example list of certified products, services, etc.?

**BSCA procedure for the evaluation of multinational CAS**



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**Amendments registration sheet**

N	Date of introduction of the amendment	N of notification of change, date of approval	Paragraph changed	Signature of the person who introduced the change	Full name of the person who introduced the change
1	2	3	4	5	6