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EA Procedure and Criteria For the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members

PURPOSE

This document contains the procedure and criteria to be applied by EA accreditation body members when evaluating conformity assessment schemes (CAS). It has been specifically designed for CAS where there is an identifiable scheme owner holding contractual agreements with the conformity assessment bodies operating within the scheme.

Authorship

The publication has been prepared by the EA Horizontal Harmonisation Committee (HHC)

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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CONTENTS

1 SCOPE OF APPLICATION

1.1. This document describes:

I. The mandatory procedure and criteria to be used by EA accreditation body members (hereafter referred to as NABs (national accreditation bodies)) when evaluating a defined conformity assessment scheme (CAS) (Clause 4.1).

II. The process established by EA to provide a common approach to CAS operating in different EA member countries (Clause 4.2).

III. The evaluation of a CAS owned by the European Commission (Clause 4.3).

IV. The requirements to be fulfilled by the SO (Clause 3).

1.2. General provisions for application:

a) This document is of mandatory application of CASs in the voluntary (i.e. non-regulated) field. The procedures and criteria contained in this document may also be applied for the evaluation of mandatory CAS in the regulated field.

Note, however, that regulated schemes: still need to correspond to a conformity assessment activity listed as level 2 in EA-1/06; still need to use a standard listed as level 3 in EA-1/06; and still may not omit any requirement of the chosen standard.

b) This document has been specifically designed for CAS where there is an identifiable scheme owner (SO) holding contractual agreements with the CABs operating within the CAS.

c) In other situations (for instance when the SO has no contractual relationship with the CABs), some requirements may not apply. The decision on applicability of requirements in such instances shall lie with the hAB.

d) This document is not mandatory where the SO is a CAB seeking accreditation for a CAS that only it operates as such situations are appropriately covered within the conformity assessment standards. However it is still recommended that the evaluation of such CASs follows the process outlined in Annex 1.

2 DEFINITIONS AND CHOICE OF TERMINOLOGY

2.1 Conformity assessment scheme (CAS): For the purpose of this document a conformity assessment scheme, as defined in ISO/IEC 17000, is a documented and publicly available set of requirements which establishes the following:

- The object of conformity assessment, i.e. product, process, service, system, person to be assessed for conformity;
- The requirements against which conformity is to be assessed;
- The mechanism by which conformity is determined, e.g. testing, inspection or auditing and any other supporting activities to ensure conformity;

- Any requirements placed on CABs by the SO, and any specific applications or interpretations thereof, if applicable;
- Any specific applications or interpretations of ISO/IEC 17011, if applicable.

This document is essentially an instrument to provide a harmonized response by NABs to SOs and CABs in relation to definition of the most appropriate standard to be used for accreditation of CABs that want to be active in a specific CAS.

For the purposes of this document, a multinational CAS is one where CABs legally established in more than one EA member country are involved.
It deserves to be noted that being a multinational CAS does not depend on the locations where the object of conformity assessment is utilised.

2.2 Scheme owner (SO): A scheme owner is an identifiable organization which has established a CAS and which is responsible for the CAS design. The following are examples of SOs:

- Standardisation bodies[1];
- CABs;
- Organizations that use services provided by CABs;
- Organizations that buy or sell products subject to conformity assessment activities;
- Manufacturers or their associations that have established their own CAS.

NABs cannot be SOs.

2.3 Scheme owner recognition of a conformity assessment body: SO recognition means that the SO 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 CAS. As a result, the CAB can perform conformity assessment activities covered by the CAS or may have the right to use the SO's mark.
The nature and scope of recognition may vary between CAS and SOs. There may also be differences in how it is made known to the market.

2.4 Scheme specific requirements for the CABs: specific requirements on the CABs laid down by the SO.

2.5 Scheme specific requirements for NABs: Additional applications of any ISO/IEC 17011 requirements for a particular CAS established by the SO (for example, specific competence criteria for assessors, assessment criteria, specific details in the assessment reports, etc.).

2.6 Home Accreditation Body (hAB): The local NAB which takes the lead for evaluating a 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. The hAB must be, in those cases where the CAS is to be implemented in several countries, a signatory to an EA MLA Accreditation Activity appropriate to the CAS[2].

[1] Does not include cases where the scheme is fully defined in standards and the role of standardisation body is limited to the standard production.

[2] References to the EA MLA and EA MLA signatories are also applicable to EA Bilateral Agreements and their signatories.

2.7 **Acceptance of a CAS (by an EA member)**: Confirmation by a NAB of the suitability of the standard to be used to accredit CABs participating in the CAS and fulfilment of the requirements included in clause 3 of this document.

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

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

Note1: EA acceptance of a given CAS does not mean a judgment on the market value or usefulness of the technical requirements of the CAS. The responsibility for the technical robustness and market acceptance of the CAS lies entirely with the SO.

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

3 MANDATORY REQUIREMENTS FOR THE ESTABLISHMENT OF RELATIONSHIPS WITH SCHEME OWNERS

A NAB shall co-operate with a SO under the following conditions:

3.1 The SO shall be legally identifiable.

3.2 The SO has the authority to establish and change the requirements of the CAS.

3.3 The SO shall have the mandate to cooperate with the hAB.

3.4 The SO shall be able to demonstrate market support for the CAS. Such support may include government initiatives or regulatory needs. The SO shall be able to provide evidence of market support for the CAS coming from relevant interested parties. EA acknowledges that the number and nature of these "relevant interested parties" may be different for different CASs. Of particular relevance and importance in the demonstration of market support is the view-point of interested parties representing the CAS end-users (e.g. consumers or industry).

3.5 The conformity assessment process described or chosen by the SO shall fall within the scope of one of the EA MLA Level 3 standards (see EA-1/06).

3.6 Scheme specific requirements placed on CABs by the SO shall not contradict, or exclude, any of the requirements included in the standard referred to in 3.5.

3.7 If a CAS places additional 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. Additional requirements to ISO/IEC 17011 for international CASs require endorsement by the EA General Assembly (GA) based on a recommendation from the EA HHC. If a national CAS intends to expand to become international, then any agreement with the hAB on additional requirements to ISO/IEC 17011 will not

automatically be binding on other NABs. These requirements will first need to be accepted and endorsed by the EA GA.

3.8 CASs in the voluntary sector with requirements applicable to objects of conformity assessment shall neither contradict, nor simply be the fulfilment of, applicable legal requirements.

3.9 The SO shall commit to accept results from CABs accredited by any EA MLA signatory (for the relevant scope) which follows the requirements laid down by the SO.

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

- A description of the purpose of the CAS;
- A description of the requirements of the CAS;
- An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the CAS;
- A description of the methods to be used for determining fulfilment of the requirements;
- An analysis of the appropriateness of the described methods to be used for determining fulfilment of the requirements;
- A decision on the conformity assessment activity to be used (including the identification of the applicable conformity assessment standard);
- An analysis of the appropriateness of the selected conformity assessment activity.

3.11 The SO shall reserve 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.

3.12 The SO shall be responsible for keeping all active NABs and CABs informed of any relevant information and developments relating to the CAS, including in particular any proposed change in requirements.

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

4 CONFORMITY ASSESSMENT SCHEME EVALUATIONS

4.1 CAS Evaluation

4.1.1 General

This clause describes the mandatory procedure and criteria to be used by NABs when evaluating, upon request by a SO, if a given CAS is appropriate and acceptable as an EA MLA Level 4 CAS (see EA-1/06) and, if so, under which harmonized standard (EA MLA Level 3 – see EA-1/06) containing general requirements for CABs.

The acceptance of a CAS by a NAB requires:

- the identification of the most suitable conformity assessment standard to be used to assess the competence of the CABs participating in the CAS: This shall be determined by considering the nature of the conformity assessment activities and the content of the conformity declaration. Consequently that standard will be the one used as the reference for the accreditation of CABs. Note: The SO may need to change some elements of the CAS in order to enable CABs to fulfil all of the requirements of the selected standard;

- that the CAS and the SO meet the requirements laid down in this document.

A NABs' 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.

It is however the responsibility of the NAB to ensure that the process undertaken for ensuring the technical robustness and market acceptability of the CAS by the SO was suitable and thorough.

Once a NAB signatory of the relevant MLA has decided that a CAS is considered appropriate as an EA MLA Level 4 CAS and accredits CABs for that CAS the NAB is declaring that the CAS is covered by the MLA (see clause 7.2 in EA 1/06).

4.1.2 Process

Before evaluating a CAS for the purposes of accrediting CABs working within the CAS, NABs shall ensure 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 the NAB is not required to undertake any assessment but shall follow the directions given by the hAB.

If no hAB has been nominated, NABs shall use Annex 1 and shall recommend that the applicant SO uses Annex 2 of this document. The concerned NAB shall give notice to the applying SO on the estimated time period needed for evaluation. Records of the evaluation shall be maintained, including the basis on which the decision to accept was taken.

Before the evaluation of a CAS commences the SO needs to inform the NAB, in writing, if it intends to operate the CAS in more than one EA country and, if so, if it agrees to follow the evaluation procedure described in 4.2. If the SO of a CAS operating in several countries chooses not to follow the procedure described in 4.2 of this document, the NAB shall inform the SO in writing that EA NABs will not be obliged to follow the decisions of the hAB and therefore it will have to deal with each NAB where it operates separately, and accept any potential differences in approach by them.

If the initial intention is for a CAS to only be operated at the national level, the NAB shall inform the SO that the CAS will be evaluated at the national level only and that if the situation changes in the future, and the SO wants to have a common approach across all EA countries, the evaluation process described in 4.2 will need to be applied. In this case the original decisions of the NAB that evaluated the CAS can be challenged and modified.

Note: National schemes already accepted before the first revision of this document (21st May 2015) do not need to be evaluated according to the procedure defined in this document while they remain at national level.

4.2 EA common approach to the evaluation of a multinational CAS

4.2.1 General

This clause describes the process established by EA (based on the identification of a home AB (hAB – see 2.6), that will be the contact between the SO and EA, to provide a common approach to CAS operating in different EA member countries and to manage and solve the possible conflicts that may arise among NABs regarding the outcome of the evaluation of a CAS by the hAB.

This process is mandatory for all NABs provided the SO commits in writing to follow it.

The acceptance of a CAS by a hAB does not place an obligation on other NABs to also offer accreditation of conformity assessment activities in accordance with the CAS. However if they choose to do so then they shall be required to follow the decisions taken by the hAB and abide by the provisions of this document in the case of conflicts.

4.2.2 Process

4.2.2.a Initial evaluation

Step 1: Before starting an evaluation of a multinational CAS, the NAB must receive notification from the SO in writing:

i. that it is aware of the fact that the NAB will be the hAB for that CAS and it will work with the hAB without contacts with other EA NABs about the particular CAS until the evaluation is finished;

ii. whether the CAS includes additional requirements to ISO/IEC 17011, Regulation (EC) 765/2008 and/or, where applicable, EA mandatory documents and IAF or ILAC documents endorsed by EA as mandatory. 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 such endorsement by the EA GA is not a guaranteed outcome; and that the endorsement process may affect the timing of the evaluation process;

iii. that it agrees to follow the evaluation procedure described in 4.2 of this document.

Step 2: Once this notification has been received, the concerned NAB shall inform the EA Secretariat that it has been approached by the SO and intends to perform the initial evaluation. It shall commit to be the hAB.

Step 3: The EA Secretariat will inform all EA members that a new CAS is under evaluation and will identify the hAB. Records of this will be kept in the EA intranet. During this step, the hAB and NABs shall not offer accreditation to CABs in relation to this CAS.

Once the hAB has performed the initial evaluation of a CAS to be operated in several EA member countries, it will report the outcome of the evaluation to the EA Secretariat. This outcome must include:

i. The confirmation by the hAB that the CAS fulfils, or not, the requirements in this document, using a report based on the elements in Annex 1;

ii. Identification of the standard to be used to accredit CABs, including a justification for why the standard has been chosen;

iii. The documentation (or a link to the documentation) of the CAS (in English).

Step 4: The EA Secretariat shall circulate the CAS documents and hAB evaluation report to NABs for a 30 day comment period.

Until the commenting stage has been finalised, it is recommended that the hAB and other NABs do not start assessment activities related to the CAS under evaluation unless the need to start the assessment before the end of the commenting period can be fully justified. In such cases, the hAB shall make the SO and the CABs it proposes to assess explicitly aware that its conclusions may be challenged by other NAB members and that this may result in changes to the assessment approach. However, where assessment work does commence before the commenting stage is finalised, accreditation cannot be granted before the CAS has been accepted.

Step 5: Once the comment period has finished, if no adverse comments have been received, then the hAB conclusions can be confirmed and the Secretariat shall inform the hAB. The hAB shall also make the information on the new level 4 accreditation service offered publicly accessible in accordance with EA-1/06, 5 (q).

The result 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 and the hAB holding the responsibility as contact point for the CAS.

Step 6: If any negative comments have been received then the EA Secretariat shall report these to the hAB for resolution in the first instance. The hAB shall get 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 the hAB, NABs having provided the comments, other NABs volunteering and the SO.

4.2.2.b Subsequent actions

Once the conclusions of the hAB to accept the CAS for accreditation have been confirmed and published on the EA intranet, any other NAB accrediting to the CAS should inform the hAB and, in accordance with EA-1/06, make publicly available, e.g. on their website, that they are now offering accreditation to that CAS.

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

A national CAS may develop into an international CAS. If this occurs and a new active NAB has strong objections to the initial decisions on the CAS, then it shall contact the NAB responsible for that CAS 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 4.2.2. In these cases, the NAB accrediting the CAB at national level will be appointed the hAB.

Analysis of proposed changes to the CAS shall be led by the hAB involving all active NABs. The hAB shall keep records of the communication with other active NABs (and the SO if needed) and of the conclusions and decisions.

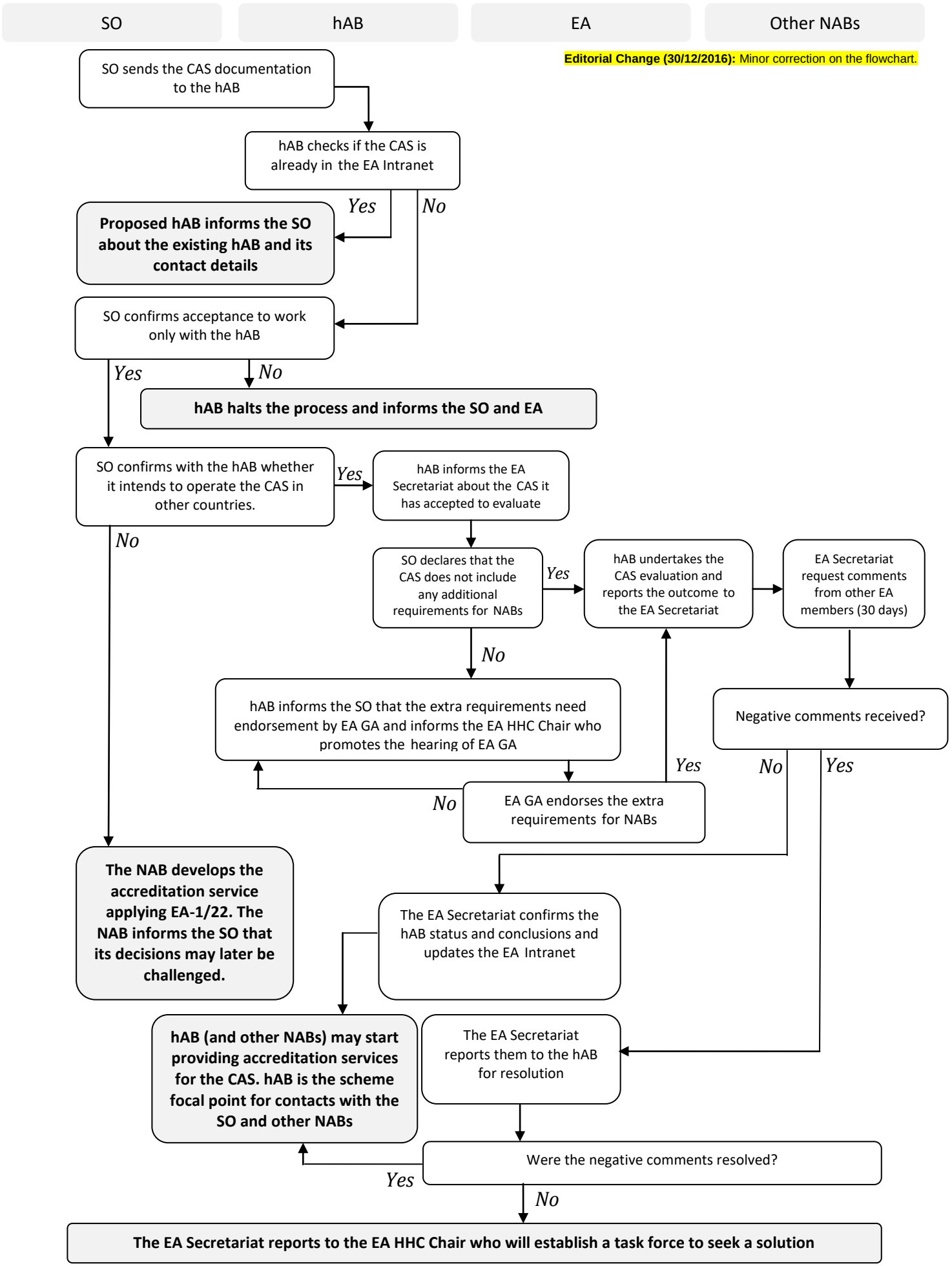
Any conflicts between the hAB and any active NABs in a specific CAS shall be referred to the EA HHC for discussion and decision involving a task force and a voting process as above if and when necessary.

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

4.3 CAS owned by the European Commission

Where the EC requests EA to evaluate the scheme, this will be undertaken by EA as a membership body rather than an individual hAB. As such the approval process by HHC as described in this document is not applicable: Responsibility for progressing such a request will lie with the Executive, and will involve the input of a task force competent in the area of the scheme that shall report directly to the Executive committee but which will take the technical decision with respect to scheme acceptance. Final decision on the implementation of the scheme shall be taken by the GA.

The appointment of a hAB for the future monitoring of the CAS will also be considered.


SO
hAB
EA
Other NABs
Editorial Change (30/12/2016): Minor correction on the flowchart.
SO sends the CAS documentation to the hAB
hAB checks if the CAS is already in the EA Intranet
Yes
No
Proposed hAB informs the SO about the existing hAB and its contact details
SO confirms acceptance to work only with the hAB
Yes
No
hAB halts the process and informs the SO and EA
SO confirms with the hAB whether it intends to operate the CAS in other countries.
Yes
hAB informs the EA Secretariat about the CAS it has accepted to evaluate
No
SO declares that the CAS does not include any additional requirements for NABs
Yes
hAB undertakes the CAS evaluation and reports the outcome to the EA Secretariat
EA Secretariat request comments from other EA members (30 days)
No
hAB informs the SO that the extra requirements need endorsement by EA GA and informs the EA HHC Chair who promotes the hearing of EA GA
Negative comments received?
Yes
No
Yes
No
EA GA endorses the extra requirements for NABs
The NAB develops the accreditation service applying EA-1/22. The NAB informs the SO that its decisions may later be challenged.
The EA Secretariat confirms the hAB status and conclusions and updates the EA Intranet
hAB (and other NABs) may start providing accreditation services for the CAS. hAB is the scheme focal point for contacts with the SO and other NABs
The EA Secretariat reports them to the hAB for resolution
Were the negative comments resolved?
Yes
No
The EA Secretariat reports to the EA HHC Chair who will establish a task force to seek a solution

ANNEX 1

INFORMATION TO BE PROVIDED BY SCHEME OWNERS

The information below is considered mandatory for the NAB to make a proper evaluation of the CAS. SO feedback to the questions and the NAB conclusions are records that must be kept within the NAB management system. These records must include the rationale for the NAB decision in relation to the CAS and may be requested by other NABs or EA. They shall be available for peer evaluations.
Some questions may not be applicable to some CASs.

1. Is the SO willing to use the NAB as the unique contact point for the evaluation of the CAS?

2. Is the CAS intended to be used only at a national level? If no, please specify.

3. Is the CAS currently being used by CABs under accreditation from any of the EA members? If yes, please identify the EA member. If no but it has previously been reviewed by an AB, please provide details and outcome of the evaluation.

4. Provide a full description of the SO including:
   - Name and acronym,
   - Type of legal entity,
   - Address and web address
   - Members (if relevant) and membership rules,
   - Brief history,
   - Any other activities performed if relevant,
   - Relations to or links with other organizations and the authorities, both at international and national levels, if any,
   - Technical area of activity, for example aerospace, electrical testing, food safety, etc.;
   - Conformity assessment procedure suggested by the SO, for example product certification, inspection, etc.
   - Geographical area of acceptance, for example a few European countries, all of Europe or global.

   Does the SO perform any kind of activity to confirm recognition of CABs which wish to work within the scope of the CAS, beyond requiring that they are accredited to the CAS requirements? If so, describe it and identify the CAS document(s) where this is stated.

5. Provide evidence of market support for the CAS.

6. Under which conformity assessment procedure(s) does the CAS operate? (For example product certification, testing, etc.) Include the rationale for your choice and identify the CAS document where it is established.

7. Has the SO established CAS specific requirements for the operation of CABs wishing to operate within the CAS? If YES, please describe the specific CAS requirements and identify the CAS documents where these are described. State also how such requirements are made publicly available.

8. Does the SO (by itself or through another organization) perform any kind of assessment of the CAB? If so, describe it and refer to the CAS document where it is required.

9. If the answer to question 8 is YES, does the SO request the NABs to accept or take into account such an assessment during the accreditation process? If so, please identify the CAS document where this is stated and described.

10. Does the CAS request EA or EA members to cooperate with the SO on issues other than accreditation of CABs? If so, specify the areas of cooperation required and refer to the CAS document where these are described.

11. Has the SO established CAS specific requirements for the operation of NABs? If YES, please identify the CAS document where these are described.

12. What is the object of conformity assessment? Please state as specifically as possible. *(Objects of conformity assessment may be products, services, materials, installations, processes, systems, persons or bodies.)*

13. What are the specific requirements relating to the characteristics of the object of conformity assessment? Please identify the CAS documents where these are stated.

    Notes:
    - Requirements shall be written in a clear, direct and precise manner and that they shall result in accurate and uniform interpretation, so that parties making use of the normative document are able to derive from the contents of the normative document a common understanding of its meaning and intent.

    - Requirements shall be written in terms of results or outcomes, together with limiting values and tolerances, where pertinent.

    - Requirements shall be stated unambiguously using wording that is objective, logical, valid and specific.

14. Are all measurement values expressed in SI units (International System of Units)?

15. If the CAS involves sampling, which procedures are required for sampling? *(To gain consistent and reproducible results, sampling methods should be based, whenever possible, on statistical methods provided in International Standards.)*

16. Are there test methods or inspection procedures involved in the CAS? Where are these documented?

17. Does the CAS cover the following typical elements of a conformity assessment scheme?

    - **selection** of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities;
    - **determination**, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample;

- **review and attestation**, including the review of evidence from the determination stage, and a subsequent attestation that the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements, and any subsequent marking or licensing and their related controls, where applicable;
- **surveillance** (if needed), including the frequency and extent of surveillance activities and reassessments to ensure the object of conformity assessment continues to fulfil the specified requirements.

18. Does the CAS consider the use of marks of conformity? If that is the case, provide evidence to demonstrate that it has protected those marks and laid down rules for their use.

19. Provide evidence that the CAS was designed by persons demonstrably competent in that capacity. The competence shall cover both the technical field of expertise and the conformity assessment procedure used.

    Note: CABs may be involved in the development process of CASs within the limitations given in the standards used for their accreditation.

20. Provide evidence that the interested parties for the CAS were analysed, identified and consulted, and that their feedback was supportive.

21. Provide evidence that the CAS is validated, considering the details given in clause 3.10. As a minimum validation must demonstrate that the CAS has successfully completed a test period, demonstrating that it is fit for purpose. Some of the questions to considered are:
    - Is the conformity assessment, as described, practicable?
    - Do the determination activities as described quantify or in other ways identify and confirm the characteristics which the SO intends and expects to identify and which constitute the basis for conformity assessment?
    - Are the requirements specified in a way that ensures reproducibility and reliability of results?

ANNEX 2

GUIDANCE ON CONFORMITY ASSESSMENT SCHEMES

This Annex states the guidance to be considered by a SO when designing a CAS in order to facilitate acceptance by NABs. The criteria stated in this annex and in other parts of the document reflect the contents of the relevant ISO/CASCO standards and guides. A full list of these standards and guides is available in the CASCO Toolbox, which is available on the ISO website (www.iso.org).

SOs should follow ISO/IEC 17007 as a general guide when designing normative documents for conformity assessment, with a particular focus on the principles in clause 4 and the guidance in clauses 5 and 6.

ISO/IEC 17067 provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services. The guidelines are related to:

- SO (clause 6.3);
- Scheme development (clause 6.4);
- Content of a scheme (clause 6.5);
- Maintenance and improvement of a scheme (clause 6.6);
- Scheme documentation (clause 6.7).

These guidelines should be applied by SOs establishing certification schemes for products, processes and services. They can also be used as applicable when establishing inspection and management system certification schemes or schemes including testing and calibration activities.

The requirements for establishing certification schemes for persons are contained in clause 8 of ISO/IEC 17024.

The following table provides an overview of elements that a CAS should include, as a minimum, for various types of activities.

Conformity assessment activity	**Description of (at least):**
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 activity	**Description of (at least):**
Inspection	• The application area (object, matrix, scope); • 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; • 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.
Certification	• The object of certification: o Management systems; or o Products, services and processes; or o Persons (expertise, competence); • 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

1. **Object**
   a. What is the object of certification;
   b. Which (group of) products / services / processes / systems / competencies does the conformity assessment scheme cover?
   c. What aspect of the product / service / process / system / competency does the statement of conformity relate to?

2. **Certificate**
   a. What is the conformity statement which appears on certificates?
   b. What are the validity conditions of the certificate or the statement of conformity?
   c. How is the applicable certification system stated or referred to?

3. **Certification mark**
   a. How is the significance of the certification mark communicated to the market?
   b. Is there any significant risk of the certification mark being misinterpreted or misused?

4. Certification requirements

a. Identify the scheme documents where the requirements are stated?
b. How is it demonstrated that the requirements are possible to evaluate?
c. Are legal requirements included?
d. Does the scheme only contain legal requirements?
e. How is compliance with legal requirements determined?
f. Are there documents explaining or interpreting the requirements?
g. Have the documents under “f” been published?
h. Who is the author of the interpretation document(s)?

5. Certification system

a. Which is the evaluation method used in order to determine conformity?
b. How do you demonstrate that your method is suitable for supporting the conformity statement?
c. Which method do you rely on to monitor that the certificate holder continues to comply with requirements?
d. How do you demonstrate the suitability of your method in order to monitor that the certificate holder continues to comply with requirements?

6. Conditions

a. Which criteria are required for granting, maintaining, expanding, reducing, extending, suspending or revoking certification?
b. Is the definition of nonconformity in line with the competence standards for CABs and/or IAF guidance?
c. What rights and obligations are stipulated for the SO, certification bodies and the applicants?
d. What records are kept demonstrating continued compliance with the requirements?
e. What are the arrangements relating to registration of complaints by certificate holders?

7. Procedures

a. Are the certification procedures described and where?
b. Has the suitability of the procedures been demonstrated?

8. Expertise

a. Are there competency requirements for certification auditors?
b. Are there competency requirements for decision-makers?
c. Are there competency requirements for other staff members?
d. How has it been substantiated that the competency requirements are appropriate?

9. Public nature

a. Where are the scheme documents published?
b. Are they made public?
c. Does the SO have any market surveillance, for example list of certified products, services, etc.?