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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.

Authorship

The publication has been prepared by the EA HHC Committee

Official language

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

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1 SCOPE OF APPLICATION

This document contains the procedure and criteria to be used by EA members when evaluating, upon request by a scheme owner (SO), if a given conformity assessment scheme (CAS) is appropriate and acceptable as an EA MLA Level 4 CAS (see EA-1/06) and, if so, under which harmonized standards (EA MLA Level 3 – see EA-1/06) containing general requirements for conformity assessment bodies (CABs).

The acceptance of a CAS by an EA member requires:

- The identification of the most suitable standard to be used to assess the competence of the CABs participating in the CAS. Consequently that standard will be the one used as the reference for the accreditation of CABs;
- That the CAS and the scheme owner (SO) meet the requirements laid down in this document.

EA members' acceptance of a given CAS does not mean a judgment on the technical robustness, 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.

It is however the responsibility of the home AB (hAB – see 2.6) to ensure that the process undertaken for ensuring the technical robustness and market acceptability of the scheme by the SO was suitable and thorough.

This document includes a procedure to handle CAS running in several EA member countries and also a mechanism to manage the possible conflicts that in these cases could arise among EA members regarding the outcome of the evaluation of the CAS.

The acceptance of a CAS by a hAB does not place an obligation on other EA member NABs to also offer accreditation of conformity assessment activities in accordance with the scheme.

This document is of mandatory application of CASs in the voluntary field. The procedures and criteria contained in this document can, where relevant, also be applied for the evaluation of legally regulated national schemes.

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 EA members to SOs and CABs in relation to definition of the better 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 consumed.

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:

- Standardization bodies¹;
- 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.

National Accreditation Bodies (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: Specific 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.).

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.

2.6 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 CAS².

3 PREREQUISITES FOR THE ESTABLISHMENT OF RELATIONSHIPS WITH SCHEME OWNERS

An EA member 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 any CAS specific requirements are placed 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. Supplementary 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 supplementary requirements to ISO/IEC 17011 will not automatically be binding on other

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

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

- 3.8** CAS in the voluntary sector with requirements applicable to objects of conformity assessment shall neither contradict, nor simply be the fulfillment 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 scheme;
 - A description of the requirements of the scheme;
 - An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the scheme;
 - A description of the methods to be used for determining fulfillment of the requirements;
 - An analysis of the appropriateness of the described methods to be used for determining fulfillment 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 have reserved the use of the scheme to accredited CABs with which an agreement has been entered into. Such an agreement must guarantee at least that the CABs will use the scheme as it is, without any limitations and without any additions.
- 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 in general

When evaluating CASs for the purposes of accrediting CABs working within the CAS, EA member NABs shall use Annex 1 and should recommend to the applicant SO to use Annex 2 of this document. 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 is prepared to work with the NAB without contacts with other EA NABs until the evaluation is finished. If this is not the case then the CAS evaluation cannot proceed;
- It intends to operate the CAS in more than one EA country. If that is not the case, the SO shall be informed that the CAS will be evaluated at the national level only and that if the situation changes in the future the decisions of the NAB affecting the CAS can be challenged and modified;
- The CAS includes supplementary requirements to ISO/IEC 17011, Regulation (EC) 765/2008 and, where applicable, EA mandatory documents and IAF or ILAC documents endorsed by EA as mandatory. If that is the case, and the CAS is to be operated in more than one EA member country, the SO shall be informed that those supplementary requirements will need to be endorsed by the EA GA before the evaluation process by the NAB starts, and that this may introduce a considerable delay into the evaluation process.

4.2 Evaluation of a multinational CAS

Before starting an evaluation of a multinational CAS, a NAB shall inform the EA Secretariat that it has been approached by the SO and intends to perform the initial evaluation.

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

- The confirmation by the hAB that the CAS fulfills the requirements in this document, using a report based in elements in Annex 1;
- Identification of the standard to be used to accredit CABs, including a justification for the why the standard has been chosen;
- The documentation (or a link to the documentation) of the CAS (in English).

The EA Secretariat will inform all EA members that a new CAS is under evaluation and circulate the CAS documents and hAB evaluation report for a 30 day comment period.

During the comment period, the hAB cannot assess any CAB for activities related to the CAS under evaluation.

Once the comment period has finished, if no comments are 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.

The EA Secretariat shall report any negative comments for resolution to the hAB in the first instance. If agreement cannot be reached then it shall be escalated to the EA HHC Chair. A task force comprising the hAB, NABs having provided the comments, other NABs volunteering and the SO will be established to seek a solution. If consensus cannot be established within the task force group, it will be taken to the EA HHC.

Once the conclusions of the hAB have been confirmed and published on the EA intranet, any other EA member 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 should be raised via the hAB.

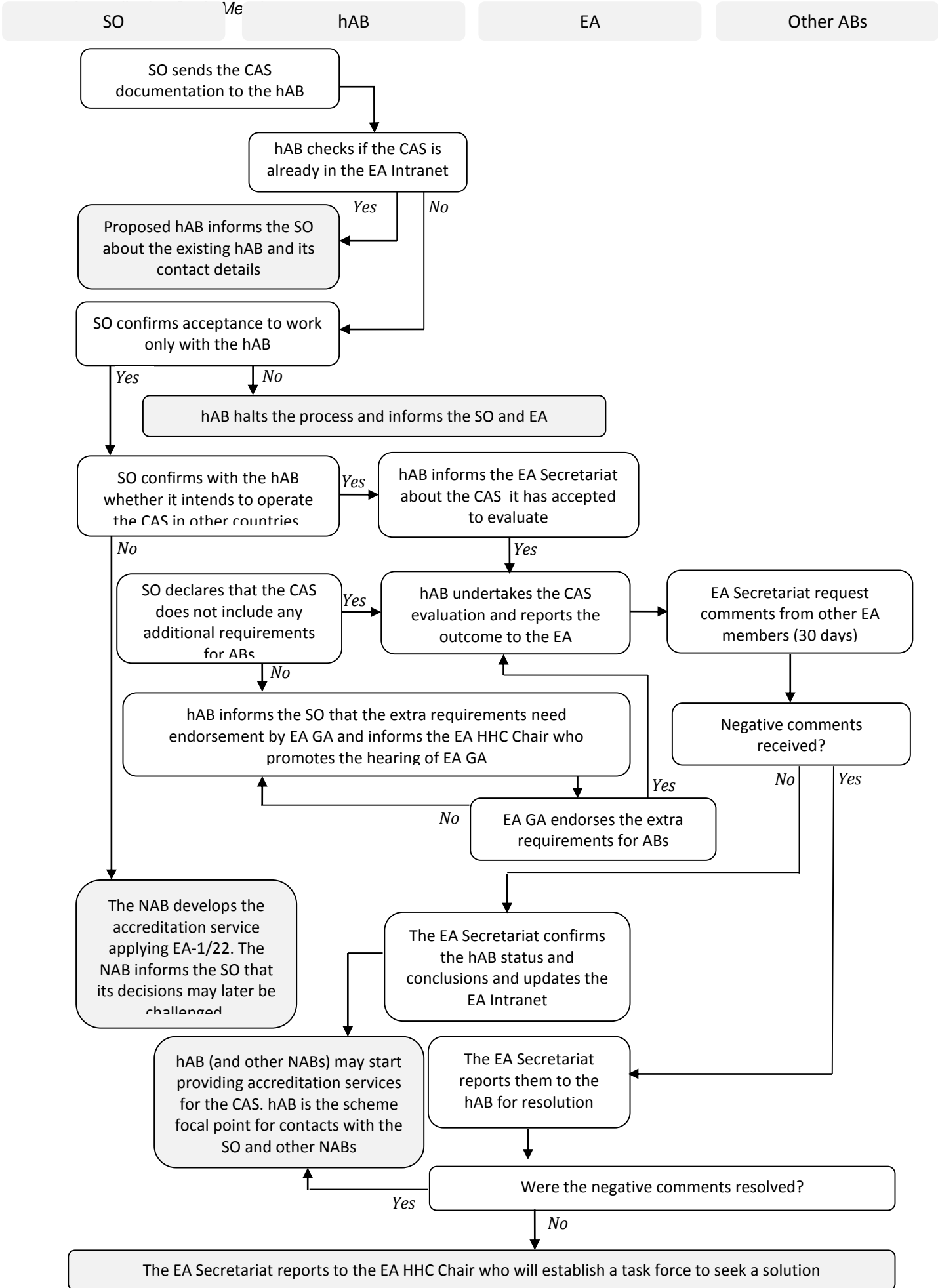
Cases may arise where a national CAS could expand into an international CAS, which could be driven by the market or CABs. In these cases, if a new active NAB has any strong objections with the CAS requirements the new NAB should contact the hAB regarding their concerns, which should initiate the process described above regarding negative comments.

Schemes already active only at national level need to be subject to the process defined in this document before they can be considered accepted multinational schemes.

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 next page.



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 schemes.

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 specify.
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 scheme, beyond requiring that they are accredited to the scheme requirements? If so, describe it and identify the scheme document(s) where this is stated.

5. Provide evidence of market support for the scheme.
6. Under which conformity assessment procedure(s) does the scheme operate? (For example product certification, testing, etc.) Include the rationale for your choice and identify the scheme document where it is established.
7. Has the SO established scheme 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 scheme document where this is stated and described.
10. Does the Scheme 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 scheme document where these are described.
11. Has the SO established scheme specific requirements for the operation of NABs? If YES, please identify the scheme 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 scheme 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 scheme 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 scheme? Where are these documented?

17. Does the scheme 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 the SO needs to demonstrate that it has protected those marks and laid down rules for their use. The SO shall monitor compliance with those rules.

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 the interested parties for the CAS were analysed and identified. Relevant interested parties shall be consulted.

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 be considered are:

- Is the conformity assessment, as described, practicable?
- Does 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 EA members. 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)	<ul style="list-style-type: none">• 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

Conformity assessment activity	Description of (at least):
	<p>standards set out within the sector or specifications of a group of manufacturers;</p> <ul style="list-style-type: none"> • Specific requirements concerning e.g. internal and/or external quality control procedures and/or performance characteristics, if any.
Inspection	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • The object of certification: <ul style="list-style-type: none"> ○ Management systems; or ○ Products, services and processes; or ○ 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 non conformity 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?