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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).

Authorship

The publication has been prepared by the EA Horizontal Harmonization 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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1 SCOPE OF APPLICATION

1.1 This document describes:

- I. The requirements to be fulfilled by the Scheme Owner (SO) (Clause 3).
- II. 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). This will fulfil the requirements of ISO/IEC 17011: 2017 Clause 4.6. to have procedures to determine the suitability of conformity assessment schemes and standards for accreditation purposes.
- III. The process established by EA to provide a common approach to CAS operating in different EA member countries (Clause 4.2).
- IV. The evaluation of a CAS owned by the European Commission (Clause 4.3).

1.2 General provisions for application:

- a) This document is of mandatory application by NAB's for 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 SO holding contractual agreements with the CABs operating within the CAS.
- c) 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.
- d) 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 NAB.
- e) If a CAS is in the sub scope of IAF MLA or ILAC MRA (and the SO is signatory of MoU), the CAS is automatically accepted by EA in line with IAF MLA/ILAC MRA under principle of multilateral recognition and will not be evaluated by EA. The CAS accepted by IAF/ILAC is monitored by IAF/ILAC and will not be included in the list of EA evaluated schemes.

After an EA evaluated CAS is presented by the SO to IAF/ILAC, resulting in acceptance of the scheme by IAF/ILAC, the monitoring of the CAS by EA (represented by the Home Accreditation Body (hAB)) will be terminated and the CAS will be deleted from the list of EA evaluated 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, e.g. product, process, service, system, person;
- The requirements against which conformity is to be assessed;
- The mechanism by which conformity is determined, e.g. testing, inspection, verification, validation 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.

For the purposes of this document, an international CAS is one where CABs legally established in more than one EA member country are involved and more than one NAB is requested to provide accreditation for the CAS in question.

It should be noted that being an international CAS does not depend on the locations where the object of the conformity assessment is utilised.

This document does not apply to CAS only established by a CAB and used by that CAB only. Nevertheless, the content of annex 2 may be used as a guidance for the validation of the CAS by the CAB.

Where all the requirements for a CAS are documented in one single standard (def. of ISO/IEC Guide 2) published by international, regional or national standardisation body, the evaluation of the CAS according to this document is not applicable.

2.2 Scheme owner (SO): A scheme owner is an organization responsible for developing and maintaining a specific CAS. The following are examples of SOs:

- Standardisation 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.

NABs cannot be SOs.

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

- 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 and may have the right to use the SO's mark.
- 2.4 Scheme specific requirements for NABs:** Additional requirements to any ISO/IEC 17011 requirements for a particular CAS established by the SO. Additional requirements are defined as requirements that will result in additional efforts for the NABs with regard to resources, specific procedures, time spent on assessments, reporting, training and competence of assessors, keeping records, collecting data, fees etc.
- 2.5 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. 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.
- 2.6 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 and in clause 4.1 of this document.
- 2.7 Acceptance of an international CAS (by EA):** confirmation of the satisfactory evaluation of the CAS by the hAB and publication on EA intranet.

Note: EA acceptance of a given CAS does not mean a judgment on the market value or usefulness of the technical requirements of the CAS.

3 MANDATORY REQUIREMENTS FOR SCHEME OWNERS AND CONFORMITY ASSESSMENT SCHEMES

3.1 Requirements for SOs

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

- 3.1.1** The SO shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its activities.
- 3.1.2** The SO has the authority to establish and change the requirements of the CAS.

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

- 3.1.3** The SO shall have the mandate to cooperate with the NAB or hAB. The SO shall have a mechanism to provide for feedback from the NAB or hAB on the operation of the CAS.

Note: Where for some reason (e.g. no accredited CABs anymore), the actual hAB is no longer willing to act as the hAB, the hAB will inform the SO. It will be the responsibility of the SO to ask another NAB to take over the role as hAB.

- 3.1.4** The SO shall be able to demonstrate that there is a need in the market for the CAS. This may include demonstration of added value, the involvement of interested parties, government initiatives or regulatory needs. The SO shall be able to provide evidence of market need for the CAS coming from relevant interested parties.

Note: 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 need is the viewpoint of interested parties representing the CAS end-users (e.g. consumers or industry).

- 3.1.5** 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 in the CAS.

- 3.1.6** 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;
- In case of an ISO/IEC 17065 scheme, and as mentioned in Clause 6.2 of that standard, the identification of the applicable requirements of the relevant International Standards. The same applies to an ISO/IEC 17020 scheme where reference is made to testing
- 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.

Note: validation might not be required in the case of evaluation of an existing (old) CAS which has been used for accredited conformity assessment purposes.– see 4.2.2.b Evaluation of a CAS operated before 21st of May 2015 below.

- 3.1.7 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.
- 3.1.8 The SO shall be responsible for keeping the hAB and CABs informed of any relevant information and developments relating to the CAS, including in particular any proposed change in requirements.
- 3.1.9 The SO shall be prepared to pay for the costs of the evaluation of its CAS by the NAB or hAB.
- 3.1.10 The SO shall commit in writing to comply with the evaluation procedure.

3.2 Requirements for CASs

- 3.2.1 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).
- 3.2.2 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 3.2.1.
- 3.2.3 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.

Any requirements for NABs must be included in the CAS and may not be enforced by MOU's or other contractual agreements with (individual) NABs

Scheme specific requirements to ISO/IEC 17011 to NAB's 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 be considered as Scheme specific requirements to NABs and will not automatically be binding on other NABs. These requirements will first need to be accepted and endorsed by the EA GA.

The EA secretariat will maintain an overview of additional requirements for all of the CAS that have been successfully evaluated according to EA-1/22.

- 3.2.4 CASs in the voluntary sector shall neither contradict, nor simply be the fulfilment of, applicable legal requirements.

4 CONFORMITY ASSESSMENT SCHEME EVALUATIONS

4.1 Evaluation of all CASs

4.1.1 Common approach

This clause describes the mandatory procedure and criteria to be used by NABs when evaluating, whether a given CAS is suitable for accredited conformity assessment activity'

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 CAB(s) participating in the CAS: This shall be determined by considering the nature of the conformity assessment activities and the content of the statement of conformity. Consequently, that standard will be the one used as the reference for the accreditation of CAB(s).
Note: The CAS may need to be changed on some elements in order to enable CAB(s) 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 NAB's 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 CAB(s) 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 CAB(s) 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 shall inform the NAB, in writing, that it intends to operate the CAS in more than one EA country and consequently, 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 there will be no hAB, that EA NABs will not be obliged to follow a common approach and therefore it will have to deal with each NAB where it operates separately, and consequently accept any 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 an international 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) to determine the acceptability 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. It provides 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.

The hAB will be the contact between SO and EA

This process is mandatory for all NABs

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.a Initial evaluation of a new CAS

Step 1: SO's agreement and choice of hAB

Before starting an evaluation of an international 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 contact 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: EA registration of CAS in process

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: Analysis by hAB

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. A report giving evidence on the elements in Annex 1, supporting why the NAB deems the scheme as compliant with the requirements of this document.
- ii. Confirmation 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: EA Consultation

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 and or the CAS requirements. The NABs that have proposed to assess CABs shall provide these CABs with the same information. However, where assessment work does commence before the commenting stage is finalised, accreditation cannot be granted before the CAS has been accepted.

Step 5: EA Conclusion and registration on the list of CAS Accepted

Once the comment period has finished, if no negative 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 (r)

After the successful evaluation of the CAS, the name of the CAS, including version number and/or date and the conformity assessment standard used for accreditation, will 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. If a CAS consists of various modules, where not all modules were part of the evaluation, only the evaluated modules will be identified in the list.

Step 6: Process for dealing with negative comments

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.

As the last possibility to reach a decision, the HHC chair may decide to ballot.

4.2.2.b Evaluation of a CAS operated before 21st of May 2015

This chapter applies to international CASs that were in operation (on one or more scopes of more than one NAB) before 21st of May 2015 for which the SO introduces changes / puts up new versions of the CAS. For all other international schemes, the process of 4.2.2.a applies.

Steps 1 and 2 apply in full

Step 3: In addition to what is described under step 3 the SO shall identify all the EA NABs implementing the CAS and demonstrate to the hAB what measures have been taken so the

NABs currently accrediting CABs for the scheme perform the accreditation in a harmonized way (at least use the same conformity assessment standard). At this stage, the SO may need to revise some requirements of the scheme to ensure a harmonized implementation following the analysis made at step 3 and the feedback from the hAB. The hAB will document this in the evaluation report.

The hAB evaluation report will mainly focus on providing confidence that the scheme is implemented in a harmonized way in EA. For these CASs it is not necessary to redetermine the conformity assessment standard chosen, as accreditations are already delivered by more than one NAB.

Conditions where a scheme cannot be accepted -by EA NABs should be specified including when:

- some NABs don't use the same conformity assessment standard,
- the SO demonstrates disharmonized implementation by NABs,
- the SO would like to change the conformity assessment standard,
- or for another cases of dispute.

Steps 4, 5 and 6 apply in full.

4.2.2.c Responsibilities of NABs operating an accepted CAS

NABs commit themselves to accredit CABs participating in the CAS according to the standard and conditions established by the home AB.

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 shall inform the hAB and, in accordance with EA-1/06 5 (r), make publicly accessible, 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. In this case, the NAB accrediting CABs for the national scheme will be appointed as hAB and the process as outlined in 4.2.2.a shall be followed.

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.

4.2.2.d Changes of a CAS

The SO shall inform the hAB as soon as possible of any proposed revision for all or for part of the CAS. This information shall identify all the changes in the CAS and will provide a documented evaluation of their impact on the initial validation of the CAS. Where applicable, the SO shall also include information on the transition requirements (e.g. deadline and arrangements for CABs and for clients of CABs).

The hAB informs the active NABs and the EA secretariat that it has received a request to evaluate a revision of the CAS and that further communication will follow from the hAB. NABs which have advised the hAB that they are offering accreditation to the scheme are considered as active NABs.

The hAB will evaluate the impact on the accreditation process and on the validation of the CAS. If the conformity assessment standard was to change then this would require a full evaluation of the CAS as described in 4.2.2.a. The same applies in case there are additional requirements to NAB's (refer to 3.7).

Evaluation 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 SO, other active NABs and of the conclusions and decisions.

The hAB will send the results of the evaluation and documentation to the other NAB's for a commenting period

In case of comments, the SO shall be informed by the hAB. The SO shall take appropriate actions to the given comments which do not contradict the transition period

After completion of the evaluation process of the new version of the CAS, the EA secretariat will update the EA list of CAS evaluated according to EA-1/22 with revision date and or number of the CAS and will inform all NABs accordingly.

4.3 CAS owned by the European Commission (EC)

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 or TMB once established, and will involve the input of a task force competent in the area of the scheme that shall report directly to the Executive committee or Technical Management Board once established, 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.

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 and is considered mandatory to be provided by the SO. 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 and information requested, 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 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 NAB, please provide details and outcome of the evaluation.
3. 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.;
4. Provide evidence of market need for the scheme.
5. Under which conformity assessment standard(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 specified.
6. Is the CAS intended to be used only at a national level? If no, please specify geographical area of acceptance, for example a few European countries, all of Europe or global.
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 yes, refer to the CAS document where it is described. Does the SO perform any other 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 the activity and identify the CAS document(s) where this is stated.
9. If the answer to the first question under 8 is yes, does the SO request the NABs to accept or take into account such an assessment during the accreditation process? If yes, please identify the CAS document where this is described.
10. Does the CAS request EA or EA members to cooperate with the SO on issues other than accreditation of CABs? If yes, 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 and submit a copy of the certificate containing the specific attestation.
(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 CAS normative document are able to derive from the contents of the normative document have 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, , valid and specific.

14. Are all measurement values expressed in SI units (International System of Units)?
15. 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** (where applicable), including the frequency and extent of surveillance activities and reassessments to ensure the object of conformity assessment continues to fulfil the specified requirements.

16. 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.)
17. Are there test methods or inspection procedures involved in the CAS? Where are these described?
18. Does the CAS consider the use of marks of conformity? If yes, the SO shall provide evidence to demonstrate how it has protected those marks and laid down rules for their use in accordance with the requirements of the conformity assessment standard chosen.
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 any issue has been solved”.
21. Provide evidence that the CAS is validated, considering the details given in clause 3.1.6. As a minimum validation must demonstrate that the CAS has successfully completed a test period, demonstrating that it is ‘fit for purpose’ (i.e. capable of consistently achieving its stated objectives). As a minimum the validation should demonstrate that:
- the conformity assessment, as described, is practicable?
 - 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?
 - the requirements are specified in a way that ensures reproducibility and reliability of results?
22. For the evaluation of existing CASs the SO shall identify all the EA NABs implementing the CAS and demonstrate to hAB what measures have been taken so that the NABs currently accrediting CABs for the CAS perform the accreditation in a harmonized way.

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).

Also following guidelines provide examples of certification schemes:

ISO/IEC 17026 Example of a certification scheme for tangible products

ISO/IEC TR 17028 Guidelines and examples of a certification scheme for services

ISO/IEC TR 17032 Conformity assessment -- Guidelines and examples of a certification scheme for processes

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.

Laboratory activity/ Conformity assessment procedure	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. 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.
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 laid down in 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

(Depending on the kind of CAS some of the questions may be not applicable)

1. Object

- a. What is the object of certification;
- b. Which (group of) products / services / processes / systems / person competencies does the conformity assessment scheme cover?
- c. What characteristics 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 certification scheme stated or referred to?

3. Certification mark

- a. Is the use of the mark fulfilling the requirements the selected conformity assessment standard?"
- b. How is the significance of the certification mark communicated to the market?
- c. 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 be evaluated?
- 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?

5. Certification scheme

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

6. Conditions for certification

- a. Which criteria are required for granting, maintaining, expanding, reducing, extending, suspending or withdrawing certification?
- b. Is the definition of non conformity in line with the applicable conformity assessment standards and IAF guidance?

- c. What rights and obligations are stipulated for the SO, certification bodies and the applicants?
- d. What records are required to be kept by CABs demonstrating continued compliance with the requirements?
- e. What are the arrangements relating to registration of complaints by certificate holders?
- f. Is the client clearly defined and fulfilling the requirements of standard used for accreditation?
- g. how it is demonstrated that the certification requirements substantiate the characteristics of the object that the statement conformity relates to?
- h. how it is demonstrated that the certification process fulfil all certification process requirements of the chosen standard used for accreditation?

7. Procedures

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

8. Competence

- a. Are there competence requirements for each function of the certification process
- b. How has it been substantiated that the competence 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?