



IAF Mandatory Document



CRITERIA FOR EVALUATION OF CONFORMITY ASSESSMENT SCHEMES

Issue 1

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The International Accreditation Forum, Inc. (IAF) facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members are accepted globally.

Accreditation reduces risk for business and its customers by assuring them that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that are members of IAF and the CABs they accredit are required to comply with appropriate international standards and the applicable IAF application documents for the consistent application of those standards.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are regularly evaluated by an appointed team of peers to provide confidence in operations of their accreditation programs. The structure and scope of the IAF MLA is detailed in IAF PR 4 – Structure of IAF MLA and Endorsed Normative Documents.

The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of a Level 2 activity and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- The main scope of the MLA includes activities e.g. product certification and associated mandatory documents e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.
- The sub scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO TS 22003. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

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Introduction to IAF Mandatory Documents

The term “should” is used in this document to indicate recognised means of meeting the requirements of the standard. A Conformity Assessment Body (CAB) can meet these in an equivalent way provided this can be demonstrated to an Accreditation Body (AB). The term “shall” is used in this document to indicate those provisions which, reflecting the requirements of the relevant standard, are mandatory.

Criteria for Evaluation of Conformity Assessment Schemes

0. SCOPE

This document contains minimum requirements for conformity assessment schemes (CAS) to be applied by IAF member ABs when evaluating national, regional or international CAS to ensure they meet requirements specified in ISO/IEC 17011, Clause 4.6.3.

Note: Criteria for the inclusion of a CAS into the IAF MLA can be found in IAF PL3.

This document does not apply to CAS:

- That are included or invoked by legislation/regulation, and/or
- Developed by national, regional or international standardisation bodies.

However, this does not preclude a CAS that is included or invoked in legislation from being evaluated in accordance with this document.

Note 1: While ABs may still accept a CAS owned by regulators and provide accreditation, provided these do not contradict the applicable international standards, they may encourage regulators to follow international best practices.

1. NORMATIVE REFERENCES

For the purpose of this document, the normative references shall be the international standards used for accreditation (see the CASCO toolbox available on the ISO website <https://casco.iso.org/toolbox.html>).

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in the normative references above, ISO/IEC 17000 and the following apply.

2.1 Conformity Assessment Scheme (CAS):

Set of rules and procedures that describes the object of conformity assessment, identifies the specified requirements and provides the methodology for performing conformity assessment (Source ISO/IEC 17000).

2.2 Scheme Owner (SO):

Organization(s) responsible for developing and maintaining a CAS. The following are illustrative examples of SOs:

- Standardization bodies;
- CABs;
- Organizations that use services provided by CABs;
- Organizations that buy or sell products subject to conformity assessment activities;
- Manufacturers and their associations that have established their own CAS;
- Organizations set up specifically for that purpose; and
- Governmental Authorities including regulators and other governmental bodies.

2.3 SO Authorization of a CAB:

SO authorization means that the SO accepts certificates, reports, statements or attestations issued by a CAB for the purposes of confirming that the object of the conformity assessment meets the requirements of its CAS.

Note: SOs may use different wording to denote/state/describe authorization, such as listing, approval, recognition, designation, etc.

2.4 Scheme Specific Requirements for CABs:

This refers to specific requirements for the CAB prescribed by the SO for operating under its CAS, in addition to the AB's rules and the applicable IAF Level 3, International Standard.

Note: IAF Levels can be found IAF PR4 https://iaf.nu/en/iaf-documents/?cat_id=8

2.5 Scheme Specific Requirements for ABs:

This refers to specific requirements for the ABs prescribed by the SO for undertaking accreditation activity related to the CAS in addition to, but not excluding, any IAF/Region's rules nor ISO/IEC 17011 requirements.

2.6 Regulator:

Governmental entity implementing legislation.

(Adapted from ISO 17000)

3. REQUIREMENTS FOR THE SOs

ABs shall ensure that the following conditions are met before cooperating with an SO, unless any of the conditions are not applicable to a specific CAS:

3.1 Sufficient evidence and justification that the conformity assessment activity and the standard selected for the accreditation of the CABs is appropriate shall be maintained.

3.2 The SO shall make a general description of the CAS publicly available without request. The scheme documents, including the criteria and process to be used in assessing conformity shall be publicly available.

3.3 The SO should demonstrate that the CAS has been validated. The validation should be documented and include the following aspects:

- i) A description of the purpose of the CAS;
- ii) A description of the requirements of the CAS;
- iii) An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the CAS;
- iv) A description of the methods to be used for determining fulfilment of the requirements;
- v) An analysis showing that the described methods to be used for determining fulfilment of the requirements are appropriate;
- vi) The decision on the conformity assessment activity to be used (including identification of the applicable conformity assessment standard); and
- vii) An analysis showing that the selected conformity assessment activity is appropriate.

Note: The validation can be in terms of pilot audits or by demonstrating that the scheme is based on available international or national standards.

3.4 In case the SO provides any clarification on the CAS to any interested party, this information shall also be available to the ABs and CABs within the CAS.

3.5 The SO shall have a legally enforceable agreement with ABs and/or CABs it authorizes which, as a minimum, shall ensure that the CABs use the CAS as published by the SO, without any additions or reductions, and comply with SO rules for applying the symbol/statement/mark, as applicable.

3.6 The SO shall have a procedure for dealing with complaints relating to the CAS, ensuring that complaints processes of CABs' clients, CABs and ABs are not affected. Investigation and decision on complaints shall not result in any discriminatory actions.

Note 1: A description of the complaints handling process can be publicly available with or without request.

Note 2: Guidance on the complaints handling process is available in ISO 10002.

3.7 An arrangement describing the relationship and the terms of cooperation between the SO and the AB(s) should be established. Any requirements for ABs shall be part of the CAS and not individual arrangements.

3.8 If the SO monitors the CABs, it should consider cooperation with the ABs and have a feedback mechanism to provide information on the performance of the CABs to the ABs concerned

3.9 The SO should have a process for a periodic review of the CAS taking into account the experience gained and the feedback received from parties interested in the CAS.

3.10 The SO should monitor the development and review of the standards and other normative documents, whether its own or external, which define the specified requirements used in the scheme. Where changes in the normative documents of the CAS occur, the SO should have a process for making the necessary changes in the CAS, and for managing the implementation of the changes (e.g. transition period) by the Conformity Assessment Bodies' clients and, where necessary, other parties interested in the CAS.

Note: It is expected that the SO notifies the ABs before implementing the changes.

3.11 Changes to the CAS that affect the output of the CAS, should be validated (see 3.3).

4. REQUIREMENTS FOR A CAS

4.1 The CAS should cover the following elements:

- i) **Selection** of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities;

- ii) **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;
- iii) **Review, decision and attestation**, including the review of evidence from the determination stage. Conclusion based on the results of the review as to whether fulfilment of specified requirements has been demonstrated 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; and
- iv) **Surveillance and recertification, as applicable**, systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

4.2 A CAS shall include the following:

- i) The objectives of the scheme for the specific industry or user group;
- ii) The object of conformity assessment, e.g. product or process or person or claim;
- iii) The requirements against which conformity is to be assessed;
- iv) The conformity assessment process used in order to determine conformity of the object. This process shall fall under the scope of one of the IAF MLA Level 3 standards without any contradictions or exclusions;
- v) Any specific applications or explanations of ISO/IEC 17011 (e.g. specific competence criteria for assessors/technical experts/assessment teams, assessment criteria, specific details in the assessment reports), if applicable; and
- vi) Any specific application or explanation of accreditation standard at Level 3, e.g. ISO/IEC 17021-1, ISO/IEC 17065, ISO/IEC 17024/ ISO/IEC 17029 (e.g. specific competence criteria for auditors/evaluators/inspectors/technical experts/audit teams, audit/evaluation/inspection criteria, specific details in the audit/evaluation/inspection reports), if applicable.

4.3 Where applicable, the requirements in the CAS should be written in terms of results or outcomes, together with limiting values and tolerances.

4.4 The requirements in the CAS should be stated unambiguously using wording that is objective, logical, valid and specific and enable consistent application by organizations as well as evaluation across CABs.

4.5 Where the CAS includes legal requirements, these shall be formulated in such a way that compliance is a condition for outcome of conformity assessment.

4.6 The CAS should describe the method used to monitor that the certificate or attestation or statement holder continues to comply with the requirements, if applicable.

4.7 Where the SO authorisation (2.3) is given before accreditation, which implies that the CAB can perform conformity assessment activities covered by the CAS and may have the right to use the SO's mark, the CAS shall require the CABs to be accredited in a defined period of time.

4.8 The CAS shall specify the statement of conformity which appears on the conformity assessment documents.

4.9 Where the CAS provides for the use of certificates, marks or other statements of conformity, there should be a license and/or rules or another form of enforceable agreement to control such use. Licenses can include provisions relating to the use of the certificate, mark or other statement of conformity in communications about the object of conformity assessment, and requirements to be fulfilled when the certification is no longer valid¹.

4.10 The CAS may specify a manner by which the SO monitors CABs, beyond requiring that the CABs are accredited to the CAS requirements.

4.11 If any CAS specific requirements are placed on ABs, they shall not contradict or exclude any of the requirements of ISO/IEC 17011, relevant IAF guidelines, policies and other requirements.

5. EVALUATION PROCESS

5.1 Individual ABs may design the process of evaluation of the CAS based on their needs and context considering the requirements in this document as minimum.

5.2 Evaluations should typically be completed while accepting a new SO or CAS and subsequently if there are any changes in a scheme.

¹ For verification and validation, validity of the statement is not applicable.

Note: The changes made in the scheme have to be evaluated by the AB before the changed scheme is published.

5.2.1 An evaluation of a CAS can be remote (offsite); however, should the AB feel it necessary, an onsite evaluation may be undertaken.

5.3 To support SOs and CAS', ABs may collaborate on the evaluation process as long as the ABs continue to meet their processes, IAF documents and ISO/IEC 17011 requirements. Collaboration may include:

- ABs performing an evaluation collectively.
- An AB may request another AB's evaluation results which should be provided per the request, without undue delay, provided there are no confidentiality or proprietary concerns.
- Any differences by the ABs in the evaluation results should be discussed among the ABs and, if needed, considered by the scheme owner and/or IAF Technical Committee.

End of IAF Mandatory Document Criteria for Evaluation of Conformity Assessment Schemes

Further Information

For further Information on this document or other IAF documents, contact any member of IAF or the IAF Secretariat.

For contact details of members of IAF see the IAF website: <http://www.iaf.nu>.

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