# ISAB MD 25: Criteria for Evaluation of Conformity Assessment Schemes

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## 0. SCOPE

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

## 2. TERMS AND DEFINITIONS

- **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.
- **2.2 Scheme Owner (SO):** Organization(s) responsible for developing and maintaining a CAS.
- **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.
- **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 ISAB Level 3, International Standard.

- **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 ISAB/Region's rules nor ISO/IEC 17011 requirements.

# 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.
- **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.
- **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.

# 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:**

- The objectives of the scheme for the specific industry or user group;
- The object of conformity assessment, e.g. product or process or person or claim;
- The requirements against which conformity is to be assessed;
- The conformity assessment process used in order to determine conformity of the object. This process shall fall under the scope of one of the ISAB MLA Level 3 standards without any contradictions or exclusions;
- 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
- 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, if applicable.

**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.

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

**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 ISAB 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.
- **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, ISAB documents and ISO/IEC 17011 requirements. Collaboration may include: ABs performing an evaluation collectively; an AB requesting another AB's evaluation results; discussing differences in evaluation results.