



**Criteria for Determination of Suitability  
and Acceptance of Conformity  
Assessment Schemes for  
Accreditation Purposes**

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## 1 Purpose

This document describes the ENAO Policy and the procedure for determination of suitability and acceptance of Conformity Assessment Schemes for the purpose of covering them under Scope of Accreditation of Conformity Assessment Bodies (CABs) to meet the requirements of ISO 17011-2017.

## 2 Scope

The ENAO policy and procedure as described in this document are applicable to all Conformity Assessment Schemes (CAS) for the broad categories of accreditation schemes operated by ENAO namely, accreditation schemes for specific management systems certification, product / process certification, inspection, personnel certification, and validation and verification.

## 3 References

The following documents are referenced:

ISO/IEC 17000, Conformity Assessment – Vocabulary and general principles

ISO/IEC 17011:2017 Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17007:2009 Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

ISO/IEC 17067: 2013 Conformity Assessment- Fundamentals of Product Certification and Guidelines for Product Certification Schemes

ILAC and IAF mandatory documents and guidance as applicable

Regulation No. 195/2010, Council of Ministers Regulation to provide for the establishment of the Ethiopian National Accreditation Office, revised Regulation No. 279/2012 and re-revised Regulation No. 421/2017 Council of Ministers Regulation to Provide for Re-establishment of the Ethiopian National Accreditation Office.

## 4 Terms and definitions

For the purpose of this document, the terms and definitions given in the normative references above and the following apply.

### 4.1. Conformity Assessment Scheme (CAS):

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

#### **4.2 Scheme owner (SO):**

Organization(s) responsible for developing and maintaining a specific conformity assessment scheme. The following are 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 Authority

#### **4.3 Scheme owner authorization of a conformity assessment body:**

SO authorization 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.

#### **4.4 Scheme specific requirements for conformity assessment bodies:**

This refers to specific requirements on the conformity assessment bodies laid down by the SO, in addition to AB's rules and any International standard.

### **5 Responsibility**

It is the responsibility of the Director General of ENAO and the accreditation team leader or responsible persons to implement this document.

### **6 Types/Categories of Conformity Assessment Schemes**

- 6.1.** The Conformity Assessment Schemes for which the CABs offer conformity assessment (certification, inspection, validation and verification) generally belong to one of the following categories:

a) Internationally known Conformity Assessment Schemes which are owned by independent bodies (called scheme owners) and are operated at a global level by various CABs, approved by the scheme owners directly or based on accreditation by Accreditation Bodies recognized by the scheme owners. These schemes are generally developed by the scheme owners in accordance with the principles described for example in clauses 5 and 6 of ISO/IEC 17067:2013 for product / process certification and are operated under their control by approved (generally accredited) CABs. e.g., Global Gap Scheme, FSSC 22000 Scheme.

b) Conformity Assessment Schemes embodied in regulations promulgated under the control of respective governments e.g., CE marking scheme in European Union.

c) Conformity Assessment Schemes developed by governmental agencies or operated by regulators even if voluntary e.g., Product Certification schemes Ethiopian Standards Agency.

d) Conformity Assessment Schemes developed by nongovernmental agencies in fulfillment of their organizational objectives. These could be developed by group of industries / industry associations, purchasers, distribution / retail chains, consumers / consumer associations, trade associations etc.

e) Conformity Assessment Schemes which are developed and operated by CABs themselves.

## **7 ENAO policy for acceptance of Conformity Assessment Schemes for the purpose of accreditation**

7.1. Conformity Assessment Schemes belonging to any of the types/categories as specified at Cl 6 above are acceptable provided they meet the generic criteria/requirements as specified in section 9 of this document and their suitability is established. However, in case of schemes belonging to categories specified in 5.1 a) and b), exceptions may be accepted at the discretion of CEO ENAO. The reasons for permitting such exceptions/deviations are:

a) In case of 5.1 a) the scheme owner would be an independent body who takes responsibility for validation of the scheme. The scheme should have been in the market for some time (at least 2 years) with evidence of its acceptance by the relevant stakeholders, which would be deemed to have automatically validated the scheme. In case of new schemes, if all the requirements of this document are met

with, then the same may be accepted even without having been in the market. However, the scheme will be subjected to a review by ENAO after 2 years of their acceptance.

b) In case of 5.1 b) the government/ regulator being the scheme owner takes responsibility on behalf of the stakeholders. It should not prevent ENAO from advising the government/regulator on the desirability of aligning the scheme with the policy and criteria laid out in this document which is based on international norms. In all other cases the schemes would be required to meet the criteria laid down in section 9 of this document.

**7.2.** The evaluation for determination of suitability of Conformity Assessment Scheme shall be done by ENAO at the time the application for accreditation for a specific scheme is made by any CAB for the first time. Once a specific scheme has been evaluated and accepted by ENAO, the same shall not be reevaluated in case any other CAB applies for accreditation for the same scheme. ENAO may decide to reevaluate the scheme, when any major changes occur in the contents of the scheme.

## **8. Requirements for the Scheme Owners**

### **8.1 Legal status**

The Scheme Owner shall be a legal entity. Governmental scheme owner is deemed to be a legal entity on the basis of its governmental status. In cases where the CABs themselves are the scheme owners, the legal status of the scheme owners shall be that of the certification bodies themselves. In respect of other type of scheme owners, the legal entity status shall be established and demonstrated.

### **8.2 Governing structure of SO and responsibilities**

The SO and CAS governance shall be such as to ensure that there is no conflict of interest, which could call into question its impartiality and integrity. SO and CAS governance may be separated or the same.

The scheme owner shall have in place adequate resources to effectively manage the scheme's day to day operations, and there shall be in place a defined organizational and reporting structure, key job descriptions and documented operating procedures.

**8.3** The scheme owner shall be able to take on full responsibility for the objectives, the content and the integrity, validity and robustness of the scheme. During the development of the scheme, the scheme owner should evaluate and manage the

risks/liabilities arising from implementation of the scheme and provide appropriate safeguards in such a way that the objectives of relevant Conformity Assessment to be met. Based on evaluation, the scheme owner may prescribe minimum requirements for the professional liability insurance limits for the CAB approved for operating the scheme.

- 8.4** The SO shall be able to demonstrate market need or support for the CAS nationally or regionally or internationally for evaluation by an AB or Region or IAF. Such support may include government initiatives or regulatory needs. Of particular relevance and importance in the demonstration of market support is the view of interested parties representing the CAS end-users (e.g. consumers or industry).
- 8.5** The scheme owner shall have a documented procedure in place. The SO shall have established, maintained and implemented a documented procedure for its operation including identification of the relevant documents that are applicable to its operations. The documented procedure shall enable the SO to comply with the requirements specified in this document.
- 8.6** The SO shall have implemented effective procedures for dealing with complaints related to the CAS. A description of the handling process for complaints and appeals shall be publicly available without request. Investigation and decision on complaints shall not result in any discriminatory actions.
- 8.7** An arrangement describing the relationship and the terms of cooperation between the SO and the IAF or Region or AB should be established.
- 8.8** An agreement describing the relationship and terms thereof between the SO and CABs shall be established indicating that the SO has reserved the use of the scheme to CABs accredited by ABs who are members of IAF to operate under the scheme. The agreement between SO and CABs must, as a minimum, guarantee that the CABs shall use the scheme as it is, without any limitations and without any additions.
- 8.9** The SO shall clearly define the scope of its operations and the applicability of the conformity assessment scheme's normative documents. The SO shall prepare the conformity assessment scheme documents, guides and procedures, in a transparent, open, impartial and coherent manner.
- 8.10** The scheme owner shall maintain all the information for the participation on the scheme, offered services and related fees available, along with/alongside the information on certificates that are held or granted, on scopes, etc.

**8.11** The scheme owner shall document the content and description of the scheme. The description shall be detailed enough to enable the CABs to implement the same in an unambiguous and consistent manner. The scheme documents such as like certification criteria, certification process, requirements for CABs etc shall be publicly available to all stakeholders on its website. The SO can provide general guidance to Conformity Assessment Bodies and any organizations regarding the scheme. This information shall be available to the interested ABs and CABs.

**8.12** The SO shall make a list of CABs who are authorized and operate under the CAS publicly available without request, indicating the date of authorization (optional), the date of validity (if applicable) and the scope authorized for (as applicable) besides address and other contact details

## **9. Requirements and criteria for evaluation of suitability of the Conformity Assessment Schemes**

9.1. The criteria have prescribed requirements in following verbal forms:

- a) "shall" indicates a mandatory requirement.
- b) "should" indicates a typical means for meeting a requirement, and if an alternative means is used it shall be provided if there is a suitable and adequate justification.
- c) "may" indicates a permission.

### **9.2 Development of Conformity Assessment Schemes**

9.2.1. The scheme owner shall set up an institutional structure for the development, operation and management of the scheme. The scheme owner shall ensure that the scheme is developed by persons competent in both technical and conformity assessment aspects. In cases where the CAB itself is the scheme owner, the structure may be created within the legal entity; however, it shall be independent from the structure involved in operation of the conformity assessment (certification, inspection, validation/verification). All the requirements applicable to the scheme owner as described in this document then will be applicable to this structure with in the CAB.

9.2.2. To ensure that the scheme owner understands the assumptions, influences and consequences involved in establishing, operating and maintaining a scheme on an ongoing basis and take part in the decision-making, the scheme owner shall identify stakeholders and seek their opinions and participation in development of the scheme keeping balance of interests in view. The participation mechanisms for any

interested party, as well as the names of the organizations that are involved, shall be documented and made publicly available.

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

i) description of the purpose of the CAS;

ii) description of the requirements of the CAS;

iii) analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the CAS;

iv) description of the methods to be used for determining fulfilment of the requirements;

v) analysis of the appropriateness of the described methods to be used for determining fulfilment of the requirements;

vi) decision on the conformity assessment activity to be used (including the identification of the applicable conformity assessment standard);

vii) An analysis of the appropriateness of the selected conformity assessment activity.

9.2.4 **Review of scheme operation** - The scheme owner should ensure that the scheme is regularly reviewed, including confirmation that it is fulfilling its objectives, in accordance with a process that includes participation of the stakeholders.

9.2.5 The scheme owner should define a process for reviewing the operation of the scheme on a periodic basis in order to confirm its validity and to identify aspects requiring improvement, taking into account feedback from stakeholders. The review shall include provisions for ensuring that the scheme requirements are being applied in a consistent manner.

9.2.6 **Changes in specified requirements** - The scheme owner should monitor the development of the standards and other normative documents which define the specified requirements used in the scheme. Where changes in these documents occur, the scheme owner should have a process for making the necessary changes in the scheme, and for managing the implementation of the changes (e.g. transition period) by the CABs, clients and, where necessary, other stakeholders. The scheme owner should define a process for managing the implementation of other changes to the rules, procedures and management of the scheme.



### **9.3 Requirements with respect to contents of the Conformity Assessment Schemes**

9.3.1 A Conformity Assessment Scheme shall specify the following elements (contents of the Conformity Assessment Schemes), as applicable:

- a) General aspects - such as the scope of the scheme, including the description of the objects of conformity assessment.
- b) The requirements against which the objects of conformity assessment are evaluated – assessment i.e. product, process, service, system, or person to be assessed for conformity and to which the statement of conformity applies.  
These shall generally be those contained in a standard or other normative document. These could be national / international standards, regulations, etc.
- c) Guidelines are not considered conducive to evaluation and hence will need to be converted to normative requirements/certification/inspection criteria.
- d) These requirements could be established by the scheme owner as part of establishing the Certification scheme. In such circumstances, the principles and guidance given in clauses 4 and 5 of the document ISO/IEC 17007 “Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment” should be followed.
- e) The Conformity Assessment Schemes may prescribe additional requirements for CABs. However, the requirements for CABs involved in the conformity assessment process, shall generally not be in contradiction to the requirements of the applicable standards for CABs (ISO/IEC 17021-1, ISO/IEC 17065, ISO/IEC 17020 etc). Sufficient evidence and justification that the CA activity and the standard selected for the accreditation is appropriate shall be maintained. They may be additional or stricter than those specified in the relevant standards.
- f) The conformity assessment method(s) shall be in line with the normative document(s).

### **9.4 Requirements for conformity assessment activities**

Developers of conformity assessment Schemes (Scheme Owners) should follow the functional approach to conformity assessment, which provides a framework of basic conformity assessment functions and their relationships. Some of these

functions may not be applicable to certain conformity assessment activities such as inspections as standalone activity.

- 9.4.1** Functional approach identifies the following generic functions or elements that are normally present in any conformity assessment system/scheme:
- a) **Selection** of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities;
  - b) **Determination**, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfillment of the specified requirements by the object of conformity assessment or its sample;
  - c) **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; and
  - d) **Surveillance** (as applicable), including the frequency and extent of surveillance activities and reassessments to ensure the object of conformity assessment continues to fulfill the specified requirements. The need for surveillance will depend upon the type of scheme and whether the claim for continued compliance is permitted by the client over the validity period of the certification.
- 9.4.2** The CAS may prescribe competency requirements for CAB's resources such as auditors, examiners, verifiers, decision-makers, and staff members. The CAS may specify manner of monitoring CABs beyond requiring that they are accredited to the CAS requirements. In such a case, the CAS should have a feedback mechanism to provide information on performance of CABs to the concerned ABs.
- 9.4.3** 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 and ILAC guidelines, policies and other requirements.
- 9.5 Methods and procedures to be used by the CABs –**
- 9.5.1** The methods and procedure, criteria for evaluation as well as reporting requirements shall be decided by the scheme owner/CAB responsible for conformity assessment and ensured that the same are followed by the CABs engaged for the same, for ensuring integrity and consistency of the outcome of

the process of conformity assessment. The scheme owner should make use of the provisions described in the respective conformity assessment standards for elaborating the same. Additional guidance / requirements with respect to time required for evaluation tasks, transfer of certificates, multisite considerations and impartiality requirements for CABs shall be described, as applicable.

**9.5.2** The conditions under which the client may use the statement of conformity or marks of conformity should be specified as applicable. Where marks of conformity may be used, ownership, use and control of the marks, etc should be specified, unless the requirements given in the respective conformity assessment standards (such as ISO/IEC 17021-1) sufficiently describe them.

**9.5.3** The Conformity Assessment Scheme should describe, as applicable, other generic requirements such as information to be supplied to CAB by the applicant to certification; contents of statement of conformity; resource competence requirements; sampling procedures; acceptance of conformity assessment results from other parties; outsourcing of conformity assessment activities; reporting and use of results of determination and surveillance stages by the CAB and the scheme owner; how non-conformities with the certification requirements are to be dealt with and resolved for the purpose of decision making; surveillance procedures; information about certified clients to be made available to public; general conditions for granting, maintaining, continuing, extending the scope of, reducing the scope of, suspending and withdrawing certification: this should include requirements for discontinuation of advertising and return of certification documents and any other action if the certification is suspended, withdrawn or terminated; content of contracts, between scheme owner and CAB body, scheme owner and clients, CAB and clients, including the rights, responsibilities and liabilities of the various parties; licensing and control of marks; complaint handling system to be maintained by the CAB; reporting to the scheme owners; complaints and appeals to scheme owners; fraudulent claim of certification;

**Note:** These are relevant only to certain types of conformity assessment activities, hence the scheme owner should decide about specifying them as part of the CAS. However if these requirements are specified as part of the certification scheme, then they shall be appropriate to the type and scope of

conformity assessment activity and shall not contradict the requirements specified in the relevant conformity assessment standard. Some of these are also covered as essential requirements, as applicable, in the conformity.

- 9.5.4 Evaluation of schemes** – The generic requirements/criteria given in this policy document are evaluated using a generic checklist. In addition, specific criteria for different types of conformity assessment activities such as product certification, personnel certification, validation / verification, management system certification and inspection are to be evaluated using specific checklists.



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