



NACI Requirement for Acceptance of Conformity Assessment Schemes

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1. Objectives

This document describes the NACI 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

This document applies to the Certification Body operating based on ISO/IEC 17065: 2012, this document are applicable to all Conformity Assessment Schemes (CAS) for the broad categories of accreditation schemes operated by NACI namely, accreditation schemes for specific management systems certification, product/process certification, inspection, personnel certification, and validation and verification.

3. Responsibilities

The responsibilities for these procedures are discharged under the supervision of VPs in charge of each scheme. The Management Representative supervises effectiveness of the actions.

4. References & Regulations

ISO/IEC 17011: 2017 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies

NACI-M00 Accreditation manual

ISO/IEC 17000 Conformity assessment — Vocabulary and general principles.

ISO/IEC 17065:2012, Conformity Assessment - Requirements for Bodies Certifying Products, Processes and Services

ISO/IEC 17067:2013 Conformity assessment- Fundamentals of product certification and guidelines for product certification schemes.

ISO/IEC 17026:2015, Conformity assessment - Example of a Certification scheme for tangible products.

5. Terms & Definitions

All definitions related to the normative documents listed in clause 4 above apply. In addition, the terms and definitions below apply specifically:


5.1 **NACI**: National Accreditation Center of Iran

5.2 **CAB**: Conformity Assessment Body

5.3 Types/Categories of Conformity Assessment Schemes

5.3.1 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 or clause 8 of ISO/IEC 17024 for personnel 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

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of respective governments e.g., CE marking scheme in European Union, FSSAI's Organic regulation.

- c) Conformity Assessment Schemes developed by governmental agencies or operated by regulators even if voluntary e.g. Energy star programme
- 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 e.g., BIS or Agmark certification schemes.

6. Procedure

6.1 NACI policy for acceptance of Conformity Assessment Schemes for the purpose of accreditation

6.1.1 Conformity Assessment Schemes belonging to any of the types/categories as specified at clause 5.3.1 above are acceptable provided they meet the generic criteria/requirements as specified in section 6.2 of this document and their suitability is established. However, in case of schemes belonging to categories specified in 5.3.1 a) and b), exceptions may be accepted at the discretion of NACI president. The reasons for permitting such exceptions/deviations are:

- a) In case of 5.3.1 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 (say 1 – 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 NACI after 2 years of their acceptance.
- b) In case of 5.3.1 b) the government/ regulator being the scheme owner takes responsibility on behalf of the stakeholders. It should not prevent NACI 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 6.2 of this document.

6.1.2 The evaluation for determination of suitability of Conformity Assessment Scheme shall be done by NACI 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 NACI, the same shall not be reevaluated in case any other CAB applies for accreditation for the same scheme. NACI may decide to reevaluate the scheme, when any major changes occur in the contents of the scheme.

6.2 Requirements and criteria for evaluation of suitability of the Conformity Assessment Schemes

6.2.1 The criteria has 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

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is used it shall provide a suitable and adequate justification.

c) “may” indicates a permission.

6.2.2 General requirements

6.2.2.1 The Conformity Assessment Scheme (CAS) shall have been developed and maintained by a Scheme Owner (SO) having responsibility for the CAS and fulfilling the following requirements:

6.2.2.2 The scheme owner shall be a legal entity. A 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.

6.2.2.3 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.

6.2.3 Development of Conformity Assessment Schemes

6.2.3.1 The scheme owner should 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, which is preferably independent from the structure involved in operation of the conformity assessment (certification, inspection, and 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.

6.2.3.2 To ensure that the scheme owner understands the assumptions, influences and consequences involved in establishing, operating and maintaining a scheme on an ongoing basis, the scheme owner shall identify stakeholders and seek their opinions and participation in development of the scheme keeping balance of interest in view.

6.2.3.3 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 owner shall maintain the scheme and provide guidance when required. The scheme documents shall be publically available to all stakeholders on its website.

6.2.4 Operation and maintenance of the scheme

6.2.4.1 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.

6.2.4.2 Review of scheme operation - 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.

6.2.4.3 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.

6.2.4.4 In order to confirm that the Conformity Assessment Scheme has market/stakeholder acceptance, the scheme should have been in existence for 1 – 2 years.

6.2.5 Requirements with respect to contents of the Conformity Assessment Schemes: A Conformity Assessment Scheme shall specify the following elements (contents of the Conformity Assessment Schemes), as applicable:

6.2.5.1 General aspects - such as the scope of the scheme, including the description of the objects of conformity assessment.

6.2.5.2 The requirements against which the objects of conformity assessment are evaluated – These shall generally be those contained in a standard or other normative documents. These could be national / international standards, regulations, etc. The types of standards which can be considered for NACI's accreditation programme have been detailed in the Appendix 1.

6.2.5.3 Guidelines are not considered conducive to evaluation and hence will need to be converted to normative requirements/certification/inspection criteria.


Note: Typically process and service criteria may have these kind of issues.

6.2.5.4 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.

6.2.6 **Requirements for conformity assessment activities** – These requirements should generally be described under the general heading "Conformity Assessment Process Requirements". 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.

6.2.6.1 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

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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.

6.2.6.2 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.). They may be additional or stricter than those specified in the relevant standards.

6.2.7 The methods and procedures to be used by the CABs

- 6.2.7.1 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.
- 6.2.7.2 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.
- 6.2.7.3 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;
- 6.2.7.4 These are optional requirements, relevant only to certain types of conformity assessment activities, hence the scheme owner should decide about specifying them as part of the CAS.
- 6.2.7.5 Some of the above requirements may also be covered in the relevant conformity assessment standard as essential requirements (such as ISO 17021-1), in that event the scheme owner may decide that the same shall apply. 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

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requirements, as applicable, in the conformity

- 6.2.8 Evaluation of schemes – The generic requirements/criteria given in this document are evaluated using a generic checklist NACI-F182. 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 evaluated using specific checklists.

7. Rated Documents

- 7.1 Document control procedures **NACI-P01**
- 7.2 Records control procedures **NACI-P02**
- 7.3 Accreditation application & assessment procedures **NACI-P10**

8. Forms & Records


- 8.1 Impartiality & confidentiality form **NACI-F141**
- 8.2 Document distribution form **NACI-F104**

9. Recipients

Records master list form **NACI-F105** for recording & keeping all records related to these guidelines.


10. Withdrawn Documents

NA

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Annex 1: RECOGNITION OF STANDARDS UNDER ACCREDITATION SCHEMES FOR CERTIFICATION / INSPECTION BODIES

1. NACI would essentially base its accreditation on international and national standards
2. Any industry specific standards that have been endorsed by the IAF Membership (presently Global GAP has an MoU with IAF) and IAF members provide accreditation based on Global GAP standards)
3. NACI would also consider standards that are used as basis for accreditation by other IAF MLA signatories
4. For other standards which may be used in accreditation / certification / inspection NACI shall consider standards which meet the following criteria:
 - The standard is issued by a legal entity.
 - The standard has been developed in consultation with technically competent committee and stake holders of the standard and an effective mechanism exists for its periodic review/revision.
 - The standard shall have creditability and acceptance in industry and/or with appropriate regulatory authorities, if applicable
 - The standard shall be publicly available for implementation by the industry.
 - For any systems / process standards, the standard shall not allow labelling and marking of products in a manner which implies that they meet a particular product standard or specification, unless there are appropriate measures to ensure product compliance
 - The standard shall be auditable under the provisions of ISO 17021 and ISO 19011 in case of systems certification.
5. There could be inspections / product certifications against client's standards. For inspection NACI assessment team would judge the acceptability of standard based on contract with the client.
6. If it is not possible to establish acceptability of the standard on the basis of the policy outlined above for product certification then the specific standard should be accepted only after a reference to the Board and its approval.