1. General Information

These criteria set forth the requirements for obtaining and maintaining National accreditation center of Iran (NACI), Product Certification Body accreditation. Accreditation services are available to a third-party certification body that:

1.1 Certify products, processes or services,

1.2 Operates, or maintains a subcontract agreement with, a testing laboratory and inspection body, that meet the requirements of ISO/IEC Standard 17065, Sections 6.2.2, External resources (outsourcing),

1.3 Has operated and provided certification services for at least six months in accordance with ISO/IEC 17065 and completed a minimum of one certification per major category of certification, including completion of the decision-making process and issuance of certificate.

2. REQUIRED BASIC INFORMATION

Certification bodies must demonstrate compliance with the following requirements:

2.1 ISO/IEC Standard 17065, Conformity assessment – Requirements for bodies certifying products, processes and services;

2.2 NACI Rules for Product Certification Body Accreditation;

2.3 Scheme requirements under which the certification is granted.

2.4 Certification programs for processes and services must have requirements for determining continued compliance, that include assessment of the management system and the actual process or service, at least once per year.

3. ADDITIONAL INFORMATION (AS APPLICABLE)

3.1 When the certification system used as the basis for a certification activity requires surveillance at the point of manufacturing or assembly, the certification body shall have requirements that every manufacturing or assembly plant producing certified products be visited to perform surveillance activities for certified products. In the absence of a generally recognized minimum surveillance frequency, the certification body shall require that each manufacturing or assembly location authorized to produce the certified product be subject to at least one surveillance activity each calendar year.

3.2 Regardless of the surveillance techniques used, the content of the surveillance and what is reviewed during the surveillance will be the same. Surveillance techniques, include, but are not limited to:

- Announced (planned) onsite audits
- Remote audits
- Unannounced visits
- A combination of the above

3.3 It is recommended that onsite surveillance be performed as the primary technique. Minimal use of remote surveillance is recommended. Things to consider during surveillance:

- Material traceability
- Inspection and quality control test and measurement equipment calibration
- Manufacturer's management system, where required by the scheme.
- Assessment of production process

3.4 Inspection bodies and testing laboratories used as part of the certification process must meet one of the following criteria:

3.4.1 Accreditation by AB (Accreditation body) signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); or

3.4.2 Comply with ISO/IEC 17020 and/or ISO/IEC 17025 as applicable, determined through assessment of the inspection body and/or testing laboratory by qualified certification body personnel. In addition to the requirements given in ISO/IEC 17020 and/or ISO/IEC 17025, evidence of compliance shall include the qualifications of personnel conducting the assessment, and a system for determining continued compliance that includes periodic onsite assessments, review of assessment reports, and corrective action reports.

3.4.3 Product certification bodies must comply with regulatory requirements of Authority Having Jurisdiction or other regulatory entities, including specific compliance requirements for qualification, licensing, etc., of personnel and operation of product certification body.

4. Witnessing Inspection Activities:

When the certification scheme used as the basis for a certification activity requires the onsite evaluation of the production process or management system, NACI will periodically witness actual onsite inspections by each accredited certification body. The selection of location and scope for witness activity shall be made by NACI, in consultation with the certification body, based on various factors – risk, complexity, personnel changes, technology utilized, etc. Where possible, the full scope of accreditation will be reviewed over a full accreditation cycle.

5. Witness Testing:

All witness testing activities conducted at a manufacturer's facility must be witnessed by technically competent certification body staff who are trained not only in the test being witnessed, but in the appropriate sections of ISO/IEC Standard 17025. If the certification scheme to which the product is to be certified contains specific requirements or limitations pertaining to witness testing, the requirements of the certification scheme shall also apply. Appropriate measures must be taken for long-term testing or sample collection, where constant witnessing is not feasible, to ensure tampering of the sample or testing equipment does not take place.

6. Use of Manufacturer's Data:

If the certification scheme to which the product is to be certified contains specific requirements or limitations pertaining to the use of manufacturer's data, the requirements of the certification scheme shall also apply. If a certification body plans to use test data generated and submitted by a manufacturer that is not part of witness testing, the certification body must have a program in place to ensure validity and independence of the test data. The certification body shall consider one or more of the following for such a program, and shall have justification for those it chooses not to utilize:

6.1 Auditing, including unannounced random visits to the manufacturer's laboratory, to ensure key requirements of ISO/IEC Standard 17025 are satisfied;

6.2 Performing random duplicate analyses;

6.3 Having the manufacturer's laboratory participate in proficiency testing programs, where available, for applicable test method;

6.4 Technical review of the raw test data rather than acceptance of just the result.

7. Normative and Reference Documents:

Publications listed below refer to current editions (unless otherwise stated).

7.1 ISO/IEC Standard 17065, Conformity assessment – Requirements for bodies certifying products, processes and services.

7.2 ISO/IEC Standard 17067, Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes.

7.3 ISO/IEC Standard 17020, Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

7.4 ISO/IEC Standard 17021-1, Conformity assessment – Requirements for bodies providing auditing and certification of management systems – Part 1: Requirements.

7.5 ISO/IEC Standard 17025, General requirements for the competence of testing and calibration laboratories.

7.6 ISO/IEC Standard 17000, Conformity assessment – Vocabulary and general principles.

7.7 IAF MD 4, IAF Mandatory Document for the use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes.

7.8 IAF MD12, Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries.

7.9 IAF ML 2, General Principles on the Use of the IAF MLA Mark.

7.10 APAC TEC4-001 Guidance on Description of Scope of Accreditation – Product Ver. 1.0 (20190101)

7.11 APAC TEC4-002 Guidance on Application of ISO-IEC 17065 Organic Certification Ver. 1.0 (20190101)

8. LINKS TO ADDITIONAL REFERENCES

- NACI – http://naciportal.isiri.gov.ir/
- International Accreditation Forum – www.iaf.nu
- International Laboratory Accreditation Cooperation – www.ilac.org
- The Asia Pacific Accreditation Cooperationwww.apac-accreditation.org