ASEAN Guidelines for Accreditation and Conformity Assessment
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ASEAN Guidelines for Accreditation and Conformity Assessment

The ASEAN Secretariat
Jakarta
ASEAN Guidelines for Accreditation and Conformity Assessment

FOREWORD

The ASEAN Consultative Committee on Standards and Quality (ACCSQ) has established Working Group 2 as the Working Group (WG) on Accreditation and Conformity Assessment. This WG has been assigned the responsibility of overseeing the development of accreditation and conformity assessment services in ASEAN Member States to facilitate the implementation of mutual recognition of test reports and certifications.

The ASEAN Guidelines for Accreditation and Conformity Assessment were prepared by WG 2 in order to provide a common basis for the operations of accreditation and conformity assessment bodies in ASEAN Member States in order to facilitate and support mutual recognition of test reports and certifications that underpin the mutual recognitions and harmonised regulatory regimes developed by the ACCSQ through its Product Working Groups. The document which is developed and managed by WG 2, shall be reviewed every 5 years or as deemed necessary by ACCSQ. The Guidelines clarify existing practices and arrangements and are intended to serve as a reference to the product working groups and also for accreditation and certification bodies of ASEAN Members States. The ASEAN Guidelines for Accreditation and Conformity Assessment was endorsed by the ACCSQ at its 43rd ACCSQ Meeting held in Manila, Philippines from 20th to 24th April 2015.

Chair
ASEAN Consultative Committee on Standards and Quality, April 23rd 2015
ASEAN Guidelines for Accreditation and Conformity Assessment

1. Introduction

1.1. Conformity assessment procedures are a means of ensuring that goods traded or placed in the market comply with defined requirements. These procedures entail a determination of compliance that is undertaken by test and calibration laboratories, inspection and certification bodies, (collectively known as Conformity Assessment Bodies). Conformity assessment procedures are implemented by ASEAN Member States (hereinafter, AMSs) to support technical regulations that prescribe safety, health, environmental and other legal requirements for products. Conformity assessment procedures are also widely utilised voluntarily by the business community in ASEAN and provide assurance of the performance and quality of products to individual and industrial buyers and users.

1.2. Competent conformity assessment services enable trade in regulated products, and have a vital role in facilitating trade of goods in the unregulated sector. Accreditation, when conducted in accordance with internationally accepted rules, provides an authoritative statement of the technical competence of conformity assessment bodies in providing services. This assurance provides governments a basis to accept the results of conformity assessment bodies for purposes of regulatory approval and enforcement. Accreditation also enables users of conformity assessments to identify competent laboratories, and inspection and certification bodies.

1.3. The development of the ASEAN Economic Community (AEC) is reliant on the mutual recognition of the results of conformity assessments across all AMSs. Mutual recognition of the results of conformity assessments as prescribed in the current and planned ASEAN MRAs depends on the acceptance of the results from conformity assessment bodies designated by AMSs on the basis of accreditation. Mutual recognition of the results of conformity assessments remove the need for multiple testing, inspections or certification for products that are supplied across ASEAN.

1.4. The availability of accredited conformity assessment services that comply with the agreed upon criteria and rules is an essential condition for market integration. These criteria and rules should be based on internationally agreed upon standards and guides to ensure that ASEAN suppliers, while facilitating internal trade, will also serve to maintain or enhance access to external markets.

2. Terms & Definitions

2.1. Definitions for Standards, Technical Regulations and Conformity Assessment Procedures are adopted from definitions contained in the WTO/TBT Agreement.

2.2. Definitions for the Accreditation, Conformity Assessment Body, Certification, Inspection and other related terms are adopted from ISO/IEC 17000:2004: Conformity assessment -- Vocabulary and general principles. Annex 1 contains a list of these definitions.
2.3. NACB: National Accreditation Coordinating Body and NAFP: National Accreditation Focal Point. Definition of both term appears as Annex 2.

2.4. APLAC MRA: Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement

2.5. ILAC MRA: International Laboratory Accreditation Cooperation Mutual Recognition Arrangement

2.6. IAF MLA: International Accreditation Forum Multilateral Recognition Arrangement

2.7. PAC MLA: Pacific Accreditation Cooperation Multilateral Recognition Arrangement

3. Objectives and Scope

3.1. The Guidelines will enable the establishment of a network of recognised accreditation and conformity assessment bodies that provide services to support initiatives taken by the ASEAN Consultative Committee on Standards and Conformance (ACCSQ) to enable the free flow of goods within ASEAN. These Guidelines for Accreditation and Conformity Assessment are established and implemented to define:

a. Criteria and rules for the establishment and maintenance of accreditation of conformity assessment bodies and services;

b. Criteria and rules for the acceptance of conformity assessments in regulated sectors;

c. The basis for the acceptance of the results of accredited conformity assessments;

d. The role and functions of accreditation and conformity assessment bodies in supporting the establishment of the AEC; and

e. Coordination and cooperation between the accreditation and conformity assessment bodies in ASEAN.

Part 1: Accreditation

4.1. Each AMS shall either:

a. Appoint a single National Accreditation Body (NAB) to be responsible for accreditation as required for mutual recognition arrangements and other harmonised regulatory regimes implemented in ASEAN; or

b. In the case that the AMS’s policy chooses to establish more than one accreditation body, appoint a National Accreditation Coordinating Body (NACB); or

c. In the case that there is no accreditation body within the AMS’s territory, appoint a National Accreditation Focal Point (NAFP) with an overall mandate and responsibility for accreditation for purposes of mutual recognition arrangements and other harmonised regulatory regimes implemented in ASEAN.

The appointment of the NAB or the alternative appointments of the NACB and NAFP shall be notified to the ACCSQ and the ASEAN Secretariat.

4.2. Where an AMS does not have a NAB or has a limited scope of accreditation services, conformity assessment bodies established in its territory may avail the services of accreditation bodies
that are parties to the APLAC/ILAC MRA or the PAC/IAF MLA. A national accreditation body of an AMS that is party to the APLAC/ILAC MRA or the PAC/IAF MLA should be selected as a first priority to provide the service, unless there is a justification to seek services from NABs that are located outside the ASEAN region. The selected NAB from another AMS shall provide the requested services on similar terms as it provides to domestic conformity assessment bodies.

4.3. AMSs that do not establish a NAB shall designate the a NAFP to serve as a contact point for communication with other AMSs on matters relating to accreditation.

4.4. The NAB shall have the legal status of either a public service organisation or a private entity. In all cases it shall be ensured that it operates on a not-for-profit basis and conforms to national legislation. The NAFP and NACB are exempt from these requirements and shall be duly appointed by the AMS’s authority responsible for accreditation.

4.5. The NAB shall be established in accordance with the requirements of ISO/IEC 17011 Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies.

4.6. All NABs shall endeavour to be parties to the Mutual Recognition Arrangement (MRA) implemented by Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Multilateral Recognition Arrangement (MLA) implemented by the Pacific Accreditation Cooperation (PAC). It shall notify its scope of acceptance by the respective APLAC and PAC arrangements to the Working Group 2 of ACCSQ (WG 2) and the ASEAN Secretariat.

4.7. All AMSs shall accept and recognise accreditation results from any ASEAN NAB issued under an APLAC MRA or PAC MLA with respect of ASEAN mutual recognition arrangements and harmonised regulatory regimes. AMSs may additionally accept accreditation results from NABs outside of ASEAN when mutually they are agreed upon.

4.8. ASEAN conformity assessment bodies that provide services in connection with ASEAN MRAs and harmonised regulatory regimes shall seek accreditation from the national accreditation body of the AMS in which it is operating, unless the accreditation body of that AMS is not able to provide the specific accreditation service sought. In AMSs without a NAB, the NAFP shall undertake coordination and make the administrative arrangements for parties in their territory seeking accreditation from other ASEAN NABs.

4.9. When a NAB receives a request for accreditation from a conformity assessment body of another member state, it shall, upon acceptance from the applicant, inform the NAB of that AMS of the request and seek its cooperation. For AMSs having more than one accreditation body the NAB or, in the absence of a NAB, the NACB or NAFP shall be informed. NABs should not compete in providing accreditation that is linked to an ASEAN MRA or Harmonised Regulatory Regimes.

4.10. Each NABs shall inform WG2 and all other Member State’s AMS’s NABs of the scopes of its operations and of any subsequent changes.

4.11. The NABs of all AMSs shall cooperate with other ASEAN NABs on matters concerning recognition, development of new fields of accreditation and capacity building and in the delivery of services.
Part 2: Conformity Assessment

4.12. Conformity assessment should be conducted to recognised standards, preferably to standards harmonised in ASEAN, international standards, national standards, or other transparent and objective criteria, such as national or harmonised technical regulations, in a non-discriminatory manner.

4.13. Conformity assessment bodies should demonstrate competence by adhering to the international standards for conformity assessment bodies. These standards include ISO/IEC 17020 Conformity assessment -- Requirements for the operation of various types of bodies performing inspection, ISO/IEC 17021 Conformity assessment -- Requirements for bodies providing audit and certification of management systems, ISO/IEC 17024 Conformity assessment -- General requirements for bodies operating certification of persons, ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories ISO/IEC 17065 Conformity assessment -- Requirements for bodies certifying products, processes and services and other relevant international standards. Compliance should be demonstrated by accreditation from NABs that are parties to the APLAC/ILAC MRA or PAC/IAF MLA.

4.14. Implementation of conformity assessment schemes should depend on justification based on relevant technical regulation or an ASEAN harmonised regulatory regime with respect to the ASEAN Priority Integration Sectors, to serve public interests or be driven by market demand from potential users of certification.

4.15. Except where a government has special responsibilities or a unique regulatory expertise, the provision of conformity assessment services should be open and subject to competition.

4.16. Authorities in AMSs that require conformity assessment services to support regulations should accept and recognise conformity assessment services provided by ASEAN conformity assessment bodies accredited by ASEAN NABs that are parties to the APLAC MRA or PAC MLA.

4.17. The acceptance and recognition of conformity assessment results prescribed in ASEAN MRAs and harmonised regulatory schemes should be based on accreditation by ASEAN NABs that are party to the relevant recognition arrangements of the APLAC MRA or the PAC MLA. The results of conformity assessment from conformity assessment bodies that are duly designated should also be accepted and recognised when prescribed in ASEAN MRAs and harmonised regulatory regimes.

4.18. The selection of the appropriate type of conformity assessment by the regulatory authorities should be based on the appropriateness for the product and the nature of any associated risk. Reference may be made to ISO/IEC 17067 Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes.

a. Reliance on suppliers’ declarations should be considered for products posing a low risk. For such products, the declarations shall be based on ISO/IEC 17050 Conformity assessment -- Supplier’s declaration of conformity -- Part 1: General requirements 1 and. Conformity assessment -- Supplier’s declaration of conformity-- Part 2 Supporting documentation; and

b. Special and less burdensome conformity assessment procedures and shall be specified for small volume and custom made products.

1 These standards are subject to periodical revision and the reference applies to the current versions at the material time.
4.19. A product certification body that issues reports for ASEAN MRAs and harmonised regulatory schemes shall:

a. Be established under national law/legislation, have a legal status and conform to relevant legislation.

b. Be a third-party body independent of the organisation or the product it assesses.

4.20. Designation of Conformity Assessment Bodies by an AMS, when required for the purposes of ASEAN MRAs and harmonised regulatory schemes, shall be undertaken by designation bodies that are competent and endeavour to comply with the following:

a. The designation body shall be duly authorised by the AMS to undertake designation of conformity assessment bodies within a defined scope as agreed by AMSs.

b. Designation shall be based on accreditation by a signatory to the PAC/IAF MLA or APLAC/ILAC MRA unless determined to be inappropriate or exempted under the provisions of an ASEAN MRA or harmonised regulatory regime.

c. The designation body should ensure that a sufficient number of personnel are available to undertake its role as defined in its documented procedures.

d. The designation body shall operate in a non-discriminatory manner and ensure that all conformity assessment bodies located in the AMS may seek designation on the same terms.

e. The designation body shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

f. The designation body shall be organised and shall be operated so as to safeguard the objectivity and impartiality of its activities.

g. The designation body shall be organised in such a way that each decision relating to designation of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

h. The designation body shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

i. The designation body shall safeguard the confidentiality of the information it obtains.
Annex 1: Terms and definitions on Accreditation and Conformity Assessment

1. Definitions from the WTO/TBT Agreement

1.1. Technical regulation

A document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

*Explanatory note:*
The definition in ISO/IEC Guide 2 is not self-contained, but based on the so-called “building block” system.

1.2. Standard

A document approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

*Explanatory note:*
The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.

1.3. Conformity assessment procedures

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

*Explanatory note:*
Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

2. Definitions from ISO/IEC 17000: Conformity assessment — Vocabulary and general principles

2.1. Accreditation: A third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

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2 The standard is subject to periodical revision and the reference applies to the current version at the material time.
2.2. Accreditation body: An authoritative body that performs accreditation.

2.3. Third party: A body that is independent of the organisation that provides the object, and of user interests in that object.

   NOTE: The authority of an accreditation body is generally derived from government.

2.4. Conformity assessment body: A body that performs conformity assessment services.

   NOTE: An accreditation body is not a conformity assessment body.

2.5. Certification: A third-party attestation related to products, processes, systems or persons.

   NOTE 1: Certification of a management system is sometimes also called registration.

   NOTE 2: Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.

2.6. Inspection: The examination of a product design, product process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements.

   NOTE: Inspection of a process may include inspection of persons, facilities, technology and methodology.

2.7. Designation: A governmental authorisation of a conformity assessment body to perform specified conformity assessment activities.

2.8. Designating authority: A body established within government or empowered by government to designate conformity assessment bodies, suspend or withdraw their designation or remove their suspension from designation.

2.9. Recognition: The recognition of conformity assessment results or the acknowledgement of the validity of a conformity assessment result provided by another person or body.

2.10. Acceptance: The acceptance of conformity assessment results use of a conformity assessment result provided by another person or body.

2.11. Peer assessment: An assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group.

2.12. Suspension: The temporary invalidation of the statement of conformity for all or part of the specified scope of attestation.

2.13. Withdrawal: The revocation or cancellation of the statement of conformity.
Annex 2: Definition of NACB and NAFP

1. National Accreditation Coordinating Body (NACB)
   The body appointed by an AMS that has more than one accreditation body to coordinate accreditation activities within its territory.

2. National Accreditation Focal Point (NAFP)
   A National Accreditation Focal Point is the body or person appointed by an AMS that does not have a national accreditation body to facilitate access to internationally recognised accreditation of conformity assessment bodies within its territory.

   The NAFP is responsible for:
   i. Providing the national administrative link and joint assessment between potential clients and Partner Accreditation Bodies in ASEAN that are signatories of the regional and international Mutual Recognition Arrangements;
   ii. Developing the competence of its own accreditation body in order to achieve signatory status of regional and international Mutual Recognition Arrangements; and
   iii. Representing its AMS in the relevant ASEAN working groups and committees.
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