



Guidelines for Implementation of Harmonised Accreditation in ASEAN



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Guidelines for Implementation of Harmonised Accreditation in ASEAN

The ASEAN Secretariat
Jakarta

Guidelines for Implementation of Harmonised Accreditation in ASEAN

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Abbreviations

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|------------------|-------------------------------------------------------------------------------------------|
| ACCSQ | ASEAN Consultative Committee on Standards & Quality |
| AEC | ASEAN Economic Community |
| AG STRACAP | ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures |
| AMS | ASEAN Member State(s) |
| APAC | ASIA Pacific Accreditation Cooperation |
| AG-2015 | ASEAN Guidelines for Accreditation and Conformity Assessment 2015 |
| ATIGA | ASEAN Trade in Goods Agreement |
| CA | Conformity Assessment |
| CAB | Conformity Assessment Body |
| IAF | International Accreditation Forum |
| ILAC | International Laboratory Accreditation Cooperation |
| MLA | Multilateral Recognition Arrangements |
| MRA ₁ | Mutual Recognition Arrangements |
| MRA ₂ | Mutual Recognition Agreements |
| NAB | National Accreditation Body |
| NAFP | National Accreditation Focal Point |
| WG 2 | ASEAN Working Group 2 on Conformity Assessment |

Guidelines for Implementation of Harmonised Accreditation in ASEAN

1. Introduction

1.1 Accreditation of Conformity Assessment is a means of an assuring competence of conformity assessment bodies and facilitating public and private sector users' access to trusted conformity assessment services. Accredited conformity assessments bodies are accepted by government agencies as independent third parties and are often relied on to undertake conformity assessment on behalf of regulators. Accreditation and conformity assessment are key components of a nation's quality infrastructure to support trade and industry. By providing confidence in products, processes, services, management systems and personnel, accredited conformity assessment supports transactions between businesses. In many instances trade partners rely on accredited conformity assessment. In such situations, requirements for test reports, certification, or inspection results are specified in contracts.

1.2 The declaration of the ASEAN Economic Community (AEC) by ASEAN Leaders in 2015 has led to intensified efforts to transform ASEAN into a single market and production base and a region fully integrated into the global economy. The AEC is based on the principles of an open, outward-looking, inclusive, and market-driven economy consistent with multilateral rules as well as adherence to rules-based systems. As per the AEC Blueprint 2025, ASEAN leaders have set the targets of a deeply integrated and highly cohesive ASEAN economy to integrate principles of good governance, transparency, and responsive regulatory regimes through active engagement with the private sector, community-based organisations, and other stakeholders of ASEAN. Accredited conformity assessment is an integral part of the standards and quality infrastructure that facilitates and enables the achievement of these targets.

1.3

AG STRACAP para 11: Member States shall ensure that the operations of national accreditation bodies and designated conformity assessment bodies are consistent with the ASEAN Guidelines on Accreditation and Conformity Assessment.

ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures (AG STRACAP) have been developed by ACCSQ to provide the guiding principles for the implementation of the individual and joint efforts of Member States in the area of standards, technical regulations, accreditation, conformity assessment, metrology and other related activities, both in regulated and non-regulated sectors, for enabling the economic integration of the ASEAN and realisation of the ASEAN Economic Community (AEC).

The *ASEAN Guidelines for Accreditation and Conformity Assessment (Accreditation Guidelines-2015)* elaborate the principles set in AG STRACAP and define a common basis for the operations of accreditation and conformity assessment bodies in ASEAN Member States to support mutual recognitions and harmonised regulatory regimes developed by the ACCSQ through its Product Working Groups and are a reference on accreditation and certification to the Product Working Groups.

- 1.4 The *Guidelines for Implementation of Harmonised Accreditation* follow the principle that the accreditation and conformity assessment will be harmonised on the basis of international standards on accreditation and conformity assessment published by Committee on Conformity Assessment (CASCO) and recognition based on the APAC MRA₁ and its linkages to the international recognitions systems established by International Laboratory Assessment (ILAC) and International Accreditation Forum (IAF) as explicitly stated in the *ASEAN Guidelines for Accreditation and Conformity Assessment*. This is essential for global recognition of accreditation performed by ASEAN Accreditation Bodies.
- 1.5 The availability of the wide range of accredited conformity assessment services is a key requirement for trade, both within ASEAN and with external trade partners in a large number of sectors. Additionally, this supports the development of quality culture in industry. The development of a comprehensive and sustainable accreditation system with competent accreditation bodies established in across ASEAN providing accreditation will encourage the development of competent conformity assessment bodies serving across relevant sectors of the ASEAN Members' economies.

2. Objectives

i. General

The main objective of these guidelines are to provide guidance on implementation of internationally recognised and accepted accreditation of conformity assessment in ASEAN Member States, based on *AG STRACAP* and the *ASEAN Guidelines for Accreditation and Conformity Assessment*. This document supplements the previously developed guidelines and focuses on the practical aspects in order that capacity and sustainability of accreditation bodies is enhanced.

ii. Specific Objectives

These guidelines additionally are intended to:

- *Guide the adoption and implementation of the ASEAN Guidelines on Accreditation and Conformity Assessment by the Member States (AG 2015);*
- Support initiatives that strengthen the role and position of accreditation bodies within ASEAN Member States;
- Enhance cooperation & coordination between ASEAN National Accreditation Bodies (NAB) and National Accreditation Focal Points (NAFP);
- Facilitate the development and adoption by NAB of harmonised criteria and procedures for accreditation with a focus on ASEAN's priority sectors;
- Create a conducive environment for the development of 3rd party conformity assessment services in ASEAN;
- Increase the utilisation of 3rd party conformity assessment for implementation of legislation by Member States' regulatory agencies; and
- Support the implementation of ASEAN MRA₂ and Harmonised Regulatory Regime especially where conformity assessment is required by ensuring the availability of credible conformity assessment.

3. Scope

The *Guidelines for Implementation of Harmonised Accreditations* are generic and applicable to all sectors across ASEAN Member States. The document

provides guidance for ASEAN Member States on harmonised implementation of accreditation. The guidelines include recommendations that are applicable to initiatives that support the integration of ASEAN's priority economic sectors. The guidelines are relevant to the full range of accreditation services that Member States accreditation bodies may provide.

4. Core Principles of Accreditation

The adoption of a set of core principles on accreditation of conformity assessment is an essential prerequisite for establishing credibility and mutual confidence between Member States. These principles are equally applicable to both NAB and NAFFP and are:

- Accreditation is a public service activity and should therefore operate in the interest of the public. It should ideally be self-supporting and not operated as profit generating activity;
- Accreditation should be at the highest level of control and should provide an authoritative statement of the technical competence of Conformity Assessment Body (CAB), integrity and reliability of their services;
- Accreditation should be operated with integrity; independent of the organisations it accredits, impartial, free from commercial pressures and free from competition;
- The NAB/NAFFP should operate to internationally recognised standards or other transparent criteria and be compliant with applicable technical requirements;
- Accreditation should be available to both the regulated and non-regulated sectors.

5. International Acceptance

By adhering to international standards and participation in the APAC MRA₁, ILAC MRA and IAF MLA, ASEAN Member States enable recognition of accreditation services and accredited conformity assessment results globally. It is recommended that ASEAN businesses, government and local authorities requiring third party conformity assessment services:

- to source such services, where they exist, from conformity assessment bodies accredited by the National Accreditation Body, and

- to recognise the equivalence of the services delivered by those accreditation bodies that are signatories of the APAC MRA₁.

Note: In the electrotechnical sector, Conformity Assessment Systems operated by the International Electrotechnical Committee (IEC) based on peer assessment serve as an alternative to accreditation and these are internationally accepted. (Annex 1: IEC Conformity Assessment Schemes).

6. Acceptance of Accredited CAB Results in AMS

AG STRACAP para 10: Member States shall ensure that the preparation, adoption and application of conformity assessment procedures and that the results of conformity assessment from designated conformity assessment bodies are accepted by other Member States as provided for in Article 76 of ATIGA.

The adoption of a set of core principles accreditation of conformity assessment is an essential prerequisite for establishing credibility and mutual confidence between Member States. These principles are equally applicable to both NAB and NAFFP and are:

Accreditation provides a means for assuring the competence of a conformity assessment body in the scope of its accreditation. This assurance of confidence enables users of certification, testing, calibration, inspection, proficiency testing as well as validation and verification services to identify Conformity Assessment (CA) service providers that may be relied upon.

Trade and industry users are thus provided with an option to evaluate suppliers products and quality systems on a global basis by relying on external CA services instead of using their own resources. This is a more cost effective and efficient approach as compared to undertaking their own evaluation of suppliers.

Regulatory agencies often rely on conformity assessment as a tool for assuring compliance to product standards and or internal management systems such as those for quality, environmental protection or safety. Accredited CA services enable reliance on 3rd party CAB to undertake this task – leading to cost savings for regulatory agencies. This approach additionally encourages the development of independent CAB and provides a choice of service providers to industry.

The reliance on regional and global recognition arrangements on accreditation that are overseen by APAC and IAF, ILAC facilitates trade and regulatory cooperation between ASEAN Member States. Bilateral agreements should be discouraged in ASEAN and international accreditation system promoted, as multilateral international and regional agreements are more efficient and cost effective.

Although it is obvious that acceptance of results from accredited CAB is reliable and cost effective, the level of acceptance in ASEAN could be increased significantly. In Member States that are not parties to the APAC MRA₁ the regulatory bodies can be encouraged by the NAFFP to accept or recognise conformity assessment results or reports from accredited CAB from other ASEAN Member States. Such recognition should also be encouraged in Member States that are signatories to the APAC MRA₁ in sectors where the accreditation system is not yet available in a particular sector.

7. Key Stakeholders and Roles

I. National Accreditation Body

AG-2015 para 4.1: Each AMS shall either:

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

A single NAB should be formally appointed by Member States. If an AMS appoints more than one accreditation body, efforts should be made to merge or centralise operations. In the interim, formal appointment of more than one body should be accompanied by clearly defined roles and a coordination mechanism to ensure absence of competition between the bodies. Member States having more than one accreditation body should appoint one of the accreditation bodies as a coordinator.

Member States should ensure NAB remain as signatories to APAC, ILAC & IAF MRA₁/MLA to participate in the international accreditation. ASEAN Member States should support the use of accredited conformity assessment by regulatory bodies and cooperate to expand the use of accredited CAB within the Member State.

The NAB should maintain close communications, coordination and regularly exchange information with regulatory bodies that rely on or intend to rely on accredited conformity assessment.

ASEAN Member States in the process of establishing a national accreditation bodies should be provided all the necessary assistance and support by established ASEAN NAB in order that these Member States successfully establish NABs that qualify to be signatories to the APAC, ILAC & IAF MRA₁/MLA. The support provided could include attachment training, provision of assessor training, sharing of good practices and of technical information.

II. NAB-Regulatory Body Cooperation

ASEAN Member States' regulatory bodies have the responsibility of implementing legislation providing for the safety, security, health of the public and protect the environment. The agencies rely on various forms of conformity assessment (testing, calibration, inspections, proficiency testing, validation and verification & certification) as a major tool of control and surveillance. Assessments to ensure compliance with safety security, health and environment protection requirements are undertaken through product and material testing, certification and examination of premises and processes and various other forms of inspections.

ASEAN NAB/NAFFP should cooperate with regulatory bodies in Member States to encourage the use of recognition of accredited national/ international CAB results in the implementation of regulation whenever appropriate. Members States should encourage the utilisation of results of accredited CAB to fulfil regulatory requirements.

At the same instance the regulatory bodies should be encouraged and supported to accept accredited conformity assessment results and reports without requiring repeated tests, assessments or inspections whenever these are expedient and appropriate. This intra-ASEAN cooperation should be further developed through increased regulatory cooperation and development of recognition arrangements and harmonisation of standards and requirements.

The reliance by regulatory bodies on conformity assessment services provided by accredited CAB serves to increase the effectiveness and efficiency while providing a choice to the users of CA services. The regular and sustained

demand created for 3rd party CAB ensures their economic viability, and the development of accredited CA services.

III. ACCSQ and Product Working Groups

The ASEAN Trade in Goods Agreement (ATIGA) assigns ACCSQ a critical role in overseeing the elimination of technical trade barriers to trade, the development of Mutual Recognition Agreement and Arrangements (MRA_{1/2}) and in Harmonised Regulatory Regimes. ACCSQ fulfils this role through its product working groups and has established guiding policies in the AG STRACAP and in the ASEAN Guidelines for Accreditation and Conformity Assessment.

ACCSQ's role thus encompasses ensuring that the Working Groups and Product Working Groups effectively adopt recommendations on the use of accreditation and accredited conformity assessment in the ASEAN MRA₂, Harmonised Regulatory Regimes and other initiatives to achieve ASEAN's market integration targets within their respective sectors.

IV. Working Group 2

Working Group 2 (WG 2), as the body assigned by ACCSQ to oversee regional development and cooperation of accreditation and conformity assessment, serves as the coordination centre and focal point for ASEAN NAB/NAFP. It should conduct periodic reviews of the developments in the region and within Member States to support the development of comprehensive network of NAB/NAFP in ASEAN by monitoring the demand arising from ASEAN MRA₂ and Harmonised Regulatory Regimes and regional trade. The ACCSQ WG 2 should initiate and lead in enabling cooperation in capacity building, harmonisation of accreditation rules and the joint development of new schemes by ASEAN NAB/NAFP.

WG 2 should support ACCSQ in its lead position with oversight of product working group to ensure that any ASEAN MRA₂, harmonised regulatory regime implemented rely on accredited conformity assessment whenever this is available and appropriate.

WG 2 should support ACCSQ in its role of facilitating the development of capacity building and cooperation activities of NAB/NAFP and conformity

assessment in all AMS. This should include development of NAB in all Member States, and initiatives for expansion of scopes of accreditation, sharing of technical and human resources, training of assessors and management personnel.

In fulfilling its role and responsibility to lead in the development and implementation accreditation systems, WG 2 should establish plans and programmes set timelines and process steps to achieve the objectives of the guidelines. The plans would include cooperation with other stake holders and appropriate organisational arrangements within WG 2.

V. Accreditation to in Support of ASEAN MRAs₂ and Harmonised Regulatory Regimes

ASEAN MRA₂ and Harmonised Regulatory Regimes rely on acceptance of results of conformity assessment as the basis for recognition. Harmonised ASEAN accreditation

AG-2015-para 4.7: All AMSs shall accept and recognise accreditation results from any ASEAN NAB issued under an APLAC MRA₁ 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.

** and the APLAC MRA and PAC MLA are now merged under the APAC MRA*

provides Member States with a uniform and recognised method for determining competence of conformity assessment bodies. The reference to and use of accredited ASEAN CAB should be the first option for qualification of CAB under all ASEAN MRA₂ and Harmonised Regulatory Regimes.

Harmonised criteria and procedures for accreditation will facilitate and ensure acceptance of results of accredited CAB services across ASEAN Member States. Such harmonisation should be undertaken with a priority in CA services that are utilised in ASEAN MRA₂ and Harmonised Regulatory Regimes. The deeper level of harmonisation at the operating level will supplement the broad harmonisation based on the adoption of international standards and APAC, ILAC and IAF guidance documents.

ASEAN Member States' accreditation bodies and accreditation focal points should ensure the availability of accreditation services in order to effectively implement ASEAN MRA₂ and Harmonised Regulatory Regimes.

8. Guidance for Member States on Implementation

I. Member States' Legislation on Accreditation

AG-2015 para 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 establishment and operations of accreditation bodies is dependent on the provisions of laws that establish national accreditation bodies on contain prescription on accreditation and conformity assessment. In order to assure Member States operate in line with the recommendations, it should be ascertained that;

- Legislation that establishes its national accreditation body is consistent with the core principles for accreditation stated in *Section 4* of this document;
- Legislation is consistent with the requirements of international standards for accreditation bodies including those for independence, freedom of conflict of interest and impartiality;
- The National Accreditation Body (NAB) supports the development of the national conformity assessment infrastructure and is authorised to establish and operate accreditation schemes for conformity assessment in all sectors of the national economy as required to serve the economic and regulatory needs in the public and private sectors.
- Domestic legislation does not hinder the use of accredited conformity assessment in implementation of regulation and other official purposes. The recognition of results of accredited conformity assessment from CABs from other AMS should also not be hindered by legislation; and
- The legislation does not hinder NAB/NAFP to fully participate in regional and international MRA_{1/2}/MLA in accreditation and comply with stipulated obligations of these MRA_{1/2}/MLA.

II. National Accreditation System

AG-2015 para 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 APAC arrangements to the Working Group 2 of ACCSQ (WG 2) and the APLAC MRA and PAC MLA are now merged under the APAC MRA.

* and the APLAC MRA and PAC MLA are now merged under the APAC MRA

Member States should ensure that the national accreditation system conforms with the recommendations of the *ASEAN Guidelines on Accreditation & Conformity Assessment*. This includes compliance with the provisions of international standards on accreditation and the rules and requirements of the APAC, ILAC, IAF MRA₁/MLA.

The NABs and NAFPs should establish and operate accreditation schemes for conformity assessment in all sectors of the national economy as required to serve the economic and regulatory needs and provide services to all interested parties, in the public and private sectors. Policies and programmes adopted should promote the development CAB that provide of a sound and sustainable conformity assessment services required by the Member State for domestic and international trade to support the implementation of regulation. In event that legacy accreditation systems exist in a Member State, efforts should be made to coordinate and rationalise these into a unitary system.

III. Cooperation between NABs and NAFPs in ASEAN

- AG-2015 para 4.10: Each NAB shall inform WG 2 and all other Member States' NABs of the scopes of its operations and of any subsequent changes.
- AG-2015 para 4.11: The NAB of all AMSs shall cooperate with other ASEAN NAB on matters concerning recognition, development of new fields of accreditation and capacity building and in the delivery of services.

It is intended that these guidelines facilitate the exchange of information and effective cooperation among ASEAN NAB and NAFP in a coordinated manner. This would enable the joint development of accreditation services and enhance sharing of resources and expertise between Member States.

NAB and NAFF should effectively participate in cooperation programmes coordinated by WG 2 on information exchange, training of personnel, development of accreditation schemes and harmonisation of specific requirements for accreditation.

- AG-2015 para 4.8: ASEAN conformity assessment bodies that provide services in connection with ASEAN MRA 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 NAFF shall undertake coordination and make the administrative arrangements for parties in their territory seeking accreditation from other ASEAN NAB.
- AG-2015 para 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 NAFF shall be informed. NAB should not compete in providing accreditation that is linked to an ASEAN MRA₂ or Harmonised Regulatory Regimes.

As a rule ASEAN NAB/NAFF should provide accreditation services to entities within its territories and adhere to cross frontier accreditation guide issued by ILAC¹. Cross frontier accreditation should be conducted when a particular accreditation service is not available domestically and undertaken through cooperation between NAB/NAFF of Member States and should be in compliance with national regulations of the Member State. NAB/NAFF should enable accreditation services in other ASEAN Member States in order that such services can be made available when required and with the coordination of the respective NAB/NAFF.

AG-2015 para 4.1, c: In the case that there is no accreditation body within the AMS's territory, appoint a National Accreditation Focal Point (NAFF) with an overall mandate and responsibility for accreditation for purposes of mutual recognition arrangements and other harmonised regulatory regimes implemented in ASEAN.

In special situations where it is not viable for a Member State to establish a particular accreditation service, that Member State should consider outsourcing.

Member States National Accreditation Focal Points (NAFF) should participate in all ASEAN cooperation and coordination activities undertaken by WG 2. Member States with developed accreditation bodies should provide full support to the developing accreditation bodies to develop accreditation services and provide accreditation services as required by the Member State. The NAFF should cooperate with developed NAB to ensure availability of accreditation services within its territories and perform the other functions and duties normally fulfilled by an NAB.

9. Reference Documents

- ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures (AG STRACAP);
- ASEAN Guidelines for Accreditation and Conformity Assessment (2015);
- ILAC-G21:09Cross-Frontier Accreditation Principles for Cooperation;
- APAC Mutual Recognition Arrangement (MRA₁) - <https://www.apac-accreditation.org/publications/>;
- APAC Mutual Recognition Arrangement (MRA₁);
- ILAC Mutual Recognition Arrangement (ILAC MRA₁) - <https://ilac.org/ilac-mra-and-signatories/>;
- IAF Multilateral Recognition Arrangement (MLA) - <https://iaf.nu/en/iaf-documents-categories>.

¹ ILAC-G21:09Cross-Frontier *Accreditation Principles for Cooperation*

Annex 1: IEC Conformity Assessment Schemes

In the electrotechnical sector, the IEC manages the operation of four worldwide Conformity Assessment Systems. These systems represent the global standardised approach to testing, inspection and certification.

- IECEE - IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components;
- IECQ - IEC Quality Assessment System for Electronic Components;
- IECEX - IEC System for Certification to Standards relating to equipment for use in explosive atmospheres;
- IECRE IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications.

These systems rely on peer assessment to confirm that CAB comply both with the ISO/IEC 17000 series of international standards as well as the IEC Systems rules and operating procedures. National accreditation, while not a requirement of the IEC Systems, it is accepted as complementary and demonstrates that the CAB competence and compliance with international standards. It is recommended that ASEAN Member States regard results from CAB under IEC CA systems in an equivalent manner to those from CAB accredited under the APAC and related international recognition agreements.

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