

ASEAN Sectoral Networks of Laboratories

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Introduction

These generic “Guidelines for ASEAN Sectoral Network of Laboratories” have been developed to serve as reference so that the laboratory networks in ASEAN are effective, support the AEC targets and are consistent with the Policy Guideline on Accreditation and Conformity Assessment. The development of these guidelines has been led by WG 2, as the body responsible for matters related to conformity assessment bodies and implementation of related regional integration initiatives.

It is intended that these guidelines provide clarity on the potential role of the laboratory networks, support the recognition of results from the laboratories in the networks, provide guidance on funding, confirming the mandates and on ensuring sustainability.

The guidelines provide for the establishment of ASEAN Laboratory Networks and ASEAN Reference Laboratories. The effective operation of the network of ASEAN reference laboratories will be facilitated through the establishment of National Reference laboratories by Member States.

The guidelines have been developed through a process that included consultation with the existing working groups and sectoral laboratory committees. The guidelines have been endorsed by the ACCSQ and apply to all ACCSQ WGs.

1. Objective and Scope of the Guidelines for Laboratory Networks

An integrated ASEAN wide network of laboratories supports the delivery of timely, high quality, and interpretable results for all users of the laboratory services. The network facilitates intra laboratory communication and information flows, mutual recognition and the sharing of resources. The laboratory networks create an inclusive forum for experts from ASEAN laboratories to share ideas, work collaboratively, and build relationships that will support a more effective integrated response to emerging needs.

A number of Product Working Groups (PWGs) under the ACCSQ are engaged in the development and implementation of mutual recognition arrangements and harmonised regulatory regimes. These initiatives depend on the services provided by laboratories. These laboratories provide essential conformity assessment services in support of ASEAN initiatives undertaken for the establishment of the ASEAN Economic Community. The PWGs have in turn established subcommittees to manage and coordinate the networks of laboratories within their respective sectors located in the member states. These laboratories have a critical role in supporting the implementation of technical regulations and in market surveillance by providing essential tests that are required for trade of goods across ASEAN.

These guidelines serve as voluntary reference document for their establishment and operation of networks in order that the laboratories within the networks are effective, support the AEC targets and operate in a consistent manner as established in the ASEAN Guideline on Accreditation and Conformity Assessment and the ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures.

2. Definitions

ASEAN Reference Laboratory¹: means a laboratory nominated by a Member State and appointed by the ASEAN Sectoral Body to serve as a reference to all ASEAN Member States in accordance with its Terms of Reference .

National Reference Laboratory: means a laboratory that has mandate from the government of a Member State to serve as a reference laboratory for official purposes in a specified field.

Official Laboratory: means a laboratory designated by the government of a Member State to undertake sampling, testing and analysis for official purposes.

Laboratory Network: means a group of laboratories in a related field that collaborate by sharing experience, developing competencies, maintain quality, develop analytical methods and take other initiatives in support of enhancing the delivery of analytical services.

ASEAN Reference Laboratory Network: means a laboratory network in which membership of the network is based on a defined specialist competency or a network of national reference laboratories.

Laboratory Committee: means a committee established by an ASEAN Sectoral Body comprising of representatives from official laboratories of Member States to manage an ASEAN Laboratory Network.

¹ An ASEAN reference laboratory should be a laboratory that can demonstrate its competence through accreditation to ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories or by other equivalent criteria such as the OECD GLP requirements.

3. Defining the Role of Laboratory Networks.

The role of the laboratory networks should be established by the Product or Sector Working Group by considering the following:

- i. The primary focus and objectives of the work of the sector group should determine the terms of reference of the laboratories in the network. Laboratories support very diverse fields of economic, social and security related activities. For example, the terms of reference for a sector group with capacity building, environmental protection or health assurance objectives would be tailored to the specific needs of the sector and differ from those with objectives for trade facilitation that support a specific recognition arrangement or harmonised regulations.
- ii. Laboratories that support recognition arrangements derive their role from the ASEAN Agreements; the terms of reference should link the role to the implementation of the agreement to ensure effectiveness in fulfilling the defined roles. The participation of such laboratories in the networks should be subject to defined qualifications in terms of designated authorisation, funding, accreditation, competency, traceability, and other factors linked to the fulfilment of the defined role and delivery of specific services.
- iii. Laboratory networks may also be established for regional technical capacity building, information sharing and technical cooperation objectives. Such types of networks may have criteria for participation that permit both official and other laboratories including commercial laboratories to participate.
- iv. The role of ASEAN Reference Laboratories Networks should be consistent with the mandate that has been provided to the laboratories to function as reference laboratories by an official ASEAN Sectoral Body² or under an ASEAN Agreement.

4. Establishment of ASEAN Laboratory Networks

- i. The decision to establish an ASEAN laboratory network is made by an official ASEAN Sectoral Body or a working group responsible for the sector concerned based on consultation and consensus of all ASEAN Member States.
- ii. The decision for the establishment should be accompanied by an explicit statement of the role and objective of its establishment.
- iii. The ASEAN Sectoral Body or Working Group responsible should initiate the establishment of a committee comprising of representatives of official laboratories in Member States to manage the ASEAN laboratory network or assign this to an existing committee. The committee assigned this responsibility of managing the network need not be a dedicated committee and may undertake additional related tasks.
- iv. The ASEAN Sectoral Body, in establishing a laboratory network should consider the options that are available for the type of network to be established this may include networks that consist of:
 - laboratories with all laboratories having an equal status;

² An Official ASEAN Sectoral Body is one that is established within the ASEAN institutional arrangements.

- ASEAN Reference laboratories only;
 - ASEAN reference laboratories and other non-reference laboratories.
- v. The Laboratory Committee should define the criteria and establish a process of acceptance of the laboratories to the network. It should maintain an up to date register of laboratories that comprise the network with details the fields of services provided by each member.
- vi. The ASEAN Sectoral Body or Working Group should define the Terms of Reference and Rules of Laboratory Committee

5. Participation of Laboratories in ASEAN Laboratory Networks

- i. Laboratories located in any ASEAN Member State should be eligible for participation in a regional network provided it complies with the participation criteria. Laboratories located outside ASEAN may be invited to participate in these networks under special conditions determined by the Committee responsible for managing the network.
- ii. The networks should establish and maintain qualification requirements for participation of laboratories in the regional networks. The membership criteria should be based on qualifications such as:
- Acceptance of the terms of reference of the network and obligations of participation by the governing body of the laboratory, including obligations to share technical data, participate in proficiency testing programmes and training programmes and for mutual recognition of test results;
 - Internationally recognised accreditation to an international standard or alternatively availability of an equivalent quality system;
 - Availability of documented policies and procedures for the laboratory's operations ;
 - Management systems for handling samples with facilities for sample storage;
 - Data management and data exchange procedures; and
 - Analytical capabilities and capacities for specific fields as per specific network requirements
 - Commitment by the management of ASEAN reference laboratories to support the planned activities of the laboratories within the network
- iii. Participation in laboratory networks that are established to support implementation of MRAs and harmonised regulations should be restricted to laboratories located in the territories of ASEAN Member States with a defined and documented authorisation to provide services recognised under an agreement or harmonised regulation.

Appointment of a laboratory as an ASEAN Reference Laboratory should be restricted to Official Laboratories located in the territories of ASEAN Member States with a defined and documented mandate from the government of the Member State.

Any Member Laboratory of the specific network may participate in the meetings of the Laboratory Committee under the direction of the lead representative of the Member State. The frequency, agenda and venue of the meetings should be as determined by the laboratory committee.

6. Activities of Laboratory Networks

The type of activities that a laboratory network undertakes depend on the objectives, role and terms of reference.

The list of activities below is a non-exclusive list of the types of typical activities that a specific laboratory network may select from.:

Scientific Activities

- the selection and/or harmonisation of sampling, test and analytical methods for use within the sector;
- development of test methods;
- the practices related to the test specifications and test methods detailed in the standards accepted for use;
- achievement of repeatability and reproducibility of test results, including implementing or coordinating proficiency testing;
- sourcing and development of reference materials;
- training of laboratory personnel;
- collaboration in technical matters, including in metrological traceability; and
- exchange of technical information.

Other Activities

- advising the ASEAN sectoral body responsible for the laboratory committee on scientific and technical matters as requested,
- responding to new situations due to technological or ASEAN policy developments; and
- establishing ASEAN Reference Laboratories for the sector and managing the operations of the network.
- sourcing technical assistance; and enabling recognition of test results across ASEAN Member States;

The Laboratory Committee shall support the ASEAN Sectoral Body responsible for its establishment in managing the establishment of ASEAN Reference Laboratories for the sector. The terms of reference, criteria and process for the appointment of ASEAN Reference Laboratories shall be subject to approval by the Sector Working Group or alternately as prescribed in a related ASEAN agreement. The ASEAN reference laboratories network should in turn be linked to national reference laboratories established by the Member States.

7. Establishment and Role of ASEAN Reference Laboratory Networks

ASEAN Reference Laboratories Network should be established on the basis of an explicit mandate from a recognised ASEAN body or defined in an Agreement between ASEAN Member States. The establishment of ASEAN Reference Laboratories should be in support of an identified role in

furthering economic integration in the region in support of an agreement between Member States in the form of a recognition arrangement, harmonised technical regulations or other instrument.

ASEAN Reference laboratories that are established to support ASEAN harmonised regulations or recognition arrangements should be official laboratories with a defined scope of competency and designated authority by the ASEAN body responsible for implementation of the harmonised regulations or recognition arrangement.

The appointed reference laboratory should serve as reference for all of ASEAN on matters such as the development of test and analytical methods, provision of proficiency testing services, provision of training, expert advice and assistance in resolution of disputes on the validity of test results.

A laboratory that accepts appointment as an ASEAN Reference Laboratory should ensure that it makes adequate provisions to operate as an ASEAN laboratory when undertaking its tasks. In addition to its official functions, the laboratory should ensure that it has the financial and other resources allocated to fulfil its obligations as an ASEAN reference laboratory.

8. Operations of ASEAN Reference Laboratories Network.

- i. The ASEAN Reference Laboratories are selected from the national reference labs or official laboratories in ASEAN Member States officially appointed by an ASEAN Body under authority provided in an Agreement between Member States or other equivalent instrument to undertake defined tasks within a specified technical or scientific sector.
- ii. The operations of ASEAN Reference Laboratories network in a particular sector should be managed and overseen by a committee appointed by the ASEAN body establishing the network.
- iii. The appointment as an ASEAN Reference Laboratory should be accompanied by a documented and defined scope of appointment, obligations and a period of appointment not exceeding 5 years.
- iv. The appointment as an ASEAN reference laboratories should be based on the following:
 - Formal acceptance of the obligations as an ASEAN Reference Laboratory by governing body/top management of the laboratory;
 - Evidence that the laboratory has a mandate from its government authority to accept appointment as an ASEAN reference laboratory;
 - Declaration or evidence that funding and other resources are available for its functions as a ASEAN reference laboratory;
 - Demonstration that the laboratory make adequate provisions to fulfil its obligations to function as an ASEAN reference laboratory in addition to any other national tasks it may undertake;
 - Availability of suitably qualified staff with adequate training in analytical techniques in their area of competence;
 - Availability of equipment needed to carry out the tasks assigned to them;
 - An appropriate administrative infrastructure to comply with obligations;
 - Arrangements for assurance of confidentiality of results or communications;

- Availability of reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;
 - Demonstration of competence through accreditation to ISO/IEC 17025 - *General requirements for the competence of testing and calibration laboratories* or by other equivalent criteria such as OECD GLP requirements.
- v. The scopes of testing that a reference laboratory is appointed for should be based on harmonised test methods or common approaches adopted in the particular sector in ASEAN Member States. The scopes should be precisely and unambiguously defined to focus on the mandated role.
- vi. Funding obligations and requirements and sources of funds of the operations of reference laboratories should be defined in appointment of the laboratories.
- vii. The formal appointment of an ASEAN Reference Laboratory should be made by the Laboratory Committee based on an assessment of documentary evidence of the particular laboratory having satisfied the defined qualification criteria.
- viii. The obligations of an ASEAN Reference Laboratory should be defined by the Laboratory Committee responsible that may include the following:
- support the development of national reference laboratories in all Member States within the field of expertise and maintain a register of the laboratories;
 - establish regular communication with national reference laboratories;
 - providing national reference laboratories with details of harmonised test methods, methods within the scope of appointment;
 - coordinating application by the national reference laboratories of the harmonised methods by organising proficiency testing in accordance with ISO/IEC 17043;
 - informing national reference laboratories of advances within their area of competence, and assistance in the application of new analytical methods;
 - conducting training courses for the benefit of staff from national reference laboratories; providing scientific and technical assistance to the ASEAN Bodies, to support the implementation of regional agreements, including in cases where Member States contest the results of analyses;
- ix. ASEAN reference laboratories should support any initiatives taken for the development of mutual recognition of test results throughout ASEAN.
- x. Fee rates, if levied for services such as those for proficiency testing, training, supply of reference materials, should be based on actual costs and be made available.

9. Monitoring and Maintenance of Laboratory Network

- i. The work of a laboratory network should be monitored by the ASEAN sectoral body responsible for its establishment. The Laboratory Committee should, at a minimum, submit

annual reports of the work the network has undertaken, the results, its membership and other significant developments or changes.

- ii. The Laboratory Committee is responsible to ensure the maintenance of the network and should:
 - Monitor the continued compliance to the criteria of participation in the network by member laboratories;
 - Regularly update the register of laboratories within the network;
 - Monitor the results of any proficiency testing undertaken;
 - Monitoring the effectiveness of any training undertaken;
 - Address the issues and concerns arising; and
 - Progress of other ongoing initiatives of the network.

10. Development of Guidance Documents and other documents.

The committee responsible for a Laboratory Network and/or Reference Laboratories should develop procedures and/or other documents for use by the laboratories to assist in the implementation and coordination of activities within their sectors.

In addition The network should develop technical guidance for the its activities. These guidance documents should be based on international protocols whenever these are available. The guidance documents may include the following:

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- Criteria for the selection of ASEAN reference laboratories and process for appointment
- Guidance on the provision of proficiency testing
- Guidance on provision of training for laboratory personnel from ASEAN Members states
- Guidance on harmonisation of analytical and test methods, including the publication
- Guidance on undertaking selection, verification and validation of methods Facilitating mutual recognition of test results provision of test services across the region
- Assuring the quality of results and control of data
- Guideline for appeal of selection of ASEAN reference laboratories