

法規名稱：ASIA PACIFIC LABORATORY ACCREDITATION COOPERATION MUTUAL RECOGNITION
ARRANGEMENT

簽訂日期：民國 94 年 11 月 16 日

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PREAMBLE

The Asia Pacific Laboratory Accreditation Cooperation (APLAC) is an organisation of laboratory, reference material producer and inspection body accreditation bodies in the Asia Pacific Region, formalised with the signing of a Memorandum of Understanding (MOU) in April 1995, among 20 accreditation bodies.

Signatories to the MOU committed to cooperate so as to generally improve standards of testing, calibration, inspection in the economies of the region, and to enhance the free trade objectives of the region, and between the region, and economies elsewhere.

APLAC is one of the Specialist Regional Bodies supporting the trade facilitation activities of the APEC1 Subcommittee on Standards and Conformance (SCSC).

This document describes the elements of a Mutual Recognition Arrangement (MRA) as a means by which the signatories formally recognise with mutual confidence one another's accreditations within each signatory's scope of recognition under this MRA. The scopes of recognition (testing; calibration; inspection) are listed below for each signatory.

This MRA does not supersede other recognitions required by laws and regulations in the economies of the signatory bodies.

PRINCIPAL ELEMENTS OF MUTUAL CONFIDENCE

The principal elements of the APLAC (MRA), listed below, establish confidence among the signatory accreditation bodies.

These elements are designed to ensure conformity with the requirements in order to establish and maintain mutual confidence in the technical competence of APLAC signatories and their accredited laboratories, inspection bodies. The elements are:

- 1 Exchange of information on the development and operation of APLAC member laboratory, and inspection body accreditation bodies.
- 2 Participation in the work and decision making of the APLAC General Assembly, including timely return of postal ballots.
- 3 Participation in international interlaboratory comparisons and proficiency testing programs.
- 4 Participation in the technical and other work of APLAC related to accreditation of testing, calibration and inspection in various technical fields.
- 5 Evaluation of applicants to this Arrangement is in the form of visits by teams of evaluators constituted and operating to the provisions of the document, APLAC MR 001, Procedure for Establishing and Maintaining Mutual Recognition Arrangements Amongst Accreditation Bodies to determine if the applicant meets the requirements of ISO/IEC Guide 58, Calibration and testing laboratory accreditation systems- General requirements for operation and recognition, and/or ISO/IEC TR 17010 General requirements for bodies providing accreditation of inspection bodies accreditation bodies.
- 6 Evaluation of signatories to the Arrangement takes place at intervals of approximately four years for the purpose of assuring that the signatory bodies continue to meet the requirements of ISO/IEC Guide 58 (from 1 January 2006, ISO/IEC

17011) and/or ISO/IEC TR17010 (from 1 January 2006, ISO/IEC 17011).

- 7 Observation of applicant bodies' assessments of their laboratories to determine if these laboratories meet the requirements of ISO/IEC 17025, General requirements for the competence of calibration and testing laboratories (previously ISO/IEC Guide 25), or of ISO 15189, Medical laboratories - Particular requirements for quality and competence (for medical laboratories), and/or observation of applicant bodies' assessments of their inspection bodies to determine if these inspection bodies meet the requirements of ISO/IEC 17020
General criteria for the operation of various types of bodies performing inspection.
- 8 Application, evaluation, decisions, and maintenance pertaining to the MRA are conducted in accordance with the APLAC MR 001 Procedures for establishing and maintaining mutual recognition arrangements amongst accreditation bodies or its equivalent.
- 9 Appropriate information developed during the evaluation of applicants and periodic reevaluation of signatories is shared among the signatories on a confidential basis.
- 10 Confidence in the national measurement institutes that underpin the traceability claimed by accredited laboratories, inspection bodies and support for the measurement comparison activities of CIPM2 and regional metrology organisations.

ARRANGEMENT

Upon fulfilling the requirements described in the Principal Elements of Mutual Confidence described above, each signatory to the APLAC MRA enters into the following Arrangement:

1 Each APLAC MRA Signatory for Testing, Calibration, and/or Inspection:

- (i) uses equivalent procedures in the accreditation of laboratories under ISO/IEC Guide 58 (from 1 January 2006, ISO/IEC 17011) and ISO/IEC 17025 (previously ISO/IEC Guide 25), or ISO 15189 for medical laboratories, and/or uses equivalent procedures in the accreditation of inspection bodies under ISO/IEC TR 17010 (from 1 January 2006, ISO/IEC 17011);
- (ii) recognises, within its scope of recognition of this MRA, the accreditation of a laboratory, or inspection body by other signatories as being equivalent to an accreditation by its own organisation;
- (iii) accepts, for its own purposes, endorsed calibration, test or inspection reports, issued by laboratories or inspection bodies, accredited by other signatories on the same basis as it accepts endorsed calibration, test or inspection reports issued by its own accredited laboratories, and/or inspection bodies;
- (iv) recommends and promotes the acceptance by users in its economy of endorsed test, calibration, and inspection reports issued by organisations accredited by other signatories;
- (v) investigates all complaints initiated by a signatory resulting from test reports and calibration certificates issued by their accredited testing and calibration laboratories and/or inspection reports issued by their accredited inspection bodies;
- (vi) contributes to the work of the APLAC MRA Council;

- (vii) participates in the work of APLAC including the return of ballots;
 - (viii) provides evaluators for the evaluation and re-evaluation of accreditation bodies appropriate to their size and to the needs of the APLAC MRA Council as resolved periodically by the MRA Council;
 - (ix) uses all information obtained from the peer evaluation process in a confidential and professional manner;
 - (x) informs one another, as soon as possible, of any significant changes that have occurred or will occur in the status and/or operational practices of its accreditation body.
- 2 The scope of recognition of a signatory may be extended or reduced following reevaluation.
- 3 The addition of new signatories to the APLAC Mutual Recognition Arrangement or the withdrawal of an APLAC MRA signatory will not change the terms of this Arrangement.
- 4 The conclusion of a further Arrangement between APLAC and a recognised laboratory, reference material producer and/or inspection body accreditation body not participating in APLAC, or between APLAC and another regional association of laboratory, inspection body and reference material producer accreditation bodies, does not change the terms of this Arrangement. The evaluation information may be shared with these bodies only with the agreement of the evaluated laboratory, and/or inspection body accreditation body.
- 5 This Arrangement will be null and void if the incorporation and Constitution referred to in the preamble are terminated.

- 6 This Arrangement may be amended at any time by agreement in writing among the signatories.
- 7 In the event of a dispute between signatories to this Arrangement or with applicants concerning elements, objectives, procedures, and requirements, the matter will be referred to the APLAC General Assembly.
- 8 This Arrangement will come into effect for each participant upon signature by the affected parties.
- 9 If a signatory wishes to withdraw from this MRA, it shall notify the APLAC MRA Council in writing not later than three months in advance of the withdrawal. The MRA Council will notify the other signatories. Upon withdrawal of a signatory, its signature sheet shall be deleted from this MRA.
- 10 It is recognised and accepted by each of the signatories that this Arrangement does not create any rights, liabilities or obligations that would have binding effect in domestic or international law. This Arrangement by itself does not provide any recognition or accreditation under any law or regulation in the economy of any signatory.

However, the signatories commit to promote to their governments the use of this Arrangement in support of recognition arrangements in the regulated sector.

MEMBER, APLAC MUTUAL RECOGNITION ARRANGEMENT
SIGNATORIES

We, the undersigned, endorse the terms of the APLAC Mutual Recognition Arrangement and undertake, to the best of our ability, fulfilment of its objectives.

Testing, Calibration, Inspection

Organisation: NATA

Economy: Australia

Authorised Representative: Regina Robertson

Organisation: HKAS

Economy: Hong Kong, China

Authorised Representative: Terence SS Chan

Organisation: IANZ

Economy: New Zealand

Authorised Representative: Dr W L Richards

Organisation: SAC

Economy: Singapore

Authorised Representative: Chang Kwei Fern

Organisation: CNAL

Economy: People's Republic of China

Authorised Representative: Wei Hao

Organisation: BoA

Economy: Viet Nam

Authorised Representative: Dr Ho Tat Thang

Organisation: KAN

Economy: Indonesia

Authorised Representative: Dr Sunarya

Organisation: IAS

Economy: United States of America

Authorised Representative: Patrick McCullen

Organisation: TAF

Economy: Chinese Taipei

Authorised Representative: Neng-Jong Lin

Organisation: ema

Economy: Mexico

Authorised Representative: Maria Isabel López Martínez

Testing and Calibration

Organisation: A2LA

Economy: United States of America

Authorised Representative: Peter S Unger

Organisation: NVLAP

Economy: United States of America

Authorised Representative: Warren Merkel

Organisation: Standards Council of Canada/Conseil canadien des
normes

Economy: Canada

Authorised Representative: Peter Clark

Organisation: NABL

Economy: India

Authorised Representative: Dr Sulbha Gupta

Organisation: KOLAS

Economy: Korea

Authorised Representative: Yang Whan Jeong

Organisation: TLAS

Economy: Thailand

Authorised Representative: Pairoj Sanyadechakul

Organisation: IAJapan

Economy: Japan

Authorised Representative: Dr Katuo Seta



Organisation: JAB

Economy: Japan

Authorised Representative: Yuichiro Isu

Organisation: DSM on behalf of the Government of Malaysia

Economy: Malaysia

Authorised Representative: Mariani Mohammed

Organisation: PAO (previously BPSLAS)

Economy: The Philippines

Authorised Representative: Cirila Botor

Testing

Organisation: BLQS, DMSc

Economy: Thailand

Authorised Representative: Panadda Silva

Organisation: VLAC

Economy: Japan

Authorised Representative: Seiichi Kawashima

Organisation: CAEAL/ACLAE

Economy: Canada

Authorised Representative: J E J Gravel

Chair, APLAC MRA Council: _____

Barry Ashcroft

Date

Chair, APLAC: _____

Terence S S Chan

Date