



APLAC

Asia Pacific Laboratory Accreditation Cooperation

ASIA PACIFIC LABORATORY ACCREDITATION COOPERATION

MUTUAL RECOGNITION ARRANGEMENT

PREAMBLE

The Asia Pacific Laboratory Accreditation Cooperation (APLAC) is an organisation of laboratory, reference material producer, proficiency testing provider 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. In October 2006 APLAC became incorporated in New Zealand and the APLAC Constitution was adopted.

Under its Constitution APLAC members commit to cooperate so as to generally improve standards of testing, calibration, inspection and related activities (that include reference material production and proficiency testing provider services) 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; ISO 15189; inspection; reference material production; proficiency testing provider services) are maintained for each signatory on the APLAC website (www.aplac.org) and in APLAC SEC 039.

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, reference material producers, and proficiency testing providers. The elements are:

- 1** Exchange of information on the development and operation of APLAC member laboratory, inspection body, reference material producer and proficiency testing provider 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 (including medical) and calibration laboratories, inspection bodies, reference material producers and proficiency testing providers in various technical fields.

¹ Asia Pacific Economic Cooperation

- 5 Evaluation of applicants to this Arrangement is in the form of visits by teams of evaluators constituted and operating in accordance with the requirements of the APLAC document, APLAC MR 001, *Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement Amongst Accreditation Bodies* to determine if the applicant meets the requirements of ISO/IEC 17011, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment 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 17011.
- 7 Observation of applicant bodies' assessments of accredited and applicant:
 - (i) laboratories to determine if these laboratories meet the requirements of ISO/IEC 17025, *General requirements for the competence of calibration and testing laboratories*, or of ISO 15189, *Medical laboratories – Particular requirements for quality and competence* (for medical laboratories);
 - (ii) 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*;
 - (iii) reference material producers to determine if these reference material producers meet the requirements of ISO Guide 34, *General requirements for the competence of reference material producers (until November 2019)* and/or ISO 17034 *General requirements for the competence of reference material producers*;
 - (iv) proficiency testing providers to determine if these proficiency testing providers meet the requirement of ISO/IEC 17043, *Conformity assessment – General requirements for proficiency testing*.
- 8 Application, evaluation, decisions, and maintenance pertaining to the MRA are conducted in accordance with the APLAC MR 001, *Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement Amongst Accreditation Bodies* and the APLAC MR 008, *APLAC MRA Council – Rules for its Operation*, or their equivalent.
- 9 Appropriate information developed during the evaluation of applicants and periodic re-evaluation of signatories is shared among the signatories on a confidential basis.
- 10 Confidence in the national measurement institutes that underpin the traceability of measurement claimed by accredited laboratories, inspection bodies, reference material producers and proficiency testing providers, 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, ISO 15189, Inspection, Reference Material Production and Proficiency Testing Provider services:

² Comité International des Poids et Mesures

- (a) uses equivalent procedures in the accreditation of:
 - (i) laboratories under ISO/IEC 17011, any additional normative documents as specified in APLAC MR 001, and ISO/IEC 17025, or ISO 15189 for medical laboratories;
 - (ii) inspection bodies under ISO/IEC 17011, any additional normative documents as specified in APLAC MR 001, and ISO/IEC 17020;
 - (iii) reference material producers under ISO/IEC 17011, any additional normative documents as specified in APLAC MR 001, and ISO Guide 34 (*until November 2019*) and/or ISO 17034;
 - (iv) proficiency testing providers under ISO/IEC 17011, any additional normative documents specified in MR001, and ISO/IEC 17043;
- (b) recognises, within its scope of recognition in this MRA, the accreditation of a laboratory, inspection body, reference material producer or proficiency testing provider by other signatories as being equivalent to an accreditation by its own organisation;
- (c) accepts, for its own purposes, endorsed test reports, calibration certificates and inspection reports issued by laboratories and inspection bodies, endorsed reference material certificates and statements issued by reference material producers, and endorsed proficiency testing reports issued by proficiency testing providers accredited by other signatories on the same basis as it accepts endorsed test reports, calibration certificates, inspection reports, reference material certificates and proficiency testing reports issued by its own accredited laboratories, inspection bodies, reference material producers and proficiency testing providers;
- (d) recommends and promotes the acceptance by users in its economy of endorsed test reports, calibration certificates, inspection reports, reference material certificates and statements, and proficiency testing reports issued by organisations accredited by other signatories;
- (e) investigates all complaints initiated by a signatory resulting from endorsed test reports and calibration certificates issued by their accredited testing and calibration laboratories, endorsed inspection reports issued by their accredited inspection bodies, endorsed reference material certificates and statements issued by their accredited reference material producers, or endorsed proficiency testing reports issued by their accredited proficiency testing providers;
- (f) contributes to the work of the APLAC MRA Council;
- (g) participates in the work of APLAC including the return of ballots;
- (h) 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;
- (i) uses all information obtained from the peer evaluation process in a confidential and professional manner;

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- (j) 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 a re-evaluation.
 - 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, proficiency testing provider and/or inspection body accreditation body not participating in APLAC, or between APLAC and another regional association of laboratory, inspection body, reference material producer and proficiency testing provider 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, reference material producer, proficiency testing provider 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.