

Accreditors' View of the Value of MRAs: The APLAC View

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Abstract

In November 2001 CIPM/BIPM and ILAC (International Laboratory Accreditation Cooperation) signed a Memorandum of Understanding (MOU) that commits each to referencing each other's Mutual Recognition Arrangements (MRA) when implementing their own MRAs. The ILAC Arrangement is supported by regional MRAs amongst accreditation bodies in Europe (EA MLA) and the Asia-Pacific region (APLAC MRA).

This paper outlines how accreditation bodies use the CIPM/BIPM MRA in relation to demonstration of traceability to SI units of measurement.

This paper then outlines the work that APLAC is doing to increase regulator confidence in the APLAC MRA that is written into various APEC (Asia Pacific Economic Cooperation) MRAs. The APLAC MRA is a means of support for the MRAs in the regulated sector specifically in relation to test and calibration data associated with the products covered by the MRAs (e.g. telecommunications equipment under the APEC TEL MRA).

Text

The inaugural signing of the ILAC (International Laboratory Accreditation Cooperation) Arrangement amongst 37 laboratory accreditation bodies from 28 economies in Washington, DC in November 2000 was a major achievement by the international laboratory accreditation fraternity. The Arrangement enhances the acceptance of technical data accompanying goods traded across national borders and is, thus, a major step towards reducing or eliminating the need for retesting of the goods by the importing country. For many years the retesting of goods by an importing country has been considered as a major technical barrier to trade. The WTO has identified such technical barriers as a major concern to world trade since the mid-1970s. The key to the Arrangement is the developing network of accredited testing and calibration facilities around the world that are assessed for compliance with ISO/IEC 17025 and are recognised as being competent by laboratory accreditation bodies. Equally, the cornerstone of the Arrangement is the utilisation of existing or developing arrangements established in the Americas, the Asia Pacific region, Europe and Southern Africa. The laboratory accreditation bodies participating in

these regional arrangements are responsible for maintaining the necessary confidence in the accreditation bodies from their region that are signatories to the ILAC Arrangement. In November 2000, all 16 current signatories to the APLAC (Asia Pacific Laboratory Accreditation Cooperation) Mutual Recognition Arrangement (MRA) were inaugural signatories to the ILAC Arrangement. As of April 2002, 19 of APLAC's 28 members are now signatories to the APLAC MRA and ILAC Arrangement, and the remaining APLAC members are in various stages of preparation to become signatories to the APLAC MRA.

In some cases, these mutual recognition arrangements have been an initial component in concluding trade negotiations between economies, e.g. between the European Union and Australia. Trade negotiators and laboratory accreditation bodies sought a similar formalised process for demonstrating equivalence amongst national metrology institutes (NMIs), and in 1999 CIPM set up a formal global MRA framework, known as the "mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes".

The CIPM global MRA requires participating NMIs to demonstrate the equivalence of their national standards with the SI, and to demonstrate their competence to provide calibration or measurement certificates. The equivalence of national standards with SI is demonstrated through key comparisons. These key comparisons test capability at the highest level of accuracy and so not all laboratories have the capacity to participate. The key comparisons coordinated through the CIPM Consultation Committees are supplemented by regional key comparisons conducted by regional metrology organisations such as APMP (Asia Pacific Metrology Program).

To obtain mutual recognition of its calibration and measurement certificates a NMI must provide its regional metrology organisation with a statement of Calibration and Measurement Capability (CMC) accompanied by evidence that the NMI can perform at the stated capability, and evidence that it has a quality system complying with ISO/IEC 17025 or equivalent. Compliance with ISO/IEC 17025 may be by self-declaration or by third party accreditation. The information on the status of national standards in each economy and on the measurement capabilities of NMIs is entered into the Key Comparison and Calibration Database accessible through the BIPM website.

On 3 November 2001 in Kyoto Japan, ILAC and CIPM signed a Memorandum of Understanding (MOU), recognising the need to strengthen the links between accreditation and metrology. The MOU states that, amongst other things, the two organisations agree to make appropriate cross references in their Mutual Recognition Arrangements and to promote cooperation at the regional level.

There are two main ways in which laboratory accreditation bodies make use of the CIPM global MRA. Both ISO/IEC 17025 (section 5.6), the standard used for the accreditation of testing and calibration laboratories, and ILAC P1 (section 5.2.1), Requirements for Evaluation of Accreditation Bodies, require traceability to SI to be demonstrated. A laboratory accreditation body may accredit a testing laboratory outside its own economy. It needs, therefore, to know if traceability to SI through the NMI in its own economy is equivalent to the traceability established through the NMI in the foreign economy. Appendices B and C of the Key

Comparison and Calibration Database provide this information. As part of the evaluation of a laboratory accreditation body prior to its being granted signatory status with the regional MRA (e.g. APLAC MRA), the international evaluation team needs to assure itself of the traceability to SI available in the applicant body's economy. The team examines the metrological infrastructure within the economy and the list of international and regional key comparisons in which the local economy's NMI has participated. Again, Appendices B and C of the Database assist in providing this information.

The CIPM global MRA, therefore, assists in the maintenance of the regional laboratory accreditation MRAs and the ILAC global Arrangement. Equally, though, the regional MRAs and the ILAC Arrangement support the CIPM global MRA because a NMI can demonstrate compliance with ISO/IEC 17025 through accreditation by its local laboratory accreditation body. Australia's National Measurement Laboratory is just one NMI that has chosen the accreditation route.

The Asia Pacific Laboratory Accreditation Cooperation (APLAC) was initiated in 1992 to provide a forum through which laboratory and inspection body accreditation organisations in the regional can meet, discuss issues and develop procedures for the establishment of a Mutual Recognition Arrangement such that laboratory test and calibration data and inspection reports produced in one economy in the region could be accepted throughout the region, and internationally through agreements with other regions. The APLAC Memorandum of Understanding (MOU) was signed in April 1995 by 16 economies in the region. Since then another three economies have joined APLAC. The membership of APLAC now almost mirrors that of APEC (Asia Pacific Economic Cooperation). The only exceptions are Chile, Peru and Russia that have not yet applied for APLAC membership, and India that is a member of APLAC but not of APEC.

The APLAC MRA was first signed amongst seven APLAC members in Tokyo in November 1997. As stated above, as of April 2002 nineteen of APLAC's twenty-eight members are now signatories to the APLAC MRA.

APLAC's role is, amongst others, to develop laboratory accreditation procedures and practices in the APEC region, to recognise competent test and calibration facilities in the APEC region, and to promote laboratory accreditation as a trade facilitation tool. Its primary objective is to ensure acceptance of test and calibration reports amongst all MRA signatory economies. This demands mutual confidence in the technical competence of accredited laboratories. This confidence cannot be legislated.

In parallel with the APLAC developments, the Standards and Conformance Sub-Committee (SCSC) of the APEC Committee on Trade and Investment has fostered the development of government to government MRAs for conformity assessment activities in regulated sectors such as electrical and electronic goods and foods. Other APEC groups, including the APEC Telecommunications Group and the APEC Energy Working Group, have also been actively developing government to government MRAs to reduce technical barriers to trade caused by lack of acceptance of exporting countries' conformity assessment activities.

APLAC has been identified by the APEC SCSC as one of five Specialist Regional Bodies whose MRA activities in the voluntary sector can complement and underpin the government to government MRAs being developed within the APEC region. Additionally, the Joint Statement of the Ninth Ministerial Meeting of APEC held in Vancouver on 21-22 November 1997 declared, inter alia, that:

“Ministers... encouraged participation by additional members in the Asia Pacific Laboratory Accreditation Conference (sic) Mutual Recognition Arrangement recently signed among accreditation bodies in five APEC economies”.

The APEC government to government MRAs recently developed in the telecommunications and electrical and electronic sectors acknowledge the APLAC MRA as one mechanism for supporting these regulatory sector MRAs. Australia has adopted use of the APLAC MRA as the preferred means of demonstrating the competence of its conformity assessment bodies. However, regulatory bodies in a number of other APEC economies are less familiar with the roles and capabilities of their own national laboratory accreditation bodies and the potential for use of the APLAC MRA to support their acceptance of test data from other APEC economies.

In 2000 the National Association of Testing Authorities, Australia (NATA) obtained funding from the Australian government's Department of Industry Science and Resources (ISR), through its APEC Market Integration Program, to undertake a project on behalf of APLAC to promote the APLAC MRA to regulators in selected APEC economies. Regulators in the People's Republic of China, Japan, Chinese Taipei, the Republic of Korea, Canada and the USA were visited. The project was undertaken by John Gilmour, the Immediate Past-Chair of APLAC, and Helen Liddy, APLAC Secretary. The objectives of the project were:

- to identify the appropriate regulatory areas in target APEC economies that could potentially use the APLAC MRA to accept test data from abroad
- to brief fully such regulators in the history, objectives and credibility of the APLAC MRA and its signatory bodies (including those resident in the target economies)
- to seek adoption of the APLAC MRA as the preferred mode or an agreed option for acceptance of test data from the relevant regulatory purposes
- to identify and attempt to resolve any concerns individual regulatory bodies may have about use the APLAC MRA.

From the discussions with the regulators visited it was clear that, in most of the economies, there is no fundamental objection to the concept that MRAs developed in the voluntary sector can be used to support regulatory sector MRAs, although there is a varying level of acceptance of this concept. There are, however, some objections to the concept of MRAs in the US; OSHA is one organisation that is not receptive to the use of MRAs, including at the government to government level.

Initially there was some misunderstanding amongst some regulators as to the case being presented by the project team. It was necessary to emphasise:

1. an exporting economy's laboratory would be accredited to test against the standards and/or regulations of the importing economy;
2. an exporting economy's laboratory test reports would not in any way take over the regulatory function of the importing economy's regulators.

In other words, it was important to distinguish between the acceptance by a regulator of test reports from a foreign laboratory and the regulatory decision made by the regulator. The APEC TEL MRA clearly distinguishes between the Regulatory Authority, Designating Authority, Accreditation Body, Conformity Assessment Body.

The main concerns highlighted by the regulators visited were:

- the need for a more specific definition of the scope of recognition of individual MRA signatories
- the need for MRA evaluations to target areas of particular interest to regulators and of importance to trade flows, e.g. those areas covered by current APEC MRAs
- the need to ensure that accreditation body assessors are competent to assess against foreign regulations
- the need to demonstrate that MRA evaluators are competent to evaluate that an accreditation body can accredit to foreign regulations
- the need for more targeted proficiency testing programs in areas important to trade flows, and an associated need for more transparency in publishing proficiency testing results
- the need for interpretative guidelines and/or checklists to assist accreditation bodies in assessing compliance with foreign regulations.

The team made a series of 15 recommendations for adoption by APLAC to assist in enhancing regulator confidence in the voluntary sector MRA process. The APLAC General Assembly and APLAC MRA Council accepted these recommendations in principle and the various Committees of APLAC are now working on them. For example, one recommendation was that proficiency testing programs, that are an integral part of the assessment process, should be more targeted to areas covered by the APEC MRAs and areas of trade significance. To this end, APLAC is seeking funding from the APEC Trade and Investment Liberalisation and Facilitation (TILF) fund to assist in the organisation of a series of testing and calibration proficiency testing programs particularly in the areas of regulatory interest. APLAC is also examining ways of setting up a series of technical meetings amongst regulators, accreditation bodies and relevant laboratories to discuss and resolve specific technical concerns in sectors such as telecommunications, electrical safety and food.

Although the project highlighted some areas for concern amongst regulators, there are success stories and the APLAC Public Information Committee has collected many of them to circulate amongst APLAC members to assist them in promoting laboratory accreditation to regulators within their own economies. APLAC is also providing funding for an Australia regulator (the Australian Communication Authority), that makes considerable use of laboratory accreditation, to present a paper at the forthcoming ILAC Conference in Berlin on the benefits to regulators of laboratory accreditation.

In conclusion, APLAC believes that MRAs in the voluntary sector are not an end in themselves but are important trade facilitation tools, and that dialogue between the voluntary MRA sector and regulators is critical. Regulator confidence in the MRA process cannot, however, be legislated. The signatories to the MRAs must work to demonstrate why the regulator can have that confidence.