Laboratory Accreditation and the APLAC MRA

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Abstract

Laboratory accreditation is independent, authoritative, credible recognition of competence of the laboratory to undertake specific tests. The accreditation assessment process is by peer review, and uses compliance with ISO/IEC 17025 as the basis of the competence assessment. Details of the relevance of such assessments, in a number of industrial sectors, are given.

In the Asia Pacific region (which includes Canada, the United States and Mexico as an integral part of its geography), a number of accreditation bodies have worked together to form the Asia Pacific Laboratory Accreditation Co-operation (APLAC). APLAC developed a regional mutual recognition arrangement (MRA) in 1997, which now has 23 accreditation authorities as signatories, from 17 economies. APLAC signatories include accreditation authorities from Canada, Mexico and the United States. Full details of all signatories to the APLAC MRA are given.

The APLAC (MRA) provides a means to recognise competent laboratories from other economies, where they have been accredited by their local accreditation authority. Many regulators throughout the Asia Pacific region now rely upon accreditation, and the APLAC MRA, as assurance of rigour and credible validated measurement, in test reports to meet their mandatory requirements. Details of such recognition, and the consequent reduction in technical barriers to trade, are given with examples. The role of regulators, and their use of accreditation is discussed in some detail.

1.1 Accurate Measurement

Accurate measurement is critical. It is critical for consumers, for industry, and for regulators. In sectors that rely on accurate measurement, the accuracy of measurement plays a major role in both purchase decisions, and the price paid. An example is the wool industry, where the price of fine wool is very largely determined by the measurement of the diameter of the wool fibre. When wool is purchased, a number of parameters are determined that affect the price. These tests include diameter of the fibre, elasticity, strength, colour, and many other parameters.

For the buyer to accept these test results – these measurements, it is essential that they have credibility with regard to their accuracy. To have this necessary credibility, they must come from a laboratory that has been accredited by an accreditation authority recognised by the IWTO (International Wool Textile Organisation) – and most of the major wool buyers are members of this body.

1.2 Laboratory Accreditation

For any measurement to be useful, it must be recognised by the user – the buyer, the regulator, the manufacturer. Clearly, each of these could do their own checks on each laboratory they use, or they could use the laboratory accreditation system that has become a global institution. In most countries there is a single laboratory accreditation authority – in the United States there is more than one. These authorities use similar processes in accrediting laboratories. They are really looking to ensure the laboratory is competent to carry out the tests it undertakes. They also all use a technical expert as part of a peer assessment of the laboratory. The key issues that are examined include the competence and experience of staff – particularly those doing the actual testing; the integrity and traceability of equipment and materials; the technical validity of the methods used; the validity and suitability of the results (good quality control procedures); and compliance with the Standard ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*. The assessment of laboratories is both rigorous and comprehensive, so other parties can have confidence in the recognition of competence provided by the accreditation authority.

Confidence in a laboratory's competence to produce accurate results is imperative. I would suggest there is no point in a measurement – at all – unless you have confidence in its reliability. The example I give above was for wool testing. However, measurements from accredited laboratories are now part of our every-day life.

1.3 Sectors Using Laboratory Accreditation

If you need a medical test – whether it is your HIV/AIDS test, or your cholesterol, or blood sugar, you assume the laboratory result is correct. Similarly if you have a chest x-ray, you assume the radiology practice is competent.

When you buy food at a supermarket, you assume two things – if it is refrigerated or fresh produce, you assume it is safe (chemically and microbiologically). If it is a manufactured

food product, you assume the food label gives a true and fair indication of the item's composition. But how do you know your assumptions are correct?

Some of you may have heard of bird flu. The veterinary testing laboratories that test for avian flu are accredited in most economies – at the insistence of their regulatory bodies.

Electromagnetic compatibility (EMC) testing gives some assurance that when you are talking on your roving phone at home, your neighbour is not listening to your conversation through his television set.

The variety of products and situations in which laboratory accreditation is important are far too many to cover them all, but include drinking water, air quality, aviation fuel, wine and beer – the list is endless.

2.1 The APLAC MRA (Asia Pacific Laboratory Accreditation Cooperation mutual recognition arrangement)

During the early 1980s, laboratory accreditation authorities recognised that if another accreditation authority had followed similar processes in assessing the competence of laboratories, there was no reason why they could not also recognise such competence in their own economy. The first such mutual recognition arrangement was signed in 1981, and was followed over the next 15 years by a number of bilateral recognition "arrangements". During the late 1990s, it was clear that if a number of accreditation bodies recognised each other's accreditations on a bilateral basis, then a regional arrangement was a more efficient, cost effective mechanism than continuing with multiple bilaterals. The APLAC MRA was signed by seven accreditation authorities in 1997, and has now grown to include 23 accreditation authorities from seventeen economies.

2.2 APLAC Member Signatories

The APLAC membership is largely based on the economies of APEC (the Asia Pacific Economic Cooperation), which includes Canada, the United States and Mexico as an integral part of its geography. APLAC gives automatic entry to its organisation to government endorsed accreditation authorities from APEC economies (as members – not as MRA signatories). The only APEC economies not within APLAC are Chile, Peru and the Russian Federation. All three North American economies are strong supporters of APLAC, and actively participate at all levels, with representatives from Canada and the United States also on the APLAC Board of Management.

The full list of APLAC MRA signatories (who recognise the accreditation of laboratories by other signatories as equivalent to accreditation by its own accreditation authority) is shown in Table 1 [1]. Only those APLAC member accreditation bodies which have been peer evaluated, and accepted by the APLAC MRA Council are APLAC MRA signatories.

Table 1 Parties to the APLAC MRA (November 2005).

Economy	Organisation	Acronym	Area/s Included
Australia	National Association of Testing Authorities, Australia	NATA	Testing/Calibration; Inspection
Canada	Standards Council of Canada	SCC	Testing /Calibration
	Canadian Association of Environmental Analytical Laboratories	CAEL	Testing
People's Republic of China	China National Accreditation Board for Laboratories	CNAL	Testing/Calibration: Inspection
Hong Kong, China	Hong Kong Accreditation Service	HKAS	Testing/Calibration; Inspection
India	National Accreditation Board for Testing and Calibration Laboratories	NABL	Testing/Calibration
Indonesia	Komite Akreditasi Nasional	KAN	Testing/Calibration; Inspection
Japan	Japan Accreditation Board for Conformity Assessment	JAB	Testing/Calibration
	International Accreditation Japan (IAJapan)	IAJapan	JCSS
			JNLA
			ASNITE Testing
			ASNITE Calibration
	Voluntary EMC Laboratory Accreditation Centre	VLAC	Testing
Republic of Korea	Korea Laboratory Accreditation Scheme	KOLAS	Testing/Calibration
Malaysia	Department of Standards, Malaysia	DSM	Testing/Calibration
Mexico	Entidad Mexicana de Acreditacion	ema	Testing/Calibration/ Inspection
New Zealand	International Accreditation New Zealand	IANZ	Testing/Calibration; Inspection
Philippines	Bureau of Product Standards Laboratory Accreditation Scheme	BPSLAS	Testing/Calibration
Singapore	Singapore Accreditation Council	SAC	Testing/Calibration; Inspection
Chinese Taipei	Taiwan Accreditation Foundation	TAF	Testing/Calibration; Inspection
Thailand	Thai Laboratory Accreditation Scheme	TLAS	Testing/Calibration
	Department of Medical Sciences	DMSc	Testing
United States of America	American Association for Laboratory Accreditation	A2LA	Testing/Calibration;
	International Accreditation Service, Inc.	IAS	Testing/Calibration; Inspection
	National Voluntary Laboratory Accreditation Program	NVLAP	Testing/Calibration
Vietnam	Bureau of Accreditation	BoA	Testing/Calibration; Inspection

2.3 The Purpose of the APLAC Mutual Recognition Arrangement (MRA)

As noted earlier, the APLAC MRA grew from a series of bilateral agreements between individual accreditation authorities. While accreditation gives recognition of competence of a laboratory by its own accreditation authority, that competence is not necessarily recognised elsewhere. The concept of mutual recognition between accreditation authorities first began in 1981 [2], with the agreement between New Zealand and Australian accreditation authorities. This was not to recognise each other, but to recognise the accreditation of a testing laboratory by the other organisation as being equivalent to an accreditation by its own organisation. The key point is accepting for its own purposes, endorsed test reports issued by a laboratory accredited by the other organisation on the same basis as it accepts endorsed test reports from its own accredited laboratories. There is also a requirement to promote such recognition in their own economies and elsewhere, including the acceptance of endorsed test reports.

The concepts developed by this first agreement have in essence been included in the APLAC MRA. The whole purpose of the MRA is to provide a mechanism where test reports (from accredited laboratories) can be accepted everywhere.

There is also a specific requirement in the APLAC MRA for signatories to promote to their governments the use of this arrangement in support of recognition arrangements in the regulated sector.

The key point regarding the APLAC (and ILAC) MRA is that it exists to provide recognition for test reports from accredited laboratories.

3.1 Technical Barriers to Trade

Many of you will be aware of the concept of technical barriers to trade (TBTs), also referred to as non-tariff barriers (NTBs). Clearly, if acceptance of test-reports is a requirement for trade, then the non-acceptance of such a test-report is a non-tariff barrier.

In many economies, regulators now recognise the benefit of the enormous cost savings to taxpayers, and the reduction in compliance costs, by several regulators all accepting test-reports from an accredited laboratory, rather than undertaking their own duplicate audits. In general, regulators have recognised that the assessment undertaken by an APLAC MRA signatory is both more rigorous, and more comprehensive, than the audit generally undertaken by a regulator. The involvement of a technical expert as a peer-assessor gives added credibility to the accreditation assessment.

In many jurisdictions, the regulators who recognise the value of laboratory accreditation also recognise and use the benefits from the APLAC MRA process. In the EMC example I gave earlier, the New Zealand radio frequency spectrum regulator now recognises all test reports from all countries, provided they are from a laboratory that is accredited by an IANZ (International Accreditation New Zealand) mutual recognition partner signatory, including SCC (Canada), NVLAP, IAS and A2LA (USA) and EMA (Mexico).

3.2 The Role of the Regulator

Clearly the primary role of any regulator is to protect the health and safety, or the environment, for its own citizenry. However, many regulators have recognised that they can achieve their primary aim, and still not hinder trade, by utilising some basic common elements.

In areas where many regulators use the same common standards (as in the case for EMC), then a common process for recognising competent laboratories to test against these common standards should be welcomed. The APLAC MRA provides just such a process, in a cost-effective, transparent manner.

In areas where different technical standards are used (frequently an issue between the United States and Europe), the recognition of competent laboratories provides an ever more valuable tool, as an accredited laboratory in "Country A" can be recognised as competent to assess compliance with the testing standard mandated by the regulator in "Country B". Even though the regulatory requirement differs in the two economies, the ability to recognise the same conformity assessment process actually facilitates trade, and removes the need for further intervention (and increased cost) at the regulatory level.

As an example, in New Zealand, regulators recognise and use the IANZ accreditation process in a number of sectors, as shown in Table 2.

Table 2. New Zealand regulators using IANZ accreditation.

(a)	New Zealand Food Safety Authority • Domestic Food Safety Programme auditor (inspection) • Dairy industry Product Safety Programme auditor/inspectors (inspection) • Meat industry Risk Management Programme auditors/inspectors (inspection) • Dairy industry testing laboratory accreditation • Wine industry testing laboratory accreditation
(b)	Ministry of Health • Drinking Water Risk Management Programme assessors (inspection) • Drinking Water Approved Laboratories • Accreditation of medical testing laboratories • Assessment of providers to the MoH National Cancer Screening Unit surveillance programmes
(c)	Department of Labour • Inspectors under the PECPR (Pressure Equipment, Cranes and Passenger Ropeways) Regulations • Inspectors under the Petroleum Exploration Regulations

In sectors relevant to trade, such as electrical safety and electromagnetic compatibility, New Zealand regulators also recognise IANZ MRA partners, and the test results from laboratories accredited by IANZ's signatory partners. These regulators have recognised the enormous cost saving enabled by using accreditation – for the consumer, the manufacturer, the supplier, themselves, and the taxpayer.

They believe they can utilise the cost-effective benefits of accreditation, and the APLAC MRA, and still provide the assurances necessary regarding public health and safety, and environmental protection. Clearly, they are also satisfied with the conformity assessment procedures used in other economies as providing the necessary assurances of meeting their own applicable technical regulations and standards.

While the use of accreditation, and the APLAC MRA, is not the only means of meeting regulatory requirements, they do provide an efficient, cost-effective mechanism, now used increasingly around the world.

The APLAC MRA is clearly a very robust mechanism enabling and facilitating the recognition of test reports from accredited laboratories – A mechanism that is working very well.

References:

1 APLAC Document SEC 039 listed on the APLAC web site www.aplac.org
2 NATA –TELARC Bilateral Mutual Recognition Agreement 1981