APLAC GUIDELINES ON ASSESSING LABORATORIES AND INSPECTION BODIES TO MEET FOREIGN REGULATORY REQUIREMENTS

PURPOSE

This document provides guidance to APLAC members on assessing laboratories and inspection bodies to meet foreign regulatory requirements.

AUTHORSHIP

This publication has been written by the APLAC Technical Committee.

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FURTHER INFORMATION

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1. INTRODUCTION

Regulatory authorities in all economies make use of testing and calibration laboratories and inspection bodies to verify regulatory compliance to protect the health and well being of their constituency, to protect their environment and natural resources, and to safeguard the integrity of their commerce and trade. For regulatory enforcement to be effective, regulators must be assured of the integrity of the test or inspection results upon which they make a decision on compliance. Generally, this is achieved through either the establishment of their own testing laboratories or inspectorates, or through a mechanism of approval of second or third party laboratories or inspection bodies. Increasingly in many economies, regulators make of accreditation as an integral part of their mechanism for laboratory or inspection body approval.

Generally, however, accreditation in itself may not fully meet the needs of regulators. Regulators set regulatory requirements that reflect the demands of the society they represent. The specific requirements of domestic regulations are influenced by many factors such as the natural environment, culture and customs, political ideology, and economic wealth. To facilitate globalisation of trade, such fora as APEC and the WTO seek to standardise common aspects in regulatory requirements, but recognise there will always be differences between economies. The goal is to increase transparency where there are differences and to provide justification of these requirements.

As a more global free trade market develops, some economies are entering into smaller multi-lateral or bi-lateral free trade agreements (FTA). At the most formal level these are in the form of Government to Government FTAs. These agreements do not necessarily recognise each other's regulatory regime as being equivalent, but recognise a trading partner's means of demonstrating compliance (conformity assessment) with their economy's domestic regulations as being equivalent to their own domestic conformity assessment system. This acceptance of equivalence of the conformity assessment systems within each economy of the FTA may be formalised through a Government to Government Mutual Recognition Agreement (MRA).

The conformity assessment infrastructure within each economy must be able to deliver the outcome required by all other partner economies in the MRA. To ensure this is effective, each Government is responsible for approving organisations to demonstrate regulatory compliance of traded goods and services with the other partner economies' requirements. This process is usually known as "designation". In several economies within the Asia-Pacific region and elsewhere, accreditation is used in the designation of testing laboratories and inspection bodies, either as a pre-requisite for designation by another (usually Government) body or as the mechanism for demonstrating full compliance with designation criteria.

2. ACCREDITATION AND THE DESIGNATION OF CONFORMITY ASSESSMENT BODIES

The use of accreditation as an integral part of the designation process places additional demands on the accreditation bodies. The accreditation community has committed significant resources to the promotion of accreditation to Governments as the legitimate and preferred option for demonstrating the technical competence required of conformity assessment bodies in a robust designation process. It is critical that accreditation meets the expectations of trade negotiators and regulatory agencies within MRA or FTA partner economies.

In addition to the generic criteria for accreditation of laboratories and inspection bodies (using the international standards ISO/IEC 17025 and ISO/IEC 17020 respectively), accreditation bodies need to apply additional criteria in the assessment of a laboratory or inspection body to ensure its competence to be designated under a MRA or FTA. The laboratory or inspection body should be able to demonstrate:

- a knowledge of the technology of the relevant products, processes or services called up under the MRA or FTA;
- an understanding of the technical standards and the general risk protection requirements for which designation is sought;
- experience relevant to the applicable legislative, regulatory and administrative provisions, and an understanding of these provisions;
- the physical capability and competence to perform the relevant testing or inspection activity;
- an adequate management of the testing or inspection concerned;
- and any other circumstances necessary to give assurance that the testing or inspection activity will be adequately performed on a continuing basis.

While several of the above points are inherent in the generic accreditation criteria (e.g. capability, competence and management of the testing or inspection activity), some are not; in particular, a demonstrated knowledge of the technical standards and general risk protection requirements, and experience in and understanding of the legislative, regulatory and administrative provisions. Before assessments of a laboratory or inspection body that needs to meet foreign regulatory requirements, the accreditation body must ensure that it has access to expertise necessary to conduct an effective assessment of the competencies.

2.1 First steps

The accreditation body needs to ensure it is fully familiar with the requirements of the Government to Government MRA in relation to conformity assessment. Ideally, the accreditation body should have been involved in its Government's delegation during the negotiation of the MRA. Where this has not been possible, the accreditation body should liaise with the responsible Government officials to ensure their requirements and expectations are clearly established and that effective lines of communication are put in place.

It is also desirable that the accreditation body has the opportunity to liaise with the regulatory agencies in the other Governments that are parties to the MRA. Their requirements should be clearly understood so that the accreditation services provided fulfil the expectations of the designation process. It is advisable to involve the relevant accreditation bodies in the partner economies in these liaisons. These accreditation bodies may or may not be directly involved in the domestic designation processes but at the least they can advise on the local legislative, regulatory and administrative processes and should be able to provide a link to the relevant Government agencies.

Once the technical, regulatory and administrative requirements of all MRA partners in relation to conformity assessment are clearly established and documented the accreditation body is in a position to assess any laboratories or inspection bodies for the purposes of designation.

2.2 Assessments as part of regulatory designation

The accreditation body will be assessing the laboratory or inspection body against the requirements of foreign technical standards or specifications. Assembling an assessment team with the necessary knowledge and expertise to conduct an effective assessment of technical competence against these foreign standards can present some challenges. The following options may be available to ensure an effective assessment is done:

- Subcontracting the assessment to the accreditation body from the partner economy. This accreditation body may already have the requisite knowledge, experience and access to expertise to provide the required assessment service.
- Conduct of a joint assessment with the accreditation body from the partner economy.
- Using technical assessors and/or technical experts from the partner economy who are familiar with the technical and regulatory requirements. These should come on the recommendation of the accreditation body and/or the regulatory agency in the partner economy.
- Sourcing the necessary expertise (technical and regulatory) locally.

The assessment team must ensure the applicant laboratory or inspection body fully understands the designation processes and its roles and responsibilities on behalf of the regulators in the partner economy. This includes not only the technical standards and specifications, but also the legislative, regulatory and administrative environment in the partner economy. Sufficient time must be allocated to ensure an effective and thorough assessment of technical competence to a level expected in relation to conformity assessment by the Government to Government MRA.

2.3 The assessment outcome

The accredited laboratory or inspection body must have demonstrated a level of technical competence in all relevant aspects of the MRA and all relevant technical standards and specifications. The assessment report should specifically record the level of compliance with the MRA requirements and technical standards. Once full compliance has been demonstrated, the accreditation body follows the required or agreed administrative procedures that lead to the formal designation of the laboratory or inspection body.

The accreditation documents describing the scope of accreditation should clearly show those technical standards and specifications for which the laboratory or inspection body has demonstrated competence. This information should be readily accessible by all interested parties e.g. the domestic Government, the partner economy regulatory agencies, the accredited laboratories or inspection bodies, and the exporters and importers of the goods and services covered under the MRA for which conformity needs to be demonstrated by an approved conformity assessment body.

2.4 On-going actions

The accreditation body needs to ensure the requirements of foreign regulators continue to be assessed in an effective manner under its surveillance activities. This means keeping up-to-date with any changes in the partner economy regulatory requirements and/or processes, and ensuring that the accredited designated laboratories or inspection bodies also keep up-to-date. Maintaining effective lines of communication with the relevant Government agencies responsible for the maintenance of the MRA is essential in this regard.

3. ACCREDITATION OUTSIDE A FORMAL GOVERNMENT TO GOVERNMENT MRA

Laboratories or inspection bodies may request accreditation for tests or inspection activities required by foreign regulatory agencies in the absence of any formal Government to Government agreement on the conformity assessment mechanisms, i.e. without any formal designation process. The reason for this may be that the regulatory agencies in the importing economy accept accreditation without the need for any formal MRA. The laboratory or inspection body may be seeking accreditation to assist its clients (exporters) to overcome potential or real problems of acceptance of their test or inspection reports or the laboratory or inspection body may wish to promote and have recognised its expertise in this area.

The accreditation body should be able to offer this service and the same principles as described above should be applied in the accreditation process. The accreditation body should clearly establish the requirements of the laboratory or inspection body; and the requirements of the customers of the laboratory or inspection body and of other stakeholders in the services provided. The accreditation body should also ensure it has access to the expertise necessary to conduct an effective assessment of technical competence. The accreditation body should make it clear to the applicant laboratory or inspection body the status of the proposed accreditation in terms of acceptance by foreign regulators. In the absence of any formal Government to Government MRA that includes requirements for conformity assessment there may be no guarantee that the test or inspection reports will be accepted on the basis of the accreditation.

4. SUMMARY

Foreign regulator acceptance of accreditation is a positive development for the accreditation community and a major step toward securing its future in the conformity assessment activities related to the globalisation of free trade. Regulatory confidence in the accreditation process can, however, only be maintained and expanded if accreditation continues to meet the needs and expectations of the regulatory agencies around the world. Failure to do so will see the credibility of accreditation diminished and could result in costly regulatory inspection, duplicating the accreditation activities in the voluntary sector.

Accreditation bodies that are asked to accredit laboratories and inspection bodies against foreign standards and specifications in support of Government to Government trade agreements and MRAs must ensure that they deliver a service that meets the needs of all parties to the agreements. This requires the accreditation body to familiarise itself with all aspects of the designation processes, and to ensure that a thorough and focussed assessment of the competence of their accredited organisations has been done. The competence of the accredited organisation in the requirements of the regulatory agencies must be clearly demonstrated – not only to the accreditation body, but to all parties in the Mutual Recognition Agreement.