# How does using an Accredited Laboratory benefit Government and Regulators?







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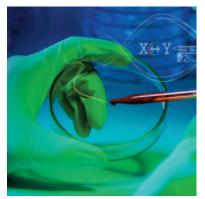
Government bodies and regulators are constantly called upon to make decisions related to:

- Protecting the health and welfare of consumers and the public
- Protecting the environment
- Developing new regulations and requirements
- Measuring compliance with regulatory and legal requirements
- Allocating resources, both technical and financial

In order to make informed decisions, they must have confidence in the data generated by laboratories carrying out testing, measurement or calibration in these fields. Using an accredited laboratory can help establish and assure this confidence.

When a laboratory is accredited by a recognised accreditation body, it has demonstrated that a prescribed level of technical competence to perform specific types of testing, measurement or calibration activities has been achieved. The result is assurance that the laboratory is capable of producing data that is accurate, traceable and reproducible – critical components in governmental decision-making.







# Accreditation in support of Regulation

Using an accredited laboratory benefits government and regulators by:

- Increasing confidence in data that is used to establish baselines for key analyses and decisions
- Reducing uncertainties associated with decisions that affect the protection of human health and the environment
- Increasing public confidence, because accreditation is a recognisable mark of approval
- Eliminating redundant reviews and improving the efficiency of the assessment process (which may reduce costs)

Using an accredited laboratory also increases confidence that:

- Decisions regarding multiple facilities are based on comparable data
- Purchases received from suppliers are safe and reliable
- Costs associated with laboratory problems, including re-testing, re-sampling, and lost time are minimised
- False positives and negatives, which can directly affect compliance with regulations, are minimised

Using accredited laboratories also facilitates trade and economic growth. The accreditation process relies on a uniform approach to determining laboratory competence – an approach that has been accepted and implemented across many borders; it is in fact worldwide industry practice. Because of internationally accepted testing and measurement practices, data generated by accredited laboratories may lead to the more ready acceptance of exported goods in overseas markets. This reduces costs and eases exports and imports as it reduces or eliminates the need for retesting in another country.

In the early days of accreditation in the 20th Century, it was predominantly seen as a voluntary activity. However, now, in many economies, accreditation has been widely embraced by governments and accreditation has become "mandatory" in many regulated areas as more and more governments and regulators appreciate the benefits that accreditation brings to help governments meet their responsibilities and safeguard the public.

For example, in the Asia-Pacific region, APEC (the Asia Pacific Economic Cooperation) endorses accreditation, with the Asia Pacific Laboratory Accreditation Cooperation (APLAC) recognised as an APEC Specialised Regional Body. Accreditation is now used to underpin the conformity assessment component of the APEC agreements.



### Accreditation in support of Regulation

Similarly, ASEAN (the Association of Southeast Asian Nations) with its ten member states, has included accreditation in the ASEAN sectoral MRA for electrical and electronic equipment as a means of meeting the mandatory requirements of each member and to facilitate the implementation of the ASEAN Free Trade Area (AFTA).

In Europe, the Council of the European Union and the European Parliament have agreed on a Regulation that provides a legal framework for the provision of accreditation services across Europe. The Regulation, covers the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by legislation. The Regulation recognises the benefits of accreditation by legislating that accreditation be used as a means to show compliance with mandatory requirements.

The Regulation also recognises the European co-operation for Accreditation (EA) as the co-ordinating organisation for the national European accreditation infrastructure.

In the Americas, regulators and government entities throughout the region are increasingly relying on results from accredited laboratories to meet their mandatory requirements in areas as diverse as food safety, environmental protection, toy safety, and the quality of concrete, steel, electrical products and a variety of other products and services. The InterAmerican Accreditation Cooperation (IAAC) is committed to disseminating the concepts and advantages of accreditation and is responsible for ensuring that accreditation bodies in the region operate their programs to stringent international requirements. In 2014, the three Regional Quality Infrastructure Organizations in the Americas, the Inter-American Accreditation Cooperation (IAAC); the Inter-American Metrology System (SIM); and the Pan-American Standards Commission (COPANT), signed a Memorandum of Understanding (MOU) to create the Quality Infrastructure Council of the Americas.

The mainstream acceptance of accreditation by pan-regional bodies, and domestic regulators within individual governments, also helps member governments of the World Trade Organisation (WTO) to meet their responsibilities of the Technical Barriers to Trade Agreement (TBT Agreement), and Sanitary and Phyto Sanitary Agreement (SPS Agreement).

Further examples of how accreditation benefits Government departments and regulators can be found at **publicsectorassurance.org** 





Accreditation is often provided by one nationally regulated and recognised accreditation body, within a country. There are also several economies where there are multiple accreditation bodies that are signatories to the ILAC MRA. In some developing economies without established accreditation bodies, laboratories may have to seek accreditation from an established accreditation system in another country.

Specialist technical assessors from the accreditation body conduct a thorough evaluation of the laboratory's practices, staff and equipment that impact on the production of test or calibration data. The laboratories are evaluated against particular international standards that are used throughout the world, either ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*, or ISO 15189 *Medical laboratories – Requirements for quality and competence*.

Accredited laboratories are regularly re-examined to ensure that they maintain high standards of technical expertise. Laboratories may also be required to participate in regular proficiency testing programs as an on-going demonstration of their competence.

Government representatives, at their option, are welcome to take part in on-going assessments in order to maintain their confidence in the accreditation system.

How does laboratory accreditation differ from ISO 9001 certification? ISO 9001 certification demonstrates that a laboratory has an established quality management system, but it does not address technical competence. Laboratory accreditation takes the next step, using criteria and procedures specifically developed to determine technical competence.

#### How do I find an Accredited Laboratory?

To find out if your country has an accreditation body that is a signatory to the ILAC MRA, visit the ILAC website at **www.ilac.org** and use the signatory search option to identify an appropriately recognised accreditation body.

Accreditation bodies in most countries publish lists or directories of the laboratories they have accredited, which include laboratory contacts and individual testing capabilities. The ILAC website also includes links to directories of accredited laboratories in many countries. Accreditation bodies may also assist you by identifying laboratories that they have accredited that can perform the tests or calibrations you require.



## What factors are important when choosing a Laboratory?

When selecting a testing, calibration or measurement laboratory, you need to be sure that it can supply you with accurate and reliable results that meet your requirements.

The list of the test, calibration, or measurement procedures for which the laboratory is accredited is specified in a laboratory's Scope of Accreditation, which can either be provided by the laboratory upon request, or is contained within the directory of accredited laboratories produced by the accreditation body.

You should check that the laboratory is accredited for the specific work that you require to be undertaken.

When an accredited laboratory carries out work covered by accreditation, it usually includes an accreditation symbol or endorsement on test or calibration reports.

The technical competence of a laboratory depends on a number of factors, including:

- Qualifications, training and experience of the staff
- Correct equipment properly calibrated and maintained
- Adequate quality assurance procedures
- Proper sampling practices
- Appropriate and valid testing procedures and methods
- Traceability of measurements to national standards
- Accurate recording and reporting procedures
- Suitable testing facilities

By being accredited, the laboratory is demonstrating that these requirements, amongst others, have been and continue to be met.







#### Where can I get more information?

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement – among Accreditation Bodies (ABs) in order that the data and test results issued by laboratories and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of "accredited once, accepted everywhere".

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

ABs that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent application of those standards.

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ABs having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.



The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at: **www.publicsectorassurance.org.** 

#### For more information contact:

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