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Trade Capacity Building

Laboratory Accreditation in Developing Economies

Tested Once - Accepted Everywhere

Working paper No.2

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

economy environment employment

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INTERNATIONAL LABORATORY
ACCREDITATION COOPERATION

UNITED NATIONS INDUSTRIAL
DEVELOPMENT ORGANIZATION

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Contents

Executive Summary

This publication has been developed in support of a joint project between the International Laboratory Accreditation Cooperation (ILAC), the International Organization for Standardization (ISO) and the United Nations Industrial Development Organization (UNIDO) to prepare laboratory accreditation bodies in developing countries for participation in the ILAC Mutual Recognition Arrangement (the Arrangement).

The preliminary work on what was to eventually become the Arrangement effectively started as long ago as 1977, and events led to the signing of an MoU in 1996 to accelerate the process of confidence building between the two main regions, APLAC and EA. Following this there was intensive activity including a lot of peer evaluation work and assistance from the BIPM in terms of their evaluation of the various national measuring systems. The outcome of all this work was the formalisation of the Arrangement by ILAC in 2000 to address problems associated with the existence of a multitude of bilateral and regional multi-lateral Mutual Recognition Agreements and Arrangements (MRAs or MLAs) which required multiple, and duplicative, peer evaluations for accreditation bodies seeking mutual recognition with like organisations. The ILAC Arrangement seeks to give global recognition to laboratory accreditation bodies through a single peer evaluation against internationally agreed criteria. The peer evaluation may be at the regional level or may be organised directly by ILAC where no suitable regional infrastructure exists or where it is inconvenient to use the regional body. Either way, common criteria and harmonised procedures are used irrespective of which body carries out the evaluation.

UNIDO has developed a programme in co-operation with ILAC and ISO that exposes accreditation bodies in eligible countries to the peer evaluation process used by ILAC to determine the acceptability of an accreditation body for signatory status in its Arrangement. In so doing, areas of both strengths and weaknesses are identified enabling early action to be taken prior to any formal peer evaluation, thereby facilitating admission to the Arrangement. This process, called a Pre-Peer Evaluation Procedure (PPEP), should assist eligible accreditation bodies to more easily understand the requirements of the Arrangement and, therefore, satisfy the formal process for admission.

This publication discusses the reasons why an accreditation body might be established (Section II) and provides some background into its essential operational requirements (Sections III and IV). It then outlines the international and regional organisations that exist and the pathways to participation in the ILAC Arrangement (Section V) while the role of UNIDO and the process of Pre-Peer Evaluation are discussed in Section VI. An Annex to the publication provides information on key web-sites where further detailed information can be found.

I. Introduction

Today the world has become a global village and domestic and export trade is vital to the development of any country's economy. A developing country's economy may be dependent on the export of foodstuffs and minerals and while such trade has existed for centuries there is an enhanced awareness today in regard to the safety of the former and the quality of the latter, even if it is mere coal. In the developed world the large fully integrated companies of the past (the automotive sector being a good example) have moved away from self dependence to focus on their core activities, outsourcing many components, devices and systems. In this industry this includes wheels, jacks, exhausts, electronic devices and even dashboard assemblies and many developing countries with lower cost labour have taken the opportunity of entering this expanding market. Export is critical to the growth of any country's economy, be it fresh fruit, minerals or manufactured goods. Adjacent countries can also be involved in the export of infrastructural goods or services that include electricity, water and telecommunications services.

The key to lowering of the barriers to international trade is accreditation, the whole basis of which is to create confidence in the work carried out by certification and inspection bodies, as well as testing and calibration laboratories, located anywhere in the world. In the absence of internationally recognised accredited facilities, tests carried out in the exporting country would have to be repeated by a recognised laboratory in the importing country and a adverse test report could result in the rejection of an entire shipment of food or manufactured goods. As these may have already have been transported halfway around the world this could be a very costly exercise for the exporter. In the field of accreditation this is often summarised by the saying "Tested once – Accepted everywhere". While international trade is fundamentally linked to supply capacity and cost, laboratory accreditation and the recognition of test results is a final determinant as to whether the goods produced by the exporter are acceptable in other countries. In terms of manufactured products, particularly components that must be built into value-added devices, the customer will most usually insist that the factory supplying them has a quality system based on ISO 9000:2000 and here again accreditation is key to providing assurance that certification bodies operating in one country follow the same strict procedures as those in others.

While accreditation is often thought to be mainly required for export purposes

it has an even larger role to play within a country's domestic economy. Accreditation or conformity assessment provides confidence to the buyer or user of services. In the internal economy accredited laboratories are used to test food and water, concrete and other building materials, electrical and telecommunication test equipment and the basic measuring instruments used in the manufacturing industry. When you have a blood, urine or other medical test you need to have confidence that the outcome is correct and that you are not incorrectly diagnosed as having HIV/Aids, malaria or a host of other diseases. Veterinary practices must be able to correctly diagnose rabies and the many bovine diseases that affect both domestic and export sales such as foot and mouth, anthrax, mad cow disease etc. Another core value of accreditation is that it provides confidence for consumers that everything from food and water, to electrical appliances and children's toys, and even motor vehicles, are safe and meet the conditions and standards imposed by the country's regulatory authorities. Protection of consumers has become increasingly necessary with the opening up of global trade which has seen a vast increase in the number of products and services available. Once again reliable results are essential and the role of accreditation is to ensure that within certain acceptable (and quantifiable) limits, tests of any type made on a product in say the Far East can be repeated with confidence in any other country in the world.

Conformity assessment is a term used to describe the whole process of accreditation and certification and is the process of determining whether products, processes, systems and people meet specified requirements. The ISO 9000 quality management system is well known throughout the world and here certification bodies that grant registration have to be accredited by recognised national accreditation bodies. These same accreditation bodies directly accredit inspection bodies as well as testing and calibration (metrology) laboratories as here the requirements go far beyond a formal quality management system and require evaluation of the technical and infrastructural ability of the organisation to perform specific tests or measurements or to be proficient in declaring that for example pressure vessels are indeed safe.

The purpose of this publication is to address the issue of accreditation for testing and calibration laboratories with special emphasis on the developing economies. The details of the intricacies of such accreditation are covered in the relevant ISO/IEC Guides and Standards, and references are given to the appropriate documentation that is available from national and international standards organisations. What this document provides is a detailed step by step guide to the process of accreditation and its requirements in terms of governmental, technical and human resources support. The need for accreditation,

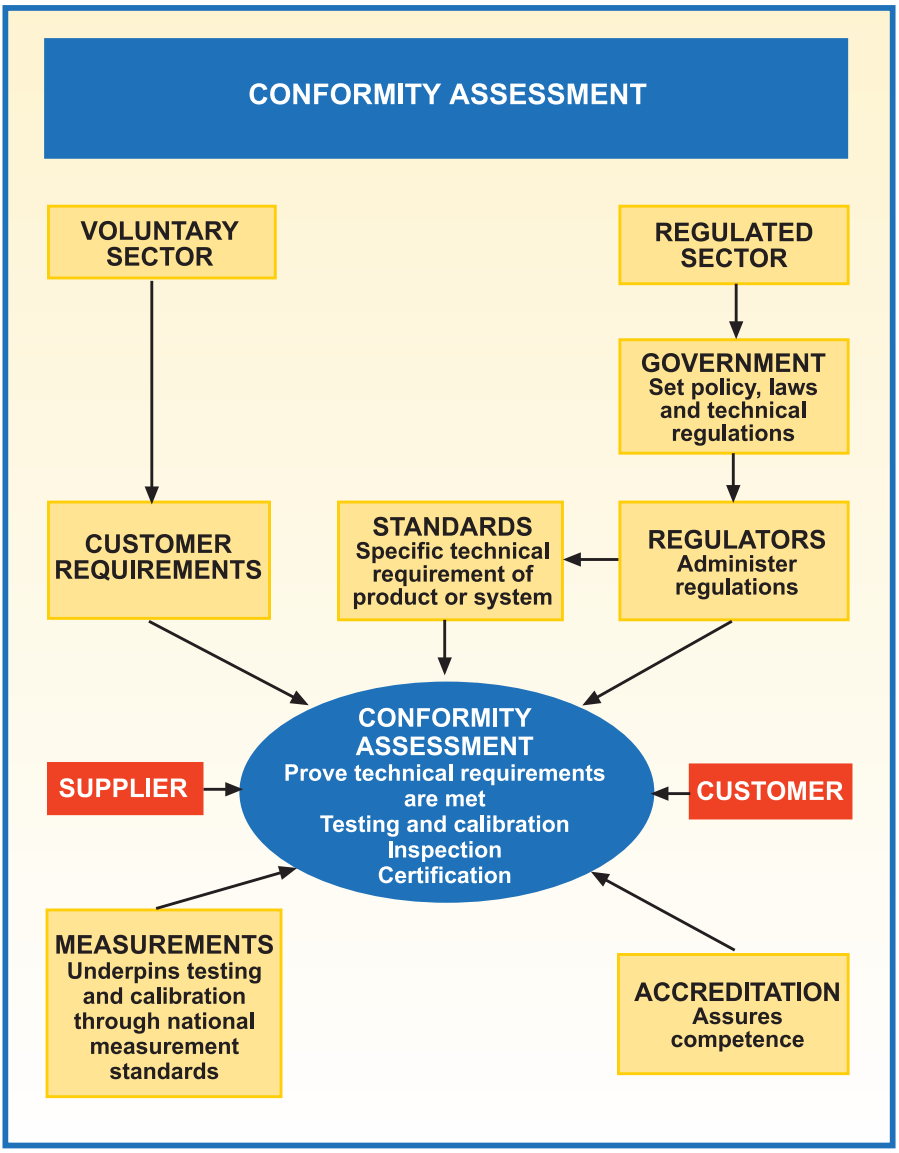
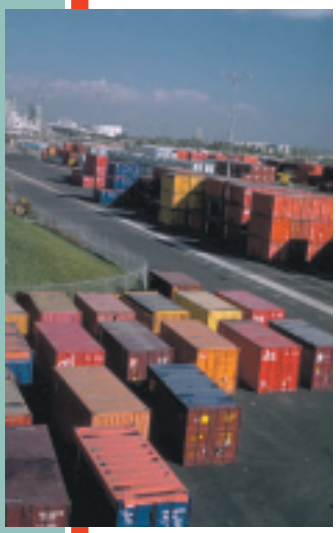


Figure 1. Example of a conformity assessment model

what it means for the economy of any country and the role that it plays in the facilitation of both domestic and export trade is also addressed. It is stressed that accreditation is not the only recognised route for conformity assessment but it is the one that offers the least duplication of effort, is the most transparent, most widely accepted and is the least discriminatory option.

It should however be stressed that while this is a guide to accreditation for developing economies there is no easy panacea for international recognition.

The core inherent value of accreditation for laboratories is that a test or measurement carried out on a sample or physical artefact in one country should produce the same result (within the limits of uncertainty of measurement) when carried out by another accredited laboratory elsewhere in the world. This means that all accredited laboratories throughout the world are subject to the same strict requirements, this creating the confidence in the whole accreditation process and ensuring that results produced by an accredited laboratory in one country will be accepted by authorities in any other country that is a signatory to the ILAC Arrangement or where a specific existing MRA exists.



The document does however address many issues pertinent to developing economies and the first of these is to provide guidelines in regard to whether there is a real need for such a body in terms of cost effectiveness and viability, and whether the needs of the economy could be better served by using another recognised national accreditation body. Where a decision is taken to establish such a body guidelines are provided on the necessary supportive infrastructure that must be established and ways in which the services of established bodies can be used during this formative process are defined. This assistance starts with the basic training of manpower and goes right through to the process of Pre-Peer evaluation which allows corrective action to be taken before formal application for approval. It should be noted that competition between accreditation bodies is rare or non existent. ILAC encourages accreditation of laboratories by a local body where it exists and it is only in exceptional cases, such as lack of the required technical expertise in a specific area, where accreditation by another nation's accreditation body would be condoned.

The circumstances of the emerging economies has been further alleviated through the establishment in 2000 of a Pre-Peer Evaluation Procedure in cooperation with UNIDO, ILAC and ISO. The scheme was based on one that has been in operation since 1997 under the auspices of UNIDO, the IAF and ISO and which was aimed at countries wishing to establish an accreditation system for certification bodies. The Pre-Peer Evaluation Process (PPEP) which is managed by UNIDO with the support of a joint Steering Committee with ILAC and ISO is fully operational and Pre-Peer Evaluations have already been provided to several emerging economies, those addressed since 2000 including Argentina, Colombia, Cuba, Egypt Jordan and Tunisia. Full details of the PPEP and the requirements for application for assistance are provided in this publication.

While the requirements for accreditation are onerous many poor and developing economies have committed themselves to the process and several are already full members of the ILAC Arrangement. Many others are associate members with operating accreditation bodies, and they are striving for full membership and recognition. Another category of ILAC membership is found in the affiliates. Affiliate members are mostly developing countries that are establishing or have declared their intention to establish an accreditation body in line with the requirements of ILAC. As stressed further in this document the board of ILAC is fully aware of the fact that the creation of the ILAC Arrangement was driven by the needs and foresight of the developed countries. The organisation actively promotes the participation of people from developing countries in their various fora so that their specific problems can be better understood. A joint IAF/ILAC committee to address the needs of developing countries has been established and this activity, which forms an active part of the business plans of both bodies, has its own funding allocation.

Towards the end of this publication reference is given to the regional accreditation organisations. For developing countries the most relevant of these is probably the SADC Cooperation in Accreditation (SADCA). SADCA has fourteen member states all of which are classified as developing economies and all of these countries support the concepts and application of accreditation. Only one country (South Africa) has an established and recognised accreditation body and only one other country in the region (Mauritius) has declared its attention (at this point in time) to establish one. The other member countries have decided that the most effective way for them to benefit from accreditation is to use one of the other bodies in the region to accredit their in-country laboratories. Although governmental issues may still have to be resolved this model could possibly be extended into other developing regions of the world, most notably perhaps the rest of the African continent.

In summary, conformity assessment covers a number of complementary activities related to demonstrating to end users that products and services satisfy certain requirements, or meet user specifications. As indicated above conformity assessment covers activities such as testing, calibration, inspection and certification. Services in terms of conformity assessment do not have to be provided nationally but all countries should have access to them either through international or regional organisations or through cooperative arrangements with neighbouring countries. Where a country establishes its own infrastructure it should ensure that all elements are addressed at a level sufficient for its requirements and it need not be more elaborate than necessary.

II. Role of Accreditation

A. What is laboratory accreditation?

Laboratory accreditation may be defined as:

> *A formal recognition that a laboratory is competent to perform specified tests or measurements.*

Irrespective of the precise wording of the definition, the essential elements are *formal recognition, competence* and *specified tests or measurements.*

When a laboratory is accredited its demonstrated capability is defined in a schedule of specific tests and calibrations granted by the accreditation body. This occurs only after the accreditation body is satisfied that the laboratory seeking accreditation has access to all necessary resources to undertake these particular tests correctly and is managed in such a way that it is likely to do this consistently.

In practice, this means that the laboratory is able to convince a team of technical experts that it is properly equipped, has available other necessary resources and that its staff have all appropriate qualifications and skills necessary to perform the tests in question. It is adequacy of the total package that establishes that the laboratory is competent to undertake the nominated tests. It must also be able to demonstrate that it is managed in compliance with the international standard ISO/IEC 17025.

Accreditation is designed to be a transparent process in which all interested parties should be aware of the rules and processes underlying the system. It is also non-discriminatory in that any laboratory

able to demonstrate competence and which complies with the rules can be accredited. All laboratories are treated equally, irrespective of ownership, and it is on these grounds that it provides an open and fair mechanism for the selection of a laboratory to undertake particular projects or contracts.

It is important to understand the difference between accreditation to ISO/IEC 17025 and certification or registration to ISO 9001 and not to confuse the two approaches. The ISO 9000 family of standards is concerned with quality management and these may be applied to any organisation. ISO/IEC 17025 and laboratory accreditation are concerned with competence and quality management of laboratories only. ISO/IEC 17025 specifies all the relevant quality management elements of ISO 9001 (1994) and, in addition, addresses other matters of a technical nature, such as competence of staff, test method validation, uncertainty of measurement and use of reference materials. It is suggested that none of the ISO 9000 standards are appropriate as benchmarks for selection of a laboratory. ISO/IEC 17025:1999 is aligned to ISO 9001:1994 and consideration is already being given to its alignment with ISO 9000:2000. An official communiqué (IAF/ILAC JWG/12) clarifying the differences between accreditation and certification has been prepared by an IAF-ILAC-ISO/CASCO Joint Working Group and was issued in December 2002.

Certification:

- Means compliance with a standard or specification (e.g. systems or product standards)
- Uses management system auditors who are certified by an independent body as meeting internationally agreed criteria
- May be general in the scope of recognition
- Considers the total business.

Accreditation:

- Is the recognition of specific competence and its scope is normally highly specific
- Evaluates people, skills and knowledge
- Uses assessors who are recognised specialists in their fields
- Evaluates the supporting management systems for a specific activity
- Involves practical tests as appropriate (proficiency testing and measurement audits).

While this publication deals essentially with laboratory accreditation, for most countries setting out to establish an accreditation body it would be sensible to consider a single accreditation body to offer accreditation for all conformity assessment and management system activities. This could extend to laboratories, quality management certification and product certification bodies and inspection bodies as well as bodies providing certification of environmental management and, possibly, occupational health and safety and food safety. Many of the general issues considered in this publication apply across all areas mentioned above but laboratory accreditation has special technical needs not found to the same extent in the other activities. All examples given in this document are in the context of testing or measurement.

B. What it can and cannot do

Accreditation of laboratories, in one form or another, has been practiced for well over one hundred years. The earliest programmes were often associated with purchasing by various armed forces and other large government procurement agencies such as civil construction authorities. Some large private corporations have also had systems for approval of suppliers to test products prior to shipping. In many countries, these systems remain.

All of the early programmes were what today would be called "second-party" schemes in that they were intended to serve only the immediate needs of the body making the evaluation. These organisations, such as the military

procurement agencies and other government authorities, established their own standards, usually without reference to any other body, and often ignoring equivalent standards developed by national and international consensus standards setting bodies. They generally have been unconcerned about whether or not others used or recognised their systems. Some of these organisations maintained (and continue to do so) quite substantial bureaucracies to manage their particular systems, including employing the inspectorial staff needed to make the evaluations of the external laboratories.

The purpose of all second-party systems of course is to minimise testing and inspection to be conducted by laboratories operated by the authority itself after products had been delivered, at which stage rejection costs are greatly increased. In many countries different agencies have maintained comparable inspection programmes in parallel without giving any recognition to the other programmes operating concurrently. Such duplication leads to inefficiencies, inconvenience to suppliers and, sometimes, outright conflict as suppliers were subjected to conflicting demands from different customers.

In more recent times, many of these second-party programmes have given increased recognition to standards prepared by national and international standards setting bodies rather than rely on their own internal standards.

Third-party accreditation, much as it is practiced today, was introduced into Australia in 1947 as part of a deliberate policy by the national government to foster industrial development and to up-grade the quality of manufactured goods. It followed a very successful programme launched by Australian Defence procurement authorities during World War II to facilitate manufacturers' declarations of compliance of products with specifications. Its novelty was to recognise that there are many elements common to all such laboratory approval programmes, irrespective of the end user of the test data, and it was possible to unify the disparate, and sometimes idiosyncratic, approaches that had previously existed. The development of a single common set of criteria applicable to all laboratories was a forerunner of ISO 17025.

This initiative recognised that valid measurements were necessary to underpin the successful and efficient manufacture of industrial products. The Australian

government first established a national measurement institute (now the National Measurement Laboratory) in 1939 and, in 1947, created an organisation, the National Association of Testing Authorities (NATA) whose objectives were to:

1. Set standards of good laboratory and measurement practices.
2. Identify laboratories seeking, on a voluntary basis, recognition to those standards.
3. Encourage all laboratories to aspire to meet those standards.
4. Optimise use of scarce testing resources by means of recognition of a single test from an approved laboratory.
5. Promote the use of accredited test reports to eliminate, or at least minimise, duplicate testing.
6. Promote good testing and measurement practices.

No other country followed this model at the time and tended to maintain their existing systems of second-party approval programmes. Internal political considerations were generally not conducive to major restructuring of domestic conformity assessment systems. It was only the advent of the discussions within the General Agreement on Tariffs and Trade (GATT) in the 1970s, discussed later in this document, when the concept of accreditation as a tool for trade facilitation was introduced.

Its possible use for domestic purposes has only been appreciated in very recent times as governments have moved to smaller bureaucracies and to contract out delivery of many services, including laboratory testing. To do this successfully, there must be some form of evaluation of the competence of laboratories offering their services to replace the government's own establishments.

The principles articulated for the Australian model are, therefore, particularly relevant today as the domestic testing needs increase for most countries and international trade imposes additional technical requirements on many products.

In 2003, the objective of actively promoting good measurements as an element of national technical infrastructure may have little attraction to governments in developed countries as this will be driven by industrial needs. But for those countries seeking to build their national technical capabilities it must still be an important consideration. Many developing countries lack adequate testing facilities to meet even basic needs. An accreditation system has the potential to form a network of laboratories that can work cooperatively thereby broadening the coverage of equipment and skills that are available. There are opportunities, for instance, for sharing reference equipment, spare parts and maintenance

arrangements.

Much of the international discussion about accreditation and metrology is focused on the trade implications but accreditation adds value to a community in a number of other ways.

The decision to seek accreditation implies a commitment by the laboratory owners and management to the implementation of the internationally defined "best practice" standard for laboratory operations. This imposes a discipline on laboratory staff to maintain standards which together with the laboratory organisation are subject to regular audit and assessment by the accreditation body to insure that the standards are indeed applied. Accreditation gives the owner confidence that the laboratory is being operated at a competent level. Accreditation also brings laboratory technical staff into direct contact with people of acknowledged expertise which in itself facilitates a form of technology transfer in measurement science.

It can be argued, therefore, that there is value in accreditation with direct benefit to the laboratory, even if the market does not insist on it for commercial reasons. For instance, in the report of a public inquiry into Australian government laboratories in 1983, the committee undertaking the inquiry made the following comment with respect to government laboratories:

"We are unable to imagine any reason why the Commonwealth should be so unconcerned about the capability of even one of its service laboratories as to exempt it from external assessment".

The same argument applies to the value of accreditation to any laboratory owner – it provides an assurance of technical competence. Owners of all businesses demand financial audits to determine financial health. An accreditation assessment gives a technical audit of a laboratory's technical and scientific health.

In many markets it is the customer or the user of test results, such as a regulator, who often stipulates that accreditation is a pre-requisite for business. It is the customer or user of the test report who seeks the reassurance that the data contained in the report is valid.

In most countries regulatory authorities have traditionally either operated their own laboratories or have designated another laboratory, often

another governmental institution, to undertake all testing required for its statutory purposes. Similarly, commercial and industrial customers have often reserved all acceptance-testing to their own laboratories. In more recent times, the inherent inefficiencies in these monopolistic practices have been recognised and, increasingly, both regulators, because of cutbacks in government spending, and commercial organisations, seeking to focus on their core activities, have sought ways to out-source testing operations while perhaps reserving acceptance decisions for themselves.

It is common, therefore, to now find users of test reports encouraging competition between laboratories and using mechanisms such as accreditation to control the acceptable sources of testing. Accreditation in this way sets the benchmark for technical competence leaving market forces such as price and service levels to inject fair competition into the laboratory services market.

Increasingly, there is recognition that simply using standards alone is insufficient to give complete confidence as to the compliance of products with market requirements and international markets are using accreditation as a mechanism to enhance confidence in test reports and calibration certificates produced in foreign countries.

Accreditation does not guarantee all test results; it simply enhances the confidence that the user is entitled to have in the competence of a particular laboratory supplying test data. It does this by ensuring that the laboratory has been able to convince a panel of experts that it has the necessary staff and facilities to correctly perform the specific tests for which it is accredited and that it has management systems in place to minimise mistakes and reduce the risks of fraudulent behaviour. While neither of these last two undesirable possibilities can be eliminated entirely, accreditation bodies go to considerable lengths to monitor the in-service performance of their accredited laboratories to give ongoing confidence in their competence and to encourage ever-increasing reliability and customer satisfaction.

Accreditation also has another unique feature. It identifies groups of laboratories that have demonstrated to an independent body that each member of the group meets the same international standards and has satisfied a committee of its peers that it is technically competent in its specified fields. Any commercial or regulatory environment underpinned by accreditation enhances possibilities for competition since the issue of technical competence is removed from the equation and choice of laboratory rests on questions such as price and level of service.

The system gives the opportunity to any laboratory operating in any field of

testing in a country to be given recognition. It does not mean that all laboratories are of equal skill or of equal scientific merit. Each is judged competent to perform tests at specified, or implied, levels of measurement capability and, within those limits, all are indeed equal. For instance, one calibration laboratory may be able to measure length with a measurement uncertainty of 0.5µm for sizes up to 25 mm while another may be limited to a measurement uncertainty of 1.5 µm for the same size range. Similarly, two chemical laboratories may have atomic absorption capability but with different element ranges in different matrices and at different levels of detection. Within the defined scopes, the laboratories are indeed equally able to produce test or calibration data. The user of laboratory services must understand his own needs for accuracy and also the limits within which suppliers of such services can operate competently.

All other forms of giving recognition to laboratories suffer from either some form of discrimination or non-transparency. The discrimination issue is most prevalent when government authorities simply designate, perhaps for reasons of ownership, a few laboratories to provide services to the detriment of other,

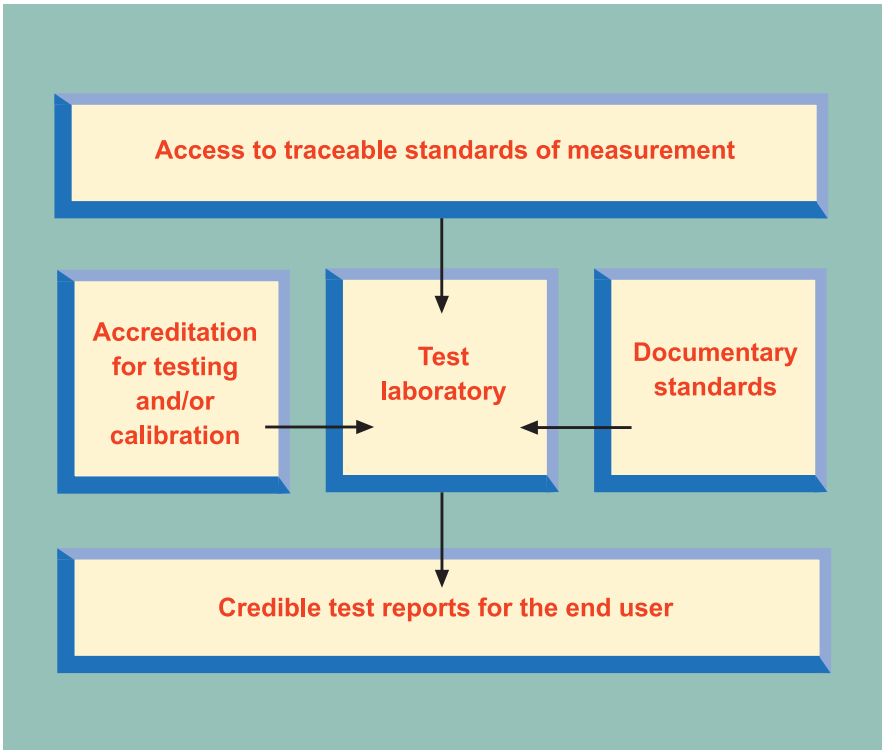


Figure 2. Framework for a credible testing system

equally competent, laboratories offering identical services. In some jurisdictions only government owned laboratories are regarded as acceptable and are recognised without any evaluation as to their competence. Such unsatisfactory practices are compounded when the designation is made without identification of any formal criteria against which the selection is to be made or of the methods and objectivity of any evaluation process used, if any.

In international terms, the features of non-discrimination and transparency of the accreditation process are most valuable as these are the fundamental requirements of the rules of the World Trade Organization (WTO).

As remarked earlier, accreditation does not provide a guarantee that all test results from an accredited laboratory will be correct. Nor does it say anything at all about the competence and reliability of non-accredited laboratories. However, recipients and users of test reports, without needing to make their own evaluations, may reasonably have greater confidence in the competence and reliability of laboratories that have been able to demonstrate competence and compliance with international best practice standards to an authoritative body than in those laboratories that have not, for one reason or another, done so.

Over the years there has been considerable confusion and debate about the respective roles of laboratory testing and product certification. Accreditation is sometimes seen as a threat to the traditional product certification bodies in so far as claims have been made to suggest that an accredited laboratory may, in some circumstances, be authorised to sentence (make statements as to the conformity or otherwise of a product with specifications) individual products or batches of product.

This argument is not one for this publication; except to mention that product certification bodies are expected to comply with ISO/IEC Guide 65 whereas accredited laboratories are assessed for technical competence and for compliance with ISO/IEC 17025. Any laboratory wishing recognition as a product certification body would, therefore, also require accreditation or assessment in terms of Guide 65. Guide 65 places the onus on the certification body to ensure that its service laboratories are competent. This places such bodies in the position of giving recognition to laboratories, at least on a second-party basis. The laboratory accreditation community is firmly of the view that product certification bodies should require that all

laboratories providing them with data on which they make certification decisions be accredited for the appropriate tests.

The situation is, therefore, that where a product standard sets out the requirements for sentencing products or batches of product based on test reports, then this activity may be covered in the laboratory's terms of accreditation. In this situation, the accreditation body will need to pay close attention to sampling regimes but, provided these are well documented, test reports may then draw conclusions as to the compliance of the product with the standard. This is very common with products such as pre-mixed concrete for instance. Where a standard does not make these specific provisions, the test report may only reflect the test results on the sample tested and no inference as to the compliance of the whole batch can be made.

C. Its possible roles in any economy

Every community needs testing and measurement as part of the normal operations and controls of various aspects of its systems.

Governments, for instance, use testing and measurement for:

- Enforcement of safety regulations
- Protection of the environment
- Enforcement of road traffic legislation
- Health services
- Control of commerce and trade
- Forensic investigations
- Assessment of quality of goods and services purchased for their own use.

Industry and commerce have particular interests in:

- Quality assurance of goods and services
- Quality control of manufactured goods
- Advertising data
- Risk assessment and management
- Failure investigation
- Resolution of complaints and disputes.

Consumers have particular interests in the safety and performance of products.

In all cases the recipient of the test report needs to have confidence that the data in it is reliable. In fact, unreliable data is actually more dangerous than the absence

of any data. If, indeed, unreliable data can be used with impunity, it is a reasonable question to ask why call for the data in the first place. For this reason there is great interest in the integrity of test data used for any purpose. A common problem is a failure to recognise the difference between *accuracy* and *precision* of data. The user of test data must understand his needs with respect to both attributes as each affects the cost and relevance of the testing or measurement. If useful and reliable, but less accurate, data would suffice in certain situations, then the user of the data would be better advised to seek the less expensive data in the purchase specification.

Governments have a particular responsibility to their communities, particularly with respect to health and safety and, increasingly, protection of the environment. There are also questions of justice, fair-trading and efficiency of government management.

The question of use of test data in regulation has been mentioned briefly earlier in this document in the context of out-sourcing and tendencies to smaller

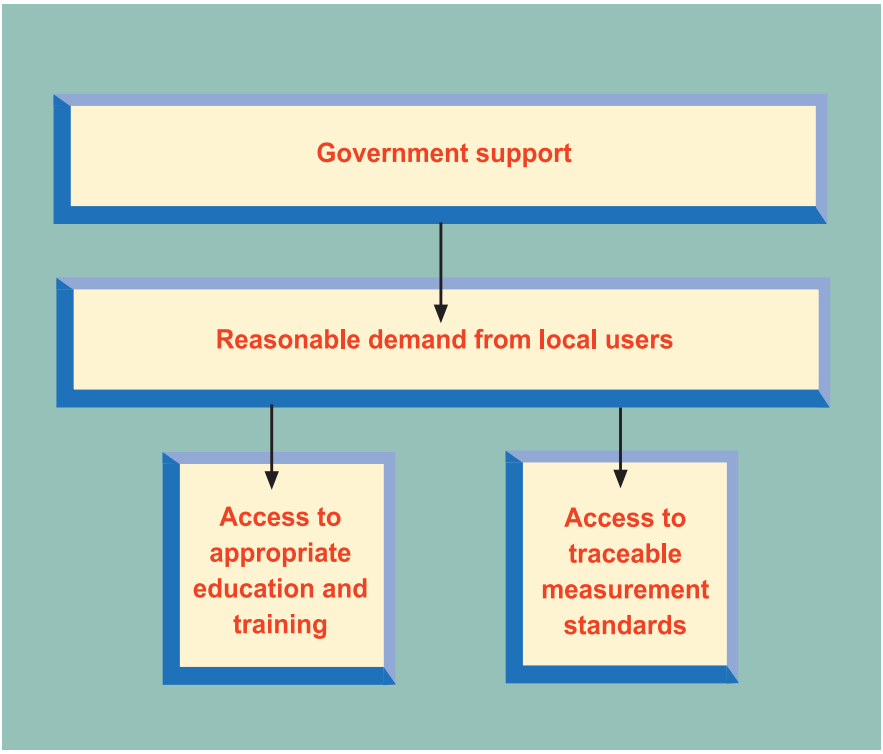


Figure 3. Prerequisites for a laboratory accreditation programme

government in many countries. In addition to the use of accreditation as the basis for the acceptance of locally produced test data, regulatory and acceptance authorities are increasingly faced with the need to recognise data generated by laboratories in foreign countries about which the acceptance authority may have little information. If an acceptance authority is familiar with and confident in the competence of its own national accreditation system, mutual recognition arrangements between accreditation bodies offer an effective mechanism for giving confidence to those authorities with respect to foreign laboratories.

Governments use test data for many other purposes. In most countries, governments are responsible for large infrastructure projects such as roads and other major construction works. The purchase of defence equipment and provision of health services are invariably large parts of national budgets. Governments have responsibility for the safety, and often their operation, of infrastructure services such as water and electricity supply. Testing and measurement are crucial elements of these activities.

Testing and measurement underpins all quality control activities in manufacturing and, often, in the conclusion of commercial transactions. Again, if the test data is important in the decision-making process, then it is important that it be reliable. For the buyer lacking the resources or knowledge and skills to make an evaluation of the competence of the source laboratory, accreditation provides a reliable mechanism to make a decision with confidence.

As industries become more and more global in nature with components being sourced from a variety of manufacturers in any number of countries, the need for compatibility of measurements from one country to another becomes absolutely essential. The initiatives taken by the BIPM (Bureau International des Poids et Mesures) to substantially extend the range of measurement inter-comparisons at the higher levels are an important element in this process and are to be commended.

D. Essential prerequisites

Establishing an accreditation body is not a step to be taken lightly. It requires, firstly, a need to do so, as might be demonstrated by there being organisations wishing to be accredited. These could be laboratories, certification bodies or inspection bodies. Secondly, it demands some political and governmental support, not necessarily financial support, on an on-going basis if international recognition is a consideration; and, thirdly, there are certain technical requirements even for systems that will never aspire to high levels of technology capability.

A number of countries have established accreditation bodies to cater for the credibility needs of only a very few laboratories. It is suggested that this is perhaps not the most appropriate action and that other solutions should be investigated. This issue will be further discussed in a subsequent section of this publication. It is suffice to say here that a financially and technically viable accreditation programme requires in excess of one hundred laboratories and perhaps at least ten certification bodies.

Nowhere in the world, with the possible exception of the very large markets such as the United States of America, is accreditation a commercially viable activity unless it has strong support from the government of the home market. In large markets, the accreditation body can be financially self-sufficient but relies on government policies, and sometimes legislation, to provide the incentive for potential clients to seek accreditation. There is no accreditation body that

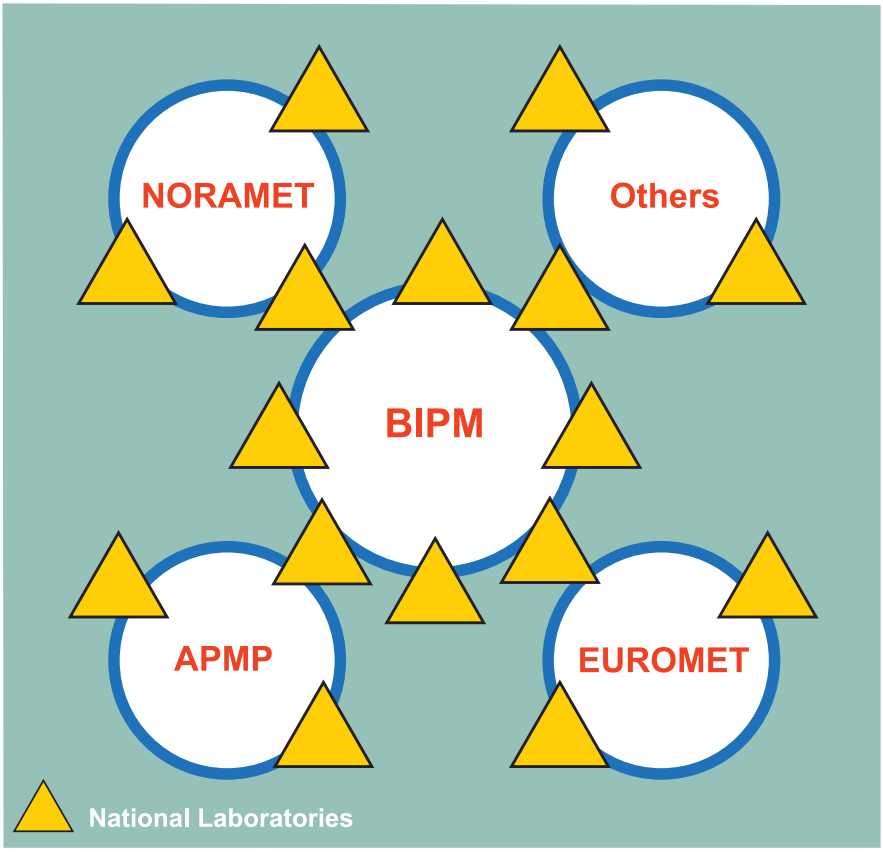


Figure 4. A schematic of the global measurement system

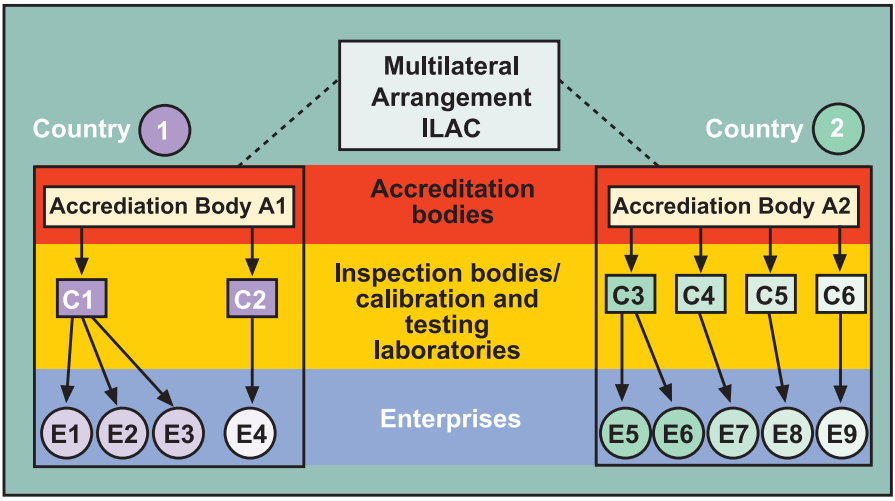


Figure 5. ILAC Mulitlateral Arrangement offers recognition amongst its members

could survive, financially, on the work generated by the testing and certification requirements of foreign markets to which its laboratories provide test data. Without a reasonable domestic base an accreditation body cannot hope to develop the skills and experience necessary to give credibility in a foreign market.

A successful laboratory accreditation body requires competent, or at least potentially competent, laboratories that might seek accreditation. There must, therefore, be an environment with an infrastructure that provides technically qualified and trained personnel, access to physical standards at a level appropriate to the test being performed, access to calibration and maintenance resources for laboratory equipment and reliable sources of power and other essentials for the proper operation of a testing laboratory. Access does not mean that these services must be provided nationally. In a number of cases, such as traceability of measurement, this may be achieved through laboratories in neighbouring countries or in regional facilities.

III. How to do it

A. Establishing an accreditation body

For some developing countries the decision should be not to set up an accreditation body, but rather to provide an accreditation service through regional cooperation or by engaging an accreditation body from a foreign country to provide those services on mutually agreeable terms. As the number of accreditation bodies has increased in recent years, some are prepared to offer their services direct to laboratories in foreign countries. While this can be an effective option, some caution is required as in some trade agreements the government of the exporting country is required to stand behind the accreditation service (mutual recognition agreements with the European Union for instance). This may not be possible where the accreditation body is operating purely on a commercial basis without the government having any authority or influence over it.

The contract option permits a government to contract a foreign accreditation body to undertake national accreditation activities on its behalf but to maintain some authority over it through the terms of the contract. Within this option, models exist whereby a national accreditation body is established to protect issues of sovereignty but contracts the laboratory assessment activities to another body.

Regional accreditation bodies are still in an experimental stage but they offer the possibility of a cost-effective solution to the inherent difficulties of many accreditation bodies with very small numbers of laboratories to be accredited. Such national bodies will always have difficulty with technical credibility and financial viability. The regional approach requires that problems of sovereignty and political differences have to be resolved.

An accreditation body intending to seek international recognition of its own competence, as well as for the competence of its laboratories and certification bodies, will be required to ensure that its structure, rules and operational procedures are in compliance with the relevant ISO/IEC guides and standards such as Guides 61 and 58 and TR 17010. These latter three documents are currently under revision

and will be published as ISO/IEC 17011.

An accreditation body wishing to serve only a domestic market would have other options. For instance it could choose to establish quite different standards to those adopted internationally (ISO/IEC 17025 and Guide 58) and limit itself to certain products of domestic interest only. This may be entirely satisfactory for a particular market, or sector of a market, but experience shows that any subsequent attempt to make the transition to an internationally recognised system at a later date will be quite difficult for both the accreditation body and its accredited laboratories. For the accreditation body it may require a complete re-engineering of its procedures and systems to meet Guide 58 requirements for instance and, for its laboratories, the introduction of some of the more difficult ISO/IEC 17025 technical requirements. Examples of these difficulties may be observed in bodies that formerly operated as second-party approval organisations seeking to broaden their activities into general accreditation.

The strong recommendation is, therefore, to ensure that the new body's overall structure and procedures are internationally compatible right from the start and then to focus immediate development on the direct needs of the market.

B. Possible structures

Using ISO/IEC Guide 58 as the basic specification, many structures are permissible but there are some over-riding considerations specified in the Guide with which all bodies must comply. The principle structural issues, that must be addressed, relate to ensuring:

- Impartiality
- Objectivity
- Non-discriminatory policies and practices and
- Avoidance of conflicts of interests.

These are all matters difficult to define and perceptions of what constitutes an effective solution will vary from case to case and from person to person. This matter remains under current discussion within the ISO CASCO Working Group dealing with a revision of Guides 58 and 61 and their transformation into the ISO/IEC Standard 17011.

It has been common for small countries, in particular, to centralise some or all of what are called standards related activities into a single organisation. Such activities as standards writing, standards of measurement, legal metrology, accreditation and certification, and sometimes testing laboratories, may all be

located within the same body. For international recognition such arrangements are fraught with difficulties.

In all of these co-locations of functions there is potential for conflicts of interest. The most obvious possible conflict is when the owner of the accreditation body is also the owner of testing laboratories or other possible candidates for accreditation such as a certification body or inspection body. For this reason, both laboratories having responsibility for maintaining national measurement standards and those providing test results for product certification services should be very carefully separated from the accreditation body.

But even standards writing can be in conflict with any of the other functions when there are other service providers of those functions operating in competition with services offered by the standards writer. It is not uncommon for standards setting bodies to provide laboratory and certification services. There will be an inevitable perception of preferential treatment by the standards writer if its laboratory or certification arm is in competition in the market.

Guide 58 permits any form of ownership and, indeed, throughout the world examples can be found of government ownership with accreditation bodies operating within a Department or Ministry (as in China, India, Japan, Jordan, Malaysia, Tunisia and the USA) or sometimes as a Statutory Authority (Brazil, Colombia, Egypt, New Zealand and Singapore). But there are also a number of bodies that operate as not-for-profit corporations of one or another of the many possible forms (Argentina, Australia, Canada, Cuba, France, Mexico and South Africa). Experience shows that irrespective of the form of incorporation, a close relationship with government is perceived to be important, particularly with respect to international recognition.

There is no current (2003) example of a commercial profit-making body being accepted into any mutual recognition arrangement for international acceptance of test data. Nevertheless, commercial accreditation bodies exist, essentially to service particular clients or particular industry needs. By their very nature commercial bodies seek to provide services only in those areas likely to be

profitable which means that they are unlikely to provide a comprehensive accreditation service and their participation in MRA activities is likely to be confined to their narrow areas of operation. Within the process of revision of Guide 58 to create a new standard, ISO/IEC 17011, the question of whether or not accreditation as a commercial activity should be permitted remains a contentious issue.

Among developing countries the concept of regional accreditation bodies, as distinct from sovereign national bodies, is becoming increasingly attractive. The model of the Southern African Development Cooperation in Accreditation is the most well-developed of these. In this model, some member states will choose to establish an accreditation body while others may not. Each will, however, appoint a national focal point for accreditation activity. Any of the established accreditation bodies within the region may be approached to provide services in those states where one does not exist. Mutual recognition arrangements will be such that all accredited laboratories in the region have equal status. This model is presented in more detail on page 62 where the model being developed for the Southern African countries (Southern African Development Community or SADC) is described. For the purposes of international recognition, however, particularly by regulatory authorities, the government of the exporting country must be prepared to stand behind the body providing accreditation services and this has yet to be tested at the regional level.

There is no single model that is demonstrably superior to any other. There has been a trend in recent years to favour some form of separation from direct government control and the Statutory Authority and non-profit corporation models are equally favoured over the government managed model. This has been due to the need for greater flexibility and some freedom from the rigid government budget process and the need to be able to demonstrate independence in decision-making, particularly on accreditation decisions. In such structures it is often easier to construct governing boards in which there is a balanced representation of various interested parties.

In whatever structural model is adopted, it is highly desirable, perhaps essential, to involve the potential stakeholders, at least in policy and

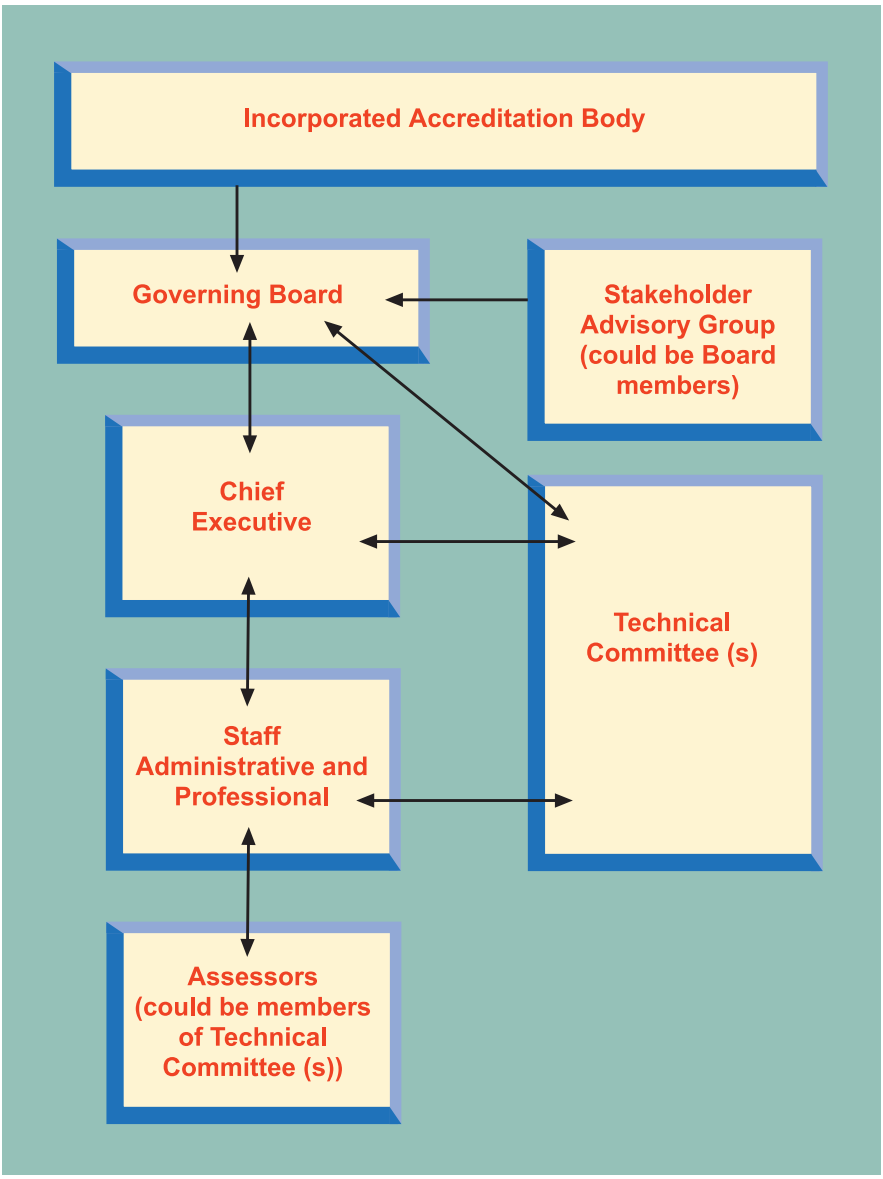


Figure 6. Typical structure and interactions in an accreditation body

technical development. Accreditation cannot succeed without government support but neither can it succeed unless the potential clients and the client's clients have a strong interest in its activities. Provision must therefore be made for the inclusion of inputs from government, laboratories, certification bodies, regulatory authorities and specifiers and other stakeholders.

C. Human resources

Accreditation bodies need access to people with a variety of knowledge, skills and other attributes. The more technically diverse the accreditation programme the wider the net has to be cast to attract the appropriate individuals.

ISO/IEC Guide 58 addresses human resources in Clause 4.2 for accreditation body staff, and for the appointment of other workers, and in Clause 5 for assessors.

1. Accreditation body staff

The most common situation is to establish an administrative secretariat and management team staffed with a few technically qualified and competent people with necessary support personnel. For small and newly emerging bodies these may be effectively part-time positions although experience would suggest that fully committed staff will usually make more rapid progress with the development of the organisation. Experience also suggests that there are advantages if an individual who is also technically qualified leads the organisation.

It is not essential that the professional staff be experts in a particular area of testing. What is important is that they are able to understand advice from experts, appreciate the common principles of good laboratory practices and be able to blend the two into a consistent approach to assessment of competence of a laboratory. Staff of accreditation bodies therefore need to be able to operate outside their own particular discipline but have sufficient scientific and technical training to manage the process and understand the principles involved in performing reliable measurements and tests.

Accreditation body staff do not usually come "ready-made". It requires a special open-mindedness and flexibility of outlook, which normally comes with careful training. Laboratory accreditation has been developing for over fifty years and there is considerable international expertise available. Some of the more mature accreditation bodies offer a variety of training programmes for the staff of new accreditation bodies. These include extended periods of attachment to a host body both attending formal courses and, more importantly, working alongside accreditation officials with

some years of field experience. New and developing accreditation bodies are encouraged to seek out such opportunities for staff training.

The assessment process demands teams having the collective knowledge and attributes necessary to make a reliable evaluation of the competence of the laboratory under assessment. Sometimes the staff member will provide the leadership but in other cases this responsibility may rest with an external technical assessor. At all times the team must have access to advice on the accreditation body's policies, a role often taken by a staff officer who may also monitor the assessment process.

In recent times the concept of "mentoring" by a mature accreditation body of a emerging body has been canvassed and some trials are underway. Such an arrangement provides possible long-term support for the emerging body and could facilitate international recognition. Such schemes would have financial implications for both bodies but these should not preclude more of such arrangements in the future.

2. Assessors

Occasionally, an accreditation body will employ, as permanent staff, individuals with the technical expertise necessary to undertake formal technical assessments of laboratories. This is not the norm, however, as the purpose of an assessment is to expose the laboratory to examination by assessors with current knowledge of modern laboratory equipment, techniques and practices. Full time assessors, on the other hand, may find it difficult to maintain the required level of current knowledge. It is more common for accreditation bodies to engage the technical experts, known generally as assessors, either on short-term contracts or on a voluntary basis, to undertake particular assessments. They are normally drawn from the staff of laboratories in government, academic and technical institutions and from commercial and industrial laboratories. Assessors may come from laboratories which themselves are accredited and, indeed, in a mature well-developed accreditation system, this will be very common. Another frequent source of assessors is to make use of recently retired technical experts.

The heart of laboratory accreditation is an assessment of technical competence of it to perform tests accurately and reliably. The assessment team must, therefore, have sufficient collective knowledge about the technical and scientific foundations for the tests and the skills necessary for their performance to determine if the laboratory staff is sufficiently knowledgeable and properly resourced to carry out those tests. The team, itself must, through processes of discussion and observation, be able to form reliable opinions on these matters.

It must also understand and be knowledgeable in management systems necessary to produce reliable test results and of the disciplines necessary to maintain ethical standards of behaviour throughout the organisation. Assessors from private laboratories will normally be selected so that there is no competitive conflict of interest with the laboratory being assessed.

The international standard against which many of these judgements are made is ISO/IEC 17025 and all members of an assessment team must be familiar with its requirements and their application in the specific environment being assessed.

The current draft of the new standard for accreditation bodies (ISO/IEC 17011) identifies three types of individuals who might participate as members of an assessment team. These are *lead assessors, assessors* and *technical experts*. The implication is that technical experts need not necessarily be assessors and, therefore, not subject to the same training requirements as defined for assessors. In practice, this distinction is rather artificial and it is most common for the technical expert to be an integral and equal partner in the assessment team. Such technical experts must have the requisite knowledge of the tests and measurements being conducted and be familiar with both ISO/IEC 17025 and the requirements of the accreditation body. Lead assessors are however by definition in charge of a particular assessment and they would typically have been monitored during prior assessments by other fully trained and experienced personnel before being appointed to this role.

While potential assessors can be identified by reputation and position, their selection and utilisation depends on the possession of some additional skills and attributes. They must be astute listeners, skilled at drawing out from the laboratory staff information about both the strengths and the weaknesses of the laboratory; they must be good observers of the actual practices being used in the laboratory; and they must be objective and fair-minded in their responses to the information provided.

These are special skills and assessor training is therefore an important part of the establishment and maintenance of an accreditation body. As with accreditation body staff, the established accreditation bodies have well developed training programmes for assessors that may be available to foreign accreditation

bodies. Such participation would involve joining in assessments in another country alongside very experienced teams. Experience suggests that this is most useful for emerging bodies. Formal assessor training courses and "train-the-trainer" courses are also available for presentation to developing accreditation bodies. Similarly, foreign assessors can also be engaged by an accreditation body, at least initially, to work with prospective assessors in the newly emerging body. The regional cooperation bodies Asia-Pacific Laboratory Accreditation Cooperation (APLAC), European Accreditation (EA) and UNIDO provide assistance in this area.

Overall, the ultimate success or failure of an accreditation body and its recognition both at home and abroad will depend on the competence of its assessment teams and the wisdom of their judgements so assessor training is a high priority for all accreditation bodies.

3. Committee members

ISO/IEC Guide 58 requires an accreditation body to establish at least one technical committee and lays down some criteria for the structure of such committees. The most important issue is concerned with ensuring that a balance of interests is maintained and that committees are not dominated by any sector which could interfere with the impartiality of any advice given to the accreditation body. It is not absolutely necessary to establish an elaborate committee system to assist in the development of an accreditation body; however, many bodies find the inputs from external sources very beneficial.

The common arrangements are to have some form of board as the top decision making organ and this may be supported by one or more technical advisory committees including specialist working groups who may focus on particular areas of testing or measurement.

Where the accreditation body is within government, the top committee may have only advisory responsibilities with final authority resting with some designated official. In other situations, it may be the Board of Directors (by whatever name) of a statutory authority or other incorporated entity. In either situation, the board level committee brings independent opinions and broad community values to the decision-making process and exercises a degree of supervision over the activities of

the full-time staff.

ISO/IEC Guide 58 nominates ISO/IEC 17025 as the basic standard against which laboratories will be judged. This is a generic document to be applied to all laboratories irrespective of the field of testing or the nature of the tests being conducted. An accreditation body can ask their assessors to use the standard and prepare a report of their findings but this leaves the assessors with wide powers to interpret the standard. Most accreditation bodies, however, seek to provide assessors with more precise guidance and a uniform interpretation of the standard for the circumstances applicable to a particular laboratory and any special conditions that may apply for a particular country. Such guidance may come through the endorsement of interpretive documents prepared by other bodies or documents prepared by the accreditation body. It is in this work that technical committees are most valuable.

Guide 58 also is careful to specify the need for an accreditation body to ensure that confidentiality is maintained of all information made available to all elements of its system.

D. Management procedures

Clause 4.3 of Guide 58 specifies the requirements for the management system of the accreditation body.

As is common to all management systems, there is much emphasis on documentation of the system as operated by the accreditation body. It is necessary to address at least the following issues:

- Organisational structures
- Functions and duties of individual members of staff
- Administrative procedures and document control
- The accreditation process
- Feedback and corrective actions
- Appeals procedures and complaints handling
- Internal audit procedures
- Management reviews
- Selection and training of assessors.

Guide 58 pays particular attention to internal audits and system review to ensure that the implemented system is indeed effective in delivering an accreditation programme that is technically rigorous and administratively transparent and non-discriminatory.

E. Operations

1. Laboratory assessment

The purpose of an assessment of a laboratory is to form a judgement as to whether or not a laboratory is competent to undertake certain specified tests and measurements and if it has management policies and practices that are likely to produce reliable test data each time a test is performed. The fundamental document defining the requirements against which a laboratory will be assessed is ISO/IEC 17025 but over and above those that are contained in the standard, the accreditation body will have precise requirements specific to the tests being undertaken. For instance, it may have special requirements for the intervals at which equipment must be recalibrated, periodic checks that must be undertaken or some particular educational requirements for certain types of laboratory staff.

The assessment consists of preparatory work prior to any visit to the laboratory, a visit by the assessment team to the laboratory, follow up activity such as proficiency testing and resolution of any problems or failures to satisfy the assessment team as to either technical competence or the effectiveness of the management system. It is only when the process is completed to the satisfaction of the accreditation body that accreditation is granted. While the accreditation body should not provide a consulting service, the assessment process can also be very instructive to the laboratory and the assessment team will often be able to make comments and suggestions that will lead to improvements to laboratory performance. There is often a legitimate element of technology transfer from the expert assessment team to the laboratory staff.

Application and preparation for on-site visit

Prior to lodging an application for accreditation, a laboratory is well advised to make contact with the accreditation body to ensure that it fully understands the processes involved and the requirements that will need to be met. Accreditation bodies usually offer a non-consultative counselling service to prospective applicants as this clarifies many issues that must be addressed and facilitates the formal processes.

Guide 58 requires that accreditation bodies ensure that its requirements are documented and publicly available and it is in the best interests of all parties that these are clearly understood and that any ambiguities and doubts are resolved well in advance of the assessment process. Questions as to liability for fees and other charges should be addressed along with other administrative requirements

and responsibilities such as limitations of use of accreditation body logos.

In making a formal application for accreditation, a laboratory is usually committed to doing its utmost to succeed in its quest for accreditation. The formal application form will vary from accreditation body to accreditation body but it can be used as the basis for the contractual relationship that will exist between the accreditation body and the laboratory. In it there should be reference to acceptance by the laboratory to the conditions for accreditation and future commitments following accreditation.

At this stage the accreditation body also seeks information on the range of tests and measurements to be covered by the application and the essential background information such as staff and equipment information from the laboratory. It is from this information that the assessment team will be briefed prior to the on-site visit.

The application will also normally involve the submission of certain fundamental documentation, such as the laboratory's quality manual, which will be subject to review, probably by the assessment team leader, prior to the on-site visit. A seriously inadequate set of documentation would justify the postponement of the on-site visit.

It is vital to select a well-balanced assessment team. A small laboratory or one performing a narrow range of work may be assessable by a single assessor although a team of at least two may add more flexibility and balance when on-site. Large laboratories or laboratories with a diverse range of testing will require larger teams with expertise sufficient to match the range of work being undertaken. It is normal practice for a laboratory to have some limited rights to object to particular individuals (e.g. where there are competitive issues) on the assessment team but this should not be allowed to interfere with the appointment of the proper balance of expertise.

Even experienced assessors will need to prepare themselves for the assessment. Formal briefing will normally be prepared by the accreditation body staff or by an external lead assessor but other team members will also need to ensure that they are fully conversant with the test methods and procedures that will be within their particular area of expertise. They will also need to ensure that they are up to date with their knowledge of the accreditation body's requirements.

The assessors will wish to witness testing activities and the laboratory should be given adequate notice of those particular activities or test procedures nominated by the assessors.

Well-prepared and presented briefing for the assessment team will facilitate an efficient on-site visit. The more complete the factual information, the less data needs to be collected during the visit, and the team can focus on probing technical issues and verifying the correctness of essential information without the distraction of having to elicit routine information. As a minimum, the briefing should include:

- Information on qualifications and relevant experience of the key personnel in the laboratory
- An organisational chart or similar for the staff structure
- A comprehensive statement of the tests and measurements for which accreditation is sought including, where applicable, ranges of measurement and uncertainty of measurement expectations
- A list of major items of laboratory equipment and information regarding its calibration status
- Information about the physical facilities available to the laboratory
- A summary of the findings of any preliminary review of the laboratory's quality manuals and other documentation
- Any information on laboratory performance in proficiency testing activities.

Equipped with such information the assessment team comes to the on-site visit with an impression of the laboratory and knowledge as to where problems are likely to be found. These areas can then be probed in more depth in discussion with the staff.

In most accreditation systems, the accreditation body staff have the responsibility to make all logistical arrangements for the assessment but, irrespective of who make the arrangements, there must be some room for negotiation of mutually convenient times and dates, particularly if the assessment team has some special needs to observe specific activities. However, the laboratory should not be permitted to unreasonably delay the date of the on-site visit. For initial assessments it is imperative that all senior and supervisory staff are present during relevant parts of the visit and be available for interview when requested by the assessors.

The on-site visit

The on-site visit is an indispensable element of the assessment of the laboratory and it is therefore crucial that it be organised in the most efficient way, conducted with rigour but in a constructive and positive manner and be reported, both to the laboratory and the accreditation body decision makers, with timeliness, clarity and objectivity.

Assessment team meeting

Where possible it is desirable that the assessment team meet in advance of the visit to the laboratory. For teams of experienced assessors this may be a short meeting to agree on arrangements for the visit, to allocate particular responsibilities to the individual team members and to agree on a timetable to complete all necessary tasks in the time available. When less experienced assessors are involved the meeting may also need to address some additional briefing on the requirements of the accreditation body and on conduct of the proceedings while on-site. There may also be the need to update information as well as make some personal introductions.

Opening meeting

The on-site visit will invariably begin with a meeting between the assessment team and the senior laboratory staff. This meeting sets the tone for the remainder of the visit so it is important that it be cordial, diplomatic but business-like. It provides the assessment team with the opportunity to brief the laboratory staff on the proceedings for the visit and to ensure that all arrangements are in place for any activities that the assessment team wishes to observe.

It is at this opening meeting that the team should clarify the scope of the testing or measurement sought for accreditation and address any concerns that the laboratory may have about the assessment process.

2. In the laboratory

In large or diverse laboratories, the assessment team may break up into particular areas of expertise but in smaller ones or in those with limited scope the team may work together throughout the visit.

During the course of the visit, the assessors will deal with issues related to management of the laboratory and the way it is organised to provide the services for which it seeks accreditation. They will also need to satisfy themselves that the individual staff members understand the tests which they are performing and that the equipment and facilities are adequate for those tests. The order in

which these matters are dealt with is at the discretion of the assessors.

The briefing will have identified the adequacy or otherwise of the overall system documentation and the assessors will need to address outstanding issues identified by it. On-site, however, they will be able to focus their attention on test methods and their documentation. Not only must the documentation be adequate but the staff must be very familiar with it and apply it when performing the tests.

Staff

The assessment team will benefit from having had the opportunity to familiarise themselves with organisational charts and reporting relationships and the documentation associated with staff training and qualification. It is important to verify that the documented structures are those that are implemented in practice.

While education and formal training courses are readily documented, skill levels are often hard to define, particularly in tests that require considerable manual dexterity or optical perception or discrimination. For instance, for some tests, testing operators may need to be tested for colour-blindness or visual acuity and an ability to interpret the images that are observed. Assessors should seek to witness tests requiring particular expertise being performed by the operators who normally do them. Laboratory staff performing tests are expected to be trained in the specific techniques of each test and to carry them out with diligence and in safety.

Professional and supervisory staff are expected to understand the science and technology underlying the tests being undertaken and the equipment in use. They should understand what factors can lead to erroneous results and be able to make intelligent decisions as to likely causes of problems. Assessors will probe these issues with such staff. Where deputies have been appointed their competence should also be assessed.

Safety

While safety is not normally a specific concern of accreditation bodies, poor safety practices may be reflected in poor practices elsewhere. Assessors should be specifically advised to refuse to enter areas that they consider to be unsafe. In some cases this could lead to the assessment being abandoned.

Equipment management and traceability of measurement

Equipment management is a key issue for all laboratories. It covers purchasing, installation, documentation, availability, calibration, maintenance and serviceability.

All laboratories should have standards of measurement appropriate to their activities. These may be as basic as a calibrated thermometer and a set of reference masses or they may extend across many physical quantities. Irrespective of the range, accuracy and precision of such standards they must meet the essential traceability requirements specified in the ILAC policy document on the subject.

Traceability is a somewhat misunderstood subject but, for accreditation purposes, all laboratories must be able to demonstrate that the measurements they make are made with instruments whose accuracy can be traced back to SI units as maintained by the BIPM in Paris. This traceability chain may be through a number of steps each of which increases the uncertainty of measurement but, provided the measurement at the end of the chain is fit for its purpose, the measurement is regarded as traceable. Each step in the calibration chain must be documented and technically credible.

In addition to standards of measurement, laboratories will have some general equipment, common to most laboratories working in their field and also have equipment which is unique to the tests they perform and which is normally specified in the test methods. In all cases, a laboratory must provide an environment that ensures that the equipment is protected from corrosion, excessive dust, vibration and other factors which could lead to its failure or deterioration. Additional requirements may include laboratory temperature stability.

Equipment must be maintained at a satisfactory level of performance. For large items this may mean regular servicing by competent service personnel and regular calibration against higher level standards either by laboratory staff or by external specialists. Again the requirement is that whoever performs this work must be demonstrably competent and must use properly calibrated standards to ensure continued measurement traceability.

Equipment that has been damaged or is otherwise unfit for service must be clearly identified as such and laboratories are encouraged to adopt sound preventative maintenance practices to minimise the possibilities for use of unserviceable equipment.

Instruction manuals should be maintained and readily available to all operational staff.

Laboratory reference materials, where used, must be treated with care. They

must be stored under conditions that will ensure their stability and the maintenance of their specified characteristics for their expected life. They must be clearly identified with proper records of their history and performance. When appropriate, they should be re-verified, downgraded or discarded at the end of their certified life.

Policy for dealing with reference materials is a difficult area for accreditation bodies as there is, as yet, no international system for their verification nor is there a transparent mechanism to provide users with objective evidence that particular materials are what they purport to be. At the moment there are a number of reference material producers and suppliers that have earned a reputation for providing well-characterised materials with reliable documentation but acceptance or rejection based on reputation alone is a dangerous practice.

ILAC and its members are currently examining possibilities for accreditation of reference material providers to give some objective evidence that these materials are of a satisfactory standard and to enhance the transparency of the process. ILAC Guideline document G12 expresses its current thinking on the subject.

Laboratory accommodation and facilities

The laboratory accommodation and facilities must be fit for the performance of the tests being performed. If the test specification demands certain environmental conditions then these must be provided and monitored for compliance with the specified conditions.

For instance, for the testing of textiles the test sample must be conditioned in an atmosphere of specified temperature and humidity prior to testing. The laboratory must have equipment, appropriately calibrated, to monitor both parameters in those areas set aside for conditioning samples. For testing of pharmaceuticals, sterile conditions may be specified. On the other hand, most engineering testing requires only protection from bad weather.

Similarly, certain facilities and services may be necessary to undertake certain tests and these must be available. Lighting and ventilation must be adequate to ensure reasonable and safe working conditions. Hazardous materials must be stored safely.

In many cases it is also necessary to provide accommodation that is secure and that access to various areas is controlled appropriately. Sample receipt areas obviously must be accessible to clients but access to the testing areas should be restricted. Record storage areas may need to be fireproofed and protected from accidental damage or deliberate tampering.

Laboratory practices

Assessors often find it useful to assess the laboratory's operations by following typical processes from the time a sample enters the laboratory to their completion. This includes examining the order from the client, logging receipt of samples, allocation of work, internal quality control, recording of data, reporting of results and sample storage or destruction and archiving of records.

Contract review

The term "contract review" is a generic one found in management systems standards and in the context of a laboratory it usually covers discussion with the client and the agreement as to methods to be used and time frames to be met. It is particularly important that any changes to methods that may be agreed must be documented. There should be complete transparency with the client as to the tests to be performed and also advice given to the client as to any technical limitations that may be inherent in the test as applied to its particular product or material.

Can the laboratory, in the view of its management, meet its commitments to its clients? Is it suitably equipped and does it have adequate human resources to deliver the service as promised without undermining the integrity of the technical work to be performed?

There are two sides to the importance of contract review. The client is entitled to receive a professional outcome from an accredited laboratory and the laboratory must also be alert to possible future misuse of its test reports by unscrupulous clients.

Sample collection and identification

In many situations laboratories test only samples or specimens as received from their client or their agents. But, just as often, the laboratory staff will also be responsible for the collection of samples from the field. In this latter situation, sampling procedures both in their practice and documentation will need to be examined by the assessment team.

In the case of testing only of samples as received, the sample registration or logging system must cater for information such as date of receipt, client's identification as received, sampling history (where relevant), laboratory's identification, contract details/name of client, condition of the sample (particularly with respect to any damage or unusual condition of the sample) and tests required. Where there is apparent damage to the sample, the client would normally be advised and consulted as to further action. This must be recorded.

Whatever the system, there must be complete traceability of the sample as presented to the technical staff to the sample registration and, eventually, to the test report on that sample. In all circumstances, the integrity of the test performed is dependent on the validity of the sample.

When the laboratory is also responsible for taking samples it has increased responsibility with respect to the final test report and any conclusion that may be drawn from it. Sampling procedures must seek to be statistically valid and be fully documented. Sampling staff must be trained, properly equipped and aware of the importance of their duties.

In some cases, the test standards or the product specifications will define the sampling plans and procedures. In this situation, an accreditation body may provide accreditation for the sampling function and permit laboratories to issue test reports which draw conclusions as to whether or not the product meets specification. Accreditation bodies must have well defined policies on this issue and these must be addressed during the assessment.

Test methods and their validation

Test methods range from making measurements from fundamental principles using conventional laboratory equipment to purely empirical tests using apparatus with highly specific features and using techniques requiring considerable practice and skill by the operator. In most cases, however, test methods are defined in standards and similar documents and are combinations of the application of fundamental scientific principles and practical skills.

In all circumstances it is necessary that the laboratory ensure that it is capable of properly applying methods that have been previously validated such as is the case with those described in most international and national standards. Where methods are developed within the laboratory itself it is necessary to test their validity. This requires comparison with standard methods and the use of reference materials and the development of accuracy and precision data over the range of application of the method.

Test methods from any source should:

- Be fully documented and be readily available to all relevant staff
- Include document information
- Make appropriate reference to sources and known limitations
- Include validation data
- Describe quality control procedures and criteria for the acceptability of results
- Specify the units of measurement to be used
- Be reviewed periodically.

It is not uncommon to find that standard methods are not available in a form suitable for routine reference at the workbench and laboratories prefer to produce their own methods manuals. This permits them to clarify some procedural matters, draw together material which may be cross-referenced and select specific options when these are permitted in the standard.

There are a number of standards for formats of test methods that laboratories may find useful when preparing their own manuals.

Whether a recognised standard test procedure is used, or an existing method modified to meet special requirements, or an entirely new method is developed, the laboratory should establish that its performance characteristics are suitable for the intended purpose.

Some confusion exists as to the meaning and usage of the expressions "validation" and "verification" of a test method. A method is validated by inter-laboratory comparisons to determine its technical soundness and robustness and its capability for use in more than one environment. It is not always possible to thoroughly validate in-house methods.

On the other hand, a laboratory should verify its ability to perform all test methods, including well-established standard methods, it uses. This process involves studies, using reference materials and other check samples, demonstrating that the laboratory can apply the method across the range of intended use within the published validation data for the method.

The assessment team will consider evidence of such validation data during the assessment.

Testing processes

The assessment team will certainly wish to witness some testing in progress. In many cases it will have advised the laboratory which tests it would like to see in progress. Where testing conducted in the field is to be witnessed, such as field sampling and testing of wet concrete, good planning is necessary to ensure that this is covered without too much loss of time from the other assessment activities. In other cases, the assessment team may simply observe routine operations as they occur. The team would expect to see tests being undertaken by those operators who normally perform those tasks.

Measurement uncertainty

Calibration laboratories have had to deal with assessment of uncertainty of measurement for many years but the conventional testing laboratory was not

confronted with the issue until the publication of ISO/IEC 17025. It is not that scientists of all persuasions have not been concerned about errors and accuracy in testing in the past; it is that ISO/IEC 17025 requires a more rigorous approach than before.

Accuracy is a general term and a concept readily understood at that level. Uncertainty of measurement, on the other hand, is defined as the parameter, associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand (the quantity subject to measurement).

For many years, it was accepted that in reported test results the last significant figure quoted in numerical data was indicative of its accuracy or uncertainty. The more modern approach is scientifically more rigorous and now considered to be much superior but it will be a number of years before the concept is widely adopted for all testing situations.

ISO/IEC 17025 itself notes that:

> *The degree of rigour needed in the estimation of uncertainty of measurement depends on factors such as:*
>
> *the requirements of the test method;*
>
> *the requirements of the client;*
>
> *the existence of narrow limits on which decisions on conformance to a specification are based.*

Nevertheless, despite some difficulties associated with acceptance of the concept by some laboratories, all accreditation bodies must begin to address this issue and encourage laboratories to do likewise. Education of clients will also be necessary in most cases. There is much discussion on future policy on the issue currently taking place in ILAC and the regional cooperation bodies such as APLAC and EA and all accreditation bodies are encouraged to participate in these discussions. Much of the literature available is in the context of calibration and measurement but there is an increasing amount being developed for testing laboratories in specific areas.

Internal monitoring

ISO/IEC 17025 requires that laboratories have quality control procedures for monitoring the validity of tests and calibrations. It also requires that this data be collected in such a way that trends are detected and statistical techniques applied to reviewing results. It suggests a number of techniques such as:

- Regular use of reference materials, including secondary reference materials;
- Participation in proficiency testing programmes;
- Replicate testing;
- Retesting of retained samples.

Any programme for monitoring the reliability of test results should include criteria for rejecting suspect results. Quality control data should be fully documented in such a way that it is readily accessible for evaluation of trends in particular analyses and with appropriate corrective action being taken when necessary. In general, a laboratory should carry out regular performance checks on infrequently performed tests or techniques to demonstrate continuing competence in those tests. Such checks should be recorded along with other quality control data. The assessment team must examine these records.

Records and reports

As a general principle, a laboratory should record all information necessary to repeat a test if required and maintain a record system which contains all original observations, derived data and other information necessary to establish an audit trail between the original sample received and the final report or calibration certificate issued on it. More specific information is contained in ISO/IEC 17025 Clause 4.12.2.

Clause 5.10 of ISO/IEC 17025 specifies minimum requirements for the content of test reports and calibration certificates. In some cases, the form and content of a test report may be specified by the product or test standard or by a regulatory requirement.

It is common practice for assessment teams to test the record system by taking a report that has been issued and tracing back through the system, including workbooks or record sheets, to the original purchase order or request for the test.

Document control procedures

Clause 4.3 of ISO/IEC 17025 sets out the requirements for control of laboratory documentation. Key considerations include:

- A consolidated list of all current documents
- Prompt removal of obsolete documents from circulation
- Written policies on development, approval, distribution and review of all documents.

When documents are maintained and distributed electronically, procedures are required to ensure that only current versions are in use.

Sample retention and archiving of records

In many cases it is not possible or necessary to retain samples following the completion of the test and the issue of the final report. This is a matter for the laboratory and its clients and will vary from case to case. Nevertheless, it may be prudent where there is the possibility of some subsequent inquiry or dispute, for the laboratory to retain a sample so that the test could be repeated if need be. If samples are retained then care should be taken to ensure that they are not subject to influences that would cause their deterioration and loss of integrity.

Records must be retained for a reasonable period, the length of which depends on statutory requirements for tests on particular products or possible time-frames within which the results may be called into question but it is generally considered that three years should be the minimum. In some situations this period may be extend to perhaps ten years. In some large projects such as a pipeline or a bridge, the contract may require test results to be retained in perpetuity. In these latter cases, final archiving of records is normally the responsibility of the client.

The laboratory must ensure that its storage and archive facilities are secure and protected from potential hazards such as fire, water, mould and pests.

3. Assessment report

At the conclusion of the visit to the laboratory, the assessment team discusses with the laboratory staff its findings from the visit. It cannot make decisions about the outcome of the assessment, this is a matter for the accreditation body, but it can give, by way of an interim report, its observations and summarise its conclusions and make suggestions as to areas to which attention should be paid. Following the visit, the assessment team will prepare a written report for submission to the accreditation body.

The most common situation is that there will be some matters on which the laboratory will need to take some corrective actions of one form or another. These can be handled in a number of ways including a follow-up assessment, correspondence or undertakings by the laboratory to take action to be verified at the next on-site visit by assessors or staff.

Once the technical issues have been agreed, all further action is the direct responsibility of the accreditation body.

4. Accreditation decisions

The accreditation body must be organised in such a way that its decision-making process is independent of the assessment team. Clause 6.5 of ISO/IEC Guide 58 specifies the conditions under which decisions are made.

There are a variety of approaches used by accreditation bodies to arrive at final decision on granting, maintaining, extending, suspending or withdrawing accreditation and the standard does not specify any particular mechanism. In all cases, however, there will be a review of all information available to the accreditation body which may go beyond the report of the assessment team. The review process may be through an independent member of staff or staff committees or through a committee of individuals independent of the management of the accreditation body.

Some bodies reserve such decisions to their highest levels such as the Board of Directors while others have established special purpose committees or panels to arrive at those decisions. In other cases the ultimate responsibility may rest with the chief executive (by whatever title). Whatever the detail of the process that is adopted, it is essential that the review of information and the decision making process is transparent and non-discriminatory. It is also important that the laboratory has the opportunity to appeal any adverse decision.

F. Surveillance of accredited laboratories

Accreditation bodies use a number of different techniques to assure themselves that the accredited laboratories within their system maintain satisfactory standards of technical and management competence and ethical conduct beyond the day of the assessment.

Guide 58 (Clause 6.7) states only that surveillance procedures shall be consistent with those concerning the initial assessment process. Most accreditation bodies seek a more rounded approach to surveillance which may include staff interaction with the laboratories (in the absence of technically expert assessors), proficiency testing programmes and other interactions to maintain a close relationship between the accreditation body and the laboratory.

Many accreditation bodies actively encourage the accredited laboratories to offer staff development programmes at the technical level. A number of accreditation bodies offer short term courses in laboratory management,

laboratory quality assurance and, often in collaboration with other institutions, courses in technical subjects such as uncertainty of measurement and specialist subjects such as temperature measurement or instruction in the latest techniques of testing in a particular field.

After accreditation, not only must the accredited laboratory continue to comply with ISO/IEC 17025 it must also comply with any additional requirements imposed by the accreditation body such as use of logos or marks on test reports and restraint on certain commercial activities. Use of the logo on test reports and calibration certificates provides proof to the customer that he is using an accredited laboratory and care must be taken that it is not used on reports which are for example outside of the scope of accreditation. An issue of some possible concern arises when a laboratory offering a large and diverse range of services seeks accreditation for only a small part of them. The issue is to ensure that the laboratory in its commercial activities does not misrepresent the scope of the accreditation by inferring that all its activities are accredited.

The principal tools by which an accreditation body exercises it responsibilities for surveillance of an accredited laboratory are reassessments and proficiency testing.

While the terminology varies, there are a number of common practices among accreditation bodies. Some have two levels of formal on-site visits. One, a surveillance visit by staff or an assessor only during which corrective actions from previous assessment activity are verified and some audit of the quality system may also be conducted. The second level is the formal reassessment using technical assessors which repeats the original assessment process. In large laboratories or in those with a broad scope, the reassessment process may be staged at intervals over a reassessment cycle to minimise disruption to the laboratory's normal operations.

Where this two-tier approach is used, the intervals between the formal reassessments may be extended quite significantly. There are no hard and fast rules with regard to reassessment intervals but there is general agreement that accreditation bodies need to maintain regular contact with their accredited laboratories whether this is through staff visits, reassessments, proficiency testing or other means such as questionnaires to collect updated information on activities and developments within the laboratories. There is also general agreement that in the absence of anything other than formal reassessments, these should be conducted at intervals of two years or less.

Note that in rare cases an assessment could result in suspension of the laboratory if nonconformities found are not addressed. More usually an accredited laboratory would apply for temporary suspension in cases where critical staff has been lost or where it is relocating to new premises.

G. Proficiency testing

Proficiency testing is the term applied to comparing actual test results from different laboratories. It takes many forms and the design, management and operation of a number of these are described in ISO/IEC Guide 43. They range from one-on-one comparison of a laboratory's output with that of a reference laboratory to extensive programmes involving many laboratories, often operating in many countries.

Some laboratory recognition programmes use proficiency testing only with no on-site assessment or verification. These involve frequent programmes in which all laboratories must participate and produce data acceptable to the programme manager every time or with very few outlying results. This is not regarded as laboratory accreditation and is only applicable to the needs of the programme operator with such proficiency testing regimes almost always focusing on a few tests critical to the needs of the programme manager. Laboratory accreditation bodies may, however, use results from such programmes as evidence of satisfactory performance in that area of testing.

Development of proficiency testing by bodies in developing countries is often very difficult. There may be too few laboratories in each particular field of testing to yield statistically meaningful results, or reference materials and reference laboratories are not readily accessible and local legal requirements and administrative practices may inhibit easy access to proficiency testing programmes operated by foreign organisations.

Nevertheless, for full international recognition, some proficiency testing activity must be included in any laboratory accreditation activity. Well operated programmes demonstrate a degree of sophistication on the part of the accreditation body and successful participation in such programmes adds credibility to the laboratory's claim for recognition of competence.

1. Proficiency testing in the surveillance of accredited laboratories

Proficiency testing is used by laboratory accreditation bodies to complement the on-site peer assessment process and to provide objective data about the performance of individual laboratories. Proficiency testing may also be used for other purposes such as evaluation and validation of test methods, but, in accreditation, its primary role is to assess performance.

Basically, there are two main types of programmes; concurrent testing of samples by groups of laboratories and programmes involving the examination

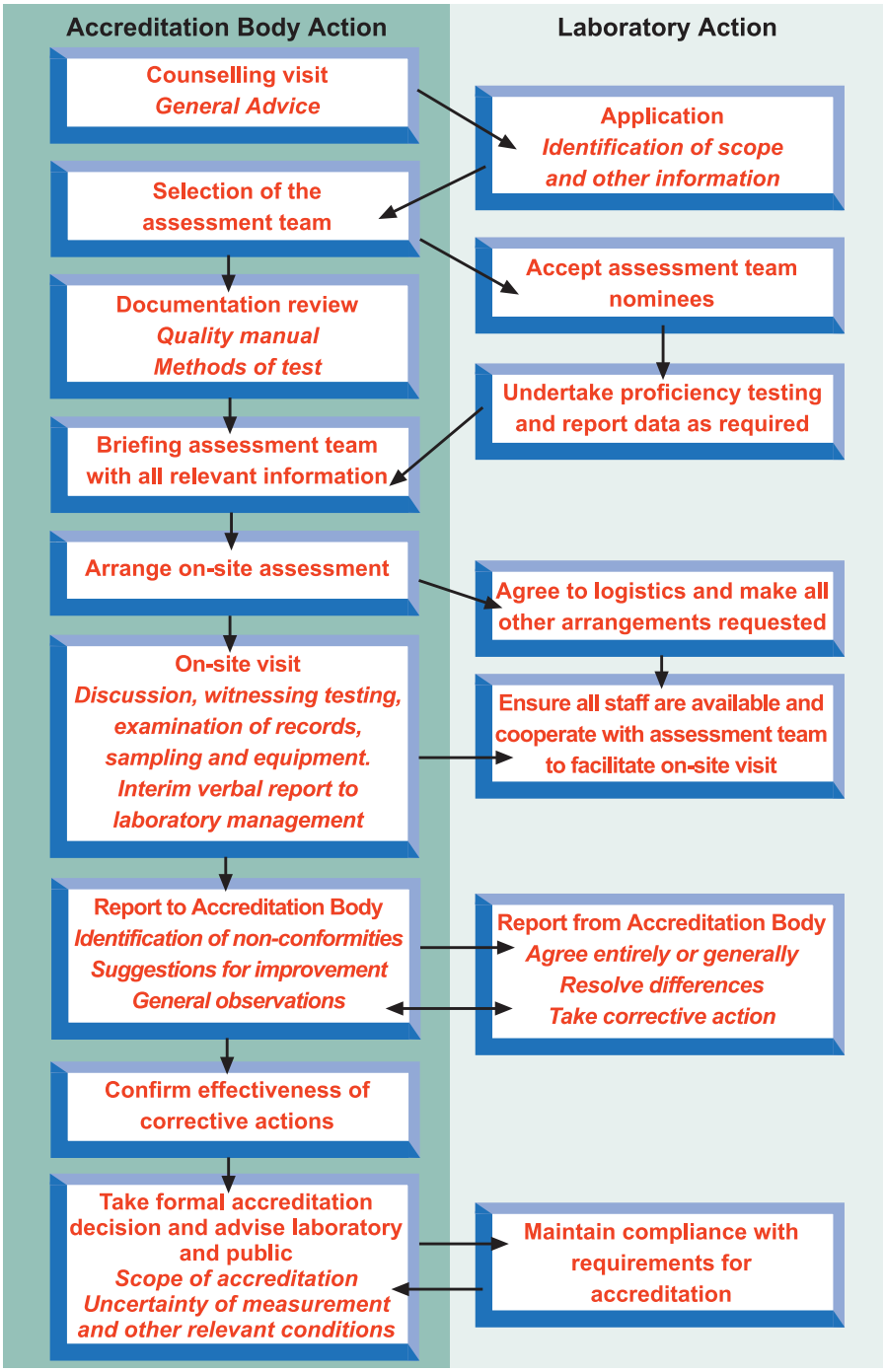


Figure 7. The Assessment Process

of a single item by laboratories in sequence. The former is most commonly used in conventional testing programmes and the latter for calibration programmes.

In the more mature accreditation bodies, where proficiency testing programmes are a routine part of their operations, all laboratories are required to participate in regular programmes relevant to their scopes of accreditation. Even then, it must be recognised that suitable programmes are not always readily available for every area of testing.

In the large, technically sophisticated economies, a wide range of proficiency testing programmes are available from commercial sources and accreditation bodies in those countries make use of those services. In smaller economies, there are fewer commercial services available and the accreditation body may be forced to provide appropriate proficiency testing programmes; at least filling gaps left by the commercial providers.

The increasing insistence by accreditation bodies that accredited laboratories participate in proficiency testing programmes operated by a variety of service providers has forced thinking towards accreditation of those services. ILAC has published a guideline document (ILAC G13) but the topic remains under discussion. It is likely that, at an appropriate time, all service providers, including accreditation bodies themselves, will need to seek some form of accreditation for that activity if its programmes are to be recognised within the context of mutual recognition activity.

In the meantime, however, accreditation bodies are obliging their accredited laboratories to participate in proficiency testing programmes from "reputable" sources and using the data generated as part of the information needed to make decisions regarding accreditation.

2. Essential requirements

ISO/IEC Guide 43 spells out the requirements for development and operation of proficiency testing programmes and criteria for their selection and use by accreditation bodies. In designing a particular programme, care must be taken to ensure both technical validity and value in the end result. Right at the beginning, technical advice should be sought on at least the following issues:

- Selection of tests to be conducted, the range of values to be covered, test methods to be used and samples to be prepared
- The paperwork to be prepared – instructions, result sheets, reporting requirements and formats and units of measurement.

As in any testing activity, the value of the output is fundamentally dependent on

the integrity of the samples to be tested. In a programme involving a number of laboratories testing samples drawn from a bulk supply, this must be carefully prepared to ensure homogeneity. Samples must also be very stable otherwise there will, inevitably, be problems with transportation and later disputes over results.

Where a single sample or artefact is to be tested or measured sequentially by a number of laboratories it must be selected bearing in mind its ease of transportation, stability and robustness.

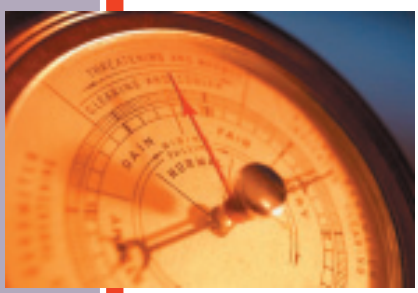
In any case, the sample or artefact must be well characterised prior to the commencement of the programme.

3. Sources of proficiency testing programmes

Even a preliminary search of the Internet yields well over one thousand providers of proficiency testing programmes. Many of these are highly focused programmes only available to a particular segment of a particular market, but a number offer services for a wide range of tests to laboratories anywhere in the world on a commercial basis.

On a less commercial scale, the regional accreditation cooperations, APLAC and EA, provide regular programmes for both testing and calibration and participation from laboratories outside of those regions can be negotiated. These programmes, however, are intended for a different purpose in that they attempt to compare performance of laboratories in one member country with laboratories in another or of laboratories in one region with those in the other. These regional and inter-regional programmes permit only the participation by a relative few laboratories as they are looking for regional anomalies.

The model is that all accredited laboratories in a particular country participate in national schemes. Some of those then participate in regional schemes and fewer still participate in the international programmes. A satisfactory result at all three levels enhances the credibility of the total network.



Nevertheless, some national accreditation bodies and the regional cooperation bodies offer their proficiency testing knowledge and skills to others so that a truly global system can be developed and the various mutual recognition arrangements strengthened. To this end, training courses are available and opportunities exist for staff in emerging bodies to be attached to more mature organisations to obtain extensive hands-on experience.

4. Proficiency testing in a developing accreditation body

Proficiency testing programmes are expensive to operate and therefore great care is required to select areas of testing that have some importance either in the context of trade or for the domestic role of the accreditation body. Emerging bodies also face the reality of having very few laboratories in any one area of testing which increases the problem of being able to deal with the proficiency testing results in a statistically satisfactory way.

Importing samples from foreign programmes is not always easy as local customs officials will be quite unfamiliar with the needs of the accreditation body and the laboratories. In many cases suitable samples may be prohibited from air transport by regulations (e.g. flammable liquids, mercury in glass instruments) or the samples are too unstable for reliable transportation (e.g. fresh foods). Nevertheless, an accreditation body seeking international recognition will need to address, to the best of its ability, the problem of having objective evidence of performance of its accredited laboratories.

In many cases, certified reference materials may be used. This is an expensive option and not without problems but it may be the only one in some situations. One obvious problem occurs when the reference material is from a well known source and may be readily identifiable by the participating laboratories.

IV. Consolidation and maintenance

A. Maintenance of the system

Accreditation is not a once-off activity. As outlined previously, the integrity of the system must be maintained through a rigorous surveillance regime, including proficiency testing programmes but it must also be able to expand to meet new community and national needs and to keep up with technical developments in the areas of testing covered by the accreditation body.

B. Domestic networks

The strength of any accreditation body depends on its place in its domestic infrastructure and the economy of its country. To play a full role in its own economy, an accreditation body will need to have close interaction with its immediate clients, the accredited laboratories, and its other stakeholders, including its governmental authorities.

C. The stakeholders

Accreditation is a mechanism by which the market can have confidence in those services it needs for its proper functioning. It must therefore have the confidence of all participants in the market. It is true to say that governments cannot ensure confidence by legislation. It is something that must be earned and this is as true for accreditation as for anything else.

For testing laboratories and other conformity assessment bodies, the stakeholders with an interest in ensuring a valid and reliable network of service providers extend from the direct customers of laboratories to their customers' customers, specifying authorities and the general community. An effective system requires some degree of participation by all such sectors and one that is transparent to all.

For these reasons ISO/IEC Guide 58 has requirements for any advisory committees that are established although it is not mandatory to establish any specific committees. It is probable that the new ISO/IEC standard 17011 will require some form of committee for "interested parties".

There are many models to be found in various accreditation bodies throughout the world. Almost all have an external committee for policy advice and to provide a forum for stakeholders to express their respective points of view. Many also

have technical committees through which they receive stakeholder participation in their standards and criteria setting processes. This involvement by the laboratory and technical user community has proven to be most beneficial in building confidence in accreditation systems.

A problem that is emerging is where accreditation bodies see their role as focusing on international recognition while ignoring domestic considerations. If they have little or no recognition at home, what then the value of any mutual recognition arrangement in which their partners obtain no access to the home market? All partners to MRAs must offer some benefit to all other partners otherwise the MRAs must, of necessity, be limited to few mutual benefit arrangements and will again become bilateral in nature.

In servicing a domestic network, therefore, an accreditation body will seek to promote the benefits of adherence to the appropriate common international standards (ISO/IEC Guide 58/17011 and 17025) irrespective of where the accreditation body may be located. In addition, however, where local requirements are different from or additional to such standards the body should try to satisfy those additional requirements for the home market and also advise its mutual recognition partners of such local variations. It is then up to each mutual recognition partner to decide whether or not it is willing to acquire any additional expertise necessary to assess its laboratories against the specific requirements of a particular export market.

For instance, in areas such as electrical safety, building materials and telecommunications equipment, there are many local variations on what are basically international product standards but the importing market usually requires complete compliance with its own requirements. Individual national accreditation bodies are not always willing to take the extra steps necessary to assess perhaps only a very few laboratories for compliance with the additional requirements and other members of the ILAC Arrangement can then be used as an exception rather than the rule.

V. International Recognition

A. Regional and international links

The laboratory accreditation community is organised at both regional and at the international levels.

At the international level, the principal forum is the International Laboratory Accreditation Cooperation (ILAC). ILAC first met in 1977 as an informal meeting of accreditation bodies who agreed to work together to promote laboratory accreditation as the most efficient solution to the then emerging problem of testing being used as a trade barrier.

Regional associations came much later and in response to specific regional issues such as the creation of the European Single Market (EC 92) and the free trade objectives of the Asia Pacific Economic Cooperation (APEC).

B. ILAC

During the Tokyo Round of the Multilateral Trade Negotiations under the General Agreement on Tariffs and Trade (GATT) the subject of technical barriers to trade (TBTs) became part of the agenda. For the first time steps were taken to address the use of technical requirements, either related to standards and technical regulations applicable to particular products or to assessment of their conformity to those regulations, as barriers to trade.

Of all the technical issues, those associated with the application of standards and conformity assessment were seen as the most pervasive and most difficult to deal with. Negotiations commenced on what became known as the GATT Standards Code and the fundamental objective was to discourage the use of standards (specifications and technical regulations) and conformity assessment (testing and certification) as trade barriers. Signatories to the Code would be encouraged to recognise foreign standards as being equivalent to their own and to accept tests performed in laboratories located in the exporting countries.

It was understood that authorities and other users of test reports could not be expected to accept tests undertaken in foreign countries without some evidence as to the competence of

those laboratories. ILAC was convened as a response to that problem.

There are a number of ways whereby a user of test reports can gain confidence in a foreign laboratory. Options include undertaking ones own evaluation of each laboratory to be considered for recognition, relying on some form of endorsement by the foreign government or relying on the reputation of particular laboratories. All such mechanisms have the potential to be anti-competitive, discriminatory and non-transparent which are contrary to GATT principles.

On the other hand, an international system for accreditation of laboratories, if properly established, could be used to give users in all countries confidence in the competence of laboratories located in other countries without the necessity of undertaking their own evaluation of those laboratories. To create such a system that would be universally acceptable required the development of rules, standards and practices that would be recognised by acceptance authorities in all trading nations.

ILAC began its work in 1977 and there was rapid progress on the basic standards and policies. The proposed solution to the trade facilitation problem

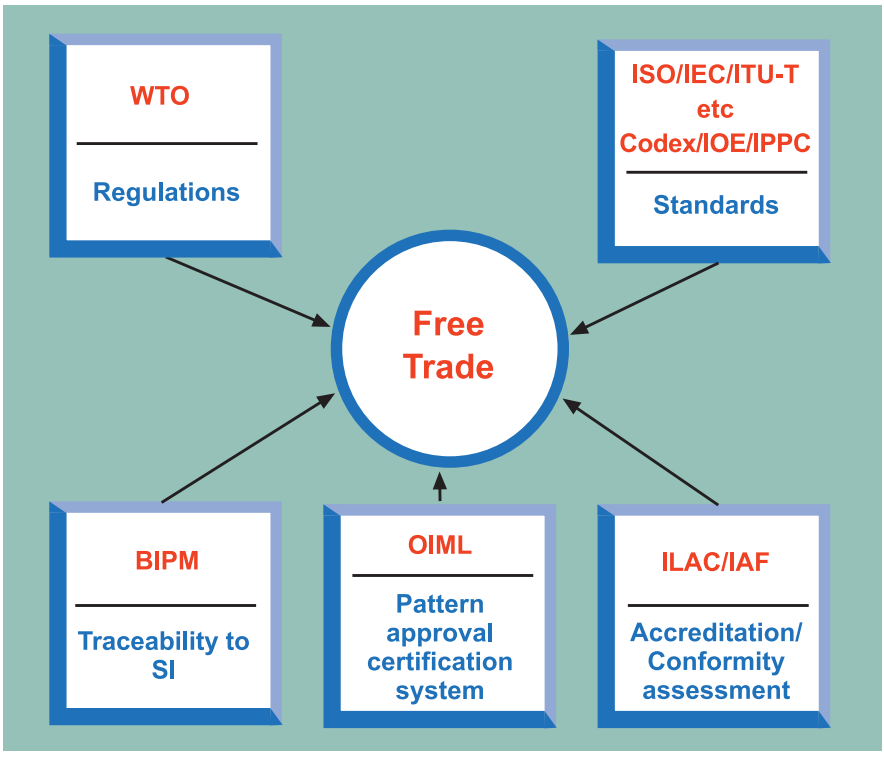


Figure 8. Infrastructure for World Free Trade

was to create a matrix of national laboratory accreditation bodies all operating to the same standards and using harmonised practices, linked by mutual recognition agreements. Such a system would be open to any laboratory able to demonstrate its competence. It would be non-discriminatory with rules and standards common to all and be fully transparent.

While much progress has been made, there will always be new issues to be addressed. In the early years ILAC was dominated by accreditation bodies from the industrialised countries and their experiences provided the background for the development of the standards and harmonised procedures. As the developing countries have increasingly sought participation in the work of ILAC, their experiences and particular problems need to be considered. Accreditation bodies in developing countries are therefore urged to play an active role in fora such as ILAC. As of September 2003 ILAC had a membership of 102 bodies representing 65 economies worldwide. It is clear that many of these are emerging economies and a full list of members and their category of membership can be found at the ILAC web site.

C. Regional cooperation bodies

Regional Cooperation Bodies currently exist in the American, Asia Pacific, European and southern African areas. Each was created to satisfy regional needs and to develop regional voices in the international fora. They all seek common international standards but have different outlooks on many issues. Although most members of ILAC are also members of regional cooperation bodies this is not a pre-requisite for membership. Examples are Israel (full member) and Egypt (associate member) who operate independently outside of any region. On the other hand South Africa is the only member of SADCA that is also a full member of ILAC although Mauritius (through MAURITAS) is an affiliate member.

1. Europe

The first regional cooperation bodies were established in Europe which initially became interested in accreditation in the calibration area. The first European accreditation body was the British Calibration Service (BCS) formed in 1964 and others in the Western European area followed soon after. At the level of accreditation, Europe extends to all of Western Europe (including countries like Iceland) and, more recently, also to much of Eastern Europe.

The first regional accreditation cooperation was the Western European Metrology Club (WEMC) which brought together in the mid-1970s, as a loose

forum, bodies, such as BCS, with national responsibility for accreditation of calibration laboratories. It was a very technical organisation focusing on inter-laboratory comparisons and technical matters such as expression of measurement uncertainties and calibration techniques. It later became the Western European Calibration Cooperation (WECC).

From the early 1980s, following the development of the GATT Standards Code, there was a rapid development in the establishment of a number of more comprehensive accreditation services for testing. In some cases two separate organisations, one for calibration and one for testing, coexisted. In some countries the two functions were brought together immediately, but there are still exceptions to this rule such as Belgium and Italy. The Western European Laboratory Accreditation Cooperation (WELAC) was established in the mid-1980s and in the early 1990s it combined with WECC to form European cooperation for Accreditation of Laboratories (EAL).

About the same time, the bodies with responsibility for accreditation of certification bodies formed a cooperation known as European cooperation for Accreditation of Certification (EAC).

The European interest in accreditation was initially inspired by trade issues and the fact that calibrations performed in one country were not accepted in others, even within the European Common Market as it was then. The GATT Standards Code led to the expansion of the interest to testing and the decision taken by the European Economic Community (EEC), now the European Union (EU), to create a single market within its borders by December 1992 (EC 92) led to intensified interest in all forms of accreditation. One of the most serious impediments to the attainment of the single market initiative was the lack of acceptance of testing and certification between Member States and accreditation offered a mechanism based on confidence rather than legislation.

The various organisations seeking to provide fora for accreditation interests were driven by the trade needs of the EEC. The development of the Global Approach to Conformity Assessment policy in 1989 also made mutual

recognition agreements between the members of EAL and EAC something of a priority for these bodies.

The early relationships between the individual accreditation bodies were informal but within WECC in particular there was long history of objective data from proficiency testing that gave much confidence to all parties about the competence of the individuals and the laboratories accredited by them. A formal Mutual Recognition Agreement was concluded by the members of WECC in 1988 which consisted of a network of bilateral agreements between each of the members.

Taken together, these political and trade objectives within Europe drove the accreditation bodies to pursue work activities that would enhance confidence in the competence of each other's systems and to put in place arrangements that would satisfy the demands of the various authorities within the European Commission (EC) and those of the Member States.

By the mid-1990s there had been substantial consolidation of accreditation activities within many of the Member States with most accreditation activities, calibration, testing and certification, being undertaken by single organisations within each country. It was not surprising, therefore, that EAL and EAC would merge to form the European cooperation for Accreditation (EA) in 1997. The activities of EA are closely tied to the needs of the EU both with respect to its internal requirements and those related to external trade.

Also by the mid-1990s, EA began to accept members from the former Eastern bloc countries, a number of which are now Full Members of EA and a number of others are preparing themselves for membership, including participation in the EA mutual recognition activities. Current full members of EA from the Eastern bloc include the Czech Republic, Latvia, Lithuania, Romania, Slovakia and Slovenia.

2. Asia Pacific

In 1989, a number of states bordering the Pacific Ocean came together in a free trade initiative known as the Asia Pacific Economic Cooperation (APEC). The members of APEC range from the most to the least wealthy nations and, therefore, there are wide disparities in technical development. The problems confronting APEC were very different to those experienced in Europe and, consequently, new strategies for their solution had to be devised. However, one issue that both had in common was that of lack of acceptance of conformity assessment results.

The world's first laboratory accreditation body was developed in Australia in 1947 and New Zealand had used a similar model when it established its national

system in 1972. Both of these bodies were established for domestic purposes, largely to encourage technical development, enhancement of measurement skills in industry and to encourage a national quality culture based on reliable testing and measurement.

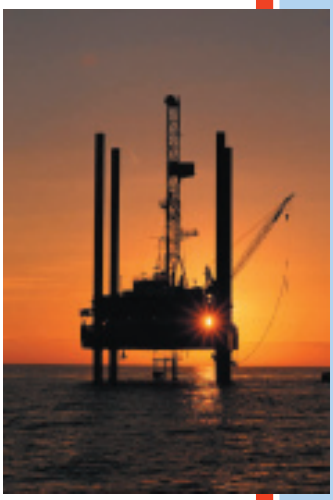
APLAC currently has some twenty seven full members and three associate members. Most North American accreditation bodies are members of APLAC while only A2LA and Canada's SCC are also members of the IAAC. The membership of APLAC includes the Peoples Republic of China, Hong Kong and Chinese Taipei in its membership that extends westward to include India.

As with European developments, development of accreditation bodies in the region began in earnest in the early 1980s as a result of the GATT Standards Code and the demands of world trade. By the early 1990s, therefore, there existed perhaps ten accreditation bodies in the Asia Pacific region with substantial experience and a reasonable level of maturity.

In 1992, in response to rapid developments in accreditation in Europe and to meet needs foreseen within APEC, the accreditation bodies of the region established the Asia Pacific Laboratory Accreditation Cooperation (APLAC).

APLAC membership is open to accreditation bodies in any APEC economy and other nearby countries as agreed by the members. While not seeking membership from outside the APEC economies, APLAC enthusiastically welcomes cooperation with other accreditation bodies in other parts of the world.

APLAC's objectives were to bring all participating accreditation bodies in the region up to a level of competence that would satisfy international requirements as well as any particular regional needs that might arise. To this end, it set about establishing a freely available database of current accreditation documentation, a newsletter, training programmes for potential accreditation body staff and proficiency testing for laboratories within the region.



APLAC, with substantial assistance from the Australian Government in support of its APEC agenda, has had a number of training programmes in which three trainees spend three months working within the Australian accreditation body, NATA, and a number of regional proficiency testing programmes. In more recent times, APEC has assisted APLAC with training activities.

APLAC has a number of training courses available as well as a web-based course for ISO/IEC 17025 implementation that is freely available. Any of this material

can be made available or tailored specially for the needs of developing countries.

3. The Americas

Led by Brazil, the InterAmerican Accreditation Cooperation (IAAC) was created in 1996 in Uruguay and became incorporated as a civil association according to Mexican law in 2001.

IAAC seeks to address accreditation in all areas of conformity assessment and it works in close cooperation with ILAC and the other regional organisations.

As with the other regional cooperation bodies APLAC and EA, IAAC seeks to develop national infrastructures within its member economies and, ultimately, to establish a regional multilateral MRA as one of the building blocks of the ILAC Arrangement. To date it has focused on training of accreditation body staff and assessors. It has amongst its members a number of developing countries and is therefore sensitive to their needs. Its working languages are English and Spanish which may be very useful to some developing accreditation bodies in other parts of the world.

IAAC currently has nineteen full members and eight associate members covering twenty countries throughout the Americas and the Caribbean. Countries recognised as full members include North America and Canada, most major South and Central American states and islands such as Cuba, with Trinidad & Tobago being an associate member. There is also close collaboration between the IAAC and SADCA.

The USA is an exception to the general rule in that it has several recognised accreditation bodies. Only one of these, A2LA, is a member of IAAC, but all are members of APLAC.

4. Southern Africa

The EA is an organisation whose members come mainly from developed economies, and while APLAC and the IAAC cover the poor to the very rich and well developed countries the latter contribute a very high level of technical and other competencies. For the developing economies

Southern Africa is the best example of a regional accreditation body, with South Africa being the strongest economy (but still a developing one) and the only country in the region and the African continent where its accreditation body (SANAS) is a full member of the ILAC Arrangement.

While Southern Africa is classified as a developing region it has as a role model the "not for profit" South African National Accreditation System (SANAS) and its predecessors. South Africa established the National Calibration Service (NCS) in 1980 based on the successful model of the BCS. The name of the body was later changed to the National Laboratory Association and accreditation of testing laboratories was taken over from the South African Bureau of Standards which as the national standards body had a possible conflict of interest in this area. SANAS itself was created in 1995, was recognised by the South African government as the sole local accreditation body, and has since extended its scope of accreditation to include certification bodies, inspection bodies, medical and verification laboratories. SANAS was a founder member of the Arrangement and in earlier days had established several MLA/MRA agreements, one of the first of these being the signing of an MRA with Europe (with the then WECC) in 1993.

In 1992 twelve States in the southern African region established, by Treaty, the Southern African Development Community (SADC). Subsequently, two further States joined the Community. Part of this initiative was the recognition that technical barriers to trade needed to be addressed and the SADC Cooperation in Accreditation (SADCA) was established.

SADCA has adopted a novel approach to a regional cooperation. Of the fourteen members States, only two (South Africa and Mauritius) have established a national accreditation organisation and only three others have indicated an intention to do so. The SADC regional approach to accreditation is currently built around the two existing accreditation bodies in SADC but will expand to include any other national accreditation bodies created in the region in the future. This approach is relevant to the region because it has the least investment and allows for optimal utilisation of scarce resources. It will also cater for the immediate accreditation needs of SADC Member States. It is also a flexible approach and will use other resources as and when they become available.

The role of SADCA is to harmonise the activities of accreditation bodies within the SADC region and ultimately it will manage the regional recognition agreement. In addition the region has identified the need to create a regional accreditation infrastructure organisation called SADCAS. This body will not compete with existing or future national accreditation bodies in the region but

will provide a cost effective and transparent mechanism for member states that do not want to establish their own national infrastructure. However by giving these member states input to the management and decision making process as well as using suitably trained national experts where appropriate it not only will satisfy existing needs but will prepare the economy for the possible future establishment of its own infrastructure if and when there is sufficient demand.

Ultimately, laboratories in the SADC region will be able to avail themselves of accreditation services provided by any participating accreditation body within the region, including SADCAS. All of the accreditation bodies, the national bodies and the proposed regional body, will be linked through a mutual recognition arrangement.

As a result of its unique role in the region SANAS has developed a comprehensive training programme with courses presented by its own staff and external consultants. These include courses on Laboratory Systems, Internal Auditing, Overview of Accreditation, System Documentation and an Accreditation Infrastructure Development Workshop for Emerging Accreditation Bodies. SANAS has presented many of these courses in countries throughout the African continent.

D. Mutual Recognition Arrangements (MRAs)

The term "mutual recognition arrangements" in this context applies to mechanisms whereby a user or acceptance authority in one country can have sufficient confidence in the validity of test reports and calibration certificates from laboratories in foreign countries without having to make individual evaluations of the competence of those laboratories.

Arrangements of this kind vary from unilateral decisions by bodies in one country to accept results from another, to bilateral arrangements or agreements or multilateral systems involving many bodies in a number of countries. Also included are government to government agreements or treaties for specific

products or sectors.

The early decisions to recognise test reports or calibration certificates from laboratories accredited by foreign accreditation bodies were in response to some domestic need to save time and resources on unnecessary duplication. The decisions were made after assessing the risk of so doing and with perhaps little formal evaluation of the operations of the foreign accreditation body.

Following the adoption of the GATT Standards Code, the concept took on more of a trade focus and a degree of mutuality was seen as necessary. It was at this time (1980) also that the process of peer evaluation of accreditation bodies was developed and codified. This process has been under constant development and refinement ever since.

The first formal bilateral agreement of this type was between the accreditation bodies of Australia and New Zealand in 1980. Throughout the 1980s accreditation bodies participated in bilateral MRAs and thus developed networks of bilateral arrangements but not every participant had an agreement with every other party. It also meant that an accreditation body that participated in a significant number of MRAs was subject to many peer evaluations, sometimes requiring subtly different conditions and standards.

EA pioneered the creation of a single multilateral arrangement on a regional basis when it formed the EAL Multilateral Mutual Recognition Agreement (MLA) involving all those European accreditation bodies that had been party to the network of bilateral agreements. The MLA also became available to all other European accreditation bodies at such time as they were able to satisfy a peer evaluation consisting of a team drawn from three EA members.

EA also introduced the concept of contracts of cooperation between the EA MLA and individual bodies in other countries. These gave only limited rights of participation in EA affairs but had the advantage of giving recognition to both the EA members and the contract partner in each other's territories.

Also in the early 1990s, APLAC developed its network of bilateral agreements which were transformed into a multilateral arrangement in 1997.

It was then intended to have bilateral agreements between the regions but before this could become a reality, it was agreed that a single

global agreement, managed by ILAC, would be established. Under this system, the regional agreements are maintained and every member of one of the participating regions automatically qualifies for the ILAC Mutual Recognition Arrangement. Individual bodies not members of a region may enter the ILAC Arrangement by direct application to ILAC.

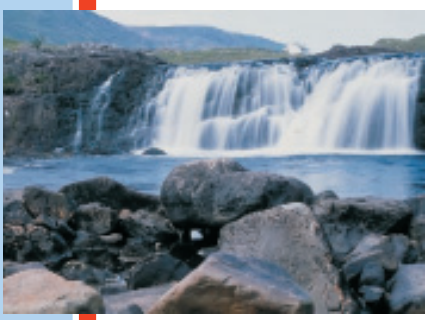
Despite the creation of the ILAC Arrangement, some accreditation bodies with contracts of cooperation with EA have decided to continue those contracts, at least for the near term.

While the developed countries in their respective regions were the first participants in both the APLAC and EA MRAs, both are open to participation by all countries within their respective regions. APLAC is well advanced in its objective to have all its members sign the APLAC MRA by 2005 and EA is progressively extending its MLA signatories from Eastern Europe.

One misconception is that each accreditation body within a MRA necessarily must cover the same scope of work but this is incorrect. The MRA process can recognise that some signatories will cover broader scopes than others but that within their respective limits, all can be recognised.

At the time of writing, there remains some debate over words such as "Agreement" and "Arrangement", but both are in use as titles for otherwise identical documents. Similarly, the terms "MRA" and "MLA" when used in the multilateral context, are interchangeable. Those who think that "recognition" is the key word prefer MRA while those who wish to distinguish multilateral from bilateral agreements prefer MLA. There is also a school of thought that would restrict the term "Mutual Recognition Agreement" (and the abbreviation MRA) to government to government instruments but, again, the term is already in use in voluntary sector agreements.

It is important to note that while laboratories are subject to regular assessment by their accreditation body, the accreditation bodies themselves are regularly assessed by their peers to ensure international conformity. Within the recognised regions (currently only APLAC and EA) this review process takes place internally. However if we take the case of SANAS (which is an unaffiliated body and not part of a current recognised region), the South African Accreditation body was recently subjected to a thirty man day peer review. The review team was truly international with two members from Canada, one from Israel, one from Germany, one from Australia and one from



Participants at the signing of the ILAC Arrangement, Washington DC, November 2000

Sweden. Besides a thorough review of the systems in place at SANAS the team also evaluated the assessment work done in industry. This latter task saw the team evaluate seven accredited bodies, four of these being laboratories. This was a joint ILAC/IAF evaluation covering not only calibration and testing laboratories but QMS, EMS, product certification, and inspection body accreditation.

Note should be made of the fact that this was a review of a very comprehensive conformity assessment system and that a developing economy with perhaps only a laboratory accreditation system may only require one or two man days. At the other end of the scale developed countries like the USA might require 60 to 90 days for a thorough assessment review.

E. ILAC and the IAF

While this document has dealt mainly with the area of laboratory accreditation it has been stressed that in most countries the recognised accreditation bodies look after all aspects of accreditation including the accreditation of certification bodies. While ILAC looks after laboratory accreditation its sister body, the International Accreditation Forum (IAF) has responsibilities in the other areas of accreditation and operates similar international MRA schemes. The IAF and ILAC work closely together in the field of conformity assessment and besides having a number of joint working groups (including one addressing the needs of developing economies), peer reviews of accreditation bodies is often carried out jointly.

VI Technical Assistance to Developing Countries through UNIDO

A. Accreditation activities

Since its inception in 1967, the United Nations Industrial Development Organization (UNIDO) has provided technical assistance to institutions in more than 80 countries in the fields of Metrology, Standards, Testing and Quality (MSTQ). Between 1974 and 1997, UNIDO activities in MSTQ amounted to over US$ 55 million, including delivery of measurement and testing laboratory equipment, training and upgrading to attain accreditation.

In 1995 and 1997 UNIDO conducted two surveys on the implications of international standards for quality, environmental management systems and eco-labeling for developing countries and economies in transition, in cooperation with ISO and the International Trade Centre (ITC, UNCTAD/WTO). National accreditation bodies were reported to concentrate their activities in accrediting national laboratories and national certification bodies. Results of these surveys also revealed developing countries' concerns about the lack of international recognition of certificates issued in their countries and expressed the need for

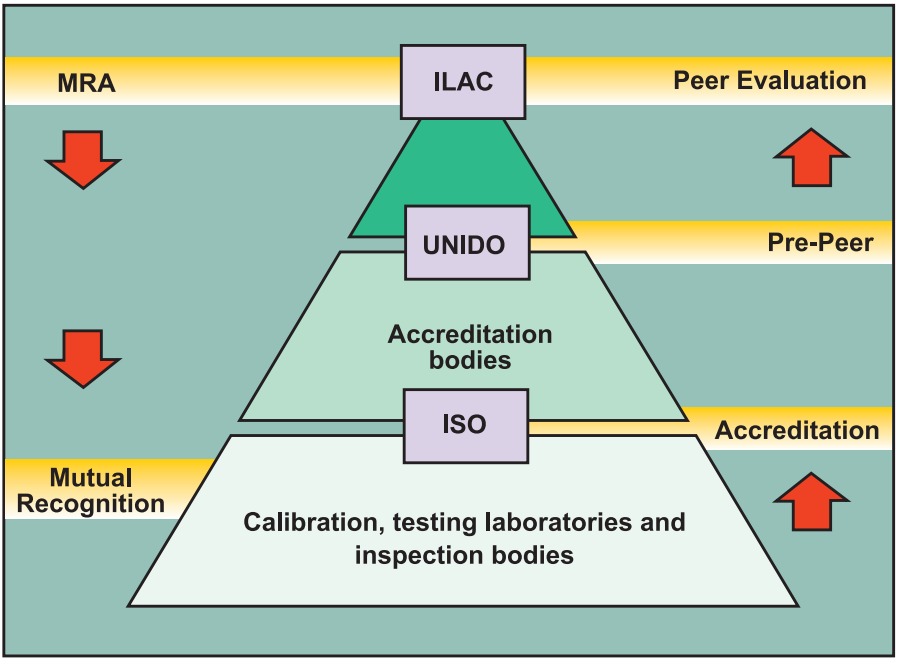


Figure 9. Conformity assessment structure

support of the relevant bodies in developing countries and economies in transition; whereas potential solutions to the lack of recognition were sought either through obtaining certification from an organisation operating internationally (considered as expensive) or gaining international acceptance of certificates through the Quality Systems Assessment Recognition initiative (QSAR).

Analysis of these surveys led to the idea of establishing a UNIDO scheme of Mutual Recognition Agreements (MRA) among countries to better ensure compatibility of certificates and their mutual acceptance across frontiers. Further high-level discussions at an Expert Group Meeting (EGM), held in Vienna at UNIDO Headquarters in 1997, resulted in the cooperation between UNIDO, IAF and ISO. The Pre-Peer Evaluation Scheme developed by UNIDO for bodies accrediting QMS-certifiers was then established and the Pre-Peer Evaluation Procedure was agreed upon in 1998 at a second EGM, with a view to facilitating international recognition of accreditation bodies of developing countries in the context of IAF's Multilateral Mutual Recognition Agreement (MLA). UNIDO also committed to assist accreditation bodies through technical assistance projects subject to availability of resources.

In 2000 UNIDO agreed with ILAC and ISO to enlarge the coverage of the Pre-Peer Evaluation Scheme to cover laboratory accreditation. A tripartite Memorandum of Understanding was signed at the ILAC General Assembly in September 2000 and the procedures applicable to laboratory accreditation were established at an EGM in June 2001. Since then, six laboratory accreditation bodies have been considered eligible to carry out such Pre-Peer Evaluations and the findings and constraints encountered during the implementation phase were considered while compiling this publication.

B. The Pre-Peer Evaluation Process (PPEP)

1. Introduction

This part describes the procedures that the Pre-Peer Evaluation (PPE) team shall follow in evaluating the applicant body. The applicant body shall be evaluated against the requirements of ISO/IEC Guide 58 and be conducted in accordance with the provisions of ILAC P1.

Before carrying out the PPE, the team members and the applicant body shall have a clear understanding of the objectives and scope of the PPEP and a

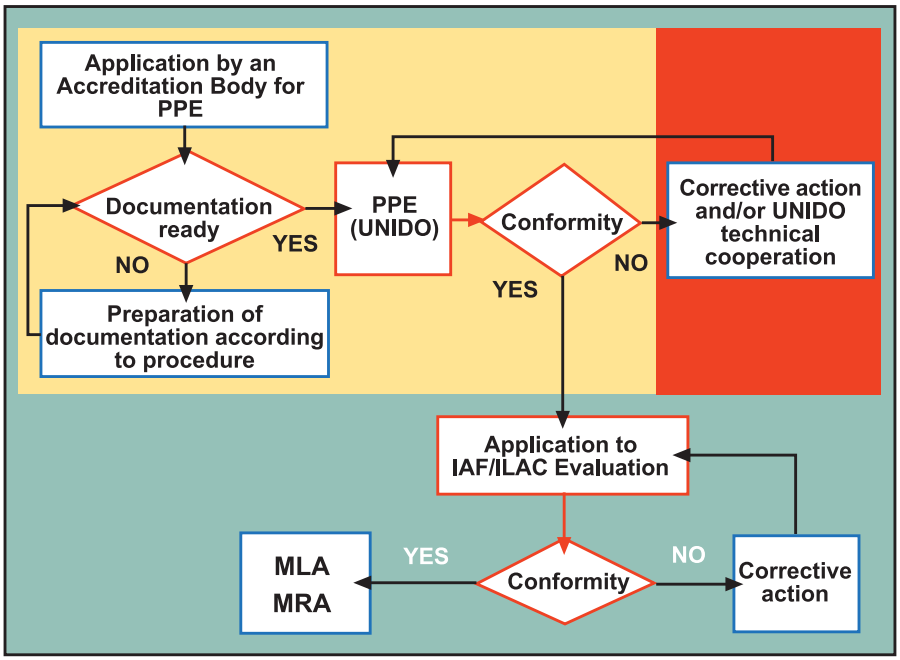


Figure 10. Pre-peer evaluation

detailed identification of the criteria and procedures that will be used which include the ILAC procedures.

2. Objective and scope

The objective of the PPE shall be to establish international confidence in the abilities of an accreditation body from a developing country to assess the performance of laboratories, by evaluating:

- The way in which the accreditation body conducts its assessments and accreditations
- Whether its procedures and practices give confidence that all of its accredited laboratories fully meet the requirements specified in ISO/IEC 17025
- Whether the accredited laboratories have achieved the level of competence needed to obtain accreditation status under the systems operated internationally in accordance with international rules.

The Pre-Peer Evaluation (PPE) Team

The PPE team consists of individuals with sound knowledge of the relevant documentation, who have experience in the evaluation of laboratory accreditation

bodies and who have been selected by ILAC, ISO and UNIDO. A workshop was organised in June 2001 to provide potential PPE team members with a common understanding of the procedures to be followed and of their responsibilities during the PPEP.

UNIDO shall select a team, normally of two evaluators, for each PPE. The criteria for selection of a team leader and his/her team member are established in the ILAC P1 document. An additional selection consideration may be knowledge of the applicant body's language.

The team leader shall have ultimate responsibility for the conduct of all phases of the PPE, and shall have been delegated the authority to make final decisions regarding the carrying out of the PPE. UNIDO's nominations for the team are sent to the applicant body for its approval. After selection of the team, the team leader shall be responsible for communicating with the applicant body.

C. Requirements to be met by Applicant Accreditation Body

The requirements for the applicant accreditation body to participate in the PPEP are that it:

- Provides laboratory accreditation services for testing and/or calibration laboratories in accordance with international standards and guidelines
- Be a legal entity
- Is not a current applicant for the ILAC MRA or one of the regional MRAs
- Has accredited at least five laboratories and, preferably, has conducted at least one round of surveillance activities.

The application to join the PPEP shall be made in writing, in English, to UNIDO. All key documents will be made available in English.

The application of the applicant body shall be accompanied by a statement indicating:

- Any membership in regional accreditation cooperations
- Its operational status
- Number of staff members
- Accreditation criteria used

- Programmes and scopes of accreditation offered
- Number of accreditations it has granted
- Its legal status.

The applicant body shall indicate that it accepts the requirements and agrees with this procedure by signing a contract with UNIDO.

Upon receipt of the written application from the applicant body, UNIDO staff shall review the documents and the signed contract. If there are no objections, UNIDO shall choose a team leader and the team members from the list of evaluators approved by all three parties to the MOU.

The applicant body shall ensure that:

- When requested, it provides the PPE team with all the information and documentation required as stated in this document
- Where an applicant body conducts assessments in a language other than English, the applicant body shall provide a competent translator, at its own expense, to assist the PPE team when needed
- It has carried out all the actions required by the PPE team.

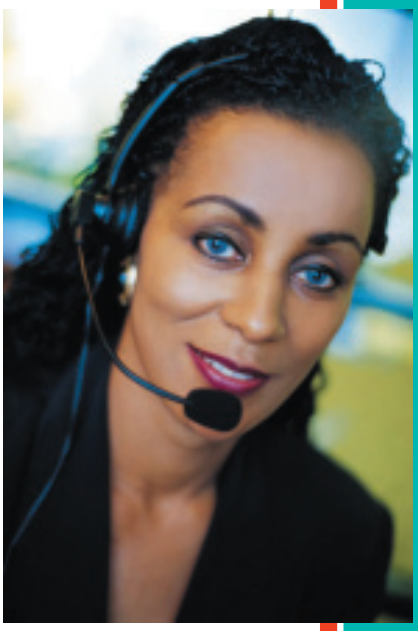
Before the PPE takes place, the team leader shall ensure that the head of the applicant body understands and accepts that the PPE will be conducted in accordance with the requirements and procedures detailed in this document. The team leader shall ensure that the applicant body is prepared to provide to all members of the team copies of all the documentation required for PPE of the applicant body. In addition, any information concerning the cultural or economic environment of the applicant body may be supplied upon request.

D. Documentation requirements for a Pre-Peer Evaluation

Prior to the PPE, the team leader, assisted by the other team member where required, shall review all available documentation. To this end, one set of the following documents (where such documents are available) shall be supplied by the applicant accreditation body to each member of the PPE team:

Set A, in English:

- A listing of all documents, forms, checklists, etc. used by the accreditation body
- The body's quality manual in which the policies and procedures of the applicant body and the responsibility for implementation of the quality system are clearly designated. Full details of the staffing of the applicant body including their backgrounds and length of experience in laboratory assessment and accreditation of laboratories shall also be provided if not given in the quality manual
- Accreditation criteria and associated generally applicable criteria that the applicant body publishes
- All other general criteria, which includes any formal rules or regulations directly affecting the applicant body's operation or which relate to the responsibilities and obligations of its accredited laboratories
- A document giving a clause-by-clause cross-referencing of the applicant body's quality system and the requirements of ISO/IEC Guide 58 and ILAC P1 clauses 5.2 and 5.3
- The policy for traceability routes for the calibration of measurement and testing equipment
- In the case of a body offering accreditation for calibration laboratories, the written guidance provided to those laboratories for the calculation and reporting of measurement uncertainty (this may be a simple reference to a document prepared by another reputable body)
- The policy on the surveillance and reassessment of accredited laboratories
- The policy on the implementation and use of proficiency testing activity
- A summary listing all recent proficiency testing activities (within the past five years), including a list of those accredited and applicant laboratories that participated in regional or international proficiency testing activities



- Operational procedures covering proficiency testing activity including criteria for statistical evaluation and corrective action procedures (where available)
- An action plan for the necessary transition from ISO/IEC Guide 25 to ISO/IEC 17025
- If available, a list of recent international comparisons in which the economy's national metrology institute has been involved (e.g. BIPM or regional metrology cooperations).

Set B, in English:

- Any other documentation that describes the mechanics of operation of the applicant body's accreditation system, including annual reports, questionnaires, newsletters, guidance documents, etc.
- A copy of the applicant body's directory or other listings providing the name and scope of accreditation of each accredited laboratory
- Detailed scopes of accreditation and draft scopes of accreditation of all laboratories to be visited during the PPE visit
- Descriptions of any separate functions or affiliations of the body to activities other than laboratory accreditation (such as accreditation of certification or personnel certification, standards writing, course providers, etc.)
- Details of any formal agreements or recognition to which the applicant body is party, either nationally or internationally, including with government authorities, private sector organisations, other accreditation systems, etc.
- Reports on any recent evaluations carried out by other relevant organisations, if applicable.

The team leader shall confirm that all necessary documents have been provided by examination of the cross references and the list of all documents. The team leader shall request any additional documents considered necessary for the document review, to be provided in English and with copies also to other team members.

The document review shall be conducted by the team leader, liaising as appropriate with the team members and using ISO Guide 58 and ILAC P1 as the standards using an appropriate review record sheet. The record should indicate conformity or nonconformity with the relevant documentation

requirements and identify any gaps in the documentation of the system. The reason for each nonconforming area shall be indicated in a report.

The team leader shall submit the report to the accreditation body with a request for a response on clarifications, corrective actions and an estimate of the time-scale to submit revised documents, if required. Where feasible, the accreditation body shall provide all amended or additional documents to the team for a further review. The team members shall review the documents, and if necessary, seek further clarification. When the document review is complete and satisfactory, the team leader shall issue a report confirming the documents are acceptable and that the PPE of the accreditation body can commence.

E. UNIDO Capacity Building Programmes and Projects

UNIDO supports the establishment or strengthening of accreditation bodies in the fields of system certifiers and laboratories.

In the context of the Regional Programme for the "Establishment of a UEMOA System for Accreditation, Standardization and Quality Promotion" funded by the European Commission, UNIDO is providing technical assistance in accreditation at regional and national levels in eight West African countries: Benin, Burkina Faso, Cote d'Ivoire, Mali, Niger, Guinea Bissau, Senegal and Togo. While at regional level an accreditation secretariat and networks of specialised laboratories are being established as well as qualified laboratory assessors trained and testing procedures harmonised, the capacity of the existing testing laboratories and their management are being strengthened at national level.

Similarly, accreditation bodies will be established or strengthened as part of the Trade Capacity Building Programmes in Central America (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama), the Mekong Delta (Cambodia, Laos, Myanmar and Viet Nam) and South Asian LDCs (Bangladesh,

Joint Committee meeting held in Vienna at UNIDO Headquarters on 23-24 April 2003

Bhutan, Maldives and Nepal).

Establishment or strengthening of accreditation bodies for accreditation of system certifiers and laboratories is therefore implemented as part of the "Capacity Building for Market Access" services offered by UNIDO and the strategy "Enabling Developing Countries to Participate in International Trade". In this context, the UNIDO Trade Capacity Building Initiative encompasses the improvement of supply capacity, conformity to market requirements to overcome technical barriers to trade, including sanitary and phytosanitary measures, and enhanced inter-agency cooperation, involving not only other UN agencies, but also relevant technical international organisations. Enhancement of strategic partnership with selected partners include the promotion and establishment of the Joint Committee on Coordination of Technical Assistance on Metrology, Accreditation and Standardization (JCDCMAS). In addition to UNIDO, the Joint Committee includes the BIPM, IAF, IEC, ILAC, IMEKO, ISO, ITU-T and OIML, while other international organisations are likely to enter into partnership soon.

A Memorandum of Understanding signed at the 5th WTO Ministerial Conference in Cancun, Mexico, establishes also a strategic partnership between UNIDO and WTO to ensure that trade and industrial development enhance economic growth, in the context of the Doha Development Agenda (DDA) and

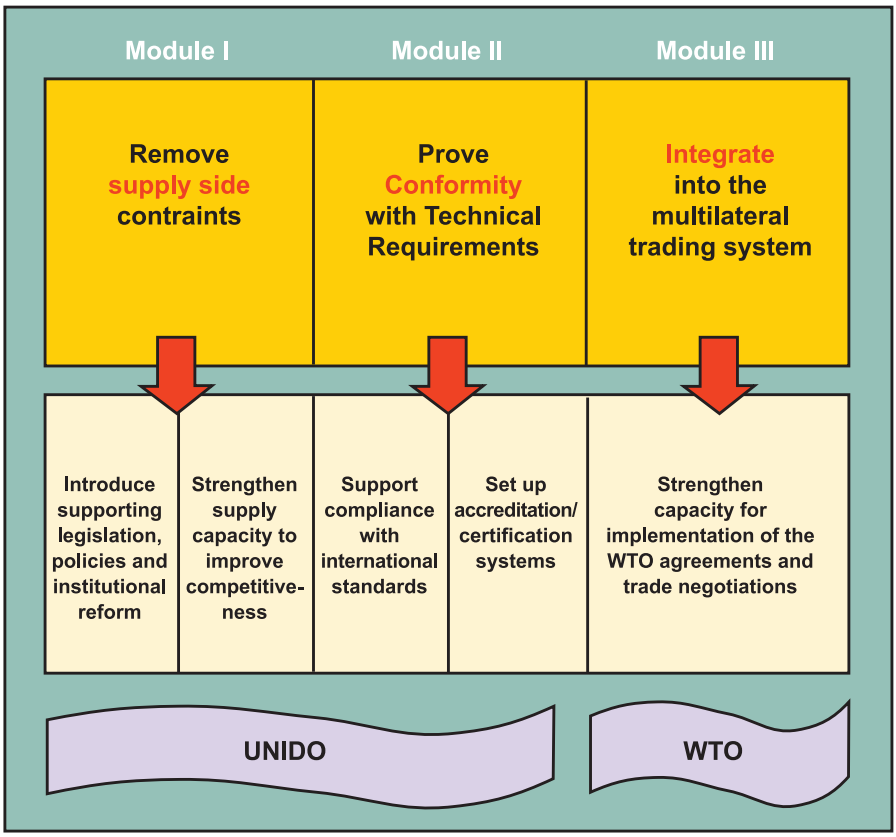


Figure 11. Programme modules UNIDO – WTO co-operation

to assist the beneficial integration of developing, least developed countries and transition economies into the global economy and the multilateral trading system.

Annexes

Annex 1. Useful sources of information

ILAC and it constituent regional cooperation body members (APLAC, EA and IAAC and SADCA through SANAS) have websites and produce newsletters on a regular basis. In addition, ILAC produces a number of brochures and information documents that are available in hard copy or by down-loading from the website.

Individual ILAC Members also have websites containing most, if not all, of their own documentation and special information with respect to their own accreditation programmes. Most of these sites have links to other useful sites, including those of their mutual recognition partners.

"UNIDO Exchange (http://www.unido.org/exchange) is the electronic business and knowledge network of UNIDO, which fosters worldwide cooperation and partnerships within its community of like-minded partners. Harnessing new Information and Communication Technologies, the platform also offers access to several knowledge-based areas of the Organization, such as the Trade Capacity Building Initiative, which offers:

- A full overview on activities undertaken in this framework,
- Access to background documentations,
- References to involved partner institutions,
- A resource sharing section with interactive databases on publications, expertise, case studies etc.
- Interactive business and technology databases,
- A specific feature on the Central America Trade Capacity Building Initiative,
- Specialised fora to foster the progressive institutionalisation of focused interactions between selected actors involved in the initiative."

Annex 2. Key websites

International Accreditation Forum (IAF)	www.iaf.nu
International Laboratory Accreditation Cooperation	www.ilac.org
ISO	www.iso.org
UNIDO	www.unido.org
Asia Pacific Laboratory Accreditation Cooperation	www.aplac.org
European cooperation on Accreditation	www.european-accreditation.org
InterAmerican Accreditation Cooperation	www.iaac-accreditation.org
SADC Cooperation in Accreditation	www.sadc-sqam.org
South African National Accreditation System (SANAS)	www.sanas.co.za

Annex 3. References

- ISO/IEC Guide 2, Standardization and related activities - General vocabulary
- ISO/IEC Guide 43, Proficiency testing by interlaboratory comparisons, Part 1 and 2
- ISO/IEC Guide 58, Calibration and testing laboratory accreditation systems – General requirements for operation and recognition
- ISO/IEC Guide 60, ISO/IEC Code of good practice for conformity
- ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies
- ISO/IEC Guide 65, General requirements for bodies operating product certification schemes
- ISO/IEC Guide 68, Arrangements for the recognition and acceptance of conformity assessment results
- ISO/IEC TR 17010, General requirements for providing accreditation of inspection bodies
- ISO/IEC 17020, General criteria for the operation of various types of bodies performing inspection
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- ISO/IEC DIS 17011 General requirements for bodies providing assessment and accreditation of conformity assessment bodies

Annex 4. Glossary of abbreviations

APEC	– Asia Pacific Economic Cooperation
APLAC	– Asia Pacific Laboratory Accreditation Cooperation
APMP	– Asia Pacific Metrology Programme
A2LA	– American Association for Laboratory Accreditation
BCS	– British Calibration Service
BIPM	– Bureau International des Poids et Mesures
EA	– European Accreditation
EAC	– European Cooperation for accreditation of Certification
EAL	– European cooperation for Accreditation of Laboratories
EC	– European Commission
EEC	– European Economic Community
EGM	– Expert Group Meeting
EMS	– Environmental Management System
EU	– European Union
EUROMET	– European Collaboration in Measurement Standards
GATT	– General Agreement on Tariffs and Trade
IAAC	– InterAmerican Accreditation Cooperation
IAF	– International Accreditation Forum
IEC	– International Electrotechnical Commission
ILAC	– International Laboratory Accreditation Cooperation
IMEKO	– International Measurement Confederation
ISO/CASCO	– ISO Conformity Assessment Committee
ISO	– International Organization for Standardization
ITC	– International Trade Centre
ITU-T	– The Telecommunication Standardization Sector
MAURITAS	– Mauritius Accreditation Service
MLA	– Multilateral Mutual Recognition Agreement
MRA	– Mutual Recognition Arrangement
MSTQ	– Metrology, Standards, Testing and Quality
NATA	– National Association of Testing Authorities
NCS	– National Calibration Service
NORAMET	– North American Cooperation in Metrology
OIML	– International Organization for Legal Metrology
PPE	– Pre-Peer Evaluation
PPEP	– Pre-Peer Evaluation Process
QMS	– Quality Management System
SADCA	– SADC cooperation in Accreditation
SADC	– Southern African Development Community
SADCMET	– Southern African Development Community Cooperation in Measurement Traceability
SANAS	– South African National Accreditation System
SCC	– Standards Council of Canada
TBT	– Technical Barrier to Trade
UNIDO	– United Nations Industrial Development Organization
WECC	– Western European Calibration Cooperation
WELAC	– Western European Laboratory Accreditation Cooperation
WEMC	– Western European Metrology Club
WTO	– World Trade Organization

UNIDO and its Trade Capacity Building Initiative

"....Trade liberalization can only benefit the developing countries if they have sufficient productive capacities to generate tradable goods and if their products satisfy international norms and standards..."

"Developing countries need to assist their industries and concerned government institutions to overcome unnecessary technical barriers to trade caused by disparities in standards, metrology and conformity assessment practices between different trading partners."

UNIDO Director-General Carlos Magariños

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