



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION



A GUIDE TO OPENING THE DOOR FOR GLOBAL TRADE

Setting up **Accreditation Bodies** in Developing Countries

Setting up Accreditation Bodies in Developing Economies

A GUIDE TO OPENING THE DOOR FOR GLOBAL TRADE

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- Colombia: ONAC – The National Accreditation Body of Colombia
- Mauritius: Mauritius Accreditation Service (MAURITAS)
- Nigeria: Nigeria National Accreditation Service (NiNAS)
- Peru: Accreditation Division of the National Institute of Quality (INACAL-DA)
- Sri Lanka: Sri Lanka Accreditation Board for Conformity assessment (SLAB)

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Foreword



Trade is broadly recognized as a potential engine of growth. The contribution it can make to poverty alleviation in developing economies figures prominently on the international development agenda. However, developing country exports and imports face an increasing number of requirements in the form of standards or technical regulations that must be met for products to be accepted when crossing borders.

The international recognition of work conducted by laboratories, certification bodies, inspection bodies and other types of conformity assessment bodies is key to whether goods produced by an exporter are acceptable to other countries. Work carried out by internationally recognized conformity assessment bodies can provide the needed proof that exports meet an importer's requirements.

The international recognition comes through the International Accreditation Forum (IAF) that oversees the accreditation of various types of certification bodies, and the International Laboratory Accreditation Cooperation (ILAC) that oversees the accreditation of laboratories and inspection bodies. IAF and ILAC work together closely; their member bodies accredit conformity assessment bodies (CABs) to international standards. Accreditation bodies are admitted into mutual recognition arrangements, which among other things, help to facilitate international trade. IAF, ILAC and the United Nations Industrial Development Organization (UNIDO), have joined together to assist developing countries to establish and strengthen accreditation and conformity assessment bodies so that those economies may also derive benefits from trade facilitation.

Not only does an accreditation system have benefits for improving trade flows, it also delivers many benefits internal to an economy. A robust system of accreditation and conformity assessment will support the improvement of the quality of products sold domestically to consumers, and can help regulators achieve their objectives. Increasingly, accredited conformity assessment can provide confidence in other non-trade arenas, such as the monitoring and measurement of progress towards the achievement of Sustainable Development Goals and their associated targets.

This publication seeks to provide a clear and comprehensive description of considerations for and the steps leading to the establishment of accreditation bodies in developing countries. It is an update of the 2003 UNIDO Publication, "Laboratory Accreditation in Developing Economies". The content has been re-focused on the establishment of accreditation bodies and reorganized into a Part 1 for policy decision-makers, and a Part 2 for those working to establish accreditation bodies. Two new sections have been added: one which describes how the implementation of accreditation systems may contribute to good governance and can help to achieve economic goals in developing countries; and, another which provides practical insight through case studies about actual accreditation body establishment.

This publication and the combined efforts that led to its development clearly indicate the increasing collaboration among international agencies to help developing countries overcome barriers to trade.

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Glossary of Abbreviations



AFRAC	African Accreditation Cooperation
APEC	Asia Pacific Economic Cooperation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
APMP	Asia Pacific Metrology Programme
ARAC	Arab Accreditation Cooperation
BIPM	International Bureau of Weights and Measures
EA	European co-operation for Accreditation
EAAB	East African Accreditation Board
EACAS	East African Community Accreditation System
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GATT	General Agreement on Tariffs and Trade
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
IEC	International Electro-technical Commission
IEC CB	International Electro-technical Commission Certification Body
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
ISO/CASCO	ISO Conformity Assessment Committee
ITC	International Trade Centre
MLA	Multilateral Recognition Arrangement
MoU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement
NQI	National Quality Infrastructure
OIML	International Organization of Legal Metrology
PAC	Pacific Accreditation Cooperation
QMS	Quality Management System
SADC	Southern African Development Community
SADCA	SADC Cooperation in Accreditation
SADCAS	Southern African Development Community Accreditation Service
SDO	Standards Development Organization
SPS	Sanitary, Phyto-Sanitary
TBT	Technical Barriers to Trade
UNIDO	United Nations Industrial Development Organization
WAITRO	World Association of Industrial and Technological Research Organizations
WTO	World Trade Organization

Executive Summary



Accreditation of Conformity Assessment Bodies is a third-party attestation to convey a formal recognition that a body is competent to carry out specific conformity assessment tasks. Conformity Assessment Bodies include, but are not limited to, calibration laboratories, medical laboratories, testing laboratories, inspection bodies, and bodies that certify management systems, products and persons. They provide for proficiency testing, produce reference materials or undertake verification and validation. The aim of this publication is to provide guidance to developing countries that are weighing the benefits of establishing accreditation bodies through a clear and structured presentation of policy and implementation considerations. It is presented in two Parts.

Part One provides policy decision-makers with an overview of what accreditation is, and how it may be applied to meet objectives such as increasing trade, addressing health and safety concerns, and improving the general overall quality of output in an economy. It discusses the need for accreditation and some overarching conditions that should exist within an economy for the successful launch of an accreditation system. It provides policy decision-makers with a framework to opt for establishing an accreditation body, or partnering with neighbouring economies to form a shared system. It touches on the benefits that an accreditation system can provide to good governance and how it works to bring an economy closer to those of its trading partners through participation in mutual recognition arrangements of accreditation.

The second aim of the document is presented in Part Two. It focuses on those who are tasked with establishing an accreditation body once the policy decision to proceed has been made. It provides those implementing the system with some background into the essential operational requirements for accreditation bodies such as organizational structure, human resource needs, management system requirements, assessment and surveillance processes, record requirements, and all the other requirements that are specified in ISO/IEC 17011¹. It offers a description of how accreditation bodies perform their work, which gives insight into why the organizational/structural requirements provide for an optimal workflow. Part Two also outlines practical building blocks to set-up an organization, such as the development of business and marketing plans. It outlines some of the resources that are available to assist those in developing countries with the task as well as some of the potential challenges that may be encountered. Case studies are provided in the final chapter to offer an illustration of the practical application of the guidance provided in this publication.

¹ Note that this Guide is based on ISO/IEC 17011:2004 (Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies). At the time of publication of this Guide, ISO/IEC 17011 is undergoing revision, and some of its requirements are likely to change. Users are advised to refer to the new version as soon as it is published.



Introduction

The world has become a global economy where trade is vital. While international trade has existed for centuries, it often consisted of lower valued commodities and products. Today all types of manufactured products or foods and beverages made in one economy are sold in another. Hence, the enhanced awareness and need for the safety and quality of traded products and services is required. Nowadays, most large manufacturers which once were fully integrated, such as those in the automotive sector, have moved from being self-reliant organizations to ones that focus on core activities and outsource a great deal to others. Activities such as the assembly of components and systems, and the manufacturing of parts such as wheels, jacks, exhausts, electronic devices and even dashboard assemblies are usually built by subcontractors, resulting in the need to ensure that outsourced products meet quality and performance standards. This increase in outsourcing has provided many developing countries with lower labour costs an opportunity to respond to, and enter these markets.

Export is critical to the growth of any economy, be it fresh fruit, flowers, minerals or manufactured goods. As a developing economy takes advantage of new global opportunities, even neighbouring countries can enjoy some benefits by supplying services to the exporting economy such as electricity, water and telecommunications. To support and facilitate this trade a system is needed whereby importers can have confidence that the imported goods and services meet performance and quality expectations that are established using standards. Conformity Assessment is the term applied to the activities used to provide confidence in the conformity of products and services to these standards. ISO/IEC 17000, "Conformity Assessment – Vocabulary and general principles", provides the definition of conformity assessment as the demonstration that specified requirements relating to a product, including process and services, system, person or body, are fulfilled.

To ensure that an accreditation and conformity assessment system is fair, efficient and cost-effective, it must not

create new trade barriers whereby importing countries add requirements for repeat testing or certification which has already been carried out by the exporter. A key to reducing technical barriers to international trade is the existence of internationally recognised systems for the accreditation of bodies that perform conformity assessment such as testing, inspection and certification. As such, the global network of bodies that accredit laboratories, inspection bodies and certification bodies, is working to maintain and extend a system to support the World Trade Organization (WTO) agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS). Accredited Conformity Assessment Bodies (CABs) that are internationally recognized are key to the successful implementation of these agreements.

Accreditation creates confidence in the work carried out by CABs located anywhere in the world. Accreditation comes from the Latin word 'accredo' which means 'give credit or acknowledgement'. In the past, in the absence of internationally recognised accredited facilities, tests and inspections carried out and certificates issued in the exporting country were often repeated by a recognised laboratory, inspection or certification body in the importing country. A failed test or unacceptable inspection report in the importing country could result in the rejection of an entire shipment of food or manufactured goods, which was very costly for the exporter, and had a negative market impact on the importer.

Although accreditation is often thought of as a means to enhance the flow of exports, it also has a significant domestic role within an economy. The demand for consumer protection is growing as global trade results in large increases in the number of products and services available in a domestic marketplace. Governments can also use accreditation to support their regulatory efforts in health, safety, environmental protection, fraud prevention or market fairness, and, therefore accreditation also serves as a risk management tool. In the past, regulators often performed their own inspections to determine if products



and services were in compliance with legal requirements; this took place with limited resources. Today, new approaches are being sought to reduce demands on government staff and resources, in order to lower costs. One such approach is for regulators to rely on accreditation bodies to provide assurance that services meet regulations, and on accredited bodies to test, inspect or certify that products and systems meet regulatory objectives. When regulators delegate compliance monitoring to accreditation bodies and accredited bodies, they can focus their own efforts on ensuring regulations reference the appropriate accreditation, testing, inspection and certification standards to mitigate risk.

Accreditation is an attestation of the competence and impartiality of laboratories, inspection and certification bodies that perform the conformity assessment work. Accreditation is an impartial and objective process carried out by third-parties; it thus offers the least duplicative, the most transparent, the most widely accepted and the least discriminatory route for the provision of credible and trustworthy conformity assessment results.

The international accreditation system is established worldwide by the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC). IAF oversees the accreditation of certification bodies and verification / validation bodies while ILAC oversees the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers. This system helps to make work carried out by accreditation bodies consistent across the globe, and maintains international standards from one accreditation body to the next. As a result, a product tested, inspected or certified once under the IAF and ILAC umbrella can be accepted everywhere with equal confidence.

It should however be noted that while conformity assessment results should be accepted in another country because of the application of equivalent competence

and standards, there is no guarantee that each and every regulator or organization in the world will accept a given report or certificate. UNIDO, the IAF, ILAC, its members and associates continue to work towards the broader recognition of accredited test and inspection reports and certificates around the world so that tests, inspections and certificates applicable to a product made in one economy can be accepted with confidence in any other economy. Through various initiatives and projects such as this publication, UNIDO is working to facilitate the participation of developing economies in this global system that will, in turn, facilitate the export of goods and services from their economies, while minimising risks.

This document addresses many questions for policy decision makers and for the implementation of accreditation in developing economies, including whether an economy should develop its own accreditation system, or access such services in cooperation with other economies. Although accreditation and conformity assessment do not have to be provided nationally, all countries should have access to these services, either through international or regional organizations, or through cooperative arrangements with neighbouring countries.

Whether the decision is made to establish a domestic accreditation system or to cooperatively use an existing one established elsewhere, the chosen system should address all requirements needed for international recognition. This document provides information regarding the necessary supportive infrastructure that must be in place for a successful system, about how the services of established bodies can be used during the formative process, and guidance on the establishment of a body that meets international standards and best practices.

Part I

Developing an Accreditation System **POLICY CONSIDERATIONS**



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► Chapter 1

Role of Accreditation



1.1 WHAT CAN ACCREDITATION DO FOR AN ECONOMY?

To understand what role accreditation plays, it is necessary to consider the drivers that create the demand for accreditation at the national, regional and international levels.

Every community needs certification, inspection, testing and measurement services to promote health and safety and the overall quality control of products, services, processes and systems. Governments have a particular responsibility with respect to health and safety, protection of the environment, issues of justice, fair-trade and the safe and efficient provision of services such as water and electricity. In addition, consumers, manufacturers, procurement officials, engineering firms, and so on, all have interests to see that products or services conform to standards, regulations, or specifications.

Regulatory authorities are increasingly being asked to recognise information generated in foreign jurisdictions about which the authority may have little information. Yet the use of accurate information to underpin regulatory and policy decisions is a necessity. Similarly, in industry, the quality of process inputs, and quality assurance to produce conforming products are important to the successful conclusion of commercial transactions. As industries become more global in nature, where components are sourced from a variety of manufacturers in any number of countries, the need for compatibility of standards and measurements from one country to another becomes absolutely essential. Conformity

assessment bodies can support all these functions and others such as the:

- » verification of conformity with standards and regulations;
- » enforcement of safety regulations;
- » safety of food and drinking water;
- » environmental protection;
- » oversight of health services;
- » control of commerce and trade;
- » conduct of forensic investigations;
- » assessment of risk and its management;
- » investigation of product or process failures;
- » measurement of greenhouse gas emissions;
- » resolution of complaints and disputes.

However, the competence of the CABs is paramount if the information provided to support policy, regulatory or commercial decisions is to be considered reliable. In fact, unreliable data or claims of conformity are more dangerous than the absence of data or claims. For the buyer or regulator that lacks the resources or knowledge to evaluate the competence of a CAB (whether domestic or foreign), accreditation provides a reliable mechanism to choose a CAB confidently and to trust its work.

1.2 WHAT IS ACCREDITATION?

Accreditation is defined by ISO/IEC 17011:2004 as a formal third-party attestation of a conformity assessment body, of its competence to conduct specific conformity assessment tasks. The earliest accreditation programmes were often applied to the purchases made by the armed forces or other large government procurement agencies. Some large private corporations also operated their own systems for approval of suppliers to test products prior to shipping.

All of these early programmes were what would today be called second-party schemes in that they were intended to serve only the immediate needs of the body making the evaluation. These organizations, such as military procurement agencies and other government authorities, established their own standards, usually without reference to any other body, and often ignored equivalent standards developed by national and international consensus standards-setting organizations. These second-party procurers were generally unconcerned about whether or not others used or recognised their systems. Some of these organizations maintained substantial bureaucracies to manage their particular systems, including employing the inspection staff needed to make the evaluations of external organizations.

The purpose of second-party schemes is to minimise testing and inspection after products have been delivered by the

supplier, 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, which affect suppliers and can generate conflict if suppliers are subjected to different demands from different customers. As such, recently, many of these second-party schemes have given increased recognition to standards developed by national and international standards developing organizations (SDOs) rather than relying on their own internal standards.

Accreditation, much as it is practiced today, was introduced in Australia in 1947 as part of a deliberate policy by the national government to foster industrial development and to upgrade the quality of manufactured goods. It followed a very successful programme launched by the Australian Defence procurement authorities during World War II to facilitate manufacturers' declarations (first-party declarations) of compliance of products with specifications. Their development of a single common set of criteria applicable to all laboratories was a forerunner of ISO/IEC 17025.

The concept of accreditation as a tool for trade facilitation was introduced during discussions within the General Agreement on Tariffs and Trade (GATT) in the 1970s. The domestic uses of

accreditation have increased as governments have moved to reduce bureaucracy and to contract out the delivery of many services, including testing and inspection in support of health and safety regulatory objectives.

Prior to the introduction of the current standards for accreditation and conformity assessment, the systems that were used to recognize CABs were apt to suffer from a lack of both rigour and impartiality. This is evident in cases where government authorities have simply designated, perhaps for reasons of ownership, specific CABs to provide services. Such designation can disadvantage other equally competent CABs that offer identical services. In some jurisdictions, only government-owned CABs are regarded as acceptable and are recognised without any evaluation of their competence. Such practices are unsatisfactory to international customers because no evidence of competence is available to provide confidence in the CAB's work. Ultimately, such practices do not help to increase an economy's exports.

There is recognition that simply using standards alone is insufficient in providing complete confidence about the conformity of products with market requirements. International markets are now using accreditation as a mechanism to enhance confidence in reports and certificates produced in foreign countries because accreditation oversees the correct application of standards. In many markets the customer, or

the user of conformity assessment services, often stipulates accreditation as a pre-requisite to ensure that the work done by the CAB is reliable. Cost-reducing governments and commercial organizations seeking to focus on their core activities have resulted in the outsourcing of work to conformity assessment bodies which, in turn, has also created the need for assurance in the reliability of those services.

The benefits of accreditation go beyond facilitating trade and improving the quality, health and safety of products for domestic consumers. Benefits also accrue directly to the organizations that are accredited. The decision to seek accreditation demonstrates the commitment by the CAB management to its competence and to implement internationally defined best practices in its operations. This creates a culture of discipline on the part of staff to maintain the standards and remain prepared for regular audits and assessments by a third party. Accreditation gives the CAB's owner confidence that the organization is operating with the expected competencies and can reduce exposure to liabilities. Meeting standards and regulations helps to reduce errors in production and, therefore, leads to more satisfied customers and less spending allocated to addressing complaints.

Figure 1 below lists the roles of accreditation identified by Frenz and Lambert², in their publication on the economics of accreditation.

1.3 ACCREDITATION: A CLOSER LOOK

By definition³ accreditation is *“a third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks”*. It is also described as *“a procedure by which an authoritative body, the accreditation body, gives formal recognition that a body (or person) is competent to carry out specific tasks”*.

Accreditation can be awarded to certification bodies, laboratories, inspection bodies, or other CABs which demonstrate to the satisfaction of the accreditation body that they have met a standard of competence to undertake the tasks for which they are seeking accreditation. Accreditation assesses the knowledge, skills, abilities, systems and equipment of CABs to undertake tasks such as particular test methods. The accreditation body publishes the accredited tasks as a scope of accreditation which entitles CABs to issue accredited certificates or accredited reports reflective of the scope.

Accreditation bodies build their operating policies and procedures to meet the requirements specified in the international standard ISO/IEC 17011: *“Conformity assessment - General requirements for accreditation bodies accrediting*

*conformity assessment bodies”*⁴. In addition to these requirements a number of documents issued by IAF and ILAC contain mandatory provisions for policies and procedures, as well as guidance for accreditation bodies to apply in the delivery of their accreditation services. The mandatory provisions must be implemented by accreditation bodies, as applicable, if those bodies are to obtain international recognition from IAF and/or ILAC.

Broadly speaking, ISO/IEC 17011 specifies requirements with respect to:

- » impartiality;
- » competence and experience of staff;
- » management system;
- » accreditation processes and assessment practices;
- » on-site assessment;
- » surveillance visits;
- » complaints and appeals;
- » contractual requirements between the accreditation body and its accredited bodies.

² The Economics of Accreditation by Marion Frenz and Ray Lambert, Birkbeck, University of London, completed in March 2013. Project funding by the UK Department for Business, Innovation and Skills and the Intellectual Property Office.

³ Definitions of many terms used in conformity assessment are provided in ISO/IEC 17000 and ISO 9000 and associated normative documents.

⁴ Note that this Guide is based on ISO/IEC 17011:2004. At the time of publication of this Guide, ISO/IEC 17011 is undergoing revision, and some of its requirements are likely to change. Users are advised to refer to the new version as soon as it is published.

ROLE 1	Accreditation improves the effective operation of markets because buyers and sellers can be more confident in the reliability and competence of their partners and in the goods and services provided.
ROLE 2	International trade is enabled through the assurance of quality and reliability while international mutual recognition of accredited testing and certification reduces potential barriers to trade. Through arrangements for mutual recognition of test reports and certificates of conformity across countries, accreditation facilitates international trade.
ROLE 3	Conformity-assessed services have impacts on public services, in particular health and welfare through applications in the health services or economic activities with health risks.
ROLE 4	Risk Management: Public health and safety are advanced by accredited services in areas as diverse as diagnostic imaging, pathology laboratories, forensic testing, water quality and the management of the risks from asbestos in buildings, the safety of electrical and other products and personal protective equipment.
ROLE 5	Gaining accreditation can also commercial benefit, in that it is often regarded as a marketing and reputational advantage.
ROLE 6	Efficiency in industry is promoted by accreditation which leads to the avoidance of costs, for example, of waste and re-work arising from non-conforming product or measurement.

Figure 1: Accreditation roles identified by Frenz and Lambert

Fundamental to these requirements is that accreditation services must be provided in a non-discriminatory manner. Any CAB that is able to demonstrate the required competence, and which conforms to the rules and procedures for accreditation, can be accredited. Accreditation is designed to be transparent so that all interested parties can be aware of the rules and processes underlying the system. All CABs are treated equally, irrespective of ownership, and it is on these grounds that accreditation provides an open and fair mechanism for users to select a CAB to undertake particular work or contracts. Accreditation authorities must be free from any political and commercial influence, even when government owned.

Accreditation cannot guarantee that every certificate, test report or other statement of conformity issued by CABs under accreditation is valid. However, accreditation reduces the risks of errors through the application of appropriate systems and their regular surveillance. Ongoing surveillance confirms that CABs remain independent, competent and meet international requirements. While accreditation bodies do not have legal powers of enforcement and cannot apply penalties such as fines or force the closure of a CAB, they can suspend, withdraw, or reduce the scope of accreditation when an accredited CAB persistently fails to meet the requirements of, or abide by, the rules for accreditation.

Accreditation does not mean that all CABs are equal in skill or in scientific capability. Each is judged competent to perform conformity assessment activities at specified levels of competence and within those limits, all are considered equal. For example, one calibration laboratory may be able to measure length with a measurement uncertainty of 0.5 μm for sizes up to 25 mm, while another may be limited to a measurement uncertainty of 1.5 μm for the same size range.

Within the defined scopes, the laboratories are equally able to produce equivalent test or calibration data. Users of laboratory services must understand their own needs for accuracy and the limits within which suppliers of such services can operate competently.

Similarly, two certification bodies accredited for certification of management systems may each be limited to apply different scopes. Within the same scopes, however, the certification bodies are equally able to supply reliable certificates. Again, the user of certification services must understand what is needed and the limits within which suppliers of such services can operate competently. Accreditation provides that assurance and sets the benchmark for competence, leaving market forces such as price and service levels to inject fair competition into the CAB's services.

The customer can be assured that the CAB has demonstrated that it has the resources and the people to complete the tasks described in its accredited scope professionally. It has demonstrated its impartiality and it has management systems in place to minimise errors and reduce the risk of fraudulent behaviour. While neither of these last two undesirable possibilities can be eliminated entirely, accreditation bodies go to considerable lengths to monitor the performance of their accredited CABs to ensure ongoing confidence in their operations and to encourage ever-increasing reliability and customer satisfaction. In addition, the accreditation requirements oblige accredited bodies to have robust systems in place to address customer complaints and effect continuous improvement. In the case of laboratories, they must participate in Proficiency Testing Schemes where available to ensure ongoing competency with respect to applied methods.

1.3.1 Accreditation of CABs

An organization can be accredited to deliver one or more types of conformity assessment services. Although different standards apply to each of the different types of conformity assessment services, all standards hold organizations to requirements for:

- » Impartiality and confidentiality;
- » Competence;
- » Resources;
- » Information provision;
- » Processes; and
- » Management system.

The most common conformity assessment bodies and their standards are given in Figure 2 below.

Regardless of the type of conformity assessment service, all CABs must adhere to similar requirements for impartiality, as

do must accreditation bodies. This gives confidence to users that the services provided by accredited CABs are consistent, objective, free from conflict of interest, and fair. CAB personnel, including internal or sub-contracted staff, individuals sitting on CAB committees, and any other person in a position that could influence the CAB's activities, must act impartially and not allow commercial, financial or other pressures to compromise their impartiality.

The list of standards used for accreditation changes from time to time as new standards are added or revisions are made. The complete and current list can be found by accessing the ISO/CASCO (ISO's Conformity Assessment Committee) section of ISO's website⁵. See also Annex 4, which provides a reference list of ISO/CASCO guides and standards by field of application. Interpretive documents for the application of most of these standards can be found in the publications sections of the IAF and ILAC websites⁶.

1.3.2 Accreditation, Certification, Inspection and Testing: What sets each apart?

Accreditation and certification are two terms that are regularly confused and, therefore, a description of the differences is useful at this juncture. The similarity between accreditation and certification is that both activities attest to an organization's conformity to a standard. While accreditation attests that a CAB is competent to perform specific conformity assessment activities, certification is an attestation related to products, processes, systems or persons. Certification involves, for example, the issue of a written assurance (certificate) or the affixing of marks of conformity following testing/inspection of products and/or auditing of an organization's management system, and verification that it conforms to specified requirements in a standard.

Certification is mostly a competitive commercial activity. Accreditation assures the integrity and competence of the services provided by CABs and some consider it to be close to a regulatory function. Accreditation bodies conform to ISO/IEC 17011 while certification bodies conform to the other technical standards. Organizations are never 'accredited' to ISO 9001 or ISO 14001; rather their management systems are 'certified'.

In this context, it is also important to understand the difference between accreditation to ISO/IEC 17025 and certification to ISO 9001, and not to confuse the two. The ISO 9000 family of standards addresses quality management system requirements and may be applied in any organization. ISO/IEC 17025 is applicable to laboratory accreditation and is concerned with both technical competence and quality management of testing and/or calibration laboratories only.

In addition to relevant quality management elements, ISO/IEC 17025 addresses technical elements including, for example, test method validation, uncertainty of measurement and use of reference materials. A joint statement issued by ISO, ILAC and IAF makes it clear and understood that a laboratory which has met ISO/IEC 17025 has a quality management system that is based on similar principles to those in ISO 9001⁷. A similar joint statement has been published for inspection bodies that meet all the requirements of ISO/IEC 17020⁸, as well as for medical laboratories meeting the requirements of ISO 15189⁹.

Just as there has been confusion between accreditation and certification, there has also been confusion and debate about the respective roles of laboratory testing and product certification. It is important to remember that laboratories are accredited to test and measure only; product certification bodies are accredited to evaluate products, including the interpretation of test laboratory results. Product certification therefore goes several steps beyond testing although testing is usually an integral part of certification. Certification bodies therefore must ensure that the service laboratories they use are competent.

Documents published on the ILAC website such as "*Securing testing, measurement or calibration services – The difference between accreditation and certification*", provide a more detailed explanation of the differences.

^{5/6} Website addresses are provided in Annex 3.

⁷ www.iso.org/iso/ilac_iaf_communique.pdf - Joint IAF-ILAC-ISO Communiqué on the Management Systems Requirements of ISO/IEC 17025:2005; January 2009.

⁸ http://www.iso.org/iso/2013_09_iaf-ilac-isocommunique-iso_iec_17020.pdf - Joint IAF-ILAC-ISO Communiqué on the Management System Requirements of ISO/IEC 17020:2012; September 2013.

⁹ Joint IAF-ILAC-ISO Communiqué on the Management System Requirements of ISO 15189; 2012 January 2015 <http://ilac.org/?download=70393>.

TESTING AND CALIBRATION LABORATORIES	Testing laboratories apply standard, non-standard or in-house developed test methods to determine specific characteristics of samples. Calibration laboratories ensure that measurement equipment used in testing laboratories is properly adjusted to give accurate measurement results within a specified uncertainty. Testing and calibration laboratories are accredited to ISO/IEC 17025.
MEDICAL TESTING LABORATORIES	Testing laboratories exist for pathological or other examination of materials derived from the human body. Testing is carried out for the purposes of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings. Medical laboratories are accredited to ISO 15189.
MANAGEMENT SYSTEMS CERTIFICATION BODIES	Bodies certify organizations for conformity of their management systems with various standards such as ISO 9001 for quality management, ISO 14001 for environmental management, ISO 22000 / 22003 for food management, and so on. Certification of a management system has in the past also been called “registration”, and certification bodies called “registrars”. Management Systems certification bodies are accredited to ISO/IEC 17021-1.
INSPECTION	Inspection bodies examine individual products, services, installations and processes using measurement and professional judgement to establish conformity with standards or specifications. Inspection bodies are accredited to ISO/IEC 17020.
PRODUCT, SERVICE AND PROCESS CERTIFICATION BODIES	These are certification bodies that grant licences for manufacturers to mark their products as conforming to particular standards or specifications. Decisions to grant such licences are made based on test and inspection reports on prototypes or selected examples of the product and other criteria. Product, service and process certification bodies are accredited to ISO/IEC 17065.
CERTIFICATION BODIES FOR PERSONS	These bodies certify persons as competent with respect to defined criteria or standards. An example is certified auditors who undertake ISO 9001 and ISO 14001 audits. Bodies that certify persons are accredited to ISO/IEC 17024.
VERIFICATION AND VALIDATION BODIES	An example of such are the bodies that verify and validate emissions of greenhouse gases. These bodies are accredited to ISO/IEC 14065.
PROFICIENCY TESTING PROVIDERS (PTP)	Providers of proficiency testing schemes are accredited to ISO/IEC 17043. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application.
REFERENCE MATERIAL PRODUCERS (RMP)	ISO 17034, establishes the requirements for the production of Reference Materials which can then be confidently used by testing laboratories.

Figure 2: Most common conformity assessment bodies and their standards

► Chapter 2

Considerations for Establishing an Accreditation Body



2.1 THE NEED

The decision to establish an accreditation system within an economy must be based on a clear need with specific measurable goals and supported by policy and other conditions. Needs can be varied and defined by several stakeholder groups. Regulators may seek assistance to meet health and safety objectives by ensuring that imported products are tested and certified to safety requirements, or that medical testing is of the highest possible standard. Consumers, be they individuals or industry or large government procurement agencies, wish to be assured that services they receive are of the highest standard, and that products perform as anticipated and are not unexpectedly hazardous. Government policy makers may have goals to grow employment in certain sectors through increasing exports, but must have the confidence of importing economies in the quality of the exported goods and services. There can also be needs that are purely domestic such as enhancing the reliability of results coming from medical testing laboratories,

environmental protection or other societal needs. Essentially the needs for establishing an accreditation system will differ from economy to economy based on a government's policy and the demands of the local economic sectors.

If the development of an accreditation system is being considered solely to serve the domestic market, it is nevertheless well advised to adopt international standards of operation. Otherwise, as experience has shown, accreditation systems that later transition to international requirements and expectations have difficulty because both the accreditation body and its accredited CABs often have to re-engineer many of their policies, procedures and systems to meet the international standards. It is far better to ensure that the overall structure and procedures of new bodies are internationally compatible from the start whether the focus is domestic, international or both.

2.2 FACTORS FOR SUCCESS

Once a need is defined, policy makers must consider whether the system should be established domestically or whether the economy can rely on the services of an outside body. There are several conditions that the policy decision-maker must consider if a domestic accreditation system is going to succeed.

First, there must be sufficient candidates for accreditation. A successful accreditation body requires a market; in other words there needs to be a demand from CABs to become accredited. Typically, many new accreditation bodies start by accrediting testing laboratories, as this type of CAB is the most active in most economies and forms the basis for many other conformity assessment activities. There must be a large enough pool of laboratories (whether public or private) to make operating the accreditation body feasible. Without a large enough network of laboratories in an economy, it will be unlikely that the accreditation body will have access to sufficient local technical expertise needed to assess the competence of those laboratories. The expertise should be local to keep operating costs down and there should be enough candidates and on-going accreditation work to maintain the effectiveness of accreditation body personnel and assessors. As accreditation bodies also typically recover some or all of their operating costs from the pool of accredited bodies, if there are too few of these, meeting cost recovery objectives will be difficult.

Second, the candidates must be ready for accreditation. If an accreditation body is to be successful, the pool of candidate CABs must also be capable of meeting the international requirements for accreditation. For example for an accreditation body accrediting laboratories, this means the laboratories have developed and implemented management systems which address the criteria in the ISO/IEC 17025 standard; those laboratories are participating in some form

of proficiency testing scheme or inter-laboratory comparisons for competency determination; their equipment is calibrated by competent calibration providers, and the standards used for calibration are traceable to the SI International System of Units (Système International d'Unités). Without first confirming a sufficient number of suitably prepared CABs, the accreditation body will not be able to grant accreditations and, therefore, the establishing effort could be seen as a failure.

Third, the accreditation body needs resources and a suitable infrastructure. There are two main resources needed for an accreditation body to function: people and money. Accreditation services are highly technical. For a body to assess the competence of an organization, it must have access to that same expertise at an equivalent if not a higher level. Accreditation bodies that accredit a wide range of bodies in different sectors cannot practically retain all the required technical expertise on hand as permanent staff assessors. Typically, therefore, they access the expertise on a short term contractual basis from organizations such as universities, research institutions, other laboratories, and industry. An economy should have the required technical expertise and infrastructure available for the accreditation body to access. While it is still possible for the accreditation system to operate if sufficient technical skills are not available locally, sourcing these skills externally will rapidly escalate operating costs. A local National Metrology Institute (NMI), for example (if available), may provide a source of accreditation assessors as well as providing metrology and technical advice.

Money is the other resource required. A policy maker considering the development of an accreditation system must think about the operating costs of the body and where the funding for those costs will be obtained. Personnel costs

are the first expense outlays that come to mind. Accreditation bodies can begin as relatively small organizations with a narrowly focused scope and few permanent staff. Operations do not require expensive or specialized office equipment and are typically simple average office type set-ups. Larger outlays of funds however will be incurred at start-up especially in areas such as training, marketing and communications to raise awareness of the accreditation system. A well thought-out marketing plan will be needed to reach the CABs that are the target for accreditation, as well as to make the industrial and government users of CAB services aware of the system and the benefits that accrue from its use. Budgets will have to be set aside to develop and implement the body's own management system and to train assessors on relevant standards and the application of accreditation procedures. Therefore, when making the decision to establish a system, some research into start-up costs to obtain a local estimate would be helpful. Accreditation services in neighbouring economies should provide useful insights for cost estimation. When estimating costs the policy decision-maker must give thought not to only these start-up cost considerations but also to the financial viability of the body in the longer term.

A fourth consideration is the legal status that the accreditation body will hold. To receive international recognition, it must be a legal entity. It can be an independent not-for-profit, a for-profit organization or it can be part of government. ISO/IEC 17011 considers a government based body to be a legal entity without the need for further legal registration. For the policy decision-maker, each type of body has advantages and disadvantages which must be weighed in the context of the local economy, and the overall policy objectives for the accreditation system. A general but not exhaustive list of the advantages and disadvantages of the different types of legal entity arrangements is shown in Figure 3 below¹⁰.

For-profit entities exhibit similar advantages and disadvantages as not-for-profit bodies, although they can suffer from a perception of being profit-focused rather than focused on the “public good” in an impartial manner. However,

all accreditation bodies, no matter what their legal status, must adhere to the same international requirements, ISO/IEC 17011 and associated IAF and ILAC Arrangement requirements. Therefore, criteria with respect to impartiality and conflict of interest must be managed in the same way regardless of whether an organization is for-profit, part of government or not-for-profit. Hence some of the above characteristics are perceptions and risks that must be managed, rather than realities.

In some countries accreditation bodies are companies “limited by guarantee,” having members instead of shareholders. The members represent those who have an interest in all aspects of accreditation, such as national and local government, business and industry, purchasers, users, consumers and quality managers.

Although the aim can be to make profit, most accreditation bodies are not-for-profit or non-profit distributing organizations and any profit made is funnelled back into the organization or used to lower fees. Accreditation bodies can be operated by government within a government Department or Ministry, or can be separated as a Statutory Authority. Experience shows that irrespective of the form of incorporation, a close relationship with government is important at the outset for broad acceptance and the perception of authority.

There is no single model that is 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. 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. Accreditation bodies have also sought to utilize the expertise available in the private sector and to reduce the burden on taxpayers.

A fifth consideration is the policy support that a government may provide to ensure the on-going robustness of the

	PROS (++)	CONS (--)
NOT-FOR PROFIT	<ul style="list-style-type: none"> Operational flexibility of private entity; Easier to comply with international requirements; Perception of greater impartiality due to absence of ministerial intervention; Quicker service to accredited and applicant bodies. 	<ul style="list-style-type: none"> Financial uncertainty; Less access to government expertise; Perception of weaker authority; Perception of commercial influence.
GOVERNMENT-BASED	<ul style="list-style-type: none"> Greater likelihood of financial stability; Perception of authority; Greater willingness to use the service from regulators; Easier access to government expertise. 	<ul style="list-style-type: none"> Bureaucratic; Slow response time to clients; Subject to Ministerial influence; More difficult to make organizational alterations of the government organization to meet international requirements.

Figure 3: Advantages and disadvantages of different types of legal entity arrangements

¹⁰ This list provides examples of considerations but each situation is different and depends on many factors.

accreditation system. This support can come in the form of a National Quality Policy and supporting technical regulations, which can promote or mandate the use of the accreditation system. Institutions such as national accreditation bodies and institutes of metrology that form part of a national quality infrastructure can rarely exist without a supporting national quality policy. Regulations to support or mandate the use of the services provided by these institutions will better assure the successful application of the quality infrastructure to achieve national goals. For the policy maker that is considering the development of an accreditation system, policy may be established that fosters accreditation in specific scopes¹¹. Scopes can be chosen to support industry or economic sectors that will benefit the economy in the form of exports, or where health and safety concerns exist. (At the very least governments should have policies to promote and use services provided by accredited bodies and to purchase products and services that have been tested, certified or inspected by accredited bodies to recognized standards).

Although some economies have more than one accreditation body, these are often specialized and work in specific sectors. As part of the national policy, when applicable, it is useful to provide a clear recognition of the role of the national accreditation body (or bodies) authorized to conduct accreditations in the regulated as well as non-regulatory sectors and to represent the country in international and regional accreditation organizations.

A sixth consideration is that an accreditation body must be independent in that it is impartial and free from conflict of interest. It has been common for developing countries to centralise some or all of what are referred to as “*standards related activities*” into a single organization. Activities such as standards writing, standards of measurement, legal metrology, accreditation and certification, and sometimes

testing laboratories, have often been located within the same body. For international recognition such arrangements are fraught with difficulties because where there are co-locations of these functions there is potential for conflict of interest. An obvious example of such a conflict is where there is common ownership of the accreditation body and testing laboratories or certification body or other types of CABs. For this reason, organizations such as 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.

Even standards writing can be in conflict with conformity assessment functions when other conformity assessment providers operate in competition with services offered by the standards writer. In developing economies, it is not uncommon for standards setting bodies to provide laboratory and certification services. While this is not disallowed under international requirements 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. The potential for conflict of interest in such cases must be very carefully managed and done so with transparency.

The international standard for accreditation allows flexibility in how a body may be structured. However, under the standard it must be structured so that it fosters and ensures certain principles of governance already mentioned including:

- » impartiality;
- » objectivity;
- » non-discriminatory policies and practices; and
- » avoidance of conflicts of interests.

How bodies are typically structured to incorporate these principles is discussed in greater detail in Chapter 5.

2.3 SUITABLE CONDITIONS NOT AVAILABLE? WHAT THEN?

If these conditions are not present or achievable in an economy, for example in smaller economies with few CABs available for accreditation, the best approach may be not to set up a national accreditation body. Instead, access to accreditation services may be obtained by engaging an accreditation body from a foreign country or through a regional cooperation to obtain the required services on mutually agreeable terms. As the number of accreditation bodies has increased in recent years, some are prepared to offer their services in foreign countries.

While this can be an effective option, some caution is required because in some trade agreements the government of the exporting country is required to stand behind the accreditation service. For example, such provisions are required under Mutual Recognition Agreements with the European Union. Contracting directly with a foreign body permits a government

to engage the foreign body to undertake national accreditation activities on behalf of the domestic government and maintain some authority over it through the terms of the contract. Another option may be the use of regional, multi-economy accreditation bodies where they exist, or their formation in cooperation with some other nearby economies. Such organizations service several economies in a geographic area and offer the possibility of a cost-effective solution to the inherent difficulties of many national accreditation bodies within a region with few CABs to be accredited. They are designed to consider the sovereignty issues of several national governments.

Examples of these regional bodies are relatively few, although some are currently being considered or developed; an example is described in the Chapter 3, *The International Dimension*.

¹¹ Accreditation is provided to CABs in the form of scopes, for example a testing laboratory may be accredited for a food testing scope which would include a number of microbiology and chemistry test methods, whereas a certification body may be accredited for a scope to certify electrical products to a series of electrical safety standards.

► Chapter 3

Good Governance, Trade Facilitation and Economic Impact through Accreditation



3.1 OBJECTIVE AND IMPARTIAL MECHANISM

The United Nations considers governance to be “good” to the degree to which a country’s institutions and processes are transparent, free of corruption and accountable to the people¹². Good governance promotes equity, stakeholder participation, pluralism, transparency, accountability and the rule of law, in a manner that is effective, efficient and enduring. Systems of good governance are meant to reduce corruption, risk and failure and provide the populace with benefits such as eradicating poverty, protecting the environment, ensuring gender equality, and providing employment and sustainable livelihoods.

Part of the practice of good governance is to seek these benefits for the citizenry through the growth obtained from increasing international trade by greater integration with the international community. However, developing economies that seek to access external markets require an internationally recognized quality infrastructure that functions to provide the buyers of products and services in the destination countries with some assurance of the quality of those goods. That infrastructure, a National Quality Infrastructure (NQI), is generally regarded to be comprised of the institutions and organizations, whether public or private, that implement the development of standards, the application of metrology (scientific, industrial and legal), and the provision of accreditation and conformity assessment services.

The establishment of an effective and efficient NQI contributes to good governance since it provides a supporting technical regulation framework that can promote the rule of law at the

institutional and private sector level; can help in the fight against corruption; simplify bureaucratic processes; and enhance macro-economic stability¹³. Governments may direct the NQI with policies to achieve objectives such as assisting its businesses to access foreign markets or enhance public health and safety.

The contemporary NQI contributes to good governance within an economy because the individual organizational or institutional components adhere to management principles and requirements contained in international standards, which are intended to foster fair competition based on the transparent application of recognised and accepted standards. As the principles of impartiality, fairness, objectivity, and so on, are implemented by an accreditation body, its endorsed conformity assessment bodies hold producers to standards in an objective and impartial manner designed to be free from bias and conflict of interest. Producers and service providers adhere to the relevant standards, rules, laws, regulations, policies and expectations that form a basis on which their performance is assessed under accreditation and conformity assessment processes. Under a robust National Quality Infrastructure, the principles contained in ISO and other international standards become translated into corporate governance codes that encourages integrity, openness and accountability and hence a reduction in corruption. A useful reference is the OIML document D1, “*Considerations for Law on Metrology*”.

3.2 ACHIEVING REGULATORY OBJECTIVES THROUGH ACCREDITATION

The institutions and organizations that operate an NQI typically do not carry legal powers nor are they regulatory bodies themselves. However, when supported by a framework of technical regulations the NQI can become a powerful tool to help implement government policy. Policy objectives may vary from environmental protection, to promotion of exports from a targeted sector, to public safety, and health protection by for example, improved testing and calibration results.

Technical regulations that refer to standards the application of those make standards mandatory. They are called technical regulations because of the scientific or mechanical requirements that most standards contain. Technical regulations can be used to protect the environment by for example setting limits on certain contaminants allowable in effluents to water, they can be used to protect health by specifying microbiological tests for food and beverages, and they can ensure safety by, for example, specifying the requirements of personal safety equipment. Under the World Trade Organization, Technical Barriers to Trade Agreement

(WTO-TBT Agreement) and Sanitary and Phyto-Sanitary Measures Agreement (SPS Agreement), technical regulations that are applied to protect the health and safety of people, plants, animals and the environment are generally allowed as long as they are not written in such a way that they constitute technical barriers to trade.

Technical regulations are developed by regulatory authorities and they may reference standards in fields as diverse as agriculture, telecommunications, mining and electrical products. The referenced standards are developed by national, regional or international standards bodies that have used a consensual and multi-stakeholder development process such as those described in the ISO/IEC Directives, *Rules for the structure and drafting of international standards*, or in ISO/IEC 17007 *Guidance for drafting normative documents suitable for use for conformity assessment*. Standards referenced by technical regulations which have been developed according to these processes can then be

¹² <http://www.un.org/en/globalissues/governance/>

¹³ Thoughts on a National Quality Policy, Martin Kellerman Physikalisches – Technische Bundesanstalt, Berlin, February 2011.

applied by the organizations and institutions of the NQI, thereby partnering with regulators to achieve their goals in a manner that is transparent, fair and objective to all participants in an economy, and which contributes to improved good governance.

Technical Regulations that are developed in this manner will therefore protect domestic consumers by confirming the safety of imported products while ensuring that they meet the same criteria as domestically produced products. Products being exported that meet the technical standard requirements of

other countries will also receive equal treatment. Exported products are therefore seen by the imported countries as meeting their requirements, the proof of which is provided by the internationally recognized test reports and certificates of the exporting country. Hence trade is facilitated and positive economic opportunities are realized by the exporting country.

Examples of the use of technical regulations to improve and support public health and safety around the world are numerous and growing. Some illustrations are provided in Figure 4 below.



Figure 4: Possible uses of technical regulations to improve and support public health and safety

▶ 3.3 TRADE FACILITATION

Manufacturers in countries with an internationally accepted accreditation system can have products destined for export tested and certified to the requirements of the importing countries. The effects of conforming to standards and procedures imply that there should be fewer border rejections of exported goods; fewer, if any, delays in the movement of goods caused by the duplicative application of conformity assessment procedures; and the costs for testing, inspection and certification are therefore reduced to the private sector. On a macro-scale this leads to greater economic opportunity for the exporting country, lower transaction costs and reduced time to access targeted export markets. Even if standards among WTO Members are not harmonized, trade

still demands that the products be tested to determine whether they conform to the importers' standards. Such testing usually happens in the country of export and further testing in the importing country is unnecessary if the system is in place for it to recognize the results¹⁰.

The impact of standards and technical regulations working together to influence and enhance trade can be clearly seen from the following table that is reproduced from the Donor Committee for Enterprise Development paper¹⁴. It shows that eight of the top traded classes of products in the world are subject to the application of standards and technical regulations (that specify the application of relevant standards).

¹⁴ Donor Committee for Enterprise Development: Leveraging the Impact of Business Environment Reform, The contribution of Quality Infrastructure, June 2014 / May 2015, and International World Trade Centre: www.trademap.org/openaccess.

RANK	COMMODITY	VALUE US \$ (000,000)	STDS	TRS
1	Mineral fuels, oils, distillation products	2,183,080	Y	Y
2	Electrical, Electronic Equipment	1,883,534	Y	Y
3	Machinery, Nuclear Reactors, Boilers	1,763,372	Y	Y
4	Vehicles other than railway, tramway	1,076,831	Y	Y
5	Plastics and articles thereof	470,227	Y	Y
6	Optical, photo, technical, medical etc. Apparatus	465,102	Y	Y
7	Pharmaceutical Products	443,597	Y	Y
8	Iron and Steel	379,113	Y	No
9	Organic Chemicals	377,462	Y	Y
10	Pearls, precious stones, metals, coins	348,155	No	No

Figure 5: The relevance of standards and technical regulations on the top 10 world traded commodities

Numerous existing trading blocks of nations such as the European Union depend on accredited conformity assessment to facilitate the movement of goods and services. The European Cooperation for Accreditation (EA), as the regional cooperation of accreditation bodies in Europe, is formally appointed as the body responsible for the European accreditation infrastructure in Regulation (EC) No 765/2008 of the European Parliament. Included in the legislation are requirements regarding the assessment of conformity assessment bodies applying for notification. A Notified Body, in the European Union, is a CAB that has been formally appointed by a national authority to assess whether a product, its design or its manufacture meet certain standards—usually those relating to specific European regulation or directives. Since 2008, the regulation has provided a legal framework for the provision of accreditation services across Europe in the regulated sectors. It places an obligation on EU Member States to accept results issued by the CABs accredited by any of the EA MLA signatories. EA also develops, harmonises and builds consistency in accreditation as a service to trade with countries outside the European Market, including those who wish to become EU Members. The aim is to reduce barriers to trade and to contribute to protecting health and safety¹⁵.

The recently-signed Trans-Pacific Partnership (TPP) is one of the most significant trade agreements in recent years. It was negotiated by 12 countries that included developed and developing economies, specifically: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. At the time the TPP was initially signed, the total gross domestic product (GDP) of the TPP parties is approximately \$27.7 trillion, comprising 40 percent of global GDP and one third of world trade¹⁶. The agreement includes references to the use of mechanisms involving standards and conformity assessment similar to those in use in Europe. To raise standards while improving market access outcomes, the TPP focuses on harmonizing standards and reducing the need for exporters to have their products tested twice - in the countries of export and import. This will be achieved by reaching agreement on equivalency of standards, mutual recognition of conformity assessment reports and designation of conformity assessment bodies¹⁷.

¹⁵ <http://www.european-accreditation.org/role>.

^{16,17} Standards and Regulations in the Trans-Pacific Partnership Agreement: Implications for India Dr. Joshua P. Meltzer; International Institute for Sustainable Development.

► Chapter 4

The International Dimension



4.1 REGIONAL AND INTERNATIONAL LINKS

Accreditation bodies that conform to international requirements can receive international recognition. This recognition means that an accreditation granted by a body in one economy is accepted by the accreditation bodies in other economies. For the accredited CAB this means the work that it performs is seen as impartial and competent, and therefore does not need to be repeated in another economy. At the international level, the fora where accreditation bodies obtain this recognition are IAF and ILAC. The global accreditation

community is further organized into regional accreditation groupings. The regions serve to deal with accreditation issues that are not of a global nature (such as regional regulatory programs) or they simply serve to bring accreditation bodies together in one part of the world for cooperation and exchange of expertise. The regional groups also perform the critical function of managing and conducting the peer evaluation process through which individual accreditation bodies obtain their international recognition.

4.2 IAF AND ILAC

IAF and ILAC originated in response to the need to eliminate the use of conformity assessment criteria as barriers to international trade. It was during the Tokyo Round of the Multilateral Trade Negotiations under the General Agreement on Tariffs and Trade (GATT) in the 1970s, that the subject of technical barriers to trade became part of the agenda for discussion and negotiation. For the first time, steps were taken to address the use of standards, technical regulations applicable to particular products, or the assessment of the conformity of products, as barriers to trade. Negotiations commenced on what became known as the GATT Standards Code. Signatories to the Code were encouraged to recognise foreign standards as being equivalent to their own and to accept tests performed in laboratories located in exporting countries. It was understood that authorities and other users of certificates or test reports could not be expected to accept certificates issued or tests undertaken in foreign countries without some evidence as to the competence of those organizations.

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 problem of laboratory testing being used as a trade barrier. IAF first met in 1993, also informally, as a group of accreditation bodies seeking to cooperate through the exchange of information and best practices. IAF and ILAC made rapid progress on agreeing to common standards and policies. The proposed solution to the trade barrier problem was to create a network of national accreditation bodies, all of which operate to the same

standards and use harmonised practices, linked by mutual recognition agreements. The vision included the development of a system that is to be non-discriminatory and transparent.

Both organizations are now made up of: accreditation bodies that have demonstrated conformance to the requirements and have signed agreements to mutually recognise each other's work; accreditation bodies that are working towards signing the agreements; and, other organizations and associations that have a significant interest in conformity assessment. Lists of these organizations classified according to various membership categories can be found on each of the IAF and ILAC websites.

IAF and ILAC publish many documents that are described and classified slightly differently by the two bodies, but essentially the documents serve the same functions. Generally, the documents:

- » Set out policies including governance requirements that accreditation body members are expected to follow;
- » Provide policies for the operation of the recognition agreements;
- » Provide guidance or mandatory requirements for application by accreditation bodies when accrediting conformity assessment bodies to assure that the accreditation bodies operate their programs in a consistent and equivalent manner;
- » Are jointly used by IAF and ILAC for the evaluation of regions and accreditation bodies which are not affiliated with a region.

4.3 REGIONAL ACCREDITATION ORGANIZATIONS

Accreditation bodies seeking recognition by IAF and/or ILAC should join a Regional Cooperation (where one exists). These are called Regional Accreditation Groups in IAF and Regional Cooperation Bodies in ILAC (hereinafter referred to simply as regions). They are not precluded from joining more than one region where two may overlap such as the Americas region and the Pacific region. The regions are responsible for the organization of peer evaluations of the member accreditation

bodies. These peer evaluations assess the bodies according to the requirements for mutual recognition in the regions as well as in IAF and ILAC. This forms the basis for confidence that all accreditation bodies, are indeed, operating to the international standard ISO/IEC 17011 for accreditation practices. Regions also act as a technical resource for their members and a focus for other regional interests on matters related to the implementation and operation policies on accreditation.

Regions can have particular roles to meet the demands of member states. For example, EA has been formally appointed as the body responsible for the European accreditation infrastructure in Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008. The regulation provides a legal framework for the provision of accreditation services across Europe and has strengthened EA's role in both voluntary and regulated sectors. The regulation places an obligation on EU Member States to accept results issued by the conformity assessment bodies accredited by any of the EA MLA signatories.

Like individual accreditation bodies, regions must meet requirements and be recognized by IAF and/or ILAC. Formal recognition of a region by the IAF and/or ILAC arrangements is based on an external evaluation of the region's competence in mutual recognition arrangement management, practice and procedures. This evaluation is conducted by a team of evaluators from other IAF and/or ILAC member Regions and Accreditation Bodies. Requirements for the recognition of regions are published by IAF and ILAC in the "A-Series" documents found in the publications sections on their website.

The regions generally work with bodies that accredit all types of CABs, with the exception of the Asia-Pacific region where, for historical reasons, bodies that accredit laboratories and inspection bodies apply to the Asia Pacific Laboratory Accreditation Cooperation while accreditation bodies of other types of CABs apply to the Pacific Accreditation Cooperation.

Regions that are recognised members of IAF and/or ILAC at the time of publication of this document are the following:

- » European cooperation for Accreditation (EA);
- » Asia Pacific Laboratory Accreditation Cooperation (APLAC);
- » Pacific Accreditation Cooperation (PAC); and
- » Inter-American Accreditation Cooperation (IAAC).

Other regions currently in development include:

- » African Accreditation Cooperation (AFRAC);
- » Arab Accreditation Cooperation (ARAC); and
- » Southern African Development Community Cooperation in Accreditation (SADCA).

Links to the websites of each of these regions are provided in Annex 3. On the websites the reader can delve into the history of each region, the membership, the stakeholders, the regulatory schemes, training available, and so on, applicable in each region.

It is important to remember that these regions are made up of accreditation bodies and therefore accreditation body members are expected in fact, required to contribute to the operation of the regions. Resources therefore must be committed to attend meetings and contribute personnel to advance the peer evaluation process. There are still some areas of the world that may not be covered by a region. In these cases, IAF and ILAC will directly evaluate the competence of single accreditation bodies.

► 4.4 MULTILATERAL RECOGNITION ARRANGEMENTS

The term Multilateral Recognition Arrangements (MLAs) in this context refers to mechanisms whereby a user or acceptance authority in one country can have sufficient confidence in the validity of test/inspection reports and certificates issued by CABs in foreign countries; and, to accept them without having to make individual re-evaluations of the competence of those CABs. Historically, the first decisions to establish these types of arrangements were in response to a domestic need to save time and resources on unnecessary duplication. Arrangements were entered into after assessing the risk and perhaps with some evaluation of the operations of the foreign body.

Following the adoption of the GATT Standards Code, the concept of recognition became more important to facilitate increasing trade flows and so a degree of greater scrutiny and more formality of the process to assess and recognize bodies became necessary. It was in 1980 that this more formal process of peer evaluation of accreditation bodies was developed and codified to support the first formal bilateral agreement between the accreditation bodies of Australia and New Zealand. Throughout the 1980s, accreditation bodies participated in bilateral MRAs and thus developed networks of bilateral arrangements.

The European Cooperation for Accreditation (EA) later pioneered the creation of a single multilateral arrangement across a region of many economies. The MLA also became

available to all other European accreditation bodies and each body was able to enter the arrangement following a satisfactory peer evaluation by a team drawn from other EA members.

EA then introduced the concept of contracts of cooperation between its EA MLA and individual bodies in other countries, generally to support trade between the EA member economies and the other country. These contracts gave only limited rights of participation in EA affairs to the other country but had the advantage of giving recognition of accreditation to both the EA members and the contract partner.

Before bilateral agreements were developed between the EA and the Pacific Accreditation Cooperation (PAC) and the Asia Pacific Laboratory Accreditation Cooperation (APLAC), it was decided that global agreements for recognition of certification and laboratory accreditation would be established and managed respectively by IAF and ILAC.

Through the course of the development of the agreements between accreditation organizations, the terms MRA and MLA have been used, sometimes interchangeably. The use of the term MLA, Multilateral Arrangement, has become the preferred expression because it better describes the fact that multiple economies are party to the agreement, and because it is felt that the term MRA is more often applicable to and distinguishes agreements that are government to government in nature.

Admission to an MLA

In order for an accreditation body to gain international recognition, it starts by making an application to join an MLA within a region recognized by IAF and/or ILAC. It may join MLAs for the different types of accreditation that it provides. Among other documentation, the application will include a copy of the body's management system documentation which must demonstrate that its policies and procedures meet the ISO/IEC 17011 standard and other applicable IAF and/or ILAC requirements.

A team will be formed by the region which is generally made up of members from other accreditation bodies that are already recognised members of the Regional MLA, hence the term 'peer evaluation'. The team size may vary depending on the amount of expertise that is required to assess the scope for which the accreditation body seeks recognition. The team will apply a process to review the application and, once complete, it will conduct on-site evaluations of the body's quality system implementation, and its records through staff interviews and file review. In addition, the team will witness accreditation activities that the body conducts in the field. Typically, an applicant can expect to receive corrective action requests from the team where the team notes that the body is not in conformance with the requirements for MLA admission. Depending on the nature of the nonconformities, the body

may have to revise its policies and procedures, implement new procedures, provide training to staff, or complete other actions to the satisfaction of the assessment team. If serious nonconformities are identified the team could require a follow-up visit to confirm implementation of corrective actions. Once the team is satisfied that the nonconformities have been satisfactorily addressed, it will recommend to the MLA Committee of the Region that the applicant be admitted to the MLA. The applicant body is invited to join the Regional MLA through a formal process of signing documents. It is at this point where the accreditation body's accreditation certificates are recognised across the region. This whole process generally takes about 2 years for applicants to become an MLA signatory.

Successful applicants to a Regional MLA can apply and be invited to become formal signatories to the IAF MLA and/or the ILAC MRA, as applicable, at upcoming meetings of the international organizations. It is upon becoming signatories at this level that the accreditations issued by the body become recognized by the signatories from economies in other regions around the world for the specified scopes. The body will undergo periodic re-evaluations every four years to maintain its international recognition. It may choose at later dates to expand its scope of recognition should it develop and implement new accreditation programs.

4.5 DEVELOPING ECONOMIES AND REGIONAL APPROACHES TO ACCREDITATION

While much progress has been made in the development of a harmonised global system, there will always be new issues to be addressed. In the early years, IAF and ILAC membership 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 developing countries increasingly sought participation in the work of IAF and ILAC, however, it became apparent that their experiences and particular problems also needed to be considered. IAF and ILAC are fully aware that the creation of the Arrangements was driven by the needs of the developed countries. Now both organizations actively promote the participation of personnel from developing countries in their various fora so that their specific problems can be better appreciated and addressed. IAF and ILAC have established a Joint Development Support Committee (JDSC) to address the needs of developing countries. The JDSC participates actively and develops input into the business plans of both bodies.

In spite of the challenging requirements for both accreditation bodies and CABs, many developing economies have committed themselves to the process and several developing economies have accreditation bodies that are signatories to the IAF and ILAC Arrangements. Others have operating accreditation bodies that are working towards recognition status. Up-to-date lists of these organizations and their contact information is available on both the IAF and ILAC websites. It was highlighted in the previous chapter that it may not be feasible for smaller developing economies to have their own national accreditation bodies and that it might be prudent to save resources and pool expertise with other countries in their region to build a regional accreditation body. Unlike the regions that were discussed

above, which bring accreditation bodies together, what is being proposed here is an accreditation body which meets all international requirements and accredits CABs across a number of economies. A good example of one such body is the Southern African Development Community Accreditation Service (SADCAS). It has been established to cater to the accreditation requirements of those Southern African Development Community (SADC) Member States, which have not set-up or fully developed their own national accreditation body. The SADC regional approach to accreditation is currently built around the existing accreditation bodies in SADC. SADCAS 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 will not only satisfy existing needs, but will also prepare an economy for the possible future establishment of its own infrastructure if and when there is sufficient demand.

Ultimately, CABs 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 regional body, will be linked through a mutual recognition arrangement. Bodies similar to SADCAS are being established for other developing regions including the East African Accreditation Board, the West African Accreditation System, and the Gulf Accreditation Council, for the Arabian Gulf States.

Part II

Developing an Accreditation System **POLICY CONSIDERATIONS**



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► Chapter 5

How to Do It



5.1 ESTABLISHING AN ACCREDITATION BODY

An accreditation body intending to seek international recognition for itself and its accredited CABs will be required to ensure that its structure, policies and operational procedures conform to the international standard ISO/IEC 17011 and other IAF and ILAC criteria. The following sections provide an explanation of the principles behind the criteria and their intent. It is meant to provide the reader with clarity and understanding of the rationale that formed the basis for the criteria and provide some ideas about how the criteria might be met in practice.

However, before discussing requirements that specifically address the operation of an accreditation body, it is important not to lose sight of the fact that the establishment of the body will require groundwork such as staffing, marketing, financing, a business plan including strategic goals, fixed assets and so on, like those expected for any organization. A sample list of building blocks and a schematic diagram outlining their implementation sequence are provided in Annex 1.

5.2 THE GROUNDWORK

An accreditation body has numerous stakeholders. They include the bodies that are to be accredited, the industries that will use the services of the accredited bodies, the governments that will introduce policies to promote the use of accredited services, and the consumers, be they institutional or individual, that will purchase products or services that have been tested, certified or inspected by the accredited CABs. Stakeholder numbers can increase dramatically as the accreditation body expands its services into different sectors. Therefore, the first step when establishing an accreditation body is to gather the representative interests together as a Steering Committee. Members of the Steering Committee should include a balance of the stakeholder groups that will be impacted in some way by the accreditation body, and whose acceptance and support will be key to the body's success.

The intelligence and input provided by the Steering Committee will contribute to the success of the venture by lending it relevance and legitimacy. Providing an understanding to the stakeholders of the role of the accreditation body and how it must operate in the context of the international community and the international standards will assist with the acceptance of the organization in the broader community.

This Steering Committee should be asked for guidance on elements such as:

- » priorities for testing, inspection and certification if they have not already been set through government policy;
- » how best to reach their member stakeholders, i.e., what messages will resonate and which media will be most effective, to encourage the use of accreditation services;
- » the design of names, logos and marks to be used by the body;

- » where to locate the required expertise;
- » business plans, initial strategies, marketing plans;
- » financial aspects such as fee structures for applicants and accredited bodies.

The Steering Committee's support should also be sought for:

- » the type of legal entity that will form the body's legal status;
- » initial input on accreditation body policy and over-arching operating procedures to ensure its impartiality; and
- » the role foreseen by government for the accreditation body.

The Steering Committee should be briefed and consulted throughout the establishment process to help ensure the body is ultimately owned as a national institution and not seen as an imposition by outsiders.

Steering Committee input is important for the creation of a strategic business plan. This should set out strategic priorities for the accreditation body, how it should market its service, and how to convince stakeholders of the relevance and importance of accreditation. It must also include basics such as forecasts of the body's financial needs, and its organizational structure. Budget estimates should include provisions for suitably competent staff, local operations such as assessments, initial and on-going training, and for participation in the regional or international accreditation community. Such early and realistic estimates of the financial resource requirements will provide a solid foundation for the accreditation body to approach potential funding agencies with confidence, to address its medium and longer-term needs.

5.3 STRUCTURAL CHARACTERISTICS

In order to build a relevant business plan and financial proposal one must take into account the characteristics unique to the operation of accreditation bodies that are contained in international standards and associated documents for accreditation. The standard for accreditation bodies allows

for flexibility in the way in which an accreditation body can be structurally organized; however, certain characteristics or principles are essential. These are explained in the following sections.

5.3.1 Organization

The body must be a legal entity. Legal entities are seen as official in the eyes of the law, they have the capacity to enter into enforceable contracts, they can be held responsible for their actions and sue or be sued in their own right. The type of legal entity can vary from a government owned organization to a private one. Examples and the pros and cons of each are discussed above in Part One.

What is common across all types of entities are the basic principles underlying how the organization is managed. There must be clarity regarding the roles of people and how they are to carry out their duties. ISO/IEC 17011 makes a point that accountability for specific functions such as finances, accreditation decisions and assuring responsibility for the organization's management system must be clearly assigned. Lines of responsibility and authority must be documented and understood, with top management being

accountable for the overall operation of the body. This principle of accountability is there to ensure that should something go wrong, responsibility can be determined, errors can be corrected and avoided in future.

Regardless of the breadth of accreditation services that the body offers, its organizational structure must be such that it supports those services by providing access to all the expertise that is needed. Personnel –whether full-time, part-time, contracted or provided by a sub-contractor, must be available and have the knowledge, skills and abilities to competently carry out the scope of the accreditation services that are offered. The competence extends across all organizational functions including administrative services, management, and technical positions. An organization that provides its services competently can be trusted and relied upon.

5.3.2 Impartiality

Accreditation bodies and their activities are required by ISO/IEC 17011 to be organized, managed and run in an impartial manner. This is to ensure that any entity that qualifies for accreditation may in fact be accredited and treated with fairness. An organization that can be trusted to operate in an unbiased and objective manner engenders confidence that its work can be relied upon across stakeholders in an economy.

To safeguard impartiality, the body must have a documented and implemented structure that provides opportunity for effective involvement by interested parties. The most common approach is to have a committee of balanced interests tasked with overseeing the body's operations for impartiality. Those who have an interest in the running of the accreditation programs include users, consumers and regulators. A balanced input from interested parties ensures that accreditation body management cannot wilfully or mistakenly prejudice an interest group that is being served by the accreditation body. It is important that the balance of interests is maintained and that committees tasked with impartiality oversight are not to be 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 a committee system to assist with impartiality management but it is the most common mechanism in use.

The committee's task is to see that the body is run in a fair and an impartial manner. Consequently, it will have functions to review major policies and operating procedures issued by

the body, review how the body has dealt with complaints, and ensure that the body effectively manages its actual and perceived conflicts of interest. The accreditation body must identify, analyse and document its relationships with related bodies to determine the potential for conflicts of interest, whether they arise from within the accreditation body or from the activities of the related bodies. Related bodies are those organizations or individuals with whom the accreditation body has entered into a contractual relationship. The committee may, for example, review the analysis of these relationships to ensure that conflicts have been properly identified and that any conflicts have been eliminated.

This committee typically does not have a technical function so it will need to be complemented by one or more technical advisory committees, with perhaps specialist working groups that may focus on particular areas of accreditation.

The principle of impartiality is carried through the chain from the accreditation body to the conformity assessment bodies which carry out the testing, certification, inspection, and so on, across the National Quality Infrastructure. The standards used to accredit those bodies include requirements for stakeholder input and conflict of interest management as well. In this way the same fairness, objectivity, confidence and trust that is found at the accreditation body level is passed down through the system so that regulators, industry and consumers can have faith in the work completed by those bodies.

5.3.3 Confidentiality

Another essential element for an accreditation body is confidentiality. ISO/IEC 17011 requires an accreditation body to understand the need for confidentiality regarding the information it collects in the course of conducting its assessments. Much of this information is commercially or personally sensitive and if released

could cause loss or injury to organizations and individuals. The accreditation body therefore must have adequate arrangements to safeguard the confidentiality of the information obtained in the process of its accreditation activities at all levels of the body, including its committees and external bodies or individuals

acting on its behalf such as staff, individual contractors and organizational subcontractors. The accreditation body must not disclose confidential information about a particular CAB outside the body without written consent of the CAB, except where the law requires such information to be disclosed regardless of consent.

Accreditation body staff must keep in mind two principles regarding confidentiality:

- » To gain access to the information it needs to conduct its activities, the accreditation body and its staff must provide confidence that the collected information will not be disclosed; and
- » All organizations and individuals have a right to expect that the information they provide will not be shared with third parties without their authorization, except under exceptional circumstances such as court orders or subpoenas.

5.4 HUMAN RESOURCES

Accreditation bodies need access to people with a wide variety of knowledge, skills and abilities. This includes not only the typical leadership and administrative skills needed to run an organization, but also extends to a wide range of technical competencies. These must include address not only the typical leadership and administrative skills needed to run an organization, but also extends to a wide range of technical competencies for the assessors and staff who are needed for the effective operation of accreditation programs. In addition, assessors need to be capable of understanding the fields

of operation of the bodies that are being assessed. For example, the assessment of a food and beverage testing laboratory will require the accreditation team to have knowledge of the relevant areas related to the testing methods in order to complete a competent evaluation of the capability of the testing laboratory. This class of assessor is referred to as a 'technical assessor' or a 'technical expert'. The more technically diverse the accreditation programme, the broader the range of technically knowledgeable people that will be needed to carry-out the assessments.

5.4.1. Accreditation body staff

The most common organizational model is to establish an administrative secretariat and management team staffed with qualified and competent people and have technical resource staff on contract. For small and newly emerging bodies, the secretariat and management team may also be part-time positions although experience suggests that full-time staff will usually make more rapid progress with the development of the organization.

It is not essential that the administrative staff be experts in a particular area. What is important is that they are able to understand advice from experts, appreciate the principles behind conformity assessment practices, and be able to blend the two into a consistent approach. Staff of accreditation bodies therefore need to be multidisciplinary in their approach and have sufficient education, training, technical knowledge, skills and experience necessary to manage the process and understand the principles involved in performing reliable assessments.

Accreditation body staff do not come "ready-made". Accreditation requires strong management, communication and analytical skills, as well as attributes such as open-

mindedness, all of which need to be supplemented by specialized training. Accreditation has been developing for over half a century and so considerable expertise is available globally. Some of the more mature accreditation bodies offer training for the staff of new accreditation bodies. Such training can include extended periods of attachment to the host body, attending formal courses and, more importantly, working alongside accreditation body personnel with some years of field experience. New and developing accreditation bodies are encouraged to seek out such opportunities for staff training through IAF, ILAC and the regions.

Assessment teams are required to have the collective knowledge and attributes necessary to make a reliable evaluation of the competence of the CAB under assessment. Accreditation body staff may provide the leadership in an assessment process or the accreditation body may be structured such that this responsibility rests with an external contracted assessor. At all times the team must have access to advice about the accreditation body's policies, a role normally taken by staff who may also monitor the assessment process.

5.4.2 Assessors

The core of the work of an accreditation body is the assessment of the competence of a CAB to perform audits, make evaluations and/or conduct accurate and reliable tests or calibrations. The accreditation body must have procedures for selecting, training and formally approving assessors and experts to be used for the assessment process. Each assessment team that

is put together by the accreditation body must have sufficient collective knowledge about the applicable standard(s), and/or other normative documents that are being applied by the specific CAB that is being assessed. If it is to produce reliable assessment results the team must understand and be knowledgeable in the management systems used by the

CAB, and the CAB's areas of operation. Through discussion, observation and analysis, the team must be able to form reliable opinions regarding the conformity of CABs with accreditation standards.

Occasionally an accreditation body will employ permanent staff with the technical expertise necessary to undertake the technical portion of the assessments. This is not the norm, however, because it is not usually financially practical for a body to retain in its permanent staff all the knowledge it needs to conduct a wide range of activities. It is more common for accreditation bodies to engage technical assessors or experts either on short-term contract or on a voluntary basis to undertake particular assessments. These experts are normally drawn from the staff of government, academic and technical institutions, or from commercial and industrial organizations. Another frequent source of experts may be recently retired technical people from the accreditation or related industries. Assessors can come from CABs which themselves are accredited and in a mature, well-developed accreditation system; this is common especially in laboratory accreditation where technical skills are not easy to obtain. In such cases, conflicts of interest and impartiality must be very carefully managed. For example, there cannot be any existing, former or possible links or competitive positions between contracted assessors or their organizations and the CAB being assessed.

Assessors are also expected to uphold specific principles and characteristics to maintain professionalism and ethical standards of behaviour. ISO/IEC17011 requires that the accreditation body ensures that assessors and experts:

- » are familiar with accreditation procedures, accreditation criteria and other relevant requirements;
- » have undergone relevant accreditation assessor training;
- » have a thorough knowledge of relevant assessment methods;
- » are able to communicate effectively, both in writing and orally, in the required languages;
- » have appropriate personal attributes (see ISO 19011: Personal Behaviour); and
- » disclose any existing, former or possible links with the CAB to be assessed.

While potential assessors can be identified by reputation

and position, their selection and utilisation depends on the possession of some additional skills and attributes. ISO 19011 *“Guidelines for auditing management systems”* provides guidance on the principles of auditing, managing audit programmes, conducting management system audits, as well as guidance on the competence of management system auditors. ISO 19011 is also applicable for accreditation assessments provided that special consideration is paid to identifying the competence needed by the assessment team members in each case.

Adherence to certain principles during an audit are prerequisites for reliable audit reporting. ISO 19011 lays out the six principles listed in Figure 6 below for assessors to apply in the course of their work.

In summary assessors must be:

- » astute listeners;
- » skilled at drawing-out information from the CAB staff about the organization's strengths and weaknesses;
- » good observers of the actual practices being applied; and
- » objective and fair-minded in their interpretation of the information provided.

These are sophisticated skills. Assessor training therefore is an important part of the establishment and maintenance of an accreditation body. Established accreditation bodies have well-developed training programmes for assessors that may be available to foreign accreditation bodies. Such participation could involve observing assessments in another country alongside very experienced teams. Experience suggests that this is most useful for emerging accreditation bodies. Formal assessor training courses and train-the-trainer courses are also available for presentation to developing accreditation bodies. Similarly, foreign assessors can be engaged by an accreditation body, at least initially, to work with prospective assessors in the newly emerging body. The global and regional accreditation organizations and UNIDO may be able to provide direction or assistance in this area.

Ultimately, the 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 on the professionalism of their judgements.

5.4.3 Assessment team

The teams of individuals that are assembled by the accreditation body to conduct the assessments or surveillance work are at the heart of an accreditation body's likely success. Team composition will vary from CAB to CAB depending on the management system and the technical aspects that are being assessed. ISO/IEC 17011 identifies three types of individuals that might participate as members of an assessment team. These are lead assessors, assessors and technical experts. Lead assessors are, by definition, in charge of the assessment and they typically are seasoned and experienced in the management system standard. Typically, assessors are those

who are trained but less experienced and are assigned to assist the lead assessor, usually when the size of the CAB creates a workload too great for the person. Technical experts need not necessarily be expert assessors of the accreditation standard because they focus instead on the technical standards and sector processes being applied by the CAB.

The route to become a lead assessor is not simple, and may take a number of years. Knowledge of the standards being applied is needed, skills managing and dealing effectively with people are essential, and project management capabilities

INTEGRITY	Trust, integrity, confidentiality and discretion are essential.
FAIR PRESENTATION	Findings, conclusions and reports reflect truthfully and accurately the assessment findings.
DUE PROFESSIONAL CARE	Assessors exercise care in accordance with the importance of the task they perform and the confidence placed in them by clients and other interested parties. Having the necessary competence is an important factor.
CONFIDENTIALITY	Assessors should use discretion and protect the use of information gathered in the assessment.
INDEPENDENCE	Assessors are independent of the activity being assessed and are free from bias and conflict of interest. Assessors maintain an objective state of mind throughout the assessment process to ensure that the audit findings and conclusions will be based only on evidence.
EVIDENCE-BASED APPROACH	Assessment evidence is verifiable. It is based on samples of the information available, since an assessment is conducted during a finite period of time and with finite resources. The appropriate use of sampling during an assessment is closely related to the confidence that can be placed in the conclusions.

Figure 6: Six ISO 19011 principles for assessors to apply in the course of their work

are required. One does not become a lead assessor without having honed one's knowledge, skills and abilities through the experience of assessing. ILAC publishes guidelines for the qualification and competence of assessors and technical experts on its website (currently document G11).

ISO/IEC 17011 requires the accreditation body to formally appoint the team consisting of a lead assessor and, where required a suitable number of assessors and/or experts for each specific scope. When selecting the assessment team,

the accreditation body shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a *whole* must have appropriate knowledge of the specific scope for which accreditation is sought, and an understanding sufficient to make a reliable assessment of the competence of the CAB to operate within its scope of accreditation. The sum of the knowledge, skills and abilities of all members of the team are what is needed to carry out the assessment.

5.4.4 Human resource monitoring

The performance of accreditation body staff must be monitored since competency is so central to the delivery of accreditation services. ISO/IEC 17011 requires that the accreditation body establishes procedures for monitoring the performance and competence of the personnel involved. The monitoring of assessors is typically accomplished by conducting periodic on-site observations, and by using other techniques such as the review of their written assessment reports and feedback from CABs. Recommendations for supplementary training may be put forward to improve and follow-up on performance if this has been deemed to be unsatisfactory. The standard

currently requires that each assessor be regularly observed on-site, at least every three years, unless there is sufficient supporting evidence that the assessor is continuing to perform competently. In addition to assessors all personnel involved in the delivery of the services must be monitored including decision-making since errors affecting the quality of service delivery can occur at the management or clerical levels as well. In addition to managing competency, monitoring has implications for annual budgeting and start-up costs in business planning because the travel and accommodation associated with on-site monitoring can be significant.

5.5 MANAGEMENT PROCEDURES

To ensure that all of the accreditation body's work is done *consistently* in a reliable and competent manner, the organization must operate a management system appropriate to the type, range and volume of work performed. Therefore, written policies and procedures must be current, cover all aspects of the organization's business and be clearly

understood by the responsible staff. They must be written to address and incorporate the applicable requirements of ISO/IEC 17011 and other requirements that the organization must meet including legal requirements and those issued by international or regional accreditation organizations such as IAF and ILAC.

The required policies and procedures are specified by ISO/IEC 17011¹⁸. There are numerous areas to document, including those listed in Figure 7 below.

The standard places considerable focus on internal audits and management review to ensure that the accreditation body is proactively attending to the effectiveness of its system across the scope of its accreditation services. Guidelines for conducting internal audits can be found in ISO 19011. Procedures for internal audits must be written to verify that the requirements of ISO/IEC 17011 are addressed by the management system, and that the system is implemented and maintained. Internal audits should be performed according to

a defined schedule.

In the interest of transparency and communication, the accreditation body is required to make information available to organizations about its accreditation procedures, policies, fees, complaints and appeals processes and so on. An understanding that comes from clear communications promotes trust among all those who deal with the accreditation body. Applicants know what to expect from the assessment process, and what is required on their part. Therefore, there should be no surprises, so that confidence in the relationship with the accreditation body can be generated.

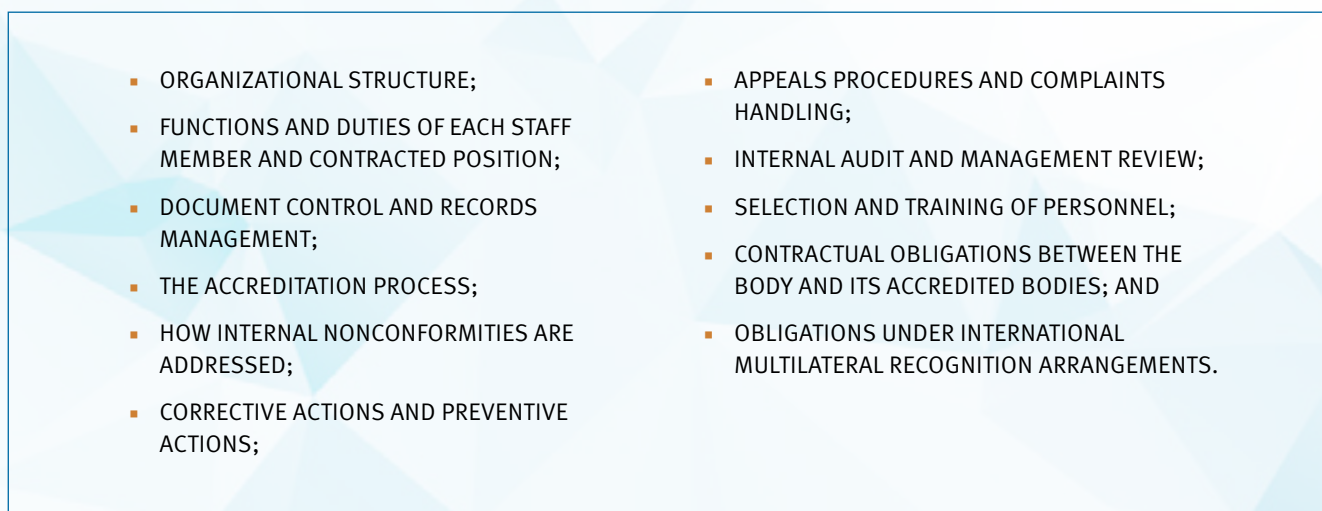


Figure 7: Possible areas to document in any industry

► 5.6 ASSESSMENT OF A CAB

5.6.1. Purpose

An accreditation body conducts an assessment of a CAB to come to a professional conclusion as to whether or not the CAB has competent staff, conforms to the relevant standard, and that the CAB's management system can be expected to produce consistent and reliable results. The assessment will ensure that what is being done by the CAB is reflected by the CAB's procedures and that those carrying out the work have an appropriate understanding of the policies and procedures.

The assessment, like all accreditation body work, must be objective. It results in a snapshot of how the CAB is operating at a point in time with respect to the requirements. This "picture" must not be influenced by the actions of the accreditation body because then it would not be a true reflection of the CAB's competencies. Consequently, there are strong obligations on accreditation bodies not to interfere in the CAB's operations

and specifically to refrain from providing consulting services to CABs. Consulting removes the impartiality from the accreditation body's work. It could result in the accreditation body assessing its own advice, and there would be uncertainty as to whether the CAB was truly competent to carry out its duties. If a problem were to occur in the course of the CAB's work as a result of consulting, the accreditation body could be found legally liable. That said, the assessment process can be very instructive to the CAB when the assessment team is allowed to identify opportunities for improvement that will lead to enhancements in the performance of the CAB. There is often a legitimate transfer of knowledge from the assessment team to the CAB staff. Training provided to accreditation assessors must address the fine line between providing consulting advice and citing opportunities for improvement.

¹⁸ Note that these requirements may change in the new version of ISO/IEC 17011 (still under development at the time of publication of this Guide).

5.6.2 Preparation and application

Prior to making an application for accreditation, a CAB is well-advised to make contact with the accreditation body to ensure that it fully understands the processes involved and the requirements that it must meet. The accreditation body, for its part, must review its own ability to carry out the assessment of the applicant, in terms of policies, its competence and the availability of suitable assessors and experts. The accreditation body must also do this in a timely manner. This review ensures the quality and competency of its services. If it is unable to meet the standard of delivery, it must communicate to the applicant the reasons for such and suggest alternatives.

Again, in the interest of fairness, trust and confidence that comes from clear communications, accreditation bodies are required to make efforts to ensure that the requirements are fully understood by applicants and that any ambiguities and doubts are resolved well in advance of the assessment process. So for example, questions regarding fees and other charges should be addressed along with the contractual obligations and expectations that will come following accreditation such as the program of future surveillance audits and the use of accreditation body logos by the accredited organization.

In most accreditation systems, the accreditation body staff will have the first contact with the applicant and throughout the process they will make the logistical arrangements and provide other administrative technical support to ensure the process runs smoothly. Applications for accreditation are typically received and reviewed by staff to ensure basic requirements for processing are met, and that the accreditation body is able to process it without unreasonable delay. The standard actually specifies that a formal application must be made and it lists the types of information that must be submitted by the CAB. The application form itself is usually designed so that it forms the basis for the contractual agreement that the body and the CAB will later conclude.

As part of the application submission the CAB will be required to provide a copy of its management system policies and procedures and related documentation. This submission should demonstrate that its system addresses the requirements of the standard to which it is being accredited, as well as any other applicable requirements such as those issued by IAF and/or ILAC. It is the job of the team to review and assess the documentation to ensure it does not contain any gaps with respect to the requirements. This work is typically conducted by the team leader; however, the leader may assign some portion of the work to other team members if deemed appropriate. This document review is conducted prior to any site visit to be sure that the visit will be fruitful. If the document review identifies gaps in the requirements, corrective action requests are issued to the CAB for it to bring its system in line up to par with accreditation criteria. These requests should be completed to the satisfaction of the team prior to travelling to the site. Arriving at an applicant's site where a quality system is incomplete will mean that there may be a lack of records to verify effective implementation. Hence it could be a waste of time and money for all concerned. Inadequate documentation might justify the postponement of the on-site assessment.

In such a case, a preliminary visit may be advised to review significant deficiencies or to clarify confusion about the process.

In consideration of these duties, it is clear that an assessment team must be assembled with the right set of competencies, and be the right size to complete the assessment in the planned time. A small CAB or one performing a narrow range of work may be assessed by a single assessor although a team of at least two will add more flexibility and help with objectivity while on-site. Large CABs or CABs with a broad scope of accreditation will require larger teams with expertise sufficient to match the range of work being undertaken.

Even experienced assessors will need time to prepare for the assessment. A formal briefing will normally be prepared by the accreditation body staff for team members to ensure that the team is fully conversant with the CAB's system and its business, including any applied test methods or standards. Given that some contracted assessors and experts may not work frequently with the accreditation body, it is in everyone's interest to ensure that all team members are also up-to-date about current accreditation body practices.

It is clear that, in all likelihood, it will not all CAB activities or files to be scrutinized by the team in the allotted time, especially where the scope of the CAB covers a variety of standards or test methods. It is a well-accepted norm that an assessment or surveillance audit of a CAB is based on "sampling." Therefore, assessments must be planned to ensure that adequate sampling is conducted of records, of personnel and of activities to obtain sufficient evidence of conformity. The concept of sufficient sampling can be complex and is best left for discussion in assessor training courses. Typically, accreditation body staff will discuss the sampling plan needed for an effective assessment with the lead assessor before drafting the assessment plan that is then provided to the applicant. This discussion will ensure that the correct expertise, the right numbers of people and the proper amount of time are assigned to complete the work.

If the CAB operates out of numerous sites, the plan will likely involve a sampling of those sites. Such sampling however is directed by ISO/IEC 17011 in that it defines certain key activities that when conducted at a location makes that location subject to mandatory assessment. Key activities are those that, if not performed correctly, pose the greatest risk to the outcome of the conformity assessment process. Key activities are defined in ISO/IEC 17011 and further elaborated in IAF / ILAC interpretive documentation. Key activities vary depending on the type of CAB being assessed, but, in general, they include:

- » policy formulation;
- » process and/or procedure development and, as appropriate;
- » contract review;
- » planning conformity assessments;
- » review; and
- » approval and decision regarding the results of conformity assessments.

The assessment team normally starts the assessment of the CAB's main office and then moves to those in which one or more key activities are performed.

Well-prepared assessment teams will facilitate an efficient on-site visit. The more prepared the team is in terms of its familiarity with the CAB, the more time can be spent on site to probe and collect evidence to support conformity. Figure 8 below includes some basic information typically provided by the CAB to a assessment team for preparation.

Equipped with this information, the assessment team can arrive at the on-site visit with a clear impression of the CAB and knowledge as to where issues with conformance are likely to be found. These areas can then be discussed and probed in interviews with the staff and through file and record reviews. On-site, the team will focus on the performance of the work, familiarity of the staff with the work and work instructions, and the documented records resulting from the work.

If possible, the assessment team should convene in advance of the visit for a planning and exchange session on the task ahead. They will discuss the adequacy (or lack thereof) of the overall system documentation and how they will address outstanding issues that have been identified during the preparatory work. 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 entail additional briefing on the requirements of the accreditation body such as policy, and on the manner in which the proceedings will be conducted' while on-site.

The assessment team should witness some audits, testing or examination in progress. In many cases it will have advised the laboratory, certification or inspection body which audits, tests or examinations it would like to see in progress. Where

the witness of field testing is to be included, good planning is necessary to ensure that it is done without interference or interruption of the normal processes of the CAB or the CAB's client. The assessment team may also observe routine operations as they occur. The team would expect to see audits, tests and examinations being undertaken by those persons who normally perform those tasks. In management system certification, the assessment team will accompany the certification body's auditor for at least one entire audit and take note or examine documents or other items along with the certification auditor. Witnessing is a very important part of assessment and surveillance because it provides the accreditation body with a true picture of how the applicant's system and its people come together to deliver the task. There are extensive requirements issued by IAF as to when and under which circumstances witnessing is to be done. It becomes an important part of the assessment and surveillance planning process and requires collaboration between the accreditation body, the applicant and the applicant's client to choose and organize mutually acceptable activities to witness.

All of this planning however must also include consideration of the applicant because accreditation is a collaborative process. The accreditation body has responsibilities to the accredited bodies to ease the process in terms of providing both information and reasonable accommodation. This includes giving the CAB adequate notice of activities, explaining the necessity for each activity and scheduling to ensure that senior and supervisory staff can be present during relevant parts of the assessment. If the team is to witness CAB activities such as audits or laboratory tests, the CAB should be given adequate notice and the time needed to arrange for those activities. It is also a required accreditation practice to allow the CAB to object to particular individual(s) on the team. Objections are usually limited to areas where the CAB believes it will be subjected to unfair treatment due to past relationships or where there may be confidentiality issues due to the presence of members of competitor staff on the assessment team.

- BACKGROUNDS ON THE COMPETENCIES, QUALIFICATIONS AND EXPERIENCE OF THE KEY PERSONNEL;
- AN ORGANIZATIONAL CHART;
- A COMPREHENSIVE STATEMENT OF THE SCOPE FOR WHICH ACCREDITATION IS SOUGHT;
- INFORMATION ABOUT THE CAB'S PHYSICAL FACILITIES AND ITS EQUIPMENT;
- WHERE APPLICABLE, INFORMATION ABOUT UPCOMING CAB ACTIVITIES IF A WITNESS OF ACTIVITIES IS TO BE INCLUDED AND SELECTED;
- MANAGEMENT SYSTEM DOCUMENTATION AND A SUMMARY OF ITS CONFORMANCE;
- WHERE APPLICABLE ANY INFORMATION ON PERFORMANCE IN PROFICIENCY TESTING ACTIVITIES;
- GENERAL INFORMATION ON THE ORGANIZATION SUCH AS ANNUAL REPORTS AND WEBSITES.

Figure 8: Basic information typically provided by the CAB to a team for preparation

5.6.3 The on-site assessment

The on-site visit is where the accreditation body collects the objective evidence that the policies and procedures reviewed by the team during the quality system analysis are actually implemented and working as they should in practice. This is a critical part of assessment and it must be carried out in an efficient, rigorous, positive and constructive manner within the agreed time constraints. Results must be compiled and reported by the team both to the CAB and to the accreditation body decision-makers with timeliness, clarity and objectivity.

The team typically commences the on-site assessment with an opening meeting, generally with all CAB staff that work in the areas that are being audited. It is meant to provide them with information about the process and to set them at ease. If the process is not carried out in a collaborative manner, the team may find it difficult to collect the information it needs to arrive at a valid conclusion. The opening meeting will set the tone for the remainder of the visit, so it is important that it be cordial and diplomatic, but at the same time business-

like. It provides the assessment team with the opportunity to ensure that all arrangements are in place for activities that the assessment team had planned to observe. It is at this opening meeting that the team should clarify the scope of the assessment and address any concerns that the CAB may have about the assessment process. ISO 19011 provides guidance on the types of issues that should be dealt with at the opening meeting and in what manner they should be addressed.

Accreditation assessments should be flexible in terms of how the team organizes itself on site to complete the plan as efficiently as possible. At large or diverse CABs, the assessment team may break-up with different individuals focusing on particular areas, while in smaller ones or in those with limited scopes the team may work together throughout the visit. The way in which the assessment plan is completed is at the discretion of the assessors.

5.6.4 Approaches to assessment

Although the subject of how to complete an assessment is the subject of lengthy training courses and is perfected with years of practice, it is useful at this point to describe several approaches that can be adopted in the work of an assessor.

There are checklist approaches to assessment and process approaches. The more historical and now less favoured checklist approach is one whereby, through interviews and record reviews, the assessor seeks evidence to demonstrate that each individual criteria of the requirements are met. In the process approach, the assessor may, for example, pick an accreditation file and follow the steps taken to process the records found in the file to confirm that all the requirements in

the process were addressed. The process approach is favoured because it gives the assessor a picture of how the system functions as a whole to produce the result.

In applying the process approach, one can review files “vertically” or “horizontally”. Vertical assessments examine many elements of a process sequentially through one file at a time. It is a detailed check that all criteria associated with a chosen process have been implemented. In any assessment or surveillance, a number of files that have recently been processed by the CAB are randomly selected and subjected to this review.


REQUIREMENT	RECORDED FILES			
1. Content of the certificate	1	2	3	...
2. Certification Process				
3. Certification decision				
4. Evaluation process records				
5. Competence of the examiners				
6. Process for monitoring				
7. Procedure for confidentiality				
8. ...				

Figure 9: Vertical assessment option in applying the process approach

The horizontal assessment examines one element in a process or one requirement of a standard in several files at a time. It is a detailed check of a particular aspect of the documentation and implementation of the management system or examination processes. The items for assessment can be formulated

as questions, for example: “Are the requirements for the competence of examiners met in all records of different cases?” Such a method might be used where a weakness in the CABs process has been detected and the assessor wishes to confirm if the problem is recurrent.



REQUIREMENT	RECORDED FILES			
1. Content of the certificate	1	2	3	...
2. Certification Process				
3. Certification decision				
4. Evaluation process records				
5. Competence of the examiners				
6. Process for monitoring				
7. Procedure for confidentiality				
8. ...				

Figure 10: Vertical assessment option in applying the process approach

It is useful to assess the CABs’ operations by following typical processes such as from the time the application for certification and order is received or a sample enters the laboratory to completion of the CAB’s process. An assessor can begin work by randomly selecting a specimen container, a computer record, a worksheet, or a printed report. The principle is that all the activities that contributed to the final result are assessed for conformity with the applicable standard.

Assessors also use techniques where a record system is checked in reverse chronological order by selecting, for

example, a report that has already been issued and tracing back, instead of forward, through the system, including workbooks or record sheets, to the original purchase order or contract. This can include a contract review or examining the order from the client, if applicable logging receipt of samples, allocation of work, internal quality control, recording of data, reporting of results and, if applicable, the sample storage or destruction and archiving of records. These and other techniques are taught in various assessor training courses offered by international experts and training organizations.

5.6.5. Interviews

In addition to records, people are the other main source of information. The assessment team will benefit from having had the opportunity to familiarise themselves with organizational charts and reporting relationships and the documentation associated with staff training and qualification. It is important to verify that the documented structures and written job responsibilities are those that are actually in place. Assessment of human resources capabilities can only be validated through interviews where assessors discuss a job description with the individual and essentially have a conversation about how the individual gets the work done. A sense of the individual’s competency rapidly takes shape in the mind of the assessor through interviews.

The CAB must have processes to ensure that personnel have appropriate knowledge relevant to the type of work they conduct. While education and formal training courses are readily documented, skill levels are often hard to define, particularly with work that may require manual dexterity or optical perception or discrimination. Valuable evidence of conformity will come from interviews with the staff or witnessing of them in the course of performing the job.

Assessors will look for evidence that staff have knowledge of the tasks that are carried out by the CAB, for example of the science and technology underlying the work or of the equipment in use. They should understand what factors can lead to erroneous results and be able to make rational decisions as to likely causes of problems.

5.6.6 Closing and reporting

At the end of the on-site assessment and before the team leaves the premises, a closing meeting takes place between the assessment team and the CAB. The lead assessor will present a summary of the assessment results as well as answer questions raised by the CAB staff. At this meeting, the assessment team provides a written and/or oral report on its findings obtained from the activity in a manner that can be understood by the staff. Occasionally disagreements may arise between the team and CAB. Typically, this involves diverging interpretations regarding a non-conformity. Any unresolved diverging opinions will be discussed, and if not resolved, it will be agreed that the concerns will be forwarded to accreditation body staff for resolution. Such issues must be handled by accreditation body staff because it is important that

interpretations and application of accreditation requirements are applied consistently across all CABs. It is also important in the cases of disagreements that the accreditation body ensure its team members have the correct interpretation of the criteria. For these types of reasons, the assessment team must defer to accreditation body staff when it comes to questions of accreditation policy application.

Following the visit, the assessment team will prepare a written report for submission and distribution as required. ISO 19011 contains guidance on running a closing meeting and suggestions regarding the contents of the report. ISO/IEC 17011 contains requirements for reporting procedures.

5.7 ACCREDITATION DECISIONS

The accreditation body must be organised in such a way that its decision-making process is independent of the assessment team, to ensure impartiality and the assurance of valid conclusions. The accreditation body must ensure that each decision on accreditation is taken by a competent person(s) or committee(s) different from those who carried out the assessment. This removes any potential bias and generally prevents errors by having a “second set of eyes” review the results from the assessment.

There are a variety of approaches used by accreditation bodies to arrive at final decisions about the granting, maintaining, extending, suspending or withdrawing accreditation. The standard does not specify any particular mechanism but it

does provide a list of the information that must be provided to the decision maker(s). The decision process may involve an independent member of staff, or staff committees, or the decision may be taken through a committee of individuals independent of the management of the accreditation body. Some bodies defer 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 mechanism is selected, the process must be transparent, competent and impartial, and the CAB must be offered the opportunity to appeal any decision it believes is adverse.

5.8 REASSESSMENT AND SURVEILLANCE

Of course, accreditation is not a one-time activity. It is on-going and therefore requires on-going surveillance activities in the form of audits and reassessments to ensure that the accredited CABs maintain their competencies, and that their management systems remain in conformity with all accreditation requirements. The accreditation body must establish procedures and individual plans tailored to each CAB for carrying out periodic surveillance. The standard requires that the surveillance activities and reassessments be performed at sufficiently close intervals, and that representative samples of the scope of accreditation are assessed on a regular basis. Here, as well, the standard provides some degree of flexibility so that the accreditation body can tailor its activities to the maturity of each accredited organization. ISO/IEC 17011 provides options for formal surveillance activities which allows some flexibility to accreditation bodies to manage and design

their programs.

Reassessment is similar to an initial assessment, except that experience gained during previous assessments is taken into account. Surveillance on-site audits are less comprehensive than reassessments and may focus in depth on specific areas that were identified as weak in the past. Accreditation bodies may choose to rely on reassessment alone to assess on-going conformity, in which case the ISO/IEC 17011 standard requires that it take place at intervals not exceeding two years¹⁹. If the body wishes to establish a program that combines reassessment with surveillance audits, the standard requires that a reassessment must be done at least every five years. Full details are in the standard but it is important to remember that:

- » whatever reassessment and surveillance practices (including permissible deviations) are decided upon by an

¹⁹ Note that this requirement may change in the new version of ISO/IEC 17011 (still under development at the time of publication of this Guide).

accreditation body it must be disseminated in a policy to all CABs and applied consistently; and

- » on-site surveillance activities can be and should be supplemented by other types of activities such as:

reviewing a CAB's publications and websites, and reviewing complaints against the CAB. Such activities can support surveillance by providing important information regarding the CAB's adherence to its stated policies.

► 5.9 PROFICIENCY TESTING AND TRACEABILITY

There are some key areas applicable to bodies that conduct testing - that is laboratories and some inspection bodies - which can be especially demanding for organizations in developing economies. These, therefore, deserve mention here. One of these areas is proficiency testing (PT); the other is calibration and traceability. A discussion of the special challenges presented to bodies in developing economies (in these and other areas) is provided in section 7.3 of this Guide.

The standards used to accredit laboratories contain requirements that accredited bodies must meet in regards to PT, calibration and traceability. ILAC issues policies on these topics by which its recognised accreditation bodies and the CABs they accredit must abide. Extensive information on calibration, traceability and measurement can be found on the BIPM website.

► 5.10 ACCREDITATION RECORDS

Records are of utmost importance and must be retained by the accreditation body to demonstrate, whether to a peer evaluator or a regulator, that adequate evidence of conformity was collected to validate the accreditation and that any non-conformity was properly addressed. Typically, bodies will maintain records as required by regulatory obligations in their jurisdiction. At a minimum, detailed records are kept from reassessment to reassessment to assist the subsequent teams

to understand the history, the organization's strengths and weaknesses, and thereby help them to prepare adequately for the assessment or surveillance work. It goes without saying that since records are so crucial to the credibility of the body, their storage must be secure and protected from potential hazards such as fire, water, mould and pests as well as unauthorized access. Reliable IT systems can support the management of this information.

► 5.11 COMPLAINTS AND APPEALS

In the standards that govern accreditation and conformity assessment, much emphasis is placed on the role of complaints and appeals and on their serious treatment by these bodies. The principle behind handling of complaints is that *"effective resolution of complaints and appeals is an effective means of protection for the body, its clients, stakeholders and other users of conformity assessment [and accreditation] against*

*errors, omissions or unreasonable behaviour. Confidence in conformity assessment [and accreditation] activities is safeguarded when complaints and appeals are processed appropriately"*²⁰. Behind this principle lies the trust in the system when problems are addressed objectively in a transparent manner, as well as continually improving systems so that the quality of output is enhanced.

► 5.12 REFERENCE TO ACCREDITATION AND USE OF SYMBOLS

The accreditation body is encouraged to allow the CAB to use logos and symbols to promote the fact that the CAB is accredited which, among other things, serves to increase the visibility of the international system and promote its use. The accreditation body, as proprietor of the accreditation symbol, must have a policy governing its protection and use. This symbol must have, or be accompanied by, a clear indication as to which activity the accreditation is associated with. An accredited CAB is

allowed to use this symbol on its reports or certificates that are issued within the scope of its accreditation. A combination of the accreditation logo with marks is allowed on labels, business cards, publicity material, written announcements etc., provided that no suggestion is made that the accreditation body has approved a product or system. Use of accreditation symbols on test reports and certificates provides proof to the customer that s/he is using an accredited CAB.

²⁰ ISO PAS 17003: Conformity Assessment: Complaints and Appeals, Principles and Requirements: 2004.

The accreditation body must monitor the CABs' use of logos and symbols which can, through misunderstanding or mal-intent, be used to misrepresent the scope of the accreditation by inferring that something is accredited when in fact it is not. The accreditation body must take suitable action to deal with incorrect references to accreditation status, or misleading use of accreditation symbols, to protect its own reputation and uphold the confidence in the reliability of accreditation. Suitable actions include requests for corrective action, suspension or withdrawal of accreditation, publication of the transgression and, if necessary, other legal action.

Accreditation bodies that are full members of IAF and/or ILAC (signatories to the IAF Multilateral Recognition Arrangement and/or signatories to the ILAC Arrangement) are able to enter into a licensing agreement with ILAC or IAF for the use of the ILAC-MRA mark or IAF MLA mark, as appropriate, in combination with their own mark. Once licensed, members can enter into a sub-licensing agreement, with their accredited CABs. This will allow accredited CABs to use the ILAC and IAF mark. Explanation of the rules that govern the use of these marks are found in IAF and ILAC policy documents on their websites (IAF ML 2:2011 and ILAC-R7:2015).



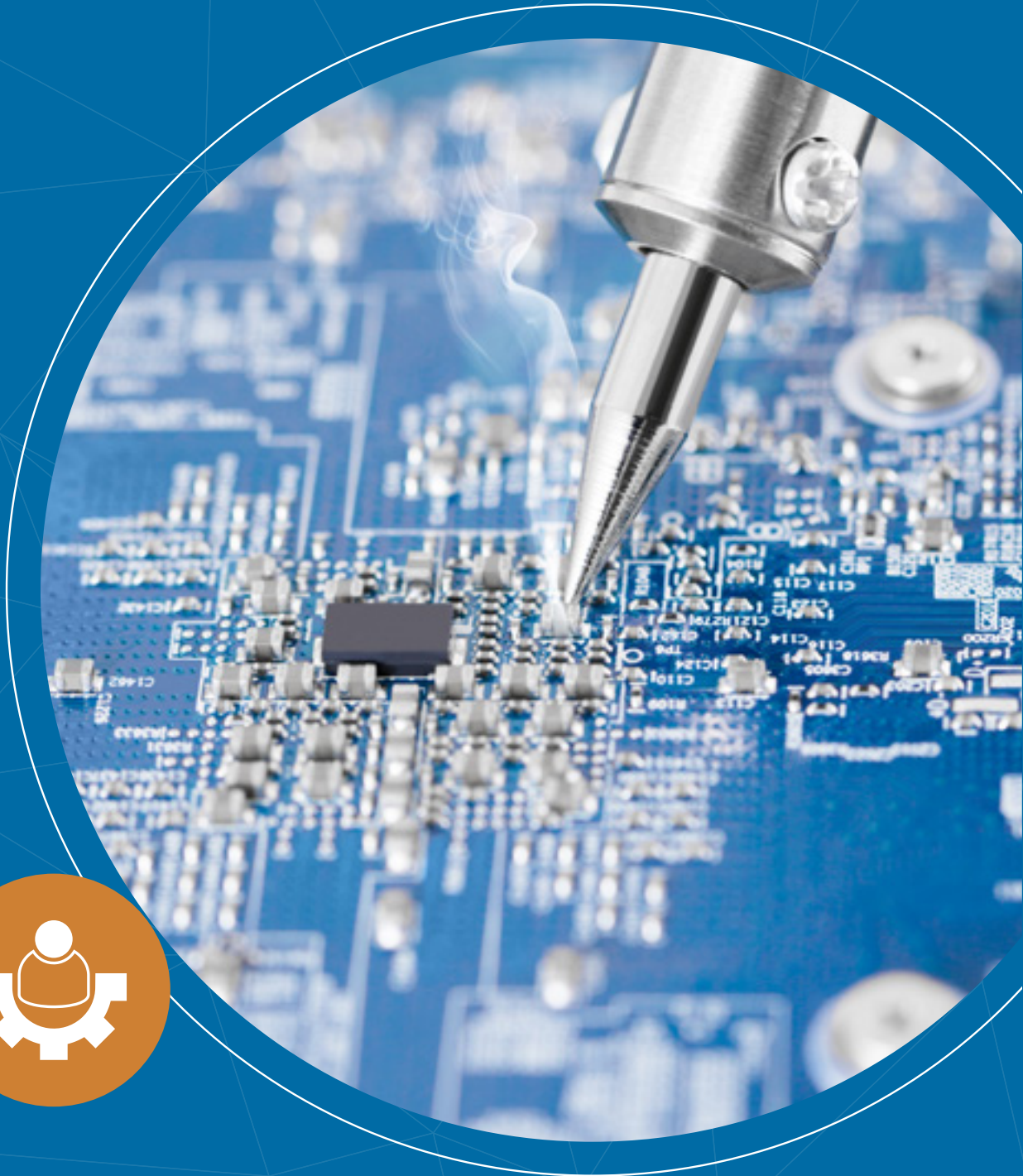
IAF MULTILATERAL RECOGNITION ARRANGEMENT MARK



ILAC ARRANGEMENT MARK

► Chapter 6

Maintenance and Development



6.1 MAINTENANCE OF THE SYSTEM

Accreditation is not a one-time event nor is it static. Surveillance audits and reassessment of CABs are usually carried-out annually, and peer evaluations of accreditation bodies are done regularly. In the course of all this work one seeks not only to demonstrate that an organization remains in conformity, but also to validate that it makes continuous improvements over time. Continuous improvement is fostered by the various standards on which accreditation is based, and CABs accomplish this through the refinement of their systems, the building of competencies, and by making processes more efficient.

In addition to the changes brought about by continuous improvement within the bodies, the standards themselves are regularly reviewed to determine if revisions are needed to ensure their on-going relevance and to keep them current. IAF, ILAC or the regions may publish interpretive type documents. These documents will help with the understanding of the intent of the revisions to the standards, ensure the requirements are

implemented with greater consistency across the globe, as well as to address issues that will improve the quality of the services delivered by accreditation bodies and their accredited organizations.

The issue of new or revised standards and associated documents from IAF and/or ILAC demand that training be provided by accreditation bodies to staff, assessors and stakeholders to ensure changes are properly interpreted, consistently applied and competently assessed. Furthermore, resources will be needed to update quality system documentation and step up communications to accredited bodies to assist them in their transition to apply the new requirements.

Therefore, even if an accreditation body does not broaden the range of accreditation services that it offers, the maintenance of its system requires investment for on-going updates of documentation and peoples' knowledge, skills and abilities.

6.2 DEVELOPMENT AND EVOLVING DEMANDS

In recent years, new standards have emerged within existing areas of certification, for example, those that address industry-specific quality systems. These can range in areas as diverse as food safety to event management. Also, entire new areas of accreditation have emerged under the IAF and ILAC systems such as the accreditation of certifiers of persons, and the accreditation of reference material producers.

Another phenomenon during the past decade has been the rise of the industry-based sector schemes that develop outside IAF or ILAC. Two examples of such schemes include:

- » GlobalGap, a certification scheme for food products. It is an initiative begun by retailers that became attuned to consumers' growing concerns regarding product safety, environmental impact and the health, safety and welfare of workers and animals. As a consequence, the retailers harmonized their standards in these areas and developed an independent certification system for Good Agricultural Practice (GAP). The scheme has become a leading farm assurance program, translating consumer requirements into Good Agricultural Practice.
- » The Programme for the Endorsement of Forest Certification (PEFC) is an international non-profit, non-governmental managed scheme dedicated to promoting sustainable forest management through independent third-party certification. The goal of PEFC is to work throughout the entire forest supply chain to promote good practices and to ensure that timber and non-timber forest products are produced with respect for the highest ecological, social and ethical standards. Consumers can then look for a label to identify product that has been certified to the Scheme.

These are just two examples of the numerous schemes that have developed relatively recently. They use their own standards, which have been developed through the multi-stakeholder and consensus-based process, and have their own rules for elements such as the number of surveillance audits, the amount of file sampling during assessments and audits, and, of course specific technical competency requirements for accreditation bodies and CABs. The international accreditation organizations such as IAF do have criteria for the recognition of industry developed sector schemes and together partner with several to deliver an internationally recognized accreditation for such schemes. The schemes can become recognized under IAF and ILAC, but to do so, scheme rules must comply with the requirements of IAF PL3.

Any developing country to which such certification schemes may be of interest should have its accreditation body contact the scheme owner and determine the process to qualify to offer these programs. Interest may stem from the fact that industries in export markets require products to meet scheme requirements, or countries may wish to adopt schemes for domestic purposes such as consumer or environmental protection.

As the accreditation services offered by a body become more diverse and sophisticated, the body must make the obvious investments to expand documentation and competencies. In addition, it will also have to reconsider the stakeholder make-up of its various policy and technical committees, to ensure the correct representation to maintain overall impartiality and the provision of fair, objective and technically sound accreditation services.

► Chapter 7

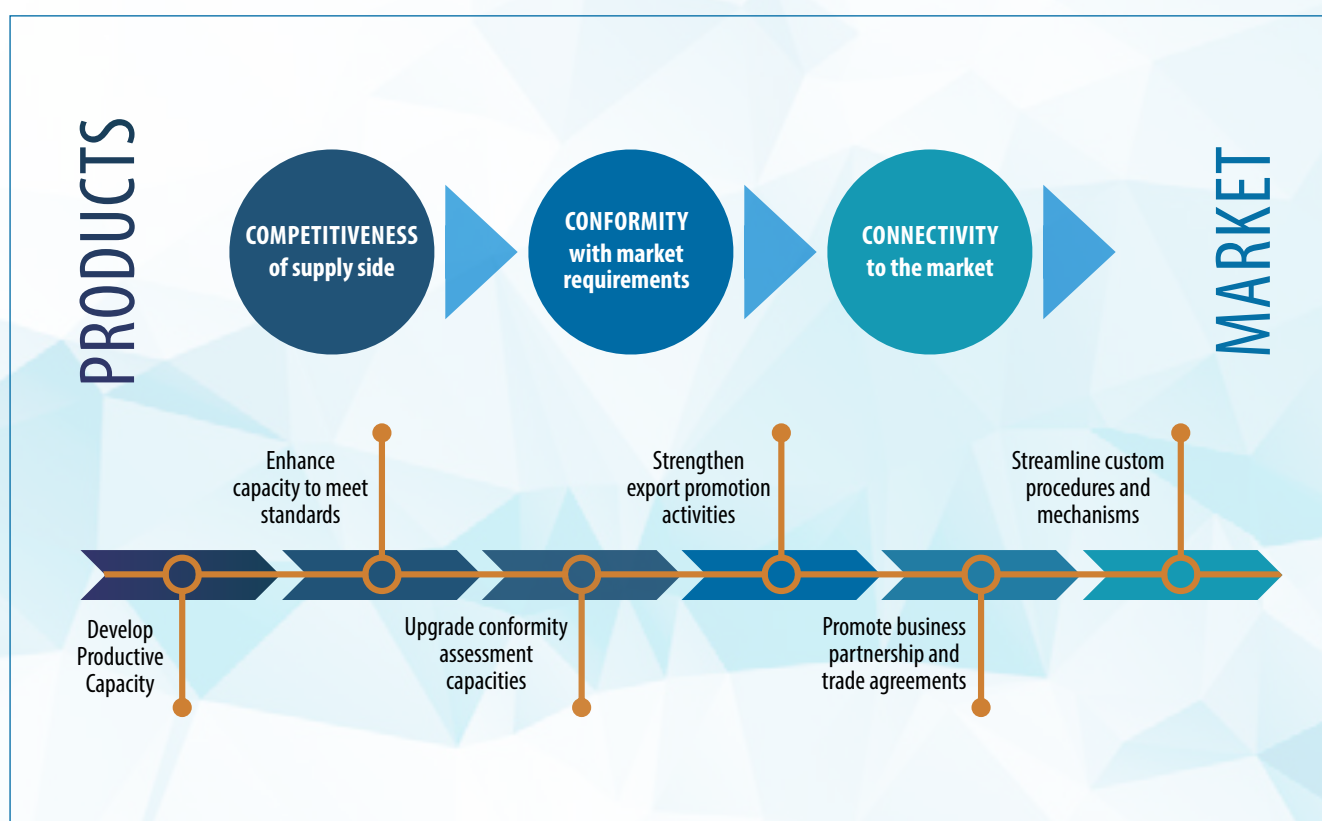
Technical Assistance to Developing Countries through UNIDO



7.1 UNIDO TECHNICAL CAPACITY-BUILDING PROGRAMMES AND PARTNERSHIPS

Since its inception in 1967, UNIDO has provided technical assistance to institutions in more than 80 countries in the fields of National Quality Infrastructure for the development of metrology, standards, accreditation, and conformity assessment. Over the years, UNIDO has successfully completed

a large number of trade capacity building projects, both for the development of competitive productive supply capacities, and for the development of standards and conformity assessment infrastructure and services.



One of UNIDO's initiatives is to support the development and capacity building of national and regional accreditation bodies and CABs in its member countries. Initiatives have ranged from direct hands-on assistance, such as the establishment of bodies in Bangladesh, Pakistan and East Africa, to assistance in other forms, such as electronic infrastructure to facilitate knowledge transfer, for example www.labnetwork.org.

To that end UNIDO has developed partnerships with international agencies in the trade capacity building field, such as the WTO, World Bank, FAO, ITC and UNCTAD, to increase synergies and enhance collective impact. MoUs have been entered into with the WTO, BIPM-OIML, ISO and IAF-ILAC, which directly apply to the use of standards and conformity assessment to improve the economic situation of developing countries.

UNIDO signed an MoU with the WTO in 2003 to work together to help developing countries and transition economies to remove supply-side obstacles to trade, to ensure conformity of their products to market requirements, and to become better integrated into the multilateral trading system. Improving

supply side-capacities, diversifying and increasing the value added by the export base, and reducing reliance on volatile, low-value added commodities are seen as sustainable ways out of poverty.

In 2004, a partnership was established between UNIDO and IAF – ILAC. Under this agreement, joint activities aim at raising awareness of the importance of accreditation and its role in trade facilitation by promoting the acceptance of accredited test and calibration results and accredited certificates to overcome technical barriers to trade.

In 2008, UNIDO, BIPM and OIML signed an MoU to establish a strategic partnership to enhance the impact of industrial development on economic growth, to minimize technical barriers to trade, and to assist in the beneficial integration of developing countries and transition economies into the global economy. The MoU ensures that all of the following are used in the best way possible to ensure improved implementation of capacity-building activities in standards and compliance, as well as compliance with sanitary and phyto-sanitary (SPS) measures.

- » OIML's worldwide technical structure which provides its members with metrological guidelines for the development of national and regional requirements concerning the assessment and use of measuring instruments in legal metrology applications;
- » BIPM's expertise in scientific metrology which provides the basis for a single, coherent system of measurements throughout the world, traceable to the International System of Units (SI); and
- » UNIDO's significant experience and a large portfolio of ongoing projects in the area of standards, metrology, testing, certification and accreditation,

It also optimizes UNIDO's delivery of trade-capacity-building technical assistance in metrology. This is of great importance due to UNIDO's position as a key agency for the implementation of projects related to TBT and SPS issues and standards and conformity capacity-building.

A 2009 MoU between UNIDO and ISO strengthens the long-standing strategic partnership between the two organizations in order to promote sustainable development and economic

growth through standards development and implementation, capacity building and training, joint publications and related research. Under this MoU, ISO and UNIDO undertake joint projects including seminars and workshops at the regional, sub-regional and national levels on topics such as:

- » standardization practice;
- » environmental and energy management;
- » food safety;
- » energy use and energy efficiency;
- » social responsibility;
- » conformity assessment

In 2014, UNIDO and IAF-ILAC signed a MoU to upgrade their partnership to a strategic one in the field of accreditation to enhance the impact of industrial development on economic growth, and to assist in the beneficial integration of the developing countries and transition economies into the global economy.

7.2 ACCREDITATION ACTIVITIES

UNIDO is the leading United Nations development agency in the provision of development projects that result in the establishment of functioning and viable NQIs. NQIs improve the competitiveness of industry in developing countries and therefore its access to external markets. Examples include

the establishment or strengthening of national and regional accreditation bodies. Recent UNIDO support has been provided to national bodies that include Bangladesh, Pakistan, Vietnam and Nepal. Support to regional accreditation bodies include East Africa and West Africa.

UNIDO'S RECENT SUPPORT TO NATIONAL ACCREDITATION BODIES AND REGIONAL INITIATIVES		
Bangladesh	BAB	EU funded
Pakistan	PNAC	EU funded
Viet Nam	BOA	Swiss funded
Nepal	NBA	EU funded
REGIONAL		
East Africa(EAAB)	EAC	Norway funded
West Africa (Ecowas & UEMOA)	SOAC	EU funded

Based on this experience UNIDO has developed a list of building blocks and their expected outcomes to guide the process of establishing an accreditation body. These are provided in both tabular and chart form in Annex 1 this Guide.

Broader considerations and guidelines for various components of Quality Infrastructure are provided in the DCED Document, *Leveraging the Impact of Business Environment Reform: The Contribution of Quality Infrastructure*. May 2015

BANGLADESH

The Bangladesh Quality Support Programme under EU financing (€7.5Mn), and with additional support from NORAD, is jointly implemented by UNIDO and ITC. It aims to contribute to growth and poverty reduction in Bangladesh, by supporting the competitiveness of the key export sectors fisheries and textile/garments. UNIDO targets improving production processes, technology upgrading, quality management and developing the national quality infrastructure to comply with TBT/SPS requirements in the export markets. ITC supports export diversification, packaging, value chain analysis, and export competitiveness development.

PAKISTAN

The Pakistan Trade Related Technical Assistance Programme funded by the EU (€2.5 million) has been successfully implemented by UNIDO. The programme aimed at helping Pakistan with upgrading and strengthening the standards related to hygiene and quality for the export of seafood as the country was at risk of losing access to the North American and European markets. Moreover, the Programme provided for an upgrading of hygiene conditions, redesigning and upgrading of landing sites and auction halls, and strengthening of the EC designated Competent Authority (Marine Fisheries Department) for inspection procedures. In addition, it provided expertise and technology transfer to processing enterprises. Over 1500 fishermen and operators were trained and more than 250 fishing vessels were guided on the upgrading. Amicro-biological and chemical laboratory for the analysis of fisheries' products was equipped and developed towards accreditation. A traceability scheme along the fisheries supply chain was also helped to develop. The fisheries could, as a result, start their exports a new.

► 7.3 CHALLENGES IN DEVELOPING ECONOMIES

Developing countries face a number of particular challenges in the course of accreditation body establishment. Every component of a National Quality Infrastructure, including the provision of accreditation services is heavily dependent on: access to a certain skill set, on-going training, financing for

start-up and sustainability, supporting infrastructure, as well as reinforcing government policy and regulation. With all of these addressed, there remains the problem of resistance to change when introducing a new institution with a broad multi-disciplinary reach and mandate.

7.3.1 Knowledge, skills and abilities

Accreditation is about evaluating the competence of the delivery of conformity assessment services. Therefore, the accreditation body must have access to technical competence that is at least as sophisticated as that which is found in the bodies it is accrediting. Obtaining technical expertise in a wide variety of areas may be difficult in developing countries and may have to be sourced from neighbouring countries or beyond if there are not sufficient experts within a country.

The full time staff and assessors of a body will have to come with the usual management knowledge and business acumen, but in addition will have to be trained on the standards and documents that govern accreditation and the CABs. Assessors will require a special skill set that can only be honed over time. External experts will be required to provide this training whether they are brought on site or accreditation body staff are exposed through a tutoring process with existing accreditation bodies at their sites. The travel, accommodation and consulting expenses associated with this training will be one of the larger outlays in accreditation body establishment. It will have to be carefully budgeted for and provided by the funding organization be it the local government or an international agency.

There may exist various stakeholder groups or institutions from which individuals with the needed knowledge, skills and abilities may be sourced. For example, in Nigeria there are several large institutional laboratories that were accredited by international organizations and, therefore, well-equipped to be considered as hosts for PT Schemes. Also present were a number of laboratory associations which proved to be a source of individuals with competencies that were strong foundations for their training as accreditation assessors and technical experts. Each economy will present a different set of circumstances, strengths and weaknesses as to the stakeholder groups that are present and their readiness and interest in being involved with the establishment of an accreditation body. A scan of these groups at the outset and their involvement in the process may be instrumental to the effort.

The various accreditation body members of Regional groups may prove to be a good source of information. Their experience may provide ideas for the identification of potential funding sources, and they may be of assistance in locating or obtaining training for both start-up and for the on-going maintenance of competencies.

7.3.2 Financing

Establishing any institution requires a monetary investment and an accreditation body is no different. An initial injection of funds will be required to hire staff, purchase office equipment, establish office procedures, find and secure office premises. Expense outlays for these items are relatively low and predictable since accreditation bodies are typically office operations that do not require expensive equipment and should begin with few permanent staff and make good use of part-time contracted personnel. However larger expenditures come with the engagement of external expertise to train, mentor and monitor staff, to develop relatively sophisticated business and marketing strategies and plans, and to create an awareness and a demand for these “new” services.

International donors may assist with funding of the start-up but cannot be expected to sustain funding over the longer-term. Business planning at the outset can forecast the revenues required to finance operating expenses in the coming years. If those expenses cannot reasonably be recovered from the bodies that are paying for the accreditation services, some arrangements will have to be made with the local government to cover the costs of operation until such a time when the organization can become entirely self-funding through fees charged to applicant and accredited bodies. The actual method used for long-term financing of the accreditation body should be a policy deliberation when establishing the body by considering the role of the body in the economy and its objectives.

7.3.3 Proficiency testing

ILAC requires laboratories to participate in regular Proficiency Testing (PT) Programs or Schemes relevant to their scopes of accreditation. PT Schemes can be expensive to operate and require specialized equipment and skills. In large technically sophisticated economies, a wide range of PT Schemes for all types of testing and parameters are usually available from commercial sources. Accreditation bodies located in any country can try to make use of those services.

Even a preliminary search of the internet yields well over one thousand providers of PT programs. Many of these are highly focused programs 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. The regions often provide programs for both testing and calibration and participation from laboratories outside of those regions. These can be negotiated.

Importing samples from foreign programs is not always easy because of problems encountered with customs officials and transportation issues. The latter becomes problematic with samples that are hazardous in nature because they may be prohibited from air transport (e.g. flammable liquids, mercury in glass instruments) or the samples are too unstable for reliable transportation (e.g. fresh foods).

In smaller economies, there are fewer services available and the accreditation body may itself be forced to provide the necessary PT schemes; at least to fill gaps left by the commercial providers. In many developing economies there are no PT schemes in use and the only ones available are sourced from other countries or they must be established. If the establishment route is chosen, 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. Developing economies may also have few laboratories in any one area which may be problematic because of the statistical element involved with PT schemes.

Solutions may be found by combining a number of strategies; for example, by selectively developing PT programs by the accreditation body or through national reference laboratories, where a large number of laboratories exist. International schemes can be employed in areas where a country has few labs or where transportation and spoilage is not a significant issue. Regardless, the PT issue should be addressed with the assistance of an experienced international consultant.

7.3.4 Metrology and standards

For recognition by ILAC, accreditation bodies must apply the ILAC policy on calibration which requires that testing equipment that has a significant impact on the outcome of results be calibrated using measurement standards that are traceable to the standards held at the BIPM in Paris. Normally this is carried out through the use of standards that are held in national metrology institutes which have, in turn, been calibrated to those at the BIPM. Many developing countries however do not have metrology institutes and those that do may not hold all the relevant measurement standards. So once

again laboratories are forced to go outside their borders at a higher cost to access the required service. Here again the Regions will be able to point the laboratories through the national accreditation body to the closest and cheapest source of traceable calibration.

PT and traceability are complex topics and must be addressed by suitably competent individuals. More information can be found in ILAC policy documents on the ILAC website and from the BIPM (International Bureau of Weights and Measures) website.

7.3.5 Policy and regulation

In addition to financial support, another very important support from the local government comes in the form of policy. A National Quality Infrastructure (NQI) including an accreditation body is not likely to exist in a developing country without the support and credence given to it by a National Quality Policy (NQP). Fundamental laws and technical regulations to promote the use of standardization, metrology, conformity assessment and accreditation are needed to make the newly introduced quality institutions operational through their uptake in the economy.

For developing countries, the introduction of such policies and regulations may be new and different to regulators and require external expertise to assist with the drafting of policies and regulations that will meet government objectives and remain

in compliance with the requirements of the WTO's Sanitary and Phyto-sanitary Standards measures and Technical Barriers to Trade agreements.

The re-engineering of policy and regulations to meet these requirements and introduce new quality infrastructure can require a wide review and drastic retooling of existing legislative instruments which can be a time-consuming process for a developing country. UNIDO has assisted countries such as Nigeria with this policy and regulatory aspect. It has facilitated bringing local regulators and stakeholders together with international experts to discuss and draft national policy focused on quality, and support government in its review of regulations with a view to harmonise them using a National Quality Policy as a basis.

7.3.6 Change

Change is not a challenge that is particular to a developing country, but the sudden introduction of an accreditation system means that it is no longer business as usual for a large number of stakeholders. Its introduction therefore must be managed not only in terms of the technical and financial aspects discussed above, but, most importantly, in regard to stakeholder, whether they expectations. Stakeholders be they the bodies that are to be accredited, the industries that will use the services of the accredited bodies, the governments that will introduce policies to promote the use of accredited

services, or the consumers, be they institutional or individual, will have to be educated as to what can or cannot be expected from accreditation. Those that are being accredited must understand and be convinced of the effort involved and the benefits that will be accrue as a result. A patient and informed marketing effort on the part of those establishing the body to include and communicate with many, and a broad range of local stakeholders from the outset, is key to creating understanding and acceptance of the new institution and help ensure its success.

7.4 LABNETWORK

LABNETWORK is a web-based system that provides information on standards and conformity assessment to assist developing countries to quickly become informed about laboratory accreditation. The online platform disseminates information of value to testing and calibration laboratories from all fields of science, and those seeking their services. It incorporates a joint program by UNIDO, WAITRO and other global players to address issues of Certified Reference Materials (CRM) and proficiency testing. It can be found at: www.labnetwork.org.

UNIDO has provided resources for setting up LABNETWORK within the framework of its various regional programs, while WAITRO is identifying organizations that would be willing to participate in the project and commit to hosting and maintaining the system on a rotational basis. For CRMs, a link has been proposed with WAITRO member organizations in India, China and Korea, and a link for proficiency testing with India's National Accreditation Board for Testing and Calibration Laboratories (NABL). As trade between countries grows by the day, countries are putting up non-tariff barriers

to trade, such as quality specifications for imports that require the testing of products. LABNETWORK will provide information about mandatory tests for exports to different countries, which will be very useful for exporters around the world.

Users of LABNETWORK will be able to contact each other either directly or through LABNETWORK's message board, where they can post their problems to be answered by experts in their field chosen by UNIDO, or by other members of LABNETWORK. Its vision is to:

- » Provide access to and disseminate information related to testing laboratories;
- » Share experiences about testing laboratory capabilities, management, design, development and maintenance;
- » Provide an avenue for promoting and sourcing laboratories and their services;
- » Facilitate the dissemination of information to industry and trade on testing and calibration, including product-specific information.

LABNETWORK



Case Studies

Accreditation Body Establishment in Developing Countries



MAURITAS: Mauritius Accreditation Service

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BAB: Bangladesh Accreditation Board

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ONAC: The National Accreditation Body of Colombia

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NiNAS: Nigeria National Accreditation Service

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ARAC: Arab Accreditation Cooperation

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SADCAS: Southern African Development Community
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BAB: Sri Lanka Accreditation Board for Conformity assessment

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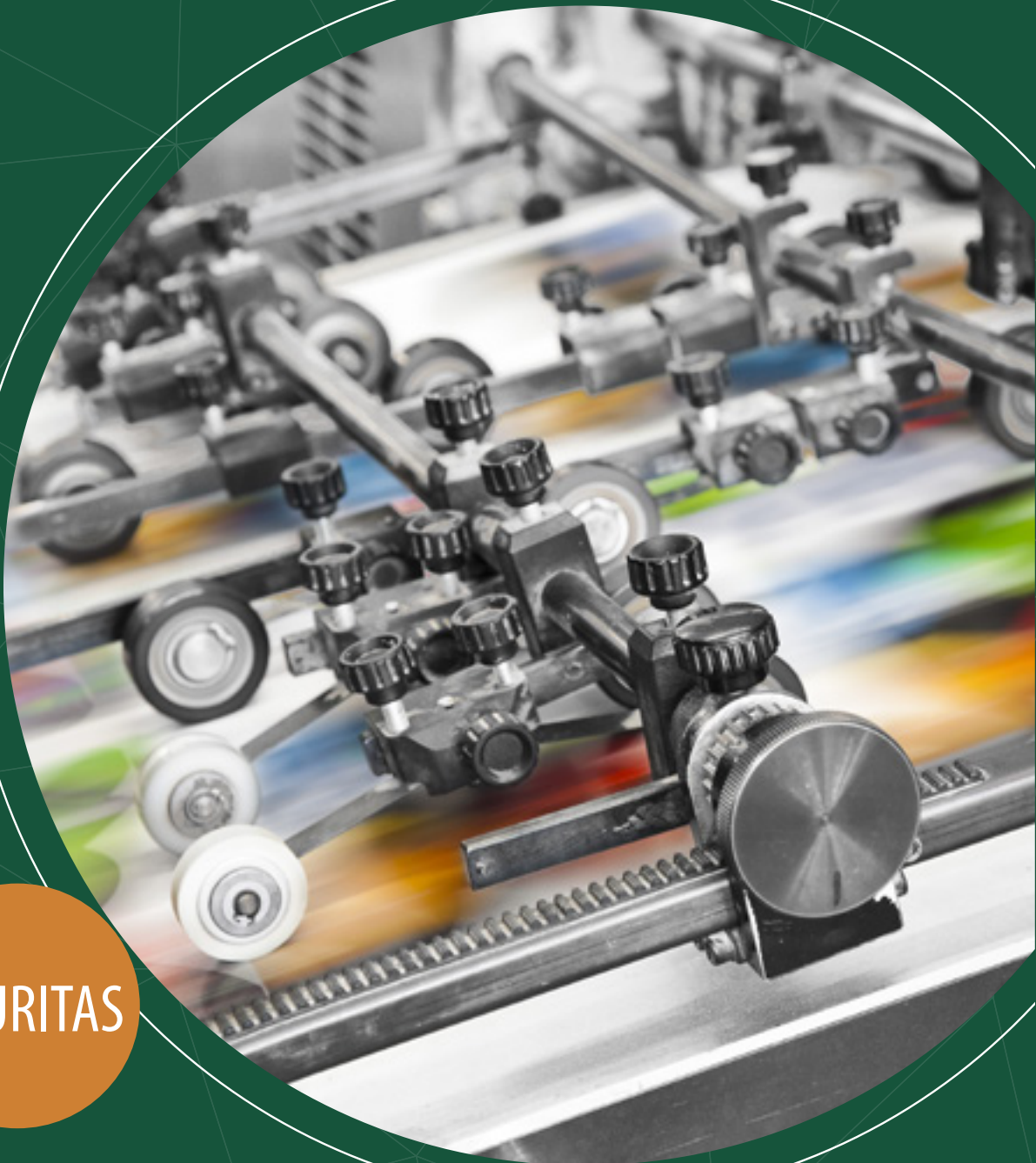


INACAL-DA: National Institute of Quality – Directorate of Accreditation

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► Case Study 1

Mauritius Accreditation Service



MAURITAS



NAME OF THE ACCREDITATION BODY

Mauritius Accreditation Service (MAURITAS)



ECONOMY

Mauritius



ORGANIZATION

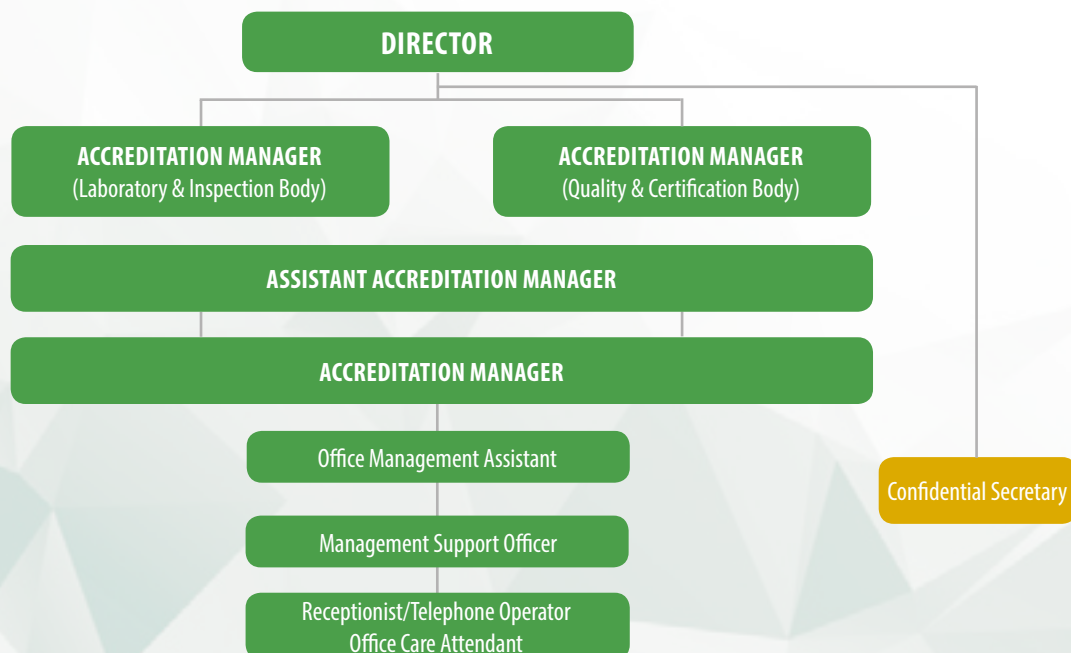
The Mauritius Accreditation Service (MAURITAS) was established following the adoption of the MAURITIUS ACCREDITATION SERVICE ACT in December 1998. It was initially set up as the National Laboratory Accreditation Council (NLAC) in 1997, following the recommendation made by the World Bank in the context of the “Technical Assistance project to Enhance Competitiveness (TAEC)” implemented in 1994-1997. It was then decided that the national accreditation body should cater for the needs of all types of conformity assessment bodies (CABs). Consequently, the MAURITIUS ACCREDITATION SERVICE ACT 1998, also referred to as Act No 23 of 98, was adopted in December 1998 and promulgated in August 1999.

The parent organisation of MAURITAS is the Industry Division of the Ministry of Industry, Commerce and Consumer Protection. MAURITAS is presently set up as a Department in the Ministry responsible for the subject of Industry. The financial and human resources activities are managed by the finance section and human resources section of the Ministry respectively. MAURITAS operates as a not-for-profit organisation.

As at 30 March 2016, MAURITAS has accredited a total of **30** conformity assessment bodies as follows:

- ▶ **2** calibration laboratories (ISO/IEC 17025)
- ▶ **22** testing laboratories (ISO/IEC 17025)
- ▶ **5** medical testing laboratories (ISO 15189)
- ▶ **1** certification body for QMS, HACCP and ISMS (ISO/IEC 17021).

The list of accredited entities can be viewed on the website www.mauritas.org



ESTABLISHMENT OF THE AB

Under the TAEC project, carried out and funded by the World Bank, the Bank consulted with the major stakeholders, namely the National Standards and the Metrology organization (the Mauritius Standards Bureau), national industry associations and the Ministry responsible for Industry, and recommended the establishment of a national body for accreditation in Mauritius.

There is no National Quality Policy in Mauritius. Accreditation activities are carried out as per the provisions of the Act No. 23 of 98.

During the last 15 years, Government has funded the financial provisions of MAURITAS through the budget of the Ministry. MAURITAS has also benefited from a number of other donor partners such as the European Union technical assistance programmes (EU/SADC, EU/ACP TBT), Agence Française de Développement (AFD), International Atomic Energy Agency (IAEA), and Physikalisch Technische Bundesanstalt (PTB).

MAURITAS generates income from fees payable by its clients which are consolidated in the Government revenue. The fees are prescribed by regulations for the levying of fees and charges for laboratory and certification body accreditation. MAURITAS is not directly paid by CABs, but aims to be an operation that fully recovers costs.

MAURITAS started its activities by launching its accreditation program for laboratories in 2005. The main reasons were that there was a higher number of laboratories among the CABs operating in Mauritius and that the laboratories were already carrying out conformity assessment activities for the economic pillars of sugar, textiles & garments, jewelry and the sea food. MAURITAS invited all the Government laboratories to lead by example by becoming accredited.



RELEVANCE AND IMPACT

MAURITAS is the sole national accreditation body. It is not yet internationally recognized but it collaborates with other globally recognized accreditation bodies to provide conformity assessment bodies with a solution if international recognition is required for the export of specific goods and services. MAURITAS provides accreditation services in the following areas:

- ▶ Testing laboratories ISO/IEC 17025
- ▶ Calibration laboratories ISO/IEC 17025
- ▶ Medical Testing Laboratories ISO 15189
- ▶ Certification bodies ISO/IEC 17021 (QMS, HACCP, ISMS).

Although no surveys have been carried out, it is assumed that the establishment of MAURITAS has been beneficial to the conformity assessment infrastructure and in particular to the laboratories and certification bodies. Their level of operations has been improved and some of the accredited laboratories have been awarded contracts for testing services.



BEST PRACTICE

Following the adoption of the legislation, MAURITAS joined ILAC as an Affiliate in 2000 and became an Associate in 2008. MAURITAS joined IAF as a full member in 2000. MAURITAS is an ordinary member of the SADC Cooperation in Accreditation (SADCA) and a full member of the African Accreditation Cooperation (AFRAC). In July 2015, it applied for signatory status of the ILAC, IAF, SADCA and AFRAC MRA/MLAs for the following scopes:

- ▶ Testing ISO/IEC 17025
- ▶ Calibration ISO/IEC 17025
- ▶ Certification ISO/IEC 17021 (QMS sub scope).



SUSTAINABILITY

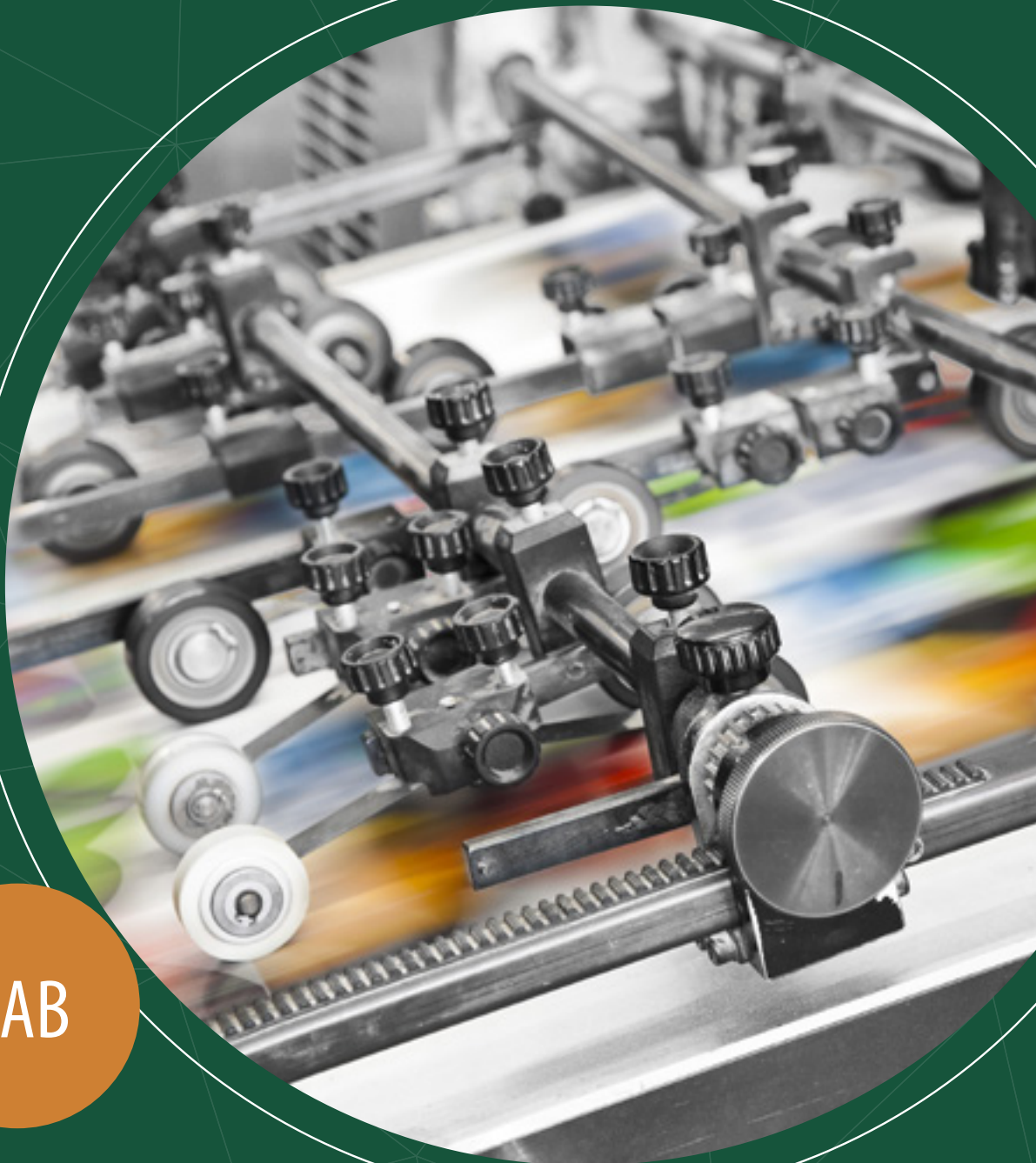
The biggest challenges faced so far relate to the recruitment of permanent staff and to the enlistment of technical assessors in all the fields/scopes of operation of MAURITAS.

The main challenge for the immediate near future will be to amend the legislation to be in line with the requirements of international standards for achieving signatory status with the ILAC and the IAF Multilateral Mutual Recognition Arrangements.

Accreditation is recognized by the World Trade Organisation as one of the tools for removing Technical Barriers to Trade. With the dismantling of preferential agreements, it is important that the exporters from Mauritius have a mechanism to demonstrate that the goods and services they intend to export are in compliance with international standards.

► Case Study 2

Bangladesh Accreditation Board



BAB



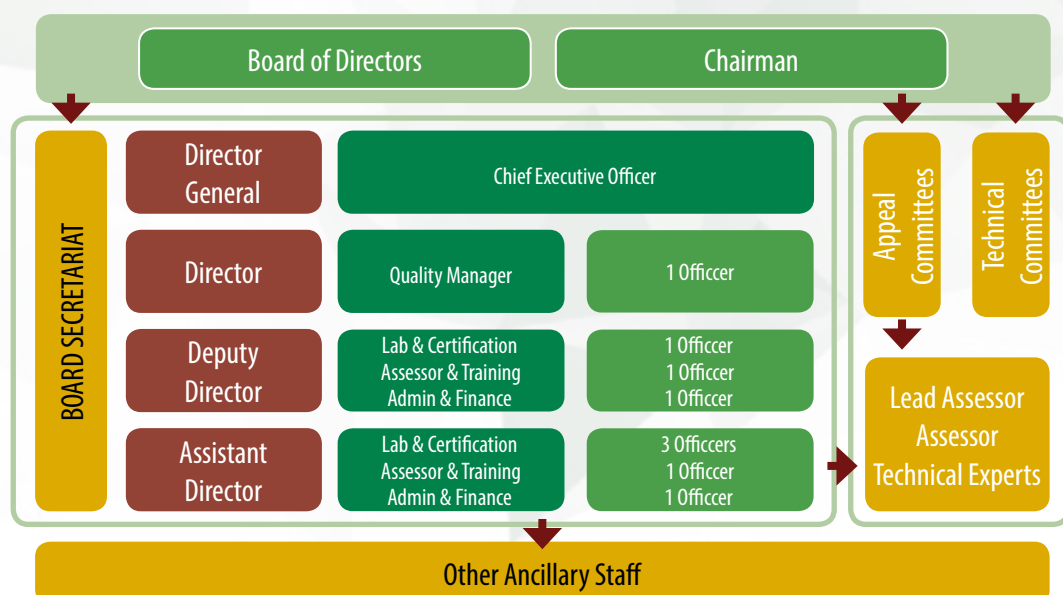
Bangladesh Accreditation Board (BAB)



Bangladesh



The organizational structure is as follows:





ESTABLISHMENT OF THE BAB

BAB was established through a working arrangement between the Ministry of Industry, the Bangladesh Standards and Testing Institution (BSTI) and UNIDO. Donor funding was provided by the EU and the Norwegian Agency for Development Cooperation (NORAD). Following consultations with various trading partners and development organizations, an Act governing accreditation, the Bangladesh Accreditation Act was issued in 2006. In November 2015 Cabinet approved a National Quality Policy which references accreditation as a key part of the National Quality Infrastructure (NQI). Such has been helpful since the elements of the NQI are interdependent. For example, accreditation requires National Measurement Standards, traceability, proficiency testing and other services before laboratories can be accredited.

Although there was no formal Business or Marketing Plan at the outset, there was a business development strategy which was to start with the accreditation of testing and calibration laboratories due to the large number of labs in the country and hence the potential opportunity for accreditation activity.



RELEVANCE AND IMPACT

BAB was created with the aim to gain access to overseas markets, particularly the EU market, and to achieve protection for domestic consumers in the process.

The main scope of accreditation activities offered by BAB are testing for textiles, food testing, building materials and in calibration for balances, volume, length, mass, temperature, time interval and pressure.

International recognition of the certificates issued by BAB was achieved under the ILAC MRA in 2015, thus an assessment of the impacts has not yet been carried out at the time of the publication of this document. One impact already evident however was the lifting of EU requirements for pre-shipment testing and the testing on arrival of shrimp exported from Bangladesh.



BEST PRACTICE

The BAB has been a member of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) since 2007. BAB also obtained membership from International Laboratory Accreditation Cooperation (ILAC) in 2010, the Pacific Accreditation Cooperation (PAC) in 2011, and the International Accreditation Forum (IAF).

BAB has been admitted for the following mutual recognition arrangements (MRA)/Multilateral Recognition Arrangement (MLA):



- ▶ ILAC MRA for ISO/IEC 17025 (testing in March 2015 and calibration in June 2015)
- ▶ APLAC MRA for testing and calibration.

BAB is also a member of the South Asian Association for Regional Cooperation (SAARC). Although SAARC is not an organization directly associated with accreditation, it provides policies with the aim to promote welfare economics, collective self-reliance among the countries of South Asia, and to accelerate socio-cultural development in the region; thus areas in which accreditation has a role to play.



SUSTAINABILITY

Those responsible for the development of BAB saw the biggest challenges faced in its development as: (1) staff recruitment and provision of the requisite training to personnel; and, (2) the implementation of a quality system that conformed to the applicable international standards. Such expertise is not readily accessible in a country where accreditation systems do not exist and therefore trainers must be identified and brought into the country at significant expense.

In terms of the future, BAB personnel see the maintenance of this expertise as a challenge. The peers of accreditation bodies are not usually in close proximity and thus attendance at international meetings is necessary to maintain and grow expertise. Attending these functions however also comes at significant expense.

BAB specifically sees the following challenges around expertise: regular attendance of APLAC and ILAC meetings; retention of trained staff; preventing the dilution of technically qualified professional staff; and expanding the number of professional staff in line with the growth in the number of accredited CABs.

► Case Study 3

The National Accreditation Body of Colombia



ONAC



NAME OF THE ACCREDITATION BODY

ONAC – The National Accreditation Body of Colombia



ECONOMY

Colombia



ORGANIZATION

The National Accreditation Body of Colombia, ONAC is a non-profit corporation established on November 20th 2007 under the Civil Code and Science and Technology rules. The Corporation is a partnership between Colombian State and other interests. ONAC is the sole accreditation body designated by law and has its head office located in Bogotá D.C., Colombia.

ONAC's governmental mandate come from two legislative sources: (1) the statutory Decree 4738 of 2008 which provides rules for accreditation and conformity assessment and it forms part of the National Quality System; and (2) Article 2 of the Superintendency of Industry and Trade (SIC), which states that the exercise of accreditation is applied "...in market conditions, by entities organized under private law, in accordance with the requirements for that purpose determined by the Ministry of Commerce, Industry and Tourism".

A national law addressing accreditation, CONPES 3446, was issued on 30 October 2006, by the National Council of Economic and Social Policy (CONPES). This law established the guidelines for a National Quality Policy including the use of accreditation. Among the strategies that was set out by these guidelines was a recommendation to transfer the accreditation function from SIC to ONAC, to be independent of ministerial activity. Decree 4738 (2008), Decree 2124 (2012) and Decree 865 (2013) designates ONAC as a National Accreditation Body by modifying the structure of SIC, and Decree 1595 (2015) dictate rules to the National Quality System. These added to the Government issued Decree 2269 of 1993 which organized the National Standardization, Certification and Metrology System to promote marketplace quality in production processes and competitiveness.

As a result of all of this legislation, ONAC was created as a private, not-for-profit corporation and registered in the register of Chamber and Commerce on December 18, 2007. ONAC acts with administrative, financial and operational independence, while incorporated and organized under the laws of Colombia, as part of the Civil Code.

Government agencies have a third of the members on the Board of ONAC (9 members out of a total of 27). The Board Chairman is the representative of the National Government, through the Ministry of Commerce, Industry and Tourism.

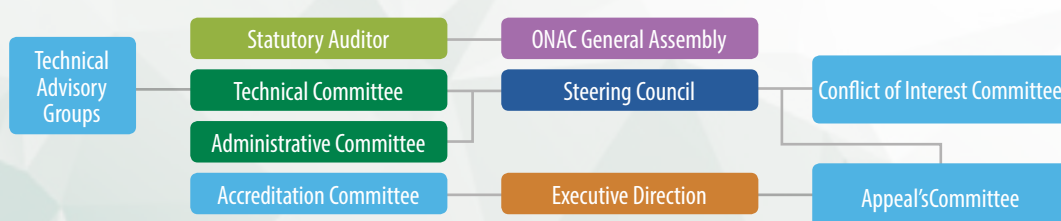
ONAC is made up of four directorates: Executive, Administration and Human Resources, Technical, Management Development and Improvement. The responsibilities and staffing of each Directorate are as follows:

- ▶ Executive, including legal advice, professional support, and communications (4 people);
- ▶ Administration & Human Resources, which includes financial services and provides assistants to the professional staff, (21 people);



- Technical, for each accreditation program (30 people); also under this group are the assessors and technical experts, classified as Lead Assessors, Assessors, Technical Assessors, Technical Experts, or Assessors/Experts who participate in accreditation or appeals committees (400 people);
- Management, Development and Improvement, which coordinates the work of Management System, Monitoring, Assessment Schedules with support of professionals for Development and Improvement, Investigation and Development, and Customer Service Management (10 People).

ONAC's organizational structure is as follows:



ESTABLISHMENT OF THE AB

Through a Bilateral Project between Colombia and PTB (Metrology National Institute of Germany), PTB provided consulting to support the Superintendent of Industry and Commerce which first managed accreditation activity in Colombia.

Ninety one private and public organizations signed the ONAC constitution. The national government, through the Ministry of Commerce, Industry and Tourism, decided to contribute seed capital in the amount of 600 million Colombian pesos, which added to contributions from private sources and the support from the founding members.

ONAC began with a strategy to accredit organisations which would assess for compliance with technical regulations. Operating strategies are supported by a business plan, which reflects a continuous evaluation of its efforts to support improvement to the country's competitiveness and technical capacity for the commercial and industrial development. There is at present no marketing plan. ONAC is the only accreditation body in Columbia and therefore it does not compete or duplicate services provided by other organizations.

ONAC began accreditation activities for calibration and testing laboratories and to work towards obtaining recognition for these programs from the Inter-American Accreditation Cooperation (IAAC). ONAC achieved IAAC recognition at the IAAC General Assembly held on March 17, 2014, in Mexico City, Mexico. ONAC signed the IAF MLA for its accreditation programs for Product Certification and Management System Certification (ISO 9001 and ISO 14001) in October 2015.

In the course of the establishment of ONAC, given that it was a monopoly, special care was needed to ensure its operations took into account the needs of the CABs and that customers be provided with services of high quality. One way to ensure that the interests of its customers and stakeholders were heard and taken into account is the presence of many of those interests on ONAC's Boards. Government is represented by the areas of science, innovation, metrology and trade and indirect interests are represented by universities, consultants, and quality and user associations. It is believed that as a result ONAC not only works purely on technical issues of accreditation but also provides an environment where customers can participate, thus ensuring efficient communication channels.



RELEVANCE AND IMPACT

ONAC was conceived as a tool to facilitate international trade and therefore to seek signatory status to the IAAC, IAF and ILAC multilateral recognition agreements. ONAC's accreditation activities are the following areas:

- ▶ Testing Laboratories;
- ▶ Calibration Laboratories;
- ▶ Medical Laboratories;
- ▶ Product Certification Bodies;
- ▶ Management Systems Certif. Bodies (QMS, EMS, ISMS, FSMS and QMS for Medic. Devices);
- ▶ Inspection Bodies;
- ▶ Proficiency Testing Providers;
- ▶ Digital Certification Entities.

A notable impact that has resulted from the creation of ONAC is that it has allowed Colombia to strengthen the quality inspection of its transportation sector and thereby increase road safety. Additionally it has enabled the flow of trade by reducing transaction costs and eliminating technical barriers to international trade.



BEST PRACTICE

ONAC is a signatory member of IAAC for the following scopes:

- ▶ Testing and calibration laboratories;
- ▶ Product certification bodies;
- ▶ Management Certification Bodies for QMS, EMS, ISMS, FSMS, and Medical Devices.

It is also a signatory to ILAC and anticipated becoming a signatory to the IAF MLA for:

- ▶ Product certification;
- ▶ Management Systems (QMS, EMS).



SUSTAINABILITY

The biggest challenge faced in the development of ONAC was to increase its credibility in public and private institutions and promote the benefits of accreditation with respect to its ability to improve the country's competitiveness. The main challenges for the future are anticipated to be the strengthening of national and global confidence in ONAC accreditation, and to distinguish it as a guarantor of excellence and credibility.

The objectives that were desired in the course of the establishment of ONAC to achieve multilateral recognition of its accreditation services and financial sustainability of the institution through cost-recovery are being met with a concurrent growth of the accreditation scope that are being offered with the necessary technical expertise. ONAC is expected to be self-funded in the future.

► Case Study 4

Nigeria National Accreditation Service



NiNAS



NAME OF THE ACCREDITATION BODY

Nigeria National Accreditation Service (NiNAS)



ECONOMY

Nigeria



ORGANIZATION

NiNAS was created in 2015 under a component of the National Quality Infrastructure Project for Nigeria (NQIP). The NQIP was an initiative of the Nigerian Federal Ministry of Industry, Trade and Investment (FMITI), the European Union (EU) and the United Nations Industrial Development Organization (UNIDO). Funding was provided by the EU and project management and implementation was carried out by UNIDO. NiNAS was registered by the Corporate Affairs Commission of the FMITI as an independent not-for-profit corporation overseen by a Board of Trustees.

While the Board of Trustees is there strictly for specific purposes as defined in legislation, NiNAS will be governed by a Board of Directors, along with a balanced multi-stakeholder Policy Advisory Committee and possibly other committees such as Audit and Technical Committees. Membership on the committees will include representatives from Government, Industry, Accredited Organizations and other interested stakeholders such as consumer or environmental groups. NiNAS will also be answerable for its adherence to international standards of operation for accreditation bodies, to the African Accreditation Cooperation (AFRAC), the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).

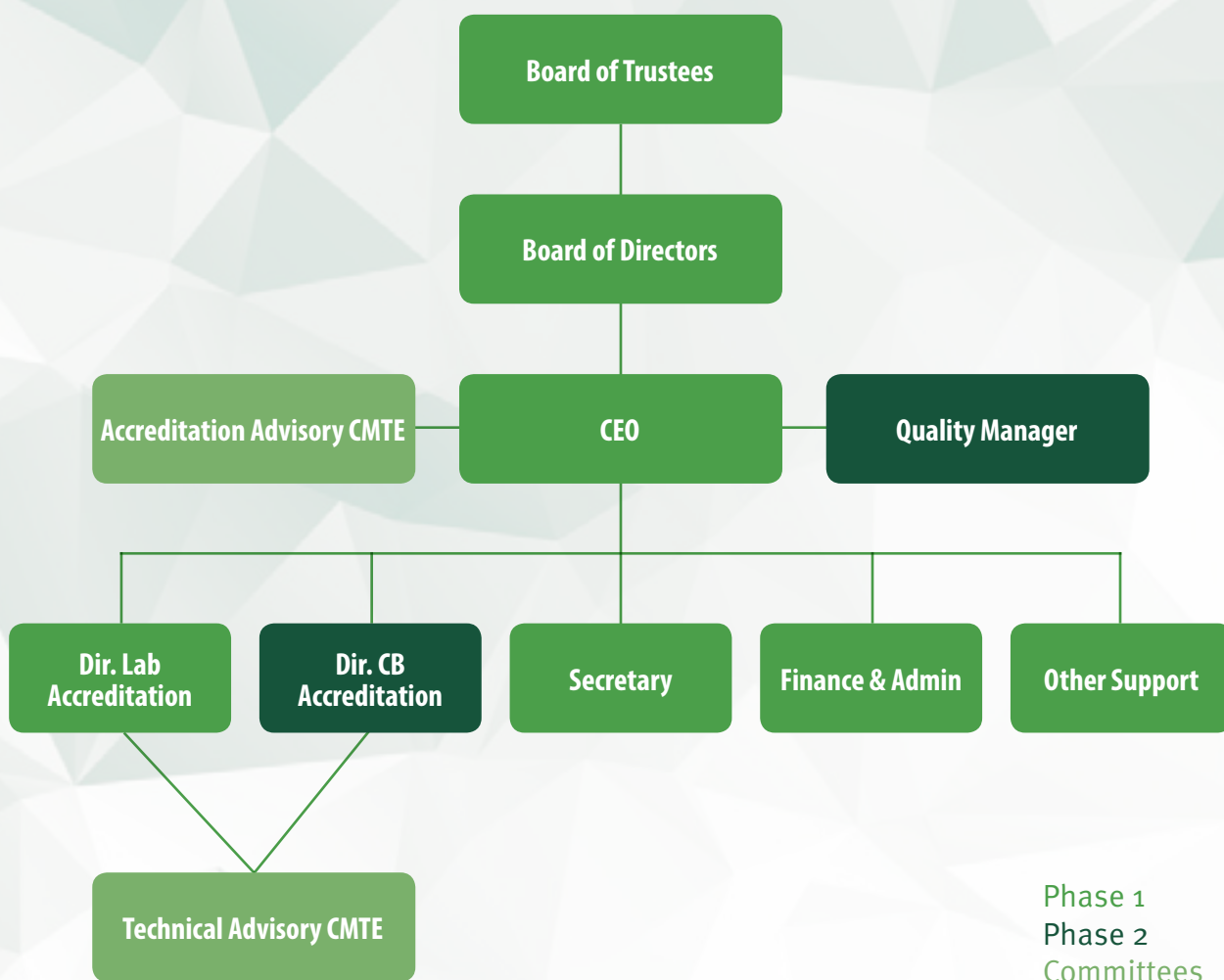
It is anticipated that NiNAS will work with various Government Ministries to deliver accreditation services to different sectors of the Nigerian economy as needed by regulators or as mandated in technical regulations. CABS may also apply on a voluntary basis for business reasons.

As a start-up organization, NiNAS will begin with minimal staff, a CEO, a Director of Accreditation and several support staff to economise on the costs of operation. The assessment and auditing functions for accreditation are to be carried out by contracted assessors on an as-required basis. Other services such as legal advice obtained on a contracted / as-needed basis. The start-up organizational structure being proposed is as shown in Figure following below.

The Board of Directors will oversee the legal compliance of NiNAS, the performance of the CEO, the finances of the organization, and the execution of business strategies by the CEO and Director(s). Other committees in the technical area are established as necessary to ensure the body has access to all of the needed technical expertise to competently operate the accreditation programs.



The Advisory Committee will provide advice to the entire management team of NiNAS. This multi-stakeholder policy Advisory Committee is established to ensure impartiality of the organisation as required by ISO/IEC 17011 and in addition, to gain access to a broad spectrum of input from stakeholders in the Nigerian economy for accreditation policy development. The advice provided will be largely in the form of feedback on operational policies and procedures to ensure they are drafted and implemented in a way that results in an impartial service delivery to applicant and accredited organizations. The Advisory Committee will also have a role in reviewing internal and external audit results of NiNAS, as well as how NiNAS addresses any complaints.





ESTABLISHMENT OF THE AB

The European Union provided funding for the National Quality Infrastructure Project of Nigeria, in which start-up financing for the establishment of the accreditation body was included. Medium-term funding is being sought from a variety of internal and external sources to ensure the organization's viability over the first few years. A business plan based on anticipated costs and revenues indicate that the organization will operate in deficit for the first three to five years and therefore financing is required. Over the long-term it is expected that NiNAS will be largely self-funding through accreditation revenues.

A multi-stakeholder steering committee representing many sectors and groups that have an interest in the operation of an accreditation body was established to guide the process of NiNAS establishment. Sectors represented included: various government ministries, manufacturers, small and medium sized enterprises, consumer groups, organizations promoting quality, laboratory groups and laboratory practitioners, exporters, educators, environmental protection and others. It is anticipated that some of this membership will continue on the NiNAS Policy Advisory Committee.

A CEO and Director of Laboratory Accreditation were engaged in 2016 and support staff will soon follow, along with a physical location of its own. NiNAS is has actively trained assessors through a four-phased training program. Theoretical training was carried out in the first 3 phases with a focus on the accreditation standard, management system auditing, and NiNAS policies and procedures. The fourth phase is a practical one to provide assessors with real-life experience in assessing laboratories. With the fourth phase completed, pilot accreditations commence.



RELEVANCE AND IMPACT

NiNAS was conceived with the purpose to obtain greater acceptance of Nigerian exports on the international market beginning with agricultural exports and for the protection of domestic consumers that were often exposed to low quality products. The accreditation services that are envisioned to be initially provided will be to testing laboratories for food and beverages, light manufacturing, and calibration laboratories to support the testing labs. Food laboratories were chosen as the initial target due to the large number in the country, because of their fundamental role in the health and safety of consumers, and to support a potentially large export sector in Nigeria. In addition, laboratories provide an essential basis to other conformity assessment activities in an economy on which the accreditation of the latter are often based. Following the establishment of programs to accredit labs, it is foreseen that NiNAS will expand to accredit personnel and product certification bodies, and inspection bodies.

There are other organizations within the Nigerian economy that have regulatory mandates to deliver accreditation. The plan therefore is for the services provided NiNAS to partner with the technical expertise of these other organizations in one seamless national accreditation system that achieves national goals as well as international recognition.



BEST PRACTICE

NiNAS is an associate member of the African Cooperation for Accreditation (AFRAC) and attends IAF and ILAC meetings. Application for affiliate membership in ILAC has been made and associate membership will be sought once NiNAS has completed a number of laboratory accreditations.



SUSTAINABILITY

The greatest challenges during development of the NiNAS are:

- ▶ Ensuring accreditation prerequisites are in place such as access for laboratories to Proficiency Testing programs and access to traceable calibration providers;
- ▶ Making certain that CABs that are ready for accreditation in terms of standard implementation;
- ▶ Convincing CABs on accreditation in the absence of technical regulations that mandate accreditation; and
- ▶ Obtaining the required medium term financing.

The greatest challenges envisioned for the first few years of operation are:

- ▶ Ensuring stability of financing; and
- ▶ Maintaining the needed expertise for auditing and assessment.

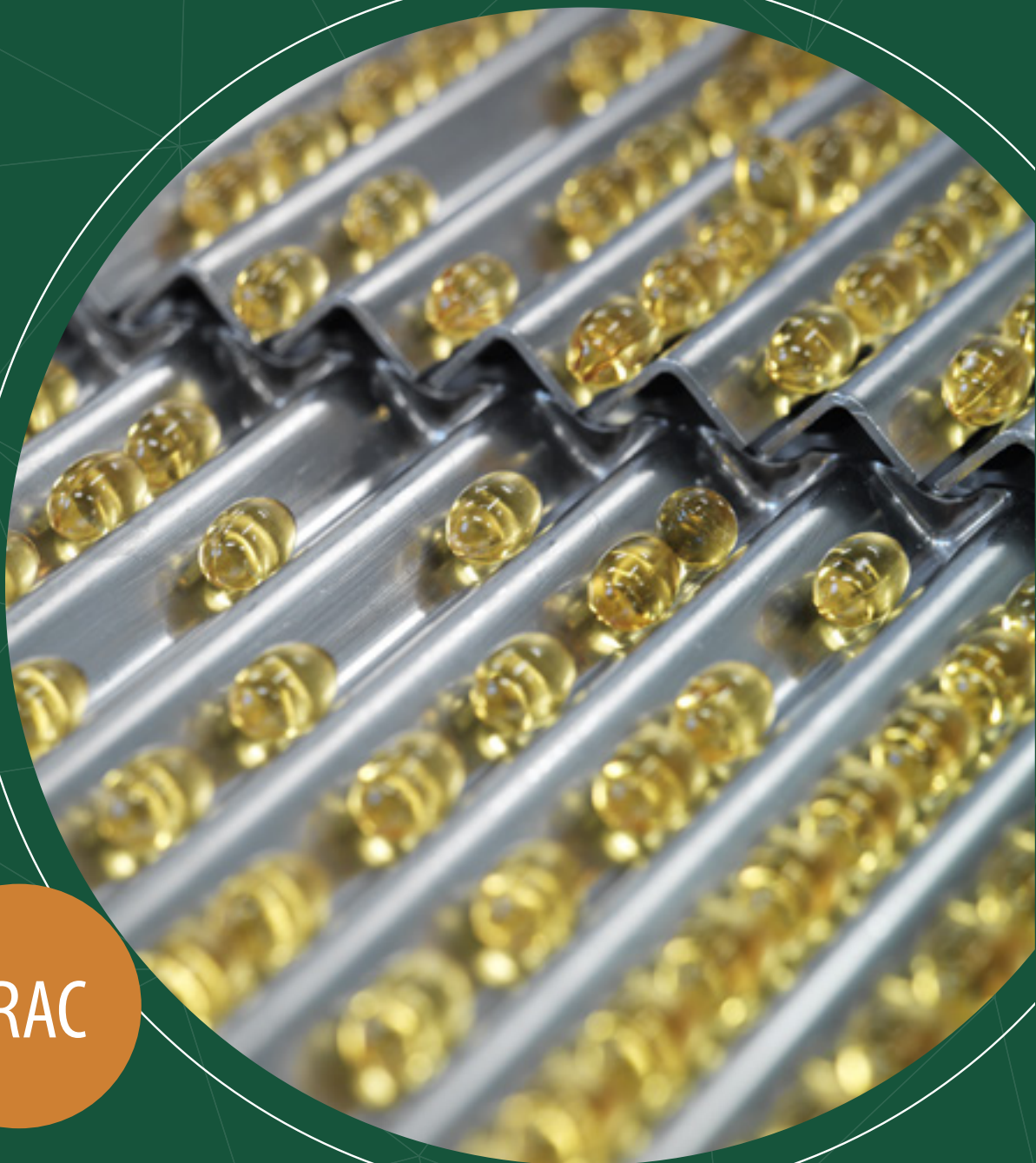
To date the greatest lessons learned during the establishment of NiNAS has been:

- ▶ Guaranteeing that there is a sufficient pool of CABs that are ready to apply for accreditation before launching the organization;
- ▶ Ensuring the CABs have access to the prerequisites for accreditation and have the systems in place prior to launching the organization; and
- ▶ Ensuring there is sufficient understanding about accreditation in the economy to result in a demand for accreditation, such as its specification in technical regulations.

Challenges: To work closely with those stakeholders that have accreditation roles defined in legislation, in order to ensure the smooth establishment of the accreditation body as per international best practices.

► Case Study 5

Arab Accreditation Cooperation



ARAC



NAME OF THE ACCREDITATION BODY

Arab Accreditation Cooperation (ARAC)



CRITERIA FOR MEMBERSHIP OF THE REGION

The ARAC membership is divided into four categories which define their rights and obligations under the ARAC implementing regulations:

Full member: All third party accreditation bodies, legally established and operating in the nations or bloc of nations in the Arab region, committed to operate according to the requirements of ISO/IEC standards, guides and the relevant requirements of IAF and ILAC.

Associate member: Organizations in the nations or bloc of nations of the Arab region intending to become accreditation bodies where no accreditation body has been established and operating; Other international, regional and national organizations that are interested in conformity assessment and accreditation and are not included in the Stakeholder Member category;

Stakeholders members: International, regional and national organizations having an interest in the work of ARAC and include bodies such as associations of conformity assessment bodies (CABs), purchasing organisations, regulatory authorities, consumer associations and trade organisations from the Region.

Affiliate member: Non-Arab accreditation bodies which are committed to operate according to the requirements of ISO/IEC standards, guides and the relevant international documents of IAF and ILAC.



ECONOMIES CURRENTLY COVERED BY THE REGION

The current membership of ARAC includes 15 members covering 17 Arab countries (**Algeria, Bahrain, Egypt, Iraq, Jordan, Kuwait, Libya, Mauritania, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Sudan, Tunisia, United Arab Emirates & Yemen**). Among the ARAC 11 full members, three are ILAC MRA and IAF MLA signatories: (Dubai Accreditation Center, Egyptian Accreditation Council and Tunisian Accreditation Council).



ORGANIZATION

Following the 95th Ministerial Economic and Social Council meeting of the League of Arab States [LAS], held on 19th February 2015 at LAS headquarters, in Cairo, Egypt, the Ministerial Economic and Social Council recognized ARAC as one of the main pillars of the Pan Arab quality infrastructure for the support of intra-regional trade and the Arab Customs Union. In addition, ARAC is one of the main pillars of the Pan-Arab quality infrastructure established by Ministerial Decree of the Arab Industrial Development and Mining Organization (AIDMO), in June 2008.



FINANCIAL

Currently, ARAC is supported by UNIDO. The ARAC Bylaws state that the members will pay fees as determined by the ARAC General Assembly. In addition, a decision taken during the 8th ARAC Executive Committee meeting held in Abu Dhabi, UAE on 12 February 2015, committed ARAC to develop a Strategy Business plan and Sustainability Plan for the period 2016 – 2021. Based on these documents ARAC will be implementing decisions related to its sustainability at its next GA meeting.



ESTABLISHMENT OF THE REGIONAL COOPERATION BODY

After consultations and discussions at regional level made under the High Consultative Accreditation Committee of AIDMO between the period 2000 -2008, and following the Ministerial Decree of the AIDMO regarding the establishment of ARAC, the UNIDO - AIDMO - SIDA “Swedish International Development Cooperation Agency” project was initiated to support the establishment of ARAC. It commenced with the approval of the first draft of the ARAC Bylaws in 2011 by 12 Arab countries.

The Organizational Structure of ARAC

The ARAC currently includes a General Assembly, an Executive Committee, Secretariat, Technical Committee, MLA Committee and Communication & Marketing Committee. There are also working groups that are assembled on demand, such as the Mapping Group, assembled for the purpose of developing roadmaps for accreditation system development within the Region.



General Assembly (GA): Comprised of all the members, it is the highest authority of ARAC.

Executive Committee: Consists of ARAC Chair, ARAC Committees Chairs, ARAC vice Chair, one member from ARAC associate members.

ARAC Secretariat: The main responsibilities of the ARAC Secretariat are:

- ▶ To do the daily business of ARAC including maintaining records and documents;
- ▶ To coordinate with ARAC members and follow up the implementation regarding the actions approved by the ARAC GA and EC;
- ▶ To prepare for the ARAC General Assembly and Executive Committee meetings and their minutes;
- ▶ To represent ARAC to the judicial and legal authorities.

Technical Committee: Is the forum for the discussions of all technical matters related to the accreditation of CABs.

ARAC MLA Committee: The main objectives of the MLA Committee are :

- ▶ To plan and manage the implementation and maintenance of ARAC Multilateral Recognition Arrangements (MLA);
- ▶ To decide on and manage membership in the ARAC MLA.

ARAC Communication and Marketing Committee: To provide support to the development of ARAC's activities in all matters related to promotion, internal and external communications.

The ARAC MLA

The ARAC MLA is a signed agreement among Full Members whereby they recognize and accept the equivalence of the accreditation systems operated by each other, as well as the reliability of the conformity assessment results provided by CABs accredited by the Members.

This recognition is based on the proper operation of the accreditation systems of the signatories to the MLA. To maintain confidence among the signatory bodies the following activities are implemented:

- ▶ Participation in peer evaluation and re-evaluation;
- ▶ Exchange of information on the development and operation of accreditation systems;
- ▶ Participation of personnel from ARAC MLA members in assessment, re-assessment or surveillance visit to conformity assessment bodies performed by other ARAC MLA member bodies;
- ▶ Participation in ARAC Committees meetings.



The scope of the ARAC MLA, as endorsed by the ARAC General Assembly is the following:

- ▶ Accreditation of Testing Laboratories (Test) (ISO/IEC 17025);
- ▶ Accreditation of Medical Testing Laboratories (Test) (ISO 15189);
- ▶ Accreditation of Calibration Laboratories (Cal) (ISO/IEC 17025);
- ▶ Accreditation of Inspection Bodies (Insp.) (ISO/IEC 17020);
- ▶ Accreditation of Management Systems Certification Bodies (MS) (ISO/IEC 17021):
 - › QMS (ISO 9001);
 - › EMS (14001);
 - › FSMS (ISO 22000).



RELEVANCE AND IMPACT

Importing goods and services with an ARAC MLA-accredited report or certificate can be both less risky and cheaper because accreditation confirms conformity to recognized standards of consistency and quality and can therefore also avoid the costs of re-testing. The ARAC MLA helps remove barriers to trade and supports development of a free market in the Arab region. After achieving the International recognition of the ARAC MLA, its ARAC MLA also opens new opportunities on the global market.



BEST PRACTICE

In December 2012, ARAC has been accepted by ILAC as Regional Cooperation Body and in September 2013 as an IAF Special Recognition Organization - Regional Accreditation Group Member. Since that ARAC is an active member in their committees and working groups. In April 2015 ARAC submitted its application for the recognition of its MLA for the following scope:

- ▶ Accreditation of Testing Laboratories (Test) (ISO/IEC 17025);
- ▶ Accreditation of Calibration Laboratories (Cal) (ISO/IEC 17025);
- ▶ Accreditation of Inspection Bodies (Insp.) (ISO/IEC 17020);
- ▶ Accreditation of Management Systems Certification Bodies (MS) (ISO/IEC 17021):
 - › QMS (ISO 9001);
 - › EMS (14001).

The peer evaluation process of ARAC by ILAC&IAF already started and the upcoming peer evaluation of the ARAC Secretariat will be in September 2016.



SUSTAINABILITY

In the development of ARAC the biggest challenges faced were:

- ▶ Convincing accreditation body members to believe in the success of the cooperation;
- ▶ Supporting non-recognised Accreditation bodies to reach signatory status;
- ▶ Establishing and implementing the ARAC MLA process;
- ▶ Involving ARAC in the international activities at ILAC&IAF levels.

The main challenges foreseen are:

- ▶ The evolution of the cooperation and the level of the performance of the ARAC committees;
- ▶ More commonality to support and advise regulators to reference accreditation in legislation;
- ▶ Improved harmonization of peer evaluators in order to increase consistency in evaluations.

Many objectives as fixed by ARAC are being achieved, namely:

- ▶ Promote cooperation to train peer evaluators and other personnel of accreditation bodies;
- ▶ Encourage and facilitate the adoption and implementation of applicable documents and guidelines that have been developed by IAF and ILAC;
- ▶ Facilitate collaboration, cooperation and mutual assistance among members by various means;
- ▶ Obtain International recognition of its MLA by ILAC&IAF.

► Case Study 6

Southern African Development Community Accreditation Service



SADCAS



NAME OF THE ACCREDITATION BODY

Southern African Development Community Accreditation Service (SADCAS)



THE ECONOMIES CURRENTLY SERVED

A total of 13 Southern African Development Community (SADC) Member States namely: **Angola; Botswana; Democratic Republic of Congo (DRC); Lesotho, Madagascar; Malawi; Mozambique; Namibia; Seychelles; Swaziland; Tanzania; Zambia; and Zimbabwe**, are serviced by SADCAS.



ORGANIZATION

SADCAS is a multi-economy accreditation body established in terms of Article 15 B of the Technical Barriers to Trade (TBT) Annex to the SADC Protocol on Trade with the primary purpose of ensuring that conformity assessment service providers operating in those SADC Member States which do not have national accreditation bodies are subject to an oversight by an authoritative body. SADCAS was registered in December 2005 as a not for profit company limited by guarantee under the Botswana Companies Act, 2003 (Act No. 32 of 2004). SADCAS was approved by the SADC Council of Ministers in August 2007 as a Subsidiarity Institution of SADC. The relationship between SADCAS and SADC is formalized through a Memorandum of Understanding (MOU) on General Cooperation which serves as the basis for the recognition of SADCAS, by SADC Member States, as a multi economy accreditation body. The objects, powers and rules for the operation of SADCAS are set out in the Memorandum and Articles of Association lodged with the Registrar of Companies, Botswana. SADCAS Headquarters are situated at Gaborone, Botswana.

SADCAS is governed by a General Assembly which comprises of:

- ▶ Subscribers to the Memorandum and Articles of Association;
- ▶ Members of the Board of Directors;
- ▶ Appointed representatives of National Accreditation Focal Points (NAFPs) in each SADC Member State using the service of SADCAS; and
- ▶ Individuals or organizations who apply for admission as members of SADCAS.

SADCAS is composed of three functional units. The technical unit, responsible for technical aspects of accreditation including the management of assessors. The administration unit, responsible for ensuring that all administration needed to effect the assessment processes are effectively managed. The financial administration unit, responsible for financial management, human resources management and general administration of the company.



National Accreditation Focal Points (NAFPs) established by the governments of the SADC Member States using the services of SADCAS serve as the administrative link between SADCAS and clients/potential clients in Member States and are mainly responsible for marketing and promoting accreditation in their respective countries.

As at 31 March 2016, SADCAS had a staff compliment of 8 staff: the CEO; Technical Manager; Financial Administrator; 2 Lead Assessors; 2 Accreditation Administrators; and an Administrative Assistant.



ESTABLISHMENT OF SADCAS

The Southern African Development Community (SADC) is a regional bloc established by a Treaty in 1992 to achieve development and economic growth, alleviate poverty and enhance the standard and quality of life of its people. The bloc consists of 15 Member States namely: Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. The SADC Free Trade Area (SADC FTA) was launched in August 2008. Industrialization and regional integration are key to the development of SADC Member States' economies. The SADC Industrial Policy identifies the priority sectors for development and further recognizes the need for the accreditation of conformity assessment service providers so as to ensure the quality and quantity of supplies and to prove conformity of exports with international standards. SADCAS was therefore established to provide assurance of conformity assessment bodies' competence thus meet accreditation needs of SADC Member States.

Within the SADC region only South Africa and Mauritius have their own national accreditation bodies. The rest of the SADC Member States i.e. 13 in all are serviced by SADCAS. SADCAS was conceptualized in 1996 by a group of experts from the region with input from international accreditation experts. In developing the model for SADCAS, the group of experts took into account:

- ▶ The cost of establishing an accreditation body;
- ▶ The cost of sustaining such a body which is based on the number of conformity assessment bodies operating in that country;
- ▶ The need to optimize limited resources be they technical, financial etc.; and
- ▶ The need to develop the technical expertise in the area of accreditation.

Upon conception, the SADCAS model realized that some countries may in future establish their own national accreditation bodies and would benefit from SADCAS experience. However a number of countries indicated that they would not establish accreditation bodies in the immediate to long term. A good 10 years was spent developing the model and getting its approval by the region and acceptance by the international accreditation fora being the first multi-economy accreditation body in the world.



RELEVANCE AND IMPACT

SADCAS provides accreditation services and training in accreditation associated activities. SADCAS offers the following accreditation programmes for CABs:

- ▶ Calibration Laboratories Accreditation Programme (CLAP) in accordance with ISO/IEC 17025;
- ▶ Testing Laboratories Accreditation Programme (TLAP) in accordance with ISO/IEC 17025;
- ▶ Medical Laboratories Accreditation Programme (MLAP) in accordance with ISO 15189;
- ▶ Management Systems Certification Bodies Accreditation Programme (CBAP–MS) in accordance with ISO/IEC 17021;
- ▶ Inspection Bodies Accreditation Programme (IBAP) in accordance with ISO/IEC 17020;
- ▶ Personnel Certification Bodies Accreditation Programme (CBAP – Pers) in accordance with ISO/IEC 17024; and
- ▶ Product Certification Bodies Accreditation Programme (CBAP – P) in accordance with ISO/IEC 17065.

SADCAS will broaden its scope of accreditation programs as needs arise. SADCAS accreditation services were kick started through a Twinning Partnership Arrangement (TPA) with the South African accreditation body (SANAS) in December 2009 in order to ensure credibility of services whilst transferring skills to SADCAS. In an effort to address the accreditation needs of DRC and Madagascar where the business language is French, another TPA was entered into with the Tunisian Accreditation Council (TUNAC) under which a number of applications for accreditation from DRC are being handled. Plans are underway to address the accreditation needs of Angola and Mozambique where Portuguese is the business language. SADCAS will be ready to process applications in Portuguese in the last quarter of 2017. Meanwhile any applications received from these countries in English will be handled by SADCAS whilst applications in Portuguese will be referred to IPAC (Portugal). Following the achievement of signatory status in the AFRAC and ILAC MRAs for testing (ISO/IEC 17025) and calibration (ISO/IEC 17025) in October and November 2015 respectively, the SADCAS/SANAS TPA now only covers all the other accreditation programmes for which signatory status has not yet been achieved. The same applies to the SADCAS/TUNAC TPA which going forward will only be limited to those accreditation programmes for which signatory status has not yet been achieved.

In order to determine the number of CABs operating in the region, their accreditation status and accreditation needs, surveys were undertaken initially in 2005 and then in 2011/12. The 2011/12 survey was undertaken through the network of NAFPs to reach out to the CABs in the 13 SADC Member States serviced by SADCAS. The information from the surveys was used for strategic planning purposes including prioritization of accreditation programmes to develop and training services to focus on.

SADCAS is now in its 7th year of operation as a multi economy accreditation body and significant progress has been made in fulfilling SADCAS' mandate. By 31 March 2016 SADCAS had issued 67 accreditation certificates to 50 accredited facilities in 8 SADC Member States namely: Botswana (12), Mozambique (1), Namibia (5), Seychelles (2), Swaziland (1), Tanzania (13), Zambia (3) and Zimbabwe (13). Most of the accredited facilities (48%) fall under the testing laboratories (ISO/IEC 17025) accreditation programme, followed by 26% under the medical laboratories (ISO 15189) accreditation programme, 18% under the calibration laboratories accreditation programme and 8% under the inspection bodies' accreditation programme.



BEST PRACTICE

SADCAS is:

- ▶ A full member of the International Laboratory Accreditation Cooperation (ILAC);
- ▶ An accreditation body member of the International Accreditation Forum (IAF);
- ▶ An arrangement member of the African Accreditation Cooperation (AFRAC); and
- ▶ An ordinary member of the SADC Cooperation in Accreditation (SADCA).

SADCAS is signatory to the AFRAC and ILAC MRAs for testing (ISO/IEC 17025) and calibration (ISO/IEC 17025). SADCAS is working towards signatory status of the other programmes and has prioritized medical (ISO 15189) and inspection (ISO/IEC 17020) accreditation programmes for which it has gathered adequate competence and intends to apply for scope extension by September 2016.

National Accreditation Focal Points who are employed by their respective governments serve as administrative links to clients and potential clients in Member States. Upon engagement, staff and NAFPs were attached to internationally recognized accreditation bodies. Both SADCAS staff and NAFPs undergo continuous professional development to keep up with developments in their respective professions. Training needs are identified on an ongoing basis and through performance reviews undertaken based on the Balanced Score Card Performance Management System. At the same time SADCAS has access to expertise from the Board, Committees, assessors and experts.

Training of assessors started in 2005 with the first group of 17 experts being trained. The 2-stage training program was funded by PTB Germany. Another group of experts from the region was trained as assessors in 2009 to 2010 under the auspices of the SADC SQAM EU EDF 9 project. In 2011, 47 assessors were mentored under a project which was funded by PTB Germany. In July/August 2014 another 25 experts from the region underwent a technical assessor (ISO/IEC 17025) training course. The training program was undertaken under the auspices of the SADC EU regional Integration Support (REIS) Program of which 22 proceeded to the mentoring in February/March 2016. In January/February 2016 another group of 40 experts were trained as assessors (ISO 15189 and ISO/IEC 17020) and will undergo mentoring during the 2016/17 financial year.

By 31 March 2016 SADCAS had registered 70 technical assessors and 34 Lead assessors who undertake assessments on behalf of SADCAS. The pool of assessors is still very limited taking into account the field and scope of accreditation services offered by SADCAS, geographical and language diversity of the countries serviced by SADCAS. As much as possible assessors have to be locally based so as to minimize the accreditation costs. Currently travel and subsistence constitutes almost 55% of the accreditation costs which can be reduced if assessors are locally based. The challenge of limited pool of assessors is being addressed through the ongoing training of assessors, use of assessors from other accreditation bodies and use of assessors from SADC Cooperation in Accreditation (SADCA) member accreditation bodies based on an agreement resolved at the SADCA annual general meeting.



SUSTAINABILITY

Being a fairly young organization, SADCAS' thrust has been on marketing and promoting the benefits and importance of accreditation, creating awareness on the existence of SADCAS, and marketing its services. Missions to Member States were undertaken in 2009. Accreditation awareness seminars are ongoing.

SADCAS generates its own income from accreditation services and training on accreditation associated activities, with governments of Member States that are serviced by SADCAS meeting the administration budget shortfall.

The set up and operationalization of SADCAS were the main components of a 5 year integrated programme for the removal of TBTs through accreditation which was funded by the Norwegian Government to the tune of US\$ 2.2 million through the Norwegian Agency for Development Cooperation (NORAD). The funding covered SADCAS infrastructure, operational costs, IT and capacity development of NAFPs and project management costs. The funding was phased out over a defined period of time and the project came to an end in March 2012 at a time when SADCAS had not yet achieved targeted accreditations or achieved break even on operational costs.

In August 2012 a proposal was made through SADC for Governments of Member States serviced by SADCAS to contribute towards SADCAS sustainability. Meanwhile SADCAS went into the 2012/13 financial year with a deficit budget and no funding assured for SADCAS sustainability for the period 2012 to 2017. Bridging funding was availed by NORAD, controls were put in place to minimize expenditure, and funding was secured from various cooperating partners to fund critical activities. In 2013 governments of SADC Member States that are serviced by SADCAS committed to contribute towards SADCAS sustainability, with most governments indicating that they would only be able to start contributing in 2014/15 financial year. In view of the urgency in funding requirements an appeal was made to those Member States which contribute to do so during the 2013/14 financial year and Zimbabwe and Mozambique came to the rescue with more governments contributing in subsequent years and some still to contribute.

Over the past 7 financial years since SADCAS started to offer services, operational income has been steadily growing while its dependency on donor/government support has been decreasing. Donor/Government dependency reduced to 31% by 31 March 2015, from 100% in 2008/9. By 31 March 2015 accreditation income constituted 66 % and training 34% of the operational income.

The multi economy accreditation body is a viable and cost effective means of meeting accreditation needs of a number of countries. Government support is critical during the establishment and operationalization stages, the most challenging phase in the development of any organization. Whilst it is desirable for SADCAS to become self - sustaining, this will not be achieved overnight.

► Case Study 7

Sri Lanka Accreditation Board for Conformity Assessment



SLAB



NAME OF THE ACCREDITATION BODY

Sri Lanka Accreditation Board for Conformity assessment (SLAB)



ECONOMY

Sri Lanka



ORGANIZATION

The Sri Lanka Accreditation Board for Conformity Assessment (SLAB) was established as a corporation by an Act of Parliament, No. 32 of 2005, and commenced its operations in January 2006. SLAB is the national accreditation authority for Sri Lanka and functions as an autonomous body under the then Ministry of Science, Technology and Research. As at December 2015, SLAB has 24 internal staff and uses assessors contracted from an external pool which exceeds 200 in number. SLAB has to date accredited 70 facilities and has issued about 100 accreditations (details are on SLAB website at <http://slab.lk/Default.aspx>).

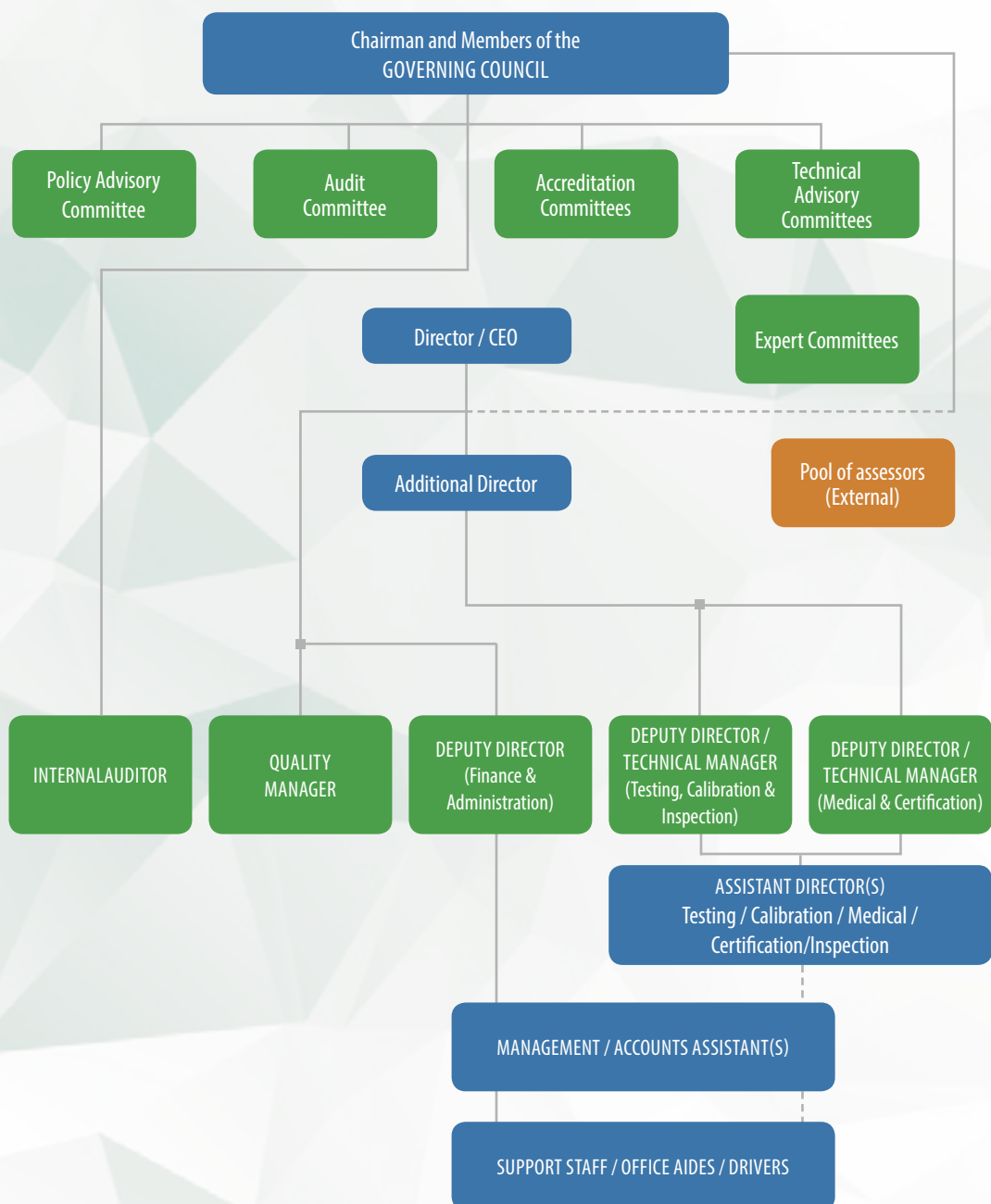
According to the Act, SLAB is governed by a 13-member Council constituted as follows: 6 representatives of different ministries; 3 members from the fields of science, technology, education, trade, industry or administration; 1 representative from the Sri Lanka Standards Institution; 1 representative from Department of Measurement Units, Standards and Services, appointed by the Minister in charge of that Department; 1 representative of the National Academy of Sciences; and 1 representative from the Federation of Chambers of Commerce and Industry.

Although the Council is predominantly composed of representatives of ministries and public bodies, in accordance with provisions under the Act, SLAB has appointed a Policy Advisory Committee (PAC) with one representative from each of the following bodies: Institution of Engineers of Sri Lanka, Sri Lanka Association of Testing Laboratories, Sri Lanka Food Processors Association, Central Environment Authority, National Chamber of Commerce, National Chamber of Exporters of Sri Lanka, Consumer Affairs Authority, Food Authority, Ministry of Healthcare, Ceylon National Chamber of Industries, Institute of Chemistry Ceylon, Department of Labour, Federation of Chambers of Commerce and Industry, and Ceylon Chamber of Commerce.

The PAC advises the Governing Council of SLAB on all policy matters concerned with the development and operation of SLAB's accreditation activities. In view of the fact that it is composed of mostly non-governmental interest groups, a balance of interests is maintained such that the governance of SLAB is structured to safeguard the critical requirements for impartiality as specified in "ISO/IEC 17011:2004, Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies".



SLAB organizational structure is as follows:





ESTABLISHMENT OF SLAB

As is typically the case in many developing countries, the need for having accredited test reports to demonstrate conformity of products destined for export came from abroad; in particular, export of fishery products from Sri Lanka to the EU. In response to these external requirements, the Government approached the Swedish International Development Cooperation Agency (SIDA) for assistance to establish an accreditation body in Sri Lanka.

Between 1995 and 2003, the then Ministry of Science and Technology implemented a technical assistance programme supported by SIDA which consisted of bringing the Sri Lanka Standards Institution (SLSI) together with the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) to provide accreditation services locally. Accordingly, the Accreditation Scheme for Testing Laboratories (ASTEL) was established at SLSI.

The National Quality Policy (NQP¹) of Sri Lanka was initially developed by SLSI with the assistance of SWEDAC as part of the first SIDA project from 1995 to 2003. By taking the route of defining the needs of the national quality infrastructure for the country, Sri Lanka ensured that the rationale for establishing accreditation services, first through ASTEL and SWEDAC and then through SLAB and SWEDAC was founded on a sound basis. Given the time required to set-up an accreditation body and achieve its international recognition, the decision was made to set up a parallel system for providing accreditation services that could be immediately recognised internationally through ASTEL/SLAB and SWEDAC. The start of operations of SLAB thus bridged seamlessly with the results achieved under the ASTEL. SLAB started by providing accreditation services to testing laboratories, since the ASTEL scheme had previously accredited 8 laboratories, services were then expanded to calibration laboratories, medical laboratories, certification bodies and inspection bodies, with a priority for chemical and microbiological laboratories.

The partnership between SLSI and SWEDAC ensured a number of important elements:

- ▶ International recognition of Sri Lankan laboratories;
- ▶ Building local knowledge and capacity in accreditation; and
- ▶ Assistance in the development of SLAB legislation which was passed by Parliament in 2005, following the provision of technical assistance.

Overall, SWEDAC's technical assistance to SLAB comprised of:

- a.** Development of quality manuals, procedures and methods of SLAB;
- b.** Training of assessors for SLAB accreditation schemes;
- c.** Joint assessments of laboratories with participation of SWEDAC and SLAB performed in Sweden and Sri Lanka;
- d.** Participation of a selected number of SLAB officials in SIDA's international training programme on 'World Trade and Conformity Assessment, Quality Infrastructure Development';
- e.** Support to SLAB to develop and install a computerised system to manage accreditation activities and a public website (www.slab.lk);
- f.** Support in participating in international and regional laboratory accreditation cooperation bodies.



A significant capacity-building objective was achieved through the joint assessments under (c) above as this was real-world field experience.

Once SLAB was legally established in 2005, the Sri Lanka Ministry of Science and Technology requested and obtained SIDA's support for the development and strengthening of the national quality infrastructure. In April 2007, a 3-year contract funded by SIDA for the delivery of consulting services was signed between the Ministry of Science and Technology in Sri Lanka and SWEDAC.



RELEVANCE AND IMPACT

SLAB was established for the purpose of ensuring that the results of testing, certification and inspection were recognized which was critical for supporting the export sector. From experience gathered during the last 10 years of SLAB's existence, it is clear that Sri Lankan regulatory bodies and industry in general rely to some extent on conformity assessment results from SLAB-accredited bodies as a basis for technical decisions. The trust in SLAB accreditation schemes was reinforced after it achieved international recognition.

Prior to SLAB's international recognition these recognized accreditation services were provided by several foreign accreditation bodies, including RvA (Netherlands), UKAS (United Kingdom), SWEDAC (Sweden), and NABL (India). However the high costs charged by these bodies and the significant delays in obtaining accreditation were problematic. Although SLAB is now fully operational, some foreign bodies still provide a small number of accreditations in Sri Lanka.

Although SLAB provides services for many schemes, the number of accreditations in some areas are small, for example accreditation for the certification of persons. The scope of accreditation services provided are found on SLAB's website. No study has yet been conducted to determine the impact of SLAB accreditation on the industry.



BEST PRACTICE

SLAB has been admitted for the following mutual recognition arrangements (MRA)/Multilateral Recognition Arrangement (MLA):

- ▶ ILAC and APLAC MRA for testing, against ISO/IEC 17025 and ISO 15189, (since 2009) and calibration (since 2012);
- ▶ IAF and PAC MLA for ISO 9001, ISO 14001 & ISO/IEC 17065 (since 2014);
- ▶ IAF & PAC MLA for ISO 22000 (since 2015).

SLAB has applied for APLAC MRA for inspection and PAC MLA for GHG validation & verification (as of November 2015).



SUSTAINABILITY

One of the biggest challenges faced when developing SLAB was the approval of legislation. Although under the first SIDA project (1995-2003) the text of the Bill was finalized it was not passed before the project lapsed. As a result, SIDA made it a condition that any future support for the national quality infrastructure would be contingent on the law being approved. The law was approved in 2005 and SIDA launched the second project in 2007.

The Act established SLAB as an autonomous body which allows it to collect revenue and spend it in the way that is best for the organization. This is a huge advantage for public bodies which retain the flexibility of operations but can still avail themselves of public funding. In the case of SLAB, the ratio of Income over expenditure at December 2015 is 65%. It is expected that by 2020 that figure will be 100%, although full cost recovery is not a requirement under the Act or by government. It is clear that continuity of donor support was another key factor as it allowed the final results to be satisfactorily achieved. It is also important to highlight that the project implementation methodology, namely an institutional partnership with SWEDAC, was very effective due to the fact that the provision of the various training, consultancy and advisory services were coordinated by a single organization.

Another challenge for SLAB is operating in a small economy with limited market for accreditation services. In such cases it may be helpful for the accreditation body to be aware of various government industrial development projects and to assess whether national needs would also require investment in new accreditation services. If the answer is positive, then strengthening the accreditation body should be part of the project. As an illustration, an EU-funded project which aims at improving SME competitiveness for spices and food also provides for the technical capacity building of SLAB for the accreditation of personnel certification bodies and of producers of certified reference materials.

SIDA noted in 2011 that a key success factor was the strong Sri Lankan ministerial support and high awareness among other key stakeholders such as local laboratories. A weakness remains however in that regulators are still not fully engaged to agree that proof of compliance with regulations can be based on accredited conformity assessment results. If such was improved the demand for accreditation services would increase. In response, SLAB has a 5-year corporate plan which includes a business plan highlighting priority areas, goals, key performance indicators (KPIs) and targets. Creating public awareness and engaging regulators are two priority focus areas of the corporate and marketing plans.

► Case Study 8

National Institute of Quality – Directorate of Accreditation

A circular inset image showing several stacks of petri dishes containing yellow agar, likely in a laboratory setting. The dishes are arranged in a row, with the focus on the ones in the foreground.

INACAL-DA



NAME OF THE ACCREDITATION BODY

Accreditation Division of the National Institute of Quality (INACAL-DA)



ECONOMY

Peru



ORGANIZATION

INACAL's Directorate of Accreditation (INACAL-DA), was created on July 11 2014 by the "Law establishing the National System for Quality and the National Institute of Quality" (Law 30224). However, accreditation in Peru has existed since 1993; the name of the predecessor agency to INACAL-DA was the National Accreditation Service. This service also formed part of the institution called INDECOPI²¹.

The parent body of the Directorate of Accreditation is the National Institute of Quality (INACAL). It is the competent national authority that runs the policy and accreditation management, enjoys technical and functional autonomy and exercises functions nationwide. In addition to the Accreditation Directorate, INACAL has three more directorates, namely Standardization, Metrology and Strategic Development.

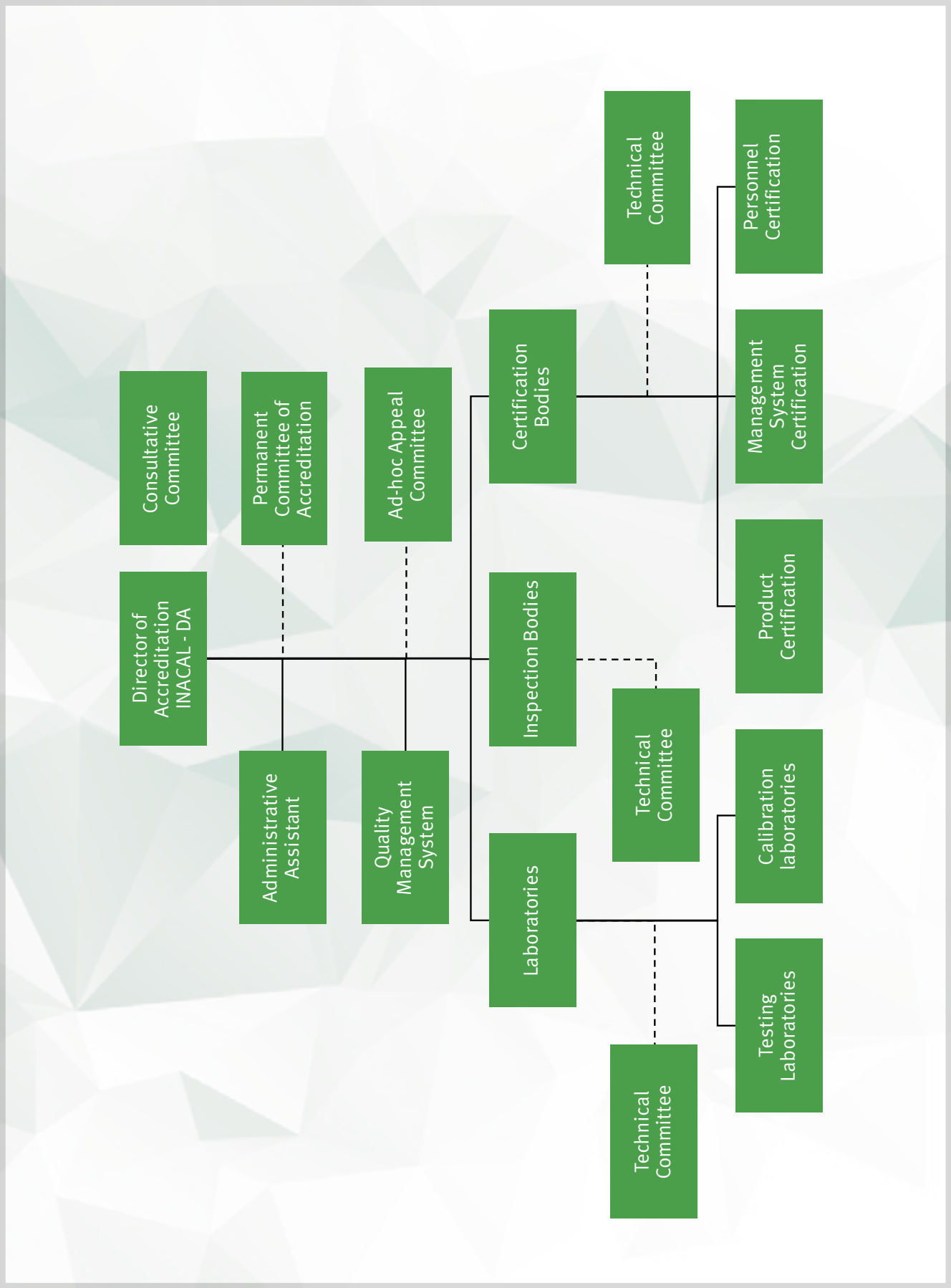
INACAL is a Specialized Technical Public Body attached to the Peruvian Ministry of Production, with legal public status. It has nationwide jurisdiction and administrative, functional, technical, economic and financial autonomy. INACAL is the governing body and maximum technical authority of the National Quality System.

The Directorate of Accreditation has 16 people on the technical side. However, INACAL has administrative staff supporting all the 4 directorates of INACAL; where approximately 15 more people are involved.

As of September 2016, there was a total of 144 valid accreditations issued by INACAL-DA:

- ▶ 75 Testing Labs;
- ▶ 18 Calibration Labs;
- ▶ 1 Quality Management Systems Certification Body;
- ▶ 2 HACCP Systems Certification Bodies;
- ▶ 5 Product Certification Bodies;
- ▶ 43 Inspection Bodies.

²¹ Instituto Nacional de Defensa de la Competencia y Protección de la Propiedad Intelectual





ESTABLISHMENT OF SLAB

A diagnosis of the National Quality System in Peru was carried out by an international consultancy organization, with particular focus on the strengths and weaknesses of standardization, accreditation and metrology, and its future outreach. One of the diagnostic findings was the need to create the INACAL as the governing body for quality in the country, one of whose directorates would be the National Accreditation Body. The diagnostic study was submitted for consultation and comments from various stakeholders, such as:

- ▶ Public sector entities such as the ministries of Economy, Production, Foreign Trade and Tourism, Health, and Agriculture;
- ▶ Institutions such as the National Competitiveness Council, and the National Council of Science and Technology;
- ▶ Private entities such as industry and business associations, Trade and Exporters;
- ▶ Academic Sector including Universities;
- ▶ Accredited Conformity Assessment Bodies.

Act No. 30224 created the National System for Quality and National Quality Institute (INACAL). Within INACAL, the Directorate of Accreditation was created and appointed as the National Accreditation Body. This law was published in the official newspaper “El Peruano”, on July 11th 2014.

There is a National Quality Policy, which was adopted on July 1st, 2014, through the Supreme Decree No. 046-2014-PCM. One of the specific objectives of this Policy is “To strengthen the institutional framework, in order to harmonize the components of the *quality infrastructure* to ensure effective management for the benefit of citizens and the competitiveness of economic agents.” When the Policy refers to *Quality Infrastructure*, it indicates that it covers the activities of standardization, metrology, accreditation and conformity assessment through testing, inspection and certification.

INACAL receives funding from the following sources:

- ▶ As assigned by the Annual Budget Law for the Public Sector according to the Annual Proposed Budget;
- ▶ Fees and charges levied in fulfilling its duties;
- ▶ From borrowing or donations, in accordance with current regulations;
- ▶ Revenue from the intellectual property rights of Peruvian Technical Standards and related texts, international and foreign technical standards according to agreements, income from subscription databases, revenue from dissemination activities, training and specialized technical assistance, resources from international technical cooperation, according to current regulations, as well as other activities compatible with each directorate, from public resources and/or grants that are intended for that purpose.

In relation to a business plan, INACAL has a medium-term Institutional Strategic Plan and annual goals, which seek to implement the National Quality Policy. There is currently a communications plan for marketing that includes a marketing plan to position INACAL both nationally and internationally.



RELEVANCE AND IMPACT

INACAL-DA was conceived based on the requirements of the country as well as the global trend to use accredited Conformity Assessment (CA) for the export of domestic products (mainly food), as was the case for consumer protection and domestic production.

INACAL –DA provides accreditation services in the following areas:

- ▶ Testing Laboratories; Calibration Laboratories
- ▶ Certification Bodies in Quality Management Systems (ISO 9001);
- ▶ Certification Bodies in Environmental Management Systems (ISO 14001);
- ▶ Certification Bodies in Occupational Health and Safety Management Systems (OHSAS 18001);
- ▶ Product Certification Bodies (Food products, plastics, etc.);
- ▶ Persons Certification Bodies;
- ▶ Inspection agencies.

Given that the Accreditation Directorate of INACAL is a signatory of the Multilateral/ Mutual Recognition Agreements in IAAC, IAF and ILAC, it has been contributing towards increasing the competitiveness of export products, obviating the need for additional certifications in the export destination country and reducing costs of production. While there are no specific measures in this regard, an increase in the number of applications for accreditation to meet the needs of domestic exporters can be observed.

While several factors have contributed to improving the country's economy, one can state that international recognition of INACAL-DA has also contributed to this improvement. For example:

- ▶ It increased the number of conformity assessment bodies - mainly laboratories and inspection bodies - which requested accreditation with INACAL-DA. Some even already had foreign accreditation and changed to accreditation in Peru to reduce their costs;
- ▶ CABs that already had accreditation, increased the accreditation scope;
- ▶ Increase in the number of public entities that requested the participation of accredited CABs for control and monitoring of their technical regulations;
- ▶ Improved competitiveness of our exports because the costs of conformity assessment were reduced. This, under the certificates issued in the country began to be recognized abroad;
- ▶ It increased confidence among producers, consumers and the State on the results of CABs accredited by INACAL.



BEST PRACTICE

INACAL – DA is a part of the IAAC, APLAC and PAC. Under the IAAC, INACAL is a signatory to the MLA for the accreditation of testing laboratories, calibration laboratories, certification bodies for Quality Management Systems, product certification bodies and inspection bodies. INACAL-DA is a member of IAF and ILAC.



SUSTAINABILITY

The biggest challenges faced in INACAL-DA development were:

- ▶ To train and strengthen the technical capabilities of INACAL staff;
- ▶ Expand and strengthen the technical capabilities of the Assessors and Technical Experts subcontracted by INACAL to carry out assessments;
- ▶ Raise public and private sector awareness for the use of accredited conformity assessment bodies;
- ▶ Coordinate with competent authorities in order for accredited bodies to carry out the control and surveillance of their respective technical regulations; and
- ▶ Promote country-wide growth of accredited bodies.

In relation to the future, the main challenges foreseen are with regards to the new accreditation schemes:

- ▶ Strengthening the technical capabilities of INACAL staff;
- ▶ Extending the work of INACAL to meet the needs of new accreditation schemes;
- ▶ Extending the scopes of Mutual/Multilateral Recognition Agreements (MRA), for example: clinical laboratories, proficiency testing providers, environmental management, occupational health and safety; food safety management is also a potential challenge;
- ▶ Increasing the number of accredited conformity assessment bodies nationwide.

Several of the desired objectives have been reached since the establishment of the AB, one of the main achievements was to become a signatory to the Mutual/ Multilateral Recognition Agreements in IAAC, IAF and ILAC. However, there is still a more to be achieved - the main objective is an increase in the number of nationally accredited bodies and to expand to new accreditation schemes.

The Main lessons learned during the establishment of INACAL-DA are:

- ▶ Maintain the technical competence of the accreditation personnel, Assessors and Technical Experts, through ongoing training and competency evaluation;
- ▶ Be able to count on a robust, dynamic and continually improving Management System;
- ▶ Work together with State sectors promoting the use of accredited CABs for the control and surveillance of their regulations;
- ▶ Promote the benefits of using the services of accredited CABs within the voluntary sector, these being: improving competitiveness, developing new products, etc.;
- ▶ To be at the forefront of issues on accreditation it is recommended to continually participate in the Technical Committees of the regional and international Accreditation Organizations;
- ▶ Maintain a presence in international forums and lead projects related to quality infrastructure.

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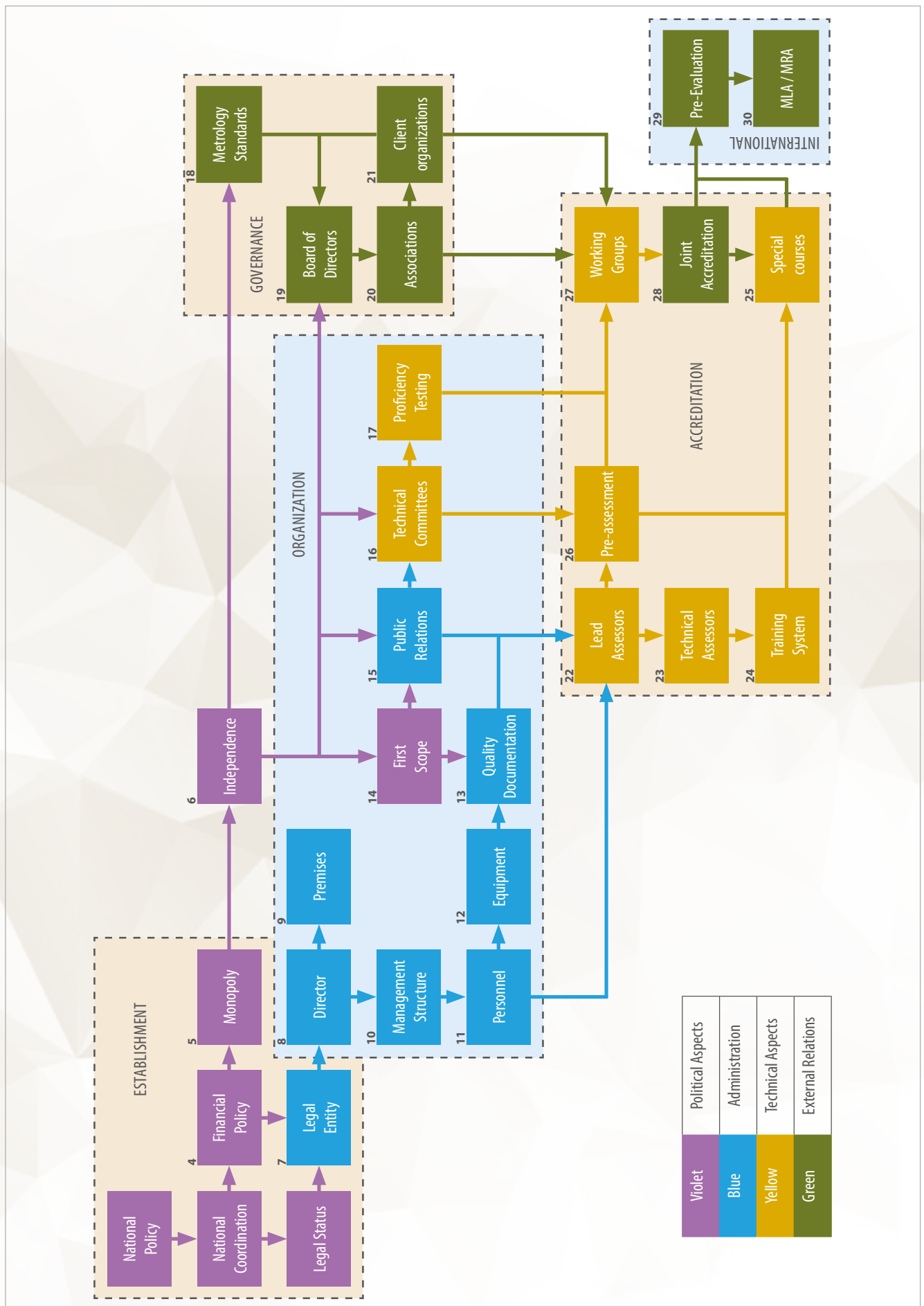
Annex 1

Building blocks for accreditation body establishment

Building blocks for a national accreditation body: UNIDO TCB Approach	
No.	Expected Outcome
1. NQI policy on accreditation	A Policy approved by the highest political levels on the establishment, scope and financing of a national accreditation body, including a decision in principle on the organizational form and structure.
2. National Coordination	Establishment of the coordination mechanism and authorities of the accreditation body amongst stakeholders, i.e. the Ministries, regulatory authorities, industry and civil society. May be included in the National Quality Policy.
3. Legal Status	Clear definition of the legal status of the national accreditation body as contained in legislation.
4. Financial Policy	Long term financial certainty for the accreditation body to ensure: <ul style="list-style-type: none"> its continued existence and operational fitness; appropriate membership of international and regional accreditation organizations; and continuous involvement in accreditation activities at the international and regional level.
5. Authority	Clear definition of the national accreditation body authorized to conduct accreditations in the regulated as well as non-regulatory domain and to represent the country in international and regional accreditation body for a.
6. Independence	An accreditation body that is demonstrably free from undue influences of authorities, agencies and other stakeholders.
7. Legal Entity	The national accreditation body established as a legal entity.
8. Director	Appointment of the accreditation body Director (CEO).
9. Premises	Appropriate premises for the accreditation body separated from any of the other NQI establishments.
10. Management Structure	Clear definition of management structure and approval thereof by the Board of Directors and line Minister.
11. Personnel	Appointment of relevant staff in managerial and technical positions in the accreditation body.
12. Equipment	IT and other equipment purchased, installed and users appropriately trained.
13. Quality Documentation	A complete set of quality policy and procedure manuals, work instructions and records approved by the peer review group.



14. First Scope	A clear definition of the first scope, aligned with the needs of the country, for which international recognition is sought.
15. Public Relations	An accreditation body well-known and respected amongst the stakeholders in public and private domains.
16. Technical Committees	Established technical committees able to provide the accreditation body management with technical advice appropriate to the defined scopes.
17. Proficiency Testing	Established proficiency testing schemes to support the accreditation of testing and calibration laboratories.
18. Metrology, Standards	Strong mechanisms for cooperation with the standards body and the metrology institutions.
19. Board of Directors	An effective Board of Directors established and properly functioning.
20. Associations	Industry and business organizations fully understanding the need and value of accreditation. An established stakeholder's forum to provide the accreditation body with advice on accreditation matters as they relate to the users.
21. Client Organizations	See 20 above.
22. Lead Assessors	A pool of properly trained and registered lead assessors appropriate for the scope of the accreditation body.
23. Technical Assessors	A pool of properly trained technical assessors appropriate for the scope of the accreditation body.
24. Training System	Establishment of a training department in the accreditation body for future lead assessors, technical experts and quality managers of accredited bodies.
25. Special Courses	Skilled officers to run an effective and efficient operation.
26. Pre-assessments	Successful pre-assessments of bodies that have applied for accreditation.
27. Working Groups	Effective working groups to support the accreditation body in establishing effective operations.
28. Joint Accreditations	Joint accreditation exercises that serve the purpose of enhancing the skills of the newly established accreditation body and provide an opportunity for it to benchmark itself.
29. Pre-Evaluation	A successful evaluation of the accreditation body by a peer evaluation group from ILAC, IAF, and/or regions.
30. MLA/MRA	Accreditation body a signatory of the ILAC and/or IAF MLA/MRA.



Annex 2

Useful sources of information



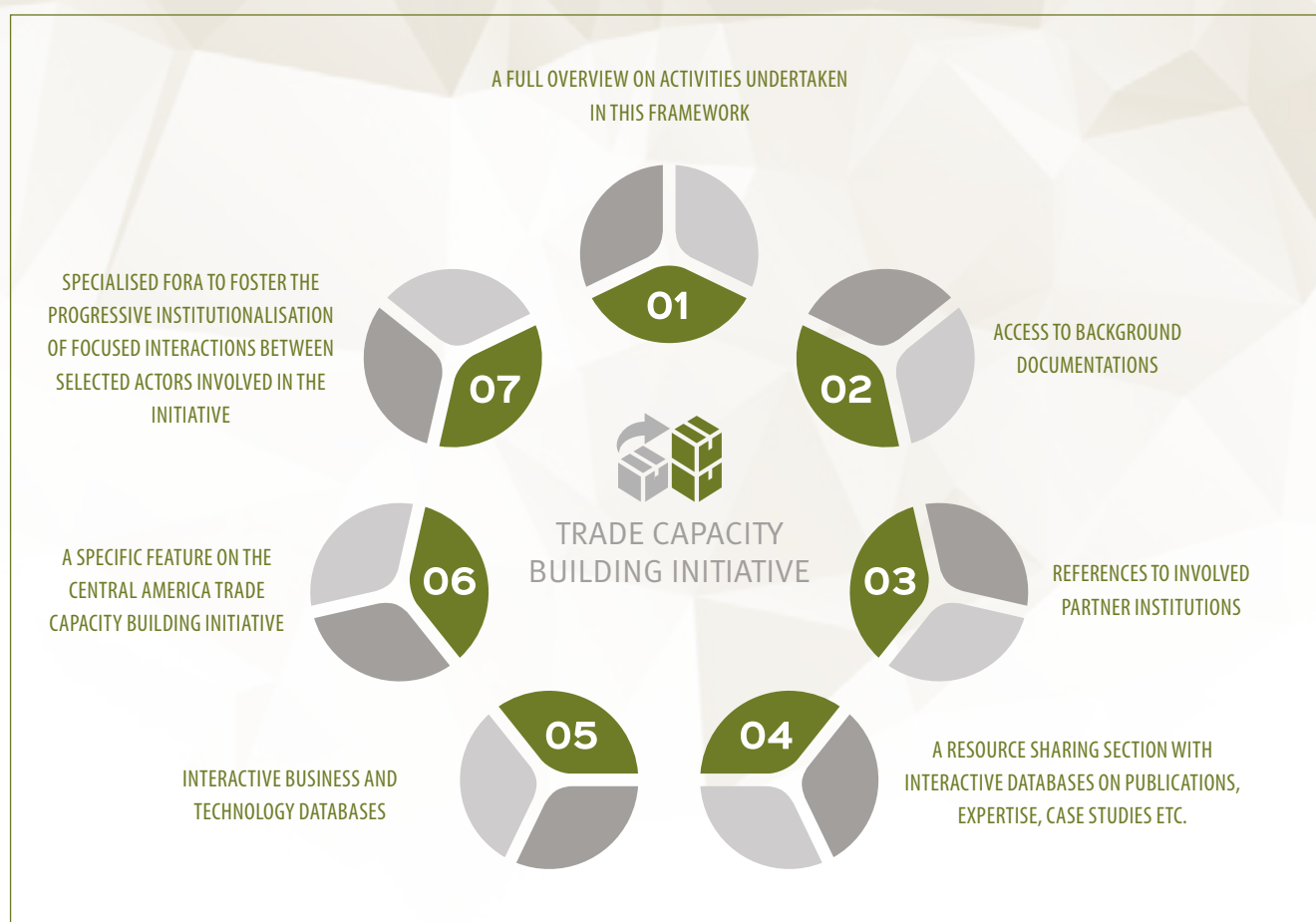
IAF and ILAC and their constituent regional cooperation body members (APLAC, PAC, EA and IAAC and the developing regions, AFRAC, ARAC and SADCA) have websites and produce newsletters on a regular basis. In addition, IAF and ILAC produce a number of brochures and information documents that are available by down-loading from their respective websites. Up-to-date copies of IAF and ILAC documents applicable to the peer review process, accreditation and conformity assessment bodies are available through the publications sections of their respective websites.

Individual Accreditation Body members also have websites containing information about their own accreditation programmes.

The ISO website contains information on the standards development process and all ISO standards including the set of standards applicable to conformity assessment, can be purchased at the ISO store accessible through the ISO site.

Most of these sites have links to other useful sites.

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 provides access to several knowledge-based areas of the Organization, such as the Trade Capacity Building Initiative, which offers the services listed in the figure below.



Annex 3

Key Websites



[1]	African Accreditation Cooperation www.intra-afrac.com
[2]	Arab Accreditation Cooperation www.arabarac.org
[3]	Asia Pacific Laboratory Accreditation Cooperation www.aplac.org
[4]	International Bureau of Weights and Measures www.bipm.org
[5]	European Accreditation www.european-accreditation.org
[6]	Inter-American Accreditation Cooperation www.iaac-accreditation.org
[7]	International Accreditation Forum (IAF) www.iaf.nu
[8]	International Laboratory Accreditation Cooperation (ILAC) www.ilac.org
[9]	ISO www.iso.org
[10]	ISO/CASCO www.iso.org/iso/Casco
[11]	Pacific Accreditation Cooperation www.apec-pac.org
[11]	Southern African Development Community Accreditation www.sadca.org
[12]	Southern African Development Community Accreditation Service www.sadcas.org
[13]	UNIDO www.unido.org
[14]	PUBLIC SECTOR ASSURANCE www.publicsectorassurance.org

Annex 4

Reference list of ISO/CASCO guides and standards by field of application



Note: this list of documents changes frequently as guides and standards are issued or updated and reissued. For the most updated listing please refer to the ISO/CASCO Standards Catalogue at the following website address:

http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=54998&published=on&includesc=true

Vocabulary, principles and common elements of conformity assessment	ISO/IEC 17000: 2004	Conformity assessment - Vocabulary and general principles
	ISO PAS 17001: 2005	Conformity assessment - Impartiality - Principles and requirements
	ISO PAS 17002: 2004	Conformity assessment - Confidentiality - Principles and requirements
	ISO PAS 17003: 2004	Conformity assessment - Complaints and appeals - Principles and requirements
	ISO PAS 17004: 2005	Conformity assessment - Disclosure of information - Principles and requirements
	ISO PAS 17005: 2008	Conformity assessment - Use of management systems - Principles and requirements
Product certification	ISO/IEC Guide 23: 1982	Methods of indicating conformity with standards for third-party certification systems
	ISO/IEC Guide 60: 2004	Conformity assessment - Code of good practice
	ISO/IEC Guide 68: 2002	Arrangements for the recognition and acceptance of conformity assessment results
	ISO/IEC 17065: 2012	Conformity assessment - Requirements for Certification Bodies certifying products
	ISO/IEC 17067: 2013	Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes
	ISO/IEC TR 17026: 2015	Conformity assessment - Example of a certification scheme for tangible products
Accreditation Bodies	ISO/IEC 17011: 2004	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
Inspection	ISO/IEC 17020: 2012	Conformity assessment - Requirements for the operation of various types of bodies performing inspection
System certification	ISO/IEC 17021-1:2015	Conformity assessment - Requirements for bodies providing audit and certification of management systems – Part 1: Requirements
	ISO/IEC TS 17021-2: 2012	Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 2 – Competence requirements for auditing and certification of environmental management systems
	ISO/IEC TS 17021-3: 2013	Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 3 – Competence requirements for auditing and certification of quality management systems
	ISO/IEC TS 17021-4: 2013	Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 4 – Competence requirements for auditing and certification of event sustainability management



System certification	ISO/IEC TS 17021-5: 2014	Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 5 – Competence requirements for auditing and certification of asset management systems
	ISO/IEC TS 17021-6: 2014	Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 6 – Competence requirements for auditing and certification of business continuity management systems
	ISO/IEC TS 17021-7: 2014	Conformity assessment – Requirements for bodies providing audit and certification of management systems Part 7 – Competence requirements for auditing and certification of road traffic safety management systems
	ISO/IEC TS 17022: 2012	Conformity assessment – Requirements and recommendations for the content of a conformity assessment third-party report on management systems
	ISO/IEC TS 17023: 2013	Conformity assessment – Guidelines for determining the duration of management system certification audits
Certification of persons	ISO/IEC 17024: 2012	Conformity assessment - General requirements for bodies operating certification of persons
	ISO/IEC 17027: 2014	Conformity Assessment – Vocabulary related to the competence of persons used for the certification of persons
Testing/calibration	ISO/IEC 17025: 2005	General requirements for the competence of testing and calibration laboratories
	ISO 17034	General requirements for the competence of reference material producers
	ISO/IEC 17043: 2010	Conformity assessment – General requirements for proficiency testing
Marks of conformity	ISO Guide 27: 1983 Reconfirmed in 2003	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
	ISO/IEC 17030: 2003	Conformity assessment - General requirements for third-party marks of conformity
Peer assessment	ISO/IEC 17040: 2005	Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Department of Trade, Investment and Innovation (TII)

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www.unido.org