Building trust

The Conformity Assessment Toolbox

Contents

i) About ISO 1

ii) About UNIDO 2

iii) Preface 3

iv) Disclaimer 5

v) Acknowledgements 5

vi) Introduction 6

vii) Acronyms and abbreviations 9

Chapter 1 Basic concepts of conformity assessment 11

Chapter 2 Conformity assessment techniques 29

46 Chapter 3 Conformity assessment schemes and systems

59 Chapter 4 Conformity assessment bodies

91 Chapter 5 What UNIDO can contribute to setting up a quality infrastructure

137 Chapter 6 Case studies

166 Appendix 1 ISO/CASCO sets conformity assessment standards

175 Appendix 2 The role of international and regional accreditation body forums

185 Appendix 3 Conformity assessment and the WTO Agreement on Technical Barriers to Trade

i) About ISO

ISO (International Organization for Standardization) is a global network that identifies which international standards are required by business, government and society, develops them in partnership with the sectors that will put them to use, adopts them by transparent procedures based on national, multi-stakeholder input, and delivers them to be implemented worldwide.

ISO standards distil an international consensus from the broadest possible base of stakeholder groups. Expert input comes from those closest to the needs for the standards and also to the results of implementing them. In this way, although voluntary, ISO standards are widely respected and accepted by public and private sectors internationally.

ISO – a non-governmental organization – is a federation of national standards bodies, from all regions of the world, one per country, including developed and developing countries as well as countries with economies in transition. Each ISO member is the principal standards organization in its country. The members propose the new standards, participate in their development and provide support in collaboration with ISO Central Secretariat for the 3000 technical groups that actually develop the standards.

Within ISO, the conformity assessment policy development committee ISO/CASCO has a dual function. It is responsible for developing and making recommendations on conformity assessment policy to the ISO/CASCO membership and for developing conformity assessment standards and guides.

ii) About UNIDO

The United Nations Industrial Development Organization (UNIDO) helps developing countries and countries with economies in transition to develop competitive and environmentally sustainable industry to accelerate economic growth, reduce poverty and achieve the Millennium Development Goals.

In pursuit of these objectives, UNIDO draws on global resources and expertise, and combines operational technical cooperation services with analytical, normative and convening activities, both globally and locally.

UNIDO holds a special place in the United Nations system as the only organization promoting the creation of wealth and tackling poverty through manufacturing. The Organization focuses on three inter-related thematic priorities : poverty reduction through productive activities, trade capacity-building, and energy and environment

UNIDO has 173 Member States and is headquartered in Vienna, Austria, but operates worldwide.

Established in 1966, it became a specialized agency of the United Nations in 1985.

iii) Preface

Businessmen, consumers and public officials have certain expectations about the quality, safety, reliability, interoperability, efficiency, effectiveness and environmental sustainability of products and services. Conformity assessment provides the means for testing the compliance of such products and services with these expectations, in accordance with relevant standards, regulations and other specifications. It helps to ensure that products and services deliver on their promises. In other words, conformity assessment builds trust.

By obviating the need for buyers to verify directly whether the products they acquire meet the required specifications, conformity assessment facilitates trade at both national and international levels. It allows buyers to make their decisions on the basis of test reports and certificates issued by specialized laboratories and certification bodies thereby creating confidence of customers that their expectations will be met.

However, non-acceptance of test reports and certificates of conformity continues to be an obstacle to international trade. This often requires exporters to submit to costly multiple testing and/or certification of their products. The World Trade Organization has sought to overcome this problem through its Agreements on Technical Barriers to Trade and on the Application of Sanitary and Phytosanitary Measures, which are intended to ensure that technical regulations and standards, and the procedures for assessing conformity with them, do not obstruct international trade.

Successive reviews of the Agreement on Technical Barriers to Trade have noted the usefulness of the conformity assessment standards and guides developed by ISO and the International Electrotechnical Commission (IEC) in harmonizing conformity assessment practices and as benchmarks for the technical competence of assessment bodies. The use of these standards and guides therefore helps to overcome trade barriers. ISO also promotes the international harmonization of conformity assessment activities and the worldwide acceptance of the results of these assessments. UNIDO, meanwhile, has acquired more than 40 years of experience in supporting the establishment and upgrading of standards and conformity assessment structures worldwide.

Building trust – The Conformity Assessment Toolbox is a comprehensive, user-friendly handbook covering all aspects of conformity assessment and its role in international trade, and will be useful for business managers, regulators and consumer representatives. It is the latest in a series of joint publications issued by ISO and UNIDO, and is the result of the long-standing and fruitful partnership between the two organizations to strengthen the standardization and quality infrastructures of developing countries and countries with economies in transition. Although aimed specifically at this group of countries, these publications are also intended to serve as handy reference tools for all who are involved or interested in conformity assessment and trade.

Rob Steele
ISO Secretary-General

Dr. Kandeh K. Yumkella
UNIDO Director-General

iv) Disclaimer

This document has been produced without formal United Nations editing. The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations Industrial Development Organization (UNIDO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries, or its economic system or degree of development. Designations such as "developed", "industrialized" and "developing" are intended for statistical convenience and do not necessarily express a judgment about the stage reached by a particular country or area in the development process. Mention of firm names or commercial products does not constitute an endorsement by UNIDO.

v) Acknowledgements

ISO and UNIDO gratefully acknowledge the dedicated work of Anthony Russell, Martin Kellermann and Ian Cleare, edited and coordinated by Beer Budoo (ISO), Sean Mac Curtain (ISO), Nicolas Fleury (ISO), Martin Chesire (ISO), Lalith Goonatilake (UNIDO), Gerardo Patacconi (UNIDO), Ouseph Padickakudi (UNIDO) and Bernardo Calzadilla Sarmiento (UNIDO, Geneva).

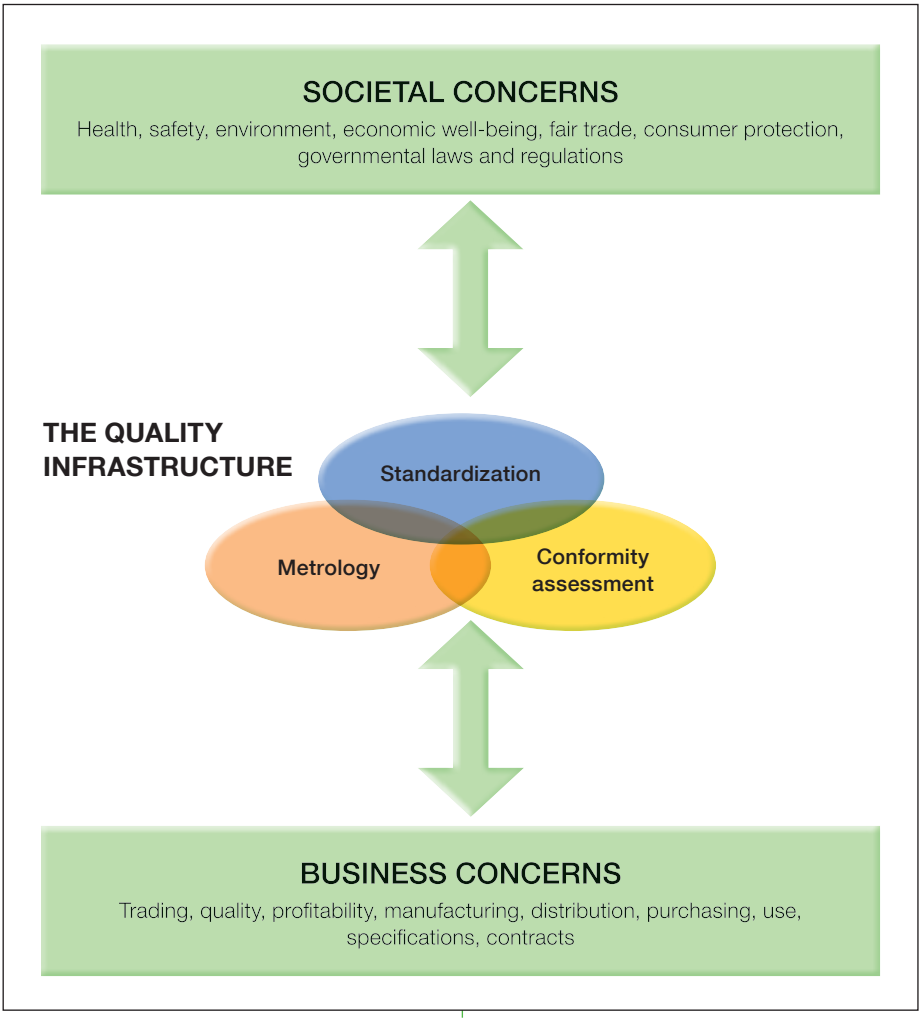
We also acknowledge the contribution made by Oswald Chinyamakobvu of the Southern African Development Community (SADC) and Vyjayanthi F. Lopez of the Caribbean Community (CARICOM) regional organization for Standards and Quality (CROSQ).

We acknowledge, too, the contribution made by Malachy Scullion, UNIDO consultant editor.

vi) Introduction

The role of conformity assessment in the quality infrastructure and its importance to trade capacity building and economic development

Figure 1 – The role of the quality infrastructure



Conformity assessment is fundamental for all economies

The UNIDO-ISO publication *Fast forward* introduced the concept of the quality infrastructure as a key facilitator of trade capacity building and economic development. The three main components of the quality infrastructure (see **Figure 1**) are metrology, standardization and conformity assessment. The benefits of standardization in improving economic efficiency and providing access to world markets cannot be achieved without the ability to make reliable measurements and to be able to demonstrate that items conform to the requirements specified in the standards.

As part of their quality infrastructure, all economies need access to credible conformity assessment services. These are needed for a variety of purposes, including:

- Demonstration that products, processes, services, commodities and personnel meet required specifications. These may include requirements specified under regulations (domestic or foreign), purchasers' specifications, trade agreements etc.
- Establishing and monitoring appropriate requirements for protection of health, safety and the environment
- Underpinning public infrastructure services in construction, energy, water and gas supplies, defence, transportation and communication systems
- Protection of consumers through control of unfair trading practices
- Demonstrating the credibility of forensic and justice systems
- Ensuring the compatibility and interoperability of components in products and systems
- Assisting the quarantining of harmful commodities, products, pests and diseases from entry into in an economy
- Improving international trading opportunities by reducing technical barriers to trade and demonstrating compliance with specifications of international standards, technical regulations and commercial specifications.

Most societies recognise the domestic benefits of their quality infrastructure and many have established the appropriate national bodies and international relationships to support their system. However, national systems that are not harmonised regionally or internationally have the potential to introduce new technical barriers to trade. Both developed and developing countries are increasingly being expected to demonstrate not only for their own citizens, but also to the wider world,

that the products and services they produce are reliable, safe and environmentally responsible. To achieve this aim, each economy requires an effective domestic technical capability (or access to foreign expertise) to underpin the conformity assessment services in their country.

This publication is intended to help those in developing countries, whether they have governmental, business or consumer interests, to understand conformity assessment and to create an effective infrastructure within their economy. It provides information to help them in setting up and running the conformity assessment arrangements which are appropriate for their needs.

Chapter 1 gives an overview of the rationale for and the benefits of conformity assessment. In **Chapter 2**, the techniques which can be used for assessing conformity are described, while **Chapter 3** looks at the way in which conformity assessment schemes can be designed and operated.

Chapter 4 examines the requirements for conformity assessment bodies while **Chapter 5** provides information about how UNIDO can help with setting up and operating a conformity assessment infrastructure as part of a quality infrastructure. It highlights relevant and current practices and the roles of key organizations which affect the contribution of conformity assessment to economic development and to international consistency of conformity assessment activities. **Chapter 6** provides some case studies to illustrate how the principles outlined in this document can be applied.

vii) Acronyms and abbreviations

A2LA	American Association for Laboratory Accreditation
APEC	Asia Pacific Economic Cooperation
APLAC	Asia-Pacific Laboratory Accreditation Cooperation
APLMF	Asia Pacific Legal Metrology Forum
APMP	Asia Pacific Metrology Programme
BIPM	International Bureau of Weights and Measures
BRC	British Retail Consortium
BSTI	Bangladesh Standards and Testing Institute
CASCO	ISO Committee on conformity assessment
CD	Committee Draft
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standards
CEOC	International Confederation of Inspection and Certification Organizations
CIPM	International Committee for Weights and Measures
CMC	Calibration and measurement capability
COFRAC	French National Accreditation Committee
COPOLCO	ISO Committee on consumer policy
CPC	Chairman's policy and coordination group (of CASCO)
CRM	Certified reference material
DEVCO	ISO Committee on developing country matters
DIS	Draft International Standard
EA	European cooperation for Accreditation
EE MRA	Electrical and Electronic Equipment Mutual Recognition Agreement (of APEC)
ETRACE	Egyptian Traceability Centre for Agro-Industrial Exports
FDIS	Final Draft International Standard
GATT	General Agreement on Tariffs and Trade
HACCP	Hazard Analysis Critical Control Point
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IFAN	International Federation of Standards Users
IFIA	International Federation of Inspection Agencies
IIOC	Independent International Organization for Certification Limited
ILAC	International Laboratory Accreditation Co-operation
IPC	International Personnel Certification Association
IQNET	The International Certification Network
ISO	International Organization for Standardization
ISONET	ISO/IEC Information Centre
ITC	International Trade Centre
ITU	International Telecommunication Union
ITU-T	ITU's Telecommunication Standardization Sector

UILI	International Union of Independent Laboratories
JAS-ANZ	Joint Accreditation System of Australia and New Zealand
JCCC	Joint Committee for Closer Cooperation (of ILAC and IAF)
JCDCMAS	Joint Committee for Coordination of Technical Assistance to Developing Countries in Metrology, Accreditation and Standardization
JDSC	Joint Development Support Committee (IAF and ILAC)
JIG	Joint Inspection Group (of IAF and ILAC)
KMG	Knowledge Management Group (of CASCO)
MAA	Mutual Acceptance Arrangement (of OIML)
MLA	Multilateral Recognition Arrangement
MOU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement
NATA	National Association of Testing Authorities, Australia
NBSM	Nepal Bureau of Standards and Metrology
NMI	National Measurement Institute
OIML	International Organization for Legal Metrology
PAC	Pacific Accreditation Cooperation
PASC	Pacific Area Standards Congress
PT	Proficiency Testing
REMCO	ISO Committee on Reference Materials
RM	Reference material
SADCA	Southern African Development Community Accreditation
SADCAS	Southern African Development Community Accreditation Service
SANAS	South African National Accreditation System
SOAC	West African Accreditation System
SPS	Sanitary and Phytosanitary Measures
STAMEQ	Directorate for Standards, Metrology and Quality (Viet Nam)
STAR	Strategic Alliance and Regulatory Group (of CASCO)
SQAM	Standards, Quality, Accreditation and Metrology
SWEDAC	The Swedish Board for Accreditation and Conformity Assessment
TA	Technical Assistance
TBT	Technical Barriers to Trade
TIG	Technical Interface Group (of CASCO)
UEMOA	West African Economic and Monetary Union
UNIDO	United Nations Industrial Development Organization
VMI	Vietnam Metrology Institute
WAITRO	World Association of Industrial and Technological Research Organizations
WELMEC	European cooperation in legal metrology
WTO	World Trade Organization

Chapter 1 – Basic concepts of conformity assessment

Why conformity assessment?

Everyone has an interest in finding out whether something (or somebody, organization or system) meets their expectations. Does the product do what I expect? Is that person competent to carry out the work I want them to do? Will the shop provide the right item at the right price when I need it? Is my product safe?

Products and services are like promises. Business customers, consumers, users and public officials have expectations about products and services relating to features like quality, ecology, safety, economy, reliability, compatibility, interoperability, efficiency and effectiveness. The process for demonstrating that these features meet the requirements of standards, regulations and other specifications is called **conformity assessment**. In brief, conformity assessment helps to ensure that products and services deliver on their promises.

Consumers benefit from conformity assessment because it provides them with a basis for selecting products or services. They may have more confidence in products or services that are supported by a formal supplier's declaration, or bearing a mark or certificate of conformity, that attest to quality, safety or other desirable characteristics.

Manufacturers and service providers need to make sure that their products and services meet their declared specifications and deliver on customer expectations. Assessing their products and services in accordance with ISO and IEC International Standards helps them to meet the current state of the art and to avoid the costs of product failures in the market.

When public health, safety or the environment may be at stake, conformity assessment is often made obligatory by government regulations. Without appropriate assessment and approval, goods may be barred from sale, or suppliers disqualified from bidding for government procurement contracts. ISO/IEC International Standards and Guides also provide requirements and guidance for good practice and recognition of such assessments.

Regulators too benefit from conformity assessment that gives them a means to enforce national health, safety and environmental legislation and achieve public policy goals.

Harmonizing conformity assessment procedures around the world also has far-reaching benefits for international trade in general. One of the main hurdles to cross-border trade that exporters face is costly multiple testing and/or certification of products. Non-transparent or discriminatory conformity assessment procedures can become effective protectionist tools, or "technical barriers to trade".

The World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT Agreement) was established to ensure that technical regulations and standards, and the procedures for assessing conformity with them, do not create unnecessary obstacles to international trade. Successive reviews of the TBT Agreement have noted the usefulness of ISO/IEC conformity assessment standards and guides in harmonizing conformity assessment practice and as benchmarks for the technical competence of assessment bodies so that credibility and confidence in their results can be obtained. ISO/IEC's conformity assessment work therefore helps to overcome trade barriers.

All countries are dependent on conformity assessment, but many developing countries face particular challenges in establishing and maintaining viable conformity assessment resources. This situation is made even more challenging in an era of globalization, where international "best practice" is becoming increasingly expected by all parties involved in trade and commerce. This not only includes those directly involved in trade, but others influencing the trading environment, such as regulators and government authorities, who are seeking to protect their citizens from dangerous or inferior products and other negative influences such as environmental degradation.

Conformity assessment has been a part of the fabric of most societies since ancient times as a tool to provide reassurance to users of products, services, and commodities that some action has been taken to affirm their quantities, qualities, characteristics, performance or other expectations. Conformity assessment, therefore, needs to be viewed in a much wider perspective than as a facilitator of trade. It is a "whole of society" activity and, in most economies, its domestic applications may far outweigh its roles in supporting trade.

While "best practice" in conformity assessment may be desirable, it is also important that it is used practically and cost-effectively. This is particularly significant for developing countries, which need to make judgments on the best solutions for their conformity assessment needs to satisfy both their domestic and international client groups.

Definition of conformity assessment

Having introduced the concept of conformity assessment, it is time to look at the subject from the point of view of the international standardization organizations, ISO and IEC. Through these organizations, practitioners and users of conformity assessment from around the world have pooled their knowledge and experience to produce a series of standards and guides setting out current best practice. These standards and guides are produced through the ISO Committee on conformity assessment, ISO/CASCO, and form what is known as the "CASCO toolbox". See **Appendix 1** for more information. The relevant standards and guides are referred to throughout this publication.

ISO/IEC 17000 defines conformity assessment as: demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled. A few points to note:

- In line with the terminology of ISO 9000, a service is regarded as a particular form of product
- The methods for demonstrating conformity include testing, inspection, suppliers' declarations of conformity and certification
- Specified requirements include those contained in suppliers' or purchasers' specifications, national, regional or international standards or governmental regulations
- Accreditation of conformity assessment bodies is included within the definition of conformity assessment
- The term *object of conformity assessment*, or sometimes just *object*, is used in the standard to refer to "product, process, system, person or body".

Conformity assessment is often characterized as part of a quality infrastructure. This publication highlights the significance of conformity assessment within a national or regional quality infrastructure and the interactions between the various elements of such an infrastructure.

In addition to testing, inspection and certification, there are other activities which may fall under the umbrella of conformity assessment and there has been considerable international debate on whether activities such as accreditation, production of reference materials and conduct of proficiency testing are conformity assessment activities.

Even within the realm of testing, there has been varying opinion on whether some forms of diagnostic testing, such as pathology services, fit the formal definition of *conformity assessment.* In practical terms, however, all of these various activities are part of the every

day world of conformity assessment and are important elements in broader national or regional quality infrastructures.

In the case of accreditation (discussed later in more detail) the relevant ISO definitions on the topic recognize that accreditation bodies carry out conformity assessment of conformity assessment bodies but are not themselves regarded as conformity assessment bodies.

The definition of conformity assessment and explanatory text in ISO/IEC 17000 provide sufficient flexibility to use the concept in a practical manner to ensure the principles can be used effectively. To illustrate this flexibility, the Introduction of ISO/IEC 17000 notes that "...conformity assessment interacts with other fields such as management systems, metrology, standardization, and statistics. This International Standard does not define the boundaries of conformity assessment. These remain elastic."

Some key components in the definition also have related activities, and subsets. For example, "certification" includes management systems, product and personnel certification. The concept of "testing" includes the related activities of calibration and measurement. The roles of different types of conformity assessment bodies are discussed later in **Chapter 4**.

Conformity assessment in the quality infrastructure

As noted in the Introduction, there are three main components of the quality infrastructure (see **Figure 1** – page 6), metrology, standards and conformity assessment. Infrastructure systems vary from country to country, but there is broad agreement that the elements making up any comprehensive system (see **Figure 2**) are:

- Capabilities to develop written standards
- Access to physical, chemical, and more recently, biological standards of measurement
- Provision of a legal metrology service
- Availability of inspection, testing and calibration services at a level of sophistication commensurate with the industrial, trading and societal needs and aspirations of each country
- Availability of assistance for suppliers of goods and services to enable them to specify the requirements which need to be met and to adopt the policies and practices necessary to ensure that the requirements are met
- Availability of third-party conformity assessment services such as product certification to meet the needs of regulatory bodies, both domestically and abroad, and those of suppliers and customers who require some independent confirmation of

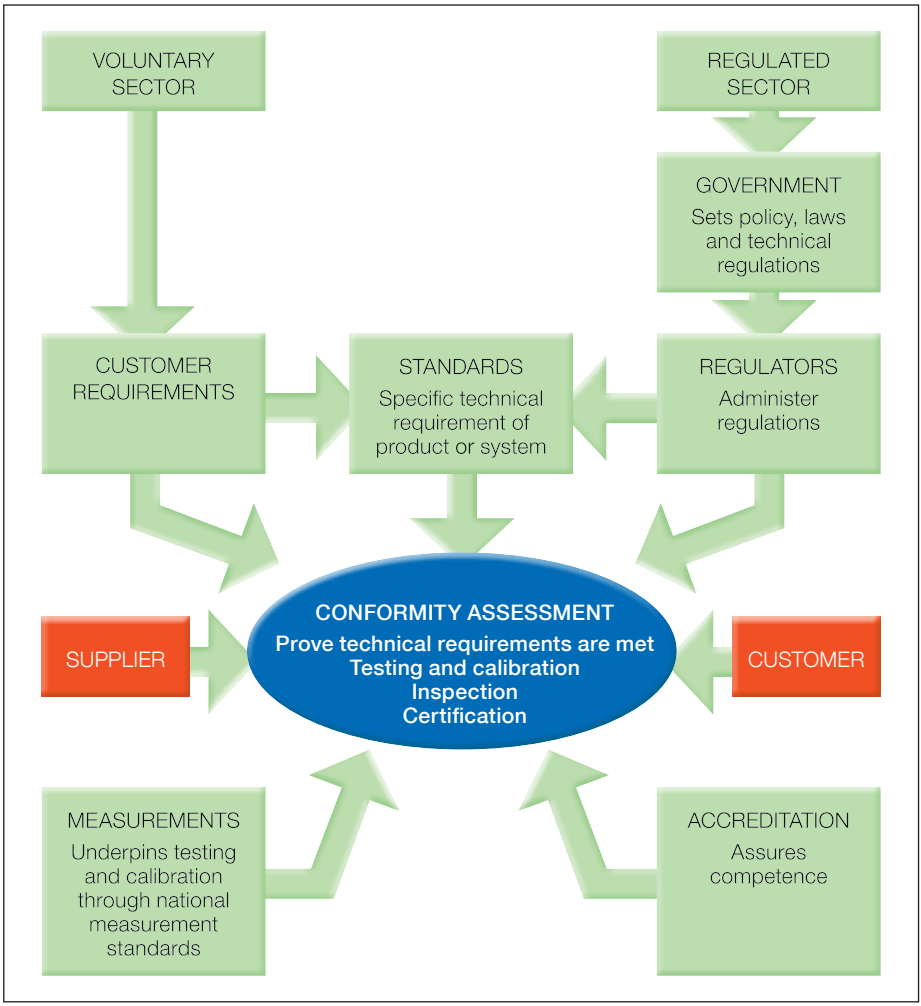
the conformity of goods and services

- Mechanisms to ensure that all service providers are competent. Accreditation is often used for this purpose.

The national system for the development of technical regulations should have an input to the quality infrastructure so as to ensure that the regulators' needs are met and that the regulations use the infrastructure to best effect.

Normally, there are also organizations dedicated to the development

Figure 2 – Example of a conformity assessment model



of people and organizations on issues related to quality improvement and development of quality and management systems auditing.

Conformity assessment and standards

It is critical that a national infrastructure has the ability to engage in the preparation, publication and distribution of documentary standards, whether at the national, regional or international level. In the context of conformity assessment there are two major aspects of standardization that need to be appreciated.

The **first aspect** is the availability of national, regional and international standards that can be used by suppliers, purchasers, conformity assessment bodies and regulators for setting the requirements for an object and assessing its conformity with them. ISO/IEC 17007 gives an overview of the essential features of a standard to be used for conformity assessment:

- The standard must be so written that it can be applied by any of the following:
  - a manufacturer or supplier (first party)
  - a user or purchaser (second party)
  - an independent body (third party).

  Conformity with the standard must not be dependent on a particular form of assessment such as certification or accreditation
- The scope of the standard should be clearly stated in terms both of the type of objects to which it relates and to the characteristics of those objects which it specifies. For example, a standard could relate to plastic pipes for water supply, but be limited to their suitability for use with potable water. Other characteristics such as dimensions and mechanical strength might be specified in a different standard or be left to the manufacturer to specify
- Standards should always be written in such a way that they facilitate and do not retard the development of technology. Usually, this is accomplished by specifying performance requirements rather than product design requirements
- The requirements should be clearly specified, together with the required limiting values and tolerances, and the test methods to verify the specified characteristics
- The requirements should be free from subjective elements; the use of such phrases as "sufficiently strong to" or "of adequate strength" should be avoided
- Test methods should be clearly identified and be consistent with the purpose of the standard. They should be objective, concise and accurate, and produce unambigu-

ous, repeatable and reproducible results, so that results of tests made under defined conditions are comparable. It is recommended that the description of test methods incorporate a statement as to their accuracy, reproducibility and repeatability

- To the extent practicable and consistent with their objective, the tests should provide results within a reasonable period of time and at a reasonable cost
- Non-destructive test methods should be chosen, whenever they can replace, within the same level of confidence, destructive test methods
- When choosing test methods, account should be taken of standards for general test methods and of related tests for similar characteristics in other standards. As regards the description of test methods, it is recommended that reference be made to other relevant standards, rather than quote the test methods in full in each standard
- Where test equipment is only available from one source, or is not commercially available and has to be individually manufactured, the standard should include such specifications for the equipment as to ensure that comparable testing can be conducted by all involved parties.

While these features apply more to tangible products than other objects of conformity assessment, the principles can be applied to standards for services, processes, systems, persons and bodies. The objective is to avoid the problems which can arise from differing interpretations of the standard and the different expectations which the various parties may have.

Although standards can be prepared by many organizations, including companies and regulators, it is normally the role of national standards bodies to develop consensus standards. As such, they take into account the balanced views of all stakeholders affected by such standards. National standards bodies also provide the linkages and conduits for national inputs into the development of international standards. Many such standards are used by regulators as discussed later in this chapter.

The roles of national standards bodies in developing countries are described in detail in the ISO/UNIDO handbook *Fast forward – National Standards Bodies in Developing Countries.*

The ISO policy committee dedicated to developing country matters, ISO/DEVCO, has also produced a number of information documents and handbooks designed to assist developing countries in development and administration of their national standards bodies and related functions.

The **second aspect** of particular relevance to conformity assessment bodies is the availability of standards which set out requirements for best practice of conformity assessment and the bodies which carry it out. These standards are intended to ensure that there are consistent and internationally harmonized practices amongst conformity assessment bodies and the bodies with which they work (such as accreditation bodies). The responsibility for preparation and maintenance of these conformity assessment standards lies with ISO/CASCO (see **Appendix 1**).

It is essential that conformity assessment activities are as consistent as possible internationally as they play such a significant role in the trading of goods and services. It is also of benefit to domestic consumers of products and services if conformity assessment is conducted consistently within economies. This is why standardization of conformity assessment practices is so critical.

It is also essential to note that standards not only play a key role in trade and commerce, but they also cover many aspects of people's daily lives including social issues such as public health, worker safety, and environmental and consumer protection. Again, conformity assessment is comprehensively involved in verifying that the regulations affecting these aspects of our lives are being adhered to, and, if not, it should be a catalyst for action by the relevant authorities.

Conformity assessment and metrology

The third major component in a quality infrastructure is the availability of a national measurement system that can ensure that measurements are made with appropriate accuracy and reliability and can be related to other measurements made domestically or internationally. This is essential to ensure compatibility in trade and commerce.

Measurement also underpins testing (and often inspection) as many items of equipment require calibration by competent specialist laboratories to ensure that such tests are traceable to international standards of measurement.

Manufacturing also requires consistent and reliable measurements for interoperability of components, as do measurements associated with traded commodities.

When products are certified (as discussed in **Chapter 4**), such certification is usually based on testing for conformity. Here again there is a fundamental reliance on capable measurement for certification itself to be reliable.

This fact demonstrates the great degree of interdependence between various types of conformity assessment and between the other segments of quality infrastructures.

The international framework for providing compatibility of measurements is coordinated at the national level by national measurement institutes (NMIs). It is their responsibility to provide the measurement capabilities needed within their economies (to the extent possible) and to maintain their own measurement capabilities at levels which provide comparability with institutes in other economies. However, in many economies (in both developed and developing countries), access to appropriate high level measurements for some quantities needs to be through NMIs in other economies.

International coordination of measurement science and capabilities is provided through the International Bureau of Weights and Measures (BIPM). The activities of BIPM and its member NMIs have a number of key interactions with conformity assessment bodies and standards. These include:

- BIPM's member NMIs make available appropriate ranges of measurement standards with uncertainties commensurate with the technical needs of their countries' laboratories, industry users and other clients of their calibration services (including foreign users)
- They maintain traceability of national measurement standards to international standards and the *SI* units through a credible and transparent process of international intercomparisons. (Traceability to international measurement standards is a fundamental requirement of a number of ISO/CASCO and other ISO standards, such as ISO/IEC 17025, ISO/IEC 17020 and ISO 9001)
- They implement the CIPM Mutual Recognition Arrangement between NMIs. This MRA uses ISO/IEC 17025 as a fundamental criterion for NMIs participating in the MRA and accreditation of NMIs is one of the pathways to its membership. (The other mechanism for membership is based on a peer review by experts from other NMIs). Participating NMIs include bodies from developed and developing countries
- BIPM maintains a publicly available database of the calibration and measurement capabilities (CMCs) of each of the NMIs in the CIPM MRA. This information is based on key intercomparisons regularly conducted between the NMIs
- BIPM members provide technical expertise for use in accreditation assessments and often provide reference values and measurement

artefacts for measurement and calibration proficiency tests.

Information on the roles and activities of BIPM is available at **www.bipm.org**.

Information from the key comparisons data base is accessed through **www.kcdb.bipm.org**.

BIPM is also actively involved in the development of a number of relevant conformity assessment standards as an A-Liaison member of ISO/CASCO.

Legal metrology

A national standards and conformity infrastructure should include a body or bodies responsible for legal metrology. This branch of measurement science deals with metrology in the domestic market and is sometimes referred to as trade measurement. It includes the approval of measurement devices used in daily commerce to ensure fair trading practices. Examples include scales and other weighing devices, volume measures, gas and electricity meters etc. It also embraces the regulation of package sizing for retail items.

It does, however, have a wider application beyond trade measurement in many economies, dealing with other forms of measurement which may have a legal or regulatory basis, such as vehicle speed measurement and breath analysis for alcohol content.

The international forum for legal metrology is the International Organization for Legal Metrology (OIML). It and its member bodies also have a number of conformity assessment roles and interactions. These include:

- OIML members undertake pattern approval of measuring devices used in legal metrology applications. Essentially these national type approvals are a device-specific form of product certification. This process requires testing against specific OIML specifications (often with some national variations)
- OIML has also developed its own mutual recognition arrangement to reduce the need for multiple testing and certification of measuring devices. This arrangement is called the OIML Mutual Acceptance Arrangement (MAA) and is intended to facilitate acceptance of OIML Certificates of Conformity across national borders
- The OIML MAA uses ISO/IEC 17025 compliance as part of the acceptance requirements for signatory bodies and also uses either accreditation or peer evaluation as the processes for determining acceptance into the MAA.

Information on OIML is available on its website at **www.oiml.org**.

The Website also provides details of OIML's Permanent Working Group on Developing Countries.

Conformity assessment and regulations

Technical regulations are a feature in most economies and most have some direct or indirect interaction with both standards and conformity assessment. While most technical regulations are country-specific, there are some regulations which are multi-national in nature. European Directives, for example, often contain technical regulations which are applicable in all the member states of the European Union.

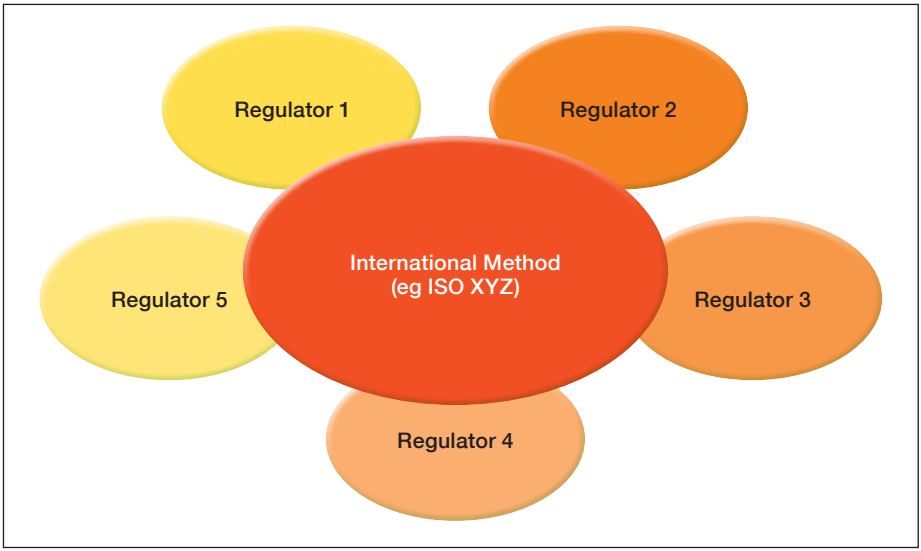
Often technical regulations include compliance with a national or an international standard, technical specification or code of practice, but may contain additional requirements set by the regulator (such as product labeling specifications). Some technical regulations also may only specify parts of standards, such as those aspects affecting safety and might not cover product performance or quality aspects.

Most regulatory arrangements have some common features such as:

- A nominated organization responsible for the implementation and administration of compulsory specifications – the regulator
- Conformity assessment requirements – how compliance with requirements will be assessed. (Sometimes alternative conformity assessment arrangements might be allowed.)
- The essential technical requirements that must be satisfied – often through specification of a specific standard or the equivalent standards that can demonstrate compliance with essential requirements (deemed to satisfy provisions, often in technical guidance supplements to technical regulations)
- Post-market surveillance arrangements, (where applicable) – these might require repeated conformity assessments or different forms of conformity assessment to those needed for initial approval
- Sanctions to be applied when failures to conform are identified – additional conformity assessment may be required as a result of such failures
- Labeling and marking requirements – such markings may be different to the marks of conformity issued by the conformity assessment bodies.

Clearly, conformity assessment is a fundamental activity in administration of many technical regulations. However, the possibility for economies to introduce unnecessary regulations or technical requirements which are substantially different to those in other economies can lead to technical barriers to trade. Such barriers become even more complicated when there is no basis in an importing economy to accept conformity assessment results from foreign bodies

Figure 3 – The challenge of multiple specifications



The ISO/IEC brochure *Using and referencing ISO and IEC standards for technical regulations* (ISBN 978-92-67-10454-6) provides practical advice for regulators on how to use International Standards to achieve their objectives.

Ideally, regulators will use uniform or standard technical requirements in their regulations and will be able to access the results of conformity assessments conducted by competent bodies in other economies. This task is made easier if conformity assessment bodies operate under internationally agreed standards, and additional confidence is also achieved if the conformity assessment bodies are independently assessed for their competence through a process of accreditation.

These mechanisms to reduce technical barriers to trade are highlighted in the WTO Agreement on Technical Barriers to Trade (see **Appendix 3**). If regulators in different economies make amendments to core technical standards, then testing, inspection and certification bodies, acting on behalf of exporters to those markets, need to be aware of all the variations and their significance when undertaking their conformity assessment tasks.

Such add-on variations by regulators (see **Figure 3**) may add considerable extra costs to exporters and import-

ers and place additional responsibility on conformity assessment bodies to be aware of each of the variations on a core standard needed to satisfy multiple markets.

Conformity assessment and economic development

While much attention in economic development is paid to international trade, there are many aspects of the national economy which benefit from a systematic approach to the development of a national or regional quality infrastructure which includes conformity assessment. The quality infrastructure can help to promote international best practice in all the fields where it is applied and can improve the economics of agriculture, manufacture, distribution and commerce. It can also provide a sound basis for social development, education, health and legal justice systems.

It is as important to apply the principles of conformity assessment to imported goods and services as it is to their export. Having confidence that the items meet the specification in terms of quality and quantity, indeed that the specification is sufficiently clear in the first place so that there are no misunderstandings and surprises later on, will avoid waste of time and money as well as disappointment among those affected.

It is helpful to specify that imported goods and services must comply with clearly stated requirements such as those given in ISO or IEC standards. It is also important to state the means by which suppliers will be required to demonstrate conformity with the specified requirements. Will a supplier's declaration of conformity suffice, or will it be necessary for a third party attestation such as a certificate of conformity or an inspection certificate to be provided?

In the case of voluntary transactions, the parties concerned in the transaction are free to decide for themselves on the conformity assessment procedures. If the purchaser is willing to accept the supplier's assurances of conformity (supplier's declaration of conformity), then there is no need to involve a third party.

In large transactions, where risks of making a mistake are higher, third party conformity assessment providers may be called in to provide unbiased and factual assurances to both parties, thereby facilitating the exchange of goods and services. In many developing countries, however, the use of third party conformity assessment providers has become a necessity in practice, owing often to an absence of strict product liability legislation.

Where technical regulations govern the transaction, the decision as to the means of conformity assessment may be taken out of the hands of the two main parties to the transaction, and proof of conformity, in a prescribed format, might be required. This raises the question of how the competence and independence of the third party conformity assessment providers can be demonstrated, and introduces the subject of accreditation.

ISO/IEC 17000 defines accreditation as the "third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks". Accreditation can relate to competence in the performance of tests and calibrations in laboratories, or to the competence of certification and inspection bodies.

Accreditation bodies need themselves to show that they are independent and unbiased, and for this reason are often established as national or regional entities that in practice need to demonstrate the existence of mutual recognition arrangements by means of membership of relevant international bodies that engage in peer reviews of each other.

In the accreditation sphere, two key international groups are the International Laboratory Accreditation Cooperation

(ILAC) and the International Accreditation Forum (IAF) both having the aim of facilitating international trade through enhanced confidence.

Developing countries often do not have the resources or the expertise to establish national accreditation bodies, and frequently are operating at a low economic level that makes it unprofitable for third party conformity assessment providers to operate exclusively in their territory.

One of the major decisions for a developing country therefore involves the way in which its conformity assessment and accreditation requirements are to be carried out. Use of a combination of national and foreign conformity assessment providers, backed up by regional accreditation structures, may be an answer, although specific solutions to specific countries' needs will always require to be tailored to suit the circumstances.

For more details on IAF and ILAC see **Appendix 2**.

The "CASCO toolbox" (see **Appendix 1**) can be used to provide the basis of a quality infrastructure that is effective, tailored to the specific needs of the country concerned, and is compliant with the requirements of the WTO.

Conformity assessment and international trade

For developing countries, particularly, there needs to be some prioritization of competing needs for scarce resources and judgment on whether the establishment and maintenance of particular conformity assessment activities (or their supporting infrastructure bodies) are justified.

Conformity assessment needs of developing countries

As with all economies, developing countries have needs for testing, measurement, inspection and certification. To satisfy some markets, they may also need access to accreditation services for their conformity assessment bodies.

Testing laboratories will also often need complementary services such as:

- Access to specialist calibration services (able to demonstrate traceability to international measurement standards) to support their own testing and measurement
- Access to reference materials (RMs) and certified reference materials (CRMs)
- Access to proficiency testing services
- Access to equipment repair and maintenance expertise
- Access to research and development expertise to meet new demands for testing
- Training of technical, management and support staff.

Similarly, inspection and certification bodies may have needs for the supporting activities of:

- Specialist laboratories to provide inputs to their own inspection or certification activities
- Specialist auditors, or other key personnel
- Training of staff.

Additionally, if there is an agreed need for a locally available accreditation body (or bodies), that body will also need access to a number of supporting resources. These resources may include (depending on the type of accreditation required):

- Access to experts to act as technical, product-specific, management-specific or other specialist assessors
- Access to a national metrology infrastructure
- Access to membership of multilateral MRAs at either the regional or international level.

Within a developing country there may also be needs for information services, including access to details of foreign standards, technical and other regulations, and associated translation services.

Resolving the needs of developing countries for conformity assessment

Chapter 5 lists some of the activities that UNIDO itself undertakes to assist the development of conformity assessment and supporting infrastructure bodies, such as metrology centres and accreditation bodies. Additionally, UNIDO and other international bodies such as ISO, IAF, ILAC, BIPM, and OIML, and their associated regional bodies, have implemented a number of training and awareness-creation projects on topics of relevance to conformity assessment and its support.

Other aid agencies have also been active at both a single-country and a regional level to assist development and training in these areas. No doubt these activities will continue as specific needs are identified. The identification and prioritization of such needs will always need to be a matter of judgment by the governments and industry bodies in individual countries, in cooperation with the appropriate sources of development assistance.

Some of the approaches used (or proposed) to satisfy developing country needs for conformity assessment access and development have included:

- Attachment training abroad of personnel at well-established conformity assessment and supporting bodies, such as accreditation bodies
- Twinning of new or proposed bodies with an established conformity assessment or supporting body (often also abroad)
- Development of a regional solution to a conformity assessment or related service need. An emerging example of that approach (to pooling scarce resources between countries) has been the recent establishment of the Southern African Development Community Accreditation Service (SADCAS), which will provide accreditation services to many economies within the region
- Selected contracting of foreign assessors to complement the available pool of technical experts within the country
- Facilitating access to regional or other proficiency testing programmes
- Facilitating membership of regional and international bodies (some of these bodies have reduced fees for developing country members)
- Facilitating access to measurement traceability through services of foreign metrology institutes (including institutes in other developing countries)
- Full project development of a new conformity assessment or related service capability
- Facilitating access to repair and maintenance expertise for equipment; and, where justifiable

- Facilitating use of established foreign conformity assessment and accreditation bodies.

This latter activity (direct use of foreign conformity assessment and related services) is also a matter requiring judgement and sensitivity. On the one hand, it may be more cost effective in the short term to use-well established foreign bodies, rather than create a similar capability in the developing country.

On the other hand, the activity of foreign bodies in a developing country may inhibit the use of newly developed local bodies and the transfer of knowledge domestically. UNIDO has a process for effective implementation of a quality infrastructure which can be helped by "cross-frontier policies" adopted by both IAF and ILAC which require their accreditation body members to have appropriate policies to cover their foreign accreditation activities.

The World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT) underscores the significance of conformity assessment in global trade and its potential to act as a barrier to trade. Non-acceptance of foreign standards and conformity assessment results has long been recognized as a significant non-tariff trade barrier. As such, all members of the World Trade Organization are required to adhere to the WTO Agreement on Technical Barriers to Trade.

The Agreement acknowledges the significant contributions that international standards and conformity assessment can make in improving efficiency of production and facilitating international trade and encourages the development of international systems. However, its prime purpose is to ensure that technical regulations, standards and the systems used to demonstrate conformity with technical regulations and standards do not create unnecessary obstacles to trade. For more information on WTO/TBT see **Appendix 3**.

Having established that conformity assessment has much to offer in facilitating economic development, in the next chapter the various techniques which are available to those involved in implementing a national or regional quality infrastructure are examined.

Chapter 2 – Conformity assessment techniques

Introduction to conformity assessment techniques

In this chapter, we will look more closely at the techniques which can be used in conformity assessment and draw attention to the relevant tools in the CASCO toolbox mentioned in **Chapter 1**. One characteristic of conformity assessment is that it can take on different forms, using different techniques according to the purposes for which it is being used. The information provided in this document sets out the main techniques in current use but should not be considered to be exhaustive.

In the conformity assessment field as in any other, the competence of the people managing and carrying out the conformity assessment activities is of paramount importance. Whether the work is being carried out by the supplier of the products, the purchaser or an independent body, there must be a clear understanding of the knowledge, skills and experience necessary for those performing the conformity assessment tasks. Every organization, whatever its role, should operate a competence management system in which the required competences are laid down and the means of demonstrating that individuals meet the requirements are specified.

Too often "conformity assessment" is taken to mean certification and nothing else. In fact, as discussed in **Chapter 1**, conformity assessment can be undertaken by many people, including the supplier of a product or service, its purchaser and other parties which might have an interest such as insurance companies and regulatory authorities. It is convenient when talking about conformity assessment to refer to the parties as follows:

- First party (1st party) – the person or organization that provides the object which is being assessed
- Second party (2nd party) – a person or organization that has a user interest in the object
- Third party (3rd party) – a person or body that is independent of the person or organization that provides the object, and of user interests in the object.

In general, the conformity assessment techniques described in this chapter can be carried out by a 1st, 2nd or 3rd party. The decision as to which party should carry them out is addressed in **Chapter 3**.

ISO/IEC 17000 sets out the "functional approach" to conformity assessment. The functional approach involves the basic process:

Selection – Determination – Review & Attestation, plus Surveillance when required.

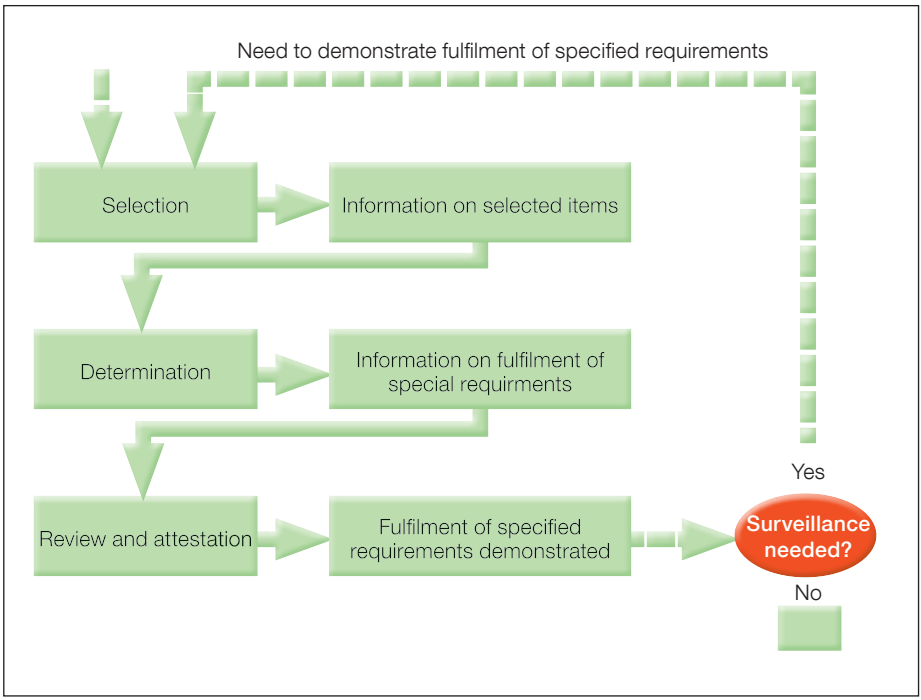
Each stage involves certain activities which are described below, the output from one stage being the input to the next. **Figure 4** shows an outline of the functional approach.

The activities carried out in each stage can include:

Selection

- Specification of the standard(s) or other document(s) to which conformity is to be assessed
- Selection of the examples of the object which is to be assessed
- Specification of statistical sampling techniques if applicable.

Figure 4 – Functional approach to conformity assessment



Determination

- Testing to determine specified characteristics of the object of assessment
- Inspection of physical features of the object of the assessment
- Auditing of systems and records relating to the object of assessment
- Evaluation of qualities of the object of assessment
- Examination of specifications and drawings for the object of assessment.

Review & attestation

- Reviewing the evidence collected from the determination stage as to the conformity of the object with the specified requirements
- Referring back to the determination stage to resolve nonconformities
- Drawing up and issuing a statement of conformity
- Placing a mark of conformity on conforming products.

Surveillance

- Carrying out determination activities at the point of production or in the supply chain to the marketplace
- Carrying out determination activities in the marketplace
- Carrying out determination activities at the place of use
- Reviewing the outcome from the determination activities
- Referring back to the determination stage to resolve nonconformities
- Drawing up and issuing confirmation of continued conformity
- Initiating remedial and preventive action in the case of nonconformities.

In the following sections, we look at these techniques in greater detail.

Selection

Selection involves planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function. Selection activities vary widely in number and complexity. In some instances, very little selection activity may be needed.

Some consideration may need to be given to selection of the object of conformity assessment. Frequently, the object may be : a large number of identical items ; ongoing production ; a continuous process or a system, or involve numerous locations.

In such cases, consideration may need to be given to sampling or selection of specimens to be used for determination activities. For example, the sampling plan for river water related to a demonstration that pollution requirements are

fulfilled would be an example of a sizeable and significant sampling activity.

However, occasionally the object may be the whole population, for instance when a single, individual product is the object of conformity assessment. Even in such cases, sampling may be necessary to select a part of the entire object that is representative of the whole (e.g. selection of critical parts of a bridge for a determination of material fatigue).

It may also be necessary to consider the specified requirements. In many cases, a standard or other pre-existing set of requirements exists. However, care should be taken when applying the pre-existing requirements to the specific object of conformity assessment. For example, caution might be needed when applying a standard written for metal pipes to plastic pipes. In some cases, only a very general set of requirements may exist which must be expanded for assessment to be meaningful or acceptable to the users.

For example, a government regulator may require that products pose no unacceptable safety risks (the general requirement) and expect a certification body to establish specific requirements for individual certified products or types of products. Alternatively, general management system requirements may need to be more focused when the management system addresses **fulfilment** of specific service requirements.

Selection may also include choice of the most appropriate procedures (for example, testing methods or inspection methods) to be used for determination activities. It is not uncommon that new or modified methods need to be developed to conduct determination activities. It may be necessary to select the proper locations and the proper conditions, or the individuals to perform the procedure.

Finally, additional information may be needed in order to perform determination activities properly so that the demonstration that specified requirements are fulfilled will be effective. For example, the scope of testing to be covered by laboratory accreditation must be identified before appropriate determination activities can be performed. Alternatively, a description of a service may be needed before performing appropriate determination activities.

In addition, a determination activity may be a review of information alone, and that information must be identified and collected. For example, a copy of a product's instructions for use or warning markings may be needed.

In **Figure 4** (see page 30), all the information, samples (if sampling is used),

decisions and other output from the selection function is represented as "information on selected items".

Determination

Determination activities are undertaken to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample. Some types of determination activities are described below.

The terms testing, inspection, audit and peer assessment, which are defined as types of determination activities only, may be used with "system" or "scheme" to describe conformity assessment systems or schemes that include the type of determination activity indicated. Thus, a "peer assessment system" is a conformity assessment system that includes peer assessment as the determination activity.

Various determination activities have no specific name or designation. An example is the examination or analysis of a design, or other descriptive information, in relation to specified requirements. Individual sub-fields of conformity assessment (e.g. testing, certification, accreditation) may have terms defined for determination activities that are unique to that sub-field. There is no generic term used or in practice to represent all determination activities.

Care should be taken to understand clearly the determination activities characterized as testing or inspection.

In **Figure 4**, all the output from the determination function is represented as "information on fulfilment of specified requirements". The output is a combination of all the information created through determination activity, as well as all the input to the determination function. The output is usually structured to facilitate review and attestation activities.

Testing

As noted earlier, there is a degree of overlap between testing, calibration and metrology. For the purposes of conformity assessment – demonstration that an object conforms to specified requirements – calibration and other aspects of metrology would fall outside this definition. However the confidence in the measurements made during testing (and inspection) depends on the national measurement system and the traceability to international measurement standards through calibration.

Conformity assessment related to testing and calibration

Testing, measurement and calibration affect almost all facets of daily life.

They affect trade and commerce, manufacturing, professional services, public health and safety, construction, environmental monitoring, transport, agriculture, quarantine, forensic sciences, meteorology, telecommunications, mining, forestry, and defence, to name just a few sectors. Of these, testing conducted in human medicine is perhaps the most comprehensive undertaken on a daily basis around the world.

Testing is the most common conformity assessment technique that is used. It is therefore of interest to examine its definition, as it relates to conformity assessment. ISO/IEC 17000 defines testing as:

> "determination of one or more characteristics of an object of conformity assessment, according to a procedure".

Where a procedure is defined as a specified way to carry out an activity or a process. A note to the definition of testing states that testing typically applies to materials, products or processes. In the case of testing used for conformity assessment, the characteristics will be included in the "specified requirements" which form the focus of the assessment.

It is noteworthy that calibration, while an essential input to testing, is not considered to be a conformity assessment technique. It comes within the field of metrology which is outside the scope of this publication. However, it is worth considering the definition of calibration in the *International Vocabulary of Metrology – basic and general concepts and associated terms (VIM)*:

> "Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step uses this information to establish a relation for obtaining a measurement result from an indication."

Noting that here the "standards" referred to are measurement standards traceable to the SI units of measurement, e.g. mass and length, not documents which specify requirements. Calibration is covered in the scopes of both ISO/IEC 17025 (for testing and calibration laboratory competence) and ISO/IEC 17011 (for accreditation body requirements).

ISO/IEC 17025 specifies the requirements for testing and calibration laboratories and is discussed in detail in **Chapter 4**. Included in its requirements are all of the elements essential to the conduct of testing for conformity assessment:

- Competent people
- Validated methods which are repeatable and reproducible
- Properly maintained and calibrated equipment

- Measurements which are traceable to the SI standard units of measurement
- Sampling and handling of test items
- Reporting of the testing results.

For the most reliable test results, the test methods should be specified in the standard or other document to which conformity is being assessed. Where a test is used for a number of different purposes it could be specified in a separate standard such as ISO 3452-2, *Non-destructive testing – Penetrant testing* – Part 2: *Testing of penetrant materials,* or ISO 13982-2, *Protective clothing for use against solid particulates* – Part 2: *Test method of determination of inward leakage of aerosols of fine particles into suits,* which can then be referred to in standards specifying requirements for particular objects.

In other cases the test method could be defined in the requirements standard itself as in ISO 15012-2, *Health and safety in welding and allied processes – Requirements, for testing and marking of equipment for air filtration* – Part 2: *Determination of the minimum air volume flow rate of captor hoods and nozzles,* or ISO 11199-2, *Walking aids manipulated by both arms requirements and test methods* – Part 2: *Rollators.*

In some cases, the requirements standard might simply give a value for a particular characteristic such as mass without specifying the method by which the characteristic is to be determined. In such cases, the testing laboratory would need to decide on the method to be used, following good laboratory practice. Where a number of testing laboratories are involved in conformity assessment work for the same set of requirements, it could be necessary for them to work together to agree a test method so that reliable and comparable results can be obtained.

Inspection

Inspection is a form of conformity assessment which has a long history. Some inspection activities are closely aligned with testing activities; others may be closely associated with certification activities (and particularly product certification); while other inspection is a stand-alone activity without any relation to testing or certification. The ISO/IEC 17000 definition for inspection is:

> "Examination of a product design, **product (3.3)***, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.
>
> **Note:** inspection of a process may include inspection of persons, facilities, technology and methodology."

* ISO/IEC 17000: 2004 Clause 3.3 quotes the ISO 9000:2005 Clause 3.4.2 definition of product as "the result of a process" which includes services, software, hardware and processed materials.

The requirements for inspection bodies are specified in ISO/IEC 17020 and are discussed in more detail in **Chapter 4**. Looking here at inspection as a conformity assessment technique it can include:

- Visual examination of physical items
- Measurement or testing of physical items
- Examination of specification documents such as design drawings
- Comparison of the findings with the requirements of specification documents or with generally accepted good practice in the field
- Drawing up a report on the results of the inspection.

One of the key phrases in the definition of inspection is "on the basis of professional judgement…". This underlines the fact that the competence of inspection bodies is highly dependent on the knowledge, experience and interpretive skills of the inspection bodies' personnel. For some types of inspections there may be specified requirements for the qualifications and experience of the inspectors involved. In some cases certification of such personnel may be a requirement. This is common, for example, in some types of safety-related inspection activities.

Inspection also covers a very broad spectrum of sectors and characteristics being inspected. It may, for example, cover cargo-superintending of commodities and products, for determination of quantity, quality, safety, fitness for use, and compliance of plants, installations, operating systems, and design suitability. Inspection might also, for example, embrace the rating systems used to classify accommodation, airline services, tourism services, etc.

As has already been pointed out, conformity assessment is an elastic concept in that particular types of activities might be called testing in some fields, inspection in others and certification in yet further fields. This fact highlights the need to concentrate on deciding what is needed for a particular situation and specifying it accordingly.

For example, is the inspection required in its own right, such as that relating to regulatory inspection of pressure vessels, or is it one of the inputs to a certification process? **Chapter 3** looks at the design of conformity assessment systems and schemes, where such matters have to be considered.

Auditing

ISO 19011 provides guidance on auditing. The ISO 9000 and ISO 14000 series of International Standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organization's quality and/or environ-

mental policy. Audits are also an essential part of conformity assessment activities such as external certification/registration and of supply chain evaluation and surveillance.

An audit is defined in ISO 19011 as a systematic, independent and documented process for obtaining *audit evidence* and evaluating it objectively to determine the extent to which the *audit criteria* are fulfilled.

Audit criteria are contained in a set of policies, procedures or requirements which have been established by the organization being audited as meeting their needs, including the implementation of such management system standards as ISO 9001. The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry/business sector codes of conduct.

Audit evidence comprises records, statements of fact or other information relevant to the audit criteria and which are verifiable. Audit evidence may be qualitative or quantitative.

Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization itself for management review and other internal purposes, and may form the basis for an organization's self-declaration of conformity. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing registration or certification of conformity to the requirements of ISO 9001 or ISO 14001.

When a quality management system and an environmental management system are audited together, this is termed a combined audit. When two or more auditing organizations cooperate to audit a single organization this is termed a joint audit.

A typical audit process should consist of the following:

- Identification of sources of information
- Collecting the information by appropriate sampling and verifying
- Establishing audit evidence from the information
- Evaluating the information and evidence against audit criteria

- Identifying audit findings
- Reviewing the audit findings and evidence
- Audit conclusion.

Methods for collecting audit evidence include interviews, observation of activities and review of documents

Evaluation

Evaluation is the term used in ISO/IEC Guide 65 and ISO/IEC 17024 to cover the range of activities concerned with gathering evidence of conformity. These activities can include testing, inspection and auditing but can also include other activities such as studying design drawings and specifications to ascertain that the features required to meet the specified requirements are adequately defined.

For some products, for example where the internal parts are protected by a cast resin, it would not be possible to verify from a finished product that components of the correct rating had been incorporated. Having a definitive set of drawings of a product helps in the control of changes which may need to be made after conformity assessment has been completed.

Examination

Examination is one of the terms used almost interchangeably to cover a number of determination activities, but it is used in a more specific way when referring to methods for measuring the competence of a person. In this context, as explained in ISO/IEC 17024, an examination may be carried out in written, oral or practical form.

Examinations need to be planned and structured in a manner which ensures that all specified requirements are objectively and systematically verified, with sufficient documented evidence produced to confirm the competence of the candidate.

Peer assessment (peer evaluation)

Peer assessment, also known as peer evaluation, is a process used to ascertain the conformity of a person or organization with a set of requirements for membership of a group which the person or body wishes to join. The assessment is carried out by members of the group, in other words the peers of the applicant.

For the conformity assessment field, the process is specified in ISO/IEC 17040 and is used by groups of bodies which wish to be able to accept each others' conformity assessment results.

Peer assessment is used for example by certification bodies in the IEC conformity assessment systems and by accreditation bodies in ILAC and IAF. Peer assessment requires the following elements:

- Competent assessors, drawn from members of the group
- Clearly specified membership criteria decided by the group
- A methodical assessment of the candidate organization's conformity with the criteria
- A report of the findings with sufficient information for the group to decide on the candidate organization's suitability for membership.

The group will decide upon whether there is a need for periodic auditing and re-assessment of the members of the group. If so, the relevant parts of the process will be undertaken.

The members of peer assessment agreement groups are generally all expert in the particular technical areas covered by the agreement and so provide a high level of technical competence for the peer assessment. On the other hand, the bodies could be in competition with each other and might not be totally impartial. The peer assessment scheme needs to be well-managed in order to maintain its effectiveness in inspiring confidence in the work of its members.

One aspect of peer assessment in a multilateral arrangement is to ensure that the assessment teams are drawn from across the membership and do not involve assessors from two different members assessing each others' organizations.

Accreditation

Accreditation is a conformity assessment technique specifically related to the assessment of the conformity of conformity assessment bodies by a third party body, generally known as an accreditation body. The requirements for accreditation bodies are specified in ISO/IEC 17011 and are discussed in **Chapter 4**. Accreditation generally involves the use of auditing techniques by assessment teams including experts in the organizational aspects such as management systems and also in the technical activities of the body. For example, for a testing laboratory the team would include one or more experts in the types of measurement and testing being carried out.

Report

At the completion of every determination activity it is necessary to produce the evidence of conformity which has been gathered. The evidence is usually contained in a report, sometimes referred to as a technical file, which includes:

- A definitive identification of the item which has been assessed
- A statement of the requirements to which conformity has been assessed
- Details of the determination activities which have been carried out, such that it would be possible to repeat the activities in the same manner if it was necessary to verify the evidence
- Details of the resources used, including people, measuring instruments and other evaluation tools, to provide traceability of the results
- The results of the activities in sufficient detail for a person not involved in the activities to verify conformity (or nonconformity) with the specified requirements.

The report is passed to the person or body responsible for review and attestation and should be made available to the person or organization for which the work has been done.

Review & attestation

In the functional approach, review and attestation are presented as a combined activity. It is possible, though, for different people to carry out each of them. What is important is that neither activity should be carried out by a person who has been involved in the determination activities. Of course, where the risks of nonconformity

are low, this safeguard might not be necessary, but the principle of having the results reviewed by someone else does provide an enhanced level of confidence in the statement of conformity. As the risks of nonconformity rise, so the degree of independence of the reviewer(s) should increase.

For lower levels of risk, another person in the same department could be used. For medium risks, the review could be done by a person from another department in the organization while, for higher risks, the work should be undertaken by an independent organization.

It is important that, whether the conformity assessment is being carried out as a 1st, 2nd or 3rd party process, the person(s) conducting the review have the competence to understand the information presented to them and to analyze it for demonstrating conformity with the specified requirements.

The reviewer must have the necessary competence relating to the specified requirements, the object being assessed and the determination activities that have been used. For example, knowledge of the test methods would enable the reviewer to identify anomalous results and refer the report back to the person(s) who carried out the test for it to be repeated.

In some 3rd party attestation schemes the body may only carry out the review and attestation, with the selection and determination having already been carried out either by another 3rd party or by the supplier of the object. It is particularly important in such cases for the reviewing and attesting body to have arrangements to keep the competence of its reviewers up to date with the current state of the art.

The conclusion of the review stage is a recommendation for a statement of conformity to be issued. The recommendation should make reference to the report and to any other findings from the review which substantiates the conformity of the object with the specified requirements.

Resolution of nonconformities

One possible outcome from the review is a finding that the object does not conform to the specified requirements in one or more respects. Alternatively it could be the case that the evidence of conformity is incomplete and one or more of the specified requirements has been overlooked. In either case the report should be returned to the person responsible for the determination activities for remedial action to be taken.

In the case that the object is found not to conform, the person or organization responsible for the object, e.g. the development engineer or, for a 2nd or 3rd party situation, the supplier, should be informed and invited to make the changes necessary to achieve conformity. It is important that the reviewer does not suggest possible solutions so as not to lose their objectivity when the object is returned for a further review. Discussion of the assessment results is permissible so that the person or organization responsible can understand the cause of the nonconformity.

The relevant determination activities will need to be repeated and a further report will be presented for review. By agreement with the reviewer, the report need only deal with the changes which have been made.

Statement of conformity

The conclusion of the conformity assessment process is the issuing of a statement of conformity which can take a number of forms as described below. Whichever form it takes, the statement should provide unequivocal identification of the object and of the specified requirements with which it has been found to conform. The statement may be on paper or in some other retrievable means such as photographic or digital media.

Declaration of conformity

A statement of conformity issued by a 1st party, e.g. the supplier of a product, or a 2nd party, e.g. the purchaser, is known as a declaration of conformity. This practice has been adopted to differentiate these statements from those issued by a 3rd party body, which are known as "certificates".

ISO/IEC 17050 provides information on the content of a supplier's declaration of conformity. A declaration by a 2nd party could take a similar form.

Certificate of conformity

A statement of conformity issued by a 3rd party is often referred to as a certificate of conformity. However the term used and the specific content can vary according to the object being assessed and the nature of the specified requirements. The related ISO/CASCO standards referred to in **Appendix 1** provide information on the nature and content of the conformity statements.

Mark of conformity

It is common for products to bear marks of conformity, whether these are the supplier's own trade mark, a certification mark controlled by a certification body or a conformity mark required by legislation, such as the EU's CE marking. Advice on marks of conformity is contained in ISO/IEC 17030 and ISO Guide 27. Marks must be distinctive and their ownership and conditions of use should be clearly stated. In particular the use of a mark should not be misleading to purchasers and users of the products. For example, a supplier which has a certified management system conforming to ISO 9001 must not place the certification body's mark on its products, since that would imply that the body had certified the products.

Frequently, the use of a mark of conformity is controlled through a licence issued by the owner of the mark or by an organization operating on behalf of the owner such as a certification body. The licence spells out the conditions under which the licensee can use the mark such as the restriction to use it only on products which the supplier has verified as conforming to the certified product type.

Policing of the use of marks of conformity is vital for the interests of the owner and licensing body, since products bearing their mark are often produced under a system in which only occasional samples of product are verified by the licensing body. See **Chapter 3** for more information on different conformity assessment systems.

Surveillance

Conformity assessment can end when attestation is performed, but where there is a need to provide continuing assurance of conformity, surveillance can be used. Surveillance is defined as a systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

The needs of users drive such activities. For example, an object of conformity assessment may change over time, which could affect its continuing fulfilment of specified requirements. Or, users may demand ongoing demonstration that specified requirements are fulfilled ; for example, when a product is produced continuously.

The activities undertaken in surveillance are planned in order to satisfy the need to maintain the validity of an existing statement resulting from attestation. A complete repeat of the initial assessment is usually not necessary in every iteration of surveillance to satisfy this need. Thus, the activities in each function in **Figure 4** (see page 30) during surveillance may be reduced, or different from, the activities undertaken in the initial assessment.

Selection activities take place in both the initial assessment and in surveillance. However, entirely different choices might be made in surveillance. For example, a test for a product may have been selected in the initial assessment. In surveillance, an inspection might be selected to determine that a sample of the product is the same as the sample originally tested. In fact, the choices in selection may change from time to time, based on information from previous iterations of surveillance and other inputs. Ongoing risk analysis or consideration of market feedback regarding actual fulfilment of specified requirements may be part of selection activities in surveillance.

Choices about the specified requirements can be different as well. For example, only a subset of the specified requirements might be selected in any given iteration of surveillance. Or, similarly, only a portion of the object of conformity assessment may be selected for determination activities in surveillance ; for example, only a portion of an accredited certification body may be audited during surveillance.

As noted above, the different choices in selection can lead to different determination activities for surveillance purposes. However, in both initial assessment and surveillance, the output from selection defines the determination activities and how they will be carried out.

The review and attestation function is also used in both initial assessment and surveillance. In surveillance, a review of all the inputs and outputs in **Figure 4** leads to a decision whether the statement resulting from attestation continues to be valid. In many cases, no special action is taken if the statement continues to be valid. In other cases, for example, if the scope of attestation has been extended, a new statement of conformity might be issued.

If the decision is that the statement of conformity is no longer valid, appropriate activities are necessary to advise users; for example, that the scope of attestation has been reduced or that the statement has been suspended or withdrawn.

Market surveillance

Market surveillance is a particular form of post attestation activity. It could be conducted by the supplier in the form of customer surveys or periodic inspection of installed products, perhaps as part of a servicing contract. Market surveillance is also carried out in some certification schemes, where samples of certified products are taken from the marketplace and subjected to inspection or testing to determine whether they conform to the specified requirements.

In many countries, the regulatory authorities have a responsibility for protecting consumers and enforcing the health and safety regulations by carrying out market surveillance. This kind of work can be carried out on a routine basis but the economic constraints usually lead to a targeted surveillance, either concentrating on the highest areas of risk or responding to reports of nonconforming products. A report on the ISO/CASCO workshop on market surveillance is available from **http://iso.org/cascoworkshop2008**

Whether the market surveillance is carried out by the supplier, a certification body or the regulatory authorities, it needs to be done in a systematic way with comprehensive and accessible records. There should also be a systematic follow up so that any adverse effects can be corrected, if possible, and can be prevented from happening in the future. Measures can include remedial action and product recall.

In today's global economy, it is advantageous for regulatory authorities in different countries to share market surveillance information, so that lessons learned from an incident in one country can be used in others to prevent defective items from reaching the market or to take them out of use before they cause damage.

Chapter 3 – Conformity assessment schemes and systems

Who carries out conformity assessment?

The question of who should carry out the conformity assessment is a crucial one when it comes to putting theory into practice. One of the basic principles of conformity assessment is that the organization which owns the object of assessment or places it on the market has the primary responsibility for its conformity with the stated requirements. In this chapter we discuss the role of other parties and how the arrangements for particular situations can be decided. Reference to relevant tools from the CASCO toolbox is included.

To illustrate the principle of primary responsibility, the supplier of a product will have a contractual and a legal duty to the user that the product will perform its declared function and that it will not endanger the health or safety of the user. Even if the supplier obtains a certificate from an independent body stating that the product conforms to the relevant specification, if anything goes wrong, the supplier remains responsible.

Although the independent body might incur some degree of liability, particularly if it had been negligent in performing the conformity assessment, that would not absolve the supplier from the primary responsibility. Of course, misuse by the end user, particularly a failure to carry out proper maintenance, could absolve the supplier from liability for subsequent damage and its consequences.

1st, 2nd and 3rd parties – roles and responsibilities

In order to identify the parties which might be involved in conformity assessment it is useful to refer to first, second and third parties as referred to in **Chapter 2**.

In the case of commercial transactions such as the supply of a product or service, the supplier is the first party, the purchaser is the second party and any other organization which has no commercial interest in the transaction is a third party. Looking at the roles and responsibilities of the different parties, using the example of a product:

- The first party provides the product and is responsible for its conformity with the specified requirements. These requirements could be the first party's own specification, a

specification provided by the purchaser or legal requirements relating to the product or any combination of the three. In any of these cases reference could be made to one or more national, regional or international standards

- The second party specifies its requirements and is responsible for assuring itself that the product conforms to them
- A third party could be requested by the first or second party to assess conformity of the product with the specified requirements and would be responsible for providing a statement of conformity (or nonconformity).

Definition of schemes and systems

Before looking in detail at the activities of the different parties it is useful to introduce the idea of conformity assessment schemes and systems. While each conformity assessment situation could be treated differently, there are many advantages to a systematic approach. The basic building block is a *scheme* which relates to a particular group of objects having sufficiently similar characteristics that the same set of rules and procedures can be carried out under the same management for assessing conformity with the same set of specified requirements.

A conformity assessment *system* uses a common set of rules, procedures and management for several conformity assessment schemes. The rules and procedures may need to be detailed in different ways for different schemes, but there are advantages in terms of efficiency and consistency to working within a common framework.

Scheme owner

Each conformity assessment scheme will have an owner. A number of different arrangements could apply and some examples are:

a. A manufacturing organization could set up a conformity assessment scheme for its products, including testing, inspection and auditing, leading to the issuing of declarations of conformity.
b. A scheme could be developed by a certification body for sole use of its clients, in which case the certification body takes on full responsibility for the design, application, management and maintenance of the scheme. The body would be the scheme owner.
c. An organization such as a regulatory body or a trade association might develop a scheme and invite one or more certification bodies to operate it. In that case, the organization would be the scheme owner and would take responsibility for

the operation of the scheme, probably through a contract or other formal agreement with the certification bodies.

d. A group of certification bodies, perhaps in different countries, might together set up a certification scheme. In that case, it would be necessary for the bodies, as joint owners of the scheme, to create a management structure so that the scheme could be operated effectively by all participating bodies.

If it was found necessary to operate several schemes which used the same rules, procedures and management, the scheme owner could set up a product certification system under which the different schemes could operate without the need for replicating the management structure for each scheme. In that case, the scheme owner would become the system owner and be responsible for the management of the system and the schemes operating within it.

Scheme design based on risk

A key decision when setting up a scheme is who should be involved in carrying out the conformity assessment. The decision should be based on an assessment of the risks which could arise from nonconformity, looked at from the point of view of both the likelihood and the consequences of the product, service, etc. failing to conform to the specified requirements.

Sometimes the consequences could be of a commercial nature such as loss of market reputation and sales volume if a series of product failures occurred or interruptions to production if a supplier delivered faulty goods. In other situations it could be hazards to the health and safety of people which could be of concern.

Conformity assessment costs money and takes time. The amount of money and time to spend on it needs to be balanced against the risks of nonconformity. While conformity assessment carried out in-house by the supplier could be limited to inspection, the inspector has to be paid and there can be delays to production or dispatch while the inspection is carried out.

As the nature of the product becomes more complex and the risks of nonconformity become higher, conformity assessment activities will become more extensive, possibly involving expensive test equipment and extended testing programmes. Sometimes it can be more cost effective to contract out the conformity assessment work to a third party, but this is more of a commercial decision by the supplier.

Where the risks of nonnconformity are high, it is usual to require an independent body to carry out some defined conformity assessment activities and at least to review the evidence of conformity and issue an attestation document such as a certificate. The body will charge for its services and will need to take time to complete its work. The scheme owner will need to specify whether the work is to be carried out by one particular body or by any body which meets the scheme's requirements.

Costs associated with conformity assessment

When deciding on the appropriate conformity assessment arrangements for a particular situation, it helps to be aware of the nature and extent of the costs of alternative approaches. As stated above, there are costs entailed in carrying out self assessment but as soon as another party becomes involved it is necessary to take account of what additional costs might be incurred and by whom. If the purchaser of a product decides to carry out their own assessment, they will generally have to bear the costs of employing their own inspectors.

If an independent body is contracted to carry out conformity assessment, the body will need to recover its costs from whoever it is working for. In the case of product certification, it is usually the supplier who will engage and pay the certification body. The body's costs will not only relate to the assessors involved in the assessment work, but also all of the expenditure incurred in running its business, a proportion of which will be charged to each certification customer.

Thus the decision to establish a certification scheme can add to the costs incurred in the supply of the certified products. Similarly, a decision to require certification bodies to be accredited will add a further layer of costs as the expenditure incurred in operating the accreditation body has also to be recovered.

In addition to the direct costs of conformity assessment, there are other factors which have financial implications particularly for suppliers of certified products. The involvement of a 3rd party can lead to delays in producing and delivering products if there is a significant time lag between the application for certification and the receipt of the certificate of conformity.

With the ever-accelerating pace of product and market development, such delays can lead to lost opportunities to sell products and can even have an adverse effect on the reputation of the

supplier. The financial consequences can be serious and measures need to be adopted to minimize them, such as fully understanding the specified requirements and maintaining good communications with the certification body from the outset.

One important aspect to consider when designing a conformity assessment scheme is whether to allow or encourage competition between conformity assessment bodies. The main benefits of competition are to provide choice for the suppliers and to prevent a single body from abusing a monopoly position. At the same time, competing bodies might be tempted to cut corners in an effort to meet the needs of customers and care needs to be taken to prevent the standard of assessment from falling. Accreditation or peer assessment can help to counteract the adverse effects of competition.

In summary, the benefits of independent conformity assessment in terms of market acceptance and the avoidance of the consequences of product failures can far outweigh the direct and indirect costs of the conformity assessment arrangements, but such an outcome should be the result of a careful analysis of the risks, rather than being a matter of simply following the current fashion.

Voluntary and regulatory schemes

Conformity assessment schemes can be set up for commercial purposes such as to improve market perception for a group of suppliers, to share assessment facilities by a group of purchasers or to respond to market needs by a third party assessment organization. In each of these cases there is no legal requirement for suppliers or purchasers to use the scheme, although there can be strong market and peer pressure to do so.

At the same time, regulatory authorities can find it useful to introduce specific conformity assessment arrangements in order to provide assurance that legal requirements are being met. The authorities will consider the dangers to workers, consumers, the environment and the economy posed by deficient goods, services or processes. The measures which they adopt will need to be proportional to the risks involved, with statutory inspection or certification schemes being introduced where the risks are highest.

Setting the "specified requirements" – standardization

When it comes to specifying the requirements to which conformity is to be assessed, there are many benefits in using

international standards such as those published by ISO and IEC. To begin with, the standards represent the current, collective wisdom of those involved in the particular technical areas where the standards are being applied; so users of these standards can apply well tried and tested solutions. In addition, products, services and other objects of assessment will gain acceptability on world markets more readily if they conform to these standards. The UNIDO-ISO publication *Fast forward* provides information and advice on standardization

Supplier's declaration of conformity

Regardless of whether any other parties are involved in the conformity assessment, there will always be some form of declaration of conformity by the supplier of the product or service. The declaration might take the form of an advertisement or leaflet describing the features of a product or could be incorporated in a formal document setting out the identification of the supplier and the product, the specification of the standards or other documents to which conformity is being declared, perhaps the particular regulations with which the item complies and the signature of a responsible person.

Even the placing of the supplier's name, trade mark or logo on or in conjunction with the product implies that it conforms to the supplier's specification. ISO/IEC 17050 provides guidance on the content of a supplier's declaration of conformity.

Independent and expert conformity assessment

Where the risks of nonconformity have been judged to be sufficiently high, an independent body could be involved in the conformity assessment. Whether the scheme owner is a group of first parties, one or more second parties, a third party or a regulatory authority, the decision to provide for or require third party conformity assessment needs to be accompanied by a careful selection of the criteria which will be used to judge the suitability of third party conformity assessment bodies. It is recommended that the CASCO toolbox (**Appendix 1**) is used for this purpose, as discussed in **Chapter 4**.

Sector schemes

Most conformity assessment schemes will be developed by and used in a particular sector of industry or commerce. Even management system schemes which monitor the application of generic system standards such as ISO 9001 and ISO 14001 require the bodies and the auditors to have knowledge and experience relevant to each sector.

There is some discussion over what constitutes a sector. There are the broad sectors covering:

- Primary activities such as farming and mining
- Secondary activities such as manufacturing
- Tertiary activities including distribution and retailing and the provision of services.

Each of these sectors can be subdivided into further sectors according to the nature of the activities. Within manufacturing, for example, there could be metal goods, cars and trucks, electrical products, processed food, chemicals, pharmaceuticals, and so on.

What matters for a sector definition for conformity assessment purposes is that the characteristics of the objects being assessed and their means of production and delivery are sufficiently similar that a single scheme can work effectively. Where, for example, diverse areas of competence, differing testing equipment and varying assessment methods are required then it could be advantageous to set up a scheme for each sector.

From the point of view of the economics of conformity assessment, one of the dangers with setting up narrow schemes for small sectors is that the practices could diverge from sector to sector, making it hard to operate to a single set of policies and procedures under the same management. There can also be pressure to develop diverging general requirements for the conformity assessment activities, making it more difficult to maintain international equivalence and recognition.

Product certification systems

ISO/IEC Guide 67 describes seven major types of product certification systems, while noting that the elements in those systems can be combined in other ways to create additional systems. The features of the seven systems described in Guide 67, with the terms updated to those used in the functional approach, are as follows:

System 1a *(based on testing)*

- Product samples requested by the certification body
- Determination of the relevant product characteristics by testing (ISO/IEC 17025) or assessment
- Review of the test or assessment report
- Attestation of conformity.

In this system, the samples taken may not be representative of, or be statistically significant for, the entire population of products as, for example, in a system where the initial products are tested

and subsequent conformity of production items is assessed and attested by the manufacturer with no 3rd party involvement. Such systems are sometimes referred to as "type approval" systems.

Manufacturers need to be careful not to refer to production items as "certified" as only the initial sample was tested by the certification body. Such statements as "produced to a design certified by xxx" might be acceptable but purchasers and end users need to be aware of the limitations of the statement.

System 1b *(based on testing all products)*

- Samples requested by the certification body
- Determination of the relevant product characteristics by testing (ISO/IEC 17025) or assessment
- Review of the test or assessment report
- Attestation of conformity
- Issue of a licence to use certificates or marks on the products.

In this system, the entire population is available to the certification body, which will decide whether and to what extent statistical sampling is appropriate. The attestation of conformity will relate to the whole population and a certificate of conformity for each product could be provided by the certification body. Where the system includes the use of a mark of conformity, the certification

body will licence the manufacturer to apply the mark to all of the products covered by the attestation.

System 2 *(based on testing plus market surveillance)*

- Samples requested by the certification body
- Determination of the relevant product characteristics by testing (ISO/IEC 17025) or assessment
- Initial auditing of the production process or quality system
- Review of the test or assessment reports
- Attestation of conformity
- Issue of a licence to use certificates

or marks on the products
- Surveillance by certification body taking samples from the market and testing or inspection to confirm ongoing conformity.

While this system may identify the impact of the distribution chain on conformity, the resources it requires can be extensive. Also, when significant nonconformities are found, effective preventative measures may be limited since the product has already been distributed to the market.

System 3 *(based on testing and factory surveillance)*
- Samples requested by the certification body
- Determination of the relevant product characteristics by testing (ISO/IEC 17025) or assessment
- Initial auditing of the production process or quality system
- Review of the test or assessment reports
- Attestation of conformity
- Issue of a licence to use certificates or marks on the products
- Surveillance by testing or inspection of samples from the factory and auditing of the production process.

This system includes testing and factory surveillance. Factory surveillance is conducted and samples of the product from the point of production are assessed for ongoing conformity. This system does not provide any indication of the impact the distribution channel plays on conformity. When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution depending on the frequency of surveillance. For example, if surveillance is carried out every six months and nonconforming product is found, the entire production since the previous surveillance could be suspect.

System 4 *(based on testing plus surveillance from factory or open market, or both)*
- Samples requested by the certification body
- Determination of the relevant product characteristics by testing (ISO/IEC 17025) or assessment
- Initial auditing of the production process or quality system
- Review of the test or assessment reports
- Attestation of conformity
- Issue of a licence to use certificates or marks on the products
- Surveillance by testing or inspection of samples from the factory and auditing of the production process
- Surveillance by testing or inspection of samples from the market.

This system can both indicate the impact of the distribution channel on conformity and provide a pre-market

mechanism to identify and resolve serious nonconformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.

System 5 *(based on testing, quality system assessment and surveillance, plus ongoing surveillance of product from production, market or both)*

- Samples requested by the certification body
- Determination of the relevant product characteristics by testing (ISO/IEC 17025) or assessment
- Initial auditing of the production process or quality system
- Review of the test or assessment reports
- Attestation of conformity
- Issue of a licence to use certificates or marks on the products
- Surveillance of production process or quality system or both
- Surveillance by testing or inspection of samples from factory, open market or both.

This system includes both testing and the assessment of that part of the quality system which relates to the conformity of the products with the specified requirements. Surveillance of the quality system is conducted and samples of the product may be taken from either the market or the point of production, or both, and are assessed for ongoing conformity.

The extent to which the three elements of ongoing surveillance – quality system, factory samples and open market samples – are conducted may be adjusted for a given situation. As a result, this system provides significant flexibility for ongoing surveillance.

System 6 *(covering certification of processes and services)*

- Determination of characteristics of processes or services by assessment
- Initial auditing of the quality system
- Review of assessment results
- Attestation of conformity
- Issue of a licence to use certificates or marks in relation to the process or service
- Surveillance by audits of the quality system
- Surveillance by assessments of the processes or services.

This system uses techniques adapted to the characteristics of the service or process under assessment.

Flexibility of conformity assessment

The systems described above represent some of the more common approaches to conformity assessment but other combinations of techniques can be used according to the nature and purpose of the system. The descriptions illustrate the flexibility which is

available to designers and owners of conformity assessment systems. The systems need to be fit for purpose so that the costs involved in their operation and maintenance are consistent with the benefits being obtained and the risks being managed.

International conformity assessment systems

The International Electrotechnical Commission (IEC) operates three conformity assessment systems under the control of its Conformity Assessment Board (CAB):

- IECEE for electrical and electronic products for industrial and domestic use. The IECEE system includes two schemes
  - The CB Scheme, through which test reports prepared by approved testing laboratories and endorsed by national certification bodies using a CB test certificate can be accepted by other national certification bodies in issuing their own national (or regional) certification
  - The CB-FCS Scheme which includes assessment and periodic surveillance of the manufacture of the products as well as the type testing as in the CB Scheme.

- IECQ for electronic components. There are three schemes:
  - The Process Approvals Scheme which provides independent verification that electronic components and related materials and processes, including those below the user's level of specification in the supply chain, are compliant to appropriate standards, specifications or other documents
  - Hazardous Substances Process Management (HSPM) Scheme using a quality management standard that companies can use to ensure their processes and controls adhere to local regulations about hazardous substances, such as lead, mercury and cadmium, in electronic components
  - Electronic Component Management Plan (ECMP) Scheme for avionic components, providing accredited third party assessment of electronic component management plans, prepared to comply with IEC TS 62239.

- IECEx relating to safety in explosive atmospheres and comprising four schemes:
  - The Certified Equipment Scheme for products used in explosion hazard areas, "Ex products"
  - The Certified Service Facilities Scheme for the repair of Ex products
  - The Conformity Mark Licensing System to be used in conjunc-

tion with the certified equipment scheme
– The Certified Persons Scheme providing evidence of the competence of people for a range of specified duties relating to explosive atmospheres.

The European Union's Global Approach to conformity assessment

The Global Approach to conformity assessment is part of a package of legislation designed to remove technical trade barriers within the European Union (EU) and the wider European Economic Area (EEA) by aligning the legislation of the member states in areas of particular sensitivity such as safety.

Originally introduced in 1993, it was amended in 2008 through a new legislative framework including Decision No. 768/2008/EC 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC. The decision was published in the Official Journal of the EU No. L/ 218 dated 2008-08-13.

The Global Approach specifies a series of conformity assessment modules to be used by legislators when drafting legislation to align the laws of member states, usually on matters relating to safety, where differing laws have impeded trade between member states. For each piece of legislation, usually in the form of an EU Directive, the modules will be chosen in relation to the risks arising from nonconformity with the requirements specified in the directive.

For low risks, a supplier's declaration of conformity will suffice while for the highest risks third party assessment of products and quality management systems will be specified. Various combinations of modules can be included so as to give suppliers an element of choice according to their circumstances while still maintaining the required level of assurance of conformity.

The conformity assessment modules cover:

- Self assessment by the manufacturer
- Type assessment by an independent body ("notified body")
- Quality assurance assessment by a notified body
- Inspection of production items by a notified body.

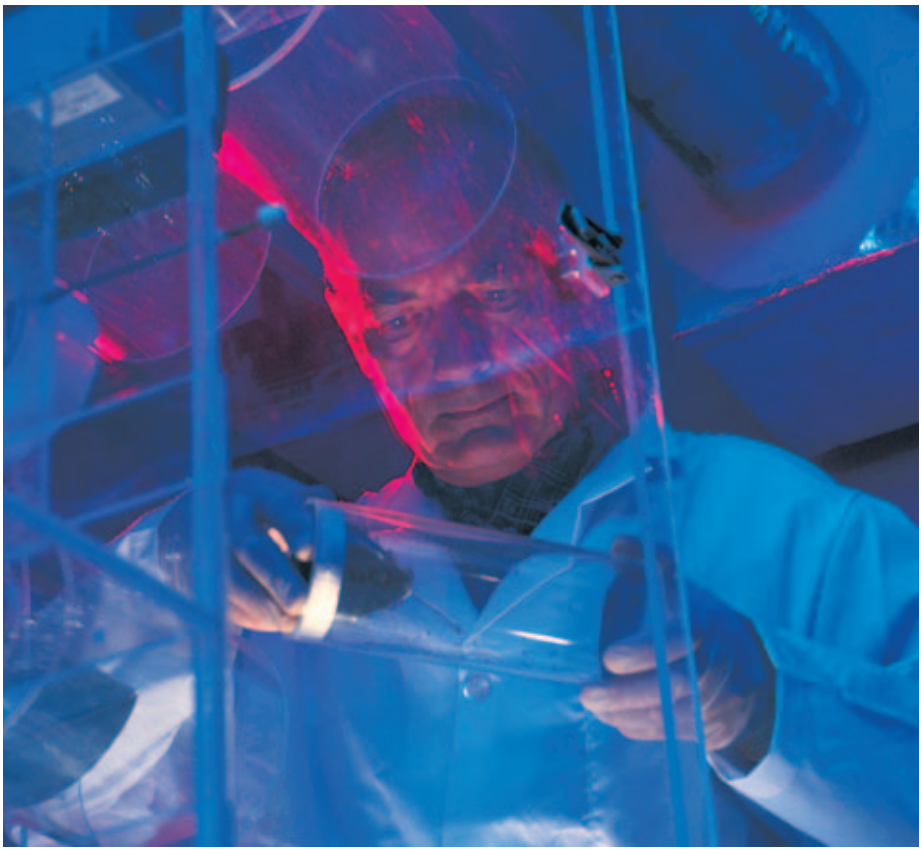
The Global Approach could be regarded as a conformity assessment system with the arrangements for each directive being regarded as separate schemes.

For more on the EU system, see **http://ec.europa.eu/enterprise/newapproach/index_en.htm**

Potential barriers to trade

The potential for conformity assessment systems, particularly those operated by regulatory authorities, to create barriers to trade has been recognized and the WTO/TBT Agreement was made in order to harmonize the regulations and conformity assessment practices in signatory countries (see **Appendix 3**).

Nevertheless, the procedures operated by conformity assessment bodies can inadvertently discriminate against suppliers from other countries. Regulatory authorities and bodies operating in the non-regulated sector are encouraged to ensure that the conformity assessment systems operate in an open and consistent manner. Bodies conforming to the requirements of the ISO/IEC standards for conformity assessment bodies are required to operate in an even-handed manner.



Chapter 4 – Conformity assessment bodies

Reference to ISO/CASCO tools

The ISO/CASCO standards and guides (se **Appendix 1**) define the characteristics for a number of different types of conformity assessment bodies. Some, such as testing laboratories and inspection bodies can work as 1st, 2nd or 3rd party bodies, while certification can only be conducted as a 3rd party activity.

Where bodies act in a 3rd party capacity, an important feature is that they have to act in an impartial way so that the results of their work can be objective and maintain the highest degree of confidence. The standards for certification bodies mentioned in the following sections set out the requirements for demonstrating and maintaining impartiality.

Testing laboratories

Requirements for testing and calibration laboratories

For testing, the main international standard that is used to specify the basic requirements against which competence is assessed is ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*. ISO/IEC 17025 has two types of requirements, namely:

- Management systems requirements
- Technical requirements.

While the management system requirements will be common to all laboratories, there is a need to apply the technical requirements to their specific field of work. The potential need for such additional requirements is recognised in ISO/IEC 17025 where it includes an informative annex (Annex B) on guidelines for establishing applications for specific fields.

For example, medical laboratories have had to develop supplementary criteria for medical sub-disciplines (such as biochemistry, microbiology etc). In fact, in this instance a separate standard for medical laboratories ISO 15189 has been produced, but it remains compatible with ISO/IEC 17025.

It is important for the laboratory to specify the scope of its testing work so that it can be confident that it has the people, equipment and facilities to carry out the work competently. In many cases, the laboratory will use standardized test methods and it is useful for the scope to be specified by

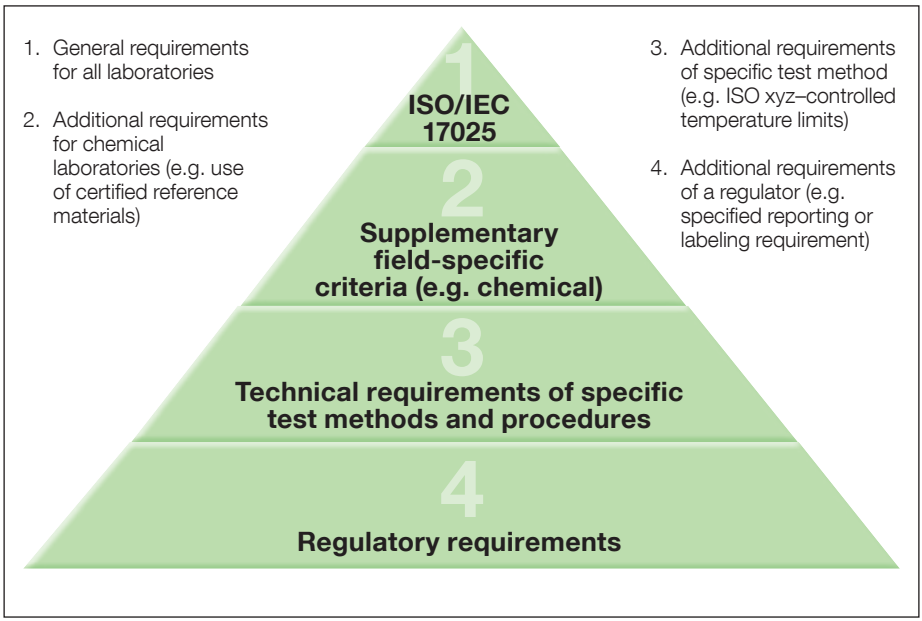
reference to the standards. In this way, clients of the laboratory will be confident of its capability to perform the tests which they require.

When the laboratory seeks accreditation, the accreditation body will not only assess compliance with the general standard and any field-specific supplements, but also their compliance with the technical requirements of specific standard test methods for which the laboratory is recognised. In some cases this will also include specific requirements of regulators.

There thus becomes a hierarchy of criteria which laboratories may need to satisfy as shown in **Figure 5**.

The management systems and technical requirements of sector specific standards such as ISO 15189 for medical laboratories are compatible and cover similar issues. However, the language of ISO 15189 is more aligned to terminology used in clinical testing and includes some specific needs of such laboratories. The content of the management systems requirements of both standards is aligned with the principles in ISO 9001, but again the language has been tailored to the needs of laboratories.

Figure 5 – Hierarchy of laboratory criteria



Inter-laboratory comparison testing and proficiency testing

Testing laboratories may need to become involved in inter-laboratory comparison testing and in particular with proficiency testing. Inter-laboratory comparison testing may be used for a number of purposes including:

- Establishing the effectiveness and comparability of new test or measurement methods and similarly to monitor established methods
- Identifying the reasons for differences in the results obtained by different laboratories
- Determining the performance of individual laboratories for specific tests or measurements and to monitor laboratories' continuing performance.

Proficiency testing is the use of inter-laboratory comparison testing for the last of these items but it can also provide information for other purposes including those listed above.

One of the tasks of ISO/CASCO has been to produce the guide and, more recently, the standard which applies to proficiency testing. Its ISO/IEC Guide 43 was expected to be replaced in 2009 by the new standard, ISO/IEC 17043, *Conformity assessment – General requirements for proficiency testing.*

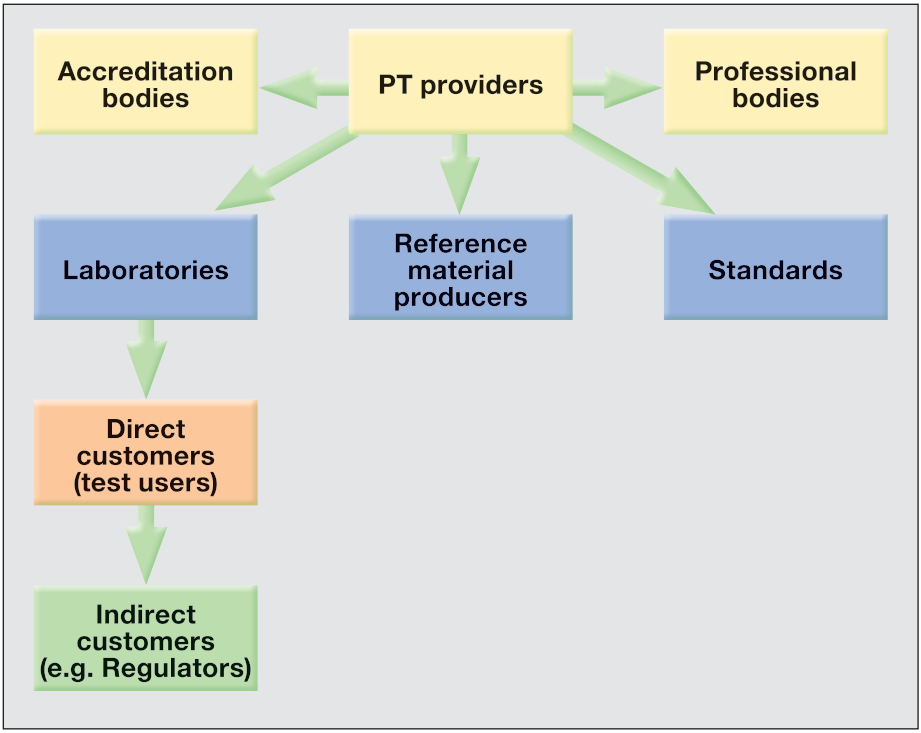
Proficiency testing can be a powerful tool for the laboratories. Successful performance can be a major risk management tool, while any poor performance arising from their participation can be the catalyst to investigate the causes and take appropriate corrective action. Because competent proficiency testing is so critical to the confidence which accreditation bodies need in their recognition of the competence of testing and calibration laboratories, a number of accreditation bodies are now actively involved in accrediting proficiency testing providers.

Many proficiency tests also benefit other stakeholders, as the results of the inter-laboratory tests might also be used in determining values for certified reference materials; in improving standard test methods; in re-assuring clients of laboratories, including regulators; and as an educational tool for professional bodies. **Figure 6** (see page 62) shows some of the stakeholders in proficiency testing.

Case study – Competence of laboratories in Pakistan

The significance of access to credible testing and calibration laboratories to support trade development and access to foreign markets is well illustrated in a recently conducted programme for trade related technical assistance in Pakistan. This involved inputs from a number of agencies over the period 2004-2007, including a number of

Figure 6 – Stakeholders in proficiency testing (PT)



specific activities supported by UNIDO which were targeted at developing the capacity and competence of key testing and calibration laboratories and having their competence confirmed through accreditation by a well established foreign accreditation body.

While developing domestic testing capabilities, the UNIDO inputs also included parallel upgrading of the capacity of Pakistan's national accreditation body, to ensure the ongoing availability of a domestic resource to demonstrate the competence of Pakistan's testing and calibration services.

The specific needs for competent testing and calibration were first established through various assessments of constraints faced by Pakistan's exporters in relation to supply side proof of conformity and market connectivity issues. These assessments included specific testing needs associated with:

- Pakistan's agro-based exports and sanitary and phyto-sanitary com-

pliance (conducted as a joint World Bank-UNIDO initiative)
- Trade related challenges facing exporters in Pakistan by 157 local firms. These included a focus on sectors such as textiles, leather, agro-based processing and fisheries (conducted as a joint initiative of UNIDO and the Pakistan Institute of Development Economics)
- A survey of the compliance issues affecting enterprise clusters in the Punjab province of Pakistan. This covered 195 firms in sectors producing fans, cutlery, textiles and garments, mangos and tangerines. It included specific needs associated with testing, certification, calibration and CE marking, labelling and branding (conducted jointly by UNIDO and the Small and Medium Enterprise Authority).

Exporters in Pakistan had historically relied heavily on foreign testing of their products to achieve international acceptance of their compliance. This was costly and time consuming and particularly for small exporters.

The testing capacity building achievements in Pakistan resulted in:
- Strengthening the metrology infrastructure through development support of the National Physical and Standards Laboratory. This included upgrading of its calibration services and their international traceability for mass, volume, length, temperature, pressure and electrical quantities
- Upgrading 19 key testing laboratories to achieve compliance with ISO/IEC 17025, including facilitation of their access to certified reference materials and 35 international proficiency testing schemes. The focus was placed on microbiological, chemical, textile, leather, and electrical testing
- Successful accreditation of 18 of these laboratories by NA (Norwegian Accreditation).

Drivers and benefits for testing and calibration

Examining first the drivers and benefits for *calibration,* it is critical to acknowledge that testing depends on the support of competent calibration. If test equipment is not appropriately calibrated, the results it generates will not be reliable. (Poor data leads to poor decisions based on that data.)

Some calibrations will not require a high level of expertise, and many calibrations may be performed routinely by testing laboratories for their own needs. In these circumstances the calibration can be considered a routine operation of the laboratory, rather than a conformity assessment activity. However, where special measurement expertise is required, laboratories usu-

ally need to use the services of competent calibration services.

The drivers and benefits for laboratories in using these services include the access they provide to traceability of measurement to international standards and information on the measurement uncertainty of the devices and equipment calibrated for them. If a testing laboratory wishes to comply with standards such as ISO/IEC 17025, they need to have both measurement traceability and appropriate determination of the measurement uncertainty of their own tests. So, the fundamental benefit and driver for such laboratories in using competent calibration services, is that calibration underpins most laboratory activities.

However, calibration is also a foundation for confidence in manufacturing, telecommunications, construction, defence, aviation, meteorology, mining, health services, general commerce and many other facets of life where decisions are based on measurement. Where the measurements concerned, or the decisions based on those measurements, are critical, it is essential that those performing the measurements and calibrations are competent to do so.

In some cases, the calibrations may be performed by the organizations themselves. In other cases, the use of specialized, independent calibration services may be needed. For the most accurate measurements needed in a country, they are usually provided by a national measurement institute.

The primary drivers and benefits for *testing* are similar to those for calibration. Many decisions in society require the availability of data and information which can only be obtained through testing. Testing is therefore an essential feature of daily life. The primary drivers and benefits for testing depend on the criticality of the decisions being made. Judgment on the costs of testing and the levels of expertise needed for their conduct will vary depending on individual circumstances. Some testing may only need to be indicative, while other tests may require highly developed expertise. The degree of benefits derived from testing will thus depend on the needs of individual users, as will the levels of risk taken in choosing appropriate testing services.

Inspection bodies

Requirements for inspection bodies

The CASCO standard relevant to inspection bodies is ISO/IEC 17020, *General criteria for the operation of various bodies performing inspection.* It was adopted as an Interna-

tional Standard after originally being produced as EN 45004 by CEN (the European Committee for Standardization) and CENELEC (the European Committee for Electrotechnical Standards).

The structure of ISO/IEC 17020 is similar to the standards for laboratories and management systems certification bodies, but it has some unique features. One of these is the classification system it uses for the different types of bodies involved. That system is described in three Annexes to the standard, as follows:

***Type A** inspection bodies*
These bodies provide third-party services and are expected to be:

- Independent of the parties involved
- Not involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items
- Accessible to all parties interested in their services
- Not subject to undue financial or other conditions and be administered in a non-discriminatory manner.

***Type B** inspection bodies*
These bodies provide first-party services to their parent body and are expected to:

- Be a separate and identifiable part of the organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects
- Have clear separation of the responsibilities of the inspection personnel from those personnel employed in the other functions with established organizational identification and reporting methods for the inspection body within the parent organization
- Ensure the body and its staff does not engage in activities that may conflict with their independence of judgement in respect to their inspection activities, including involvement in design, manufacture, supply installation, use or maintenance of the items inspected, or similar competitive items
- Only provide inspection services to the organization to which the inspection body belongs.

***Type C** inspection bodies*
These bodies are first-party inspection bodies which may also provide inspection services to other organizations, which are not their parent organization. They may be involved in the design, manufacture, supply installation, use or maintenance of the items they inspect. They are expected to:

- Provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities in the provision of inspection services through their organizational structure and documented procedures.

The requirements to be met by inspection bodies, as specified in ISO/IEC 17020 include:

Administration – Be legally identifiable; be properly identifiable within a parent organization; document its functions and scope of its technical competence; have adequate liability insurance or be protected by national laws; document its business conditions; and have independently audited accounts

Independence, impartiality and integrity – Comply with the obligations for Type A, Type B or Type C inspection bodies

Confidentiality – Ensure confidentiality of information obtained during inspection; and protect proprietary rights

Organization and management – Operate to maintain capability to perform its technical functions; define and document responsibilities and reporting structure, including any relationship with its testing or certification functions; employ a permanent, qualified and experienced technical manager; provide effective supervision; nominate deputies for inspection managers; and provide job descriptions specifying required education, training, technical knowledge and experience

Quality system – Documented quality policy and objectives; operate a system appropriate to type, range and volume of work performed; fully documented system, including a quality manual containing the information required by the standard; designate person authorized and responsible for quality assurance and the quality system; maintain documentation control; conduct planned and documented internal audits with auditors independent of functions audited; and conduct and record management reviews

Personnel – Sufficient personnel with expertise required; inspection staff with appropriate knowledge, training, experience and specific knowledge of the inspections performed, with ability to make professional judgment and knowledge of the manufacturing technology, manner inspected items are used and defects which may occur; operate a documented training system; provide guidance for the conduct of staff; and ensure remuneration is not directly dependent on the numbers of inspections performed and the results of such inspections

Facilities and equipment – Use suitable equipment and facilities; rules for use of and access to specified equipment and facilities; ensure continued suitability; properly identify equipment; maintain equipment according to documented procedures; where appropriate, ensure calibration and re-calibration of equipment; ensure applicable measurements are traceable to national and inter-

national standards of measurement; reference standards used only for reference; maintain in-service checks; procedures for selection of qualified suppliers, purchasing documents, inspection of received materials and storage facilities; monitor deterioration of stored items; ensure computers and automated equipment and software are adequate, data is protected, equipment maintained; security of data maintained; and records of equipment identification, calibration and maintenance

Inspection methods and procedures – Use methods and procedures defined to demonstrate conformity; documented instructions for inspection planning, sampling, and inspection techniques; document any non-standard methods or procedures; keep up to date and accessible all instructions, standards or written procedures, worksheets, check-lists, and reference data; operate a contract or work order control system; timely recording of inspection data; checking of calculations and data transfers; and documented instructions for safe performance of inspections

Handling of inspection sample and items – Unique identification of items and samples; note suitability for inspection; appropriate preparation of the item; and documented procedures and facilities to avoid damage or deterioration of inspection items

Records – Maintain appropriate system and comply with applicable regulations; include sufficient information for satisfactory evaluation; and safe storage, while secure and confidential unless otherwise required by law

Inspection reports and inspection certificates – Ensure retrievable inspection reports or certificates; include results and determination of conformity with any additional information needed for understanding and interpretation; identify any work performed by subcontractors; appropriate signatures or other approvals by authorized staff; and details and justifications recorded for any corrections or additions to inspection reports or certificates

Subcontracting – Demonstrate competence of subcontractors; advise clients of their use; ensure client approval; record results of investigations of subcontractors' competence; maintain a register of subcontracting used; ensure access to qualified, experienced and independent persons used for specialized activities; and maintain responsibility for conformity with requirements subject to inspection

Complaints and appeals – Documented complaints and appeals procedures; and maintain records of all complaints and actions taken by the inspection body

Cooperation – Exchange experience with other inspection bodies and contribute to standardization processes as appropriate.

Case study – Use of inspection for compliance with European Directives

Under the "New Approach" Directives established by the European Commission, use is made of "Notified Bodies" which are designated by the Member States of the European Union as competent bodies for confirming compliance of products with specific regulations (Directives). Member States are expected to accept the outputs of notified bodies in other States without the need for separate testing, certification, inspection etc.

These Directives provide a number of Modules which may be used to determine compliance with the essential safety or other requirements applicable to a regulated product. When a product is evaluated by a notified body using an appropriate Module, a supplier can confidently label its products with the "CE" Marking to demonstrate compliance with the relevant Directive. (There is a separate EC Directive on use of the "CE" Marking. For some products, the compliance Modules for the Directives do not require the intervention of a "notified body", and suppliers can use manufacturers' declarations of conformity to assign the "CE" Marking to their products.).

For some Directives, a Notified Body may use inspection as the means of determining compliance with the essential requirements of the Directive. One such directive is the "Measuring Instruments Directive 2004/22/EC".

To assist consistency in the use of inspection by Notified Bodies involved with the Measuring Instruments Directive, a guide has been produced by the European cooperation in legal metrology (WELMEC). It is entitled *Measuring Instruments Directive 2004/22/EC – Assessment of Notified Bodies Designated for module F based on EN ISO/IEC 17020 : WELMEC 8.7, Issue 1, May 2008.* (Details on WELMEC can be accessed through **www.welmec.org**).

The guide is intended to provide manufacturers of measuring instruments and the notified bodies determining their conformity with WELMEC's view on best practice in this sector. It provides a useful clause-by-clause guide on ISO/IEC 17020 and a table of the roles of inspection under the various Modules relevant to measuring instruments.

Drivers and benefits for inspection

The drivers and benefits for inspection are similar to those for testing and product certification. As with other forms of conformity assessment, inspection provides an objective assessment of whether or not an inspected item meets the specified needs of a manufacturer, purchaser, retailer, regulator, exporter, importer, designer or other end-users.

In the case of inspection, the determination of conformity may also be based on the professional judgment of people with demonstrable expertise in the technology, utility and limitations of the items under inspection.

This should provide additional confidence to the end user, as the competence of the inspection performed is not only based on the overall competence of the inspection body itself, but also on the competence of its inspection personnel.

Inspection is often an essential risk management tool. Many plants, equipment and installations require periodic inspections to ensure their safe operation and use. One of the major benefits of many such inspections is that they are performed on-site. This provides an immediate opportunity to inform clients if there are any harmful or costly deficiencies found in the items inspected.

In the context of exports of major shipments, early detection of deficiencies through inspection could provide the supplier with an opportunity to rectify the problems before shipment and save both cost penalties and possible rejection in the intended market.

Other "determination" bodies

In line with the flexibility of conformity assessment, there are other bodies than testing laboratories or inspection bodies which carry out determination activities. As new fields requiring conformity assessment emerge, such as environmental issues relating to energy efficiency and greenhouse gas emissions or food chain supervision, so new techniques are developed. Terms such as "verification" and "validation" may cover different techniques or may simply be colloquial names for the more established techniques such as inspection and testing.

Certification bodies

In the following sections, we consider bodies engaged in three types of certification activity but the list is not exhaustive:

- Product certification
- Management system certification
- Personnel certification.

The principles of conformity assessment can be applied to other bodies which are independent and impartial and which carry out selection, determination, review and attestation activities.

Product certification bodies

Product certification bodies and their activities

Product certification is a comprehensive activity in both developed and developing countries and has a much longer history than management systems certification. It is also perhaps the most visible form of certification, as so many products carry the various marks of conformity issued by product certification bodies. Some products, such as electrical appliances and telecommunications equipment, often carry multiple marks to satisfy regulators and consumers in different markets.

For the general public and consumers this form of certification is perhaps the most recognized and understood. However, many consumers will not necessarily understand the purposes of individual product standards, and thus the significance of their certification. For example, some product standards might only address safety aspects, or only durability. Other standards might cover a combination of performance and safety characteristics.

The purposes of a product standard may have other features, such as health and environmental impacts, compatibility, energy efficiency etc. Whichever purpose is intended to be covered by a standard, there are two fundamental objectives of such certification, namely:

- Assisting consumers and end-users to make better-informed decisions about products in the marketplace
- Assisting suppliers of the products to achieve marketplace acceptance.

Requirements for product certification bodies

The requirements for product certification bodies are specified in ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*. This Guide is expected to be replaced on completion of the proposed new standard, ISO/IEC 17065, under preparation by ISO/CASCO. It should be recalled that "product" in this context includes services and processes.

The basic purpose of Guide 65 is to specify the requirements that should be met by a product certification body to demonstrate that it is competent and reliable. The Guide is structured to cover the following aspects of management and operation of a product certification body:

General requirements – Unconditional accessibility; non-discriminatory administration; products evaluated against specific standards; and scope-specific

Organization – Impartial structure; responsibility for decisions; personnel responsibilities for testing, inspection, appraisal, certification, policy formulation, decisions, finances, authority delegation, and technical basis for certification; documented legal identity and structure; independence of certification decision-making staff; liability protection; financial stability; sufficient trained and knowledgeable staff; adequate quality system; freedom from undue influences; rules and structures for appointment of certification committees; maintenance of impartiality, confidentiality and objectivity from any related body activities; and compliant, appeals and dispute handling

Operations – Use of specific product standards for conformance; specification of the basis for the specific type of product certification system used; and suitability of the bodies or persons undertaking testing, inspection and certification

Subcontracting – Documented agreements; responsibility for contracted work; no delegation of certification functions; competence and independence of subcontracted bodies and persons; and applicant's agreement to use of subcontractor

Quality system – Responsibilities for policy; system effective and relevant to type of work performed; and documented manual and procedure

Conditions and procedures for certification – Specified conditions and procedures for granting, maintaining and extending certification, and for suspending or withdrawing certification; and procedures for assessing the effects of significant changes in product design or specification, or in the ownership or administration of the product's supplier

Internal audits and management reviews – Periodic internal audits; timely corrective action; documented results; and management reviews and associated record

Documentation – Authority for certification body's operation; statement of system's rules and certification procedures; evaluation procedures used; financial support and certification fees; rights and duties of suppliers of certified products, including use of marks; complaints and appeal procedures; directories of certified products and their suppliers; and authorization and control of documents.

Records – Complying with regulations; demonstrating effective fulfillment

of certification procedures; properly identified, managed, retained, disposed of and maintaining integrity and confidentiality of the process

Confidentiality – Meeting applicable laws; including confidentiality of body's own personnel, committees, and external bodies; and written consent of suppliers for information disclosure

Certification body personnel – Competent for functions; qualification criteria; contracted to comply with rules; and records of qualifications, training and experience

Changes in requirements – Due notice to interested parties; and timely adjustment by suppliers

Appeals, complaints and disputes – In accordance with procedures; and records, including remedial actions and their effectiveness

Application for certification – Information on the certification procedure; and product suppliers' compliance and cooperation

Preparation for evaluation – Requirements clearly defined; capability to perform the certification; planning; and access to appropriate working documents

Evaluation – Conducted against the required standards; and using criteria specified in the rules of the certification procedure

Evaluation report – Report of findings on conformity; and prompt provision to applicant and details of any nonconformities requiring attention

Decision on certification – Based on evaluation findings; not delegated to outside bodies or persons; formalized in relevant certification documents; effective date of certification, scope of products certified and the relevant product standards; and actions needed for amendments

Surveillance – Documented procedure; responsibility of suppliers to advise of changes to products, production processes and quality system; records of surveillance activities; and periodic re-evaluation of marked products to confirm continuing compliance

Use of licences, certificates and marks of conformity – Control over ownership, use and display; guidance on their use; and action on misleading use

Complaints to suppliers – Required to be recorded; appropriate action taken and documented; and deficiencies rectified

Case study – Product certification of electrical equipment for international acceptance of regulated products

Within the Asia Pacific Economic Co-operation (APEC), a number of multi-government agreements have been developed to facilitate acceptance of regulated products amongst member economies, without the need for duplication of conformity assessment activities, such as testing and certification.

One such agreement is the APEC Electrical and Electronic Equipment Mutual Recognition Agreement (EE MRA). While not mandatory for all APEC member economies, it does provide a framework for countries' regulators to establish processes for acceptance of products from other economies which have agreed to join the MRA.

The EE MRA has three parts available for participation:

- Part 1: Information Interchange
- Part 2: Acceptance of Test Reports
- Part 3: Acceptance of Certification.

The MRA is intended to cover both pre-market and post-market regulatory compliance needing to be demonstrated through testing or certification. Each economy signing the MRA is expected to designate competent testing and/or certification bodies in their economy.

Where certification is the basis for regulatory compliance, the MRA signatories' designated certification bodies are expected to comply with ISO/IEC Guide 65, the relevant international criteria for product certification bodies.

The overall objective is to facilitate acceptance of regulated products in multiple markets though a single compliance process, thus reducing costs for manufacturers and exporters.

Drivers and benefits for product certification

As discussed earlier, the two basic drivers for product certification are the provision of information to assist consumers of products and services to make better-informed choices on products and to assist suppliers of certified products to achieve market acceptance.

There are, however, a number of other similar drivers and benefits associated with product certification. Product certification often has an important role to play with products that may be subjected to technical regulations, (for example for safety, compatibility, energy efficiency, environmental impact, conservation, and quarantine). The availability of products with clearly labeled marks, showing their compliance with

a mandatory standard set by regulators, assists regulatory bodies in their market surveillance of products covered by their responsibility.

Additionally, manufacturers may be assisted in their selection of components for their own products, if such components carry marks of conformity with the standards required by the manufacturers' end products. The availability of product-certified components might also play a role in facilitating subsequent certification of the manufacturers' own assembled products.

Retailers have a tool for additional confidence in the products they sell, if they are supported by appropriate product certification. Both importers and exporters also have similar marketing advantages if the products and services they deal with, are certified to facilitate their acceptance in multiple markets.

Management system certification bodies

Management systems certification bodies and their activities

The ISO 9000 series of standards are among the best known of the more than 18 000 standards published by ISO. They are utilised worldwide, not only by the countless organizations operating quality systems, but also as the basis for certification of such organizations' compliance with the standard. It should be noted that, in line with ISO's neutrality policy, certification is not a requirement for conformity with these standards.

The phenomenon of quality systems certification to ISO 9001 is well known in most countries. Such certification is the major activity of those certification bodies accredited by the members of the International Accreditation Forum (IAF), and most countries have multiple providers of management system certification. Another feature of this conformity assessment activity is that many of the certification bodies active in this area operate on a multi-national basis.

Apart from ISO 9001, there are other management system standards which are used as the basis for certification, including the environmental management system standard, ISO 14001. There are also emerging demands for certification to other, sector-specific standards, aligned with the quality and environmental system standards, such as ISO/IEC 27001 for information security management systems,

Another significant management system certification activity relates to food safety management, addressed by the ISO 22000 series.

A significant feature of management system certification is that the standards affected by this form of conformity assessment are produced, not only by ISO, but by many consortia and companies. For example, many major retail organizations and groups have developed management system criteria, against which they expect compliance by all of their suppliers. (Some of these are a combination of management system and product certification requirements).

While some retailers use their own second-party assessments against their proprietary standards, many use the services of recognised third-party certification bodies to demonstrate compliance by their suppliers. Bodies accrediting such certification bodies usually make provision within their accreditation scopes to accredit against both ISO management system standards and the proprietary standards of companies and groups.

Many companies also expect that bodies certifying against their criteria must be accredited to do so. An example is the British Retail Consortium (BRC) Food Technical Standard. This is used to evaluate manufacturers of retailers' own brand food products. (See **www.brc.org/uk/standards/default.asp**).

From a developing country perspective, it is critical to appreciate that the conformity assessment bodies in their countries (or used by their countries) may need to comply with such non-ISO standards. For example, many of the requirements for these standards affect suppliers of fresh foods, agricultural commodities, textiles, toys, etc, which are likely to be sourced from developing countries.

Apart from ISO 22000, there are a number of proprietary food management systems related to HACCP (Hazard Analysis Critical Control Point) systems. Some of these criteria for certification have been developed directly by certification bodies as part of their range of conformity assessment services.

Requirements for management system certification bodies

ISO/CASCO has prepared the following standard as the basic criteria for operation of management system auditing and certification bodies:

- ISO/IEC 17021, *Conformity assessment – Requirements for bodies providing audit and certification of management systems.*

The standard provides a basis for international consistency for such certification and is thus the base standard used by accreditation bodies when

assessing the competence of management systems certification bodies. It replaced two previous ISO/CASCO Guides (ISO/IEC Guide 62 and ISO/IEC Guide 66).

Implementation of this standard relies also on the availability and use of other critical standards including:

- ISO 9000, *Quality management systems – Fundamentals and vocabulary*
- ISO 19011, *Guidelines for quality and/or environmental management systems auditing.*

While referring to quality and environmental auditing, it is intended that ISO/IEC 17021 and ISO 19011 apply to all forms of management system auditing.

Examining ISO/IEC 17021 in more detail, it is important to note that there are three main features of certification bodies that the standard addresses in its principles and requirements, namely:

- Competence
- Consistency
- Impartiality.

The standard has a series of principles, general requirements and a number of operational clauses which are expected to be met by certification bodies. In outline, their content is as follows:

Principles – Impartiality, competence, responsibility, openness, confidentiality, and responsiveness to complaints

General requirements – Legal and contractual, management of impartiality, liability and financing

Structural requirements – Organizational structure and top management, committee for safeguarding confidentiality

Resource requirements – Competence of management and personnel, personnel involved in certification, external auditors and technical experts, personnel records, outsourcing

Information requirements – Public documents, certification documents, directory of certified clients, reference to certification and use of marks, confidentiality, information exchange with clients

Process requirements – Initial audit and certification, surveillance activities, recertification, special audits, suspending, withdrawing or reducing certification scopes, appeals, complaints, records of applicants and clients

Management system requirements for certification bodies – Providing two options, either in accordance with ISO 9001, or general management system requirements.

The certification process

Certification bodies will typically use specialist auditors to undertake their assessments of the management systems of their clients. Such auditors will normally require training in auditing practices and principles (such as those embodied in ISO 19011*)* as well as being qualified by auditor certification bodies (itself a form of personnel certification).

This should include examination of the auditors' knowledge of the relevant management systems standards. Prior to their recognition as competent auditors, they will be expected to participate in a number of audits in various roles as observers and, progressively, under the supervision of experienced auditors.

It is also necessary for the audit team to include expertise relevant to the technical area in which the client organization works. Such expertise could relate, for example, to the design features of a product, its means of production, the ways in which it is used and related legislation and industry codes of practice. It is not uncommon for certification bodies to use external technical auditors as part of the assessment teams to complement the expertise of their own auditors.

Figure 7 outlines a typical sequence in the process of seeking and obtaining certification.

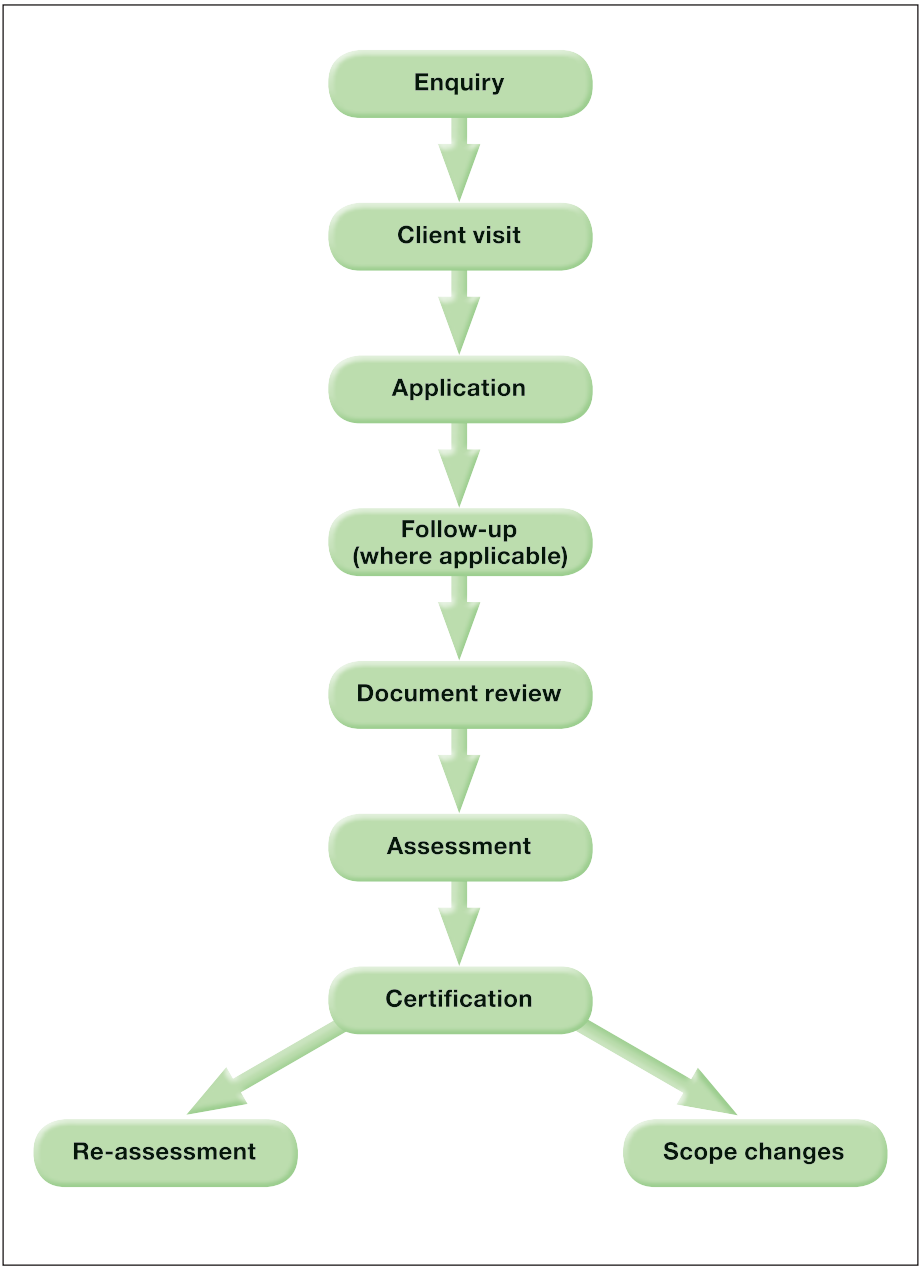
There may be a number of additional steps in the above process if, for example, a follow up assessment visit is required to confirm that deficiencies found in the initial assessment visit, have been rectified.

An important component in the process is the need for ongoing surveillance of the certified quality system's continuing compliance. The frequency of visits and off-site surveillance will vary, and details of these cycles should be publicly available from all certification bodies.

Case study – Establishment of a management system certification body in Bangladesh

A recent UNIDO Technical Assistance project illustrates the ability of existing infrastructures to be used effectively to extend the conformity assessment capabilities in a developing country. In Bangladesh, the lack of a local body for management system certification was considered a gap, but assessed as an activity with great potential for growth to upgrade the functioning of exporting enterprises and to increase Bangladesh's share in the international market.

Figure 7 – Typical certification process



Creating a totally new structure was considered to be both costly and time consuming. Accordingly, the development assistance was directed towards the existing Bangladesh Standards and Testing Institution (BSTI), which was already engaged in product certification, and was found to have an appropriate structure to also operate as a management system certification body.

Assistance was provided from an expert in a neighboring country with practical experience in the establishment and operation of a management system certification body. The expert was mandated to design, establish and implement the system. The scheme was also expected to achieve accreditation as a certification body in a short timeframe to enable it to award certifications with appropriate credibility. The work was divided into documentation, training, implementation, and accreditation phases.

Documentation of the system was duly completed in accordance with ISO/IEC 17021 and implementation of the system started shortly after. All relevant committee members and certification personnel were provided with intensive training on ISO/IEC 17021 requirements.

Early applications for certification were received after public announcement of the new management systems certification scheme, and these applicant bodies later provided valued opportunities for the new conformity assessment service to gain operational experience.

The project's second phase had started with creation of a pool of auditors and technical experts from amongst the trained officers of BSTI for their deployment in the certification process. Assistance in gaining auditing training and experience was also provided by UNIDO experts. This included use of experienced UNIDO auditors to lead initial audits for three of the applicant organizations. This constituted part of the on-the-job training of the new scheme's auditors and technical experts.

On completion of a full cycle of audits of the early applicants for certification, it is expected that the scheme should have gained sufficient expertise and experience to seek to complete the final phase of the project by applying for independent accreditation.

Drivers and benefits for management system certification

ISO/IEC 17021 notes that certification is one means of providing assurance that an organization has implemented a system for the management of rele-

vant aspects of its activities in line with its policy. Additionally, certification of such a system provides an independent demonstration that the certified system conforms to specified requirements; is capable of consistently achieving the stated policies and objectives of the organization; and is effectively implemented.

In many cases, the stated requirements for an organization to comply with a management systems standard (and to have that confirmed through third-party certification), will be specified by customers of that organization. In these circumstances, the driver for compliance may be a business necessity. However, another driver and benefit is often the value that certification of such systems provides internally. For staff of certified organizations, an external confirmation that their organization meets an internationally accepted standard can provide both motivation and satisfaction.

For the organization's top management, also, the implementation of a certified system should ensure that they have an ongoing framework for sharing their organization's objectives (for quality, environment, safety etc) with both internal stakeholders and external parties such as their clients, regulators, etc. It should also ensure that their organization has a consistent and updated source of information on the processes and resources it needs to meet its policies and objectives.

As with other forms of conformity assessment, certification also provides additional benefits, such as a marketing opportunity to inform stakeholders of an organization's certified status. In a global marketplace, where compliance with management systems standards may be either a requirement or an advantage, the use of certification may be a necessity to trade. This acceptance, in many cases, will be enhanced if the certification body is itself accredited by a body that is a signatory of the MLAs of IAF and/or its regional co-operations. Depending on the type of management system being implemented, (and certified) there are a number of other drivers and benefits. These may include, for example, the continual improvement opportunities that are available through the inputs of external auditors; additional customer confidence; reduction in waste; and management of enterprise risk related to production, the environment, worker safety, and organizational reputation.

Personnel certification bodies

Personnel certification bodies and their activities

Personnel certification bodies have the objective of recognizing the com-

petence of individuals to fulfill specific requirements. Often the need for such certification is driven by the lack of specific qualifications being available through other means, such as formal qualifications from educational or professional institutes.

Many personnel certification schemes are related to support for other conformity assessment activities. Bodies involved in management system certification activities need processes to establish the competence of auditors for various specialized assessments. For example, there are a number of personnel certification schemes for:

- Auditors of ISO 9001 systems
- Auditors of environmental management systems
- Auditors for food safety (e.g. ISO 22000 and HACCP)
- Auditors for occupational health and safety systems, etc.

Some professional bodies also operate personnel certification schemes, such as, for example, recognition of the competence of welding operators using the process defined in the ISO 9606 series of standards.

The relevant ISO/CASCO standard for personnel certification bodies is ISO/IEC 17024, *Conformity assessment – General requirements for bodies operating certification of persons.* The standard includes an informative annex on development and maintenance of a certification scheme for persons. For the purposes of this standard, there are a number of definitions which assist in differentiating certification of persons from other forms of certification. In particular, the following definitions are of relevance:

Clause 3.3 (of ISO/IEC 17024)
Certification process
All activities by which a certification body establishes that a person fulfils specified competence requirements, including application, evaluation, decision on certification, surveillance and recertification, use of certificates and logos/marks.

Clause 3.4
Certification scheme
Specific certification requirements related to specified categories of persons to which the same particular standards and rules, and the same procedures apply.

Internationally, the forum for personnel certification bodies is the International Personnel Certification Association (IPC), which previously operated as IATCA. Background on the organization can be accessed at (**www.ipcaweb.org**). One of the criteria for full membership of IPC is that the

personnel certification scheme is covered by an accreditation body that is a member of IAF or one of IAF's regional body members. IAF has also recently resolved to extend its MLA to include accreditation of personnel certification bodies complying with the appropriate standard, as discussed below.

One other differentiating feature in this standard is the use of examinations with objective criteria for competence and scoring.

Requirements for personnel certification bodies

The major requirements to be satisfied by personnel certification bodies to comply with ISO/IEC 17024 are:

Organizational structure – Assure interested parties of its competence, impartiality and integrity; assume responsibility for certification decisions; identify management with key responsibilities; documentary confirmation of its status as a legal entity; documented structure ensuring impartiality and participation of balance of interested parties; appoint a scheme committee; have appropriate financial resources; have policies distinguishing certification of persons from other activities; ensure related bodies do not affect its confidentiality and impartiality in certification; not offer training or preparation unless such is independent of the evaluation and certification of persons; define complaints and appeals policies, including their resolution in an independent and unbiased manner; and employ or contract sufficient people with requisite skills under responsible management

Development and maintenance of a certification scheme – Define methods to evaluate competence of candidates; implement a process for development, maintenance, review and validation of the certification schemes by the scheme committee; manage and inform interested parties of scheme changes; ensure criteria for competence defined to meet the standard, supported where needed by explanatory documents developed by experts, endorsed by the scheme committee and published; ensure candidates not restricted by undue financial or other limiting conditions; evaluation of the methods of examination of candidates, ensuring they are fair, valid and reliable; and reaffirm annually, with any identified deficiencies rectified

Management system – Operate a suitable, documented and effective management system meeting the standard; maintain and ensure understanding of the system at all levels; and implement document control, internal audits, management review, and provisions for improvement, and corrective and preventative actions

Subcontracting – Use documented agreement with subcontractors; do not subcontract certification decisions; take full responsibility for subcontracted work; ensure subcontractors are competent, comply with the standard, and are independent and impartial; maintain a subcontractor list; and monitor their performance

Records – Maintain records complying with laws and confirming the status of certified persons; demonstrate process effectively fulfilled; properly identified, managed and disposed of, to ensure integrity of the process and confidentiality; and retained for appropriate periods

Confidentiality – Maintain confidentiality for all information by all parties involved; and only disclose to unauthorized parties with written consent

Security – Ensure security of examinations and related items.

Requirements for employees and contractors – Define their competence requirements; contracted to comply with certification rules; documented duties and responsibilities; appropriately qualified, experienced and technically competent; maintain qualification records; ensure examiners meet relevant competence standards, are familiar with the schemes, with thorough knowledge of methods and documents for examinations, have written and oral fluency and are free of undue interests

Certification process – Provide full description of the certification process including any codes of conduct expected of certified persons; use of formal application document; use of appropriate written, oral, observational or other examination means; use of planned and structured examinations with documented evidence to confirm competence of candidates; appropriate reporting of the performance and results of examinations; decision on certification by persons independent of the examination or training of the candidates; and provide certificates but maintain their sole ownership

Surveillance – Define the process to monitor certified personnel's ongoing compliance with the schemes provisions; have the procedures and conditions for maintenance of certification endorsed by the scheme committee; and ensure impartial evaluation to confirm continuing compliance

Recertification – Define recertification requirements; and have the conditions endorsed by the scheme committee, including impartial evaluation

Certificates, logos and marks – Document conditions for use and manage

the rights for usage; require certified persons to sign agreement to comply with provisions of the scheme, including those related to use of certificates; and address any misleading use of certificates, marks or logos.

Drivers and benefits for personnel certification

The availability of an international standard for certification of persons provides a number of benefits. Firstly, it provides a consistent framework and set of requirements to allow the recognition of the competence of people within, and between, countries. This should facilitate employment of certified personnel in various locations, while also providing employers with a benchmark for appointment of staff requiring defined competencies.
There are other benefits also, including the reassurance provided when certification may need to be updated (and re-examined) as requirements for competence change or there are changes in the processes and technologies needing certified personnel.

As with other types of conformity assessment, the confidence provided by personnel certification may be further enhanced if the bodies concerned are accredited for their own competence. The proposed extension of the IAF MLA to cover such certification bodies should facilitate the greater portability of certifications of persons across national boundaries.

Qualification of conformity assessment bodies

There are several ways in which the competence and impartiality of conformity assessment bodies can be ascertained. The bodies could form a mutual recognition group such as the IECEE system for electro-technical product certification bodies or ILAC for laboratory accreditation bodies. The bodies could be assessed by an independent body, generally known as an accreditation body or they might be appointed for specific tasks by a regulatory authority. These alternatives are discussed below.

Recognition arrangements and agreement groups

In order to facilitate cross-border acceptance of conformity assessment results, conformity assessment bodies have for many years established reciprocal recognition arrangements with each other. The arrangements have included the assessment of each other's facilities and competence so as to provide confidence in the conformity assessment results. In some cases these arrangements have extended to include conformity assessment bodies from other countries, forming multilateral agreement groups. By using a

peer assessment process, such as that discussed in **Chapter 2**, these groups have been able to share the cost of the assessments and to promulgate good practice in their field.

ISO/IEC Guide 68 provides guidance on setting up arrangements for the recognition and acceptance of conformity assessment results. The guide provides information on the elements of an agreement and advice on setting up an agreement group, stressing the importance of using internationally agreed criteria such as those in the CASCO toolbox. It mentions peer assessment and accreditation as methods for establishing the basis for confidence in the results produced by the members of the group.

The guide also advises that these two techniques can be used in a complementary way as, for example, where accreditation can provide assurance on the organization and management systems of the members while peer assessment can concentrate on the technical aspects.

Accreditation bodies

Accreditation is the term applied to the third party assessment of the conformity of conformity assessment bodies with the relevant standards. It is defined in ISO/IEC 17000 as:

> **Clause 5.6**
> **Accreditation**
> third party **attestation** (5.2) related to a **conformity assessment body** (2.5) conveying formal demonstration of its competence to carry out specific tasks

The key words in this definition are *competence* and *specific conformity assessment tasks*. It is important to note that recognition of competence is the principal objective of accreditation and such recognition is for specific tasks. Some accreditation bodies have specific capabilities, such as accreditation of the competence of laboratories, for example, or for accreditation of certification bodies. Some accreditation bodies are multi-functional and cover a broad range of conformity assessment bodies and others are more narrowly focussed on speciality areas.

Accreditation bodies are often appointed by national governments and hold an important position in the conformity assessment hierarchy. They provide confidence in the impartiality and competence of conformity assessment bodies. The criteria for accreditation bodies are specified in ISO/IEC 17011. As accreditation bodies are at the top of the confidence pyramid, there is no higher level body to assess their conformity with the requirements. Instead, accreditation bodies

from different countries have formed multi-lateral agreements through which they carry out peer assessments on each other as described in **Appendix 2**.

Role of accreditation in support of governments

There are many ways in which accreditation can support and interact with governments. Governments themselves are often the operators of their economy's national accreditation bodies. Some governments also view accreditation as a public interest activity and have proposed that there should be no forms of commercial competition between accreditation bodies. This view is strongly evident, for example, in the European Commission's development of its policy on accreditation in its revision of its "New Approach" technical regulations.

In other economies and regions there may be a mixture of government and non-government accreditation bodies, or solely non-government bodies. Many of the non-government accreditation bodies also operate on a not-for-profit basis, and may have formal government support and recognition of their roles on behalf of government.

Within national quality infrastructures, governments often accept responsibility for national systems for legal metrology, provision of standards of measurement (national measurement institutes) and accreditation services. Where commercial bodies deliver some or all of a particular service, governments often accept the responsibility for the appropriate delivery of the service. These services are rarely commercial and often require government financial support.

Some of the specific ways in which accreditation supports governments include:

- *As a client of accreditation services*

Governments may operate their own laboratories, inspection activities, and certification systems. This provides the clients (or other affected parties) of government laboratories, certification systems, etc, and the public at large, with reassurance that the government's own conformity assessment capabilities are *independently* evaluated and recognised for their technical competence.

- *As a user and/or purchaser of services from accredited facilities*

Governments are significant users of non-government services, including goods and services requiring conformity assessment. Accreditation of the bodies which carry out conformity assessment provides governments with additional confidence for their purchasing needs that compliance with

their specifications has been confirmed by competent bodies.

- *As a specification body for conformity assessment services*

Government departments, regulatory authorities and agencies will often specify the use of accredited bodies. References to accredited bodies may be found in their public policies, government specifications and regulations. This again provides governments with additional confidence that consumers and society in general have been protected by the use of competent bodies in determining compliance with laws, regulations and specifications.

- *For underpinning government-to-government mutual recognition agreements for conformity assessment activities*

As discussed in **Appendix 2**, some governments have recognized (or designated) their national accreditation bodies as the bodies which will demonstrate competence of conformity assessment activities in their economy, relevant to specific regulated sectors covered by government-to-government MRAs.

- *For liaison on trade and technical barriers to trade*

Some governments work closely with their accreditation bodies, at various levels of formality, in their negotiation of trade and technical barriers to trade issues with foreign governments. The availability of a well-established accreditation body also provides governments with a resource to demonstrate that their economy has a process available to achieve the objectives of acceptance of foreign conformity assessment certificates and data as sought in the WTO Agreement on Technical Barriers to Trade.

Role of accreditation in support of private sector

Accreditation also supports the private sector in many ways. Firstly, *for accredited conformity assessment bodies operating in the private sector* accreditation provides the following support:

- *As a benchmark for performance*

Many conformity assessment bodies operate in isolation from their peers. By being subjected to assessments by experts for compliance with accreditation criteria, these bodies are able to have independent confirmation that they are operating at levels that others have judged to be competent. Where deficiencies are revealed, through the accreditation process, the bodies also have the opportunity to initiate corrective action and thus improve their ongoing performance.

- *As a recognition of competence*

Accreditation provides a public-

ly available recognition of the specific competencies of the accredited conformity assessment bodies. This enhances the acceptance of the outputs of accredited bodies by regulators, suppliers, purchasers, consumers, etc., including both the direct clients of the conformity assessment bodies, and other parties which may have an interest in their reports, certificates, qualifications of personnel, etc.

- *As a marketing advantage*

Accreditation can provide a marketing advantage for conformity assessment bodies. Customers of conformity assessment bodies that are accredited should have more confidence, knowing that such bodies have been subjected to independent evaluation of their competence through the accreditation process.

- *For international recognition*

Where conformity assessment bodies are accredited by bodies which are signatories to the MLAs of IAF, ILAC, or their regional Cooperation Bodies (APLAC, EA, ILAC, PAC and SADCA), they have access to international recognition as competent bodies in multiple foreign markets.

Secondly, *other groups in the private sector, which do not operate their own conformity assessment activities*, should also receive support from the accreditation process. These include:

- *Private sector specification and purchasing bodies*

Such bodies reduce their risks if they use accredited conformity assessment bodies. They may also avoid costly re-testing, inspecting or certifying if a non-accredited body's results are not acceptable. Use of accredited bodies should also enhance the purchaser's own customers' confidence in their goods and services.

- *Importers and exporters*

Exporters may be able to reduce costly duplication of conformity assessment of their exported goods and services if their compliance with foreign requirements is provided by accredited conformity assessment bodies. Similarly, importers may be able to accept imported goods and services with additional confidence if they are covered by foreign conformity assessment bodies that are accredited. This often will be facilitated even more if the foreign accreditation body is a signatory to the ILAC or IAF MLAs.

- *Trade associations, industry bodies, professional bodies and consumer associations*

Trade associations, and bodies representing industry groups, professional societies, and consumer associations, may be supported by accreditation in

a variety of ways. Often, for example, such bodies may be represented on the governing bodies, and the advisory and technical committees of accreditation bodies. They therefore have opportunities to contribute to the operations of accreditation bodies and to have their own members' interests considered in the delivery of appropriate services by the accreditation bodies and the conformity assessment bodies they accredit. (ISO/IEC 17011 requires accreditation bodies to ensure that there are appropriate balances of interests in their governance).

Governmental appointment

Where governmental regulations require conformity assessment to be carried out by 3rd party bodies, those responsible for the regulations should specify the criteria which the bodies should meet. The most universally acceptable criteria are those found in the CASCO toolbox (see **Appendix 1**). The criteria could include a requirement for the bodies to be accredited by a specified body or by, for example, a signatory to one of the international mutual recognition arrangements such as IAF or ILAC. In some cases those implementing the regulations could make a direct appointment of the bodies based either on the assessment of their competence by the regulatory authorities or by a body nominated by them.

Where there is an urgent need for conformity assessment arrangements to be set up, the regulatory authorities could decide to directly assess and appoint bodies. However, the basis of the assessment might not be clear and it could be difficult for the bodies and their certificates to gain recognition in other countries.

Chapter 5 – What UNIDO can contribute to setting up a quality infrastructure

UNIDO's approach to sustainable industrial development

UNIDO, the United Nations Industrial Development Organization, holds a special place in the United Nations system as the only organization that supports sustainable industrial development as a way of creating wealth and alleviating poverty.

With its portfolio of trade capacity building projects, the largest in the UN, it helps developing countries and economies in transition to better integrate with the world economy. It mobilizes knowledge, skills, information and technology to promote productive employment, create competitive economies and ensure a sound environment; and it further enhances the value of its work by promoting cooperation among international development agencies, public institutions and the private sector at global, regional, national and sectoral levels.

UNIDO's primary focus is on supporting international competitiveness in the small and medium enterprise (SME) sector, the key generator of wealth in most developing countries – and here setting up a quality infrastructure with conformity assessment at its core is an essential foundation – but it also supports environmental sustainability, playing a leading role in implementing the Montreal Protocol for the elimination of ozone-depleting substances (ODSs) and the Stockholm Convention for the elimination of persistent organic pollutants (POPs).

UNIDO'S thematic priorities

UNIDO has focused its development efforts on three inter-related thematic priorities:

- Poverty reduction through productive activities
- Trade capacity building
- Energy and environment.

UNIDO services supporting the *thematic priority of poverty reduction through productive activities* improve the business environment and lay the policy and institutional foundations for the development of a vibrant private sector. They promote domestic entrepreneurship, especially development of the entrepreneurial skills of disadvantaged groups. They link domestic enterprises to international investment and technology flows, and they facilitate access to the resources and support services that

small and medium enterprises require to become more competitive.

The *thematic priority of trade capacity building* combines services that, on the one hand, build the supply-side capacities that enable enterprises to manufacture products with high-export potential in the quantities and quality required by the markets and, on the other hand, build the quality infrastructure capacities that enable these enterprises to prove that their products conform to international standards or private buyer technical requirements.

Services supporting the *thematic priority of energy and the environment* are rural energy for productive use (with an emphasis on renewable energy); energy efficiency, including support to the Kyoto Protocol (climate change, greenhouse gasses); cleaner and more sustainable production, including National Cleaner Production Centres; water management; and support for the Montreal Protocol and the Stockholm Convention.

Partnerships with other UN agencies

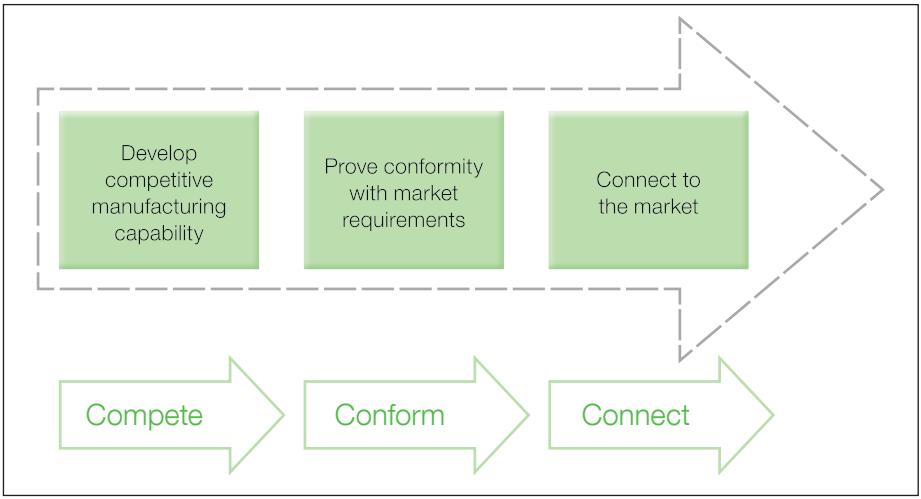
UNIDO is an active supporter of the UN "Delivering as One" initiative launched in 2007. Also known as "One UN", its aim is that the UN family deliver its services in a more coordinated way at the country level. A consolidated UN presence – with one programme, one budgetary framework and an enhanced role for the UN Resident Coordinator – that builds on the strengths and comparative advantages of the different UN agencies, will ensure faster and more effective development operations. This will reduce duplication and transaction costs so that the UN can use its resources more effectively to support partner countries achieve their development goals.

UNIDO's approach to trade capacity building – the 3Cs

The development of industrial exports is a multidimensional process. It requires effective policies and governance systems that will create a stimulating environment for trade, and a wide diffusion of knowledge, information, skills and technologies across economic agents and institutions to ensure that export growth is diversified and sustainable and contributes to the creation of an equitable society.

To effectively address the many complex factors underlying successful industrial exports, UNIDO has adopted a holistic approach to trade capacity building that takes into account the whole "product to market" chain. It has dubbed this its "3C" approach: compete, conform, connect (see **Figure 8**). The first two links, "compete" and

Figure 8 – The 3Cs: Compete, Conform, Connect



"conform", are at the core of UNIDO's mandate and address, respectively, the capacity shortfalls of supply and proof of conformity with standards. The third link, "connect", addresses shortfalls in connecting to the market and is primarily the domain of other development partners.

Supplying the market: "Compete"

Shortfalls in supply-side capacity render developing country industry unable to produce goods that are attractive to the market and meet the requirements of quantity, price, delivery time and international quality standards (safety, health and environmental).

UNIDO helps countries to compete by strengthening their capacity to produce competitive goods. Its projects are based on a rigorous analysis of competitive potential at product and sub-sector level and of supply-side constraints. Its services focus on SMEs and include the creation of a policy environment that stimulates trade, the upgrading of industrial activities (including cluster and export consortia development) and the creation of capacity to meet international standards, client requirements and environmental regulations.

Proving conformity with standards: "Conform"

Shortfalls in proving conformity with standards arise when a country's quality infrastructure does not meet international conformity assessment standards. These standards are exacting. Non-compliance can be due to an

inadequate or non-existent quality policy, the unclear legal status of the infrastructure, unsuitable premises, or problems with management structure, staff or equipment. The bottom line is that the country's laboratory results and audit certificates are not recognized and its exports not fully accepted internationally.

UNIDO helps countries prove conformity by upgrading their quality infrastructure so that they can develop and harmonize standards and ensure that their domestic laboratories have the sampling and testing capacity to certify products and enterprise systems. With the increased effectiveness and reduced costs resulting from an improved quality infrastructure, larger shares in export markets may be captured and local customers are better protected from sub-standard products.

Connecting to the market: "Connect"

In many developing countries, the customs procedures, mechanisms and documentation flows may be cumbersome and slow; roads, ports and other utilities are non-existent or in bad repair; knowledge of the multilateral trading system is poor; there is insufficient involvement in negotiating international trade agreements; and access to developed country markets is hampered by quotas, tariffs and customs duties.

Activities to help countries connect with markets include infrastructure projects, such as improving roads and ports, developing capacities to facilitate cross-border transactions, increasing the countries' understanding of international trade rules and helping them to play an effective role in international trade negotiations and agreements. Several international organizations, including UN agencies, work towards improving such infrastructures.

The WTO TBT and SPS Agreements: additional conformity challenges

Though standards and regulations may enhance the free flow of goods and services, experience has shown that they can also be used to create unnecessary obstacles to trade and protectionism, often particularly disadvantaging developing countries.

In order to prevent countries from exploiting standards as unnecessary barriers to trade, the WTO, as the global organization dealing with the rules of trade between nations, requires its members to adhere to the WTO Agreement on Technical Barriers to Trade (TBT) and to the WTO Agreement on Sanitary and Phytosanitary Measures (SPS).

Delivering services at the national, regional and sub-regional levels

Developing the quality infrastructure needed to achieve a competent conformity assessment system, which also satisfies the requirements of the TBT and SPS Agreements, is a high-cost venture for a developing country. Such an infrastructure needs to provide access to the full set of standards and adequate capacities in testing, calibration, legal metrology, certification, accreditation, inspection and traceability. A regional or sub-regional approach to trade capacity building will ease costs and may also have other advantages.

From its practical experience, UNIDO has, in fact, determined that addressing trade capacity issues at the sub-regional level stimulates greater market integration and can lead to the penetration of global markets that would lie beyond the reach of individual countries. Sub-regional development projects can also be more cost-effective – one common accreditation body may, for example, be sufficient for a group of countries.

Indeed, due to the existence of an increasing number of regional economic cooperation and trade agreements (sometimes with overlapping membership), the regional harmonization of standards and conformity assessment

procedures has now become a necessity. And regional programmes can also help developing countries to prepare a common position in trade negotiations and effectively voice their quality infrastructure needs.

UNIDO has a long experience in building and strengthening capacity at the regional level, most particularly in Africa where it has three regional programmes under way. The first, for the West African Economic and Monetary Union (UEMOA), is in its second phase while the second, for the Economic Community of West African States (ECOWAS), is in its first phase. The third, for the East African Community (EAC), is being finalized. Elsewhere, it has technical assistance programmes under consideration or already developed for Central America and the Andean Community, the Mekong Delta countries and the South Asian Association for Regional Cooperation (SAARC), and the Middle East, the latter in cooperation with the Economic and Social Commission for Western Asia (ESCWA) and the Arab Industrial Development and Mining Organization (AIDMO).

Forming partnerships to build trade capacity

Partnering with other agencies in trade capacity building is an important dimension of UNIDO's developmental work. Its 3C approach to trade capacity building embodies an integrated multi-agency response with other multilateral organizations and agencies, national agencies and professional institutions, where it has entered into a number of strategic partnerships to increase efficiency and effectiveness and to avoid duplication.

UNIDO concentrates its own efforts on developing competitive supply capacity and setting up quality infrastructures that comply with standards and technical regulations in accordance with the WTO SPS and TBT Agreements. On connecting to the market and the multilateral trading system, it looks to other organizations and agencies, such as the WTO, the ITC and UNCTAD, for specialized knowledge. This approach is in line with the recommendations of the WTO Aid for Trade Task Force, the 2005 Paris Declaration on Aid Effectiveness and the UN system-wide coherence goals.

Some of the strategic partnerships that support UNIDO's specialized role in trade capacity building are:

- The Standards and Trade Development Facility (STDF). The STDF coordinates technical cooperation, the mobilization of funds, the exchange of experience and the dissemination of best practice to assist developing countries enhance their expertise

and capacity to analyze and implement international SPS standards. Members are the WTO, the ITC, UNCTAD, the Food and Agriculture Organization (FAO), the World Bank, the World Health Organization (WHO), the World Organization for Animal Health (OIE), the Inter-American Institute for Cooperation on Agriculture (IICA), and UNIDO

- The Joint Committee on Coordination of Assistance to Developing Countries in Metrology, Accreditation and Standardization (JCDCMAS). The participating bodies are ISO, UNIDO, the ITC, the International Electrotechnical Commission (IEC), the International Bureau of Weights and Measures (BIPM), the International Organization for Legal Metrology (OIML), the International Laboratory Cooperation (ILAC), the International Accreditation Forum (IAF) and ITU-T (the Telecommunications Standardization Sector of ITU, the International Telecommunication Union)
- The Enhanced Integrated Framework (EIF). The EIF helps the least developed countries (LDCs) enhance their trade development capacity and integrate with the multilateral trading system. Members are the IMF, the ITC, the World Bank, UNCTAD, UNDP, the WTO and UNIDO (as a full implementing partner)
- The Multi-Agency Support Team (MAST), comprising the FAO, the IMF, the ITC, UNIDO, the World Bank, the WTO and the Organization for Economic Co-operation and Development (OECD). MAST was established by the UNCTAD Secretary-General's Group of Eminent Persons on Non-Tariff Barriers to work on better definition, classification and quantification of non-tariff measures (NTMs) that constitute barriers to trade, and to help policy makers and trade negotiators in developing countries, especially in LDCs, build their capacities in dealing with non-tariff-barrier-related negotiating issues at the multilateral forums.

And last, but definitely not least as partners, are the key donors to UNIDO's trade capacity building activities: the European Union, Austria, France, Italy, Japan, Norway, Switzerland and the United Kingdom.

Building a quality infrastructure: UNIDO'S approach

Building a quality infrastructure that will enable developing country enterprises to meet the demands of a multilateral trading system – to ensure and to prove that their products conform to international standards, both of private

buyers and of regulatory authorities – is a complex challenge that has to be met in several organizational dimensions. The typical building blocks of a quality infrastructure are standards, metrology and conformity assessment. The last, conformity assessment, includes the key components of inspection, testing, certification and accreditation.

Developing a quality policy

Experience suggests that there is a logical path for developing a quality infrastructure. The best start is that the government develops and approves a quality policy giving details of the quality infrastructure components and their relevant responsibilities. This would facilitate a proper division of work. The quality policy should also detail the relationship of the quality infrastructure with the country's technical regulations, e.g. if it provides services related to the technical regulations. No developing country can afford to duplicate resources in two parallel systems, one for the market place and another for the regulatory authorities.

Establishing key organizations

Once the quality policy is approved, the government takes a leading role in establishing key quality infrastructure organizations. In developing economies, this government involvement in the early stages is essential. It gives the quality infrastructure organizations a semblance of authority, both with regulatory agencies and in the marketplace, and it provides the necessary finances since industry is not yet in a position to do so. Some quality infrastructure services will, however, always be funded totally or in large part by the government. These include fundamental metrology, standards development, standards information and accreditation. This is a very real sustainability issue for all UNIDO projects.

Meeting the costs

When industry can afford to pay market prices for these services, the quality infrastructure organizations, especially those providing conformity assessment services (inspection, testing and certification), typically transform from government organizations providing subsidized services to commercial organizations providing services on the "user pays" principle at market prices. This is a very healthy development and UNIDO supports it in its projects, as far as is practicable.

However, even with the private sector paying market prices for conformity assessment services, the cost of maintaining a fully fledged national quality infrastructure at the advanced level needed to ensure that development and trade are sustained is still often prohibitive. One solution is that parts of the quality infrastructure are jointly

owned or shared by one or more countries, as is in fact the case in some developed countries where one country may rely entirely on another for specific services. Agreement to such regional or bilateral services is a policy decision to be taken by governments themselves and, though bringing net benefits in economies of scale, will require ongoing political and financial commitment.

Taking an integrated approach

The building of a quality infrastructure should be based on a thorough needs assessment of all parts of the economy and should recognize that there is no ready-made model. The specific needs, once identified, must be considered carefully and the quality infrastructure planned and built in phases, with particular attention to ensuring that it is sustainable – which will, of course, require a clear government commitment to provide the necessary resources and finance.

The success of any intervention depends on coordination and collaboration between the government ministries and development agencies. The Joint Committee on Coordination of Assistance to Developing Countries in Metrology, Accreditation and Standardization (JCDCMAS) is the forum for coordination of developing-country issues related to quality infrastructure.

In the broader context of trade capacity building, which includes building quality infrastructure capacity, an effort to improve coordination and collaboration has been made by twenty-one organizations and five inter-agency bodies under the auspices of the UN Chief Executives Board. The fruit of their efforts has been published in the 2008 Interagency Resource Guide on Trade Capacity Building (available at **http://www.unido.org/fileadmin/media/documents/pdf/TCB/TCB_Inter-agency_Resource_Guide_2008.pdf**).

This guide has been developed to make it easier for developing countries and local UN country teams to draw on the wealth of UN-wide expertise when designing technical assistance programmes. The guide is also intended to facilitate collaboration between UN agencies.

UNIDO's capacity evaluation and needs assessment tools

A UNIDO project to build quality infrastructure capacity is broadly based. It begins with context-specific desk research and field missions to identify challenges at four levels: government policy and the regulatory framework, national quality infrastructure, sectors and value chains, and enterprises. Alertness is maintained for opportunities to cooperate with other bilateral and multilateral organizations in needs

assessment and project development and implementation.

A project can call on a number of UNIDO tools to deploy in its desk and field research. These relate to trade challenges at the enterprise level, key export sector supply-side constraints, quality infrastructure constraints and product refusals / notifications.

Data on trade-related challenges at the enterprise level. Enterprise-level challenges are identified using data from a UNIDO designed survey on "Trade-Related Challenges Faced by Exporters" which has profiled a range of geographical areas, levels of economic development and economic structures.

UNIDO's Trade and Industry Competitiveness Analysis Tool is used to profile supply side constraints in a number of ways:

- A *nation-wide assessment of trade and industry competitiveness* analyses the factors that drive national manufacturing growth
- A *value chain analysis of key strategic sectors* identifies high value-added stages in the production process where a country can benefit from specialized export markets
- A *product analysis methodology for trade negotiations* helps negotiators identify potential winning and vulnerable products in trade agreements
- The *costs of doing business* presents the factors that influence investment decisions in key strategic sectors
- An *industrial observatory* gives online access to all indicators of trade and industry competitiveness so that a country can benchmark its performance against competitors, role models and global threats.

Data on quality infrastructure constraints. UNIDO has compiled data to identify the gaps and assess the specific needs of quality infrastructures (**Figure 9**) in 32 African countries. This African data is continually updated, and the scope and geographic coverage has been extended to include Asia, the Pacific Island States and the Arab region. The data is valuable in projects targeting the harmonization of standards and technical regulations at the regional level.

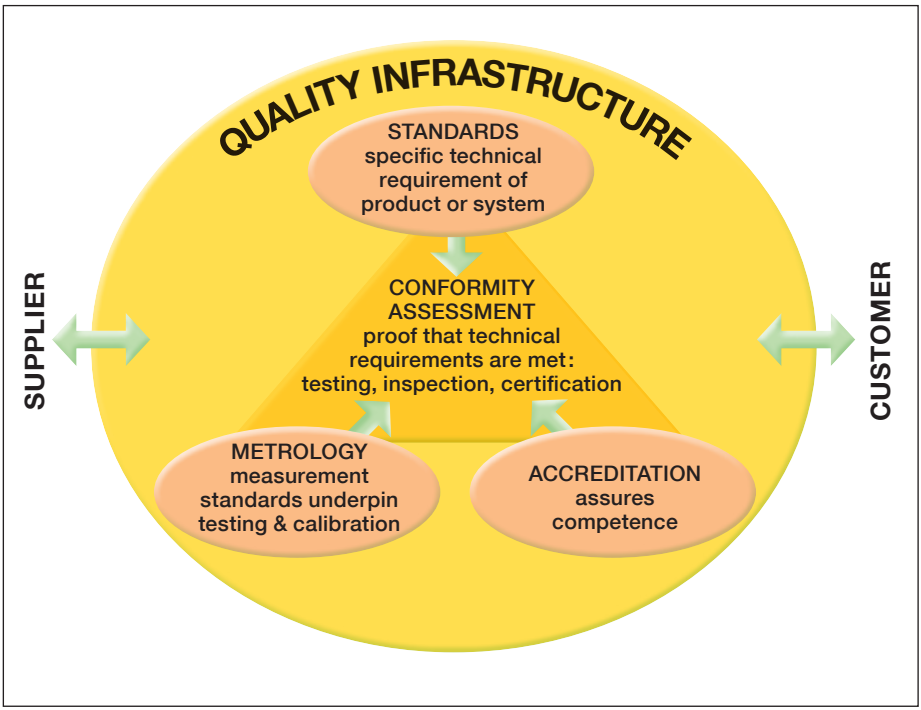
Product refusals/notifications tool. Also helpful for needs assessment is UNIDO'S "Enhanced classification of Non-Tariff Measures (NTMs) / Non-Tariff Barriers (NTBs) to Trade". The tool was developed by the Multi-Agency Support Team (MAST), comprising the FAO, the IMF, the ITC, the OECD, UNIDO, the World Bank and the WTO.

Quality infrastructure building blocks

Standards: A standards institution publishes standards – formal documents, generally developed by consensus, containing the requirements that products, processes or services should comply with. Standards are, in themselves, voluntary, i.e. suppliers can choose whether to use them or not. It is only when they form part of a contract, for example, or are referenced in technical regulation, that compliance with them becomes legally binding.

Typical standards institutions are a national standards body (NSB), sectoral standards development organizations (SDOs) and industry-based standards organizations. Although most national standards bodies are public organizations, there are a few private ones. A public national standards body is usually a monopoly, and a private one has an agreement with the government to similar effect. Standards development organizations are mostly private.

Figure 9 – Quality infrastructure



ISO/CASCO is responsible for development of joint ISO and IEC standards and guides on conformity assessment. To date, a total of 27 standards and guides have been generated. **Appendix 1** contains a full listing of these standards and guides.

Metrology is the technology or science of measurement. It can be subdivided into scientific metrology (the highest level of measurement standards), legal metrology (the assurance of the correctness of measurements that affect the transparency of trade, law enforcement, health and safety) and industrial metrology (the satisfactory functioning of measurement instruments used in industry, production and testing).

Typical metrology institutions are a national metrology institute (NMI), a national calibration service, calibration laboratories (public or private) and a legal metrology department (LMD). The national metrology institutes are invariably public organizations as are, by definition, the legal metrology departments. Calibration laboratories may be public or private.

Conformity assessment

The following items are the most common conformity assessment activities.

Inspection is the examination of a product design, product, process or installation and the determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Inspection is often conducted on consignments, for example import inspection, to ensure that the whole consignment is equivalent to the product sample tested.

Typical inspection institutions are import inspection agencies and general inspection agencies. These can be public or private agencies and normally compete in the market place.

Testing is the determination of a product's characteristics against the requirements of the standard. Testing can vary from a non-destructive evaluation (e.g. X-ray, ultra sound, pressure testing, electrical, etc., after which the product is still fit for use) to a totally destructive analysis (e.g. chemical, mechanical, physical, microbiological, etc., or any combination of these), after which the product is no longer fit for use.

Typical testing institutions are test laboratories, pathology laboratories and environmental laboratories. These can be public or private laboratories and normally compete in the marketplace.

Certification by a certification body formally establishes, after evaluation,

testing, inspection or assessment, that a product, service, organization or individual meets the requirements of a standard.

Typical certification institutions are product certification organizations and system certification organizations. These can be public or private organizations. Competition in the market place is the norm.

Accreditation provides independent attestation of the competence of an individual or an organization to offer specified conformity assessment services (e.g. testing, inspection or certification).

The typical accreditation institution is the national accreditation organization. This is usually a public body with a defined monopoly.

There are a few conflicts of interests that have to be considered when establishing a quality infrastructure:

- The accreditation function cannot be carried out by an organization that also provides conformity assessment, i.e. inspection, testing and certification
- The national standards body may also become the national accreditation body, but then it may not provide any conformity assessment services
- Although fundamental metrology and accreditation is not *per se* a conflict of interest (as defined by the BIPM, ILAC and the IAF) it is considered close to being one, and hence UNIDO encourages developing countries to avoid this combination. In particular, a body which accredits calibration laboratories cannot itself provide calibration services.

Building a standards infrastructure

Definition of a standard

There are two commonly used definitions of a standard. ISO/IEC Guide 2 defines a standard as a document established by consensus and approved by a recognized body, which provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. The WTO TBT Agreement, on the other hand, defines a standard more restrictively, highlighting aspects important for the Agreement, namely the notion that standards are voluntary and are limited to products. Hence, from a quality infrastructure perspective, the ISO definition is more useful, but the fact that standards in themselves are considered voluntary, as defined in the WTO TBT Agreement, should always be kept in mind.

Typical standards institutions

The typical standards institution is the national standards body.

Hierarchy of standards

An important consideration in developing projects on standards is the hierarchy of standards as shown in **Figure 10**. At the top we have *international standards*, published by international standards organizations, of which there are quite a few. For manufactured goods these include the top tier organizations, ISO, the IEC and the ITU. In food and agro-processing we have the Codex Alimentarius Commission (CAC), the International Plant Protection Convention (IPPC) and the Office International des Epizooties (OIE). For trade, the metrology-related standards published by the International Organization for Legal Metrology (OIML) are also very important. It is international standards that developing economies would normally adopt as their national standards. At the next level we have *regional standards*. These are very important for economies that belong to regional economic structures, such as the European Union (EU), the East African Community (EAC), the Eurasian Economic Community (EurAsEC), the Association of Southeast Asian Nations (ASEAN) and others. These regional standards are often the basis for technical regulation in the region, and hence are very important for trade. Where a developing economy is part of a regional trade block, the adoption of such regional standards is obligatory under the regional treaty or similar agreement.

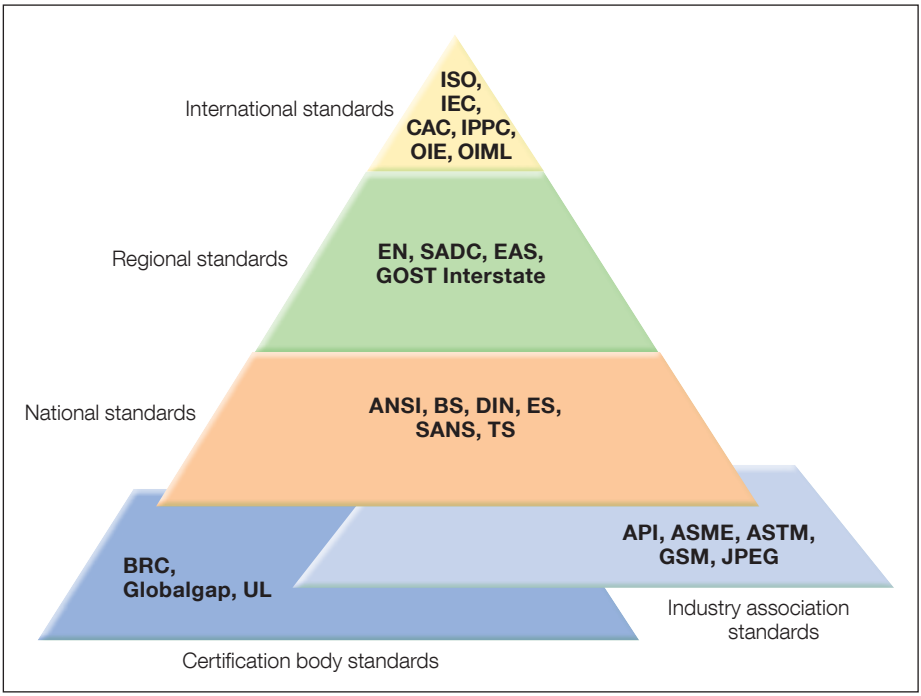
At the base of the hierarchy we find *standards published by national standards bodies*. These national standards have a specified legal standing and are freely available in local languages. There are also standards developed by industry groupings or multinational certification bodies, which are of economic importance. These include standards in the petroleum industry (API), the cell phone industry (GSM), testing (ASTM), pressure vessels (ASME), food security (Globalgap, BRC) and many, many others. The standards landscape is therefore a multi-facetted one.

Obtaining copyright to standards

It is important to understand that developing economies are generally standards "takers", rather than standards "makers" – international standards are developed by only a few of the major industrialized countries. Nevertheless, projects should not aim to establish mechanisms to develop "indigenous" standards, but rather find efficient ways to adopt international standards.

However, some of the major international standards are protected by copy-

Figure 10 – Hierarchy of standards



right, e.g. ISO and IEC standards, and cannot simply be adopted as national standards and applied at will. Full membership of such bodies is the most cost-effective way to obtain the copyright of international standards. Once transferred, though, the copyright must be protected at national level. Where a copyright does not exist, e.g. OIML Recommendations, some restrictions on their use still have to be honoured.

Accessing standards

In developed economies, standards are usually available on-line, though payment is required to download them. In developing economies, where access to the Internet is not always available, CD-ROMs are a useful electronic alternative, though the standards should be in a format that is not easily altered, e.g. PDF rather than MS Word or similar. Standards, however, will often have to be delivered in hard copy, and here a "print-on-demand" system is the best way to minimize costs and provide the latest edition – establishing a big printing press is not a good idea.

Financing standards bodies

An analysis of ISO membership data shows that approximately 30% of the member bodies at the time of the analysis are totally dependent on government funding, a similar number for more than 50% of their funds, and less than 30% for 20% or less of their funding.

In developed economies with very strong industries, the sale of standards provides a major part of the income of standards bodies, but in developing economies this covers 5% at most of their running costs. Governments must therefore make a formal long-term commitment to financing their national standards bodies if they are to be sustained. This is an issue that UNIDO's projects need to address.

Joining regional and international standards organizations

Membership of regional and international standards organizations is important on two counts: first, the needs of the country have to be represented; and second, knowledge gained in such forums about major trends in regional and international standards development can be quickly passed on to industry and the authorities. This means, however, that members should not only attend annual general meetings, but must participate actively in technical committees. Both, membership and active participation, are an important issue for UNIDO projects. To ensure that membership is maintained, the government has to commit to providing long-term financial support.

Involving private industry in national standards bodies

In many developing economies, national standards bodies have long been established. Many, however, are governed only by government representatives, with perhaps one or two representatives from industry or business associations, which does not encourage industry to accept the national standards body. UNIDO projects should ensure that industry leaders, people with a real power base, form the bulk of the governance structure, whether this is a council or a board of directors. Additionally, the council or board of directors should have real fiduciary and strategy authority over the body even if they are accountable to the relevant minister – nor should the minister attempt to micromanage the body.

The essential components of a standards infrastructure project

The components to be considered in a standards infrastructure project are listed below. Each component has one or more project outputs and related project outcomes. To some extent, the sequence of the list provides a logical

development path, even though many of the components can and should be dealt with in parallel.

1. National policy
2. National coordination
3. Legal status
4. Financial policy
5. Independence
6. Legal entity
7. Director
8. Management structure
9. Personnel
10. Premises
11. Equipment
12. Standards development
13. Technical committees
14. Public relations
15. Standards experts
16. Standard for a standard
17. Committee drafts
18. Public enquiry
19. National standard
20. Information experts
21. Standards information
22. WTO TBT enquiry point
23. Training system
24. Training courses
25. Board of directors
26. Associations
27. Authorities
28. Metrology and accreditation
29. ISO / IEC / CAC
30. Regional standards organizations.

Building a metrology infrastructure

Typical metrology institutions

The typical metrology institutions are:

- A national metrology institute
- A national calibration service
- Calibration laboratories, public or private)
- A legal metrology department.

Metrology: a basic necessity

Metrology is the science of measurement and has been part and parcel of everyday life since antiquity. Today metrology is the foundation of industrial quality control – in most modern industries, measurements constitute 10-15% of production costs. In Europe, weighing and measuring costs the equivalent of 6% of the combined GDP. The authorities, too, are dependent on weights and measures to set off alarms if measurements fall outside regulated limits. And, of course, science is completely dependent on measurements. The metrology infrastructure is therefore a basic necessity without which few if any of the other quality infrastructure activities would be possible. It is a fundamental and necessary precondition for any of the UNIDO projects.

Choosing an organizational structure for metrology

From a purist's perspective, the national metrology infrastructure con-

sists of three distinct and separate organizations representative of the three categories of metrology: the national metrology institute, responsible for scientific metrology, the legal metrology department, responsible for legal metrology, and the national calibration service, covering industrial metrology.

This is often how it is organized in developed economies, e.g. Germany with the Physikalisch-Technische Bundesanstalt (PTB) as the national metrology institute at the federal level, various Eichämpter responsible for legal metrology at the provincial level, and the Deutscher Kalibrier Dienst (DKD) at the federal level for industrial metrology.

However, developing economies frequently cannot afford three different organizations, so the metrology infrastructure has to be combined in a single organization or, quite commonly, is attached to the national standards body. Many variations are possible, and each one carries risks and advantages.

Some examples:

a. The national metrology institute is attached to the national standards body, which is also responsible for calibration services. Legal metrology is a separate government department, often called "Weights and Measures", denoting its limited scope
b. The weights and measures department is made responsible for the national measurement standards, and provides calibrations in both the regulated and the non-regulated metrology domains
c. The national metrology institute is a separate department attached to a scientific institution, and legal metrology is a separate government department or is attached to the national standards body.

All of these constructs can be made to work, but there is always the risk that one or more functions will be relegated to a lower level of activity. UNIDO projects therefore endeavour to have at least two separate metrology institutions set up, the national metrology institute with added responsibility for industrial metrology and a legal metrology department – the optimum solution for developing countries. The reason for this split is very simple: national metrology institute personnel are scientists, whereas legal metrology inspectors are basically regulators. The type of personalities and functional approaches of these two are completely different even though the technology is very similar.

Setting up a national metrology institute

The national metrology institute is designated by national decision, e.g. by legislation, to develop and main-

tain national standards for one or several quantities. Although not required by definition, most developing countries will operate a centralized metrology organization, designating only one national metrology institute.

The metrology institute's mandate

The mandate of the national metrology institute should be to:

- Establish and maintain national measurement standards demonstrably traceable to international metrology definitions/standards for the relevant metrology quantities needed by the country
- Ensure that a national calibration system is established and maintained to diffuse metrology standards to industry, the authorities and society
- Represent the country at the international level, e.g. at BIPM
- Represent the country in regional metrology structures such as AFRIMET (Africa), APMP (Asia Pacific), COOMET (Euro-Asia), EUROMET (Europe), SIM (Americas), etc.
- Represent the country at the national metrology institutes of other countries.

In many countries, the national metrology institute also conducts the type approval testing of measuring equipment that falls within the scope of legal metrology regulations. The final approval of this equipment for use in the market place, however, should remain with the legal metrology department.

Ensuring the sustainability of the metrology institute

To establish a fully working and sustainable national metrology institute, UNIDO must carefully consider the following major issues in the design of a fundamental metrology project:

Legal certainty regarding the institute, its mandate and the supremacy of the national measurement standards in the calibration hierarchy of the country. The best way to achieve this is to ensure that the legislation is developed in accordance with international best practices (e.g. OIML D1, Elements for a Law on Metrology) and promulgated by the highest legislative authority in the country.

Funding certainty for the establishment and short and long-term maintenance of the national metrology institute functions. The government will be the only source of long-term financing, so the UNIDO project must get its commitment to provide this.

Appropriate laboratory space and environmental control. Metrology laboratories are subject to some very specific requirements (e.g. OIML G13, "Planning of Metrology And Testing

Laboratories"). They also need to have strict environmental controls (e.g. temperature, humidity and dust) operating 24 hours per day, 7 days per week throughout the year (which requires consistency of electrical supply), otherwise measurement accuracy will be seriously compromised. Equipment should only be provided when there is proper metrology laboratory space and environmental controls. Dust, for example, may not be an issue in developed economies, but in developing economies it is often a major concern, especially if roads are not tarred.

National primary or secondary standards. These are the metrology standards that should be the most accurate in the country. Primary standards are extremely expensive to establish and to maintain and will be found only in the most advanced national metrology institutes. In developing economies, national secondary standards are quite adequate, provided that their accuracy is aligned with the demonstrated needs of industry and the authorities.

Training metrology personnel. Fundamental metrology is highly technological, so well-trained personnel are vital for its sustainability. Training can be provided by international experts coming to the country or by the attachment of personnel to recognized national metrology institutes, or preferably both. Retention of highly skilled personnel will affect long term sustainability.

Establishing calibration and measurement capabilities (CMCs). The rules for establishing CMCs and their acceptance through peer reviews can be obtained from the BIPM. Having the national metrology institute's CMCs accepted and published by the BIPM ensures that the country's measurements will be acceptable to the international markets, and is therefore a high priority.

Setting up a legal metrology department

Some metrology processes need to be regulated by the government to ensure a transparent and fair measurement regime. These would include:

- Type approval, calibration and verification of measuring equipment used in trade to ensure that purchasers obtain the quantities of goods they pay for, e.g. weighing scales, petrol pumps, tot measures, etc.
- Control over pre-packaging operations for the same reasons, e.g. with butter, milk, beer, wine, cereals, etc.
- Type approval, calibration and verification of measuring equipment used in health and safety to ensure that decisions are made on the basis of correct measurements, e.g. thermometers, blood pressure meters, noise meters, etc.
- Type approval, calibration and verification of measuring equipment used in law enforcement to ensure a fair enforcement regime, e.g. speed traps, alcohol meters, axle load weighing equipment, etc.

The main function of legal metrology is therefore a regulatory one, albeit on the basis of metrology technology, so the organization responsible should have regulatory powers. It must therefore be a government department, agency or regulatory authority vested with such powers through legislation. This is not a function that can be privatized easily.

Legal metrology requirements come under technical regulations and should therefore comply with the WTO TBT Agreement requirements. Fortunately, a vast body of international recommendations and standards for legal metrology have been developed and published over many years by the International Organization for Legal Metrology (OIML). These are available as free downloads from the OIML Website (http://www.oiml.org).

The legal metrology department should also be responsible for managing regional and international relationships. Because legal metrology is a regulatory function, many regions are in the process of harmonizing legal metrology rules, actively supported by the OIML, so involvement in regional organizations is critical. These include APLMF (Asia Pacific), COOMET (Euro-Asia),

EMLMF (Euro-Mediterranean), SADCMEL (Southern Africa), SIM (Americas), WELMWEC (Europe), etc.

Ensuring the sustainability of a legal metrology department

A fully functional legal metrology infrastructure has an immense impact on society and hence is often the first component of the quality infrastructure to be established in developing economies. Some have already had one for over a century. However, these long-established institutions have not been subject to a proper review for decades and often leave much to be desired.

Projects to modernize them, or to extend the scope of the original weights and measures department (dealing only with measurements in trade) to that of modern legal metrology, are therefore still very relevant. In designing a legal metrology project, UNIDO needs to carefully consider the following sustainability issues.

Legal metrology legislation. The most efficient way to promulgate legal metrology legislation is to do it in two or more levels. The primary legislation (i.e. a law approved by parliament) has to provide legal certainty about the mandate of the legal metrology department, the powers of search and seizure of the registered inspectors, the metrology standards used, the system of type approval and verification, the system of pre-packaging control, and sanctions.

Subsidiary legislation (i.e. regulations promulgated when necessary by the minister so empowered by the primary legislation) would contain the technical details and could refer to OIML, ISO, IEC and other standards. Existing legislation should be reviewed, and amended or revised as appropriate.

Funding certainty is needed for the establishment and short and long-term maintenance of the legal metrology department. The bulk of the finances will have to be provided by the government, even though users of measuring equipment can and should pay for calibration and verification work. The income from this source would certainly not be enough to cover all expenditure, and commercial pressures should not unduly influence the activities of the inspectorate. Hence the project must engage with the government to secure their long term commitment.

Laboratory and equipment for type approval. Although the requirements for these laboratories may not be as stringent as for fundamental metrology, the same basic sustainability issues apply. In many cases, measuring equipment will be brought into the country with OIML test reports, in which case no retesting should be required.

Presence in all the major centres. Legal metrology is mostly about market surveillance, hence it is very important that the legal metrology department has an appropriate physical presence in all the major centres of economic activity in the country. A legal metrology infrastructure with a head office supported by regional, provincial or city offices, as demonstrably required, is probably the most effective option for developing economies.

Calibration and verification equipment. The department needs measurement standards to be able to calibrate and verify measuring equipment that comes within the scope of the regulations. The accuracy class of this equipment has to meet the regulatory requirements, and there should be enough equipment for inspectors to be able to cover the whole of the country within reasonable time limits. This equipment needs to be regularly calibrated against departmental standards or against the national standards.

Trained and registered legal metrology inspectors. In the first instance, legal metrology inspectors need to be trained in metrology. Secondly, they need to be trained in their legal responsibilities, because they have to understand their immense legal powers. Thirdly, they need to be properly registered and issued with identity cards to present when entering premises. Obviously, once they are no longer employed by the legal metrology department, these identity cards should be withdrawn.

Proper application of sanctions. The legal metrology regime will only be as effective as the way in which sanctions are applied. It is therefore very important that a system of administrative sanctions be developed and implemented, and where this does not bring about the required behaviour, then the courts of law must be utilized.

Setting up a national calibration system

Measurements will only be accepted world-wide if the measuring equipment is properly calibrated, i.e. it is part of an unbroken traceability chain that ends with the primary national metrology standard. There are three main reasons for this:

- To ensure that readings from the instrument are consistent with measurements from other instruments
- To determine the accuracy of the instrument readings
- To establish the reliability of the instrument.

A national calibration system is the most effective way to provide a country's industry and authorities with such a calibration service. Although calibration services can be provided by the national metrology institute or

the legal metrology department, the usual case in developing economies, it is much better if calibration laboratories are eventually established so that the national metrology institute and the legal metrology department can then focus their energies on their main mandates. **Figure 11** shows the national metrology infrastructure and indicates the traceability chain from the measurements to, ultimately, the definition of the unit.

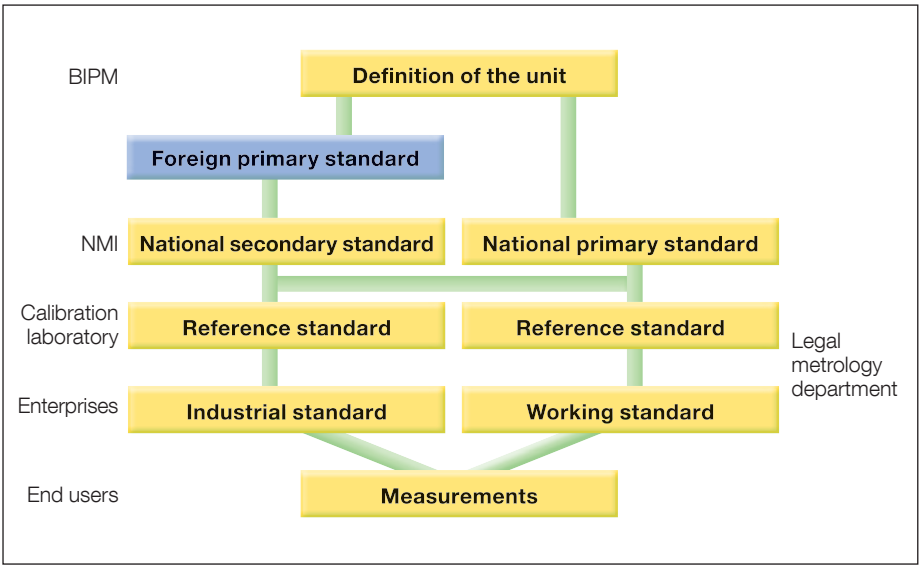
A national calibration system should be established by the national metrology institute in close cooperation with the national accreditation body. The establishment of calibration laboratories is usually a private industry initiative, and hence outside the scope of UNIDO projects. However, if calibration laboratories are to be established as a project outcome, then sustainability issues as discussed for the national metrology institute should be addressed, albeit without the legislative requirements and CMCs. The calibration laboratories must, however, be accredited against ISO/IEC 17025 and their reference standards traceably calibrated against the national standards.

Essential components of a metrology infrastructure project

The components to be considered in a metrology infrastructure project are listed below. Each of the project components has one or more project outputs and related project outcomes. To some extent the sequence of the list provides a logical development path, even though many of the components can and should be dealt with in parallel.

1. NQI policy on metrology
2. Legislation
3. Financial policy
4. Legal entity
5. Director
6. Management structure
7. Personnel
8. Premises
9. Environmental controls
10. Equipment
11. Quality documentation
12. NMI : Metrologist
    LMD : Legal metrology inspectors
13. Training system
14. NMI : Inter-laboratory comparison
    LMD : Type approvals
15. NMI : Calibration service
    LMD : Verification
16. NMI : Peer review
    LMD : Market surveillance
17. NMI, CMCs
    LMD : Sanctions
18. Council
19. Associations
20. Client organizations
21. NMI : AFRIMET, APMP, COOMET, EUROMET, etc.
    LMD : APLMF, SADCMEL, WELMEC, etc.
22. NMI : BIPM
    LMD : OIML.

Figure 11 – The national metrology infrastructure



Building an accreditation infrastructure

Typical institutions

The typical accreditation institution is a national accreditation body.

The role of accreditation

The increase in trade over the past few decades demands more certainty across borders about the integrity of conformity assessment results. Accreditation is one means of providing this assurance. It is an independent attestation that a conformity assessment body is operating in an impartial and technically competent way. This can greatly enhance the value of the conformity assessment body's output – its test or inspection reports, calibration certificates, and system or product certificates. Accreditation has played a role in the elimination of technical barriers to trade in many areas.

The confidence that accreditation provides is valuable in both supporting economic progress and protecting public interests – in both the non-regulatory and the regulatory domains. Its benefits can assist with:

- The establishment of internationally recognized conformity assessment services
- The opening of export markets to national industries
- The underpinning of industrial

development through strengthened competition
- The creation of transparency in the markets by the clear description of competency scopes and inter-laboratory comparisons
- The implementation of anti-corruption measures through the traceability of results, annual surveillance audits, on-site assessments, peer evaluations and management of the records of every step in a process.

It is no wonder that governments in many developing economies feel compelled to establish an internationally recognized national accreditation body to support their industrial development and to create certainty in the implementation of technical regulations.

Getting international recognition

At the international level, the International Laboratory Cooperation (ILAC) and the International Accreditation Forum (IAF) are the main organizations in the development of accreditation practices and procedures; additionally, they manage mutual recognition arrangements (MLAs) amongst their members. They divide their responsibilities thus:

- Laboratories (ILAC)
- Certification bodies (IAF)
- Inspection bodies (both).

The MLAs between participating members facilitate the international acceptance of test data, calibrations, inspection reports and certificates (system and product). Any UNIDO project to establish a national accreditation body should ultimately support the body in becoming a signatory of the MLAs.

NOTE: The ultimate aim in the establishment of a national or regional accreditation body is for it to become a signatory of the ILAC and/or IAF MLA.

Choosing organizational structures

Accreditation bodies come in a variety of shapes and sizes: some countries have only one, some have many, and in others it is part of a bigger organization, such as the national standards body. The tendency now, though, is for countries with many accreditation bodies to merge them into one or at most two, reflecting the ILAC and IAF division of responsibilities. At the same time, most countries realize that these bodies need to be independent of and separate from other quality infrastructure organizations to avoid any actual or perceived conflict of interest. UNIDO, too, must ensure that any accreditation body it establishes is impartial, independent and devoid of conflict of interest.

Funding an accreditation body

The authorities in most developing economies have no idea of the real costs of a national accreditation system. They commit to funding the start-up phases, believing that accreditation fees will quickly cover expenditure. The reality is different. It is highly unlikely that fees in developing countries will ever cover total expenditure. To reach break-even point a body must accredit 200 to 250 organizations, an impossible target in many developing countries. The government will therefore have to continue providing the bulk of long-term funding. And even if the magic number of 200 can be reached, the government will still have to fund international and regional obligations, such as IAF and ILAC membership fees. This is an area that needs to be carefully considered during the design phase of UNIDO projects.

Setting up regional accreditation bodies

Due to their financial and human resource constraints, some regions have begun the long journey towards a regional accreditation body, e.g. SADC. There are serious issues that the member states need to agree on. These include:

- The organizational form and statutes of the regional accreditation body
- The registration of the body in one of the member states, and its governance structures and professional liability
- The joint short-term and-long term funding mechanisms
- The appointment of a full-time director and staff
- Recognition of the regional accreditation body as equivalent to a national accreditation body, especially in the administration of technical regulations
- Acceptance of the regional accreditation body as representing the individual states in international accreditation forums and as a signatory of the mutual recognition arrangements of the IAF and ILAC
- The establishment of liaison structures, i.e. an accreditation desk, in the responsible ministry in each member state to facilitate the assessment and accreditation of organizations at the national level by the regional accreditation body
- Training and registration of lead and technical assessors in each of the participating member states.

The establishment of such a regional accreditation body is undoubtedly worthwhile, but there should be no illusions about the difficulties. It would be a long term project, with a time frame of six to eight years before it is finally a signatory of the IAF and ILAC multilateral recognition arrangements.

NOTE: Establishing a regional accreditation body requires a tremendous political will from all the governments involved. Resolving the legal and administrative issues and gaining international recognition will take as long as eight years.

Complying with ISO/IEC 17011

The accreditation body has to comply with ISO/IEC 17011, the standards used by the peer evaluation group of either IAF or ILAC or their recognized regional groupings, before it can become a signatory of their multilateral recognition arrangements. This peer evaluation will look at the accreditation body's performance in three broad categories, structure quality, process quality and outcome quality. The process is shown in **Figure 12**.

Ensuring the sustainability of an accreditation infrastructure

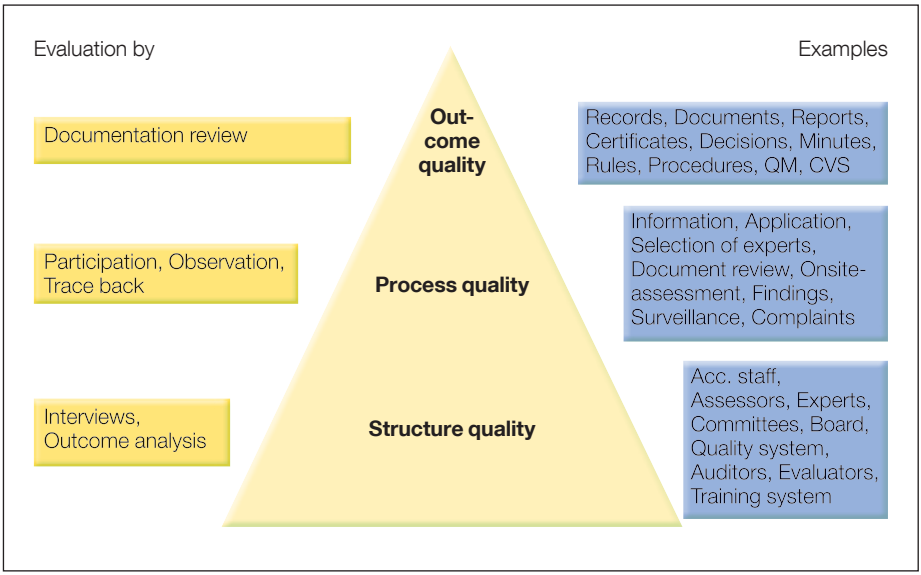
The accreditation body is in many ways the pinnacle of the conformity assurance pyramid in a country. It would therefore seem best to have just one national accreditation body which all ministries and regulatory agencies would agree to support and use. A number of developed economies have established more than one accreditation body, particularly where they cover different fields such as testing and certification.

NOTE: For developing economies the optimum situation is to establish a single, national accreditation body that is accepted by all industry and especially all ministries and authorities.

This situation is acceptable where the economy can support more than one accreditation body, but for developing economies it is usually not economically or technically viable. Problems can arise where developing economies have established several bodies, each within a different ministry and supported by a different donor organization with the result that their activities can overlap. The best way to avoid this problem is to pass legislation establishing a single, national accreditation body.

Financing. The government has to support the accreditation body financially as a long term commitment, even if it is established by donor funding – this was discussed earlier as a fundamental project consideration. This unequivocal commitment by the government is of vital importance for the sustainability of the accreditation body, and has to be obtained before a project is launched.

Figure 12 – Evaluation pyramid for compliance with ISO/IEC 17011



NOTE: Accreditation will not pay for itself in the short term, and it is doubtful whether it will do so in the long-term in developing economies, even if the magic number of 200 accredited organizations can be reached. Hence the government must recognize that it will need to support the accreditation body financially, and long-term, if it wishes to have one.

Ensuring the impartiality of an accreditation body

The accreditation body's assessment and decision making processes should not be subjected to any undue influence from within the accreditation body itself or outside, especially from ministries or their agencies. Continued and demonstrable compliance with ISO/IEC 17011 is essential.

Multilateral recognition arrangements of IAF and ILAC

Ultimately, the accreditation body has to become a signatory to the multilateral recognition arrangements (MLAs) of IAF and ILAC. Without this, none of the conformity assessments accredited by it will be accepted in the international markets.

Essential components of an accreditation infrastructure project

The components of an accreditation infrastructure project are listed below. Each component has one or more

project outputs and related project outcomes. To some extent the sequence provides a logical development path, even though many of the components can and should be dealt with in parallel.

1. NCAI policy on accreditation
2. National coordination
3. Legal status
4. Financial policy
5. Independence
6. Legal entity
7. Director
8. Premises
9. Management structure
10. Personnel
11. Equipment
12. Quality documentation
13. First scope
14. Public relations
15. Technical committees
16. Proficiency testing
17. Metrology, standards
18. Board of directors
19. Associations
20. Client organizations
21. Lead assessors
22. Technical assessors
23. Training system
24. Special courses
25. Pre-assessments
26. Working groups
27. Joint accreditations
28. Pre-evaluation
29. MLA/MRA

Building an inspection infrastructure

Typical institutions

- Trade inspection agencies
- Engineering inspection agencies
- Regulatory inspection agencies.

In **Chapter 2** we saw that **inspection** is defined as "Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements". Bearing in mind that "product" can include hardware, software, service or processed material, the potential field for inspection can be seen to be very wide. It is also a technique which is applied at different levels in the economy, including inspection of, for example:

- Food on the farm or products in the factory
- Safety and integrity of vehicles, buildings and process plant
- Items used in trade, such as weighing and measuring equipment
- Quality and quantity of traded goods.

The requirements against which the inspections are carried out are equally diverse. They could, for example, be specified in contracts for the supply of goods or services or could be laid down in legislation regarding health, safety or fair trade.

All of these factors mean that before contemplating the establishment of an inspection infrastructure it is vital that the purpose(s) are clearly defined and that the intended benefits and likely costs are understood.

The nature of inspection can vary from carrying out repetitious and simple counting or measuring operations to highly complex technical examinations and calculations for which a high level of professional expertise is needed. The range of inspection bodies described in **Chapter 4** includes those which are independent, referred to as Type A bodies, and those which carry out inspections for the organization of which they are a part, referred to as Type B bodies.

There is also a hybrid status, known as a Type C body, where inspection may be carried out for both the parent organization and others. The underpinning requirement is for the work to be carried out with integrity and in a systematic manner.

Fundamental project considerations: Inspection infrastructure

Purpose

The purpose of the inspection infrastructure could be limited to the facilitation of the development of trade and industry but could also cover such areas as the protection of the health, safety and well-being of people. Provided that the inspection infrastructure is being designed as part of the overall national quality infrastructure, the national priorities should already have been considered and will provide a good basis for determining the scope of the inspection infrastructure.

The nature and level of inspection which is required will be related to the need for confidence in the conformity of items with the expectations of the parties involved. As mentioned in **Chapter 3**, an important part of the infrastructure design process is an assessment of the risks associated with nonconformity. In what ways might items not conform? How likely is it that they would not conform? What could be the consequences if they did not conform? How much effort is it sensible to apply to the prevention of nonconformity?

Where legislation requires, either directly or by inference, inspection to be carried out, it is important to take account of the economic impact. Inspectors have to be paid, and delays waiting for an inspector to be available and to carry out the inspection can cost money. Legislators are strongly advised to apply the conformity risk assessment process when considering the introduction of regulatory inspection.

Inspection is not the only technique which can be employed to manage the many and varied risks in everyday life. The basic philosophy of the quality approach is to design quality in from the outset rather than trying to inspect it in afterwards. However, no process is perfect and some degree of inspection will be needed.

An important consideration when designing an inspection infrastructure is to ensure that all other measures to prevent nonconformity are going to be in place. In that way the demands on the inspection operation can be kept within realistic and economic bounds.

Potential client base

From the preceding discussions, it can be seen that the range of potential clients for inspection is large. A number of different situations might exist.

A manufacturer could employ its own inspectors to check the quality of its products or it could buy in the services of inspectors on a sub-contracted basis if the need is infrequent or requires specialist expertise. In either case, the manufacturer would bear the cost of the inspection.

A purchaser could employ its own inspectors to check the quality and quan-

tity of the products which it is buying. Inspection could be carried out at its premises or at the manufacturer's premises prior to shipment. Again, these inspections could be carried out by a sub-contracted agency. In these cases it is usual for the purchaser to bear the cost of the inspection.

A regulatory authority could employ its own inspectors to check whether items comply with legislative requirements or an independent agency could be appointed to carry out the work. In either case, the cost of the inspection could be borne by the authority or, as is becoming more common in some economies, the person or organization responsible for the items might be expected to pay some or all of the cost. Vehicle inspection is an example of an area where the owner of the vehicle is required to pay for periodic regulatory inspection.

The inspection infrastructure plan will need to take account of the type, number and size of client organizations and of the nature of their inspection needs. Unlike testing, much of which takes place in laboratories at fixed locations, inspection tends to take place where the items to be inspected are located. Thus a wide geographic spread of clients will add considerably to the time taken in carrying out inspections due to the time spent traveling between clients. There will also be the travel costs and, possibly, accommodation and subsistence costs for the inspectors. If the inspection work is highly specialized and requires only a few days a year, it could be more economical to bring in an inspector (or team) from another country rather than going to the trouble and expense of creating a specific element of the inspection infrastructure for this work.

On the other end of the scale, where there is a more or less continuous need for inspection, the agency could station one or more inspectors at the site. Extra care is needed with this kind of arrangement because inspectors might become too familiar with the people at the site and lose their objectivity.

Conformity requirements

Having defined the purposes, and thereby the scope, of the inspection infrastructure and ascertained the needs of the potential clients, the requirements against which the inspectors will be determining conformity can be defined. Where possible, existing standards, particularly those adopted at international level, should be used, whether in commercial contracts or in legislation.

The main benefits of this approach are that the standards represent current good practice in the technical subject and that it will be easier to find

inspectors with expertise in those subjects. If standards do not exist or are not suitable, then inspection schedules will need to be created in consultation with the clients. One feature of inspection, as stated in the definition given above, is that requirements might be general in nature and the inspectors might be required to exercise professional judgment in determining the conformity of the object which is being inspected.

However, the consistency of the conduct and results of inspections will be improved if the inspectors work to common procedures. Occasional meetings of all inspectors in a given technical area can help to promote a consistent approach; they can also assist in maintaining a sense of corporate identity amongst people who are often working on their own away from headquarters.

Resources

The main resource required for inspection is people who are expert in the relevant technical areas. In some cases, measuring or testing equipment could be needed and it is helpful for an inspection agency to have an office even if the majority of the work is carried out in the field. Each of these items is considered in more detail below.

People

The key resource of an inspection agency is its team of inspectors who are likely to be people with a high level of competence in the fields in which the agency is offering its services. The scope of inspection work to be undertaken will determine the range of competences to which the inspection agency will need to have access. It might not be necessary for all of the inspectors to be employed as full time staff if people with the necessary competence can be brought in on a contract basis when needed.

Generally speaking, there will be a break-even point in the volume of work above which it becomes more economical to employ full time staff. The agency would need to ensure that contracted-in inspectors work within its management system and that their work is properly monitored. Such requirements and the likelihood that many of its full time inspectors are working away from headquarters emphasize the need for strong management within the agency.

Above all, a high degree of professional integrity must be maintained to ensure that the inspectors carry out their work free from any commercial, financial and other pressures which might affect their judgment. Procedures must be implemented to ensure that people or organizations external to the inspection agency cannot influence the results of inspections carried out.

Equipment

The inspection agency must have available to it suitable equipment to permit all activities associated with the inspection services to be carried out. It is not always necessary for the agency to have its own equipment if it has arrangements for the use of equipment belonging to another organization, for example a testing laboratory. Whichever arrangement it uses, the inspection agency is responsible for ensuring that the equipment:

- Is used only by people authorized to do so
- Is used in the intended manner
- Is and remains suitable for its intended use
- Is properly and unequivocally identified so that the results of any measurements or tests for which it is used are traceable
- Is properly calibrated and maintained, bearing in mind that it is likely to be used in the field and subject to adverse transport and storage conditions.

Premises

Although the majority of the inspection work is likely to be carried out in the field, the inspection agency will need some accommodation for head office functions such as overall management, client interface, maintenance of records and storage, maintenance and calibration of equipment, if necessary. The inspectors might also need some office facilities for some aspects of their work. Overall, the aspect of premises is probably the least critical in the plans for setting up the inspection infrastructure.

Accreditation

Since the key feature of an inspection agency is the competence of the inspectors, accreditation may not be as important in the inspection sphere as it is in others. The inspection agency should, in any case, be set up to comply with ISO/IEC 17020 as the internationally agreed set of criteria for inspection bodies. Two main reasons for gaining accreditation to that standard would be:

- Providing objective evidence that the agency does in fact comply with the standard and is therefore most likely to provide the required level of inspection service
- The acceptance in another country of the inspection reports produced by the agency, where the inspection work relates to items exported to that country.

Because accreditation represents an ongoing expense for the inspection agency, the commitment to accreditation should only be made where it has been properly considered and justified.

Sustainability issues: Inspection infrastructure

Financial stability

Provided that the inspection agency can gain access to the appropriate inspectors, initially on a contracted basis, the entry cost for providing an inspection service is relatively low. The key feature is a technically sound business manager who can maintain a high degree of client satisfaction by building up inspection capacity in line with the growth in demand.

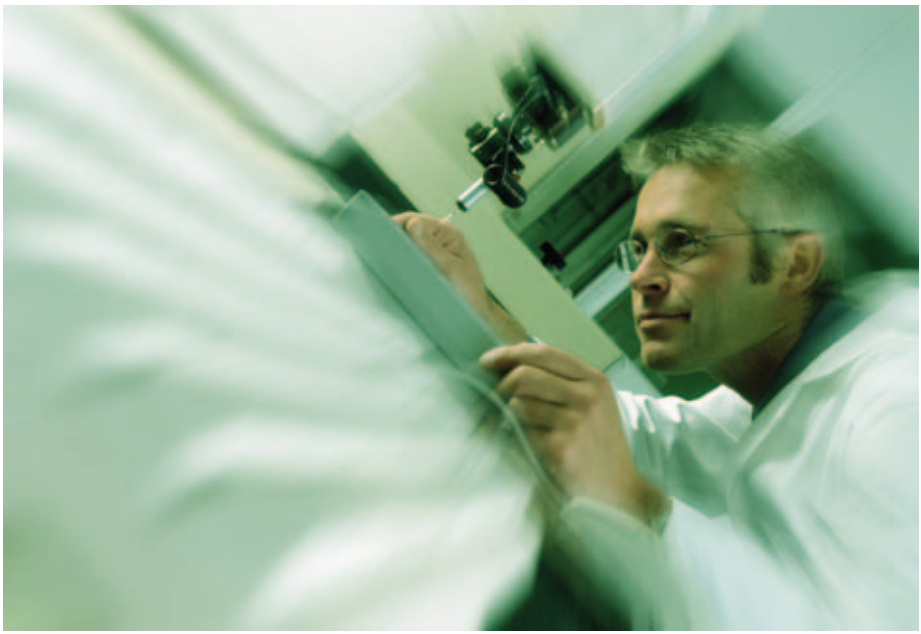
Staff retention

As with other elements of the quality infrastructure, the inspection agency must be able to recruit, develop and retain the necessary technical staff. As most of the business assets of the agency will reside in the people it employs, the agency will be vulnerable to the loss of people to competitors.

It will be important to maintain good employment conditions, including remuneration, but also, because many inspectors will be working away from head office, it will be vital for the manager to keep in good communications with them so as to retain their motivation and commitment.

Essential components of an inspection infrastructure project

The components that need to be considered in an inspection infrastructure project are listed below. Each of



the project components has one or more project outputs and related project outcomes. To some extent the sequence of the list provides a logical development path, even though many of the components can and should be dealt with in parallel.

1. Board decision
2. Legal status
3. Financial policy
4. Legal entity
5. Inspection scope
6. Director
7. Management structure
8. Personnel – inspectors and support
9. Premises
10. Equipment
11. Client interface and marketing
12. Quality documentation
13. Training and development system
14. Board of directors
15. Associations
16. Client organizations
17. Pre-assessment (optional)
18. Assessment and accreditation (optional).

Building a testing infrastructure

Typical institutions

The typical institutions in a testing infrastructure are:

- Test laboratories
- Pathology laboratories
- Environmental laboratories.

The functions of a test laboratory

A test laboratory conducts tests to determine the characteristics of a product or commodity. These characteristics are then evaluated against the requirements of a standard, and the test laboratory produces a test report or a test certificate with the results. The scope of testing is immense, covering mechanical, electrical, metallurgical and civil engineering, biological and chemical sciences, food technology, fibre technology and many, many more.

Testing can be destructive or non-destructive, mundane or extremely complex, routine, state of the art or cutting edge. In short, testing can be anything you want it to be. Hence any UNIDO project to establish test capacity will require very careful thought, otherwise it will very quickly become a black hole into which project funds disappear without trace.

Assessing testing needs

The immense scope of testing has profound implications for project design. Perhaps more than in any other quality infrastructure component, an assessment of a country's testing needs has to be absolutely thorough. In developing economies, where the state has to establish and maintain most testing facilities, such an assessment is even more relevant because every ministry

tends to establish their own test laboratories.

This fragmentation is, unfortunately, encouraged by donors, who each have one ministry as a counterpart. An overall assessment of current laboratory capacity, whether latent or active, is therefore essential in developing a new testing capacity project, as is a government policy on the allocation of staff.

Providing appropriate accommodation

Many testing laboratories are subject to some very specific accommodation requirements. Different functions, for example, have to be separated to prevent cross-contamination of samples, and laboratory space and offices need to be separated to ensure that personnel only spend testing time in the laboratories. In addition, most product testing requires consistent temperature, humidity, test speed, test force, test sequence, number of test cycles, etc.

Testing textiles and polymers, for example, requires an environment of 20 ± 2° C and 65 ± 2% relative humidity, while paper and many rubber products require 23 ± 1° C and 50 ± 2% relative humidity. On the other hand, most mechanical and electrical engineering testing can be conducted between 15° C and 30° C with a relative humidity not exceeding 70%. Continuity of electricity supply (24 hours per day, seven days per week) is of critical importance when tight environmental controls have to be maintained. These requirements must be kept in mind when new premises are being built or old ones refurbished.

Another issue that is very often overlooked in laboratory design is the orientation of the windows. In the northern hemisphere the sun comes from the south, so main windows are orientated north to avoid direct sunlight. In the southern hemisphere, this situation is reversed. Architects appointed from northern donor countries have to be aware of this.

Choosing testing equipment

Before any testing equipment is procured, the testing methodology has to be chosen. This is to ensure that the equipment fully meets the methodology requirements, and not just the preferences of the testing staff. The equipment's test results must be reproducible, under similar conditions, with those of other laboratories, as must the consumables required in testing, for example the quality of gases, chemicals, etc.

A second major issue is the availability of maintenance and technical support for a particular make of testing equipment. It is often better to buy a slightly more expensive piece of testing equip-

ment, but one for which maintenance is available, rather than a less expensive option for which there is no technical backup, either in the country or in neighbouring states.

Electricity supply is also relevant to equipment performance. In many developing economies, electricity does not meet the generally accepted stability criteria in developed economies, e.g. ±5% variance on voltage. Their variance can be as much as ±15% interspersed with frequent supply failures. Additional voltage stabilizers and UPS equipment may need to be provided; otherwise equipment may not perform to expectations.

Calibrating testing equipment

The proper calibration of test equipment is an important consideration. This presupposes a functioning metrology infrastructure within the country, or access to one in a neighbouring country. In addition, the calibration of some test equipment requires certified reference materials that are frequently only available from limited sources. The project has to assure the long term availability of such materials, often more an issue of scarce foreign exchange than anything else.

Training and retaining staff

Modern product and food testing equipment is becoming very sophisticated, using, for example, atomic absorption spectrophotometers, gas chromatographs, high performance liquid chromatographs, etc. Staff must therefore have both sound theoretical training and adequate practical experience. This is best achieved by their placement for an extended period of time in a working test laboratory.

The remuneration of staff is also an important issue. If at all possible, the project should ensure that fully trained staff are paid enough to keep them in the organization.

Achieving accreditation to ISO/IEC 17025

Depending on the type of testing performed by a laboratory, there may be a requirement from the customer or the regulator that the laboratory be accredited as an independent means of verifying the technical competence of the laboratory for the specific scope of testing. Where this is necessary, the laboratory should be accredited to ISO/IEC 17025.

Where there is no specific customer requirement for accreditation, the laboratory should operate in compliance with ISO/IEC 17025. One means for a laboratory to demonstrate their competence is to be accredited to ISO/IEC 17025. This will add to the confidence in the test results produced by the laboratory.

However a UNIDO project establishing competent test capacity has the accreditation of the test laboratory as its final outcome. It will choose the accreditation body early in the project implementation phase, since accreditation bodies have significant differences of approach, and the choice will influence some of the project activities. When choosing an accreditation body the following criteria need to be kept in mind:

- Language
- Proximity to the country, to keep down travel costs (assuming that the country does not yet have its own accreditation body)
- Accreditation costs (broad budget figures can be obtained from most accreditation bodies)
- That the accreditation body is a member of the ILAC Multilateral Recognition Arrangement (MLA)
- That the accreditation body supports programmes for inter-laboratory comparisons or proficiency testing schemes in the disciplines that the test laboratory wishes to be accredited for.

Ensuring the sustainability of the testing infrastructure

Initiatives to ensure sustainability are closely aligned with those for establishing testing capacity, detailed above, but because of their importance are briefly recapped below.

Financial stability. Since most testing laboratories in developing economies find it very difficult to cover costs from earned income, the government has to commit to providing long-term financial support.

Appropriate premises are a fundamental requirement, but long term **environmental control** can be particularly problematic. Proper maintenance of air-conditioning units and the uninterrupted supply of electricity are vital sustainability issues.

Calibration facilities and equipment maintenance. The accuracy of testing and measuring equipment degenerates with time, so equipment has to be calibrated at regular intervals. Whether calibration is provided by a national

calibration service, or certified reference materials, the fundamental principle remains the same. Without such calibration facilities, the sustainability of the testing capacity will be compromised. This also applies to maintenance and, in anticipation of equipment breakdown, to having a technical backup. Maintenance and backup services are essential to sustainability.

Accreditation support. The project may provide financial and technical support for obtaining initial accreditation to ISO/IEC 17025, but long term financial and managerial support to maintain such accreditation needs to be assured.

Retaining staff. Well-qualified staff are in short supply in developing economies. Laboratories need to have remuneration packages and other incentives to keep their trained staff from being poached, as well as training programmes to develop new staff.

Multilateral recognition arrangements of IAF and ILAC

Ultimately, the accreditation body has to become a signatory to the multilateral recognition arrangements (MLAs) of IAF and/or ILAC. Without this, none of the conformity assessment it has accredited will be accepted in international markets.

Essential components of a UNIDO testing infrastructure project

The components that need to be considered in a testing infrastructure project are listed below. Each of the project components has one or more project outputs and related project outcomes. To some extent the sequence provides a logical development path, even though many of the components can and should be dealt with in parallel.

1. Board decision
2. Legal status
3. Financial policy
4. Legal entity
5. Testing scope
6. Director
7. Management structure
8. Personnel
9. Premises
10. Environmental controls
11. Equipment
12. Marketing
13. Quality documentation
14. Scientists
15. Training system
16. Inter-laboratory comparison
17. Calibration service
18. Board of directors
19. Associations
20. Client organizations
21. Pre-assessment
22. Assessment and accreditation.

Building a certification infrastructure

Typical institutions

The typical certification institutions are:

- Product certification organizations
- System certification organizations
- Personnel certification organizations.

The growth of system certification

System certification is the success story of ISO 9001. Certification to this standard is still experiencing a remarkable growth, and is now considered a basic requirement for any company wishing to export large orders or land big contracts.

ISO policy with regard to sector management system standards is not to encourage the unnecessary proliferation of management system standards by the individual economic/industry sectors. However, ISO would accommodate the development where the sector has identified a real need for a sector standard. Today there are many examples of such documents:

ISO 22000, *Food safety management systems – Requirements for any organization in the food chain.*

ISO/IEC 27001, *Information technology – Security techniques – Information security management systems – Requirements*

Getting appropriate, affordable accreditation

System certification is a multi-billion dollar business worldwide with a large number of private and public organizations providing certification services at various levels of competence. Accreditation was introduced to provide a means for these organizations to independently demonstrate their technical competence.

Today, most certification service providers are accredited against ISO/IEC 17021, though there are still some issues with branch offices of certification organizations in countries other than those where their main offices are located. These branch offices frequently operate under the umbrella of the accreditation of their head office and are assessed by the head office's accrediting body based on a number of criteria, one of which is the activities performed by the branch office. The IAF and ILAC have implemented a cross-frontier policy which addresses the accreditation and assessment of branch offices by the accreditation body. The policy came into effect in 2007. This policy is aimed at reducing problems of branch offices not complying fully with accreditation criteria.

In developing economies where multinational certification organizations operate through less satisfactory local subsidiaries or are very expensive, small and medium-sized enteprises (SMEs) can find it very difficult to gain affordable, internationally recognized certification. This has led many governments and/or standards authorities in developing economies to put a high priority on establishing a national certification organization to support local industry, especially SMEs.

One of the requirements for accreditation is that the certification body has already conducted a minimum number of successful audits and issued certificates, the current minimum usually being two per scope of accreditation. This number needs to be checked out early in the project to ensure that there are no unpleasant surprises. Certification bodies, however, may have difficulty getting this number because few industrial organizations want to be certified by a new certification body that is not yet accredited – a classic chicken and egg situation.

A useful strategy in this case is to offer to help a few industrial companies towards certification, provided they agree to be audited and certified by the new certification body as well as by an established accredited certification company. The industrial company would then obtain two certificates, one from the established certification body and one from the new body. Once the new body has been accredited, the established body transfers the certified companies totally to the new body.

Meeting organizational requirements

The international standard ISO/IEC 17021 has detailed requirements, shown in **Figure 13** (see page 134), for the governance and organizational structure of a certification body. These have to be carefully considered when the body is being established, otherwise its accreditation will be seriously compromised.

Choosing an accreditation body

The certification body in a developing economy should be accredited; otherwise it may not be sustainable. This means that it has to demonstrate compliance with ISO/IEC 17021 as well as with the relevant IAF mandatory documents. The accreditation body should be chosen fairly early in the project implementation phase, as it will have an influence on some of the project activities – the various accreditation bodies do have differences in approaches that matter.

Figure 13 – Typical organizational structure of a certification body

Issues that need to be considered when choosing an accreditation body include the following:

- Language
- Proximity to the country to keep down travel costs (assuming that the country will not yet have an accreditation body of its own)
- Accreditation costs (broad budget figures can be obtained from most accreditation bodies)
- That the accreditation body is a member of the IAF Multilateral Recognition Arrangement (MLA)
- That the accreditation body supports programmes for newly established certification bodies, i.e. a pre-assessment to determine gaps in processes and procedures before the full assessment.

Ensuring the sustainability of a certification body

Financing. Anecdotal evidence indicates that it takes about three years to establish a system certification body, develop the internal procedures, train and register assessors, and conduct a number of trial audits, leading, hopefully, to accreditation. During this time the certification body is not fully functional, lacks international recognition and, being without customers, will have

difficulty covering costs. It is only in the fourth year of operation that most certification bodies break even or start to make a profit.

The founding organizations, whether government, the national standards body or a private-public partnership, will have to make good this shortfall. The total operating and capital costs for three years are estimated to be in the region of USD 500 000 to USD 600 000 per year, including accreditation costs and annual fees, while income is unlikely to exceed USD 150 000, creating a shortfall of USD 350 000 to USD 450 000. This is a serious sustainability issue that UNIDO must factor into any project proposal.

Choosing specific certification services. Accreditation is an expensive business, and is given only for those standards and sectors for which the certification body is shown to be competent. There is no blanket accreditation so the target market requirements need to be carefully researched and the system certification body's scope of accreditation defined accordingly before it is established. Within each of the various standards, there are also sectoral groupings that need to be considered, i.e. agriculture, fishing, textiles, machinery, etc. Complete details can be found in the relevant IAF guidelines.

Achieving accreditation is very often not an option. Without accreditation, certificates issued by a certification body in a developing economy have very little chance of being accepted in developed markets.

Essential components of a certification infrastructure project

The components that need to be considered in a certification infrastructure project are listed below. Each of the project components has one or more project outputs and related project outcomes. To some extent the sequence of the list provides a logical development path, even though many of the components can and should be dealt with in parallel.

1. Board decision
2. Legal status
3. Financial policy
4. Legal entity
5. Director
6. Management structure
7. Personnel
8. Premises
9. Equipment
10. First scopes
11. Quality documentation
12. Marketing
13. Certification committee
14. Lead auditors
15. Auditors
16. Training system

17. Auditor registration
18. Pre-assessment
19. Assessments
20. Certification
21. Impartiality
22. Board of directors
23. Impartiality committee
24. Associations
25. Client organizations
26. Pre-evaluation
27. Accreditation.

For more detailed information on UNIDO and its range of activities, including those associated with conformity assessment, see its Website at **www.unido.org.**

Chapter 6 – Case studies

This chapter presents case studies of the building of quality infrastructures, both individual conformity assessment infrastructures – testing laboratories, certification bodies, inspection bodies, metrology institutes and accreditation bodies – and integrated quality infrastructures that bring all of these components together.

The first part, "Building the components of a quality infrastructure", describes the variety of resources that UNIDO deploys and the wide range of activities it undertakes in building each of these infrastructures, illustrated with brief accounts of its experience in several developing countries, typical of the many countries that have built similar infrastructures, and the West African Economic and Monetary Union (UEMOA).

The second part, "Building an integrated quality infrastructure", exemplifies, particularly in the case of Guyana, the urgency of having a quality infrastructure that meets the challenges of global competitiveness and, in the cases of UEMOA, where UNIDO played a key role, and the Caribbean Community (CARICOM), gives detailed accounts of the experience of setting up fully integrated quality infrastructures in these two sub-regions.

Building the components of a quality infrastructure

Testing laboratories

Technical assistance for testing laboratories has always been an important component of UNIDO's support for quality infrastructure development – whether establishing new laboratories or upgrading existing ones. First, UNIDO assists the authorities, the board of directors or top management to evaluate market requirements and make an informed decision on the type of testing capacity they need.

At the same time, it ensures from the outset that the legal status of the laboratory is clear, that medium and long term funding is available, and that the scope of testing is well defined and specifies precisely the equipment, environmental controls, calibration instruments, maintenance, etc., that will be needed.

There are of course many other important activities that a UNIDO project supports to ensure that the laboratory contributes to industrial competitiveness and, ultimately, becomes accredited to ISO/IEC 17025: choosing a competent, qualified director; setting up a suitable management

structure and recruiting or developing technically qualified, able personnel; finding suitable accommodation; running a promotion campaign; preparing quality documentation acceptable to the accreditation body; introducing an appropriate training system for scientists in an established tertiary education centre; organizing inter-laboratory comparison to establish the laboratory's proficiency; and setting up a properly constituted and fully functional board of directors.

As well as direct technical assistance, UNIDO has prepared guidance documents and training on the operation of proficiency testing programmes, on the significance of certified reference materials, and on the various guides on this subject produced by by the ISO policy development committee for reference materials, ISO/REMCO.

UNIDO has also contributed to the establishment of LABNET, a valuable Web-based information source for testing laboratories, which covers accreditation, reference materials, proficiency testing, etc. A joint venture by UNIDO and WAITRO, the World Association of Industrial and Technological Research Organizations, LABNET can be accessed online at: **www.labnetwork.org**.

Sri Lanka

The UNIDO "Integrated Industrial Development Support Programme for Sri Lanka" assisted five laboratories that supported the agro-food, textile and garment sectors to comply with international standards. In the agro-food sector, the target commodities were tea and shrimps, both of export significance for Sri Lanka.

Specifically, UNIDO assisted two microbiology laboratories, two chemical laboratories and a textile-testing laboratory to pursue accreditation for their export-significant tests by a well-established foreign accreditation body. The five laboratories succeeded in achieving accreditation for compliance with ISO/IEC 17025 from the Swedish Board for Accreditation and Conformity Assessment (SWEDAC).

UNIDO's technical assistance also ensured domestic calibration support for the accredited laboratories by upgrading six of the Industrial Metrology Institute's metrology centres, covering dimensional, volume, mass, thermometry, pressure and electrical calibration services. These services were also accredited by a foreign accreditation body.

The measurable benefits of this assistance included:

- The demand for accredited over non-accredited testing and calibration services increased significantly

- Reliance on government funding for the laboratories was significantly reduced
- More small and medium enterprises were able to enter export markets on the basis of the accredited laboratories' compliance testing
- Local compliance testing costs were much less than those of foreign laboratories
- A lot of the testing was delivered faster
- Valuable experience gained in the programme was passed on to people and institutes in other developing countries.

Certification bodies

UNIDO has provided comprehensive development assistance for certification activities for many years. This focuses on management systems certification (including quality, environmental, food safety, and occupational health and safety), product certification, and personnel certification, both for enterprises and for certification and accreditation bodies.

It has assisted enterprises by working with local industry and institutes or industry associations to build the capacity of either of the latter to provide certification services. As well as projects to develop the certification infrastructure, UNIDO conducts national and regional seminars, workshops and training programmes to raise awareness of certification criteria and practices, and to assist certification auditors qualify to perform specific types of certification audits.

It has assisted certification bodies by conducting projects to help them develop the institutional structures, systems and personnel they need to carry out specific types of certification, sometimes culminating in their independent accreditation.

Like other quality infrastructure projects, certification infrastructure projects need to have a competent director, a management structure, personnel, premises, marketing services, quality documentation, etc., but they also have their own specific and critical needs: an established and fully functional certification committee acceptable to the accreditation body; a pool of trained and registered lead auditors, both on the staff of the certification body and available for sub-contractual work; a pool of trained and registered auditors, both within and outside the organization, appropriate for the accreditation scopes of the certification body; an established, fully functional and recognized training system for auditors and lead auditors; an established and internationally recognized national auditor and lead auditor registration system; a

fully functional pre-assessment system in accordance with ISO/IEC 17011 and IAF Guidelines for certification of companies; a fully functional assessment process in accordance with ISO/IEC 17011, ISO 19011 and IAF guidelines for the certification of companies; a certification process compliant with ISO/IEC 17021 and acceptable to the accreditation body; a certification body whose impartiality is acceptable to the accreditation body; a fully functional board of directors with terms of reference acceptable to the accreditation body; a fully functional impartiality committee acceptable to the accreditation body; industry and business associations fully aware of the services of the certification body; active participation of client organizations on the impartiality committee; and a successful pre-assessment of the certification body by the accreditation body.

Nepal

In 2003, Nepal joined the World Trade Organization as part of a process of economic liberalization and faster development. This included a transition to full compliance with all the obligations of a member state by 2007. UNIDO was asked to assist in bringing the country's conformity assessment procedures in line with the requirements of the WTO Agreement on Technical Barriers to Trade. It helped strengthen and upgrade Nepal's product certification infrastructure to a level where it could be accredited, thereby increasing acceptance of Nepal standard mark products in the international market.

A valuable contribution was made by a certification expert with wide practical experience in product certification who assisted the Nepal Bureau of Standards and Metrology (NBSM) implement ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*. To achieve accreditation the entire documentation had to be completed in accordance with Guide 65 and supporting ISO standards within the existing legal framework, the Nepal Standards (Certification Marks) Act, 1980.

As well as document preparation, comprehensive training was provided on implementing the documented system and auditing and inspecting under it. This included training on auditing techniques based on ISO 19011, on the accreditation requirements of the International Accreditation Forum, and on the modus operandi of the accreditation system.

Sri Lanka

UNIDO is currently implementing a project to enhance and build certification capacities in Sri Lanka for both training and conformity assessment delivery. It is:

- Supporting and promoting the establishment of private-public non-profit partnerships for certification, based on international certification practices and standards
- Building national capacities by qualifying certified national auditors and trainers against international practices and standards
- Developing training capacities by qualifying the certification body as an accredited training centre and supporting the development of customized training support tools and materials
- Supporting national accreditation initiatives to ensure credible certification activities by, and fair competition amongst, certification bodies
- Implementing pilot interventions in certification and training activities through the use of nationally trained and accredited personnel
- Promoting national conformity marks for specific sectors as focus areas for the certification bodies.

Inspection bodies

Apart from developing the inspection functions associated with legal metrology bodies, UNIDO has only had occasional requests in recent years to undertake capacity building of inspection bodies (see example below from the UEMOA Region) but does have access to expertise to assist further developments in this area.

Potential areas where UNIDO can provide awareness and capacity building for inspection activities include:

- General seminars, workshops, training and awareness programmes on inspection body issues, such as:
  - Inspection standards, including ISO/IEC 17020
  - Training and qualification of inspection body auditors
  - Accreditation of inspection bodies
  - Meeting inspection requirements for specific regulations or specifiers.
- Capacity building of specific inspection bodies that are needed to assist local industrial or service bodies facilitate the acceptance of inspected materials, products, commodities or services in foreign markets
- Training of inspection body personnel
- Facilitation of the accreditation, by foreign or local accreditation bodies, of inspection bodies who need this to gain access to markets or to support local industrial development.

UEMOA

As part of a multi-faceted project in the eight countries of the West African Economic and Monetary Union (UEMOA), UNIDO commissioned a regional evaluation of regulatory inspection capacity in the fields of plant and animal health, processed foodstuffs and the analysis of pesticide residues.

The objectives of this evaluation were to identify gaps in regulatory inspection in the region; to determine needs for analytical equipment to support the regulatory function; and to identify institutions that needed strengthening.

Subsequent elements of the project involved:

- Training phytosanitary inspectors
- Training animal health inspectors
- Discussing the harmonization of inspection criteria and techniques
- Developing guidance documents on modernizing food sanitary inspection and promoting agricultural products.

Metrology institutes

A significant part of UNIDO technical assistance in developing quality infrastructures has been directed at establishing and building the capacity of national metrology institutes, bringing international experts from different branches of metrology (mass, temperature, electrical, pressure, dimensions, etc.) to oversee the development of facilities, personnel and equipment.

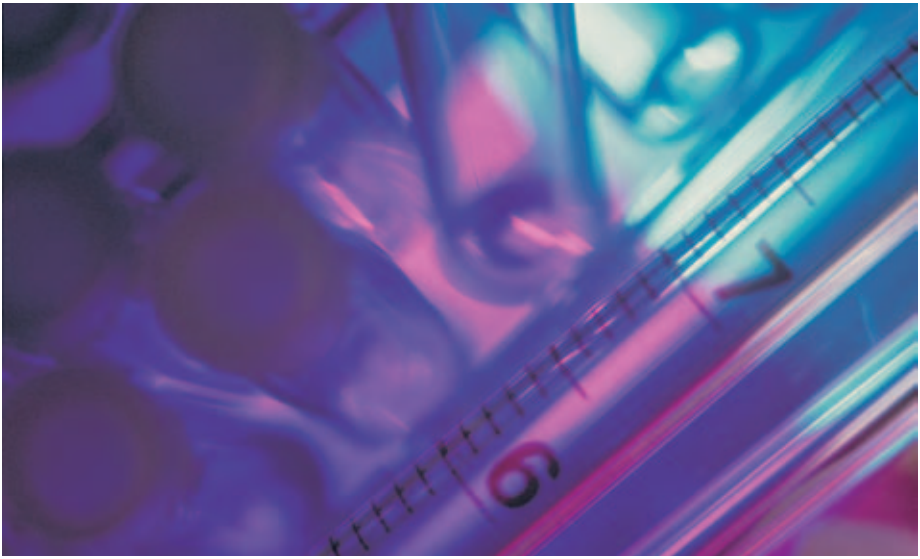
Its technical assistance has ranged from establishing instrument repair and maintenance support to providing measurement traceability of calibration standards to international standards of measurement. Projects involve surveys of users' needs for various types of calibration and measurement and the levels of accuracy required to support industrial testing and other needs. International metrology experts conduct seminars, workshops and other training activities, and fellowships are provided for staff to be trained abroad in measurement techniques.

Two recent UNIDO technical assistance projects, in Tanzania and Vietnam, are typical of the numerous projects UNIDO has undertaken over many years to develop metrology services in developing countries.

Tanzania

As with many UNIDO projects, assistance for the development of metrology capabilities in Tanzania was only one component of a broader project to enhance the quality infrastructure so that it would ensure the delivery of globally accepted metrology, testing, quality and certification services in compliance with TBT and SPS requirements.

After identifying local needs for metrology services and obtaining funding commitments, a variety of activities were undertaken to enhance metrology capabilities. These included preparing metrology facility blueprints, specifying equipment needs, installing



equipment, training staff, conducting inter-laboratory comparisons, preparing laboratories for accreditation, reviewing the legal metrology system and associated laboratories, establishing a repair and maintenance facility, and developing a mobile calibration facility.

Progress to date includes the delivery and installation of equipment for pressure, dimensional measurements and electrical calibrations, and the training of staff. Additionally, the Tanzanian Bureau of Standards' Metrology Laboratory has successfully maintained accreditation by the South African National Accreditation System (SANAS), and the mobile calibration unit is operational with trained staff and measurement instruments.

Viet Nam

A UNIDO project is underway in Viet Nam to assist the country gain better market access by strengthening its capacities in metrology, testing and conformity assessment. UNIDO has assisted three metrology laboratories in the Directorate for Standards and Quality (STAMEQ) and the Viet Nam Metrology Institute (VMI) to provide precise and recognized calibration services to industry, and has upgraded metrology facilities in Ho Chi Minh City and Hanoi with international accreditation for their mass and temperature calibration services.

The specific activities include :

- Preparing a framework for strengthening metrology laboratories, including the Viet Nam MetrologyInstitute

- Identifying the equipment and physical facilities required to meet the spectrum of measurements needed to cover industries' needs
- Installing equipment
- Providing training in calibration
- Securing overseas fellowships for key staff
- Assisting in establishing laboratory management systems that comply with ISO/IEC 17025
- Assisting metrology services to gain international accreditation.

With Viet Nam joining the WTO in January 2007, a second-phase project is now underway to assist it to comply with its TBT and SPS obligations.

Accreditation bodies

Over recent years UNIDO has undertaken numerous technical assistance projects to establish or enhance the capacities of national accreditation bodies, including helping them to reach the entry level of the mutual recognition arrangements of ILAC or IAF, or a regional recognition arrangement.
Both ILAC and IAF offer candidates for entry to their MRA or MLA the opportunity to take part in a trial peer-evaluation, or "pre-evaluation", by a small team of experienced evaluators from foreign accreditation bodies. Any deficiencies are highlighted and assistance given to rectify these before a formal evaluation takes place. UNIDO has provided pre-evaluation assistance to a number of accreditation bodies and helped them gain entry to these recognition arrangements.

UNIDO has made experts available to assist in establishing and enhancing accreditation bodies. They have advised on technical, policy, and governance issues. Understanding the latter can be important for meeting the impartiality requirements of ISO/IEC 17011, essential for entry into the ILAC MRA and IAF MLA. Often the assistance on governance issues includes inputs to the content of draft legislation or regulations that effect the establishment and roles of national accreditation bodies.

UNIDO has also facilitated the attendance of personnel from developing country accreditation bodies at various ILAC and IAF meetings, and helped them understand the technical and policy issues that affect accreditation bodies internationally, including issues relevant to joining their recognition arrangements. Other typical assistance includes awareness seminars and workshops for potential clients.
Among the many assistance projects conducted by UNIDO for the development and recognition of accreditation bodies are recent projects in Mongolia and the West African Economic and Monetary Union (UEMOA).

Mongolia

The development of Mongolia's accreditation capacity is part of an overall project aimed at reducing poverty by developing a competitive and sustainable export-oriented agro-industrial sector.

The project commenced with a review of the existing documentation of the Mongolian Accreditation Scheme for compliance with ISO/IEC 17011. Weaknesses were identified and an action plan was drawn up to implement an effective management system, develop its quality manual and operational procedures, develop its accreditation criteria and its structure, and bring it to a level where it can achieve signatory status in a mutual recognition arrangement and become a member of APLAC, ILAC or IAF.

This project highlights a number of issues critical to the smooth implementation and success of projects of this type in any country. Perhaps most significant is the effort sometimes required to establish structural arrangements that ensure an accreditation body is impartial and has no conflicts of interest. This is an essential requirement of ISO/IEC 17011 and a necessary pre-condition if an accreditation body is to achieve signatory status in the MRAs of ILAC and IAF and their regional cooperation bodies.

In Mongolia, like many other developing countries, the initial development and operation of accreditation activities was assigned to a single national organization with a number of functions: operating as the national standards body; performing the role of the national measurement institute; operating testing laboratories (particularly in support of product certification); and conducting third party certification for management systems and products.

While this may be a practical centralization of resources in a developing country, it places the accreditation body in a position of potential conflict of interest where doubts may be cast on its impartiality. If an organization is operating testing, calibration and certification services together, its credibility in accrediting other organizations' laboratories, inspection bodies or certification bodies is seriously compromised.

Such situations have arisen in a number of countries and have led projects to recommend the separation of accreditation functions into independent agencies or departments, usually within the government sector. This often requires legislative or regulatory changes since accreditation may be the subject of national laws or regulations. UNIDO has on occasion assisted in drafting such legislation.

UEMOA

UNIDO's assistance with an accreditation infrastructure for UMEOA has most of the elements of a classic integrated approach, the project's planned output being a system for accreditation, standardization and quality promotion for the eight UEMOA countries.

In accreditation, the immediate aim is a regional accreditation system for UEMOA and ultimately a West African Accreditation System (SOAC) that is recognized internationally. A number of the activities undertaken to establish the accreditation system were supported by the parallel development of the region's laboratory and inspection capacities.

The project's objectives included facilitation of access for agricultural food products, fishery products and cotton to regional and international markets; improvement of sanitary and hygiene conditions; better consumer awareness of hygiene and quality standards; increased use of standards and conformity assessment processes in public purchasing arrangements; and improvement in the quality of, and increased revenue from, sales of agricultural food products, both within UEMOA and internationally.

Specific project activities to develop regional accreditation included support from the French accreditation body, COFRAC, to design and assist the operation of the West African Accreditation System (SOAC); joint accreditation assessments by COFRAC and SOAC; preparation of the operational and technical documents for compliance with international standards by SOAC; establishment of a database of approximately 150 laboratories in the UEMOA sub-region; training of groups of laboratory assessors; training in the management systems of laboratories according to ISO/IEC 17025; provision of foreign calibration support for incubators used by microbiological laboratories in the region; and harmonization of analytical methods for testing food products in the region.

A more detailed account of the UEMOA programme is given in the following section on building integrated quality infrastructures.

Building an integrated quality infrastructure

Guyana

Guyana, like other developing countries, finds itself unprepared for integration into an open or global market place and, with its limited resources, recognises that the challenges of global competitiveness are becoming extremely complex and difficult.

The drive for economic development in the country is closely associated with its ability to export locally manufactured products. As a result, it has been involved for the last decade in negotiating many multilateral and bilateral trade agreements. However this increase in exports will only be possible if Guyana can provide assurance to the marketplace that these products meet the requirements stipulated in standards/regulations and/or are being produced under management systems that are recognized by and acceptable to the marketplace.

At the same time, there is a movement from commodities-based exports to more value added or consumer products. This means that the requirements for conformity assessment are becoming more pronounced, since the commodities-based products were being supplied for reprocessing whilst the consumer products are for direct consumption. Conformity assessment activities such as testing, inspection and certification offer an opportunity for that assurance to be provided to the marketplace. The requirements for these activities are all stipulated in the trade agreements negotiated.

Recognising that conformity assessment activities can either expedite or seriously hinder the free flow of goods in international commerce, these trade agreements establish procedural requirements for conformity assessment schemes aimed at preventing unnecessary obstacles to trade. They specify that conformity assessment procedures be prepared, adopted and applied so that like products originating from other countries (which are signatories to the agreement) are granted no less favourable conditions than those produced nationally or originating in another country, and encourage the use of international standards in this whole process.

Conformity assessment activities in Guyana, as in the majority of other developing countries, are primarily the functions of the government regulatory agencies. This practice is not in conformance with that of developed countries and has led to their results being questioned by the marketplace. The credibility of these agencies' results will continue to be an issue until a third

party provides assurance that they are operating to the relevant international standard. The recognized standards are ISO/IEC 17020 for inspection bodies, ISO/IEC 17025 for laboratories conducting testing and calibration, and ISO/IEC Guide 65 for bodies involved in certification.

These agencies need to ensure that their operations are aligned to international practices so that their results will be accepted by all the markets and the export of locally manufactured products facilitated. They would then, too, be better able to protect local consumers from substandard imports.

For Guyana to achieve the level of international trade, market access and investment that will drive its economic development, it needs to consider the principles outlined for free trade in the various trade agreements and put the necessary infrastructure in place to address them.

For this purpose, the National Committee for Conformity Assessment (NCCA), consisting of a number of organizations from government and the private sector, was established in January 2004 with the declared goal of: "Improving the quality of life for all Guyanese through the development of an internationally recognized national system of conformity assessment in Guyana". This committee is in the process of implementing actions to achieve this goal.

(This Guyana case study has been taken from the website of the Guyana National Bureau of Standards: **http://www.gnbs.info/NL%20conf%20ass.htm**)

UEMOA

Consensus on quality

The West African Economic and Monetary Union (UEMOA) comprises eight member states, Benin, Burkina Faso, Côte d'Ivoire, Guinea Bissau, Mali, Niger, Senegal and Togo. The UEMOA Commission, based in Ouagadougou, Burkina Faso, was UEMOA's technical arm in implementing the UEMOA Quality Programme. The UEMOA countries also form part of the Economic Community of West African States (ECOWAS) whose other members are Cape Verde, Gambia, Ghana, Guinea, Liberia, Nigeria and Sierra Leone.

The UEMOA Common Industrial Policy aims at a lasting industrial development process underpinned by technology upgrading and quality improvement as decisive economic success factors. In line with this policy, the member states of UEMOA adopted and implemented a comprehen-

sive "Programme for the setting-up of a system for accreditation, standardization and quality promotion" from 2002 to 2005. Also referred to as the UEMOA Quality Programme, it was implemented by UNIDO on behalf of the UEMOA Commission, with funding from the European Union to the tune of 14 million Euros. A second phase of the programme has now been implemented for the UEMOA countries as of 2007 and, in parallel, the programme was extended to the non-UEMOA ECOWAS countries and Mauritania.

The Conference of African Ministers of Industry (CAMI), at its meeting held in Cairo in June 2006, re-asserted the need to strengthen the African standardization and conformity assessment infrastructure and increase the harmonization of standards in Africa at the national, regional and continental levels.

The conference took note of the achievements of the UEMOA Quality Programme and invited development partners to build on this experience. In fact, a side-event of the 2006 CAMI was the signing of an agreement between the Commission of the African Union and UNIDO which renewed cooperation between the two organizations in various fields, including trade and production capacity building with a strong emphasis on quality, standards and conformity assessment.

There is, therefore, a clear consensus at the highest political level on the need to boost quality infrastructures across the whole African region in order to support industrialization. The experience gained in implementing the UEMOA Quality Programme constitutes an invaluable asset for similar programmes which will inevitably be set up in other sub-regions of Africa.

The UEMOA Quality Programme

The main objective of the UEMOA Quality Programme was to build and/or reinforce all the steps of a quality infrastructure for the UEMOA sub-region and to ensure its recognition at international level through the process of accreditation. The programme has assisted UEMOA countries in their goal of meeting the provisions of the WTO TBT Agreement, thus enhancing their capacity to participate with added confidence in international trade.

Highlighted below are some of the most important characteristics of the UEMOA Quality Programme as a regional approach to implementing a set of quality management, standardization and conformity assessment activities across a wide spectrum of beneficiaries in a group of countries with very disparate institutional quality infrastructures.

Several constraints weighed heavily on the execution of the programme, but at the same time many critical success factors contributed to project results that were much appreciated by the beneficiaries.

Constraints

The following constraints were noted at the beginning of the programme:

- National quality policy and infrastructure were practically non-existent in most countries of UEMOA
- Two of the eight countries did not have a national standards body (NSB) and the national standard bodies of several of the others were non-operational due to lack of human and material resources; most national standards bodies were not members of ISO, which meant that they did not have international and foreign national standards available for economic operators
- There was little demand for standards by industry, consumers and other major players like public purchasing organizations
- Only one private testing laboratory was accredited in the whole subregion; other laboratories did not work according to the accreditation standard ISO/IEC 17025 and there was a serious lack of modern laboratory testing equipment and training;
- Only one national standards body operated a product certification body and few certifications were granted
- Only about 30 enterprises were certified to ISO 9001 in all eight countries, and local consultancy support for enterprises was available in only two countries.

Success factors

There were several critical success factors, listed below with several described in more detail in subsequent paragraphs:

- Project activity formulation; use of an external specialised agency like UNIDO for project execution
- Efficient financial and administrative arrangements for fund transfer and use, impacting on the lead time for mobilising international consultancy and the procurement of goods or services
- A supranational regional organisation for anchoring the central project execution team and for following up on individual governments' commitments
- A legal framework for sustaining post-project results
- Private sector participation
- An adequate number of technically competent project coordinators at both national and regional levels
- The flexibility during implementation to take immediate and urgent conformity assessment issues on board

- Partnerships with foreign national and international technical organizations.

External specialized agency. One of the reasons that the involvement of a specialized agency like UNIDO is considered a critical success factor is that it was able to take part in both the formulation and execution of the project. UNIDO collaborated with the UEMOA Commission right from the project formulation stage. The choice of the programme's strategy and technical focus drew on UNIDO's long experience in the field, thus ensuring that quality factors at design level were appropriately included. The huge technical expertise that UNIDO could bring to bear on the programme, including its roster of independent consultants, greatly increased its effectiveness. It is noteworthy that, at the beginning of project implementation, UNIDO had secured 66 % of the total funds needed during the whole lifetime of the project, and for the final two years of implementation this proportion had risen to 86%. UNIDO actually carried out activities valued at 87 % of its share of funds by the end of the project's lifespan.

Supranational regional organization. It was a great asset that a supranational regional organization like the UEMOA Commission hosted the regional project coordination team and liaised with member governments. Both the project coordination team and UNIDO were limited in their capacity to convey instructions or guidance on project execution directly to governments.

Often, national beneficiary organizations have to be given deadlines, for example for preparing laboratory accommodation before equipment can be supplied, and there may also be financial implications. The UEMOA Commission was very effective in getting government ministries responsible for the programme at the national level to put pressure on the national beneficiary organizations (laboratories in this example) in order to meet deadlines.

Legal framework. In order to strengthen regional cooperation in accreditation, certification, standardisation and metrology, UEMOA had to harmonise its policies and set up regional coordination mechanisms through an appropriate legal framework. The UEMOA Commission took the lead in formulating such a framework and consequently a regulation (UEMOA Quality Regulation 2005) was adopted by the UEMOA Statutory Council of Ministers on 4 July 2005.

The regulation provides for the setting up of a Regional Coordination

Committee on Quality (CRECQ) and three permanent regional structures which will ensure the sustainability of the programme, namely the West African Accreditation System (SOAC); the Regional Secretariat of Standardisation, Certification and Quality Promotion (NORMCERQ); and the West African Secretariat for Metrology (SOAMET). In this case as well, the essential role played by the UEMOA Commission is clear.

Private sector participation at all levels of project coordination was critical. Under UNIDO guidance, the UEMOA Commission therefore required the ministers in charge of the programme in each country to set up national steering committees composed of representatives from the public and private sectors in equal proportions.

The positions of chair and vice-chair were shared between these two sectors. The fact that the sole Regional Steering Committee was composed of the chair and vice-chair of the national steering committees ensured that private sector inputs to the coordination of the programme reached the highest level.

Technically competent coordinators. The need to have high-level technical experts on a permanent basis at the level of central coordination, especially when such a complex programme is being implemented for the first time at a regional level, cannot be over-emphasized. The project coordination team consisted of four full-time international consultants: a chief technical adviser, who was an expert in accreditation; an expert in standardization; another in quality promotion; and one in consumer affairs and communication.

The experts not only managed the programme but also advised the UEMOA Commission on policy choices that had a long-lasting impact. Such an advisory function, for example, was critical in framing the UEMOA Quality Regulation 2005 and for subsequently ensuring its acceptance at various levels of UEMOA, namely the Commission itself, the Committee of Ministers of Industry and finally the statutory Council of Ministers. Such an expert team is also essential in managing international consultants and guiding their work since the latter very often know little about the regional context and issues when they begin their mission.

In each country, the coordination was effected by a national technical coordinator, who was a national of the country concerned and who also acted as secretary to the national steering committee. Both the project experts and the national technical coordinators were recruited directly by UNIDO after consultation with the UEMOA Commis-

sion and were supervised by a UNIDO project director based in Vienna.

The latter also coordinated project support activities in other UNIDO divisions, for example the Human Resources Branch responsible for consultant recruitment and the Procurement Division responsible for equipment purchase. In all, UNIDO recruited and supervised the missions of 132 national consultants and 88 international consultants who contributed on different technical aspects of the programme.

Flexibility. The programme was asked, in response to urgent issues that appeared in certain sectors during the course of execution, to undertake actions that had not initially been planned. Here, it is worth noting the assistance provided to the fisheries and cotton sectors, described in the following paragraphs.

The fishery sectors in Togo, Benin, Côte d'Ivoire and Guinea-Bissau have been strengthened. The assistance provided under the programme improved the quality of exported fishery products and helped the fisheries industry to meet the sanitary and normative requirements of the market. The laboratory equipment provided through the programme for Togo and Benin was mostly directed to this sector.

In Benin, the technical support was particularly timely as it enabled the country to resume exports of fishery products to the European Union. During the life of the programme, there was a fundamental change in the EU's regulations on food safety: these became stricter with the adoption by the European parliament of several regulations on hygiene and official food controls. One of the regulations specifically requires official food control laboratories to be accredited to ISO/IEC 17025.

The programme also responded to the needs of the cotton sector. Several initiatives were taken: cotton graders from six UEMOA countries were trained, and high volume instruments (HVI) for automated testing of cotton fibre delivered to selected countries; cotton standards for West African cotton were prepared for the first time, and these are expected to enable cotton producers to negotiate the true price for their cotton in the international market; and a manual covering topics such as quality standards, trade and ginning practice for cotton was prepared for the economic operators in the sector.

Cotton production and transformation has gradually become a critical sector for many UEMOA countries – UEMOA has even adopted an Agenda

on Cotton with the aim of strengthening all aspects of this sector.

Partnerships. The main partnership agreement concluded under the programme was signed between the UEMOA Commission and the French Committee for Accreditation (COFRAC). COFRAC is to support SOAC, the UEMOA regional accreditation body, to become operational and achieve international recognition.

Collaboration was also undertaken with organizations like the Physikalisch-Technische Bundesanstalt (PTB – the German National Metrology Institute) in the area of metrology; the Association Française de Normalisation (AFNOR) and the International Organization for Standardization (ISO) in the area of standards; and the international consumers' organisation (OIC).

The programme has paid subscription dues to enable all eight member States of UEMOA to become members of ISO (one member body and seven correspondent members). Two of the countries participate in the international technical work of ISO and all eight national documentation centres are connected to the ISO intranet system.

These partnerships provide the necessary link towards international recognition and are crucial for UEMOA's development of standardisation, conformity assessment and accreditation systems. The programme also sought to ensure that necessary budget allocations were made to meet future ISO subscription dues.

The power of a regional approach

Although the final beneficiaries of the programme, the productive sectors and the population at large, are at country level, UEMOA has taken a regional approach that targets both regional and national levels in order to build a robust standardization and conformity assessment infrastructure, since most of the UEMOA countries do not have the critical mass of conformity assessment needs to justify purely national approaches. The programme has therefore opted to create a unique regional accreditation body, SOAC, to provide accreditation services to all laboratories, certification and inspection bodies in the sub-region.

In laboratory strengthening as well, equipment has been provided to 46 laboratories in the eight countries with the objective of creating centres of excellence in different countries. In the notable example of pesticide residue analysis, it is clear that each UEMOA country cannot expect to have a full-fledged laboratory capable of testing

all the pesticides used in the sub-region. The material and human resources are simply not there. The same logic applies to other types of analysis, such as mycotoxin analysis. Certain laboratories have therefore been provided with equipment that will enable them to take on a regional role, e.g. by becoming regional reference testing laboratories.

The same approach has been adopted for the development of sectoral technology centres in the fields of fruits and vegetables, meat and milk products, and building and civil engineering. Nine existing institutions have been selected in four countries and provided with equipment and training to enable them to act as regional centres for the dissemination of technology-based information and training.

Another area where there is no alternative but to adopt a regional approach is the preparation of regional standards or the harmonization of national standards. In implementing this approach, the role of the UEMOA Commission has been critical in responding to queries by countries which had not been chosen to host a regional centre. The Commission could arbitrate in this way precisely because of its supranational status. This again highlights its value in dealing with governments, something no other project coordination entity could effectively accomplish.

CARICOM Regional Organisation for Standards and Quality (CROSQ)

The CARICOM Regional Organisation for Standards and Quality (CROSQ) was established in February 2002 as an inter-governmental agency to facilitate the development of regional standards, represent the interests of the sub-region in global standards work, promote the harmonization of metrology systems and support the sustainable production and trade of goods and services in the Caribbean Community (CARICOM) Single Market and Economy (CSME).

The Headquarters Agreement, signed with the Government of Barbados in January 2007, provides a permanent base for CROSQ in Barbados, where the Secretariat has been located since 2003. All member states of CARICOM are members of CROSQ, with Haiti becoming the latest addition when it signed the CROSQ Intergovernmental Agreement on 8 May 2009.

The Executive Secretary (Chief Executive Officer) manages the Secretariat and interfaces with the national standards bodies via the CROSQ Council. The Council, comprising all directors of the national standards bodies of the member states, guides CROSQ activities and reports on them to the Council

for Trade and Economic Development (COTED) of CARICOM.

In keeping with its mandate, CROSQ has been pursuing, within the last two years, the goal of developing a strong regional quality infrastructure in tandem with national quality infrastructures and has received support from a range of externally funded projects. In keeping with this effort, the project and staff complement at the Secretariat has tripled since 2007.

From standards development...

In the early years, CROSQ focused mainly on the development of regional standards. A Technical Management Committee, comprising volunteers from among the national standards bodies, met and continues to meet 3-4 times a year to coordinate the development of the standards following ISO guidelines. Regional technical committees (RTCs), comprising experts in relevant sectors and coordinated by one or more national standards bodies, develop the committee drafts (CDs).

The drafts are then circulated to the member states for public comments, which are returned to the RTC to be dealt with. Following editing and final formatting, the standards are submitted to the CROSQ council for approval and then to the Council for Trade and Economic Development for ratification. The Technical Management Committee currently has a portfolio of more than 50 standards under development.

Of these, 34 normative documents are being developed under a 2005–2009 project, co-funded by the Inter-American Development Bank (IDB), aimed at increasing the competitiveness of small and medium-sized enterprises. A two-year extension has been recently approved in order to meet the project goals and objectives. Other components of the project include awareness-raising, training small and medium-sized enterprises and setting up a regional information system.

...to regional quality infrastructure

In recent years, globalisation has shifted attention to the development of other regional quality infrastructure elements (metrology, inspection, testing, calibration, certification, accreditation). This is the focus of the second IDB-funded project for 2007-2011, which aims to improve market access and competitiveness in the production and trading of regional goods and services. The German Physikalisch Technische Bundesanstalt (PTB) has provided valuable technical and financial assistance to conduct baseline studies and needs assessments on the current status of the regional quality infrastructure in order to enhance regional capabilities.

With the signing of the Economic Partnership Agreement in October 2008, the German Ministry for Economic Cooperation and Development (BMZ) approved a complementary technical assistance project, channeled through the PTB, in December 2008. A regional planning workshop for a third project, also funded by the BMZ, was recently concluded and will address metrology and accreditation as well as enhancing the capacity of CROSQ to meet its mandate. CROSQ's role is to bring complementarities to all three projects in order to maximize scarce resources and avoid duplication of efforts.

Metrology

A recently developed concept is that of the regional Caribbean Reference Laboratories (CARLs). These laboratories will provide efficient and cost-effective traceability to primary quantities at the international level for working standards at the national level. Quantities to be developed include mass, volume, time and frequency. The capabilities of two advanced national laboratories are currently being upgraded so that they can take on the role of CARLs.

In 2008, CARIMET (the regional arm of the Sistema Interamericana Metrologia – SIM) became a Technical Committee of CROSQ. It is anticipated that the implementation of subsequent regional quality infrastructure projects through CARIMET will further facilitate the integration of CARIMET into CROSQ.

Tradecom is providing technical assistance to CROSQ for the hiring of a metrology officer to implement these projects and to hold three seminars (calibration methodologies, uncertainty estimation, and development of quality management handbooks) during 2009-10.

Inspection and certification

A conformity assessment survey is currently underway to assess the status of inspection and certification bodies in all the member states of CROSQ. Information from the survey will help establish how best to harmonise regional inspection and certification. The use of a single regional standards mark is also being considered, together with an annual regional quality awards programme.

Accreditation

Phase II of the Caribbean Laboratory Accreditation Services (CLAS) Project (9th European Development Fund-sponsored) is currently being implemented (to April 2010). This aims to assist laboratories achieve accreditation through regional cooperation and the establishment of an overarching regional accreditation cooperation mechanism. At present, two national accreditation bodies, one each in Trinidad & Tobago (Trinidad & Tobago Laboratory Services – TTLABS) and Jamaica (Jamaica National Agency for Accreditation – JANAAC), operating in conformity with ISO/IEC 17011, are preparing for international recognition. Both are associate members of the Inter-American Accreditation Cooperation (IAAC) and affiliate members of the International Laboratory Accreditation Cooperation (ILAC).

In countries without a national accreditation body, national accreditation focal points have been formed to fill this need and provide the necessary information and support for accreditation activities. A major part of the work of the Caribbean Laboratory Accreditation Services is to network member states which do not have emergent national accreditation bodies in order to continue the development of national accreditation focal points.

The regional cooperation for laboratory accreditation is to be established through the implementation of the Statement of Technical Co-operation between the national accreditation bodies and support for the development of the national accreditation focal points. Mechanisms are being established for the harmonization of processes and procedures in accordance with international standards and guidelines and for the development of a regional approach to the basic requirements for laboratories.

Human resource capacity building is being pursued to ensure that laboratory personnel, accreditation body and focal point personnel and assessors are provided with the necessary knowledge and skills to serve the needs of the accreditation system. The sustainability of the accreditation service is to be assured through advocacy for and marketing of accreditation, mobilisation of resources and maintaining a cadre of certified assessors.

In addition, the accreditation system will be continually improved by ensuring the establishment and maintenance of feedback mechanisms and systems for updating personnel and criteria. To this end, Caribbean Laboratory Accreditation Services is to conduct pilot studies on the accreditation of laboratories within the region, share best practices and assess the need for enhanced regional accreditation capacity.

Other projects

The Caribbean Development Bank (CDB) is funding a 30-month project, aimed at developing regional building standards based on the International Code Council (ICC) Codes. The main output of the project is the Caribbean Application Documents and the promotion of their use regionally. The project comes to an end in mid-2010.

The Canadian International Development Agency (CIDA – via TDV Global / Wren Group) is supporting the strengthening of CROSQ's procedures and processes, in particular the development of a quality management system (QMS) in accordance with ISO 9001.

Next steps

Going forward, the sub-region faces new trade agreements that will provide new opportunities for the export of goods and services. The recent slowdown in the global economy, on the other hand, could impede the rate of development in the region. In response, manufacturers need to consciously shift their focus from cost leadership to product and service differentiation on quality parameters, including and in particular the added value of brand imaging.

At the national level, this would require a shift in emphasis from import inspections against mandatory standards to export-led growth using international voluntary standards benchmarked against international best practices. CROSQ has a pivotal role to play in the process by realigning itself, widening its scope of operation and developing its capacity to help regional business move from a strategy of price competitiveness to quality competitiveness. This can only be achieved

by establishing the full range of quality infrastructure:

- Harmonization and implementation of regionally relevant standards
- Development of metrology and conformity assessment capability, including accreditation
- Promotion of a regional quality culture.

CROSQ's Three-year Strategic Plan (2009-2012) takes into account the new direction in which CROSQ is moving, setting up strategic themes as the pillars for developing regional quality infrastructure, with strategic objectives as the building blocks and business drivers of the future.

It also takes into consideration the necessary human, technical and financial resources as well as projects and activities that will help the organization achieve the set targets. The plan has seven strategic themes – harmonization of standards, metrology capability, conformity assessment capability, accreditation cooperation, regional quality culture, financial self-sustainability and organizational efficiency.

Southern African Development Community

Formed on 17 August 1992 in Windhoek, Namibia, the Southern African Development Community, SADC, comprises 15 member countries with a combined population of around 250 million people and a gross domestic product (GDP – 2006) of USD 375 billion (Seychelles excluded).

SADC countries include Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe.

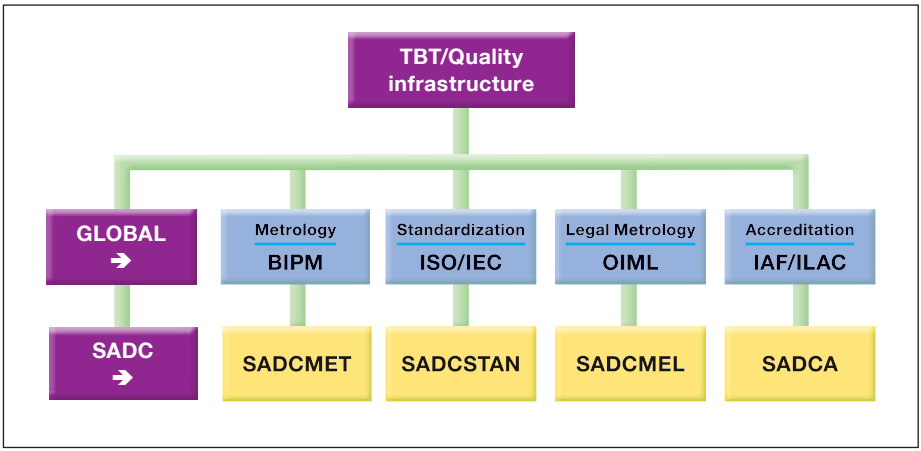
SADC's vision is one of a common future within a regional community that will ensure economic well being and improvement of the standards of living and quality of life of its people.
In its quest to achieve the above, SADC has identified trade as the main driver for regional integration and economic development. It was realized very early on that effective trade facilitation and productive competitiveness required a robust regional quality technical infrastructure.

To facilitate this, SADC member states agreed to put in place a technical regulation framework whose objective would be the identification, prevention and elimination of unnecessary technical barriers to trade (TBTs) amongst the member states and between SADC and other regional and international trading blocs through harmonized standards, technical regulations and conformity assessment procedures in order to facilitate and increase trade in goods and services. Regional cooperation structures were set up to facilitate harmonisation activities as follows:

- SADCSTAN – SADC Cooperation in Standardization
- SADCMEL – SADC Cooperation in Legal Metrology
- SADCMET – SADC Cooperation in Measurement Traceability (Industrial and Scientific Metrololgy)
- SADCA – SADC Cooperation in Accreditation
- SADCTRLC – SADC Technical Regulations Liaison Committee
- SADCTBTSC – SADC Technical Barriers to Trade (TBT) Stakeholders Committee
- SQAMEG – SADC SQAM Expert Group.

These structures have been deliberately formed to mirror the international design of bodies dealing with TBT matters to enable ease of obtaining international recognition in the various areas.

Figure 14 – SADCSQAM infrastructure mirrors the global TBT landscape



Standardization

SADCSTAN is the regional cooperation structure tasked with the harmonisation of standards based on international standards and the promotion of the use of common performance based standards rather than prescriptive standards as a basis for technical regulations.

In terms of the SADC technical regulation framework, all member states are required to withdraw conflicting standards once harmonised text is available. SADCSTAN has developed elaborate procedures, based on ISO/IEC Directives, to facilitate its standards harmonisation work.

So far, approximately 100 standards have been harmonised and about 30 are in the process of being harmonised.

Work has also started to engage regulators in the member states through SADCTRLC to identify and prioritise technical regulations that need harmonisation. It is the job of the SADCTRLC to provide a forum for the identification of common technical regulations to be implemented in the region.

All SADC countries except Lesotho now have national standards bodies (NSBs) in place and Lesotho is working towards establishing its NSB. The fact that all countries now have NSBs is attributable to SADCSQAM (see Figure 14) and is one of SQAM's achievements.

The national standards bodies of Botswana, Mozambique, Angola, Swaziland and Namibia all fully developed after the start of the SADCSQAM

Programme and these developments are in part due to the encouragement and moral support from SADCSQAM. All SADC countries are members of ISO and IEC. For the latter only South Africa is a full member of IEC whilst the rest of the countries are affiliate member bodies.

Metrology and conformity assessment

The region has hundreds of private and public sector laboratories in areas which support industrial, mining, agricultural, medical and food sectors' requirements for voluntary and regulatory testing and calibration. Tertiary education and research institutions also have test facilities that are frequently availed to industry.

The region has a significant number of certification and inspection bodies that offer services to the voluntary and regulatory sectors. The SADCTBTSC was established as the forum through which these conformity assessment service providers can cooperate at regional level. SADCTBTSC advises the other SADCSQAM structures, in particular SADCSTAN and SADCTRLC, on priority areas for inclusion in their work programmes and on any other issues that may affect the efficient operation of the SADCSQAM infrastructure and the technical regulatory framework of the region.

International recognition for conformity service providers is achieved through measurement traceability and accreditation. The key pre-requisites for traceability and accreditation for laboratories include participation in proficiency testing (PT) schemes and the use of certified reference materials and calibrated equipment.

SADC has therefore put in place two metrology structures, SADCMET and SADCMEL, to support industry with traceability requirements through regional cooperation and also cooperation with international players outside of SADC itself. Within this context, SADCMET monitors the PT schemes that are being run in member states mainly in the area of water and food.

Two regional PT schemes are being run in the area of water and food fortification supported by donor assistance. SADCMET plans to offer more PT schemes in the near future.

Access to reference materials (RMs) remains a major problem for conformity assessment service providers (both private and public) in SADC. This is one of the areas that will receive donor support in a quality infrastructure support project funded by the European Commission.

Accreditation

Two countries in SADC have national accreditation bodies, Mauritius and South Africa. The South Africa National Accreditation System (SANAS) is well established and has international recognition.

On the other hand, the Mauritius Accreditation Service (MAURITAS) is fairly new and has only recently started accrediting entities. SADCA, the regional accreditation cooperation structure, noted that the process of setting up national accreditation bodies ordinarily takes a long time and that some smaller economies in the region may not need to form national accreditation bodies as they do not have the economies of scale to sustain them.

It was therefore decided to establish a regional accreditation body – SADC Accreditation Service (SADCAS) to offer accreditation services to the countries that do not have national accreditation bodies. It is also envisaged that SADCAS will offer its services to countries with national accreditation bodies but are unable to accredit in some scopes due to lack of expertise, for example, in that particular area.

SADCAS will offer accreditation programmes for calibration and testing laboratories, certification bodies (management system/product/personnel) and inspection bodies. SADCAS office has been set up in Gaborone, Botswana. The first three members of staff took up their positions in SADCAS between April and July 2008.

SADCAS was officially launched on 23 April 2009 at a ceremony held in Gaborone, Botswana during which the SADC/SADCAS Memorandum of Understanding on general cooperation was signed.

National Accreditation Focal Points (NAFPs), who are the administrative link between SADCAS and SADC member states, have been established by the respective member states governments.

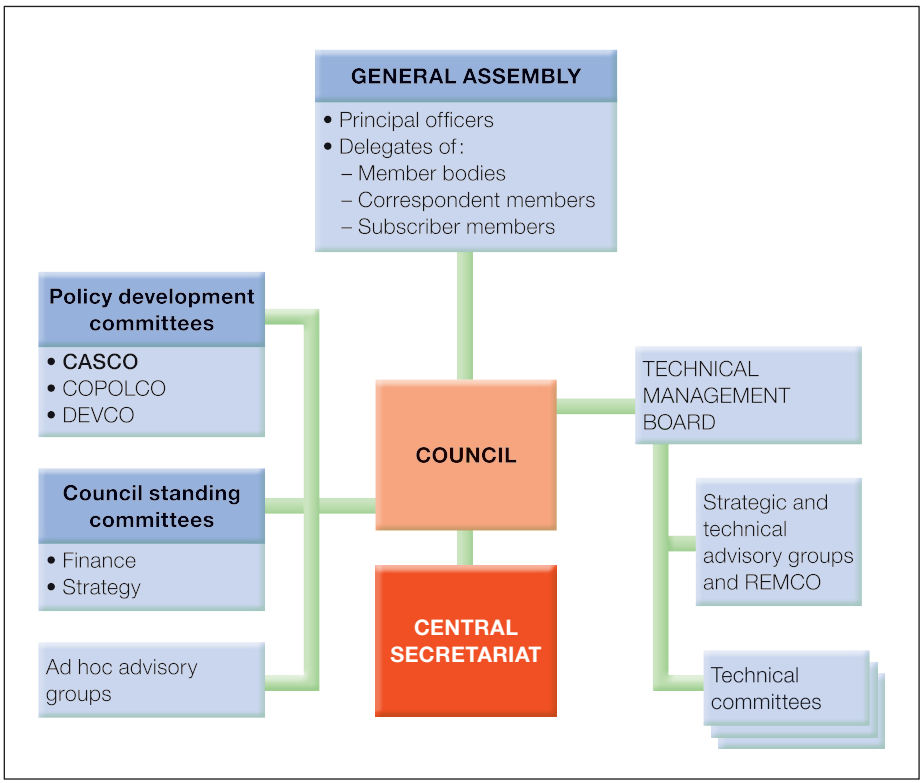
All NAFPs were officially launched by 2008. SADCAS was admitted as an affiliate member of the International Laboratory Accreditation Cooperation in November 2008. SADCAS is poised to start offering accreditation services in the latter half of 2009.

These services are aimed at supporting regional and international trade, enhancing the protection of consumers and the environment as well as improving the competitiveness of SADC products and services both in the regulatory and voluntary areas.

Appendix 1

ISO/CASCO sets conformity assessment standards

Figure 15 – Structure of ISO



As shown in **Figure 15**, the ISO Committee on conformity assessment is CASCO. It reports to the ISO Council and has the following terms of reference and objectives:

- **Study** means of assessing the conformity of products, processes, services, and management systems to appropriate standards or other technical specifications
- **Prepare** standards and guides related to the practice of testing, inspection, and certification of products, processes, and services and to the assessment of management systems, testing laboratories, inspec-

tion, certification and accreditation bodies, and their operation and acceptance
- **Promote** mutual recognition and acceptance of national and regional conformity assessment systems, and the appropriate use of International Standards for testing, inspection, certification, assessment and related purposes.

Of ISO's 151 members eligible for ISO/CASCO membership, 107 are represented in ISO/CASCO. That membership includes both developed and developing countries, and 76 of the total are participating (P) members and 31 are observer (O) members.

ISO/CASCO's outputs are both of a technical nature (standards, guides and other publications) and policy development. It has been structured to have a number of key advisory groups to complement the technical work undertaken in the CASCO Working Groups developing the ISO/CASCO suite of standards and other publications. Those advisory groups and their functions are as follows (and as shown in **Figure 16** – see page 168):

Policy and support groups of ISO/CASCO

These are:

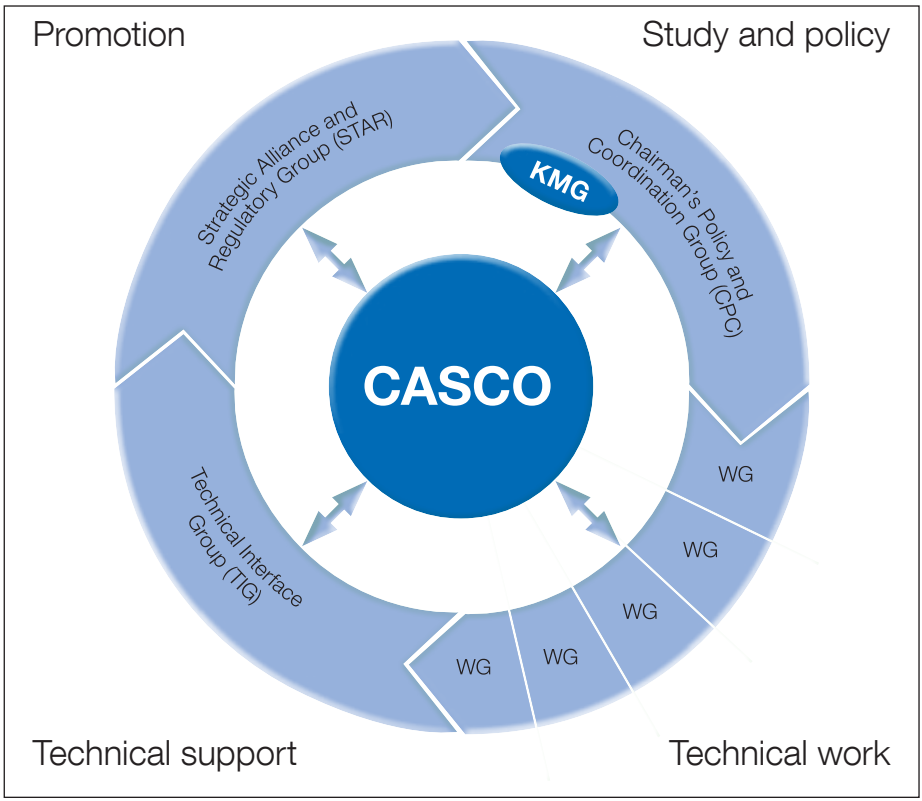
Chairman's policy and coordination group (CPC), which reviews and updates ISO/CASCO's action plan and technical work plan. This group also assists the ISO/CASCO Chair in identifying strategic conformity assessment issues and in developing policy. The CPC has also recognized the need for a ISO/CASCO Interpretation Panel to provide a consistent approach to interpretation and maintenance of existing ISO/CASCO developed standards and guides.

Technical Interface Group (TIG), is a technically focused group which liaises with other ISO technical committees in order to ensure a consistent and harmonized approach to conformity assessment amongst all committees. It seeks to ensure ISO/CASCO conformity assessment policies are adhered to and understood, while also providing internal advice within ISO on conformity assessment issues.

Strategic Alliance and Regulatory Group (STAR) provides a mechanism for industry sectors and regulators to interact with ISO/CASCO (keeping abreast of activities in conformity assessment, promoting the ISO/CASCO toolbox, and providing a forum to discuss conformity assessment needs and concerns).

Knowledge Management Group (KMG), which is a small group within

Figure 16 – Supporting and working groups in the ISO/CASCO structure



CPC that records historical decisions of ISO/CASCO.

The "ISO/CASCO toolbox"

The standards, guides and related publications produced by ISO/CASCO form what is known as the ISO/CASCO toolbox. They are the collected resources available to ensure that the various parties with an interest in conformity assessment have available the latest documents reflecting the state of the art in international conformity assessment practice. Different user-groups will need to select those documents which are of most relevance to their needs, depending on whether they conduct conformity assessment activities or are one of the many potential end-users of such services.

Some of the tools are supported by other complementary tools. For example, the vocabulary and general principles of

conformity assessment, contained in ISO/IEC 17000, should be of interest to both operators of conformity assessment and their users, such as regulators.

A laboratory using ISO/IEC 17025 as the basis of its operation may also have an interest in the toolbox elements dealing with selection and use of proficiency testing schemes (currently covered in ISO/IEC Guide 43).

An accreditation body should not only be fully aware of the requirements for such bodies in ISO/IEC 17011, but also all of the relevant standards affecting the conformity assessment bodies they accredit, for example, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17024, ISO/IEC 17025 and ISO/IEC Guide 65.

A specifier may have an interest in issues related to marks of conformity, where ISO/IEC 17030 could be of value.

The various ISO/CASCO tools are listed in the table at the end of this appendix and are referred to in the appropriate places in this publication.

ISO/CASCO's global outreach

ISO/CASCO promotes the ISO/IEC conformity assessment standards at the global level through interaction with developing countries and, through the STAR group, with industry sectors and intergovernmental agencies (regulators) that are involved in conformity assessment. The strategy is to actively promote the conformity assessment standards and try to encourage their uptake and use.

Through this work, ISO/CASCO can engage with sector organizations with which ISO does not have a formal liaison at the CASCO level but which have some global reach such as GFSI, IFOAM etc.

ISO/CASCO communicates with these organizations to make sure they are aware of the toolbox and how to use it to best effect. They are encouraged to become directly involved in the development of standards for conformity assessment activities particularly where the present contents of the toolbox are not suitable for the newly emerging sectors such as agri-food, climate change and supply chain risk management.

A list of the standards – either published or under development – making up the ISO/CASCO toolbox as of July 2009 appears on **pages 170-174**.
(The latest information on publications developed by ISO/CASCO can be accessed via links on the ISO Web site **www.iso.org**: click on Conformity assessment, then on Publications and resources, then on CASCO toolbox.)

Standard and/or project	Potential users	Status
ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles	Standards Bodies; Conformity Assessment Bodies; Accreditation Bodies; Government Authorities; Regulators; MRA Agreement Groups; Trade Officials; Academic Institutions; Industry and Trade Associations; Professional Bodies; Specifying Bodies	Current – July 2009
ISO/PAS 17001:2005 Conformity assessment – Impartiality – Principles and requirements	Standards Bodies; Conformity Assessment Bodies; Accreditation Bodies; Government Authorities; Regulators; MRA Agreement Groups	Current – July 2009
ISO/PAS 17002:2004 Conformity assessment – Confidentiality – Principles and requirements	Standards Bodies; Conformity Assessment Bodies; Accreditation Bodies; Government Authorities; Regulators; MRA Agreement Groups	Current – July 2009
ISO/PAS 17003:2004 Conformity assessment – Complaints and appeals – Principles and requirements	Standards Bodies; Conformity Assessment Bodies; Accreditation Bodies; Government Authorities; Regulators; MRA Agreement Groups	Current – July 2009
ISO/PAS 17004:2005 Conformity assessment – Disclosure of information – Principles and requirements	Standards Bodies; Conformity Assessment Bodies; Accreditation Bodies; Government Authorities; Regulators; MRA Agreement Groups	Current – July 2009
ISO/PAS 17005:2008 Conformity assessment – Use of management systems – Principles and requirements	Standards Bodies; Systems Certification Bodies; Auditor Associations; Accreditation Bodies	Current – July 2009
ISO/IEC DIS 17007 Conformity assessment – Guidelines for drafting normative documents suitable for use for conformity assessment	Standards Bodies; Regulators; Specification Writers; Conformity Assessment Bodies; Accreditation Bodies	Under preparation

Standard and/or project	Potential users	Status
ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies	Accreditation Bodies; Trade Officials; Government Authorities; MRA Agreement Groups (e.g. IAF, ILAC, APLAC, EA, IAAC, PAC, SADCA)	Current – July 2009
ISO/IEC 17020:1998 General criteria for the operation of various types of bodies performing inspection	Inspection Bodies; Specifiers and Users of Inspection Bodies; Regulators; Accreditation Bodies; Purchasing Bodies; MRA Agreement Groups (e.g. ILAC and IAF)	Current – July 2009
ISO/IEC 17021:2006 Conformity assessment – Requirements for bodies providing audit and certification of management systems	Management Systems (e.g. quality and environmental) Certification Bodies; Auditor Associations; Accreditation Bodies; MRA Agreement Groups (e.g. IAF)	Current – July 2009
ISO/IEC CD 17021-2 Conformity assessment – Part 2: Requirements for audit and certification of management systems and requirements for third-party certification auditing of management systems	Management Systems (e.g. quality and environmental) Certification Bodies; Auditor Associations; Accreditation Bodies; MRA Agreement Groups (e.g. IAF)	Draft under development by ISO/CASCO Working Group 21
ISO/IEC 17024:2003 Conformity assessment – General requirements for bodies operating certification of persons	Personnel Certification Bodies; Professional Bodies; Accreditation Bodies; Regulators; MRA Agreement Groups (e.g. IAF)	Current – July 2009
ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories	Laboratories; Specifiers and Users of Laboratory Services; Accreditation Bodies; Certification Bodies; Proficiency Testing Bodies: Reference Material Producers; Regulators; Purchasing Bodies; MRA Agreement Groups (e.g. ILAC)	Current – July 2009, (as amended in 2006)
ISO/IEC 17025:2005/Cor 1:2006	See ISO/IEC 17025 above	Current – July 2009 (minor amendments to 2005 Version)

Standard and/or project	Potential users	Status
ISO/IEC 17030 :2003 Conformity assessment – General requirements for third-party marks of conformity	Third Party Certification Bodies; Consumer Associations; Regulators; Accreditation Bodies	Current – July 2009
ISO/IEC 17040 :2005 Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies	MRA Agreement Groups; Laboratories; Inspection Bodies; Product, Systems and Personnel Certification Bodies	Current – July 2009
ISO/IEC DIS 17043 Conformity assessment – General requirements for proficiency testing	Proficiency Testing Bodies; Laboratories; Accreditation Bodies; Reference Material Producers; Regulators; Standards Bodies; Professional Bodies (for educational value of proficiency testing)	To replace existing ISO/ IEC Guide 43 Parts 1 and 2
ISO/IEC 17050-1 :2004 Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements	Manufacturers and Service Providers; Regulators; Retailers; Component Purchasing Bodies	Current – July 2009
ISO/IEC 17050-2 :2004 Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation	Manufacturers and Service Providers; Regulators; Retailers; Component Purchasing Bodies	Current – July 2009
ISO/IEC CD 17065 Conformity assessment – Requirements for certification bodies certifying products, processes and services	Product Certification Bodies; Accreditation Bodies; Standards Bodies; Regulators; Consumer Associations; Manufacturers and Service Providers; Major Retailers; Industry Associations; Importers and Exporters	To replace existing ISO/IEC Guide 65 on completion
ISO/IEC Guide 7:1994 Guidelines for drafting of standards suitable for use for conformity assessment	Standards Bodies; Conformity Assessment Bodies; Accreditation Bodies; Regulators; Trade Officials; Consumer and Industry Associations	Current – July 2009 To be replaced by ISO/ IEC 17007

Standard and/or project	Potential users	Status
ISO/IEC Guide 23:1982 Methods of indicating conformity with standards for third-party certification systems	Certification Bodies	Current – July 2009
ISO Guide 27:1983 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity	Certification Bodies; Accreditation Bodies	Current – July 2009
ISO/IEC Guide 28:2004 Conformity assessment – Guidance on a third-party certification system for products	Product Certification Bodies; Accreditation Bodies; Standards Bodies; Regulators; Consumer Associations; Manufacturers and Service Providers; Major Retailers; Industry Associations; Importers and Exporters	Current – July 2009
ISO/IEC Guide 43-1:1997 Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes	Proficiency Testing Bodies; Laboratories; Accreditation Bodies; Reference Material Producers; Regulators; Standards Bodies; Professional Bodies (for educational value of proficiency testing)	Expected to be replaced through incorporation in new ISO/IEC 17043
ISO/IEC Guide 43-2:1997 Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies	Laboratory Accreditation Bodies; MRA Agreement Groups (e.g. ILAC)	Expected to be replaced through incorporation in new ISO/IEC 17043
ISO/IEC Guide 53:2005 Conformity assessment – Guidance on the use of an organization's quality management system in product certification	Product Certification Bodies; Accreditation Bodies; Standards Bodies; Regulators; Consumer Associations; Manufacturers and Service Providers; Major Retailers; Industry Associations; Importers and Exporters	Current – July 2009

Standard and/or project	Potential users	Status
ISO/IEC Guide 60:2004 Conformity assessment – Code of good practice	Conformity Assessment Bodies; Accreditation Bodies; Trade Officials; Regulators; Consumer Associations; Industry and Trade Associations; MRA Agreement Groups	Current – July 2009
ISO/IEC Guide 65:1996 General requirements for bodies operating product certification systems	Product Certification Bodies; Accreditation Bodies; Standards Bodies; Regulators; Consumer Associations; Manufacturers and Service Providers; Major Retailers; Industry Associations; Importers and Exporters	Current – July 2009 (replacement by new ISO/IEC 17065 expected on completion and adoption)
ISO/IEC Guide 67:2004 Conformity assessment – Fundamentals of product certification	Product Certification Bodies; Consumer Associations; Regulators; Accreditation Bodies (for product certification); MRA Agreement Groups (e.g. IAF); Suppliers; Manufacturers and Service Providers; Retailers	Current – July 2009
ISO/IEC Guide 68:2002 Arrangements for the recognition and acceptance of conformity assessment results	Purchasing Authorities; Regulators; Trade Officials; Accreditation Bodies; Conformity Assessment Bodies; MRA Agreement Groups	Current – July 2008

Appendix 2

The roles of international and regional accreditation body forums

Accreditation is the top level in the quality infrastructure, providing a means of giving confidence in the work of conformity assessment bodies. Accreditation is intended to underpin the integrity, transparency and consistency of the work of these bodies. Within a national context where there is one accreditation body in any particular field, this aim can be realized but when more than one accreditation body operates in a given technical area there can be inconsistencies in the way they operate.

The result can be that some conformity assessment bodies might be subject to a more restrictive regime than others according to which accreditation body they use. Such a situation can lead to distortions in the market and can affect those using the services of the conformity assessment bodies. As a result, confidence would be undermined and, for example, test reports or certificates issued in one country might not be accepted in another.

In order to address these problems and to promote the widest possible acceptance of the work of conformity assessment bodies, the accreditation bodies have formed regional and international forums. The International Laboratory Accreditation Cooperation (ILAC) had its origins in 1977 and was formed to promote good practice in testing and calibration and the international acceptance of the work of the laboratories carrying out this work.

The International Accreditation Forum (IAF) was formed in 1993 with similar aims in relation to certification (or registration) of quality management systems conforming to ISO 9001. Subsequently the work of IAF has extended to cover other management systems such as those for environmental issues covered by ISO 14001 and to product certification. ILAC and IAF are working together to cover the accreditation of inspection bodies conforming to ISO/IEC 17020.

One of the driving forces which influenced the formation and development of these forums was the GATT (General Agreement on Tariffs and Trade) Standards Code. Its purpose was to discourage the use of standards (technical regulations and specifications) and conformity assessment (primarily testing and certification) as trade barriers. The GATT Standards Code has since been superseded by the establish-

ment of the World Trade Organization and its Agreement on Technical Barriers to Trade. That Agreement and its relevance to the roles of conformity assessment in global trade are discussed in more detail in Appendix 3.

The objectives of the two international accreditation forums are as follows:

International Laboratory Accreditation Cooperation (from ILAC Rules)

- To define criteria and standards and harmonize practices to build consistency in accreditation of testing and calibration laboratories and inspection bodies for the purposes of trade facilitation
- To develop and maintain arrangements for the mutual recognition of calibration certificates and test and inspection reports issued by laboratories and inspection bodies accredited by Signatories to the ILAC multilateral Mutual Recognition Arrangement (MRA)
- To ensure that such arrangements are relevant to the needs of users of such reports and certificates
- To promote the international recognition of such arrangements by users of calibration certificates and test and inspection reports
- To strive to ensure that the international accreditation infrastructure meets the needs of all interested parties seeking competent calibration, testing and inspection services
- To encourage and assist accreditation bodies to satisfy the needs of their domestic markets and to achieve full international recognition of calibration certificates, test reports and inspection body reports prepared by accredited laboratories and inspection bodies
- To foster the development of appropriate Regional Cooperation Bodies as the means of ensuring that laboratory and inspection bodies throughout the world have adequate opportunities to participate in the work of laboratory and inspection body accreditation and the raising of standards of laboratory and inspection body performance
- To conduct seminars and conferences and to encourage research into relevant aspects of conformity assessment
- To collaborate with regional and international bodies having complementary objectives.

International Accreditation Forum (from its Memorandum of Understanding)

- To ensure that accredited conformity assessment activities are effective in adding value to the facilitation of global trade
- To facilitate world trade by:
  - promoting common application of the requirements for inspec-

tions, certifications and/or registrations, or similar programmes of conformity assessment;
  - promoting the equivalence of accreditations granted by Accreditation Body Members of inspection programmes, certification and/or registration programmes, or similar programmes of conformity assessment
  - providing technical assistance to emerging economies that are developing conformity assessment accreditation programmes
- To establish and maintain confidence in the accreditation programmes operated by Accreditation Body Members and in the activities of conformity assessment bodies accredited by them by:
  - participation by Accreditation Body Members and Regional Groups in the worldwide Multilateral Recognition Arrangement (MLA)
  - exchange of information
  - participation in IAF activities
  - participation in regional groupings where they exist.
- To support the implementation by accreditation and conformity assessment bodies of those international standards and guides which are endorsed by IAF, and to contribute to their development as necessary
- To harmonize the application of criteria for the operation of the Accreditation Body Members' accreditation schemes, based on IAF endorsed international standards and guides, and publicly available IAF guidance documents on the application of those standards and guides
- To establish and maintain an MLA based on the equivalence of the Accreditation Body Members' accreditation programmes verified through peer evaluation and/or re-evaluation among Accreditation Body Members, such that all parties have confidence in the declared equivalence
- To promote the international acceptance of the MLA, and of regional group MLAs, on the equivalence of the operation of their accreditation programmes, and the international acceptance of conformity assessment results from bodies accredited by Members of the MLA
- To open and maintain channels for the interchange of information and knowledge between Accreditation Body Members and other relevant bodies.

How the international forums work

Because of their different origins and the different fields they are addressing, there are some differences between ILAC and IAF in the way that they are organized and operated. However, both

have multilateral recognition arrangements through which the individual accreditation bodies are evaluated for their conformity with ISO/IEC 17011 and the particular rules of the relevant forum.

The ILAC arrangement is known as the Mutual Recognition Arrangement (MRA) while that of IAF is called the Multilateral Recognition Arrangement (MLA). For more details on how these arrangements work, see the forums' websites:

- ILAC: **http://www.ilac.org**
- IAF: **http://www.iaf.nu**

The evaluation is carried out by a team of assessors from other accreditation bodies using peer assessment techniques such as those specified in ISO/IEC 17040. The results of the assessments are reviewed by a special committee which makes the decision on whether or not the body meets the requirements. Re-evaluations are carried out periodically to ensure that the accreditation bodies maintain the standard of their work.

Through the peer evaluation process confidence in the accreditations carried out by ILAC and IAF members is enhanced and the international acceptance of the work of the accredited laboratories and certification bodies is facilitated.

The membership categories of IAF are as follows:

- **Accreditation Body Members** – Open to bodies accrediting other bodies which certify* quality systems, products, services, personnel, environmental management systems or similar programmes of conformity assessment. Such accreditation bodies declare a common intention to join the IAF MLA to recognize the equivalence of other members' accreditations to their own. (* IAF uses "register" and "registration" as equivalent words to "certify" and "certification")
- **Association Members** – Open to other organizations involved in the use or implementation of certification systems
- **Special Recognition Organizations-Regional Accreditation Groups** – Open to regional groupings of accreditation bodies whose aims include the maintenance of Regional MLAs.

The membership categories of ILAC are:

- **Full Members**
  - Open to accreditation bodies that meet the requirements for Associates (below) and have also been accepted as signatories to the ILAC Mutual Recognition Arrangement. To do this, the signatory must:

- Maintain conformance with ISO/IEC 17011, related ILAC guidance documents, and a few, but important, supplementary requirements,
- Ensure that all its accredited laboratories comply with ISO/IEC 17025 and related ILAC guidance documents.

These signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence.

- **Associates**
  - Open to accreditation bodies that, while not yet signatories to the ILAC Arrangement:
    - Operate accreditation schemes for testing laboratories, calibration laboratories, inspection bodies, and/or other services as decided from time to time by the ILAC General Assembly
  - Can provide evidence that they are operational and comply with:
    - Requirements set out in relevant standards established by appropriate international standards writing bodies such as ISO and IEC and ILAC application documents
    - Obligations of the ILAC Mutual Recognition Arrangement
  - Are recognized in their economy as offering an accreditation service.
- **Affiliates**
  - Open to accreditation bodies that are:
    - Currently operating, being developed or intended to be developed for testing laboratories, calibration laboratories, inspection bodies, and/or other services as decided from time to time by the ILAC General Assembly
    - Declare their intention to operate their accreditation programmes in compliance with the requirements set out in relevant standards established by appropriate international standards writing bodies such as ISO and the IEC and ILAC application documents.
- **National Coordination Bodies** – Open to formally established national bodies with responsibility for the coordination of laboratory and/or inspection body accreditation activity in particular economies.
- **Regional Cooperation Bodies** – Open to formally established regional accreditation co-operations with objectives similar to and compatible with ILAC, which are committed to the obligations of the ILAC Mutual Recognition Arrangement and which consist of formally nominated representatives of the accreditation interests from at least four economies (Recognized Regional Cooperation Bodies are those whose regional Mutual

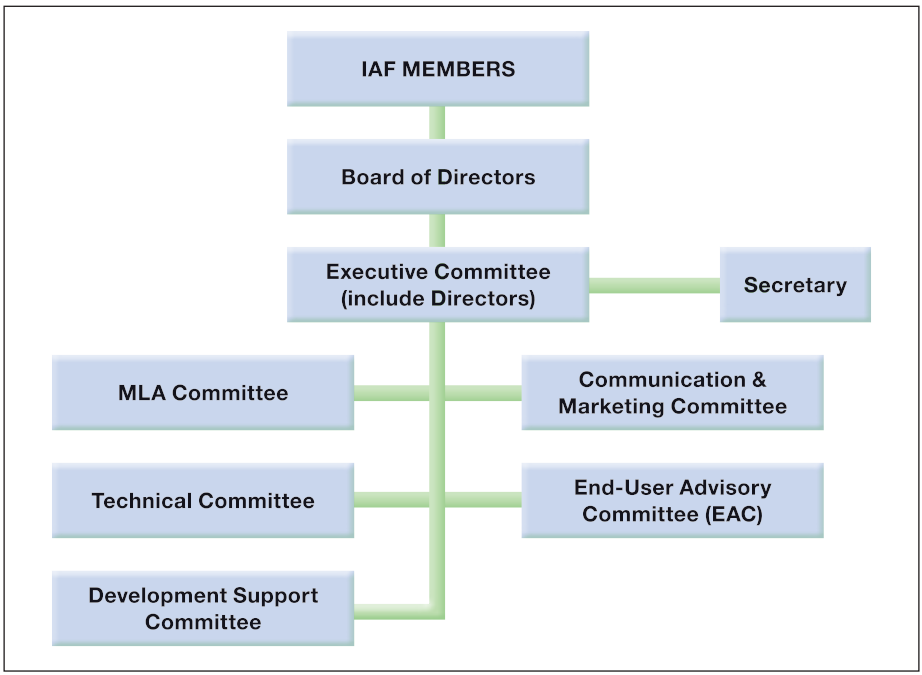
Recognition Arrangements (MRA/MLA) have been successfully peer-evaluated by ILAC).

- **Stakeholders** – Open to representative international, regional and national organizations having an interest in the work of ILAC and include bodies such as associations of laboratories, associations of laboratory practitioners, inspection body associations, purchasing organizations, regulatory authorities, consumer associations and trade organizations.

Both ILAC and IAF are organized in such a way that the accreditation body members determine the policies of the organizations while specialist committees work on different aspects such as the development of guidance material for members or promotion of accreditation. Stakeholders in the outcome of accreditation such as associations of testing laboratories and certification bodies, end users and regulatory authorities are allowed to participate in the work of the forums but their voting rights are limited.

The structures of the two international bodies are as shown in the **Figures 17 and 18**:

Figure 17 – IAF



Coordination of ILAC and IAF Activities

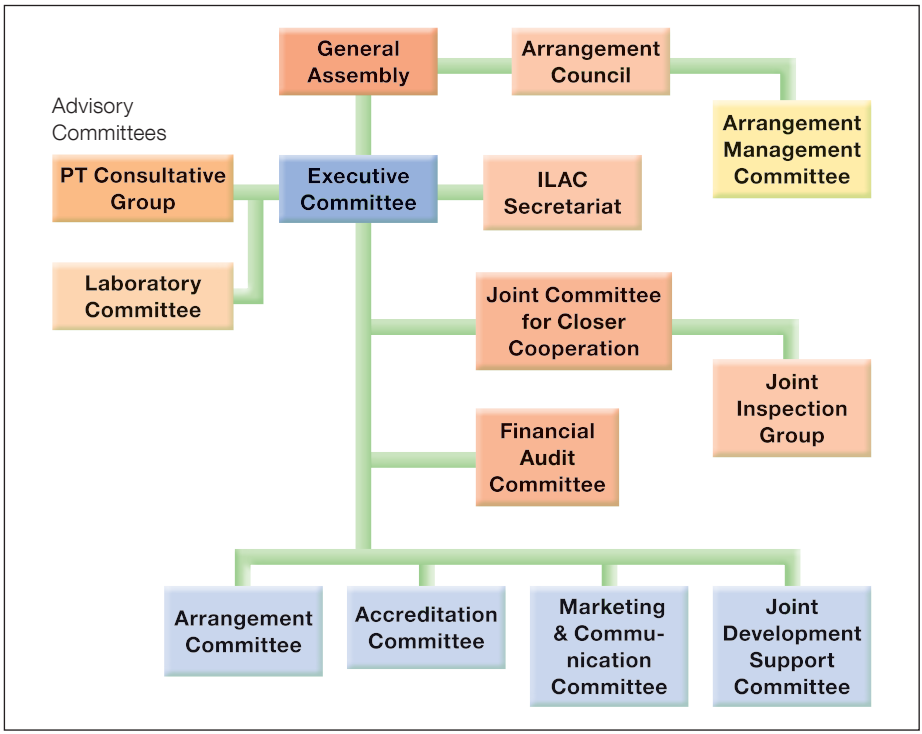
There are a number of ILAC committees and groups shown which operate jointly with IAF. Many accreditation bodies are members of both organizations and ILAC and IAF now schedule their annual meetings (and some other meetings of various committees) alongside each other.

Additionally, there is one conformity assessment activity where both ILAC and IAF are active, namely accreditation of inspection bodies. In the longer term it is expected that there will be a joint IAF/ILAC multilateral MRA for accredited inspection bodies.

Regional accreditation forums

While ILAC and IAF are able to provide a global forum for harmonization of accreditation activities, the more specific needs of different regions are being met by regional forums. Exam-

Figure 18 – ILAC



ples of these regional accreditation forums are:

- Asia Pacific Laboratory Accreditation Cooperation (APLAC) (www.aplac.org) – ILAC Regional Cooperation Body member
- European cooperation for Accreditation (EA) (www.ea-accreditation.org) – ILAC Regional Cooperation Body member; and IAF Regional Accreditation Group member
- Inter-American Accreditation Cooperation (IAAC) (www.iaac.org.mx) – ILAC Regional Cooperation Body member; and IAF Regional Accreditation Group member
- Pacific Accreditation Cooperation (PAC) (www.apec-pac.org) – IAF Regional Accreditation Group member
- Southern African Development Community Accreditation (SADCA) (www.sadca.org) – ILAC Regional Cooperation Body member; and IAF Regional Body member.

Multiple beneficiaries of MRAs

There are a number of potential beneficiaries of regional and global MRAs. They include:

- Accredited conformity assessment bodies
- Accreditation bodies
- Regulators and trade officials
- Importers, exporters and consumers
- National infrastructures.

For **accredited conformity assessment bodies** benefits from MRAs include:

- International recognition of their certificates and data
- Access to new markets
- Exposure to foreign standards and regulations
- Access to support from other accredited conformity assessment bodies, such as, for example, specialist calibration services.

For **accreditation bodies**, their benefits from MRAs include:

- Benchmarking against best practice codes through the peer evaluation process
- Opportunities to share experiences and improvements through the peer evaluation process
- Enhanced reputation internationally (greater acceptance of their accredited bodies' certificates and data
- Enhanced reputation domestically (providing reassurance to domestic stakeholders and users that they maintain the standards and discipline required by their international counterparts).

For **regulators and trade officials** the benefits include:

- Access to multiple providers of compliance data (from both foreign

and local conformity assessment bodies)
- Reduced needs for governments to undertake their own compliance testing, inspection and certification
- Opportunities to reduce technical barriers to trade within their economy
- Prompts to harmonize their technical requirements with other countries' or to accept their equivalence
- Reduced tensions with importers and exporters by provision of multiple sources for compliance assessment.

For **importers, exporters and consumers** the MRA benefits include:
- Reduced duplication and cost (one certificate for many markets)
- Opportunities for new markets
- Greater confidence in foreign data (for consumers)
- Expanded network for information on competent providers of conformity assessment (through, for example, the listings of accredited facilities available from signatory bodies to the MRAs)
- A mechanism for dispute resolution when faced with conflicting data from different sources.

For **national infrastructures**, benefits include:
- Mutual support (for example the CIPM MRA for national measurement institutes and the ILAC MRA have complementary roles in disseminating measurement traceability)
- Prompting the adoption of international standards for conformity assessment activities in domestic economies, while also providing experiences and inputs to development of appropriate standards, codes of practice etc by bodies such as CASCO
- Sharing of scarce technical resources for example by providing access to foreign experts for assessment, audits etc.

Current scopes of the IAF MLA and the ILAC MRA

As of mid-2009, the IAF MLA covered:
- Accreditation of certifiers of quality management systems
- Accreditation of certifiers of environmental quality systems
- Accreditation of product certification bodies.

As of mid-2009, the ILAC MRA covered:
- Accreditation of test and calibration laboratories to ISO/IEC 17025
- Accreditation of medical laboratories to ISO 15189 or ISO/IEC 17025.

As mentioned earlier, IAF and ILAC are working together to establish a joint MLA for inspection body accreditation. ILAC has taken in prin-

ciple resolutions to include accreditation of reference material producers and proficiency testing providers in the ILAC MRA after appropriate processes for their inclusion have been agreed. IAF has resolved to extend its MLA to cover personnel certification bodies.

At the regional level, bodies such as EA, IAAC and APLAC have already implemented expansions of their MLAs to include accreditation of inspection bodies. APLAC has recently established the first group of signatories to an expansion of the APLAC MRA to cover accreditation of reference material producers.

Appendix 3

Conformity assessment and the WTO Agreement on Technical Barriers to Trade

The TBT Agreement has 15 articles which are binding on member governments. Five of those articles deal exclusively with conformity assessment procedures and Article 6.1 requires that member central government bodies:

> "…shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding, in particular:
>
> 6.1.1 adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting members, so that confidence in the continued reliability of their conformity assessment results can exist; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence;
>
> 6.1.2 limitation of the acceptance of conformity assessment results to those produced by designated bodies in the exporting Member."

Further, in Article 6.3

> "Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements of the mutual recognition of results of each other's conformity assessment procedures…"

While Article 6 deals with the responsibilities of central government bodies, Article 8 requires Member governments to

> "..take such reasonable measures as may be available to them to ensure that non-governmental bodies within their territories which operate conformity assessment procedures comply with the provisions of Articles 5 and 6 [of the TBT]…"

The significance of this Article is that it also obliges member governments to seek to ensure that voluntary-sector providers of standards, conformity assessment and accreditation do not create technical barriers. Article 7 has similar provisions for central governments to have local government bodies follow the same principles.

The WTO TBT Agreement makes special mention of the difficulties developing countries may face in administering and establishing standards, technical regulations and conformity assessment systems. In this regard Article 11 is entitled *Technical Assistance to Other Members*. The Article places particular emphasis on technical assistance being provided to developing country members and with priority for least developed countries.

Article 12 (*Special and Differential Treatment of Developing Country Members*) has quite detailed provisions for taking into account the special financial and trade needs of developing countries, including the protection of indigenous means of production.

Conformity assessment and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures

Apart from the WTO Agreement on Technical Barriers to Trade, Member governments of the WTO are also required to comply with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

That Agreement deals with food safety and animal and plant health regulations and their potential for being used in a discriminatory manner. The Agreement encourages WTO Members to use harmonized measures and to base them on international standards, guidelines and recommendations, where they exist.

Article 8 and *Annex C* of the Agreement covers *Control, Inspection and Approval Procedures,* and notes that such procedures include sampling, testing and certification.

As with the WTO Agreement on TBT, the SPS Agreement also makes special provisions for developing countries with its *Article 9* covering technical assistance and *Article 10* dealing with special and differential treatment for developing countries and particularly least-developed country Members.

The WTO website (**www.wto.org**) provides access to the text of the WTO SPS Agreement and through the "Resources" tab of its website provides access to interactive training modules on both:

- The Agreement on SPS Measures
- SPS Handbook: *How to apply the transparency provisions of the SPS Agreement.*

Global and regional relationships, interactions and cooperation

Since the mid-1990's there has been a steady growth in the development of cooperation amongst a number of the key international and regional bodies which

have an impact on conformity assessment activities. As discussed in earlier Chapters, all of the international infrastructure bodies have well-established relationships with their regional counterparts (including ISO, BIPM, OIML, IAF and ILAC). Many of the international bodies, also, use their regional co-operations as major contributors to their standardization, accreditation, and metrology activities, including implementation of their respective MRAs.

At the regional level there are also region-to-region memoranda of understanding (MOUs) which have emerged amongst some of these bodies. (For example, to cooperate on mutual training needs and proficiency testing as set out in the MOU between IAAC and APLAC.)

There are also now well established formal and informal linkages between the international and regional infrastructure bodies. These linkages often include mutual participation at the various bodies' annual technical and policy meetings as well as through formal MOUs outlining specific cooperation activities.

Some of the relevant MOUs include those between:

- ISO/IAF/ILAC
- CIPM/ILAC
- IAF/OIML/ILAC

Details of these MOUs can be accessed through the bodies' Websites as listed earlier.

From a developing country perspective, it is noteworthy that UNIDO has also developed MOUs with ILAC and IAF and there is also a forum for a number of these international bodies to collaborate jointly on developing country issues. This is through JCDCMAS (Joint Committee on Coordination of Assistance to Developing Countries in Metrology, Accreditation and Standardization), where the participating bodies are BIPM, OIML, IAF, ILAC, ISO, IEC, UNIDO, the International Trade Centre (ITC) and ITU-T, the Telecommunications Standardization Sector of ITU (International Telecommunications Union).

Mutual acceptance of conformity assessment certificates

The World Trade Organization's (WTO) *World Trade Report 2005*, *Trade, Standards and the WTO* (page 56), discusses conformity assessment and its relevance to world trade as follows:

> "Exporters are often faced with having to test or certify their products in each of the countries to which they are exporting. Even if countries rely on internationally harmonized standards or accept as equivalent another country's

standard, they may not rely on an exporting country's conformity assessment results. This can substantially increase costs of exports in a number of ways. First of all, exporters incur the costs of redundant testing and certification for each of the destination markets. Second, they face the risk of higher transportation costs if the goods are rejected by the importing country after shipment. Third, there is a cost in terms of time required for complying with administrative requirements and inspections by the importing country's authorities. For some time-sensitive products, such as textiles and clothing, the time delays associated with product testing and certification in the importing country can severely impact on profitability and the ability to penetrate the market.

"In order to reduce such costs, a number of conformity assessment recognition agreements have been negotiated between and among countries bilaterally. Obviously, these agreements do not have an influence on the standards and technical regulations themselves. The impact of such agreements on the trade of participating countries is clearly positive due to a reduction in costs generated by the avoidance of duplicative tests, as well as lower transport and administrative costs, as handling time and uncertainty of delivery are reduced. Mutual recognition requires confidence in the competence of one another's conformity assessment bodies and in the methods employed to assess conformity. For this reason, agreements are often limited to accepting conformity assessment results from bodies that are recognized by the parties concerned, and do not extend to self-certification arrangements such as suppliers' declarations of conformity."

The *World Trade Report 2005, Trade, Standards and the WTO* also notes (on page 118):

"A lot of international cooperation is taking place to establish confidence in the work of conformity assessment bodies in other countries. An efficient way forward seems to be the conclusion of mutual recognition agreements (MRAs) between accreditation bodies such that the results of any laboratory or other conformity assessment body accredited by one of the parties are accepted in any other country. In order for this to happen, it is important that common standards on best practices are adhered to, giving other parties confidence in the work of their partners."

Accreditation bodies themselves do not use the data and certificates from foreign bodies accredited by their counterparts in the MRAs of ILAC, IAF and their regional bodies. The accreditation bodies' role is to promote to regulators and other potential users of data and certificates in their

own countries, the equivalence of foreign, accredited conformity assessment bodies, to their own accredited bodies.

It is important to note that the IAF and ILAC MRAs are in the voluntary sector. As such, they are not formally binding on governments. However, many governments and their regulators do use the voluntary-sector MRAs of ILAC, IAF and their regional cooperation bodies to accept foreign conformity assessment certificates and data.

A number of governments have also established their own government-to-government MRAs for conformity assessment. Some of these MRAs are on a bilateral basis, such as that between the Singapore and Australian Governments. Others are multi-lateral, such as the APEC Electrical and Electronic goods MRA.

Some governments have also formally *designated* their voluntary-sector accreditation bodies as the bodies which will be used to achieve mutual acceptance of conformity assessment certificates in their regulated sectors. This is also one of the pathways for acceptance under the APEC electrical MRA, where governments can use the APLAC voluntary-sector MRA to accept foreign results. In Europe also, the European Commission is encouraging the use of the EA voluntary sector MRA as support for their confidence in accredited conformity assessment bodies acting in a wide range of regulated sectors.

Internationally, there are other forms of mutual acceptance of test and certification results, such as direct acceptance at the conformity assessment body level. This is the purpose of the conformity assessment schemes of the International Electrotechnology Commission (IEC) administered by its Conformity Assessment Board. Their schemes involve the testing and certification of safety of electrical products, electrical products used in hazardous environments and electronic components and products. Full details of their schemes can be found at the IEC Website (**www.iec.ch**).

ISO Central Secretariat

International Organization
for Standardization
1, chemin de la Voie-Creuse
Case postale 56
CH-1211 Genève 20
Switzerland

Tel. + 41 22 749 01 11
Fax + 41 22 733 34 30
E-mail central@iso.org
Web www.iso.org

ISBN 978-92-67-10511-6
©ISO, 2010-02/3 000