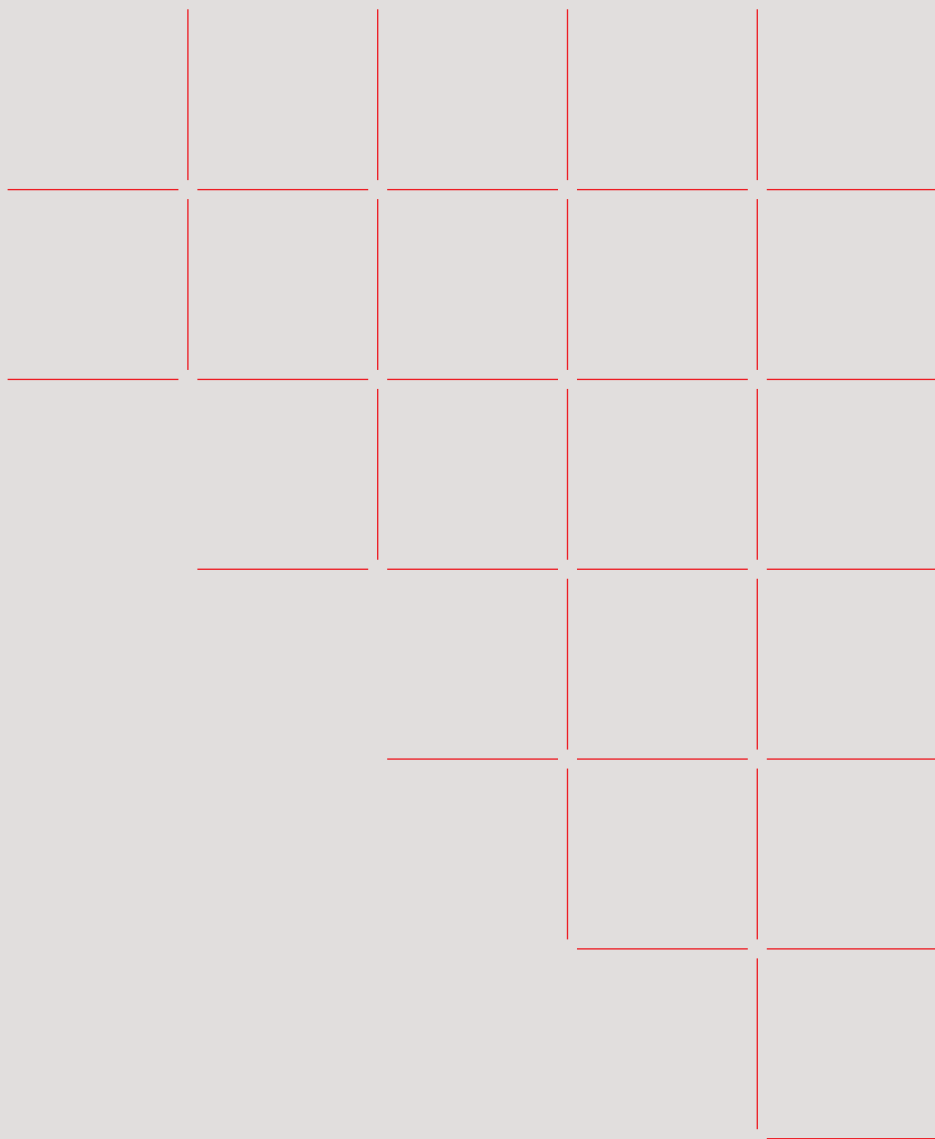




Building trust

The conformity
assessment toolbox

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About IEC

IEC (International Electrotechnical Commission) develops International Standards and operates international conformity assessment services.

IEC is a global not-for-profit non-governmental organization that brings together 174 countries; 89 are members and 85 are Affiliate. (IEC Affiliate countries are developing countries that participate in and benefit from IEC work without having to pay membership fees.)

IEC prepares and publishes globally relevant International Standards for all electric and electronic devices and systems. These standards are the result of international consensus from the broadest possible base of stakeholder groups. They directly respond to the needs of public and private organizations.

More than 20 000 experts representing all user groups cooperate on the global, neutral and independent IEC platform. They ensure that products work everywhere, safely and efficiently, with each other. Although voluntary, IEC standards are widely respected and accepted by public and private sectors internationally.

In addition, IEC operates four third-party conformity assessment systems (IECEE, IECEX, IECQ and IECRE) that provide worldwide global testing, assessment and certifications services for personal competency, components, equipment, systems and services used in homes, offices, healthcare facilities, public spaces, multimedia and IT products, cyber security, supply chain, transportation, manufacturing, medical equipment, industrial components and equipment, explosive environments and during energy generation, transmission and distribution, verification of carbon emission claims, and much more.

www.iec.ch



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 stakeholder bases. Expert input comes from those closest to where the standards are needed and is informed by lessons learned from implementing the standards. For this reason, although voluntary, ISO standards are widely respected and accepted by public and private sectors internationally.

As a non-governmental organization, ISO is a federation of national standards bodies from all regions of the world – one for each country – including developed and developing countries and countries with economies in transition. Each ISO member is the principal standards organization in its country. Members propose ideas for new standards, take part in their development under the coordination of the ISO Central Secretariat, and provide support to more than 3 500 technical groups that develop the standards.

Within ISO, the ISO Committee on conformity assessment (ISO/CASCO) has a dual function. It is responsible for developing and making recommendations on conformity assessment policy and for developing conformity assessment standards.

www.iso.org



About UNIDO

The mission of the United Nations Industrial Development Organization (UNIDO) is to promote and accelerate inclusive and sustainable industrial development (ISID) in member states.

The relevance of ISID as an integrated approach to all three pillars of sustainable development is recognized by the 2030 Agenda for Sustainable Development and its 17 Sustainable Development Goals (SDGs), which will frame the United Nations' and countries' efforts towards sustainable development until 2030. UNIDO's mandate is fully recognized in SDG 9, which calls to "Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation". The relevance of ISID, however, applies in greater or lesser extent to all SDGs.

Accordingly, the organization's programmatic focus is structured in four strategic priorities: 1) creating shared prosperity, 2) advancing economic competitiveness, 3) safeguarding the environment and 4) strengthening knowledge and institutions. Each of these programmatic fields of activity contains a number of individual programmes, which are implemented in a holistic manner to achieve effective outcomes and impacts through UNIDO's four enabling functions: (i) technical cooperation; (ii) analytical and research functions and policy advisory services; (iii) normative functions and standards and quality-related activities; and (iv) convening and partnerships for knowledge transfer, networking and industrial cooperation.

In carrying out the core requirements of its mission, UNIDO has considerably increased its technical services over the past ten years. At the same time, it has also substantially increased its mobilization of financial resources, testifying to the organization's growing international recognition as an effective provider of catalytic industrial development services.

UNIDO has 170 Member States. It is headquartered in Vienna, Austria, but operates worldwide. Established in 1966, it became a specialized agency of the United Nations in 1985.

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Foreword

Businesses, 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 checking the conformity of such products and services against these expectations, in accordance with relevant standards, regulations and other specifications. It helps to ensure that products, processes 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 based on test reports and certificates issued by competent laboratories and certification bodies, thereby giving customers the confidence that their expectations will be met.

That being said, the 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 (WTO) has sought to overcome this problem through three important agreements – the Agreement on Technical Barriers to Trade (TBT), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), and the Agreement on Trade Facilitation (TFA) – which all seek to ensure that technical regulations and standards, and the procedures for assessing conformity with them, do not obstruct international trade.

Successive reviews of the TBT Agreement have noted the usefulness of the conformity assessment standards developed jointly by IEC and ISO in harmonizing conformity assessment practices and as benchmarks for the technical competence of conformity assessment bodies. Use of these standards therefore helps to overcome trade barriers. IEC and ISO also promote the international harmonization of conformity assessment activities and worldwide acceptance of the results of these assessments. In addition, IEC operates worldwide global conformity assessment schemes and systems, that are considered to be world's best practice, and can be used as an integral part of a country's national quality infrastructure. UNIDO, meanwhile, has acquired more than 50 years' experience in supporting the establishment of quality infrastructure institutions worldwide, considering such aspects as standardization, accreditation, metrology and conformity assessment.

Building trust – The conformity assessment toolbox is a comprehensive, user-friendly handbook covering all aspects of conformity assessment and its role in international trade. It will be useful for business managers, regulators and consumer representatives. This second edition reflects the latest developments and versions of standards and requirements related to conformity assessment, while also incorporating new case studies.

This handbook aims to strengthen the understanding of quality infrastructure by developing countries and countries with economies in transition, helping them to achieve the UN SDGs and their associated targets. While specifically aimed at this group of countries, this publication is also intended as a handy reference tool for all who are involved or interested in quality infrastructure, conformity assessment and trade. It is the latest joint publication issued by IEC, ISO and UNIDO, and is the result of a long-standing and fruitful partnership between these organizations.

Acknowledgments

IEC, ISO and UNIDO greatly acknowledge the dedicated work of all those who have contributed to past editions of *Building Trust*.

This publication was prepared under the overall guidance of David Hanlon (IEC), Cristina Draghici (ISO) and Bernardo Calzadilla-Sarmiento (UNIDO).

We extend our grateful appreciation to all the cooperating parties and experts for their participation and support in preparing this publication.

Introduction

Quality infrastructure

Quality infrastructure (QI) is the system comprising organizations (public and private), together with the policies, relevant legal and regulatory framework, and practices contributing to supporting and enhancing the quality, safety and environmental soundness of goods, services and processes.

The QI is required for the effective operation of markets, and its international recognition is important for building trust and free trade. It is a critical element in promoting and sustaining economic development, as well as environmental and social well-being.

The QI relies on:

- Metrology
- Standardization
- Conformity assessment
- Accreditation
- Market surveillance

Reference: INetQI – International Network for Quality Infrastructure

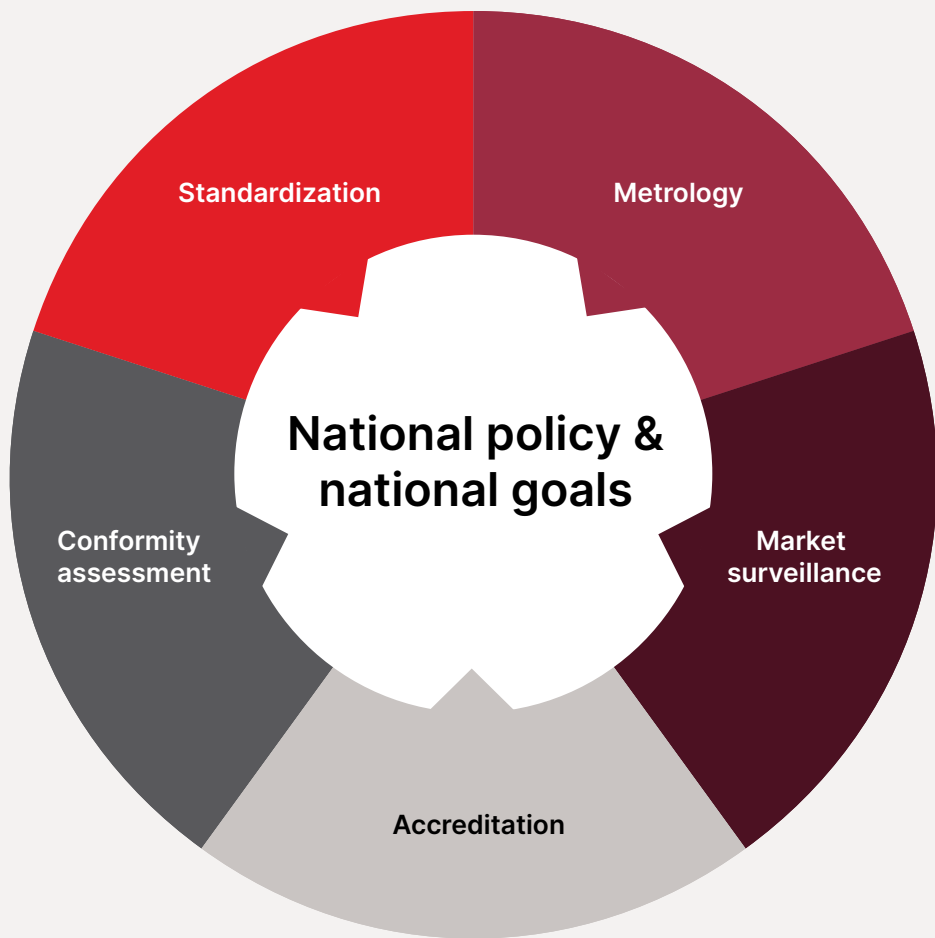


Figure 1: The components of quality infrastructure

The purpose of a national quality infrastructure (NQI) is to achieve certain national goals. Those goals may include safety for citizens, energy performance, protection of the environment, protection of critical infrastructure, fair trade, and so on. Other goals may be economic, for example to improve domestic manufacturing quality and trade facilitation, amongst others.

There are many different NQI models offered by different organizations. Each of those models looks at quality infrastructure from a specific perspective. It needs to be recognized that while none of these models is wrong, none of them are entirely correct. The following are examples of a few NQI models from different perspectives.

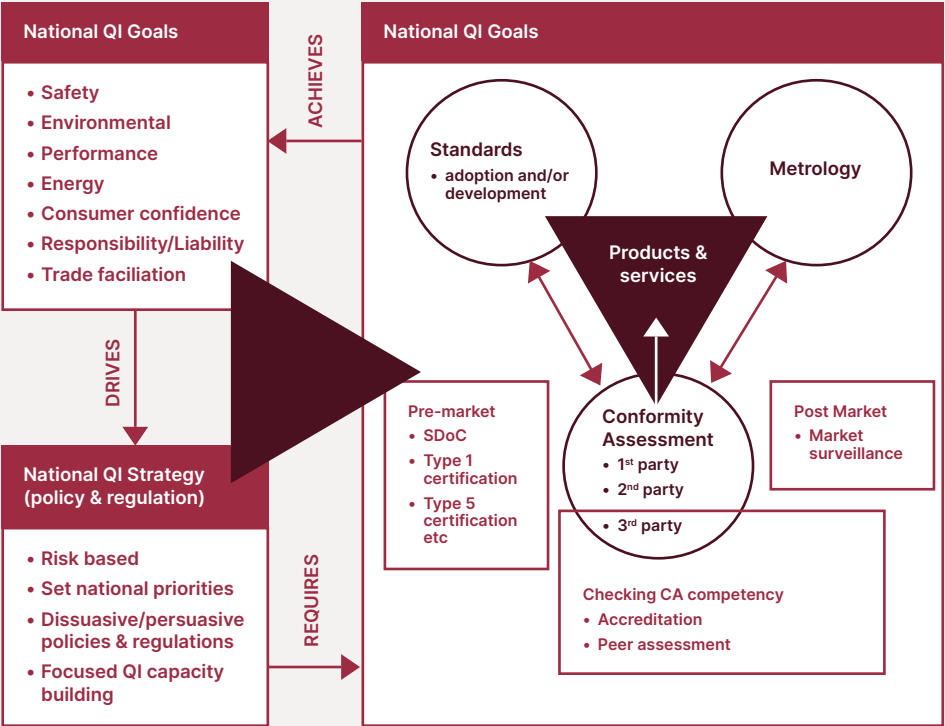


Figure 2: NQI double triangle model from a government perspective

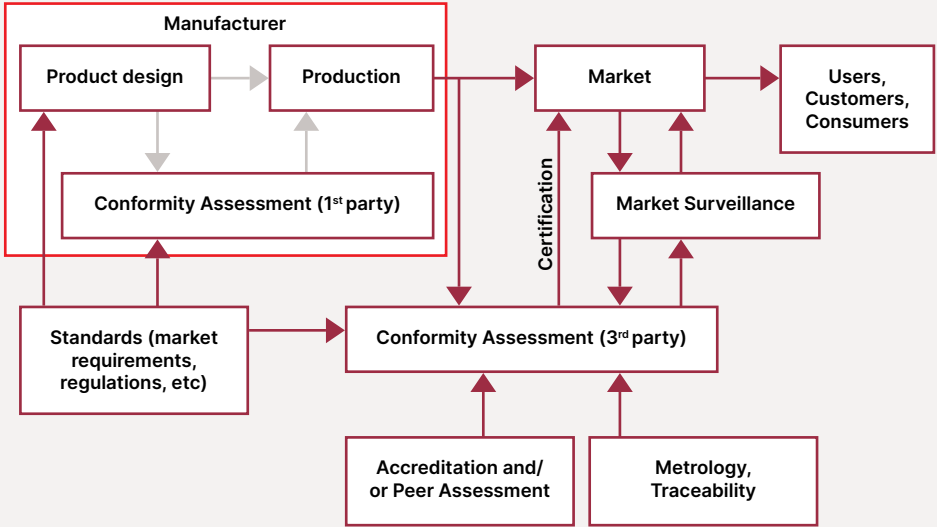


Figure 3: NQI model from a manufacturer's perspective

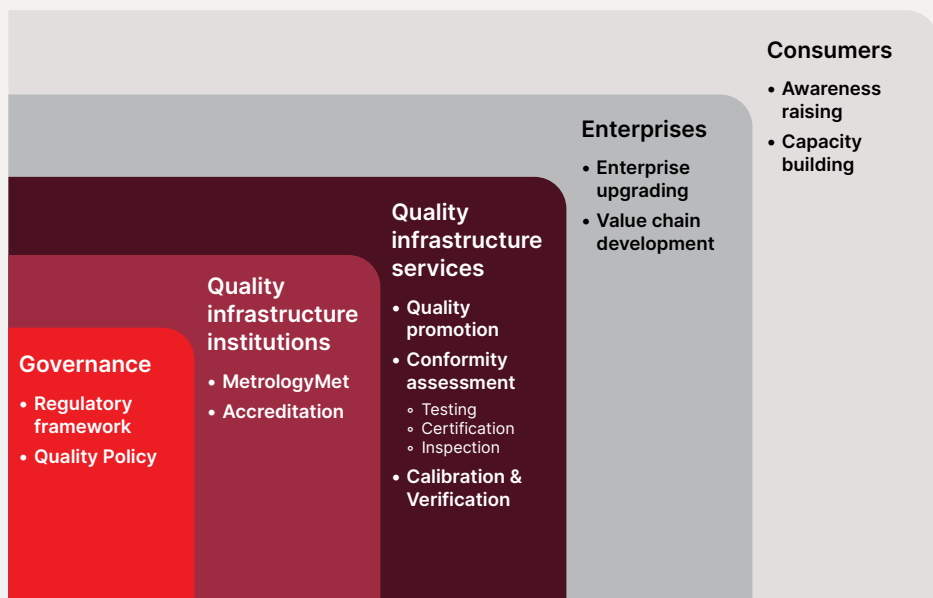


Figure 4: NQI Model from UNIDO perspective

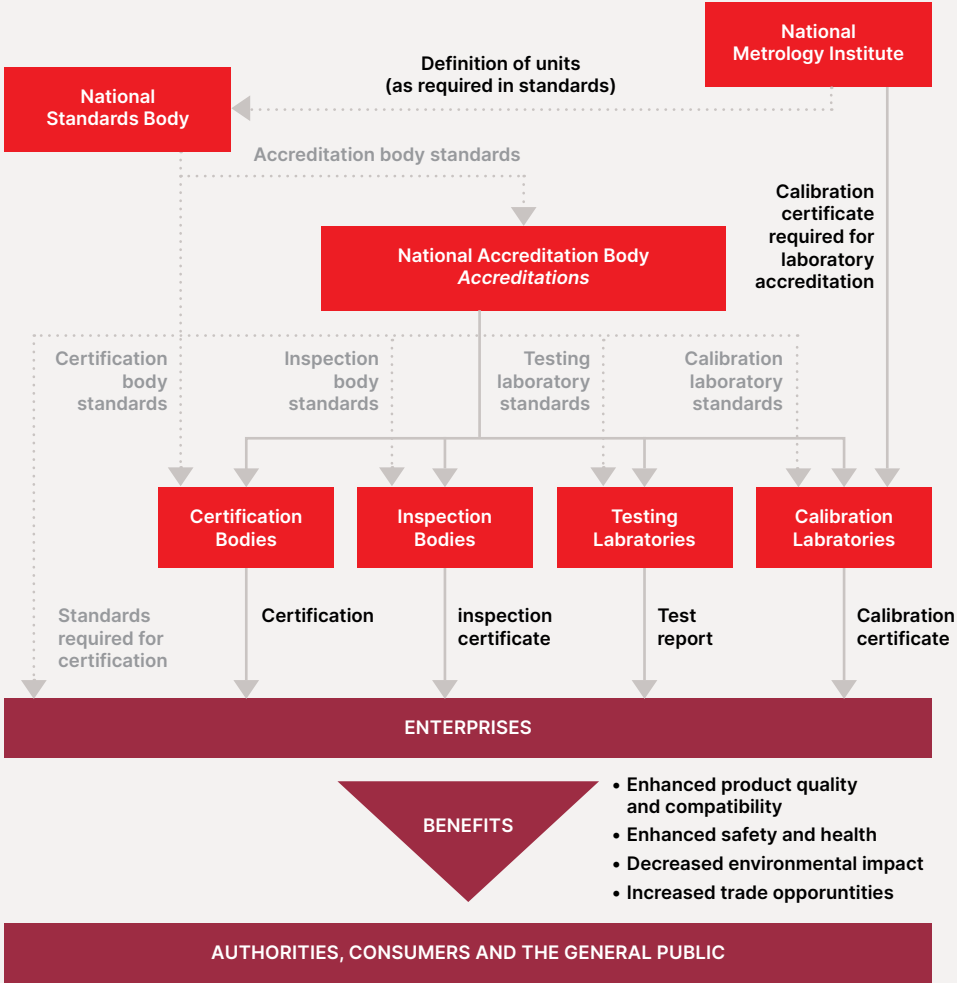


Figure 5: NPI model from World Bank perspective

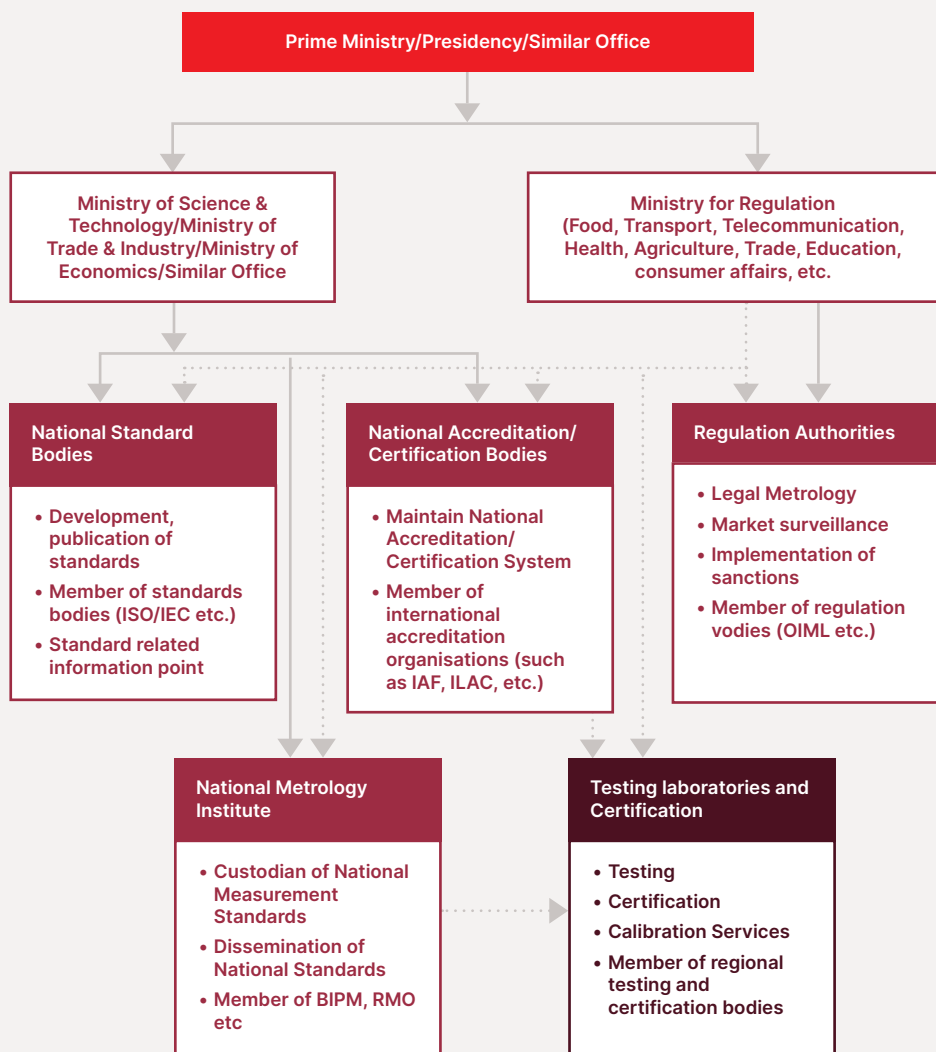


Figure 6: NQI model from a governmental perspective

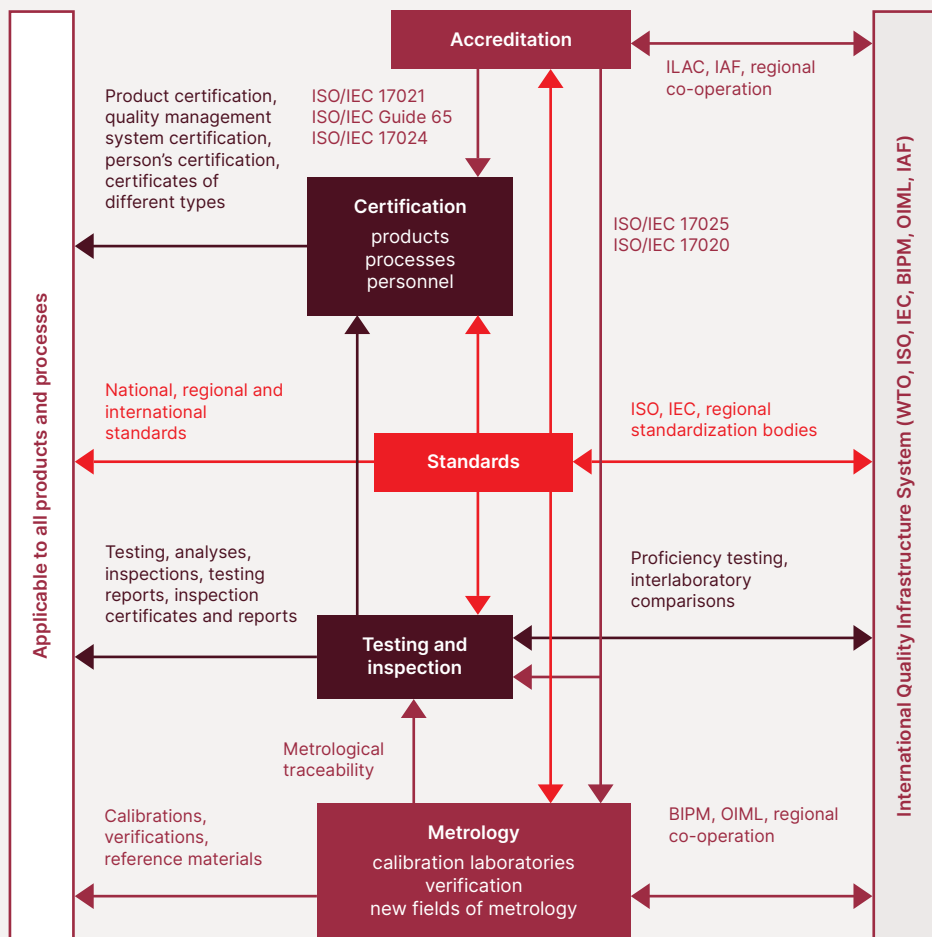


Figure 7: NQI model from an accreditation perspective

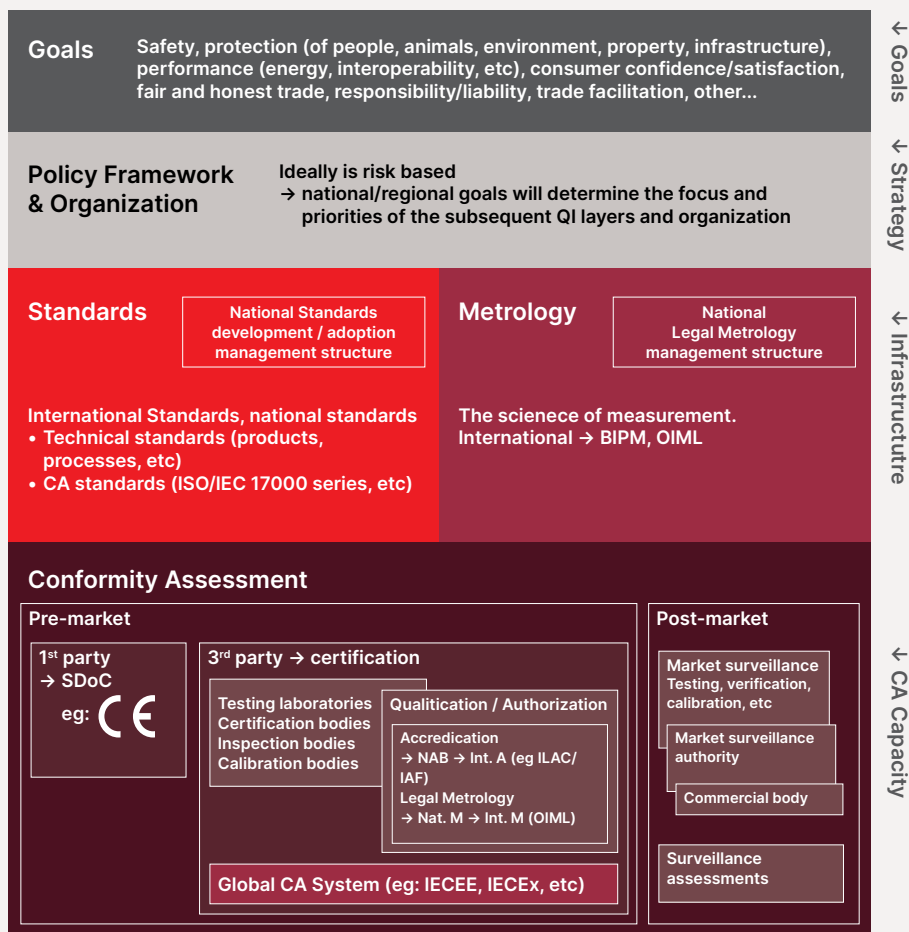


Figure 8: NQI natural flow-down model from national goals

Conformity assessment is fundamental to all economies

The main components of a QI (see [Figure 1](#)) are metrology, standardization, conformity assessment, accreditation, and market surveillance. 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 demonstrate that items conform to the requirements specified in the standards. Accreditation adds an additional level of confidence to these activities.

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

- Demonstrating that products, processes, services, commodities and personnel meet specified requirements. These may include requirements specified under regulations (domestic or foreign), purchasers' requirements or specifications, trade agreements, etc
- Establishing and monitoring appropriate requirements for the protection of health, safety and the environment.
- Underpinning public infrastructure services in construction, energy, water and gas supplies, defence, transportation and communication systems.
- Protecting 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 avoidance and quarantining of harmful commodities, products, pests and diseases from entry into an economy.
- Improving international trading opportunities by reducing technical barriers to trade.

Most societies recognize the domestic benefits of their QI and many have established the appropriate national bodies and international relationships to support their system. However, national systems that are not harmonized regionally or internationally have the potential to introduce new technical barriers to trade. All economies today are increasingly expected to demonstrate, not only to their own citizens but also to the wider world, that the products and services they produce are reliable, safe and socially and environmentally responsible. To achieve this aim, each economy requires an effective domestic technical capability, or access to foreign expertise or global conformity assessment services, to underpin the conformity assessment services in their country.

This publication is intended to help developing countries and those in transition to understand conformity assessment and create an effective infrastructure within their economies. It provides information to assist them in setting up and running conformity assessment arrangements that are efficient, economic and appropriate for their needs.

Chapter 1

Gives an overview of the rationale for, and the benefits of, conformity assessment.

Chapter 2

Outlines the techniques that can be used for assessing conformity.

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.

Chapter 5

Provides information about how UNIDO can help set up and operate a conformity assessment infrastructure as part of a QI. It highlights relevant and current practices and the roles of key organizations that affect the contribution of conformity assessment to economic development and to the international consistency of conformity assessment activities.

Chapter 6

Provides a number of case studies illustrating how the principles outlined in this document can be applied.

Acronyms and abbreviations

Acronym	Abbreviation
A2LA	American Association for Laboratory Accreditation
AB	Accreditation Body
AFRAC	African Accreditation Cooperation
APAC	Asia-Pacific Accreditation Cooperation ¹
APEC	Asia-Pacific Economic Cooperation
APLMF	Asia-Pacific Legal Metrology Forum
APMP	Asia-Pacific Metrology Programme
ARAC	Arab Accreditation Cooperation
BIPM	International Bureau of Weights and Measures
BRC	British Retail Consortium
BSTI	Bangladesh Standards and Testing Institute
CAB	Conformity Assessment Body, or IEC Conformity Assessment Board

¹ APAC was established on 1 January 2019 as a result of the amalgamation of APLAC and PAC.

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
IECEE	IEC global conformity assessment System for Electrotechnical Equipment and Components
IECEX	IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres
IECQ	IEC Quality Assessment System for Electronic Components
IECRE	IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications
IFAN	International Federation of Standards Users
IFIA	International Federation of Inspection Agencies
IIOC	Independent International Organization for Certification Limited
ILAC	International Laboratory Accreditation Cooperation
IPC	International Personnel Certification Association

INetQI	International Network on Quality Infrastructure (previously known as DCMAS)
IQNet	The International Certification Network
IRENA	International Renewable Energy Agency
ISO	International Organization for Standardization
ITC	International Trade Centre
ITU	International Telecommunication Union
ITU-T	ITU's Telecommunication Standardization Sector
UILI	International Union of Independent Laboratories
JDSC	Joint Development Support Committee (IAF and ILAC)
MAA	Mutual Acceptance Arrangement (of OIML)
MLA	Multilateral Recognition Arrangement
MoU	Memorandum of Understanding
MRA	Mutual Recognition Arrangement
NMI	National measurement institute

NQI	National Quality Infrastructure
NQP	National Quality Policy
NSB	National Standards Body
OIML	International Organization of Legal Metrology
OD	Operational Document
PASC	Pacific Area Standards Congress
PT	Proficiency testing
QI	Quality Infrastructure
QIS	Quality Infrastructure System
REMCO	ISO Committee on Reference Materials
RM	Reference material
SADCA	Southern African Development Community Accreditation
SADCAS	Southern African Development Community Accreditation Service
SPS	Sanitary and Phytosanitary Measures
STAMEQ	Directorate for Standards, Metrology and Quality (Viet Nam)
STAR	Strategic Alliance and Regulatory Group (of CASCO)

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
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 (a product, process, system, person or body) 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 such as quality, sustainability, safety, affordability, 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**. Conformity assessment is “assessing conformity” to some requirements. In brief, conformity assessment allows one to verify that products and services deliver on their promises.

Conformity assessment is not something unusual. We all do it almost every day. For example, when we choose an apple at the fruit shop, we look at it, inspect it and choose it according to our personal requirements. This is informal conformity assessment. But for products and services, personal competency, processes and systems, etc, our personal requirements and satisfaction, are not enough. What is needed is formal, consistent and precise conformity assessment. Such conformity assessment benefits all society.

Consumers benefit from conformity assessment because it provides them with a basis for selecting products or services. They can have more confidence in products or services that are supported by a formal supplier declaration, bear a mark or have a certificate of conformity attesting to the 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. Conformity assessment realized in accordance with IEC and ISO International Standards (the ISO/IEC 17000 series) helps them to meet the current state-of-the-art and 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. The ISO/IEC 17000 series of conformity assessment standards also provides requirements for good practice and recognition of such assessments.

Regulators 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 Technical Barriers to Trade (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 IEC and ISO conformity assessment standards and guides, and the IEC global CA Systems. They are instrumental in harmonizing conformity assessment practice and help benchmark the technical competence of assessment bodies. This is fundamental in establishing credibility and confidence in their results and therefore helps to overcome trade barriers.

All countries are dependent on conformity assessment, but many developing countries and countries in transition face 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 increasingly expected by all parties involved in trade

and commerce. This not only includes those directly involved in trade, but also 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 role 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 clients. It is equally important that they invest their often-limited QI resources on developing conformity assessment infrastructure that will most benefit their national goals. This may lead them to make choices in favour of developing national conformity assessment infrastructure to support local industry in a way that will raise quality level to International Standards and therefore create export opportunities. In so doing, however, they may not have the resources to create conformity assessment infrastructure for some imported goods. But, in this regard, there is often the good option to use existing, well established and reputable global conformity assessment services. This is a good option because it doesn't waste limited national QI resources on reinventing local solutions and is therefore a sensible and economical option. See [Appendix 2](#) for more information.

Conformity assessment in the quality infrastructure

As noted in the Introduction, there are five main components of the QI (see [Figure 1](#)): metrology, standards, conformity assessment, accreditation, and market surveillance. Each of these components needs to support the national goals and policies. Quality 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 standards or to choose and adopt existing standards (such as International Standards).
- Access to physical, chemical and biological standards of measurement.
- Provision of a legal metrology service (or access to one).
- Availability of inspection, testing and calibration services at an appropriate level of complexity to meet 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 that 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 (both domestically and/or abroad), such as product certification, to meet the needs of regulatory bodies, and those of suppliers and customers who require some independent confirmation of the conformity of goods and services. Global conformity assessment services are often used for this purpose (see [Appendix 2](#) for more information).
- 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 QI to ensure that regulators' needs are met and that regulations use the infrastructure to provide for the best outcome.

Normally, within the system, there are also organizations dedicated to the development of people and organizations, that are focused on issues related to quality improvement and the development of various conformity assessment tools, for example, quality and management systems auditing.

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 IEC and ISO. 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 setting out current best practice. Produced jointly by IEC and ISO, these standards are developed under the management of the ISO Committee on conformity assessment (CASCO) and form what is known as the ISO/IEC 17000 series of standards, commonly referred to as the “CASCO toolbox” (see [Appendix 1](#) for more information). The relevant standards are referred to throughout this publication.

ISO/IEC 17000 defines conformity assessment as the “demonstration that specified requirements are fulfilled”. The process of conformity assessment can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled. Conformity assessment includes activities such as, but not limited to, testing, inspection, validation, verification, certification and accreditation. The outcomes include testing reports, inspection reports, suppliers’ declarations of conformity, certificates and so on. Specified requirements include those contained in suppliers’ or purchasers’ specifications, national, regional or International Standards or governmental regulations.

Conformity assessment can be applied to product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof. For convenience, within this document, the expression “object of conformity assessment” (or “object of conformity”), is used to refer collectively to any or all of these entities.

Even within the realm of testing, there has been varying opinion on whether some forms of diagnostic testing, such as medical laboratory testing, pathology services or medical imaging fit the formal definition of *conformity assessment*. In practical terms, however, these various activities are part of the everyday world of conformity assessment and are important elements in broader national, regional or international QIs.

Testing laboratories, inspection bodies, medical laboratories, providers of proficiency testing, producers of reference materials, and bodies that certify management systems, products, processes and persons, or undertake verification and validation and so on, are collectively known as conformity assessment bodies (CABs).

While CABs check the conformity of goods and services, people and processes to the requirements of standards, specifications and other regulations, accreditation is used to check the competency and impartiality of the CABs to do that work correctly.

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

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 applied effectively. 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 CABs are discussed later in [Chapter 4](#).

The role of standards in conformity assessment

It is critical that a national QI (NQI) can either choose among existing International Standards or engage in the preparation, publication and distribution of standards at the international, regional or national 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 international, regional or national standards that can be used by suppliers, purchasers, CABs and regulators for setting the requirements for an object of conformity and assessing its conformity with them. ISO/IEC 17007, *Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment*, gives an overview of the essential features of a standard to be used for conformity assessment:

- The standard must be written so 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 form of assessment such as a supplier's self-declaration, or a certification, or an accreditation.
- The scope of the standard should be clearly stated in terms of both the type of objects to which it relates and 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 left to the manufacturer to specify.
- Standards should always be written in such a way that they facilitate and do not delay the development of technology. Usually, this is accomplished by specifying performance requirements such as safety, efficiency, hazardous substance limits, and so on, rather than product design requirements.

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- 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 unambiguous, repeatable and reproducible results, so that outcomes 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 as well as sampling.
 - To the extent practicable and consistent with their objective, the tests should provide results within a reasonable period 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 problems that can arise from differing interpretations of the standard and the different expectations the various parties may have.

Another important feature of International Standards is that they are written in a way that makes them suitable for adoption by many countries. In this regard International Standards need to be written in a way that make them neutral with respect to national laws and regulations. Since many different countries may adopt the same International Standards but apply them quite differently in their local laws and regulations, the standards need to allow this flexibility.

Although standards can be prepared by many organizations, including companies and regulators, it is normally the role of national standards bodies to develop consensus national standards. As such, they take into account the balanced views of all national stakeholders affected by the 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 UNIDO/ISO 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 the development and administration of their national standards bodies and related functions.

The IEC Affiliate Country Programme has a complete programme of e-learning modules which are freely available on IEC Website. Its aim is to increase the understanding and knowledge of specific requirements linked to conformity assessment activities and to communicate the value that can be obtained by developing countries through the use of IEC global Conformity Assessment (CA) services and their involvement in IEC CA activities. These e-learning modules also provide a global understanding of international and national QI.

<https://www.iec.ch/developing-countries>

The **second aspect** of particular relevance to CABs is the availability of standards that set out requirements for best practice of conformity assessment and the bodies that carry it out. These standards are intended to ensure that there are consistent and internationally harmonized practices amongst CABs and the bodies with which they work (such as accreditation bodies). These international conformity assessment standards are the ISO/IEC 17000 series (see [Appendix 1](#)) and are commonly referred to as the “CASCO toolbox”.

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. This is where the value of global conformity assessment services comes to the fore, because global conformity assessment services are conducted by CABs in different countries all over the world, working together, in a team environment, and not only operating as individual bodies. Their conformity assessment results must be consistent across the world, and the global conformity assessment services are designed and organized to achieve this. See [Appendix 2](#) for more information.

It is also of benefit to domestic consumers of products and services if conformity assessment is conducted consistently within economies. That is why the 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, even more importantly, that they 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 requirements and regulations affecting these aspects of our lives are being adhered to, failing which it should be a catalyst for action by the relevant authorities.

Conformity assessment and metrology

Another component of a QI 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. Manufacturing requires consistent and reliable measurements for the interoperability of components, as do measurements associated with traded commodities. 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. For example, product certification often involves testing. Here again, there is a fundamental reliance on capable measurement for certification itself to be reliable. This demonstrates the great degree of interdependence between various types of conformity assessment and between the other components of the QI system.

The international framework for providing compatibility of measurements is coordinated at the country 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 that guarantee 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 may not be available and these need to be accessed 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 CABs and standards, such as:

- Making 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).
- Maintaining 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 International Standards, such as ISO/IEC 17025, ISO/IEC 17020, ISO 15189, etc.).
- Implementing 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.

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- Maintaining a publicly available database of the calibration and measurement capabilities of each of the NMIs in the CIPM MRA. This information is based on key intercomparisons regularly conducted between the NMIs.
 - Providing technical expertise for use in accreditation assessments and often providing reference values and measurement artefacts for measurement and calibration proficiency tests.

Information on the roles and activities of the BIPM is available at www.bipm.org. Information from the key comparisons data base is accessed through www.kcdb.bipm.org

The BIPM is also actively involved in the development of several relevant standards in the ISO/IEC 17000 series and as an A-Liaison member of CASCO.

Legal metrology

In addition to a national standards and conformity infrastructure, the NQI should include a body or bodies responsible for legal metrology. Legal metrology is the practice and the process of applying regulatory structure and enforcement to metrology, and it is taken to comprise all the activities for which legal requirements are prescribed on measurement. It includes prescribed units of measurement, requirements on the use of measuring instruments or systems and methods of measurement, and activities performed by or on behalf of governmental authorities, in order to ensure an appropriate level of confidence in measurement results in the national regulatory environment. Legal metrology includes the regulation of measurement devices used in daily commerce to ensure fair trading practices. Examples include weighing instruments, systems for delivering fuels, meters for measuring utilities such as water, gas and electricity, etc. It also embraces the regulation of package sizing for retail items.

However, it has a much wider application beyond trade measurement in many economies, dealing with other forms of measurement that may have a legal or regulatory basis, such as measurement for health, safety and environment.

The international forum for legal metrology is the International Organization of Legal Metrology (OIML). The OIML is an “International Standard-setting body” in the sense of the TBT Agreement, and the OIML and its member bodies also have a number of conformity assessment roles and interactions, including:

- Undertaking type approval of measuring instruments used in legal metrology applications. Essentially, these national or regional type approvals are a device-specific form of product certification. This requires the testing and evaluation of measuring instruments against specific metrological and technical specifications (often with some national variations). These specifications are typically derived from those detailed in applicable OIML International Recommendations which are intended as model regulations.
- Developing its own mutual recognition arrangement to reduce the need for repeat testing of measuring instruments. This arrangement is called the OIML Certification System (OIML-CS) and is intended to facilitate acceptance of OIML certificates and/or type evaluation reports as the basis for issuing national or regional type approvals.
- Under the OIML-CS, OIML Issuing Authorities demonstrate their competence through compliance with ISO/IEC 17065 or ISO/IEC 17020 (with additional requirements), and test laboratories demonstrate their competence through compliance with ISO/IEC 17025. Compliance is determined through the use of either accreditation or peer assessment.

Information on the OIML is available at www.oiml.org

The Website provides detailed information on the OIML-CS, and also provides details of the OIML Advisory Group on matters concerning countries and economies with emerging metrology systems (CEEMS)

Conformity assessment and regulations

A NQI system is established to achieve national goals such as safety for citizens, energy performance, protection of the environment, protection of critical infrastructure, fair trade, improvement and development of domestic manufacturing quality and to facilitate export, and so on. The goals, and how they will be achieved, are written into national policy which can then be enacted through regulations, laws, voluntary programmes, incentive programmes, and other mechanisms.

One such mechanism is technical regulations which are a feature in most economies and have some direct or indirect interaction with both standards and conformity assessment. While most technical regulations are country-specific, there are some regulations that are multinational in nature. European Directives and regulations, for example, often contain technical regulations that are applicable in all the Member States of the European Union.

Often, technical regulations include compliance with a national or International Standard, technical specification or code of practice, but may contain additional requirements set by the regulator (such as product labelling specifications). In addition, some technical regulations 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.
- Essential technical requirements that must be satisfied – often through specification of one or several standards.
- Conformity assessment requirements.
- A procedure for how compliance with requirements will be assessed (alternative conformity assessment arrangements allowed on occasions).
- 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.

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- Labelling and marking requirements – such markings may be different to the marks of conformity issued by the CABs.

Clearly, conformity assessment is a fundamental activity in the 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. This is where the recognition and acceptance of conformity assessment results from global conformity assessment services can be very beneficial for developing countries (see [Appendix 2](#)). This is essentially a free-of-cost tool that can be used by regulators to obtain justification to claims of compliance from foreign suppliers. Since this tool is endorsed by the WTO, a country that implements regulations that require certification issued through a global conformity assessment service, will always be free of accusation of implementing technical barriers to trade.

The ISO/IEC brochure “[Using and referencing ISO and IEC standards for technical regulations](#) (ISBN 978-92-67-10633-5)” provides practical advice for regulators on how to use International Standards and conformity assessment to achieve their objectives. It can be found on the ISO Website.

Additional resources: “Conformity assessment tools to support public policy” that can be found on the CASCO Website:
www.casco.iso.org/conformity-assessment.html

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 or simply use the results of global conformity assessment services. This task is made easier if CABs operate under internationally agreed standards, and confidence is achieved if the CABs are independently assessed for their competence through a process of accreditation and/or peer assessment. Additional confidence is achieved when those CABs participate in a global conformity assessment

scheme or system, where the consistency and comparability of the conformity assessment result from different CABs is assured. See [Appendix 2](#) for more information.

These mechanisms to increase consistency and reduce technical barriers to trade are highlighted in the TBT Agreement (see [Appendix 4](#)). 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 may add considerable extra costs to exporters and importers and place additional responsibility on CABs to be aware of each of the variations of 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 is benefit to be gained, for the national economy, from a systematic approach to the development of a national or regional QI that includes conformity assessment. The QI can help to promote international best practice in all fields where it is applied and can improve the economics of agriculture, manufacturing, distribution and trade. 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 specifications in terms of quality, reliability and performance builds trust and avoids misunderstandings and unexpected consequences that lead to a 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 International Standards. It is also worth stressing that 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 this respect, the level of risk associated with the goods or services, or with their application, will have a role in determining the level of conformity assessment activities. Higher risk will call for stronger conformity assessment by independent third parties.

In the case of voluntary transactions, such as business-to-business transactions, the parties concerned 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, or those where a higher level of risk is associated with goods or services, third-party conformity assessment providers may be called in to provide unbiased and factual assurances to both parties. In many developing countries, the use of third-party conformity assessment providers has become a necessity in practice, often owing to an absence of strict product liability legislation.

Technical regulations can govern the transaction and the decision as to the means of conformity assessment to provide proof of conformity in a prescribed format. This in turn 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 CAB, conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities”. Accreditation can relate to competence in the performance of tests and calibrations in laboratories, or to the competence of certification and inspection bodies. CABs such as testing or calibration laboratories can test goods and services. In turn, the competence of CABs is verified by accreditation bodies.

Accreditation bodies themselves need to show that they are independent and unbiased. For this reason, they are often established as national or regional entities that participate in relevant international bodies engaging in peer reviews of each other and exercising a mutual recognition agreement.

In the accreditation sphere, two key international groups are the International Laboratory Accreditation Cooperation (ILAC) and the International

Accreditation Forum (IAF), both aiming to facilitate international trade through enhanced confidence. For more details on IAF and ILAC, see [Appendix 3](#).

Developing countries often do not have the resources or the expertise to establish national accreditation bodies, as the level of economic activity may make it unprofitable for third-party conformity assessment providers to operate exclusively in their territory. Similarly, developing countries often do not have the resources or expertise to establish testing laboratories for all sectors. It is therefore of strategic importance for them to evaluate in which sectors their limited resources should be invested so as to develop relevant expertise.

One of the major decisions for a developing country 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. Every country is different and therefore requires a tailored solution that will suit its circumstances.

An additional option is to take advantage of global conformity assessment services by recognizing and accepting their conformity assessment results. This is a strategic choice of high value due to the low (no) cost involved and the high quality of those conformity assessment results. This option frees-up national resources to be used elsewhere in the national QI system. See [Appendix 2](#) for more information.

The ISO/IEC 17000 series of standards (see [Appendix 1](#)) can be used to provide the basis of a QI that is effective, tailored to the specific needs of the country concerned and 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 specific conformity assessment activities (or their supporting infrastructure bodies) are justified. In this respect the recognition and acceptance of conformity assessment results from global conformity assessment services can be very beneficial for developing countries. This recognition puts no charge on the national resources and is endorsed by the WTO. See [Appendix 2](#) for more information.

The TBT Agreement 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 WTO are required to adhere to the TBT Agreement.

The TBT 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 the TBT Agreement, see [Appendix 4](#).

Conformity assessment needs of developing countries and countries in transition

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 CABs.

Of course, developing countries also have special circumstances that require careful consideration of the most effective use of limited resources. The effective use of limited resources means first identifying the primary national needs, and then focusing the capacity-building efforts on those needs. It also means identifying secondary national needs, and looking for other, lower cost solutions to satisfy those. In this case the use of transnational, regional and global solutions should be considered. It is always a lower cost option to use existing services, than to duplicate services, certainly when those services are considered to be of secondary strategic importance to the NQI.

When primary sectors have been identified that require testing laboratories, it is also important to note that they 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.
- Reference materials and certified reference materials (CRMs).

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- Proficiency testing services.
 - Equipment repair and maintenance expertise.
 - 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.
- A national metrology infrastructure.
- Membership of multilateral MRAs at either the regional or international level.

Within a developing country, there may also be need 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 institutes and accreditation bodies. Additionally, UNIDO and other international bodies, such as BIPM, IAF, IEC, ILAC, ISO and the OIML and their associated regional bodies, have implemented a number of training and awareness-creating 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 require 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:

- Use existing global conformity assessment services where appropriate. This may entirely avoid the costs of some of the following points in specific market sectors.
- Attachment training abroad of personnel at well- established conformity assessment and supporting bodies, such as accreditation bodies.
- Mentoring or 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 example of this approach (to pooling scarce resources between countries) has been the establishment of the Southern African Development Community Accreditation Service (SADCAS), which provides 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.

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- Facilitating access to repair and maintenance expertise for equipment.
 - Facilitating use of established foreign conformity assessment and accreditation bodies, where justifiable.

This final approach (direct use of foreign conformity assessment and related services) is also a matter requiring judgment 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 QI that can be helped by cooperation between accreditation bodies within IAF and ILAC.

When making the choice of which approach or which combination of approaches to adopt, it is important to consider the advice from the WTO. The TBT 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 use of international systems. See [Appendix 2](#) for more information.

Having established that conformity assessment has much to offer in facilitating economic development, the next chapter will examine the various techniques available to those involved in implementing a national or regional QI.

Chapter 2

Conformity assessment techniques

Introduction to conformity assessment techniques

In this chapter, we will look more closely at the techniques that can be used in conformity assessment and draw attention to the relevant tools in the ISO/IEC 17000 series of standards (CASCO toolbox) mentioned in [Chapter 1](#). One characteristic of conformity assessment is that it can take different forms, using different techniques according to the purposes for which it is being used. The information provided here, which is not exhaustive, sets out the main techniques in current use.

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 done by the manufacturer or 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 system for managing competence (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. In fact, as discussed in [Chapter 1](#), conformity assessment can be undertaken by various stakeholders, including the supplier of a product or service, its purchaser or end-user, as well as other parties that might have an interest in the object of conformity, such as insurance companies and regulatory authorities. It is convenient, when talking about conformity assessment, to refer to the parties as follows:

- **First party** – the person or organization that provides or is the object which is being assessed.
- **Second party** – a person or organization that has a user interest in the object.
- **Third party** – a person or organization that is not the provider of the object and has no user interest in the object.

In general, the conformity assessment techniques described in this chapter can be carried out by a first, second or third party. The decision as to which party should carry them out is addressed in [Chapter 3](#).

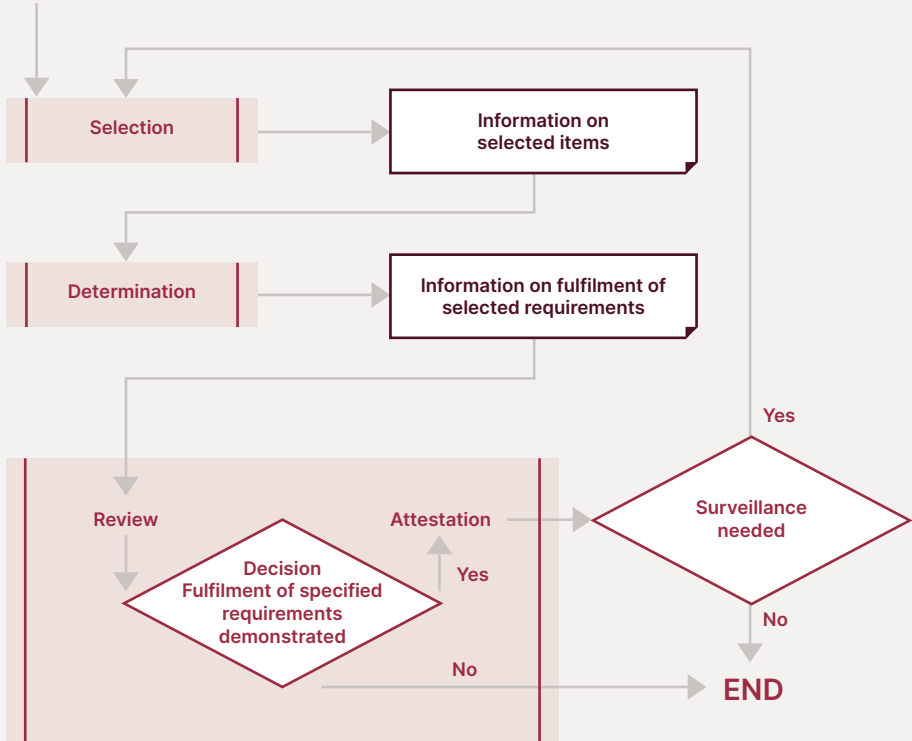
Functional approach to conformity assessment

ISO/IEC 17000 sets out the “functional approach” to conformity assessment. The functional approach involves the following functions:

- Selection
- Determination
- Review, decision & attestation
- Surveillance when required

Each function involves certain activities as described below, the output from one function being the input to the next. [Figure 3](#) shows an outline of the functional approach.

NEED TO DEMONSTRATE FULFILMENT OF SPECIFIED REQUIREMENTS



KEY



Shape A
conformity assessment function



Shape B
output form a function or input to the next function



Shape C
decision point

Figure 9: Functional approach to conformity assessment

The activities carried out in each function 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 sampling techniques, if applicable.

Determination

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

Review, decision & 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.
- Deciding whether fulfilment of specified requirements has been demonstrated or not.
- 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.
- Deciding whether fulfilment of the specified requirements continues or not to be demonstrated.
- 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 functions 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 product 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 apply or 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 applied or developed to conduct determination activities. It may be necessary to select the proper locations, conditions or 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 3](#), all the information, samples (if sampling is used), decisions and other output from the selection function are represented as “information on selected items”.

Determination

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

Testing, inspection, audit, validation, verification, peer assessment are types of determination activities that can be used within a “system” or “scheme”. Thus, a “peer assessment system/scheme” is a conformity assessment system/scheme that includes peer assessment as a determination activity to qualify participants into the system or scheme. For example, peer assessment is used within ILAC/IAF to qualify national accreditation bodies to the various mutual recognition agreements operated by the two organizations. IEC also uses peer assessment to qualify testing laboratories, certification bodies, and other CABs, into its CA Systems and schemes.

Some 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 3](#), 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 daily around the world.

Testing is the most common conformity assessment technique 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”

It should be noted that the “standards” referred to here are measurement standards traceable to the SI units of measurement, e.g. mass and length, not documents that 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 the elements essential to the conduct of testing for conformity assessment:

- Competent people.
- Validated methods that are repeatable and reproducible.
- Properly maintained and calibrated equipment.
- Measurements that are traceable to the SI standard units of measurement.
- Sampling and handling of test items.
- Reporting of test 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 IEC 60335-1, *Household and similar electrical appliances – Safety – Part 1: General requirements* 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 IEC 60335-2-15, *Household and similar electrical appliances – Safety – Part 2 -15: Particular requirements for appliances for heating liquids (such as electric kettles, coffee machines and so on)* or ISO 15012-2, *Health and safety in welding and allied processes – Requirements, testing and marking of equipment for air filtration – Part 2: Determination of the minimum air volume flow rate of captor hoods and nozzles*.

On occasion, the requirement's standard might simply give a value for a particular characteristic, such as mass or energy efficiency, without specifying the method by which the characteristic is to be determined. In such cases, each testing laboratory would need to decide on the method to be used, following good laboratory practice.

In other cases where the testing methodology is not adequately specified, or is written in a way that allows somewhat different interpretations, the conformity assessment results from different testing laboratories within a country, or from around the world, can vary. In this case a global conformity assessment scheme or system adds value by ensuring consistent and comparable conformity assessment results no matter from which participating CAB the results come from anywhere in the world. See [Appendix 2](#) for more information.

Inspection

Inspection is a form of conformity assessment with 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 still other inspection is a stand-alone activity without any relation to testing or certification.

The ISO/IEC 17000 definition for inspection is:

“examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgment, with general requirements”

The requirements for inspection bodies are specified in ISO/IEC 17020 and are discussed in more detail in [Chapter 4](#). Looking 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 findings with the requirements of specification documents or with generally accepted good practice in the field.
- Drawing up of a report on the results of the inspection.

One of the key phrases in the definition of inspection is “on the basis of professional judgment”. 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. As indicated above, this can be a source of variation in conformity assessment results.

For some types of inspections, there may be specified requirements for the competence 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. A good example of this is the IEC global conformity assessment services for the explosive environments. IECEx operates a global conformity assessment system which includes three conformity assessment schemes that cover equipment used in explosive environments, services for maintenance and refurbishing, and personnel competencies certification. It is essential that inspection staff working in explosive environments, such as mines, oil refineries, gas works, refuelling stations, airports, and so on, are appropriately trained, competent and provide consistent comparable results.

Another example is the IECQ global supply chain certification service that uses professional inspection bodies and associated testing laboratories to regularly test, inspect, audit and assess suppliers' processes and specific products or batches to ensure their supply capability. In this case, the inspectors must be competent in the context of the ISO/IEC 17000 series standards and competent in additional scheme requirements in order, again, to achieve consistent and comparable results.

Inspection also covers a very broad spectrum of sectors and characteristics being inspected. It may, for instance, cover cargo-superintending of commodities and products for determination of quantity, quality, safety and fitness for use; compliance of plants, installations and 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 instance, 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

The ISO 9000 and ISO 14000 series of standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organization's quality and/or environmental policy. Audits are also an essential part of conformity assessment activities, such as certification, and of supply chain evaluation and surveillance.

ISO 19011 provides guidance on auditing and defines audit 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 under audit as meeting their needs, including the implementation of management system standards such 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. In larger organizations, a more robust demonstration of independence may be needed.

External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, its products or services, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent 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, or a unified audit. A typical audit process should consist of the following:

- Identifying 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.

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

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

Validation and verification

Validation and verification as conformity assessment are understood to be a confirmation of reliability of information declared in claims. Both activities are distinguished according to the timeline of the assessed claim. Validation is applied to claims regarding an intended future use or projected outcome (confirmation of plausibility), while verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

Evaluation

Evaluation is the term used in ISO/IEC 17065 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 that wish to be able to accept each other's conformity assessment results.

Peer assessment is used, for example, by certification bodies in the global IEC CA Systems (see [Appendix 2](#)) or as members of IQNet, and by accreditation bodies in ILAC and IAF. IQNet is a network of mostly national certification bodies that share a global mutual recognition brand for management system certificates. The members of IQNet peer assess each other on a periodic basis.

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. However, since all members participate in the assessment of their peers, and are similarly subject to assessment by their peers, any impartiality can be quickly identified and consequences can be suspension or expulsion from the group. Although peer assessment schemes need to be well managed in order to maintain effectiveness, they are very effective in inspiring confidence in the work of their 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 other's organizations.

Accreditation

Accreditation is a conformity assessment activity specifically related to the assessment of the conformity of CABs 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, but 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 that 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 that has been assessed.
- A statement of the requirements to which conformity has been assessed.
- Details of the determination activities that have been carried out, such that it would be possible to repeat the activities in the same manner if it were 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, decision & attestation

In the functional approach, review, decision and attestation are presented as a combined function. It is possible, though, for different people to carry out each of them. What is important is that neither function should be carried out by a person who has been involved in the determination function. 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 first-, second- or third-party activity, the one or more persons conducting the review have the competence to understand the information presented to them and to analyse 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 functions 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 third-party attestation schemes, the body may only perform the review and attestation with the selection and determination having already been carried out, either by another third 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 that 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 have 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 second- or third-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 that 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 first party, e.g. the supplier of a product, or a second 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 third-party body, which are known as “certificates”.

ISO/IEC 17050-1 and ISO/IEC 17050-2 provide information on the content of a supplier's declaration of conformity. A declaration by a second party could take a similar form.

Certificate of conformity

A statement of conformity issued by a third 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. For example, the term “certificate of test results” is correctly used following an ISO/IEC 17067 Type 1 assessment, while a “certificate of conformity” is the correct term following a Type 5 assessment. The related ISO/IEC 17000 series of standards referred to in [Appendix 1](#) provides information on the nature and content of the conformity statements.

Mark of conformity

It is common for products to bear a Mark of conformity. These could be the supplier's own trademark, a certification Mark controlled by a certification body, a certification mark controlled by a global conformity assessment system (CA System), such as the IECEx Mark. A Mark of conformity should not be confused with a “marking”, such as the European Union's CE marking, which is a first-party marking and is required by legislation. Requirements and guidelines on Marks of conformity are contained in ISO/IEC 17030. Marks of conformity must be distinctive, and their ownership and conditions of use should be clearly stated. The use of a Mark should not be misleading to purchasers and users of the products. For example, a supplier that 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 in 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 a product are verified by the licensing body. See [Chapter 3](#) for more information on different conformity assessment systems.

There is a significant difference between a Mark and a marking. A marking is usually owned by an authority, but conditions for its use are often very different than for those of a Mark. Often a supplier can apply a marking to

their products or services based purely on their own declaration that they have fulfilled the requirements pertaining to the application of the marking. There are usually no licensing agreements or fees, and it is the supplier who is responsible for ensuring that the products or services actually comply with the requirements of the marking. In this situation, where there is no independent confirmation that the requirements have really been fulfilled, market surveillance becomes an essential part of the QI.

Surveillance

Conformity assessment can end when attestation is performed. However, 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. Users may demand ongoing demonstration that specified requirements are fulfilled; for example, when a product is produced continuously. Or, an object of conformity assessment may change over time, which could affect its ability to fulfil specified requirements.

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 3](#) during surveillance may be reduced, or different, from the activities undertaken in the initial assessment.

Selection activities take place both in 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 an accreditation surveillance assessment.

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 3](#) leads to a decision on 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. In a situation where the statement resulting from attestation in surveillance continues to be valid and there are no special actions required, then there is no need for the decision to be taken by an independent person and the audit team can make the decision themselves.

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 this case market surveillance is a post-market activity, where the goods and services are already available on the market.

In many countries, the regulatory authorities have a responsibility for protecting consumers and enforcing the health and safety regulations by carrying out market surveillance. An example is the CE marking in Europe. In this case, the CE marking is applied by suppliers under their own

responsibility. Once the product displays the CE marking, it is then eligible for sale within the European Union market. To ensure that these products do not endanger European consumers and workers, samples are taken from the marketplace and tested to ensure they do meet the requirements, and any issues are reported online to the European Rapid Alert System (RAPEX). 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 guide to good practice: principles and practices in product regulation and market surveillance* (ISBN 978-92-67-10594-9) was developed by ISO to assist regulators and market surveillance authorities and is freely available from the ISO Website.

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 prevented from happening again 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, injury or even death.

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 that owns the object of conformity 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 ISO/IEC 17000 series (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.

First, second and third parties

– roles and responsibilities

In order to identify the parties that might be involved in conformity assessment, it is useful to refer to first, second and third parties, as described 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 that 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. First-party conformity assessment is where most conformity assessment is done. To assume their primary responsible role, manufacturers and suppliers must be sure of their own products and services. They may also use third party conformity assessment, but they will always do their own conformity assessment first.
- 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).

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 the alternative approaches. 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 laboratory staff, inspectors, and so on.

For larger companies with greater resources it is generally more cost-effective to perform first-party assessment themselves. However, for other companies it can be more cost-effective to contract out the conformity assessment work to a third party. This is a commercial decision by the supplier.

If an independent body (a CAB) is contracted to carry out conformity assessment, the CAB will need to recover its costs. In the case of product certification, it is usually the supplier who will engage and pay the CAB. (These costs will then be recovered by the supplier from the purchaser of the product(s) or service(s), for example, consumers).

The independent body's costs will not only relate to the assessors involved in the assessment work, but also all the expenditure incurred in running its business, a proportion of which will be charged to each certification customer.

In some situations, a supplier has no choice whether or not to use an independent CAB, because either there is a national requirement to demonstrate compliance through a third-party certificate before goods can be placed on the national market, or it is the market, itself, that demands a certificate.

In other situations, a supplier will choose to pay for third-party conformity assessment to obtain a certificate for their products even when this is not required. This is often the case when a supplier enters a market for the first time and where their brand is unknown. For an unknown brand, this is a marketing decision.

In yet other situations, a supplier may choose to seek third-party confirmation of their own conformity assessment results, in order to manage risk. Having a certificate is independent proof that their product is conformant with the standard. Therefore, if an incident occurs involving their product, they can limit their liability by showing that they have independent proof of conformity with the standard.

In summary, the benefits of third-party 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.

Definition of schemes and systems

Before looking in detail at the activities of the different parties, it is useful to introduce the concept of conformity assessment schemes (sometimes referred to as programmes) and conformity assessment 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.

Generally speaking, a conformity assessment system is a system of conformity assessment schemes. A conformity assessment system uses a common set of rules, procedures and management principles 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.

A conformity assessment system could be operated within a single certification body, certainly if the certification body is large with multiple laboratories in multiple countries. In this corporate situation the single certification body can impose its common operational practices on its own sub-entities.

A conformity assessment system can also be operated by an independent body or organization that has no laboratories itself, does no testing itself and does not issue certificates itself. In this situation the system owner creates an organizational and managerial framework into which multiple different certification bodies and laboratories come to operate. In this context they operate within the system as a team of individuals. Within the team context they themselves discuss and develop the common scheme and system rules. They then allow themselves to be peer assessed to demonstrate their competence and that they follow the common rules. At the same time, they will also be carrying on their conformity assessment activities as individual entities, to their own customers. This is how the IEC global CA Systems operate (see [Appendix 2](#) for more information).

ISO/IEC 17000, *Conformity assessment – Vocabulary and general principles*, contains definitions for the terms “conformity assessment schemes” and “conformity assessment system”.

Sector schemes

Most conformity assessment schemes will be developed by and used in a particular sector of industry or commerce. 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, it could be advantageous to set up a scheme for each sector.

Another important factor in the definition of sectors is the element of risk. The products or services in a sector may be dangerous in themselves, or applied in a dangerous situation. For example, a pump can be used to pump water or flammable fuel. The conformity assessment scheme needs to be adapted to the application and the sector use of the product.

For sector schemes, it is also essential that they be market driven, and that they create market value. The best sector schemes are those that the market itself chooses to support. Schemes can be mandated through laws and regulations, but unless value is created there will always be resistance to their use.

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.

Scheme owner

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

- 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.
- A scheme could be developed by a certification body for the 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 then be the scheme owner.
- An organization such as a regulatory body, a standards 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 CABs. (The IEC CA Systems are an example of this. See [Appendix 2](#).)

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 were found necessary to operate several schemes that use 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. (The IEC conformity assessment systems are an example of this. See [Appendix 2](#)).

In some sectors, it has been found useful to operate a single system that supports a single scheme whereby one single set of standardized operating rules and procedures is developed. These are then applied by all conformity assessment bodies that have been approved by the system to participate.

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 that could arise from nonconformity, looked at from the point of view of both the likelihood and the consequences of the product or service 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 or damage to the environment, etc, that are of concern.

Conformity assessment costs money and takes time. The amount of money and time being spent on it needs to be balanced against the risks of nonconformity. It also needs to be balanced against what the market will accept, in terms of cost versus acceptable risk level. 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, or its application is in a higher risk sector, and therefore the risks of nonconformity become higher, conformity assessment activities will become more extensive, possibly involving expensive test equipment and extended testing programmes.

Where the risks of nonconformity 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 such as a certificate. The certification body will charge for its services and will need 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 that meets the scheme's requirements.

Where the consequences of nonconformity are high, for example, in the case of high-risk products or products used in high-risk environments where failure could cause harm or injury to humans or animals, damage to the economy, infrastructure, assets or the environment, stronger forms of conformity assessment are needed. In such cases, first-party self-declaration is not sufficient, and even ISO/IEC 17067 Type 1 third-party certification is generally not enough, but rather a Type 5 certification scheme is needed.

One effective way of managing exposure to risk is for the scheme owner to ensure that the relevant standards from the ISO/IEC 17000 series relating to their scheme have been met.

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, share assessment facilities by a group of purchasers or 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 may find it useful to introduce specific conformity assessment arrangements in order to provide assurance that legal and regulatory 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 inspection or certification schemes being introduced where the risks are highest.

Setting the “specified requirements” – standardization

When specifying the requirements to which conformity is to be assessed, there are many benefits in using International Standards. International Standards represent the current collective wisdom of those involved in a particular technical area, so users of these standards can apply well tried-and-tested solutions. Products that are designed according to the requirements of International Standards interoperate better with others and will gain acceptability on world markets more readily. They are also likely to be more affordable because of the economies of scale manufacturers are able to achieve when an International Standard is adopted by many countries. The UNIDO/ISO publication *Fast forward – National Standards Bodies in Developing Countries* provides information and advice on standardization. The WTO also recommends national adoption of International Standards to avoid risks related to the creation of technical barriers to trade.

Supplier's declaration of conformity

As the term suggests the supplier's declaration of conformity, or SDoC, is a declaration issued on the responsibility of the supplier or the manufacturer. The supplier may issue the declaration following the results of their own first-party conformity assessment, or based on a third-party test report or certificate.

The supplier's 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, trademark or logo on, or in conjunction with, the product implies that it conforms to the supplier's specification. ISO/IEC 17050-1 and ISO/IEC 17050-2 set up requirements on the content of a supplier's declaration of conformity.

Independent (third-party) conformity assessment

Where the risks of nonconformity are considered to be high, an independent body (third party) could be involved in the conformity assessment. The decision to provide for, or require, third-party conformity assessment needs to be accompanied by a careful selection of the criteria that will be used to judge the suitability of third-party CABs. It is recommended that the ISO/IEC 17000 series of standards (See [Appendix 1](#)) is used for this purpose.

Product certification schemes

ISO/IEC 17067 describes seven types of product certification schemes, while noting that the elements in those schemes can be combined in other ways to create additional scheme types. The features of the seven schemes described in ISO/IEC 17067 are as follows:

Type 1a scheme (based on type testing)

- Selection of product samples in accordance with the sampling provisions of the scheme.
- Determination of the relevant product characteristics by testing (ISO/IEC 17025) or assessment.

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- Review of the test or assessment report.
 - Attestation of conformity.

In this scheme, one or more samples of a product type are subjected to testing or assessment. A type certificate or other statement of conformity (e.g. a letter) is issued for the product type only, the characteristics of which are detailed in the certificate or a document referred to in the certificate.

Other product-types from the production are not covered by the certification body's attestation of conformity.

If the samples that are certified are representative of the same product type from the production, then those same product-types could be referred to by the manufacturer as being manufactured in accordance with the "certified type". Such schemes are sometimes referred to as "type approval" schemes.

Since only the original samples are certified, there are no surveillance activities carried out by the third-party product certification body.

The certification body may grant the manufacturer the right to use the type certificate or other statement of conformity (e.g. letter) as a basis for the manufacturer to declare that the same product-types conform to the specified requirements.

Manufacturers must be careful not to refer to production items as "certified" since 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.

Type 1b scheme (based on batch testing)

- Selection of product samples in accordance with the sampling provisions of the scheme.
- 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 within the certified population.

In this scheme, a defined population of products (e.g. a batch or a lot) is subjected to determination activities, generally sampled on a statistical basis in accordance with the scheme requirements. Any resulting attestation of conformity relates to the whole population of products (same product-types) and a type certificate for each product type could be provided by the certification body. Where the scheme includes the use of a Mark of conformity, the certification body will license the manufacturer to apply the Mark to all of the same product-types in the population that was covered by the attestation.

Since only a defined population of products is certified, there are no surveillance activities carried out by the third-party product certification body.

Type 2 scheme (based on testing plus market surveillance)

- Selection of product samples in accordance with the sampling provisions of the scheme.
- 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.

The surveillance part of this scheme involves periodically taking samples of the product from the market and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements.

Although this scheme also identifies the impact on conformity, of the distribution channel, including the transport to market, the resources it requires can be extensive. Also, when significant nonconformities are found, effective corrective measures may be limited since the product has already been distributed to the market.

Type 3 scheme (based on testing and factory surveillance)

- Selection of product samples in accordance with the sampling provisions of the scheme.
- 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 scheme 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 scheme does not provide any indication of the impact on conformity caused by the distribution channel to the market. 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.

Type 4 scheme (based on testing) plus surveillance from factory or open market, or both)

- Selection of product samples in accordance with the sampling provisions of the scheme.
- 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.

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- 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.

The surveillance part of this scheme allows for the choice between periodically taking samples of the product from the point of production or from the market, or both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme can both indicate the impact on conformity of the transport and distribution to the market 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.

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

- Selection of product samples in accordance with the sampling provisions of the scheme.
- 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.

The surveillance part of this scheme allows for the choice of periodically taking samples of the product either from the point of production or from the market, or both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements.

The surveillance also includes periodic assessment of the production process or audit of the management system, or both. If the surveillance includes audit of the management system, an initial audit of the management system will be needed.

The extent to which the four surveillance activities are conducted may vary for a given situation, as defined in the scheme. As a result, this scheme provides significant flexibility for ongoing surveillance.

ISO/IEC TR 17026 provides an example of a Type 5 scheme for tangible products.

Type 6 scheme (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.

Although services are considered as being generally intangible, the determination activities are not limited to the evaluation of intangible elements (e.g. effectiveness of an organization's procedures, delays and responsiveness of the management). In some situations, the tangible elements of a service can support the evidence of conformity indicated by the assessment of processes, resources and controls involved (e.g. inspection of the cleanliness of vehicles for the quality of public transportation).

As far as processes are concerned, the situation is very similar. For example, the determination activities for welding processes can include testing and inspection of samples of the resultant welds, if applicable.

For both services and processes, the surveillance part of this scheme should include periodic audits of the management system and periodic assessment of the service or process.

ISO/IEC TR 17028 provides an example of a certification scheme for services.

When to use which type of scheme

Which type of scheme to use will depend on many factors, but the main ones are market acceptance, national QI requirements and risk. For example, for low-risk products, a certification scheme may not be necessary, and a supplier's declaration may be sufficient. For medium-risk products, a Type 1a or Type 1b scheme may be appropriate. For high-risk products, or products used in high-risk environments, a type 5 scheme may be the best option. For extreme-risk situations, often a combination of scheme types may be used including Type 5, quality management process certification, services certification, personal competency certification, and so on. In each of these situations, the market will determine how much risk it is willing to accept versus the cost it is willing to pay for running the type of scheme. Governments will also regulate certain higher risk sectors and enforce certain scheme types.

Examples of the use of these scheme types is given by the IEC CA Systems. IECEE under its CB scheme, runs a Type 1b scheme for household products and equipment, office equipment, industrial equipment, medical equipment, and so on. This scheme exists because the market wants it and pays for it, and many governments use it as free QI. IECEx runs a Type 5 scheme for equipment used in explosive environments. This is a highly regulated sector, for the obvious reason of the higher risk of fire and explosions leading to possible injury and death of people, infrastructure damage and destruction, environmental damage and economic damage. In 2009, the United Nations Economic Commission for Europe (UNECE) formally approved the UN CRO (Common Regulatory Objectives) for the explosive environments sector and endorsed the use of the IECEx CA System as world's best practice. IECQ also runs Type 5 and Type 6 schemes as part of its supply chain certification services. (For more information on these IEC CA Systems see further down in this chapter, and to see how they operate, See [Appendix 2](#).)

Person certification schemes

A scheme that sets out the competence and other requirements related to specific occupational or other skills of people is another type of certification scheme. For example, people who fulfil the requirements of a scheme and relevant competence standards may result in them being recognized as a “Certified Quality Management Systems Auditor”, “Certified Welder” or a “Certified Information Technology Security Specialist”.

ISO/IEC 17024 and ISO/IEC TS 17027 are the standards that set out the requirements and vocabulary for bodies operating certification of persons. Clause 8 of ISO/IEC 17024 sets out specific requirements for the development and administration of certification schemes for persons, covering the following six areas:

- Certification scheme categories.
- Elements of a certification scheme.
- Process requirements.
- Development and review of the certification scheme.
- Continual review and validation of the scheme for persons.
- Obligations of the scheme owner.

ISO has published guidance to Clause 8 of ISO/IEC 17024:2012 entitled *How to develop schemes for the certification of persons*. It is freely available from the [ISO Store](#).

Flexibility of conformity assessment

The schemes 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 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 conformity assessment techniques can be combined into schemes in different ways depending on the sectors and associated risks. These schemes can form conformity systems, and an example is the IEC CA Systems which provide global conformity assessment services. The IEC global conformity assessment services include four worldwide conformity assessment systems under the control of its Conformity Assessment Board. These conformity assessment systems consist of multiple certification schemes (a system of schemes) that operate using qualified commercial testing laboratories (TLs), inspection bodies (IBs), certification bodies (CBs), and so on (collectively referred to as conformity assessment bodies, or CABs), in many different countries all over the world.

Due to harmonized processes and frequent peer assessment of the TLs, IBs, CBs, etc., the test results issued by these different CABs from all over the world are consistent and comparable. This is the value created and it leads to mutual recognition of those conformity assessment results. That, in turn, builds trust and facilitates commerce and trade.

All four IEC CA Systems provide global conformity assessment services but to different market sectors:

IECEE

- IECEE (since 1985) for electrical and electronic products for industrial and domestic use includes two main 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. This is essentially a Type 1b scheme. The market driver for IECEE-CB-Scheme is international market access for manufacturers and suppliers.
 - IECEE also operates global *cybersecurity* certification service focused on critical infrastructure.

See more at www.iecee.org.

IECQ

- IECQ (since 1974) covers two generic schemes focusing on the assessment of the supply chain associated with electronic components, assemblies, materials and related processes:
 - The Process Approvals Scheme, which provides independent verification that processes associated with the supply of components and assemblies meet declared manufacturers' specifications (including standards). Examples of such processes include control of electrostatic discharge in order to protect the integrity of components. This is essentially a Type 6 scheme.
 - The Approved Component Scheme, which provides assurance that components, assemblies and materials comply with declared specifications (similar to product certification). This is essentially a Type 5 scheme.
- There are also some industry-focused schemes based on the two ECQ generic schemes. These include:
 - The Hazardous Substances Process Management (HSPM) Scheme, which uses a quality management system standard that companies can refer to in order to ensure their processes and controls adhere to local regulations about hazardous substances in electronic components (e.g. lead, mercury and cadmium). This is essentially a Type 6 scheme.
 - The Electronic Component Management Plan (ECMP) Scheme for avionics components, which provides third-party assessment of electronic component management plans prepared to comply with IEC TS 62239. This is essentially a Type 6 scheme.

The market driver for IECQ services is business-to-business cost reduction.

See more at www.iecq.org.

IECEX

- IECEX (since 1996) relating to safety in explosive atmospheres comprises four schemes:
 - The Certified Equipment Scheme, which covers both electrical and non-electrical mechanical products, components and assemblies used in explosion hazard areas: “Ex products”. This is essentially a Type 5 scheme.
 - The Certified Service Facilities Scheme for services used within Ex industries, such as the repair of Ex products.
 - The Conformity Mark Licensing System to be used in conjunction 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 market drivers for IECEX services come from the need for asset owners to protect their infrastructure and investment, and from governments' need to prevent harm to people, to avoid environmental accidents, and to protect harm to the economy (e.g. if an oil refinery where to explode).

See more at www.iecex.org.

IECRE

- IECRE (since 2014) is a global, conformity assessment system of schemes for equipment used in renewable energy applications.
 - Like for all IEC CA Systems, the IECRE operates on the basis of a single, centralized set of operational rules that are consistently applied all over the world. Commercial TLs and CBs from around the world join the IEC CA Systems and are qualified through a peer assessment approval process. This peer assessment process qualifies the CBs and TLs on two distinct levels. Firstly, like an accreditation assessment, they are assessed on their competency to perform the required conformity assessment. Secondly, they are assessed on their ability to perform that conformity assessment according to the harmonized scheme rules. This second level is what creates most added value and gives real force to the multilateral mutual recognition agreement (MLA).

The market driver for IECRE is the need by renewable energy project financiers and insurers to manage their financial risk by ensuring that world's best practices are used.

See more at www.iecre.org.

The European Union's approach to conformity assessment

The EU 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 of 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 13 August 2008.

The EU 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").

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- Quality assurance assessment by a notified body.
 - Inspection of production items by a notified body.

For more on the EU system, see [ec.europa.eu/growth/single-market/ goods/ new-legislative-framework/](https://ec.europa.eu/growth/single-market/goods/new-legislative-framework/).

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 TBT Agreement was made in order to harmonize the regulations and conformity assessment practices in signatory countries (See [Appendix 4](#)).

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

The use of global conformity assessment services (see [Appendix 2](#) for more information), where appropriate, is a recommended best practice. The WTO recognizes the IEC global CA Systems and recommends their use as a means to avoid accusations of applying technical barriers to trade.

Chapter 4

CABs

Reference to the ISO/IEC 17000 series

The ISO/IEC standards and guides (see [Appendix 1](#)) define the characteristics for different types of CABs. Some, such as testing laboratories, validation and verification bodies, and inspection bodies can perform first-, second- and third-party activities, while certification can only be conducted as a third-party activity.

Where a CAB acts in a third-party capacity, it must do so in an impartial way so that the results of its work can be objective and maintain a high degree of confidence. The standards for certification bodies mentioned in the following sections set out the requirements for demonstrating and maintaining impartiality.

Testing and calibration laboratories

Requirements for testing and calibration laboratories

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, is the main International Standard specifying the generic requirements against which the competence of laboratories is assessed. Like most ISO/IEC standards that provide requirements for CABs, ISO/IEC 17025 requirements are structured in the following way:

- **General requirements**, including impartiality and confidentiality.
- **Structural requirements**, including legal status, organizational structure and responsibilities.
- **Resource requirements** for personnel, competency, facilities, equipment, metrological traceability, and externally provided products and services.

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- **Process requirements**, including review of work requests, selection, verification and validation of methods, sampling, handling, records, measurement uncertainty, reporting, complaints, control of nonconforming work, and data and information management.
 - **Management system requirements**, which allow a choice to fulfil the requirements of ISO 9001, *Quality management systems – Requirements*, or the management system requirements within ISO/IEC 17025 that include management system documentation and records, improvement activities, internal audits, corrective actions and management review.

While the management system requirements will be common to all laboratories, there is a need to apply the other technical requirements to the specific field of work. 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 the quality and competence of 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 such 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 in its capability to perform the tests they require.

When a laboratory seeks accreditation, the AB will not only assess conformity to the general standard and any field-specific supplements, but also to the specific standard test methods for which the laboratory is to be accredited and which can sometimes be regulated. Thus, there is a hierarchy of criteria that laboratories may need to satisfy, as illustrated in **Figure 4**.

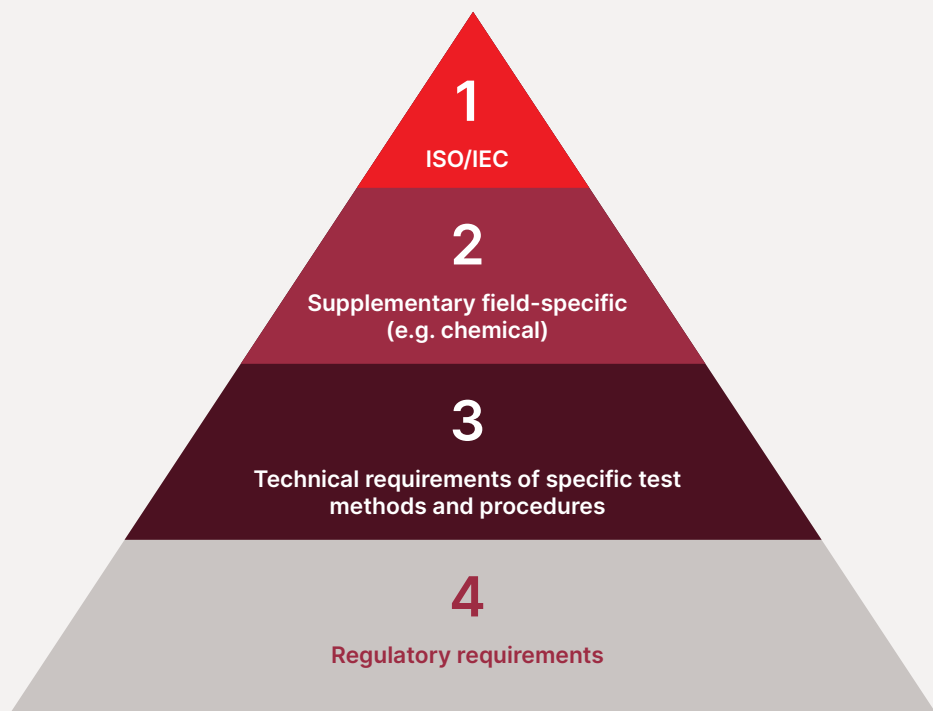


Figure 10: Hierarchy of laboratory criteria

1. General requirements for all laboratories (ISO/IEC 17025)
2. Additional requirements for chemical laboratories (e.g. use of CRMs)
3. Additional requirements of specific test method
(e.g. ISO xyz-controlled temperature limits)
4. Additional requirements of a regulator
(e.g. specified reporting or labelling requirement)

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 with the 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.

Interlaboratory comparison testing and proficiency testing

When testing laboratories are not part of a global scheme they operate as individual entities. In this situation they are free to use whatever test methodology they wish so long as the methodology is appropriate for testing the specified requirements of the object of conformity. In this situation it can be difficult to obtain consistent and comparable results from different laboratories.

When it is important that test results are consistent and comparable, testing laboratories may need to become involved in interlaboratory comparison testing and, in particular, proficiency testing. Interlaboratory comparison testing and proficiency testing may be used by laboratories for a number of purposes, including:

- Establishing the effectiveness and comparability of a new test or measurement method, and similarly monitoring 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 monitoring laboratories' continuing performance.

Proficiency testing can be a powerful tool for 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 interlaboratory tests might be used in determining values for CRMs; in improving standard test methods; in re-assuring clients of laboratories, including regulators; and as an educational tool for professional bodies.

Figure 11 shows some of the stakeholders involved in proficiency testing.

The relevant standard for proficiency testing is ISO/IEC 17043, *Conformity assessment – General requirements for proficiency testing providers*.

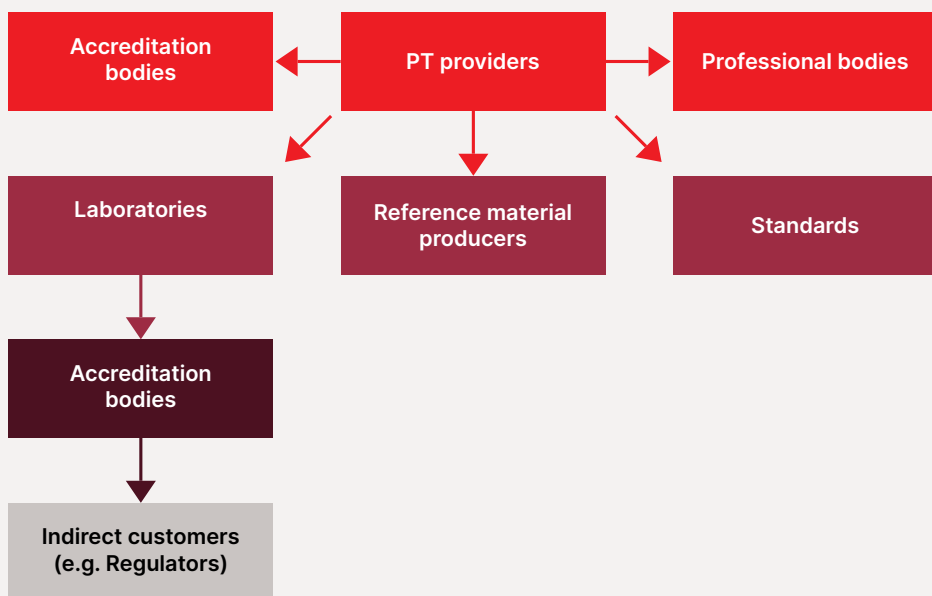


Figure 11: Stakeholders in PT

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.

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

The benefits for laboratories using these services include establishing traceability of measurement to International Standards and accessing 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 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. As 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 its 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.



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 programme for trade-related technical assistance in Pakistan. This involved inputs from many agencies, including a number of 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 that can 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 phytosanitary compliance (conducted as a joint World Bank-UNIDO initiative).
- Trade-related challenges facing 157 local exporters in Pakistan. 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, particularly for small exporters.

The testing capacity building in Pakistan resulted in:

- Strengthening the metrology infrastructure through development support of the National Physical and Standards Laboratory. This included the 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 CRMs 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 Norwegian Accreditation (NA).

Inspection bodies

Requirements for inspection bodies

The relevant standard for inspection bodies is ISO/IEC 17020, *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*. Annex A of the standard provides for three types of inspection bodies sorted by differing levels of independence.

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, purchase, ownership, use or maintenance of the items inspected.

Type B inspection bodies

These bodies provide first-party services to their parent body and are expected to:

-
- Only provide inspection services to the organization to which the inspection body belongs.
 - Have clear separation of responsibilities for inspection personnel and personnel employed in other functions, with established organizational identification and reporting methods for the inspection body within the parent organization.
 - Ensure the body and its staff do not engage in activities that may conflict with their independence of judgment in respect of their inspection activities, including involvement in design, manufacture, supply installation, use or maintenance of the items inspected.

Type C inspection bodies

These bodies are first-party inspection bodies that may also provide inspection services to other organizations, which are not their parent organization. They are expected to:

- Provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities in the provision of inspection and other services.
- Ensure that the design, manufacture, supply, installation, servicing or maintenance, and the inspection of the same item carried out by a Type C inspection body, are not undertaken by the same person, except in cases where a regulatory requirement explicitly allows this to take place.

The requirements to be fulfilled by inspection bodies, as specified in ISO/IEC 17020, are set out in accordance with the common structure that is followed in most of the conformity assessment standards. This includes the following sets of requirements:

General requirements – These include requirements that inspection shall be undertaken impartially, regardless of whether it is being carried out by a first, second or third party, and that inspection bodies identify and manage risks to its impartiality. Other requirements make the inspection body responsible for all information obtained or created during inspection activities, as well as for the confidentiality of such information.

Structural requirements – These include requirements that the inspection body shall be a legal entity; have sufficient provisions to cover liabilities; be structured to safeguard impartiality and maintain its capability to perform

inspection activities, not least the need to identify a person or persons (“technical manager”) who are competent and have overall responsibility for the inspection activities.

Resource requirements – These include requirements that the inspection body:

- Define and document competencies for all personnel involved in inspection activities; ensure an adequate number of staff with demonstrable competencies (i.e. a knowledge of manufacturing technology and the ability to make professional judgments on how inspected items are used and which defects may occur); set up ongoing training and arrange formal authorization and monitoring; and ensure that remuneration does not influence the results of inspections and that personnel remain impartial and maintains confidentiality.
- Have access to suitable equipment and facilities; know the rules for use of, and access to, specified equipment and facilities; properly identify equipment, maintain it according to documented procedures and ensure its continued suitability.
- Ensure calibration/re-calibration of equipment is performed where appropriate, ensure that applicable measurements can be traced to national and International Standards of measurement, and that reference standards are used for reference only.
- Maintain in-service checks, procedures for the selection of qualified suppliers, purchasing documents and inspection of received materials, and ensure appropriate storage facilities and monitoring for the deterioration of stored items.
- Ensure computers and automated equipment and software are adequate and maintained to ensure proper functioning;
- procedures are established for protecting the integrity and security of data; and records of equipment identification, calibration and maintenance are up to date.

Process requirements – These include requirements that the inspection body:

- Develops specific inspection methods and procedures for demonstrating conformity; maintains documented instructions

for inspection planning, sampling and inspection techniques; fully documents use of any non-standard methods or procedures; keeps all instructions, standards or written procedures, worksheets, checklists and reference data up to date and accessible; operates a contract or work order control system; keeps timely recording of inspection data; checks calculations and data transfers, and; maintains documented instructions for safe performance of inspections.

- Ensures unique identification of items and samples (noting suitability and appropriate preparation of items for inspection), as well as documented procedures and adequate facilities to avoid damage to, or deterioration of, inspection items.
- Maintains an appropriate record system and ensures traceability of inspection reports or certificates to the individual inspectors who performed the inspection.
- Ensures inspection work is covered by: a retrievable inspection report/certificate, which shall include the results and determination of conformity with any additional information needed for its understanding and interpretation; any work performed by subcontractors; appropriate signatures or other approvals by authorized staff, and; a record of details and justifications for any corrections or additions made to an inspection report/certificate.
- Maintains a documented process for complaints and appeals, as well as a record of all complaints and actions undertaken by the inspection body.

Management system requirements – These can either follow the requirements set out in ISO/IEC 17020 (Option A) or use the requirements in ISO 9001, *Quality management systems – Requirements* (Option B). If Option A is chosen, the inspection body must ensure its management system covers matters such as a quality policy, objectives and top management commitment; control of documentation and records; management review; internal audits; and corrective and preventive actions.

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. Since there is no equivalent to proficiency testing for inspection, the reliance on “professional judgment” can provoke situations of inconsistency in the conformity assessment result. For this reason global conformity assessment services define common, harmonized criteria and rules to guide the “professional judgment” and achieve highest consistency. (For more information see [Appendix 2](#).)

Inspection is often an essential risk management tool. Many plants, equipment and installations require periodic inspection 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 avoid both cost penalties and possible rejection in the intended market.



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” that are designated by the Member States of the EU 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 and so forth.

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 Notified Bodies determining 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.

Certification bodies

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

- Product certification
- Management system certification
- Personnel certification

Product certification bodies

Product certification bodies and their activities

Product certification is a comprehensive activity with a long history. It is also perhaps the most visible form of certification as, today, so many products carry 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.

The primary purpose of a product standard is safety, and then other features, such as performance, interoperability, electromagnetic compatibility, health and environmental impacts, energy efficiency etc. Whichever purpose is intended to be covered by a standard, there are two fundamental objectives of such certification, namely:

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

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

Requirements for product certification bodies

The requirements for these certification bodies are specified in ISO/IEC 17065, *Conformity assessment – Requirements for bodies certifying products, processes and services*.

Several requirements in ISO/IEC 17065 state “in accordance with the certification scheme”, hence ISO/IEC 17065 can only be fully applied in situations where a product certification scheme exists. In the standard one example is Subclause 7.9, *Surveillance*. If the product certification scheme does not address the matters referred to by ISO/IEC 17065 requirements, then each individual certification body can make its own interpretation. This highlights the need for product certification schemes to be written in a way that does address these matters to ensure consistent interpretation and application of ISO/IEC 17065 requirements.

ISO/IEC 17065 sets out requirements for product certification bodies using the common structure adopted for the ISO/IEC 17000 series of standards (CASCO toolbox). The common structure is as follows:

General requirements – These include requirements that:

- The product certification body be a legal entity, or part of a legal entity, so it can be held legally responsible for its certification activities.
- The existence of a legally enforceable certification agreement between the product certification body and the client seeking product certification, and that the product certification body exercise control, as specified by the certification scheme, over ownership, use and display of licences, certificates and marks of conformity. (These are related to the impartial undertaking of certification activities, including provisions for identification, elimination or minimization of risks to impartiality; the prohibition of certain activities by the certification body, such as consultancy on the products that it certifies; and several provisions related to ensuring the impartiality of personnel.)
- The product certification body have adequate arrangements to cover liabilities, financial stability and resources.
- The product certification body act in a non-discriminatory manner and make its services accessible to all applicants.
- Confidentiality be ensured through legally enforceable commitments.
- Certain publicly available information be maintained (e.g. a description of the certification process and rights and duties of applicants and certified clients, the use of marks of conformity, and procedures for complaints and appeals).

Structural requirements – These include requirements that the product certification body:

- Be structured and managed so as to safeguard impartiality; have a documented organizational structure with assigned responsibilities for specific duties, such as the development of policies, supervision, certification activities and delegations; and be responsive to complaints and appeals.
- Have formal rules for the appointment, terms of reference and operation of any committees it uses in the certification process; and have a mechanism to safeguard impartiality.

Resource requirements – These include requirements that the certification body:

- Have access to a sufficient number of personnel with competency to undertake the certification activities; have documented procedures for determining competence criteria, identifying training needs, demonstrating required staff competencies, delivering formal authorizations for staff to carry out certification duties, and monitoring personnel performance.
- Maintain records for each staff member, including a contract where the member of personnel commits to complying with the rules of the certification body (including the rule of confidentiality and independence from commercial and other interests), declares any prior or present association with certification clients, and reveals to the certification body any situation that may present a conflict of interest.

Resource requirements also include provisions for internal or external resources used for evaluation activities such as testing, inspection and management system auditing. In these cases, the bodies undertaking the testing, inspection or management system auditing shall meet the applicable requirements of ISO/IEC 17025 (testing), ISO/IEC 17020 (inspection) and ISO/IEC 17021 (audit and certification of management systems). The applicable requirements can be defined by the product certification scheme or can be left to the product certification body to determine. A note in the standard gives examples of why some requirements of ISO/IEC 17025, ISO/IEC 17020 or ISO/IEC 17021 may not be applicable. These include, for instance, the extent of control the certification body has over testing (e.g. witnessing the testing), inspection (e.g. specifying the inspection methods or parameters) or management system audits (e.g. requiring specific details of a management system); or when a particular requirement in ISO/IEC 17025, ISO/IEC 17020 or ISO/IEC 17021 is already covered in an equivalent way by ISO/IEC 17065.

If evaluation activities such as testing, inspection or management system auditing are outsourced (subcontracted) to other bodies, there must be a legally binding contract between the certification body and those bodies. The contract must include provisions related to confidentiality and conflict of interests. In any case, the certification body retains responsibility for all activities that are outsourced to another body, including:

-
- Ensuring the personnel of the outsourced body does not compromise the credibility of the results.
 - Qualifying, assessing and monitoring outsourced services.
 - Maintaining a list of outsourced service providers.
 - Implementing corrective actions for the breaches of any contract.
 - Informing the client in advance of outsourcing activities in order to provide the client with an opportunity to object.

Under the standard, the product certification body cannot outsource its certification decision to another body that is not under the certification body's organizational control.

Process requirements – The process requirements in ISO/IEC 17065 set out the minimum steps for the product certification process, including the need to operate a product certification scheme. The steps and requirements are:

- **Application**, through which the certification body shall obtain all necessary information to complete the certification process in accordance with the relevant certification scheme. No further specification is provided in ISO/IEC 17065, but a note does include the types of information that would be expected to be provided by a client at the time of application. Applications are often submitted through the completion of a formal application form with attached supporting documents. However, ISO/IEC 17065 does not specify the use of a formal application form and a variety of media could be used to make an application, including Internet pages, etc.
- **Application review**, whereby the certification body shall undertake a review of the application to ensure it is sufficient for the certification process; any known difference in understanding between the certification body and its client is resolved; the scope of certification is clear; the means are available to undertake the evaluation activities; and the certification body has the competence and capacity to perform the certification activity.
- **Evaluation**, in which the certification body shall have a plan for the evaluation activities. Evaluation activities include a combination of selection and determination activities, such as specifying the relevant product requirements (e.g. product standards), sampling parameters,

and types of determination methods such as product design appraisal, testing, inspection, management system auditing, assessment of product process controls, interviews and witnessing of relevant personnel of the client, etc. These plans may be generic and applicable to all certification activities undertaken by the certification body or specific to the particular product or type of evaluation activity. In some cases, the product certification scheme will set out what is required in terms of evaluation activities.

The certification body shall assign personnel to undertake the evaluation activities and manage any outsourced evaluation activities in accordance with the evaluation plan. The certification can rely on evaluation results completed prior to the application for certification as long as it takes the responsibility for those results and satisfies itself that the body producing those results has fulfilled the requirements for outsourced evaluation activities specified under the resources requirements (see above).

During evaluation, the certification body shall inform the client of any nonconformity and shall undertake additional evaluation tasks to ensure any nonconformity has been corrected. In practice, product certification schemes often have rules related to nonconformity, especially in terms of categorization of nonconformities (e.g. minor or major nonconformity, and the time frames within which a nonconformity must be closed out by the client). The results of all evaluation activities shall be documented prior to the next certification process step.

- **Review**, in which the certification body shall assign at least one person who has not been involved in the evaluation activities to review the results of the evaluation activities. The review should consider whether all the appropriate information has been gathered and the relevant processes and procedures have been followed during the evaluation process.
- **Certification decision**, to be delivered by the certification body, or body under its control, after the review has been completed. The decision is to be carried out by a person or groups of persons (e.g. a committee) who have not been involved in the evaluation activities. The same person or people undertaking the review may take the certification decision. A body “under the organizational control” of the certification body was specifically included in ISO/IEC 17065 to recognize the fact that product certification is often undertaken by

bodies that can be a network of related legal entities, often operating in different countries (e.g. multinational certification bodies with branches that are separate legal entities in each country of operation). Where the certification body does not grant certification, it shall notify the client with the reasons for its decision.

- **Certification documentation**, which shall be supplied when product certification is granted. The formal certification documentation (which can be in the form of a certificate) shall, as a minimum, state the name and address of the certification body; the date certification is granted; the name and address of the client; and the scope of certification. The scope of certification is defined in ISO/IEC 17065 as identification of the product(s), process(es) or service(s) that are certified; the applicable certification scheme; and the relevant standards and other normative documents, including their publication date. Certification documentation is only issued after the decision to grant or extend certification has been made, the certification requirements have been fulfilled and the certification agreement has been completed by the client. In an effort to combat the falsification and counterfeiting of certificates, some certification bodies are now also including unique certificate numbers or other forms of identifiers on certificates (e.g. bar codes or Quick Response (QR) codes) that link electronically to publicly available directories of genuine certificates.
- **Directory of certified products**, which is maintained by the certification body and containing at least the following information on certified products: identification of the product, standards and other normative documents to which conformity has been certified, and identification of the client. The product certification scheme is expected to state what parts of this information need to be published or made available upon request.
- **Surveillance**, which normally requires a repeat, on a periodic basis, of some or all of the evaluation activities on the client's certified product, process or service by a certification body. Surveillance activities take place as specified in the product certification scheme, or whenever continuing use of a certification mark is authorized by the certification body to be placed on the product or used in conjunction with the process or service. The purpose of surveillance activities is to ensure ongoing demonstration by the client of fulfilment of the certification requirements.

Further process requirements in the standard relate to dealing with changes that affect certification. These include:

- Termination, reduction, suspension or withdrawal of certification, especially in relation to ensuring the client takes appropriate actions to stop making references to certification where it no longer applies, and reinstatement of certification after suspension.
- Records, which require the certification body to maintain confidential records to demonstrate that the certification process requirements have been fulfilled.
- Complaints and appeals, in which the product certification body must have documented processes to receive, evaluate and make decisions on complaints and appeals, and any such decisions must be taken by a person(s) not involved in the certification activities that are the subject of the complaint or appeal.

Management system requirements – These can either follow the requirements set out in ISO/IEC 17065 (Option A) or use the requirements in ISO 9001, *Quality management systems – Requirements* (Option B). If Option A is chosen, the product certification body must ensure its management system covers matters such as policies, objectives and top management commitment to fulfil the requirements of ISO/IEC 17065; control of documentation and records; management review; internal audits; and corrective and preventive actions.



Case study

Product certification of electrical equipment for international acceptance of regulated products

Within the Asia-Pacific Economic Cooperation (APEC), a number of multi-governmental 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 the acceptance of products from other economies that have agreed to join the MRA.

The EE MRA has three parts available for participation:

- Part I: Information interchange
- Part II: Acceptance of test reports
- Part III: Acceptance of certification

The MRA is intended to cover both pre-market and post-market regulatory compliance 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. The EE MRA also makes use of test reports and certificates issued under the IEC global conformity assessment scheme, IECEE-CB Scheme.

Where certification is the basis for regulatory compliance, the MRA signatories' designated certification bodies are expected to comply with ISO/IEC 17065. The overall objective is to facilitate acceptance of regulated products in multiple markets through 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 in making better-informed product choices, and help suppliers of certified products achieve market acceptance.

Product certification often plays an important role with products subject to technical regulations (for example, for safety, compatibility, performance, energy efficiency, environmental impact, conservation, and quarantine). The availability of products with clearly labelled 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 to ensure additional confidence in the products they sell if these are supported by appropriate product certification. Both importers and exporters 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 system certification bodies and their activities

The ISO 9000 series of standards is among the best known of the ISO standards.

The trend towards ISO 9001 certification is well documented all over the world. Certification for quality management is the major activity of certification bodies accredited by the members of the 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 multinational basis.

Apart from ISO 9001, an increasing number of other management system standards are used as the basis for certification, including ISO 14001 for environmental management systems, ISO/TS 16949 for automotive production and relevant service part organizations, and ISO 22000 for food safety management systems. According to the 2020 ISO Survey of certifications to management system standards, there are about 1.6 million management system certificates issued to organizations that fulfil the requirements of ISO management system standards.

Overall, ISO now has over 80 management system standards published or under development. To help standardizers and organizations structure and assimilate the growing number of management system standards, ISO has adopted a common high-level structure that all management system standards must follow.

This allows companies to establish integrated management systems that operate a core of management system processes (such as management review, internal audit, corrective actions) while allowing the flexibility for further processes to address specific objectives such as quality management, environmental management, energy management, etc.

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 conformance by all their suppliers. (A few 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 recognized third-party certification bodies to demonstrate compliance by their suppliers. An example is the IECQ worldwide global CA System providing supply chain certification for suppliers of electronic components, assemblies, materials and related processes.

IECQ supply chain certification service provides independent verification that processes associated with the supply of components and assemblies meet declared manufacturers specifications which include standards.

Many companies also expect that bodies certifying against their criteria must be accredited to do so. An example is the **Telecommunications Industry Association** (TIA), which operates a global management-system-based scheme using TL 9000 for suppliers of telecommunications equipment. The scheme requires certification bodies to be accredited to ISO/IEC 17021-1 and its Code of Practice for TL 9000 Certification Bodies (see www.standards.tiaonline.org).

From a developing country perspective, it is critical to appreciate that the CABs 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 component manufacturing, fresh foods, agricultural commodities, textiles, toys, etc., which are likely to be sourced from developing countries.

In relation to food products, in addition to ISO 22000, there are a number of regulatory or 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/IEC 17021-1, *Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements*, contains generic criteria for the operation of certification bodies certifying management systems. This standard provides a basis for international consistency of such certifications and is thus the core standard used by accreditation bodies when assessing the competence of management system certification bodies.

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 auditing management systems*

ISO/IEC 17021-1 and ISO 19011 apply to all forms of management system auditing.

Examining ISO/IEC 17021-1 in more detail, there are three main features that the standard addresses in its principles and requirements:

- Competence
- Consistency
- Impartiality

ISO/IEC 17021-1 follows the structure common to conformity assessment standards and sets out the following principles and requirements:

Principles – Impartiality, competence, responsibility, openness, confidentiality, responsiveness to complaints, and risk-based approach;

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

Structural requirements – Organizational structure and top management, and operational control;

Resource requirements – Competence of personnel, personnel involved in certification, personnel records, and outsourcing;

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

Process requirements –

- Pre-certification activities: application; application review; audit programme; determining audit time; multi-site sampling; multiple management system standards.
- Planning audits: determining objectives; scope and criteria; audit team selection and assignment; observers, technical experts and guides; preparation of audit plan; communication of audit plan and audit team
- Initial certification: stage 1 audits; stage 2 audits; initial audit conclusions.
- Conducting audits: opening meetings; communication during the audit; obtaining and verifying evidence; identifying and recording audit findings; audit conclusions; closing meetings; audit report; cause analysis of nonconformities; effectiveness of corrections and corrective actions.
- Certification decision: information for granting initial certification; information for reganting certification.
- Maintaining certification: surveillance activities; surveillance audit.
- Recertification.
- Special audits: suspending, withdrawing or reducing the scope of certification.
- Appeals.
- Complaints.
- Client records.

Management system requirements – Similarly to the other ISO/IEC conformity assessment standards, these can either follow the requirements set out in ISO/IEC 17021-1 (Option A) or use the requirements in ISO 9001, *Quality management systems – Requirements* (Option B).

The certification process

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

ISO/IEC 17021-1, Annex A, sets out a framework for the knowledge and skills that management system auditors must demonstrate. The framework requires the certification body to determine knowledge and skills for the functions of: (a) conducting the application review, determining audit team competencies, selecting team members and audit duration; (b) reviewing the audit reports and making certification decisions; and (c) auditing and leading the audit team. The framework includes:

- Knowledge of:
 - Business management practices
 - Audit principles, practice and techniques
 - Specific management system standards/normative documents
 - Certification bodies' processes
 - Client's business sector
 - Client's product, processes and organization
- Skills in:
 - Language appropriate to all levels of the organization
 - Note taking and report writing
 - Presentations
 - Interviewing
 - Audit management

This generic framework of ISO/IEC 17021-1 has been complemented by further parts or other similar sectoral documents (e.g. ISO 22003 for food safety management systems or ISO 50003 for energy management systems) that contain more detailed requirements addressing knowledge and skills for auditing particular types of management systems.

Examination of the auditors' competence includes their knowledge of the relevant management system 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 common for certification bodies to use external technical auditors as part of the assessment teams to complement the expertise of their own auditors.

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 system's continuing conformity. 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

In Bangladesh, the lack of a local body for management system certification was considered a gap. Indeed, the activity of such a certification body was perceived as key to upgrade the functioning of exporting enterprises and to increase Bangladesh's share in the international market.

However, creating a totally new structure was considered both costly and time-consuming. Accordingly, 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 neighbouring country who had 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 help BSTI achieve accreditation as a certification body within a short time frame to enable it to award certifications with appropriate credibility. The work was divided into four phases comprising documentation, training, implementation and accreditation.

Documentation of the system was duly completed in accordance with ISO/IEC 17021-1 and the system was implemented shortly afterwards. All relevant committee members and certification personnel were given intensive training on ISO/IEC 17021-1 requirements.

Early applications for certification were received after public announcement of the new management system 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 started with the creation of a pool of auditors and technical experts from amongst the trained BSTI officers for 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, the scheme should have gained sufficient expertise and experience to complete the final phase of the project by applying for accreditation.

This UNIDO technical assistance project illustrates the ability of extending existing infrastructures to include conformity assessment services in a developing country.

Drivers and benefits for management system certification

Certification is one means of providing assurance that an organization has implemented a system for the management of relevant 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 system standard (and to have that confirmed through certification) will be specified by customers of that organization. In such instances, the driver for conformance may be a business necessity. However, another driver and benefit are often the value that certification of such systems provides internally. For staff of certified organizations, an external confirmation that their organization meets the requirements of an internationally accepted standard can provide both motivation and satisfaction.

Moreover, for the organization's management, the implementation of a certified system should ensure 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 and regulators. 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 conformance with management system 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 IAF MLAs and/or its regional cooperations.

There are a number of other drivers and benefits depending on the type of management system being implemented (and certified). These may include, for example, opportunities for continual improvement available through the

inputs of external auditors; enhanced 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 competence of individuals to fulfil 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 support 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.

There is also a need for personnel certification schemes in many other domains. It is critical to have certified competent professionals working in special or dangerous conditions or with special or dangerous materials.

An international example of this is the IECEx Certificate of Personal Competence Scheme. In this case multiple professional certification bodies from around the world, which are qualified by the IECEx System (through a peer assessment scheme), participate in the IECEx CoPC (Certificate of Personal Competence Scheme) to issue International IECEx CoPC Certificates via the IECEx live online certificate system. (refer to www.iecex.com).

The relevant standard is ISO/IEC 17024, *Conformity assessment – General requirements for bodies operating certification of persons*. It specifies requirements for the development and maintenance of a certification scheme for persons.

While IECEx requires certification bodies to comply with ISO/IEC 17024 and additional IECEx scheme documents, IECEx through its MoU with IAF utilises accreditation to ISO/IEC 17024 by IAF member accreditation bodies.

Another international example is the International Personnel Certification Association (IPC) (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 Accreditation group members. IAF has extended its MLA to include accreditation of personnel certification bodies complying with the appropriate standard, as discussed below.

Another differentiating feature in ISO/IEC 17024 is the use of examination as a mechanism within the assessment of a person, to measure a candidate's competence.

Requirements for personnel certification bodies

Like most other standards in the ISO/IEC 17000 series, ISO/IEC 17024 follows the common structure for conformity assessment standards, including:

General requirements – Legal matters; responsibility for certification decisions; management of impartiality; and financing and liabilities;

Structural requirements – Provisions for management and organizational structure and the structure of the certification body in relation to the provision of training services.

Resource requirements – General personnel; specific requirements for personnel involved in certification activities; outsourcing and other resources.

Records and information requirements – Records of applicants, candidates and certified persons; public information; confidentiality and security

Certification scheme requirements – Minimum elements for a certification scheme, process requirements within a scheme and for the development and review of schemes with input from all parties significantly concerned.

Process requirements – Application; application review; assessment and examination processes; certification decisions; suspending, withdrawing or reducing the scope of certification; recertification; use of certificates, marks and logos; and appeals and complaints.

Management system requirements – These can either follow the requirements set out in ISO/IEC 17024 (Option A) or use the requirements in ISO 9001, *Quality management systems – Requirements* (Option B). If Option A is chosen, the management system certification body must ensure its management system covers matters such as policies, objectives and top management commitment to fulfil the requirements of ISO/IEC 17024, as well as principles for person certification bodies provided in an informative annex.

For the purposes of this standard, there are a number of definitions which assist in differentiating the certification of persons from other forms of certification. For example, a differentiating feature in this standard is the use of examination as a mechanism within the assessment of a person, to measure a candidate's competence. Other definitions of relevance can be found in the following standards:

Clause 3.1 (of ISO/IEC 17024): certification process activities by which a certification body determines that a person fulfils certification requirements including application, assessment, decision on certification, recertification, and use of certificates and logos/marks.

Clause 3.2 (of ISO/IEC 17024): certification scheme competence and other requirements related to specific occupational or skilled categories of persons.

ISO/IEC TS 17027, *Conformity assessment – Vocabulary related to competence of persons used for certification of persons*.

Drivers and benefits for personnel certification

The availability of an International Standard for the certification of persons offers a number of benefits. Firstly, it provides a baseline and 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 the appointment of staff requiring defined competencies.

There are also other benefits, 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 extension of the IAF MLA to cover

such certification bodies facilitates the greater portability of certifications of persons across national boundaries.

Other “determination” bodies

In line with the flexibility of conformity assessment, there are bodies other than testing laboratories or inspection bodies that 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.

To provide clarification, a new standard for validation and verification bodies – ISO/IEC 17029 – has been developed. It contains general principles and requirements for the competence, consistent operation and impartiality of bodies performing validation/verification as conformity assessment activities. Bodies operating according to this document can provide validation/verification as a first-party, second-party or third-party activity. Bodies can be validation bodies only, verification bodies only, or provide both activities. This document is applicable to any sector, in conjunction with sector-specific programmes that contain requirements for validation/verification processes and procedures.

Competence of CABs

There are several ways in which the competence and impartiality of CABs can be ascertained. If the CABs are members of a mutual recognition group such as the IEC global conformity assessment systems (IECEE, IECEx, IECQ and IECRE) they are assessed by their peers. In this case, because these CABs will form part of an international group and will be mandated to recognize each other's results, the assessment covers more than only competency and impartiality, and includes assessment of harmonized testing, inspection and assessment practices. However, when CABs are operating as individual entities and are not involved in a group structure (which is the most typical case), then the most typical means to be assessed for competence and impartiality is through accreditation, or they might be appointed for specific tasks by a regulatory authority. The different alternatives are outlined below.

Recognition arrangements and agreement groups

In order to facilitate cross-border acceptance of conformity assessment results, CABs have, for many years, established reciprocal recognition arrangements with each other. The arrangements have included the bilateral 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 CABs from other countries, forming bilateral or 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 promulgate good practice in their field.

An example of multilateral agreement groups are the IEC CA Systems (IECEE, IECEx, IECQ and IECRE). See [Chapter 3](#) for more information about the IEC CA Systems, and see [Appendix 2](#) for how they operate.

ISO/IEC Guide 68, *Arrangements for the recognition and acceptance of conformity assessment results*, provides guidance on setting up arrangements for the recognition and acceptance of conformity assessment results. The document 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 ISO/IEC 17000 series of standards. 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, whereby accreditation can provide assurance on the organization and management systems of the members while peer assessment can concentrate on the technical aspects.

Accreditation bodies

The relevant International Standard for accreditation bodies is ISO/IEC 17011, *Conformity assessment – Requirements for accreditation bodies accrediting CABs*. It provides the following definitions:

Clause 3.1 accreditation

third-party attestation related to a CAB conveying formal demonstration of its competence to carry out specific conformity assessment tasks

Clause 3.2 accreditation body

authoritative body that performs accreditation

Note 1 to entry.

The authority of an accreditation body is generally derived from government.

Recognition of competence is the principal objective of accreditation and such recognition is for specific tasks. This means that accreditation is always given for a specified scope.

Some accreditation bodies have specific capabilities, such as accreditation of the competence of laboratories, for example, or accreditation of certification bodies. Some accreditation bodies are multifunctional and cover a broad range of CABs while others are more narrowly focused on specialty areas.

Accreditation bodies are often appointed by national governments and hold an important position in the national conformity assessment hierarchy. They provide confidence in the impartiality and competence of CABs and ensure that their conformity assessment results will be recognized within the country of accreditation. The requirements for accreditation bodies are specified in ISO/IEC 17011 as follows:

General requirements – Legal status; the need for an accreditation agreement; use of accreditation claims and symbols; impartiality requirements; finance and liabilities; and accreditation schemes.

Structural requirements – Organizational structure and allocation of responsibilities.

Resource requirements – Personnel competence and outsourcing.

Process requirements – Accreditation requirements; applications; review; assessment preparation and delivery; accreditation decision-making; information; changing the status of accreditation; complaints and appeals

Information requirements – Confidentiality and publicly available information

Management system requirements – These can either follow the requirements set out in ISO 9001, *Quality management systems – Requirements*, or the management systems requirements prescribed by ISO/IEC 17011.

CABs check that goods, services, people and bodies are conformant. Accreditation bodies check that the CABs are competent to do their scope of work. Therefore, accreditation bodies check the checkers. In this respect, accreditation bodies hold a high position of responsibility as there are no other bodies above them, on the national level, to check that their accreditation work is done correctly. For this reason accreditation bodies from different countries have formed multilateral arrangements through which they carry out peer assessments on each other, as described in [Appendix 3](#).

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 a policy on accreditation in its "New Legislative Approach".

In other economies and regions, there may be a mixture of government and non-government accreditation bodies, or solely non-government bodies (this is largely the case in North America). 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 (NMIs) and accreditation services. Where commercial bodies deliver some or all of a particular service, governments often accept

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 recognized 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 that 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.
- **To underpin government-to-government MRA for conformity assessment activities**
As discussed in [Appendix 3](#), 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 negotiations on 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 TBT Agreement.

Further examples of how accredited conformity assessment benefits government across many sectors are found on the following two Websites:

www.iso.org/sites/cascoregulators/index.html

www.publicsectorassurance.org

This second site has been developed and is maintained by the International Network on Quality Infrastructure (INetQI), to demonstrate how the quality infrastructure supports policy objectives.

Role of accreditation in support of private sector

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

- **As a baseline for competence**

Many CABs operate in isolation from their peers. By being subjected by experts to assessments for conformance 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 publicly available recognition of the specific competencies, within a well define scope of work, of the accredited CABs. This enhances the acceptance of the outputs of accredited bodies by regulators, suppliers, purchasers, consumers, etc., including both the direct clients of the CABs 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 CABs. Customers of CABs 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 CABs are accredited by bodies which are signatories to the IAF MLA, the ILAC MRA or their regional cooperation bodies (AFRAC, APAC, ARAC, EA, IAAC and SADCA), they have access to international recognition as competent bodies in multiple foreign markets. For additional information on the scope of recognition, see <https://iaf.nu/en/regional-accreditation-group/> and <https://ilac.org/ilac-membership/members-by-category/>.

Secondly, other groups in the private sector that 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 CABs accredited to the relevant scope. 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 CABs. Similarly, importers may be able to accept imported goods and services with additional confidence if they are covered by foreign CABs that are accredited. This will often be facilitated even more if the foreign accreditation body is a signatory to the ILAC MRA or IAF MLA.

- **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 CABs they accredit. (ISO/IEC 17011 requires accreditation bodies to ensure that they have an appropriate balance of interests in their governance).

- The IEC global conformity assessment services also benefit from the accreditation process. Although these global conformity assessment schemes use peer assessment to qualify CABs, the qualification process for CABs that are already accredited is simpler since some of the qualification process is already done under accreditation. In the IEC global CA Systems, accreditation audits and peer assessments can be carried out in joint or unified assessments. CABs that qualify to participate in an IEC CA System are obligated to recognize and accept the conformity assessment results coming from other participating CABs. This is the MLA at the core of the IEC global CA services. The common harmonized procedures, rules and peer assessment that are an integral part of the MLA ensure that the conformity assessment results are consistent, comparable and trustworthy, no matter from where in the world they come. The added value of being accredited is that the decision by the CAB to recognize CA results from elsewhere, must also be recognized within that CAB's own country. So imported products that were tested and certified by a CAB that is participating in an IEC CA System (and that CAB could be anywhere in the world), will be accepted onto the local market, because the test results and certificate are recognized by the local accredited CAB.

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- Further examples of how accredited conformity assessment benefits the private sector are found on the www.business-benefits.org. The site has been developed by the organizations that make up the quality infrastructure represented by the BIPM, IAF, IEC, ILAC, ISO, ITC, ITU, OIML, UNECE, World Bank Group, WTO and UNIDO. It also includes trade associations such as IIOC and IQNET.

Governmental appointment

Where governmental regulations require conformity assessment to be carried out by third-party bodies, those responsible for the regulations should specify the criteria that these bodies should meet. The most universally acceptable criteria are those found in the ISO/IEC 17000 series (see [Appendix 1](#)). The accreditation itself is to a specified scope of work, while who performs the accreditation could be a government criteria requiring a specified body or by, for example, a signatory to one of the international mutual recognition arrangements/agreements, such as the IAF MLA or the ILAC MRA. 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.

Alternatively, government regulators very often specify certificates issued from a global conformity assessment service as being sufficient and appropriate demonstration of compliance with regulated requirements (see [Appendix 2](#)).

Chapter 5

What UNIDO can contribute to setting up a quality infrastructure

UNIDO's approach to sustainable industrial development

UNIDO is the specialized agency of the United Nations that promotes industrial development for poverty reduction, inclusive globalization and environmental sustainability.

In 2015, the United Nations Member States adopted the 2030 Agenda for Sustainable Development, which defines 17 Sustainable Development Goals (SDGs) that are to be achieved by the year 2030. UNIDO is determined to carve its niche in contributing to the objectives of the 2030 Agenda by promoting and accelerating ISID to achieve shared prosperity and environmental sustainability around the world.

While UNIDO's activities contribute to numerous SDGs relating to people, prosperity, planet, peace and partnerships, its core mandate is embedded in SDG 9, namely, to build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation.

With its portfolio of quality and standards compliance projects, UNIDO helps developing countries and economies in transition to improve their economic competitiveness and better integrate into the world economy. It mobilizes knowledge, skills, information and technology to support Member States in their efforts to increase economic prosperity, improve the well-being of people, and protect our planet. UNIDO further enhances the value of its work by promoting cooperation among international development agencies, public institutions, and the private sector at the global, regional, national and sectoral levels.

UNIDO's primary focus is on supporting international competitiveness in the small and medium-sized enterprise (SME) sector, the key generator of wealth in most developing countries—in this regard, setting up a QI with conformity assessment at its core is essential. Furthermore, in its effort to support environmental sustainability, UNIDO plays a leading role in implementing multilateral environmental agreements, including the Montreal Protocol for the elimination of ozone-depleting substances and the Stockholm Convention for the elimination of persistent organic pollutants.

UNIDO's strategic priorities

UNIDO supports countries to industrialize in ways that foster digital and green transitions and accelerate progress with the SDGs.

The world is faced with an array of challenges:

- We are on the verge of a global food crisis, with a rising number of people experiencing hunger and food insecurity.
- We are in the grip of a climate catastrophe and the window to avert it is rapidly closing.
- We are reeling from the worst economic crisis in decades and small businesses in developing countries are still struggling.

UNIDO can help its Member States overcome these challenges through its priority areas, which include:

- Reducing hunger by helping businesses from farm-to-fork. This means sharing knowledge and technology to help reduce post-harvest losses and increase food security. Agribusiness can generate job opportunities for young people.
- Stopping climate breakdown by using renewable energy and energy efficiency to reduce industrial greenhouse gas emissions.

This means promoting policies, technologies and practices to provide countries with the opportunity to forge low-carbon economies. Climate action can create millions of new jobs.

- Supporting sustainable supply chains in order for developing country producers to get a fair deal and for scarce resources to be preserved.

This means supporting and promoting global environmental and social standards, alongside knowledge and technology transfer, to improve quality and add value. Supply chains are essential to trade, and trade is essential to job creation.

The UNIDO motto is "*Progress by innovation*". It is imperative that governments, industry, businesses, and society at large think outside-the-box. To this end, UNIDO supports innovation across the whole spectrum of industrial development.

UNIDO's approach to trade capacity building

Context

Effective efforts to advance inclusive and sustainable trade, investment and innovation can provide the conditions to end poverty within a generation. Over the last few decades, the world's economy has become truly global, interdependent and interconnected, with trade playing an increasingly important role. Economic transformation took place at an unprecedented speed, traversing national boundaries like never before. As a result, developing countries have become engines of growth and hundreds of millions of people have been lifted out of poverty.

Nevertheless, the economic transformation has not yet yielded the necessary job creation and poverty reduction to ensure global equality. Lack of decent work opportunities, in particular in rural areas, drives the degradation of urban areas, and informality and uncertainty have become the norm. An additional burden has been the inherent economic fragility that pervaded the globe since the financial crisis and, more recently, as a result of the COVID-19 pandemic. More than ever, countries are also faced with complex security issues, humanitarian questions as well as environmental challenges, which create uncertainties regarding a sustainable future.

Trade, investment and innovation, as well as entrepreneurship, will remain key drivers of economic transformation for inclusive and sustainable growth.

Trade capacity-building approach

Global trade is increasingly embedded within value chains and governed by multilateral trade rules, such as the TBT and SPS Agreements. Furthermore, quality and compliance of products and services with market requirements and standards on consumer health and safety, environmental impact,

labour conditions and/or sustainability, have become key elements of competitiveness in global business relations. A demand-driven quality culture, together with a QI system and its conformity assessment services, support economic operators (in particular SMEs) to achieve and prove conformity with market requirements, compete on international markets and connect to global value chains.

The need to improve the movement of goods across national borders has become ever more important with value chains spanning the globe. The requirements of the new TFA, which followed the TBT and SPS Agreements, represent a major challenge as well as a great opportunity for developing countries. Lengthy procedures and border rejections result in major financial losses for the producers, particularly for SMEs, and can damage the reputation of exporting countries. Therefore, internationally recognized testing, inspection and certification services are crucial to meeting the standards of external markets. In addition, these services need to have the required and reliable institutional infrastructure capacity to ensure the sound functions of the whole quality system.

UNIDO's interventions in this respect span from policy and governance advice to the development of QI institutions and conformity assessment services, including the support of the private sector in achieving compliance with International Standards.

Strategic partners

Together with partners from the public and private sector, academia, national and international organizations in charge of standards setting and global practices on standards and conformity assessment, UNIDO promotes good practices, capacity building and training, creation and dissemination of knowledge and global goods and fosters global cooperation in standards setting, measurement and compliance development along value chains. UNIDO's partners in the field of quality and standards include the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunication Union (ITU), the International Bureau of Weights and Measures (BIPM), the International Organization of Legal Metrology (OIML), the IAF and the ILAC, the WTO, the World Bank, the UNECE, the United Nations Conference on Trade and Development (UNCTAD), the International Trade Centre (ITC), the Global Facilitation Partnership (GFP) and the World Customs Organization (WCO).

Building a quality infrastructure: UNIDO's approach

QI – Building trust for trade

Setting up a QI system is one of the most positive and practical steps that a nation can take on the path towards developing a thriving economy as a basis for prosperity, health and well-being.

A QI supports governmental policy in areas including industrial development, trade competitiveness, efficient use of resources, food safety, health, environment and climate change.

The QI system covers essential aspects such as policy, institutions, service providers, and the value-adding use of International Standards and conformity assessment procedures.

QI for a sustainable future

A modern QI system could support public and private stakeholders in their efforts to address various challenges faced in pursuing economic prosperity, improving well-being of people and protecting our planet. QI needs to evolve – and swiftly – to be relevant in the face of ever more rapid technological innovations and the threats posed by climate change, pollution, diminution of resources and destruction of the biosphere. QI could be adapted to the impacts of the digital transformation and the “Fourth Industrial Revolution”, including artificial intelligence, smart manufacturing, smart energy, smart agriculture and the circular economy. In addition, QIs must evolve rapidly to help meet increasing societal demands, in particular, for gender equality. Gender equality is a fundamental human right, and is a necessary foundation for a prosperous, sustainable and peaceful world.

QIs also have a major role to play in bringing about a new economic paradigm. Many in society are becoming aware of the need to replace the wasteful excesses of consumerism through a circular economy, to be respectful of resources and to aim for general well-being rather than endless material acquisition. A tremendous shift is taking place in perceptions, from transforming economic growth for its own sake, with its accompanying destruction of resources and the environment, to one that seeks to preserve the environment and to increase prosperity and the quality of life for all.

The quality infrastructure system

QI, as defined by the International Network of QI (INetQI, formerly DCMAS), is the system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.

The quality infrastructure system (QIS) is required for the effective operation of domestic markets and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social well-being.

It relies on:

- Metrology
- Standardization
- Conformity assessment
- Accreditation
- Market surveillance

UNIDO's approach to QIS is holistic, from building awareness of QI to helping initiate, develop and strengthen a fit-for-purpose QIS that operates efficiently and cost-effectively. The approach emphasizes the need for strong collaboration with all stakeholders to meet shared objectives through agreed activities, leading to concrete actions.

UNIDO has extensive experience in assisting countries to strengthen their competitiveness in global markets. This assistance extends to promoting good governance, advocating good practice and supporting capacity building in quality, environmental sustainability, and social responsibility requirements.

In particular, UNIDO seeks to build up the national and regional QI needed to provide internationally recognized quality assurance services. Likewise, it provides services to strengthen national capacities to establish the legal and institutional frameworks for standards and conformity assessment.

The demonstration of conformity enables exporters to reduce compliance costs and facilitate access to global markets. Assistance is also provided to strengthen consumer authorities and consumer associations in developing countries.

The systematic approach to QI development

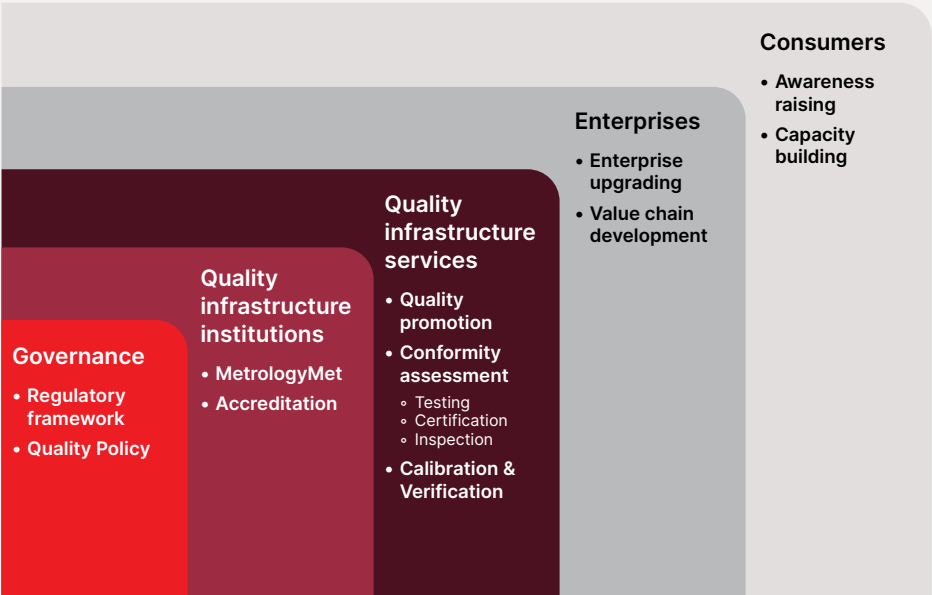


Figure 12: QI development

Governance

A fundamental component of the QIS is that of governance. The leading role in setting up a QIS is played by the country's government, which gives the initial impetus and is ultimately responsible for ensuring that the QIS fulfils policy objectives, meets the country's needs, conforms to International Standards and best practice, and complies with world trade rules. The government provides impetus by developing a national quality policy (NQP) and establishing the regulatory framework for the QIS.

National quality policy

The NQP is the basic government instrument for establishing and overseeing the QIS. It sets out the objectives of the QIS and a roadmap and schedule for setting it up. The government can use the development of the NQP as an opportunity to increase awareness of the importance of the QIS and how the different national actors can benefit from it. It can do this by inviting broad stakeholder participation to develop the NQP. Examples of stakeholders include representatives of its own ministries and agencies, regulatory bodies, trade and industry associations, chambers of commerce, consumer associations, and providers and users of calibration, testing, certification and inspection services. Their input will help ensure that the NQP and QIS meet the needs of the nation, while their participation will encourage implementation of the policy and “buy-in” of the QIS.

Regulatory framework

Since one of the main benefits expected from the QIS is to increase the country's ability to participate in global markets, it is important for the government to ensure that the nation develops and implements standards and technical regulations consistently with the multilateral trade rules. These rules are established by the WTO.

Because of the mandatory nature of technical regulations, they have the potential to become technical barriers to trade that prevent or hinder the flow of goods and services between nations. Although standards are generally voluntary, they become mandatory when referenced in regulations, for which they provide the technical content underpinning the policy objective of the regulation concerned.

In particular, the inconsistent use of standards and regulations can create technical barriers. This can happen because technical regulations in a country may be introduced by different ministries (e.g. Ministry of Transport for

seat belts, Ministry of Health for labelling of foods, Ministry of Environment for packaging materials). Therefore, the QIS needs to include a national regulatory framework that each regulator can work within to ensure consistency.

In this respect, UNIDO ***offers services which aim to:***

- Define quality-related policies and good governance strategies.
- Evaluate and modernize technical regulation regimes, including policy and legislation development, market surveillance and import inspection system development.

Available tools:

- Quality Policy – Guiding Principles
- Quality Policy – Technical Guide
- Quality Policy – A Practical Tool
- Quality Infrastructure for Sustainable Development (QI4SD) Index, measuring fit-for-purpose QI system in support of the SDGs.
- Quality Infrastructure for Trade Facilitation (QI4TF) Toolkit, identifying gaps in NQI systems to support an effective implementation of the TFA.
- *Guideline on good governance and Professional Practices for Organizations and Personnel of the National Quality Infrastructure*, with samples of tools, forms and checklists that can be used to manage and monitor the implementation of good governance and professional practices within a national institution.

QI institutions

The key institutional components in the QIS are made up of the high-level institutions responsible for standardization, metrology, conformity assessment and accreditation.

Standardization

We all have certain expectations about the products and services we buy and use. We expect them to be fit for their purpose, safe and easy to use, not harmful to health or to the environment, reliable and efficient, interchangeable and compatible with other products and to provide their benefits at an economical cost. Standards are documents that translate such

desired characteristics into dimensions, tolerances, weights, processes, systems, best practice and other specifics so that products and services that conform to their requirements provide confidence to buyers and users.

For developing countries, International Standards developed on the basis of worldwide consensus by experts in the field constitute an important source of technological know-how. By defining the characteristics that products and services will be expected to meet on export markets, International Standards give developing countries a basis for making the right decisions when investing their scarce resources.

Within a QIS, standardization is usually the responsibility of a national standards body (NSB) that may represent the country's interests within organizations such as ISO. The NSB may provide national delegations to participate in the development of standards that are of key importance to their country's economy. Whether or not the NSB participates in the development of a standard, it is free to adopt and translate International Standards as national standards. By using International Standards, it ensures that the country benefits from international, state-of-the-art knowledge and that locally produced products will meet the requirements demanded by export customers.

For consumers, conformance of products and services to International Standards provides assurance about their quality, safety and reliability.

Metrology

Metrology is the science of measurement and it is a vital part of everyday life. For example, food is bought by weight, water and electricity are metered, and instruments analysing blood samples must be precise. It is easy to understand that faulty measurements by medical devices, or in the maintenance of critical components, such as vehicle brakes or aircraft engines, can be highly dangerous. Accurate measurements and measuring equipment are needed for the protection of health, safety, the environment and consumers. They are vital, too, in contracts between individual business partners and in world trade in general.

Balances and other instruments in laboratories need to be calibrated so that they can provide reliable measurements. Firms cannot satisfactorily implement process controls to manufacture a product to standardized characteristics if control instruments, such as those measuring pressure and temperature, are not properly calibrated.

Confidence in national measurement is assured by a NMI when it becomes signatory to the mutual recognition arrangement of the International Committee of Weights and Measures (CIPM MRA). The CIPM MRA provides the institutional and technical framework for NMIs to recognize each other's measurement standards and calibration certificates, thus supporting world trade.

Accreditation

Accreditation is the process by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Within a QIS, the body made responsible for accreditation will evaluate the competence of product, management system and personnel certification bodies, testing laboratories and inspection bodies. Its official approval—known as “accreditation”—will indicate to customers and users of the services of these organizations that they can have confidence in their work.

Accreditation is often the responsibility of a national accreditation body that may seek recognition of its accreditations within the frameworks of the IAF and ILAC.

IAF and ILAC promote and manage “mutual” or “multilateral” recognition “agreements” or “arrangements” (MRA) whereby the parties involved agree to recognize the results of each other's testing, inspection, certification or accreditation. MRAs can be an important step towards reducing the multiple assessments that products, services, systems, processes and materials may need to undergo, especially when they are traded across borders. Since MRAs facilitate the acceptance of goods and services everywhere on the basis of a single assessment in one country, they contribute to the efficiency of the international trading system to the benefit of suppliers and customers alike.

In this respect, UNIDO ***offers services which aim to:***

- Strengthen capacities of national and regional quality systems (i.e. metrology, standardization and accreditation).
- Develop enquiry points and connections with single window.
- Support mutual recognition for accreditation and metrology institutions.

Available tools:

- QI system strengthening.

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- **Good Governance in Quality Infrastructure**, an online training that aims to assist QI practitioners to build a good governance system within their organizations and to guide their work with samples of useful tools.
 - Standards compliance observatory.
 - Sustainability and private-standards capacity building.

Quality infrastructure services

A further link in the QIS chain is made up of the organizations that provide conformity assessment services for the QI.

Conformity assessment

Conformity assessment is the name given to the processes and procedures that are used to demonstrate that a product or service, management system, organization or personnel meets specified requirements. These requirements are usually stated in International Standards developed by organizations such as ISO. The requirements for conformity assessment are given in International Standards and this helps to ensure worldwide consistency in promoting cross-border acceptance of results.

The use of International Standards thus harmonizes conformity assessment activities throughout the world. This has far-reaching benefits for international trade in general. Agreements among nations or regions on the mutual acceptability of requirements, assessment methods, inspection or test results, etc. can all help to reduce or remove technical barriers to trade. These are requirements and rules – often defined in regulations – relating to importation and market access that vary from country to country and may bar a foreign product from entering a national market.

The 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.

The TBT Agreement promotes the recognition by countries of each other's conformity assessment results as a way of reducing barriers to trade. It emphasizes that confidence in the reliability of conformity assessment results is a prerequisite for the recognition of assessments. Therefore, a QIS in a developing country that is able to demonstrate the conformity of the nation's products and services to International Standards, and also to provide

confidence in local conformity assessment activities, makes a significant contribution to the competitiveness of a nation's economy and industry.

Conformity assessment services are usually performed by organizations specializing in one or more activities, of which the main ones are described below. They may supply their services on a commercial basis, or they may be operated or mandated by the government.

Testing

A product is tested against a specific set of criteria, such as performance or safety. Testing is the most common form of conformity assessment. Testing also provides the basis for other types of conformity assessment, such as inspection and product certification.

Inspection

Inspection bodies play an essential role in cross-border trade. They act on behalf of governments and business partners (importers and exporters) by inspecting imported goods and materials. They are responsible for examining a huge range of products, materials, installations, plants, processes, work procedures and services, in the private as well as the public sector, and report on such parameters as quality, fitness for use and continuing safety in operation. The overall aim is to reduce risk to the buyer, owner, user or consumer of the item being inspected. Government and business often use their services to inspect imported goods and materials.

Certification

Certification is when a certification body gives written assurance that a product, service, process, personnel, organization or management system conforms to specific requirements.

The most well-known examples are the certification of quality management systems and environmental management systems as conforming, respectively, to ISO 9001 and ISO 14001. More than a million business and public-sector organizations worldwide have had their management systems certified to one or both of these standards. Newer management standards that also allow for certification address food safety (ISO 22000), energy management (ISO 50001) and information security (ISO/IEC 27001).

Product certification may consist of initial testing of a product combined with the assessment of its supplier's quality management system. This may be followed up by testing of samples from the factory and/or the open market.

Other product certification schemes comprise initial testing and surveillance testing, while still others rely on the testing of a sample product—this is known as type testing. The type of certification scheme chosen will depend on factors such as the degree of potential risk to consumers and users of the product.

In this respect, UNIDO ***offers services which aim to:***

- Build and improve conformity assessment capacities (testing, inspection, certification, calibration, etc.).
- Assist conformity assessment entities in mitigating identified risks.
- Support mutual recognition of conformity assessment procedures between main trading countries for selected value chains.

Available tools:

- Laboratory Policy Development Guide.
- Laboratory diagnostic and knowledge tools.
- Laboratory assessment tool that can be used to determine compliance with ISO/IEC 17025, by assessing the level of compliance of the laboratory in line with the requirements.
- Trade facilitation tool that helps to determine technical gaps in requirements for testing and inspection between countries.
- Conformity assessment service diagnostic tool to identify conformity assessment services along a specific product, sector or value chain.
- Inventory/directory of laboratories that lists laboratories and their scopes.
- LabNet, an innovative Web-based system that provides information on services offered by CABs in calibration, testing, inspection, and certification.

Enterprises and consumers

The increased choice of competing products brought by global markets and the downward pressure on prices resulting from competition mean that customers will tend to reject products that they do not perceive as being quality products, even though their price may be low. Global markets and competition will probably tend to give them a choice of better quality at the same price.

The emphasis of a QIS is on markets and consumers. All component parts of the QIS act dynamically between each other. This interaction is particularly intense among enterprises and customers/consumers. Enterprises offer products and services and receive direct and indirect feedback from consumers in the form of sales and levels of customer satisfaction.

Markets also provide feedback—although not necessarily as swiftly as coming from the point of sale—on compliance capacity of enterprises, QI services, QI institutions and governance. This feedback allows review, modification and improvement of the different components and of the whole QI—which underlines the dynamism and system nature of the QIS.

In this respect, UNIDO ***offers services which aim to:***

- Analyse the trade performance of specific value chains for the exporting economy.
- Assess the quality and standards compliance capacity of selected value chains.
- Support SMEs to take advantage of standards, be more competitive and thus participate in global value chains.
- Promote quality awareness with the public sector, economic operators and consumers.
- Offer advisory services to manage risks identified in the trade performance analysis.

Available tools:

- Standards Compliance Analytics, an online system used to explore, compare and assess countries' compliance record with trade standards in major markets.
- Quality and standards compliance development for value chains.

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- Rejection analysis tool which helps identify those systematic deficiencies in countries that prevent compliance with market requirements.
 - Quality along the Value Chain (QI4VC), assessing quality-related gaps along the value chain and providing tailored interventions to address them through a systematic methodology.
 - **Roadmap to Quality, a state-of-the-art e-training programme to promote understanding and facilitate the implementation of quality management effectively throughout a company.**
 - **Culture for Quality (C4Q) Tool, identifying and holistically assessing beliefs, values, and behaviours to promote quality management in a value chain ecosystem.**
 - Quality promotion and award schemes.
 - Trade facilitation toolbox.

UNIDO'S QIS expertise

The ability of developing countries to exploit commercial opportunities, to compete on global markets and to participate in international value chains is often challenged by their difficulties in demonstrating compliance with quality requirements and trade rules. UNIDO helps to tackle these challenges by working with them to set up a QI system. Such a programme is one of the specialized services that UNIDO offers among its overall activities to promote ISID. This approach offers developing countries and economies in transition opportunities to eradicate poverty and develop sustainably. ISID helps them to build up their industrial base as a platform for social inclusiveness, economic competitiveness, environmental sustainability and integrating with the global trading system.

UNIDO has an extensive and proven track record in working with government, industry and other major stakeholders in developing countries to build their QIS. As a first step, UNIDO can offer training to increase understanding of a QIS and how to get the best out of it. UNIDO's approach is holistic, from building awareness of the QIS to helping to set it up and get it running efficiently and effectively. Throughout, UNIDO emphasizes hand-in-hand and hands-on cooperation with stakeholders on collective actions based on shared objectives.

Chapter 6

Case studies

This chapter presents case studies of building quality infrastructure systems (QISs) in a holistic and integrated manner and following a value chain approach. It also details specialized interventions on individual components of the infrastructures—quality policy, metrology and accreditation.

This section describes the variety of resources that UNIDO deploys and the wide range of activities it undertakes in building each of these QISs. It is illustrated with brief accounts of UNIDO's experience in several developing countries and a regional experience of the Economic Community of West African States (ECOWAS).

Each case study sets the national/regional context, explains the challenges exporters face with regard to quality, standards and accessing markets, the tailored approach adopted to tackle these challenges and, finally, the results achieved so far through the interventions.



MALAWI

A holistic approach to quality infrastructure development

As Malawi's NQI is incipient, aspiring exporters have yet to discover their export potential. As such, exporters engage in the costly and time-consuming exercise of re-testing, re-inspection or recertification outside Malawi, which has a very negative impact on enterprise competitiveness. In partnership with UNIDO, within the framework of a project titled "Development of a robust standardization, quality assurance, accreditation and metrology (SQAM)", a major overhaul and upgrading of SQAM facilities and services helped address these constraints.

The first step was to formulate a NQP and an appropriate strategy to implement this. A major milestone was the passing of a Metrology Act, which provides for a new NMI, independent from the Metrology Services Department (MSD) of the Malawi Bureau of Standards (MBS). This was of particular significance as the separation of regulatory functions from the provision of conformity assessment services within a single body is an essential feature of a modern NQI and signals transparency and good governance.

The Act also replaced outdated laws as a result of advances in the technology of measurement systems and instruments and changes in the operating environment. MBS was also endowed with new tools, enabling the agency to properly execute its mandate of establishing a national measurement system, ensuring traceability of measurements and undertaking conformity assessment of measurements to physical standards.

Training was, of course, of paramount importance to the project; a special emphasis was placed on risk management in the regulatory framework, such that technical regulations address risks without creating unnecessary trade barriers. To this end, the British Standards Institution (BSI) delivered in-house training courses to regulatory specialists. Further, international study tours were conducted on proper handling of new equipment, which were installed in the MSD. MSD now offers verification, inspection, and calibration services.

Ancillary project activities included the strengthening of national enquiry points to enable them to respond to information requests and requirements of the TBT and SPS Agreements. At the enterprise-level, technical assistance was delivered to SMEs on the implementation of ISO 22 000 for food safety management systems and HACCP standards, with a focus on SMEs headed and operated by women and young entrepreneurs.

In conclusion, it can be stated that the project contributed to a more effective and sustainable NQI in Malawi in accordance with international and regional principles, practices (e.g. Common Market for Eastern and Southern Africa (COMESA), Southern African Development Community (SADC)), and benchmarks by strengthening MBS's technical performance. This has had direct commercial benefits for Malawi enterprises with access to enhanced local and affordable services in the NQI system and indirect regulatory impact in terms of improved trade and protection of consumer rights of Malawian citizens, residents, and visitors.



MOZAMBIQUE

Creating demand-driven QI along the value chain

As one of the world's 48 least-developed countries, Mozambique faces a tremendous challenge in bringing its manufacturing sector up to 21st-century standards. A major shortcoming is the lack of competitive supply capacity and compliance infrastructure. To help overcome these obstacles, UNIDO,

with funds from Austria and the EU, developed the Private Sector and Quality Promotion Programme for Mozambique “Competir com Qualidade”.

This assistance has helped to build a strong and sustainable NQI resting on four pillars. The first of these pillars was the formulation of a NQP—a basic government instrument that defines the objectives of the NQI in relation to standardization, metrology, accreditation and conformity assessment. Carefully thought-through policy interventions are essential to lay the foundations of a solid QIS in which roles and responsibilities are clear, thus avoiding conflicts of interest between public institutions and private quality service providers.

The second pillar supported the National Institute for Standardization and Quality (INNOQ, IP) in upgrading its services in metrology, certification and standardization. Thirdly, a number of testing laboratories have been given technical support to achieve international recognition of competence—i.e. accreditation—to enable them to assess the quality of products against International Standards. This ensures that locally produced goods meet the requirements of the global market. The fourth pillar focused on private-sector enterprises, helping them to reach International Standards such as ISO 9001 for quality management and offering quality awards in recognition of their efforts.

At the institutional level, INNOQ, IP was helped to expand the scope of accreditation in various areas, ranging from calibration services (ISO/IEC 17025) to certification of management systems (ISO 9001) and of products (ISO/IEC 17065). It has also developed a business plan, marketing strategy, and set up a training unit, all of which contributed to the sustainability of the assistance when the project ended.

Technical support to CABs included training in different testing techniques and the adoption of International Standards such as ISO/IEC 17025 on management systems for laboratories, the ISO 19011 guidelines for auditing management systems, and ISO 15189 on management systems for medical laboratories.

Sustainability considerations are a key driver in this carefully coordinated range of interventions designed to ensure a QIS that is demand-driven and responds to private-sector needs. Thus, the project fully embraced the United Nations Sustainable Development Goal 9, whose objective is to build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation.



BURUNDI

Improving market access through quality and standards

SMEs in Burundi are the backbone of the economy and of the export market. However, farmers need much greater awareness of technical regulations on products destined for trade. With funding from the Enhanced Integrated Framework (EIF) and the Norwegian Agency for Development Cooperation (Norad), UNIDO, in 2015, helped various local institutions to improve the quality of coffee, fruits and vegetables.

To achieve concrete and sustainable results, each link in the value chain needs to ensure quality, starting with seed growers through producers, coffee testers, manufacturers of processed products, packers and exporters. Just one weak link can generate problems throughout the chain. In a two-pronged approach, an existing NQI for standardization, inspection and testing is being strengthened while national and international experts work with professional associations to improve technical services and training for coffee growers and producers of fresh or processed fruits and vegetables.

To improve conformity assessment, six analytical and testing laboratories that directly support the value chains have been upgraded and training has been provided to ensure compliance with the requirements of laboratory accreditation schemes based on ISO/IEC 17025, covering testing performed using standard methods.

In addition to routine checks on quality and compliance, the fact that Burundi's exports are predominantly agricultural means that sanitary and phytosanitary regulations must also be respected. To meet this challenge, national experts have been trained to provide the relevant technical support to producers, plant owners, leaders of cooperatives and workers in processing units and exporters. Knowledge has also been transferred on quality management systems, organic certification, Fairtrade and HACCP.

At the end of the national value chain, export skills have been strengthened through assistance in the creation of several export consortia comprising members of the Federation of Commerce and Industry. Exporters are helped to draw up business plans, make contact with potential buyers and roasters interested in specialty coffees, and to cut costs by joint sourcing of inputs. Working together and respecting common production and quality standards, Burundi's producers are well on the way to carving out a niche in global markets with a unique label—"Burundi Coffee makes the world taste better!"



COLOMBIA

Quality chemical products for competitive economic diversification

The chemical industry is an important input supplier to various industries, such as for automotive parts, textiles, pharmaceuticals, cosmetics, and agribusiness, among others. In Colombia, it provides more sophisticated inputs than the average export basket and represents about 22 percent the country's non-mining energy exports. A growing and dynamic industry, it faced several acute challenges on safe management of chemicals, innovation and sustainability.

Given the industry's challenges, the Ministry of Trade, Industry and Tourism of Colombia and UNIDO identified special productive capacities for chemicals for country intervention within the framework of the Global Quality and Standards Programme (GQSP). Actors from chemical, plastic, paint and cosmetics (using natural ingredients) sectors are leading partners for upgrading the country's NQI system and for elevating the technical skills of the industry.

Complementarily, technical support will be delivered to building awareness and improving the quality performance of SMEs operating along the chemical value chain (CVC), thus contributing to income and employment generation.

Firstly, more than eight NQI key entities are undergoing technical and organizational capacity building, to strengthen the reliability and accuracy of functions or services on standardization, technical regulations, conformity assessment, metrology, surveillance and control. This has resulted in improved testing, inspection, certification, and standardization services, which will, in turn, support SMEs in the demonstration and attestation of quality of national CVC products and services internationally. The development of Buscalab, a search engine with a national offer of laboratory services, has been highlighted as an important tool that links the demand and local supply of these services.

With tailored technical support, 80 key players along the CVC, such as producers, laboratories and exporters, have been guided to adopt relevant International Standards, such as Green Seals and ISO/IEC 17025, thus boosting productivity and efficiency.

Various interventions enhance the GQSP's systemic approach. For the implementation of the Globally Harmonized System (GHS) at the country level, regulators received technical and regulatory advisory support; SMEs received tailored technical support to implement this system; and academic institutions received guidance to develop and launch GHS-related

educational programmes aimed at industry professionals. Moreover, the National Accreditation Body of Colombia (ONAC) was provided with technical guidance on building and implementing its accreditation scheme for reference materials producers under ISO/IEC 17034; in parallel, national laboratories are undergoing capacity building, to implement this standard and to achieve future international recognition against this standard.

As sustainability is another important area of intervention, the GQSP is implementing a sustainability pilot that accompanies five enterprises on practically applying the principles of the circular economy, to develop a new product from recovered polyethylene terephthalate (PET) that reduces waste and minimizes negative impact on human health and environment. The pilot is accompanied by a sustainability training programme, which is part of a larger technical training programme that has reached more than 6,000 people and 600 SMEs.

In addition to technical support, the GQSP has also developed more than 12 technical publications encompassing sectoral diagnostics, guides for exporting natural ingredients, guides for designing security data sheets under GHS, and guides for consumers and entrepreneurs about pre-packaging, among other topics. The GQSP has also supported the upgrading of an application that enables the identification of different plastic materials used in the chemical industry, which is publicly available to the entire industry.



GHANA

Strengthening collective efficiency through clusters and standards

Ghana's industry has been performing well for many years now and the country's former status of least-developed country is long forgotten. As local manufacturers integrate into global markets, they have learned that they must not only respond to consumers' needs, but also comply with an expanding range of standards in both the domestic and world markets.

Capitalizing on UNIDO's trade capacity-building programme, the West Africa Competitiveness Programme is supporting QI institutions as well as clusters and SMEs in being more competitive and knowledgeable of market requirements and regulations. The project, funded by the EU, focuses on three specific value chains: fruits (mango and pineapple), cassava, and cosmetics

and personal care products. Technical support is provided by UNIDO's experts to the different clusters to ensure better collaboration and coordination at the regional level, within the target value chains.

It was clear that local producers were often unaware of standards and of their importance to developing their businesses. At the same time, many of the existing domestic standards required updating, with a need to also introduce some new ones.

In a two-pronged approach, public institutions tasked with conformity assessment are being helped to upgrade their services in standardization, testing, certification and inspection to global standards. Simultaneously, the targeted SMEs clustered at the value chain level are encouraged to make use of these conformity assessment services and thus improve their sustainability, quality and export competitiveness.

In terms of standardization, 16 new standards have been developed within the project. If producers comply with these standards, they experience a reduced number of rejections of their goods, and so save costs while improving quality and food safety where relevant.

With respect to conformity assessment, four laboratories relevant for the cosmetic value chain have been supported for the revision of documents, such as the quality and procedures manual, with the aim of achieving accreditation. The Food and Drug Administration (FDA) cosmetics laboratory has already been accredited in 2021, and the Ghana Standards Authority – Cosmetics Laboratory, was accredited in 2022.

Furthermore, more than 60 laboratory technicians are being trained to comply with ISO/IEC 17025 and subsequently ensure that more laboratories in the country can achieve accreditation.

In parallel to this, through the Ghana Export Promotion Authority (GEPA) Export School, local capacity is developed to coach exporters and potential exporters on how to successfully and efficiently access new international markets. In this regard, a market hub for providing market information to Ghanaian SMEs is in place and an export readiness checker is available to any company willing to assess its readiness.

Thanks to the 5Cs approach (Coordinate – Compete – Conform – Connect – Credit) promoted through WACOMP Ghana, and the support provided to the QI institutions coupled with the improvement of the competencies at the SME level, the three target value chains are becoming more competitive and ready to face international competition.



PERU

Improving the quality of coffee and cocoa and the lives of its farmers

Peru is among the top ten producers of green coffee beans and cocoa beans in the world. In addition to exporting large quantities of conventional coffee and cocoa, Peru has become a recognized origin for its special characteristics. Both are products with a high export tradition and were declared national flagship products of Peru.

Coffee and cocoa are predominantly smallholder crops with largely export-oriented value chains, and facing similar problems. In Peru, coffee and cocoa are of great social importance for rural development and poverty eradication and are promoted as a replacement crop for illegal coca production.

The new trend in the world is the orientation of consumers towards sustainable, traceable and higher quality products; Peru has managed to position itself as one of the top ten exporters of coffee and cocoa, as well as one of the main suppliers of organic and fair trade certified products. However, quality remains an issue to be improved.

With funding from the Swiss Cooperation, through its State Secretariat for Economic Affairs (SECO), UNIDO in co-management with the Peruvian National Quality Institute (INACAL) is implementing the Peruvian chapter of the UNIDO GQSP. This project aims to increase the quality of the coffee and cocoa value chains and contribute to Peru's competitiveness by strengthening the competence and sustainability of the NQI system, improving SME compliance with standards and technical regulations and promoting a culture of quality.

To improve conformity assessment, the GQSP Peru has evaluated 17 laboratories serving the coffee and cocoa value chains and is supporting selected laboratories towards ISO/IEC 17025 accreditation. Furthermore, six coffee quality control laboratories were evaluated and one had already achieved an international certification.

Additionally, the project has strengthened the technical and laboratory equipment capacities of the Metrology Directorate of INACAL for the measurement of cadmium and other heavy metals in cocoa, allowing Peru to develop reference materials in support of conformity assessment activities.

Moreover, as physical, sensory and organoleptic analysis are fundamental to assure the quality of coffee and cocoa, UNIDO has trained more than 140 specialists (65 of whom were women) to increase the expertise in the San Martin Region, one of the most important coffee and cocoa regions in Peru.

As part of the support to the private sector, the project has selected eight cooperatives to strengthen their technical, infrastructural and equipment resources so that they are able to increase quality and innovate. UNIDO has also supported INACAL in the development of four new standards and 16 standards implementation guidelines to facilitate and increase their adoption by the private sector.



NAMIBIA

Laying the foundation with quality policy

The Government of the Republic of Namibia is vigorously pursuing the achievement of Vision 2030 which envisages Namibia as a country with a quality of life for all its people at the level of its counterparts in the developed world by the year 2030. Trade is of paramount importance to achieve this level of socio-economic development. It was recognized that although Namibia had been progressive in that it approved and implemented a Namibia NQP in 1999, which had served the country well, there had been substantive changes in the landscape that needed to be considered anew at the policy level. The changes included a growing population and economy, a greater emphasis on better regulation, market operation and trade as an enabler for development, and regional and global integration. Namibia has to have access to a supportive and internationally recognized QI that can provide the independent attestation of product or service quality, without which access to the international markets would remain a challenge.

The revision of the 1999 NQP was supported by the trade capacity building for exports in Namibia project which was funded by Norad and implemented by UNIDO. The consultation process for the revision consisted of a series of UNIDO-facilitated workshops which included both the public and private sector organizations in four geographic regions of Namibia. Finally, UNIDO drafted the revised NQP for circulation for comment and these comments were discussed at a validation workshop before the final draft was presented to the key government department for preparation to submit to Cabinet for approval.

The NQP is a Public Private Partnership (PPP) that provides the private sector with supportive standards, metrology and accreditation services, which, in the interests of the public and for the good of the nation, is

established and maintained by government funding. These three services are the fundamentals that allow affordable conformity assessment services to develop and to gain international recognition, thereby facilitating marketing of products under the slogan “Tested once, certified once, accepted everywhere”.

The domain of the NQP spans across a range of ministries and their agencies, as well as across various institutions and private sector stakeholders.

A significant inclusion in the revised NQP is the development and implementation of a common national Technical Regulation Framework (TRF) which includes the establishment of effective cooperation amongst the NQI institutions and the national regulatory authorities with their international counterparts. Implementation of the TRF will be overseen by a Technical Regulation Coordination Office (TRCO) either in the National Planning Commission, Attorney General or the Office of the Prime Minister.

The revised NQP will be implemented over a five-year period.



ECOWAS

Advancing economic integration through regional QI system

In West Africa, the benefits of regional collaboration are amply demonstrated in the advances made since 2000 in establishing and upgrading national and regional QI. The overall objective of this assistance is to strengthen economic integration and trade by creating an environment that facilitates compliance with international trade rules and technical regulations.

With funding from the EU, UNIDO has implemented a series of programmes, working initially with the eight-member UEMOA grouping (2000–2005) and then expanding to incorporate the remaining seven members of the ECOWAS and Mauritania. The first step was to establish national quality policies for individual countries, together with a regional quality policy known as ECOQUAL. With quality policy defined, the next move was the establishment of the West Africa QI, embracing the areas of standardization, quality promotion, conformity assessment, accreditation and metrology.

In standardization, the ECOWAS Standards Harmonization Model (ECOSHAM) was designed. In view of the wide range of products and services available

in such a large regional block of countries, ECOSHAM priority areas were identified for the adoption of harmonized standards such as agricultural products, chemicals, construction, electrical engineering and tourism.

Progress in the field of conformity assessment and laboratories has been particularly remarkable. In 2000, there were virtually no accredited laboratories in West Africa. Today, there are almost 150 operating in both metrology (mass, volume, temperature, pressure and humidity), testing (medical biology, material testing, food chemistry and microbiology), and regional cooperation is resulting in major cost savings. Thanks to the existence of accredited metrology laboratories, for example, in Benin, Ghana and Senegal in the field of mass and Ghana in the field of temperature, volume, humidity and pressure, economic operators, including industries and testing laboratories, have access to local and affordable services to connect their measurement standards to the International System of Units. As an illustration, the calibration of a temperature probe in Senegal had previously to be sent to France. With services available in situ or in the region, costs can be almost halved.

Now, a regional accreditation mechanism is taking shape in which countries without national accreditation bodies will be able to access the accreditation services of CABs via institutions in neighbouring countries. Ultimately, the ECOWAS Certification Scheme will enable national product certification bodies to deliver the ECOWAS quality mark and a regional quality brand will be truly established.



GUATEMALA

Improving metrological capacities for industrial competitiveness

As local enterprises in Guatemala, particularly in the agro-industrial sector, struggled to get a foothold in both regional and global markets, it became evident that they were not able to meet the rigorous standards prevailing in external markets. Recognizing the challenges of overcoming such technical barriers to trade in its drive to expand export markets, the government decided to overhaul the national QI system.

The successful penetration of global markets called for traceability to international metrological standards and involved product testing, legal verifications and quality control as well as the internationally recognized accreditation of laboratories.

UNIDO was called upon to support this endeavour and the first step was to carry out a review of the legal framework and the way in which the national quality system was operating. At the same time, a survey was carried out to gain an accurate picture of demand for, and supply of, metrology services. In order to comply with international requirements, a major project was designed involving the setting up of a new National Metrology Centre (CENAME) as part of the National Quality System Directorate within the Ministry of Economy.

The next step was the construction of new laboratory facilities for CENAME, including the provision of auxiliary equipment to ensure the necessary environmental conditions for mass, temperature, volume, length, pressure, electricity, dimensional and force. Technicians received additional training and international traceability was provided for equipment.

Meanwhile, and to ensure the continuity of the most vital metrology services, existing laboratories which had been operated by the former regional organization ICAITI (Central American Research Institute for Industry) were upgraded as a key step towards achieving internationally recognized accreditation.

Throughout the project, there has been an emphasis on involving all the stakeholders, for example, when assessing demand for metrology services. Independence and transparency are also vital and UNIDO's international experts and the project manager were responsible for validation of the design for CENAME. An outside company was contracted to regularly inspect progress during construction and international partner, the National Metrology Institute of Germany (PTB) confirmed the suitability of laboratory premises at the end of the construction process.

CENAME is now operational and making a tangible contribution to the government's drive to improve industrial competitiveness. Moreover, the solid foundations on which the project was built augur well for the future sustainability of Guatemala's national QI system.

Appendix 1

International conformity assessment standards

(ISO/IEC 17000 series of standards)

IEC and ISO work together through the ISO Committee on Conformity Assessment (CASCO) to develop a suite of International Standards for conformity assessment. These International Standards are published as dual logo ISO/IEC standards and are formulated in the ISO/IEC 17000 series of standards, also known as the CASCO toolbox.

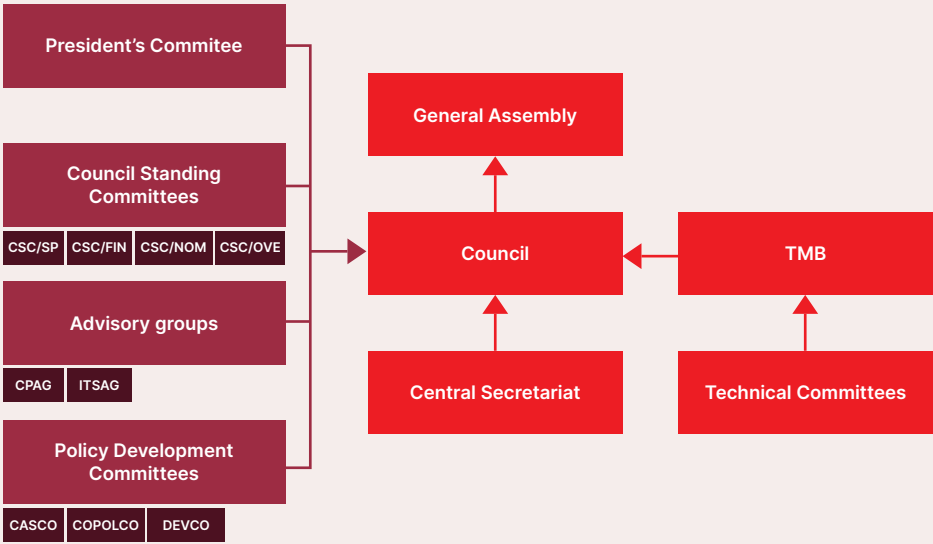


Figure 13: ISO structure and relationship

IEC CAB (Conformity Assessment Board)

IEC has both standards development activities and conformity assessment activities. To avoid conflict of interest, the management of those two sets of complementary activities has been split to ensure their separation. The standards development work is managed by the IEC Standardization Management Board (SMB) and the conformity assessment work is managed by the IEC CAB.

IEC CAB manages and operates four global IEC CA Systems that offer global conformity assessment services. They are IECEE, IECEx, IECQ and IECRE (for more information see [Chapter 3](#) and [Appendix 2](#)).

Each of these four global CA Systems create a framework into which professional certification bodies, testing laboratories, inspection bodies and so on, from around the world, come to work together in a “team” structure, with harmonized methodology and operational rules, to ensure consistent and comparable CA results and the success of the mutual recognition agreement. IEC does not do testing or certification itself, rather, it is the professional bodies that do this. This is very similar to the way in which standards are developed by both IEC and ISO. Neither organization actually writes technical standards themselves. Rather, it is subject-matter experts from around the world who come and participate in the standards development framework provided under the ISO/IEC Directives, who actually write the standards.

As ISO is exclusively a standards development organization and has no conformity assessment activities, and in order to avoid any conflict of interest between the standards development and conformity assessment activities within IEC, it was agreed, between the two organizations, that the development of ISO/IEC International Standards for conformity assessment would be managed by ISO. This is why the development of the ISO/IEC 17000 series of International Standards for conformity assessment is managed by ISO/CASCO.

ISO/CASCO

The Policy Development Committee on Conformity Assessment (CASCO) shall:

- a.** Develop International Standards and other ISO and ISO/IEC deliverables related to conformity assessment.
- b.** Promote recognition and broad acceptance of international, regional and national conformity assessment systems, and appropriate use of International Standards and other ISO and ISO/IEC deliverables for conformity assessment.
- c.** In relation to conformity assessment:
 - i.** Identify and analyze new or emerging trends.
 - ii.** Provide a forum for the exchange of information on the experience of stakeholders in the development and implementation of standards and on other related questions of interest
 - iii.** Advise the ISO Council regarding new or revised policies or actions.
 - iv.** Evaluate current and new conformity assessment methods as relevant to emerging or changing standards or other technical specifications.
- d.** Support, through advice and oversight, ISO and ISO/IEC Technical committees when developing ISO and ISO/IEC deliverables related to conformity assessment requirements and guidance, including but not limited to sectoral conformity assessment requirements, and
- e.** Prepare supporting material such as brochures and other information related to the activities covered by CASCO.

The development process of ISO/IEC International Standards for conformity assessment follows the ISO/IEC Directives. The standards developed under the management of CASCO go through a number of stages where IEC national committees (NCs) and ISO member bodies (MBs) have the opportunity to comment and vote. On the IEC side, all full member NCs are participating (P) members by default, and all other IEC NCs are observer (O) members by default. On the ISO side, all ISO national standards member bodies have the opportunity to also become members of CASCO, with either participating or observer status. At time of publication, of ISO's 167 members

eligible for ISO/CASCO membership, 144 are represented in ISO/CASCO. That membership includes both developed and developing countries, and 95 of the total are participating (P) members and 49 are observer (O) members.

CASCO reports to ISO Council for operational issues that approves CASCO work programme annually. The Technical Management Board endorse the CASCO technical programme prior to submission of the work programme to council for approval. ISO/CASCO's outputs are both of a technical nature (standards, guides and other publications) and policy development. CASCO has been structured to have a number of key policy groups to complement the technical work undertaken in the CASCO working groups developing ISO/IEC 17000 series standards (CASCO toolbox) and other publications.

For more information - [ISO - ISO committee for conformity assessment \(CASCO\)](#).

Policy groups of ISO/CASCO

The CASCO Chairman's Policy and Coordination Group (CPC) gives explicit recognition to CASCO policy role and oversees the coordination amongst CASCO WGs. This group also assists the ISO/CASCO Chair in identifying strategic conformity assessment issues and developing policy.

The 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 ISO committees. It seeks to ensure that conformity assessment policies developed within CASCO are adhered to and understood within the ISO community, while also providing internal advice to that community on conformity assessment issues.

The Strategic Alliance and Regulatory Group (STAR) provides a mechanism for industry sectors and regulators to interact with CASCO (keeping abreast of activities in conformity assessment, promoting the ISO/IEC 17000 series standards, and providing a forum to discuss conformity assessment needs and concerns).

TIG liaises with other ISO technical committees (TCS)

STAR provides a forum for industry sectors and regulators to interact with CASCO

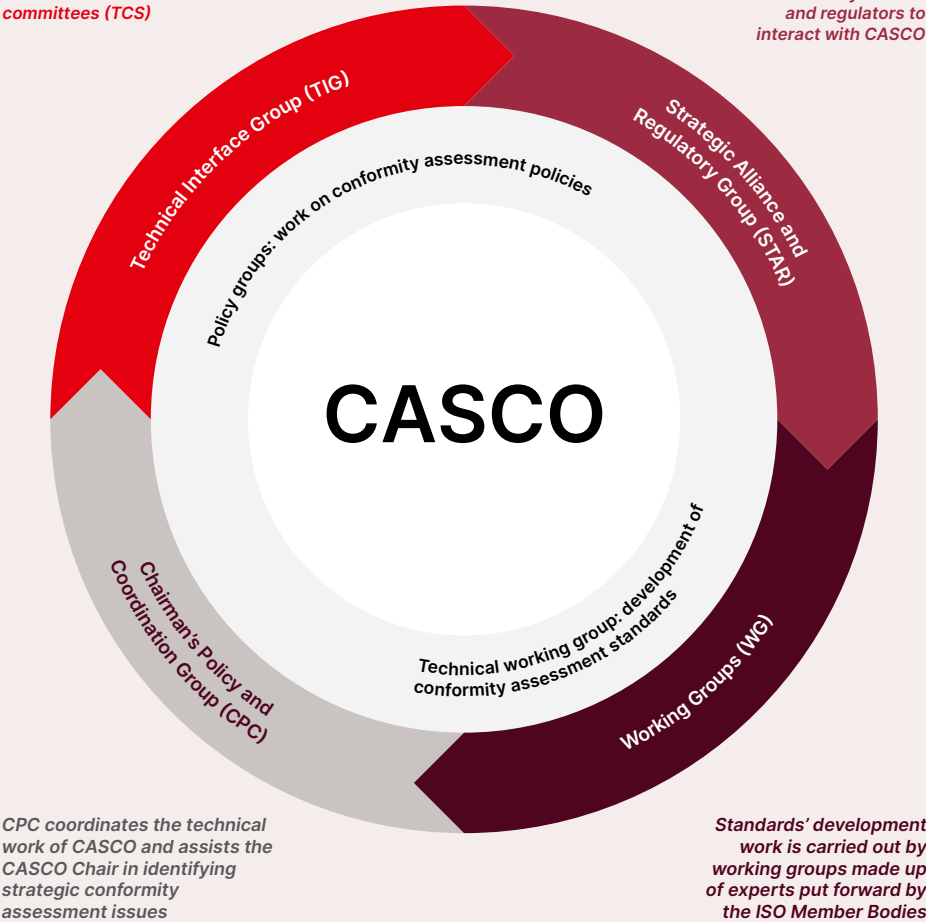


Figure 14: Supporting and working groups in the ISO/CASCO structure.

The ISO/IEC 17000 series of conformity assessment standards (CASCO toolbox)

The ISO/IEC 17000 series of standards, guides and related publications are the collected resources available to the various parties with an interest in conformity assessment, 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 standards are supported by other complementary standards.

A laboratory using ISO/IEC 17025 as the basis of its operation may also have an interest in the CASCO toolbox elements dealing with selection and use of proficiency testing schemes (covered in ISO/IEC 17043).

An accreditation body should not only be fully aware of the requirements for such bodies found in ISO/IEC 17011, but also all of the relevant standards affecting the CABs they accredit, for example ISO/IEC 17020, ISO/IEC 17021 (and all of its parts), ISO/IEC 17024, ISO/IEC 17025 and ISO/IEC 17065.

A specifier may have an interest in issues related to marks of conformity, where ISO/IEC 17030 could be of value.

The various standards that make up the ISO/IEC 17000 series are listed in the table at the end of this appendix and are referred to in the appropriate places in this publication.

CASCO's global outreach

ISO/CASCO promotes the ISO/IEC 17000 series (CASCO toolbox) at the global level through interaction with its members and, through the TIG and STAR groups, with industry sectors and intergovernmental agencies (regulators) that are involved in conformity assessment. The strategy is to actively promote the conformity assessment standards and encourage their uptake and use.

CASCO communicates with these organizations to make sure they are aware of the toolbox and how to use it to achieve the best outcomes. They are encouraged to become directly involved in the development of new International Standards for conformity assessment activities or the revision

of current ones, particularly where the present contents of the ISO/IEC 17000 series standards are not suitable for the newly emerging sectors or could be improved to address current and future needs and trends.

A list of the standards – either published or under development – making up the ISO/IEC 17000 series as of June 2021 is given in the following pages.

(The latest information on publications developed under CASCO management can be accessed via links on www.iso.org.)

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC 17000:2022, Conformity assessment — Vocabulary and general principles	Standards bodies; CABs; accreditation bodies; government authorities; regulators; MRA agreement groups; trade officials; academic institutions; industry and trade associations; professional bodies; specifying bodies	Current
ISO/IEC 17060:2022, Conformity assessment — Code of good practice	CABs; accreditation bodies; trade officials; regulators; consumer associations; industry and trade associations; MRA agreement groups	Current
ISO/IEC Guide 68:2002, Arrangements for the recognition and acceptance of conformity assessment results	Purchasing authorities; regulators; trade officials; accreditation bodies; CABs; MRA agreement groups	Current
ISO/IEC 17007:2009, Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment	Standards bodies; regulators; specification writers; CABs; accreditation bodies	Current

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC 17011:2017, <i>Conformity assessment</i> — <i>Requirements for accreditation bodies accrediting conformity assessment bodies</i>	Accreditation bodies; trade officials; government authorities; MRA agreement groups (e.g. IAF, ILAC, APAC, EA, IAAC, SADCA)	Current
ISO/IEC 17020:2012, <i>Conformity assessment</i> — <i>Requirements for the operation of various types of bodies performing inspection</i>	Inspection bodies; regulators; accreditation bodies; purchasing bodies; MRA agreement groups (e.g. ILAC and IAF)	Under revision
ISO/IEC 17021-1:2015, <i>Conformity assessment</i> — <i>Requirements for bodies providing audit and certification of management systems</i> — <i>Part 1: Requirements</i>	Management systems (e.g. quality and environmental) certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current
ISO/IEC 17021-2:2016, <i>Conformity assessment</i> — <i>Requirements for bodies providing audit and certification of management systems</i> — <i>Part 2: Competence requirements for auditing and certification of environmental management systems</i>	Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC 17021-3:2017, <i>Conformity assessment</i> — <i>Requirements for</i> <i>bodies providing audit and</i> <i>certification of management</i> <i>systems</i> — <i>Part 3: Competence</i> <i>requirements for auditing</i> <i>and certification of quality</i> <i>management systems</i>	Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current
ISO/IEC TS 17021-4:2013, <i>Conformity assessment</i> — <i>Requirements for</i> <i>bodies providing audit and</i> <i>certification of management</i> <i>systems</i> — <i>Part 4: Competence</i> <i>requirements for auditing</i> <i>and certification of event</i> <i>sustainability management</i> <i>systems</i>	Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current
ISO/IEC TS 17021-5:2014, <i>Conformity assessment</i> — <i>Requirements for</i> <i>bodies providing audit and</i> <i>certification of management</i> <i>systems</i> — <i>Part 5: Competence</i> <i>requirements for auditing</i> <i>and certification of asset</i> <i>management systems</i>	Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC TS 17021-6:2014, <i>Conformity assessment</i> — <i>Requirements for</i> <i>bodies providing audit and</i> <i>certification of management</i> <i>systems</i> — <i>Part 6: Competence</i> <i>requirements for auditing</i> <i>and certification of business</i> <i>continuity management</i> <i>systems</i>	Management systems (e.g. quality and environmental) certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current
ISO/IEC TS 17021-7:2014, <i>Conformity assessment</i> — <i>Requirements for</i> <i>bodies providing audit and</i> <i>certification of management</i> <i>systems</i> — <i>Part 7: Competence</i> <i>requirements for auditing</i> <i>and certification of road</i> <i>traffic safety management</i> <i>systems</i>	Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current
ISO/IEC TS 17021-8:2019 <i>Conformity assessment</i> — <i>Requirements for</i> <i>bodies providing audit and</i> <i>certification of management</i> <i>systems</i> — <i>Part 8: Competence</i> <i>requirements for auditing</i> <i>and certification of</i> <i>management systems for</i> <i>sustainable development in</i> <i>communities</i>	Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
<p>ISO/IEC TS 17021-9:2016, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 9: Competence requirements for auditing and certification of anti- bribery management systems</p>	<p>Management systems (certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)</p>	<p>Current</p>
<p>ISO/IEC TS 17021-10:2018, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 10: Competence requirements for auditing and certification of occupational health and safety management systems</p>	<p>Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)</p>	<p>Current</p>
<p>ISO/IEC TS 17021-11:2018, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 11: Competence requirements for auditing and certification of facilities (FM) management systems</p>	<p>Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)</p>	<p>Current</p>

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
<p>ISO/IEC TS 17021-12:2020, Conformity assessment Requirements for bodies providing audit and certification of management systems</p> <p>— Part 12: Competence requirements for auditing and certification of collaborative business relationship management systems</p>	<p>Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)</p>	<p>Current</p>
<p>ISO/IEC TS 17021-13:2021, Conformity assessment — Requirements for bodies providing audit and certification of management systems</p> <p>— Part 13: Competence requirements for auditing and certification of compliance management systems</p>	<p>Management systems (certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)</p>	<p>Current</p>
<p>ISO/IEC TS 17021-14:2022, Conformity assessment — Requirements for bodies providing audit and certification of management systems</p> <p>— Part 14: Competence requirements for auditing and certification of management systems for records</p>	<p>Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)</p>	<p>Current</p>

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC DTS 17021-15, <i>Conformity assessment requirements for bodies providing audit and certification of management systems — Part 15: Competence requirements for auditing and certification of healthcare quality management systems</i>	Management systems certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Under development
ISO/IEC TS 17023:2013, <i>Conformity assessment — Guidelines for determining the duration of management system certification audits</i>	Management systems (e.g. quality and environmental) certification bodies; auditor associations; accreditation bodies; MRA agreement groups (e.g. IAF)	Current
ISO/IEC 17024:2012, <i>Conformity assessment — General requirements for bodies operating certification of persons</i>	Personnel certification bodies; professional bodies; accreditation bodies; regulators; MRA agreement groups (e.g. IAF)	Under revision
ISO/IEC TS 17027:2014, <i>Conformity assessment — Vocabulary related to competence of persons used for certification of persons</i>	Personnel certification bodies; professional bodies; accreditation bodies; regulators; MRA agreement groups (e.g. IAF)	Current
ISO/IEC 17025:2017, <i>General requirements for the competence of testing and calibration laboratories</i>	Laboratories; accreditation bodies; certification bodies; proficiency testing bodies; reference material producers; regulators; MRA agreement groups (e.g. ILAC)	Current

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC 17030:2021, <i>Conformity assessment — General requirements for third- party marks of conformity</i>	Third-party certification bodies; consumer associations; regulators; accreditation bodies	Current
ISO 17034:2016, <i>General requirements for the competence of reference material producers</i>	Reference material producers; proficiency testing bodies; laboratories; accreditation bodies; regulators; standards bodies; metrology and research bodies	Current
ISO/IEC 17040:2005, <i>Conformity assessment — General requirements for peer assessment of CABs and accreditation bodies</i>	MRA agreement groups; laboratories; inspection bodies; product, systems and personnel certification bodies	Current
ISO/IEC 17043:2023, <i>Conformity assessment — General requirements for proficiency testing</i>	Proficiency testing bodies; laboratories; accreditation bodies; reference material producers; regulators; standards bodies; professional bodies (for educational value of proficiency testing)	Current
ISO/IEC 17050-1:2004, <i>Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements</i>	Manufacturers and service providers; regulators; retailers; component purchasing bodies	Current
ISO/IEC 17050-2:2004, <i>Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation</i>	Manufacturers and service providers; regulators; retailers; component purchasing bodies	Current

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC 17065:2012, <i>Conformity assessment — Requirements for bodies certifying products, processes and services</i>	Product certification bodies; accreditation bodies; standards bodies; regulators; consumer associations; manufacturers and service providers; major retailers; industry associations; importers and exporters	Current
ISO/IEC 17067:2013, <i>Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes</i>	Product certification bodies; consumer associations; regulators; accreditation bodies (for product certification); MRA agreement groups (e.g. IAF); suppliers; manufacturers and service providers; retailers	Current
ISO/IEC TR 17026:2015, <i>Conformity assessment — Example of a certification scheme for tangible products</i>	Product certification bodies; accreditation bodies; standards bodies; regulators; consumer associations; manufacturers and service providers; major retailers; industry associations; importers and exporters	Current
ISO/IEC TR 17028:2017, <i>Conformity assessment — Guidelines and examples of a certification scheme for services</i>	Product certification bodies; accreditation bodies; standards bodies; regulators; consumer associations; manufacturers and service providers; major retailers; industry associations; importers and exporters	Current
ISO/IEC TR 17028:2017, <i>Conformity assessment — Guidelines and examples of a certification scheme for services</i>	Product certification bodies; accreditation bodies; standards bodies; regulators; consumer associations; manufacturers and service providers; major retailers; industry associations; importers and exporters	Current

ISO/IEC 17000 series (CASCO toolbox)	Users	Current status
ISO/IEC TR 17032:2019, <i>Conformity assessment — Guidelines and examples of a scheme for the certification of processes</i>	Product certification bodies; accreditation bodies; standards bodies; regulators; consumer associations; manufacturers and service providers; major retailers; industry associations; importers and exporters	Current
ISO/IEC 17029:2019, <i>Conformity assessment — General principles and requirements for validation and verification bodies</i>	Validation and verification bodies; accreditation bodies; standards bodies; regulators; consumer associations; manufacturers and service providers; major retailers; industry associations; importers and exporters; UNFCCC; validation and verification programme administrators	Current
ISO/TS 17033:2019, <i>Ethical claims and supporting information — Principles and requirements</i>	Product certification bodies; accreditation bodies; standards bodies; regulators; consumer associations; manufacturers and service providers; major retailers; industry associations; importers and exporters	Current
ISO/IEC WD TS 17012, <i>Guidelines for use of remote methods in conducting audits of management systems</i>	Auditing management systems among customers, regulators, accreditation bodies, certification bodies, scheme owners, industry, employees, consumers and other interested parties	Under development

Appendix 2

The role of IEC global conformity assessment services

The essential advantage of IEC global CA services

IEC global CA services offer a worldwide platform where independent professional CABs, such as testing laboratories, inspection bodies, certification bodies and so on, can work together in a coordinated “team-like” manner, producing consistent, comparable and reproducible CA results that each participating member recognizes as valid.

Today, the world's best practical example of global conformity assessment services is provided by IEC. The WTO recommends using the IEC CA Systems as an effective means to avoid technical barriers to trade. In 2009, the UNECE formally approved the UN CRO (Common Regulatory Objectives) for the explosive environments sector and endorsed the use of the IECEx CA System as world's best practice. In 2019, UNECE formally approved the UN CRO Guidelines for Cybersecurity which endorses the use of the IECEE CA System cybersecurity scheme as well as the IECQ CA System supply chain scheme for cybersecurity.

How global IEC CA services operate

IEC manages the operation of four global IEC CA Systems that offer global conformity assessment services. They are IECEE, IECEx, IECQ and IECRE (for more information see [Chapter 3](#)).

Each of these global CA Systems creates a framework that allows professional certification bodies, testing laboratories, inspection bodies, auditing bodies and so on, from around the world, to work together in a team-like structure and ensures that CA results are mutually accepted by all participants.

The CABs that participate in the IEC CA Systems are all separate individual legal entities that are often in competition with each other. They choose to participate in the IEC global system because it brings them prestige and recognition as high-level conformity assessment entities, which in turn brings them business.

To participate, each CAB must agree to recognize the CA results of all other participating CABs, if those results have been issued within the context of the IEC CA System. No duplicative testing is permitted.

The consequences of recognizing CA results, such as test reports or certificates, from another CAB anywhere in the world, is that if those CA results concern products that are to be imported into their local market, and if the recognizing CAB is accredited, then that CAB becomes an approving body.

Under the rules the IEC CA System, every participating CAB must recognize the CA results of another CAB, no matter where they are located, and grant market access to the relevant goods in a way that is accepted by the national authority. By doing this the recognizing CAB takes-on a portion of the risk for those products in its market. This means that the recognizing CAB must have strong confidence and trust in the CA results and certificates issued by any other CAB participating in an IEC CA System. Since all participating CABs are, by obligation, recognizing CABs, for this to work, all CABs must have strong confidence in the CA results of all the other CABs.

Achieving such confidence in the CA results is the key element of a global conformity assessment service. The IEC global CA System's management structure, organization, use of harmonized, common operating rules and practices, as well as regular assessment by peers, ensure that CA results coming from any of the participating CABs anywhere in the world are consistent, comparable and reproducible.

Harmonized understanding and common assessment methodology

The IEC CA Systems are membership organizations. The members write the rules and must abide by those rules. Testing, inspection and other assessments are performed according to standards. However, standards can sometimes leave space for interpretation, which can lead to differing

CA results. For example, with inspection, ISO/IEC 17020 provides for “professional judgment” as part of the determination.

The section “Conformity assessment related to testing and calibration” of this document states the following:

“For the most reliable test results, the test methods should be specified in the standard...”

“On occasion, the requirement’s standard might simply give a value for a particular characteristic, such as mass or energy efficiency, without specifying the method by which the characteristic is to be determined. In such cases, each testing laboratory would need to decide on the method to be used, following good laboratory practice.”

“In other cases where the testing methodology is not adequately specified, or is written in a way that allows somewhat different interpretations, the conformity assessment results from different testing laboratories within a country, or from around the world, can vary. In this case a global CA scheme or system adds value by ensuring consistent and comparable conformity assessment results no matter from which participating CAB the results come from anywhere in the world.”

To avoid individual CABs interpreting standards differently, each IEC CA System has a committee where participating CABs agree on a harmonized understanding and interpretation of each standard in terms of testing and certification. This is documented and becomes part of the operating documents (ODs) of each IEC CA System.

This then forms the basis for all testing and assessment performed by all CABs participating in a given IEC CA System.

The role of peer assessment and accreditation

Peer assessment is used by the IEC CA Systems for two purposes. The first is to qualify the CABs for participation into the CA System. The second is as a surveillance tool to periodically check that the CA System’s rules and ODs are being systematically applied by the CABs.

In order to qualify a CAB for participation in an IEC global CA System, there are two requirements. The first concerns the competence and capability of the CAB to perform the scope of work that it is required to do within the CA

System's scheme. This is equivalent to an accreditation. It is the baseline requirement, and accreditation audits and peer qualification assessments are often carried out as unified assessments. The second concerns the knowledge, understanding and application of the scheme's own rules and ODs.

For a global conformity assessment scheme where the group of participating CABs have to be qualified as a group, peer assessment and accreditation are complementary.

Accreditation is an essential element in the world of conformity assessment. It is the basis for recognizing the competency of CABs within a country and therefore recognizing a CA result from those CABs within that country. But accreditation qualifies those CABs as individual organizations.

A good analogy is qualifying a musician. Accreditation would check if the musician has an instrument (like checking if a laboratory has equipment). Can they read music and can they play the music correctly (does the laboratory have qualified people who understand and can test to a standard)? Accreditation would not check the choice of music to play, nor the tempo or style in which it's played (accreditation does not check how the testing is done).

On the other hand, peer assessment is all about qualifying for team activities.

Again, for a musician, the basic ability to play an instrument, must of course be present. But to play in an orchestra and make beautiful music, together, requires much more. It requires the ability to play with the other musicians in the orchestra. It requires playing the same music, in a harmonized way, in accordance with the rhythm and instructions of the conductor. Each musician needs to be confident in the abilities of the other musicians. To achieve this, musicians go through auditions where musicians check musicians, or, in other words, they do peer assessment. That's what creates the confidence and allows them to play as a team.

IEC CA Systems MLA requires participating CABs to recognise CA results from any other participating CAB, anywhere in the world, and since recognizing CAB is accredited, the National Authority must recognise the CAB's decision.

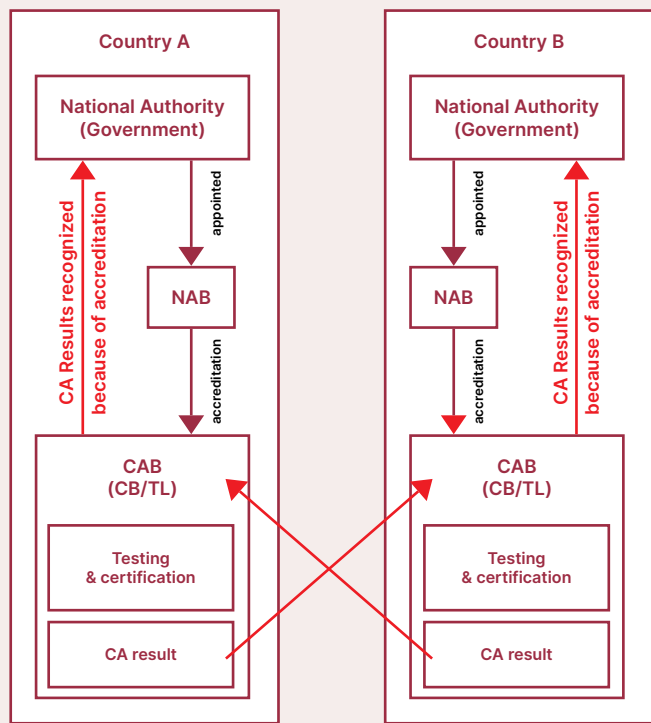


Figure 15. Accreditation supports mutual recognition of conformity assessment (CA) results

Another important aspect of accreditation for global conformity assessment services, is that participating CABs are obligated to recognize and accept the conformity assessment results coming from other participating CABs. If the recognizing CAB is accredited, then its decision to recognize a conformity assessment result must be recognized within its country.

This is a channel for the recognition of results from anywhere in the world. This is the multilateral mutual recognition agreement (MLA) at the core of global conformity assessment services (Figure 15). Of course this MLA only works because of the global conformity assessment services organization and management structure which, through common harmonized procedures and rules, and peer assessment, ensures that the conformity assessment results are consistent, comparable, and trustworthy no matter from where in the world they come.

Consistent and comparable conformity assessment results

The requirements for accreditation, and the way of conducting accreditation audits, are different from country to country and region to region. An analogy is driver's licences. Each country has its own requirements for driving tests and for issuing a driver's permit. It means that the level of required driving expertise can be very different from one country to another. It is the same with accreditation.

At the international level, ILAC and IAF are working towards the goal of achieving consistent accreditation across the national accreditation bodies of different countries. In the driving analogy, this means identical criteria and driving tests in all countries.

ILAC and IAF use peer assessment to qualify the accreditation bodies that will accredit the CABs. This is similar to how IEC uses peer assessment to qualify the CABs directly. In both cases, the goal is to achieve consistent and comparable results.

For ILAC/IAF, the goal is to obtain consistent and comparable accreditation from one country to another (this is like trying to achieve consistent and comparable driver's licence testing).

For IEC, the goal is to achieve consistent and comparable CA results from participating CABs anywhere in the world (this is like getting drivers to drive the same way on the same roads, this is much more than simply having the same driver's licence testing).

Multilateral mutual recognition of conformity assessment results

Participating CABs in the IEC global CA Systems agree to recognize CA results coming from other participating CABs that can be anywhere in the world. This could be, for example, for products entering their local market. They do this because they have confidence in those CA results. The confidence comes because of the IEC CA Systems' harmonized interpretation of standards and the common (and documented) assessment methods, all assured through peer assessment. Therefore, they trust that the CA results were achieved using the same tests and operational procedures as they would use themselves. If they did the same tests, they would get the same result.

This is the basis for the IEC multilateral MRA (MLA) at the core of IEC global CA services, and why it works so successfully for the IEC global CA Systems.

Role of IEC global CA services in support of government

There are many ways in which the IEC global CA Systems can support government goals and policy objectives.

If reputable nationally accredited CABs join an IEC global CA service, and are confident to recognize the validity of CA results from other members of that IEC global CA service, then why should governments not also recognize those results?

By simply stating that the test result, certificate or Mark of conformity issued by members of the IEC global CA System is sufficient and appropriate proof of compliance with the regulatory requirements, a high level of confidence in the products and services is achieved. And this does not prohibit the national authority from choosing other means for demonstrating compliance if those or similar products or services do not have a positive CA result from an IEC global CA service.

In this way, simply recognizing the CA results from an IEC global CA service is equivalent to having these CA services as part of the national QI, but at no cost.

For more detail about the specific IEC CA Systems, see **Chapter 3** or visit the relevant Websites:

www.IEC.ch

www.IECEE.org

www.IECEx.com

www.IECQ.org

www.IECRE.org

- **Verification of quality and safety of imported goods**

For many countries there is a risk of inferior products entering the market. These products are often low cost but also low quality. Many of them may be dangerous and can cause damage, injury or even death.

In support of government policy, to ensure the safety of the national population and the efficiency of the national economy, test reports, certificates and Marks issued by the IEC global CA Systems can be used as demonstration of compliance with national requirements for imported goods, before they enter the country. This is like having free national testing and certification services.

- **Trade facilitator for exported goods**

Governments are focused on the national economy; creating employment, assisting the growth of local business and industry, achieving balanced foreign trade, facilitating access to foreign markets for local producers, and so on. When governments recognize and promote the use of global conformity assessment services, they assist local business and industry in achieving world standards in terms of quality, safety and reliability. Having goods and products certified within the IEC global CA Systems gives them access to the world market.

- **Reduced costs for import control**

By simply recognizing the test reports, certificates and marks issued by the IEC global CA Systems, the need for additional testing, review, inspection, and so on, is eliminated. This streamlines administrative procedures; reduces costs for customs offices; eliminates redundant and costly repetitive testing; makes products more affordable and allows them to enter markets faster.

Additionally, the IEC global CA Systems have online databases where certificates can be consulted 24/7. If there is any doubt about the authenticity of a paper certificate that accompanies a product, it can be quickly verified in real-time online.

- **Reduced prices and higher quality goods**

When a national authority doesn't recognize test results, certificates or Marks issued by an IEC global CA System or issued by another global CA service provider, local testing is generally required to ensure compliance with local requirements. When local requirements are

based on International Standards, local testing would be redundant and simply repeat testing that has already been carried out within the global CA System. It will make goods more expensive without creating additional value. Some manufacturers or suppliers may decide to forgo that country's market altogether, which would deprive local consumers of access to those goods.

Additionally, if local testing laboratories are not able to match the quality of international testing providers, then there is a risk that goods of inferior quality may enter the market undetected.

Role of IEC global CA services in support of the private sector

Global conformity assessment services also support the private sector:

- **Foreign market access for local manufacturers and suppliers**
Certification from an IEC global CA System can give a national manufacturer access to multiple markets around the world faster and at lower cost. This approach avoids multiple duplicative testing for each export market, which is both time-consuming and costly.
- **Lower-price, high-quality goods for consumers**
When a national authority recognizes the conformity results from an IEC global CA System, and does not require additional local testing, consumers can benefit from better pricing and wider choice.

Any country that doesn't have appropriate local testing capabilities to verify the quality of imported goods, should have a national policy in place whereby demonstration of compliance is to be obtained through a certificate, test report or Mark issued by an IEC global CA System or another appropriate global CA service. This can be an important step to protect the national economy and consumers from harm through counterfeit and low-quality goods.

- **As a recognition of competence**

Accreditation of CABs, such as testing laboratories, inspection bodies, certification bodies, and so on, by an accreditation body being a member of ILAC/IAF, provides national recognition of competence as the baseline for doing business. Additional acceptance into an IEC global CA System demonstrates that the CABs testing competence has achieved global recognition by peers.

- **As a marketing advantage**

Many well-known brand suppliers do not need third party conformity assessment (they do not need to be certified). Their own first party declaration of conformity (SDoC) is sufficient for the market, because they are known and trusted. However, unknown brand suppliers wishing to enter a new market may use a marketing strategy based on lower prices but will also need to demonstrate that they have a quality product. They will most often use certification as the means of demonstration. A single certificate from an IEC global CA System (or from another appropriate global CA service) is the strongest demonstration of conformity and provides the most access to the most markets worldwide.

Appendix 3

The roles of international and regional accreditation body forums

Accreditation is an overseeing activity of the QI providing a means of giving confidence in the work of CABs. Accreditation is intended to underpin the integrity, transparency and consistency of the work of these bodies. Accreditation is an attestation of the competence and impartiality of CABs to carry out specific conformity assessment tasks. These bodies include, but are not limited to, calibration laboratories, medical laboratories, testing laboratories, inspection bodies, providers of proficiency testing, producers of reference materials, and bodies that certify management systems, products, processes and persons, or undertake verification and validation.

While CABs check the conformity of goods and services, people and processes, etc, to the specified requirements, accreditation checks the competency and capacity of the CABs. Simply put, “accreditation checks the checkers”. Accreditation is part of conformity assessment.

Accreditation is an impartial and objective process carried out by third parties. It is transparent and widely accepted, and reduces duplication to a minimum. It is a non-discriminatory route for the formal recognition of credibility and trustworthiness of CABs and their conformity assessment results.

For businesses trading internationally, one of the ways to achieve recognition of third-party conformity assessment results comes through the recognition of the accredited CAB via the MRAs established between the accreditation body members of IAF and ILAC.

The ILAC is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the assessment and accreditation of calibration laboratories (using ISO/IEC 17025), testing

laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189) and inspection bodies (using ISO/IEC 17020). It was formed in 1977 to promote good practice in testing and calibration and the international acceptance of results produced by laboratories carrying out this work.

IAF is a worldwide association of accreditation bodies and other bodies interested in conformity assessment in the fields of management systems, products, processes, services, personnel, validation and verification and other similar programmes of conformity assessment. It was formed in 1993. Its primary function is to develop a single worldwide programme of conformity assessment which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the body accredited.

Accreditation bodies perform accreditation assessments of CABs.

Accreditation body members of IAF and ILAC operate in accordance with ISO/IEC 17011, *Conformity assessment – Requirements for accreditation bodies accrediting CABs*. Each accreditation body can be a member of the IAF or ILAC recognition arrangements among signatory accreditation bodies that have been successfully peer evaluated in accordance with ISO/IEC 17011 to demonstrate their competence. Signatories agree to accept the results of each other's CABs under the arrangements, and so accredited conformity assessment under the accreditation of each signatory could be recognized internationally.

Both IAF and ILAC work together and coordinate their efforts to enhance accreditation and conformity assessment worldwide. Together, they have a global vision of a single worldwide programme of conformity assessment that reduces risk for business, regulators and the consumer by ensuring that accredited services can be relied upon and that government and regulators rely on IAF and ILAC arrangements to further develop or enhance trade agreements. This vision supports the freedom of world trade by eliminating technical barriers, realizing the free-trade goal of "tested, inspected, certified, verified or validated once, accepted everywhere".

At a regional level, regional arrangements are managed by the regional cooperation bodies that work in harmony with ILAC and IAF. These are currently EA in Europe, APAC in Asia-Pacific, IAAC in the Americas, AFRAC in Africa, SADCA in southern Africa, and ARAC in the Arab region.

IAF and ILAC also cooperate at the international level with IEC global conformity assessment services. The CABs participating in the IEC CA Systems must be competent and so accreditation is a useful element. To avoid duplication of assessments IEC and ILAC can conduct unified assessments. Then IEC adds to these its additional assessment to the specific scheme rules in order to ensure consistent and harmonized conformity assessment results from different CABs anywhere in the world. Global CA services require that CABs all over the world work together in a “team” structure.

Accreditation also builds upon, and is complementary to, the other key components related to quality – standards and metrology – and IAF and ILAC work closely with the relevant institutions in these fields.

One of the driving forces that influenced the formation and development of IAF and ILAC 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 establishment of the WTO and its TBT Agreement. That Agreement and its relevance to the roles of conformity assessment in global trade are discussed in more detail in [Appendix 4](#).

The objectives of the two international accreditation forums are as follows:

International Laboratory Accreditation Cooperation

- Maintaining state-of-the-art principles for assessing the competence of an accredited body against applicable standards and other requirements included in its scope of accreditation.
- Working to raise awareness and ensure that regulators and other users of services worldwide understand and accept accreditation covered in the ILAC Arrangement as the preferred tool for enhancing confidence and credibility as well as eliminating duplication of activity.
- Assisting members, especially members of developing economies, to ensure that all accreditation systems achieve the same level of competence.
- Ensuring that all documentation supporting the internationally harmonized activities of ILAC members within the ILAC arrangement

adds value to market acceptance of goods and services, supports those that are responsible for the environment and for the health and safety of the public, and increases confidence in accreditation

International Accreditation Forum

- Ensuring that accredited conformity assessment activities are effective in adding value to the facilitation of national, regional and global trade.
- Facilitating world trade by:
 - Promoting common application of the requirements for certifications and/or validation and/or verification, or similar schemes of conformity assessment.
 - Promoting the equivalence of accreditations granted by accreditation body members that are signatories of the IAF Multilateral Recognition Arrangement (MLA.)
 - Providing technical assistance to emerging economies that are developing accreditation bodies.
- Establishing and maintaining confidence in the accreditation activities of accreditation body members and in the activities of CABs accredited by them through:
 - Participation by accreditation body members and regional accreditation groups in the IAF MLA.
 - Exchange of information (subject to requirements for confidentiality).
 - Participation in IAF activities.
 - Participation in regional accreditation groups, where such groups exist, and where accreditation bodies are eligible to join.
- Supporting the implementation by accreditation and CABs of International Standards, guides and other normative documents endorsed by IAF.
- Harmonizing the application of criteria for accreditation, based on IAF-endorsed International Standards, guides and other normative documents, as well as publicly available IAF documents.

-
- Establishing and maintaining an MLA based on the equivalence of the accreditations verified through peer evaluation and/or re-evaluation among accreditation bodies, such that all parties have confidence in the declared equivalence.
 - Promoting the international acceptance of the MLA based on the equivalence of the operation of their accreditation, and the international acceptance of accredited conformity assessment results from bodies accredited by members of the IAF MLA.
 - Opening and maintaining channels for the interchange of information and knowledge between members and other relevant bodies.

How the international forums work

Because of their origins and the fields they are addressing, there are some differences in the way ILAC and IAF are organized and operate. 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 MRA while that of IAF is called the Multilateral Recognition Arrangement (MLA). For more details on how these arrangements work, see the IAF and ILAC Websites:

- IAF: www.iaf.nu
- ILAC: www.ilac.org

Evaluations are 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 evaluated body meets the requirements. Re-evaluations are carried out on a regular basis to ensure that the accreditation bodies maintain the standard of their work.

The peer evaluation process enhances confidence in the accreditations carried out by ILAC and IAF members and, ultimately, facilitates international acceptance of the work of the accredited laboratories, inspection bodies and certification bodies.

The membership categories of IAF are as follows:

- **Accreditation body members** – Open to entities that have recognition by authorities, regulators, or industrial or trade organizations within an economy, region or internationally, and are engaged in developing or conducting and administering accreditation of entities that perform conformity assessment, such as management system certification, product certification, certification of persons, verification/validation, or similar conformity assessment, which in each case also demonstrates that the operation of such conformity assessment is in accordance with International Standards and application documents that are approved from time to time by the members.
- **Association members** – Open to organizations or associations representing the interests, within an economy, region or internationally, of a like group of entities that engage in, are subject to, make use of, accept or rely on conformity assessment results from bodies accredited by accreditation body members of IAF, and which support the IAF's purpose.
- **Regional accreditation groups** – Open to associations of accreditation bodies, and possibly other bodies, that cooperate within an identified geographic region to establish and maintain a multilateral recognition agreement based on a peer evaluation system, and represent the interests of accredited entities, industry, users and similar organizations that engage in, are subject to, make use of, accept or rely on conformity assessment results from bodies accredited by accredited body members of IAF, and which support the IAF's purpose.

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 MRA. To do this, the signatory must:
 - Maintain conformance with ISO/IEC 17011 and related ILAC requirements.
 - Ensure that all its accredited laboratories and inspection bodies comply with ISO/IEC 17020, ISO/IEC 17025 and ISO 15189 and related ILAC documents, as appropriate.

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 the IEC and ISO, and in ILAC application documents.
 - Obligations of the ILAC MRA.
 - 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 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 IEC and ISO, and in ILAC application documents.

-
- **Stakeholders** – Open to representative international, regional and national organizations having an interest in the work of ILAC and includes bodies such as associations of laboratories, associations of laboratory practitioners, inspection body associations, purchasing organizations, regulatory authorities, consumer associations and trade organizations.
 - **Regional Cooperation Bodies** – Open to formally established regional accreditation cooperations with objectives similar to, and compatible with, those of ILAC, which are committed to the obligations of the ILAC MRA and which consist of formally nominated representatives of the accreditation interests from at least four economies (Recognized Regional Cooperation Bodies are those whose regional MRA/MLA) have been successfully peer-evaluated by ILAC).

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, inspection bodies and certification bodies, end users and regulatory authorities, are also allowed to participate in the work of the forums, but their voting rights are limited. Association members (stakeholders) in IAF have voting rights, as do all IAF MoU signatories.

The structures of the two international bodies are as shown in **Figures 16** and **17**.

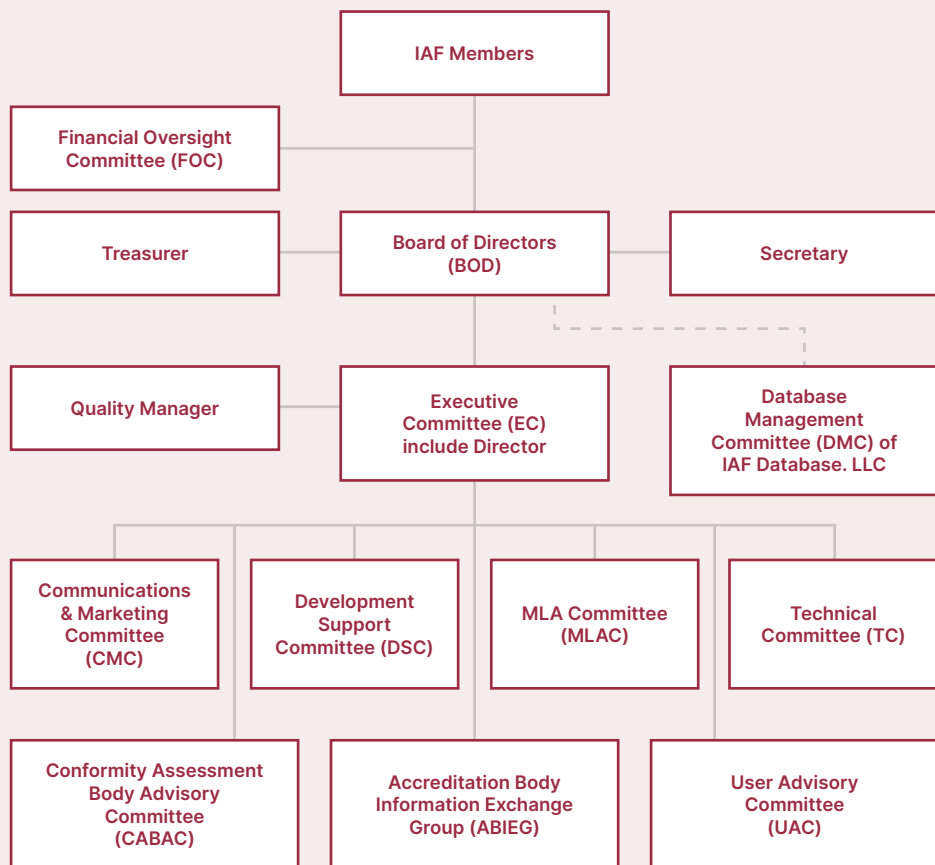


Figure 16: IAF

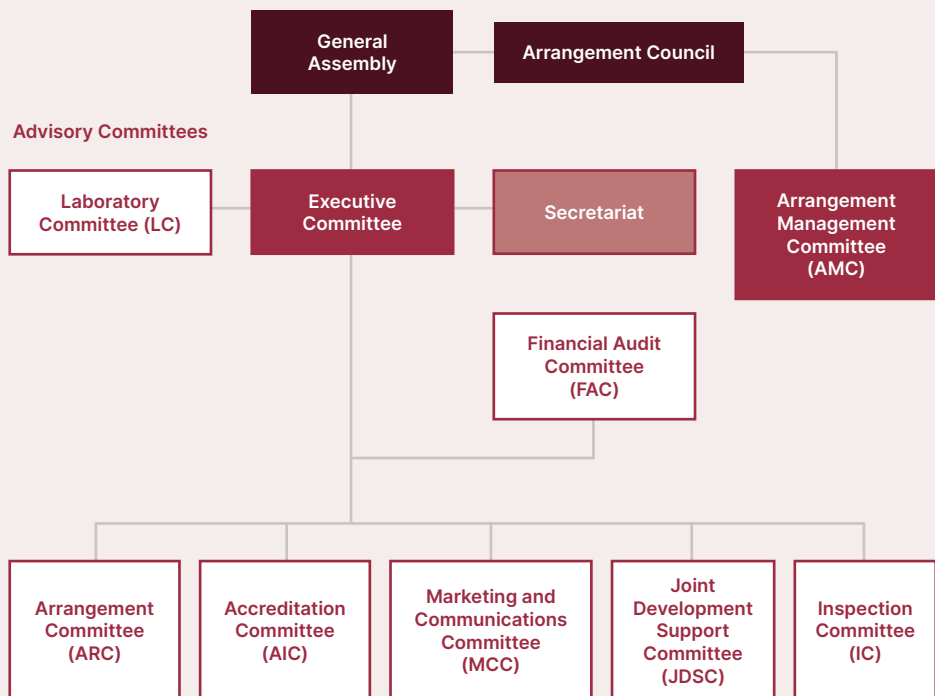


Figure 17: ILAC

Coordination of ILAC and IAF activities

ILAC and IAF have existed as separate organizations since their inception. Over time, however, the organizations have moved closer together in order to avoid duplication of activity, and to achieve improved alignment of their work programmes where this has potential to contribute to the effectiveness and efficiency of both organizations and delivery of value to their stakeholders.

As a result, during the organizations' mid-term and annual meetings, joint meetings of the IAF and ILAC Executive Committees and other committees are held in order to streamline the management and decision-making process of joint activities.

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.

Examples of these regional accreditation forums are:

- African Accreditation Cooperation (AFRAC)
www.intra-frac.com – ILAC Regional Cooperation Body member; and IAF Regional accreditation group member.
- Arab Accreditation Cooperation (ARAC)
www.arabarac.org – ILAC Regional Cooperation Body member; and IAF Regional Accreditation Group member.
- Asia Pacific Accreditation Cooperation Incorporated (APAC)
www.apac-accreditation.org – ILAC Regional Cooperation Body member; and IAF Regional accreditation group 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.
- Southern African Development Community Cooperation in Accreditation (SADCA) www.sadca.org – ILAC Regional Cooperation Body member; and IAF Regional accreditation group member.

Multiple beneficiaries of MRAs/MLAs

There are a number of potential beneficiaries of regional and global MRAs/MLAs. They include:

- Accreditation bodies
- Accredited CABs
- Regulators and trade officials
- Importers, exporters and consumers
- National infrastructures.

For accreditation bodies, their benefits 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 accredited CABs, the benefits 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 specialist calibration services.

For regulators and trade officials, the benefits include:

- Access to multiple providers of compliance data (from both foreign and local CABs).
- 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 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/MLAs).
- A mechanism for dispute resolution when faced with conflicting sources.

For national infrastructures, the benefits include:

- Mutual support (for example, the CIPM MRA for NMIs 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 for the development of appropriate standards, codes of practice, etc., by bodies such as ISO/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

Currently, the IAF MLA covers:

- Accreditation of management system certification bodies (ISO/IEC 17021-1).
- Accreditation of product certification bodies (ISO/IEC 17065).
- Accreditation of person certification bodies (ISO/IEC 17024).
- Accreditation of greenhouse gas validation and verification providers (ISO 14065).
- Accreditation of validation and verification bodies (ISO/IEC 17029).

Currently, the ILAC MRA covers:

- Accreditation of testing and calibration laboratories (ISO/IEC 17025).
- Accreditation of medical laboratories (ISO 15189).
- Accreditation of inspection bodies (ISO/IEC 17020).
- Accreditation of reference material producers (ISO 17034).
- Accreditation of proficiency testing providers (ISO/IEC 17043).

Appendix 4

WTO agreements and conformity assessment

Conformity assessment and the WTO Agreement on Technical Barriers to Trade (TBT)

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 CABs 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 (SPS)

Apart from the TBT Agreement, member governments of the WTO are also required to comply with the SPS Agreement.

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 TBT Agreement, 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-1990s, there has been a steady growth in the development of cooperation amongst a number of 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 IEC, ISO, BIPM, OIML, IAF and ILAC). Moreover, many of the international bodies use their regional

cooperations 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 APAC).

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:

- IEC/ISO/ITU
- IEC/ILAC/IAF
- ISO/IAF/ILAC
- CIPM/ILAC
- IAF/OIML/ILAC
- IEC/OIML

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 on developing country issues. This is done through the 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 ITC and ITU-T, the Telecommunication Standardization Sector of ITU.

Mutual acceptance of conformity assessment certificates

The 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 CABs 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 CABs in other countries. An efficient way forward seems to be

the conclusion of MRAs between accreditation bodies such that the results of any laboratory or other CAB 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.”

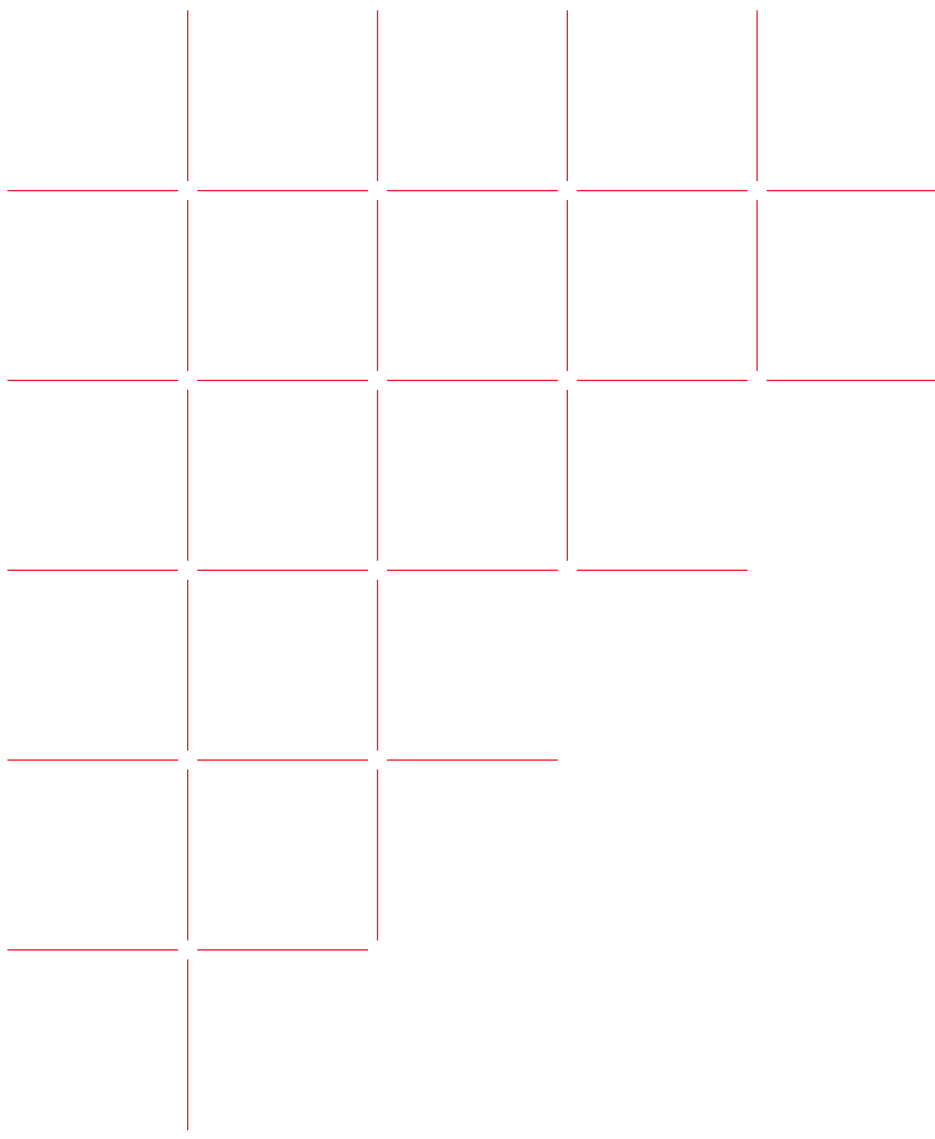
Accreditation bodies themselves do not use the data and certificates from foreign bodies accredited by their counterparts in the ILAC MRAs, the IAF MLAs and their regional bodies. The accreditation bodies' role is to promote to regulators, and other potential users of data and certificates in their own countries, the equivalence of foreign, accredited CABs to their own accredited bodies.

It is important to note that the IAF MLA and ILAC MRA 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, the MLAs of IAF and their regional cooperation bodies to accept foreign conformity assessment certificates and data.

Internationally, there are other forms of mutual acceptance of test and certification results, such as direct acceptance at the CAB level. This is the case for CABs that participate in global conformity assessment services, such as the IEC CA Systems. The IEC MLA requires participating CABs to recognize conformity assessment results from other participating CABs in other countries anywhere in the world. They accept to do this because they have been qualified into the global CA scheme through a two-level peer assessment process requiring an accreditation assessment, or equivalent, and an additional assessment at the scheme level which ensures they all know, understand and use the harmonized conformity assessment procedures and testing methodologies. Through peer assessment they know that given the same object of conformity, they would obtain the same CA result themselves. This then gives them the confidence to accept the CA results from participating CABs from elsewhere in the world. This is why the IEC MLA works worldwide. By accepting the CA results from elsewhere and thus allowing the goods into their country, they are taking on a part of the risk of those goods in their country. This is also why the IEC global CA services are recommended by the UNECE and WTO. (For more on this see [Appendix 2.](#))

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 multilateral, such as the APEC Electrical and Electronic Equipment MRA.

Some governments have also formally designated their voluntary-sector accreditation bodies as the bodies that 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 APAC voluntary-sector MRA to accept foreign results. In Europe, the European Commission is encouraging the use of the EA voluntary-sector MRA as support for their confidence in accredited CABs acting in a wide range of regulated sectors.





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