INTERNATIONAL DEVELOPMENT IN PRACTICE

Ensuring Quality to Gain Access to Global Markets

A Reform Toolkit

Martin Kellermann

WORLD BANK GROUP

PTB Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
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Foreword

An efficient and effective quality and standards ecosystem—also referred to as quality infrastructure (QI)—is an essential ingredient for competitiveness, access to new markets, productivity improvement, innovation of new products, and environmental protection, as well as health and safety of populations. In short, QI is not only key to a country's growth, but also essential in creating a safer, cleaner, and more equitable and well-integrated world.

QI can also be quite complex; thus, it is often sidelined from high-level political discussions or left out of a country's reform agenda. Instead, practitioners focus on short-term gains or single and disparate components of QI without understanding the broader interrelationships within the QI ecosystem. QI is expansive and comprehensive: it encompasses not just standards, but also matters of accreditation, metrology, and calibration, as well as conformity assessment services, such as testing, inspection, and certification.

The World Bank Group and the National Metrology Institute of Germany (PTB) fully recognize the importance of QI as an ecosystem and, as a result, I'm extremely proud that we have worked with the PTB to produce the first-ever comprehensive QI diagnostics and reform guide. This guide is designed to help development partners and governments assess and analyze a country's QI ecosystem; identify issues and gaps; and provide recommendations for how to bridge those gaps and build institutional capacities. This publication takes into consideration the achievements and lessons learned from previous reform experiences and seeks to expand on them to provide an effective set of good practices. It also provides access to an online diagnostic tool that uses a systematic methodology to assess a country's QI ecosystem. This diagnostic is critical for understanding and identifying the gaps and shortfalls quickly, so that countries can efficiently and effectively identify areas for reform.

QI is, therefore, a relevant ingredient for achieving the World Bank Group's twin goals of ending extreme poverty and promoting shared prosperity by the end of 2030 through competitiveness, trade, health and safety, and so on. This toolkit provides a useful framework for helping countries understand where and how to begin the reform process.

I hope this publication will encourage countries to take a more systematic review of their QI ecosystems and increase their visibility with both citizens and politicians. QI is indeed a complex matter, but it is of critical importance if countries want to meet the current and emerging demands of the global economy, reduce poverty, and share in global prosperity.

Caroline Freund
Director
Trade, Regional Integration, and Investment Climate
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Foreword

In today's highly competitive global markets, a country's ability to produce high-quality products is directly linked to its economic success. Product quality is at the root of Germany's economic growth and prosperity, with the trademark "Made in Germany" being a selling point across the globe.

Therefore, the German government is naturally committed to enabling its partners in emerging and developing countries to access new markets and strengthen their competitiveness by enhancing the quality of their products. In the framework of our technical cooperation, we place special emphasis on the core of our own quality production: a well-functioning quality infrastructure (QI). Such a QI system offers proof that products and services comply with the necessary market requirements regarding quality and safety. It can therefore boost trade and reduce trade costs, enhance technology transfer and innovation, increase investments and competitiveness, and protect consumers. The importance of QI for economic, ecological, and social development is reflected in the development agenda of the German government and the European Union. In the new German Aid for Trade strategy, we identified QI as one of the main pillars for enhancing the capabilities of developing countries to reap the benefits of free, fair, and safe trade.

Since 1963, the German government has entrusted the National Metrology Institute of Germany (PTB), a global player in metrology, with strengthening the QI systems in such countries. On behalf of the Federal Ministry for Economic Cooperation and Development (BMZ), the PTB advises governments and ministries, promotes QI institutions, and supports small and medium-size enterprises. These objectives are realized following a demand-oriented and systematic approach, guided by international good practices. The outstanding effects of this cooperation are reflected in economic development and the strengthening of consumer protection.

We therefore greatly appreciate the partnership established with the World Bank Group in 2016, which increased our collaboration in the implementation of QI development cooperation and led to the elaboration of this QI diagnostic and reform toolkit. This product will help practitioners and governments to analyze and assess the QI system in a particular country in a holistic manner. It also provides an overview of international good practices, as well as recommendations

for QI reforms, coherent support for those reforms, and the necessary capacity development. Most important, it represents an offer to our partner countries to continue and intensify our cooperation in this important field. We therefore invite you to browse this publication and make use of the different instruments it offers.

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The content of this publication was developed jointly by the World Bank Group and the National Metrology Institute of Germany (PTB). The preparation of this toolkit was initiated by Christine Zhenwei Qiang, practice manager for the Global Investment and Competition Unit of the World Bank's Macroeconomics, Trade and Investment (MTI) Global Practice. It was subsequently led by Catherine Masinde, practice manager for the MTI Global Practice's Global Business Regulation Unit. The principal author of this toolkit is global quality infrastructure (QI) consultant Martin Kellermann.

The World Bank and PTB team that oversaw and contributed heavily to this publication consisted of Andrei Mikhnev, World Bank lead private sector specialist; Wafa Aranki, World Bank senior private sector specialist; Bin Zhai, World Bank private sector specialist; Susanne Wendt, PTB project coordinator; Solomon Stavis, World Bank consultant; and Alexis Valqui, PTB consultant.

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The toolkit also benefited greatly from external peer reviews from relevant international organizations—namely, the International Bureau of Weights and Measures (BIPM), International Accreditation Forum (IAF), International Laboratory Accreditation Cooperation (ILAC), and International Organization of Legal Metrology (OIML).

About the Author

Martin Kellermann has more than 40 years of experience working in quality infrastructure (QI), first in the South African Bureau of Standards and thereafter as a consultant all over the world. He has worked in Central Asia, the Middle East, East Africa, West Africa, and East Asia, advising governments and QI institutions on policy, strategy, and the reengineering of business activities, as well as facilitating the drafting of national quality policies and QI legislation. During this time, he worked with the World Bank, National Metrology Institute of Germany, International Organization for Standardization, International Trade Centre, United Nations Industrial Development Organization, United Nations Development Programme, and many other organizations, and he has contributed to and authored multiple publications on QI.

Kellermann holds a master's degree in mechanical engineering from Pretoria University. He has also studied accountancy at the University of the Witwatersrand's Graduate School of Business Administration and participated in the Executive Education Program of the Haas School of Business, University of California, Berkeley. Currently, Kellermann lives with his wife in South Africa.

Abbreviations

AFRIMETS	Intra-Africa Metrology System
AIDMO	Arab Industrial Development and Mining Organization
ARAC	Arab Accreditation Cooperation
ARSO	African Organization for Standardization
AS	Aerospace Standard
ASME	American Society of Mechanical Engineers
BIPM	International Bureau of Weights and Measures
BMWi	Federal Ministry for Economic Affairs and Technology (Germany)
BRC	British Retail Council
BSI	British Standards Institution
CAC	Codex Alimentarius Commission
CAC/RCP	Codex Alimentarus Commission/Recommended Code of Practice
CARICOM	Caribbean community
CE	Conformité Européenne
CEN	European Committee for Standardization European
CENELEC	Committee for Electrotechnical Standardization
CGPM	General Conference on Weights and Measures
CIPM	International Committee for Weights and Measures
CMCs	calibration and measurement capabilities
COMESA	Common Market for Eastern and Southern Africa
COOMET	Euro-Asian Cooperation of National Metrological Institutions
COPANT	Pan American Standards Commission
CPSD	Country Private Sector Diagnostic
CRM	certified reference material
CROSQ	Caribbean Community Regional Organization for Standards and Quality
CSA	Canadian Standards Association
DCED	Donor Committee for Enterprise Development
DIN	German Institute for Standardization
EAC	East African Community

EASC	Euro-Asian Interstate Council for Standardization, Metrology and Certification
ECE	Economic Commission for Europe
ECO	Economic Cooperation Organization
ECOWAS	Economic Community of West African States
EN	European Norm
ETSI	European Telecommunications Standards Institute
EU	European Union
EURAMET	European Association of Metrology Institutes
FDI	foreign direct investment
FSC	Forest Stewardship Council
FSSC	Food Safety System Certification
GDP	gross domestic product
GFSI	Global Food Safety Initiative
GLOBAL G.A.P.	Global Good Agricultural Practice
GSO	Gulf Cooperation Council Standardization Organization
GSP	good standardization practice
GVC	global value chain
HACCP	hazard analysis and critical control points
IAAC	InterAmerican Accreditation Cooperation
IAF	International Accreditation Forum
IATF	International Automotive Task Force
ICEx	IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres
ICRE	The IED System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applicaitons (IECRE System)
ICT	information and communication technology
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ITC	International Trade Centre
ITU	International Telecommunication Union
JPEG	Joint Photographic Experts Group
KCDB	Key Comparison Database (CIPM MRA)
LDC	least developed country
LNG	liquid natural gas
MRA	Mutual Recognition Arrangement (CIPM)
NAB	national accreditation body
NAFPs	national accreditation focal points
NGO	nongovernmental organization
NMI	national metrology institute
NQP	national quality policy
NSB	national standards body
NTM	nontariff measure
OECD	Organisation for Economic Co-operation and Development
OECD-DAC	Development Assistance Committee of the Organisation for Economic Co-operation and Development
OHSAS	Occupational Health and Safety Assessment Series
OIE	World Organisation for Animal Health

OIML	International Organization of Legal Metrology
OIML-CS	OIML Certification System
OIML MAA	Mutual Acceptance Arrangement
PAC	Pacific Accreditation Cooperation
PASC	Pacific Area Standards Congress
POP	Population index
PPP	public-private partnership
PTB	National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt)
QI	quality infrastructure
QI/POP	QI/Population (index)
R&D	research and development
RAB	regional accreditation body
RIA	regulatory impact assessment
RMO	regional metrology organization
RSO	regional standards organization
SA	social accountability
SADC	Southern African Development Community
SADCSTAN	Southern African Development Community Cooperation in Standards
SARSO	South Asian Regional Standards Organization
SCC	Standards Council of Canada
SDO	standards development organization
SDoC	Supplier's Declaration of Conformity
SI	International System of Units
SIM	Inter-American Metrology System
SMEs	small and medium enterprises
SPS	sanitary and phytosanitary
SPS Agreement	Agreement on Sanitary and Phytosanitary Measures (WTO)
TBT	technical barriers to trade
TBT Agreement	Agreement on Technical Barriers to Trade (WTO)
TC	technical committee
TL	telecommunication
UKAS	United Kingdom Accreditation Service
UNCTAD	United Nations Conference on Trade and Development
UNECE	United Nations Economic Commission for Europe
UNIDO	United Nations Industrial Development Organization
UPS	uninterruptable power supply
WEF	World Economic Forum
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

Why is a functioning quality infrastructure (QI) crucial? To reap the benefits of world trade, countries must meet the quality standards of global markets. Increasingly, this requires suppliers to comply with standards, technical regulations, and sanitary and phytosanitary measures. But many countries lack the necessary QI to do so.

Helping countries to develop or strengthen their own quality and standards ecosystems—to diagnose, build, and reform the complex elements of an effective, modern QI—is the overarching goal of this toolkit.

Toward that end, Part 1 offers a primer about the importance of QI, comprising two modules:

- *Module 1: Executive Summary*. QI ecosystems are vital to overcoming technical barriers to trade while also serving the needs of governments, businesses, and consumers in many ways. Module 1 discusses these benefits and provides a quick start guide for understanding the full toolkit's workflow.

- *Module 2: Importance of QI Reform and Demand Assessment*. Without a competent and effective QI system, it may be difficult to enhance productivity; implement proper technical regulations (important for consumer protection and for the safety and health of the population, fauna and flora, and the environment); and innovate successfully, resulting in the country being less competitive in global markets. This then translates into challenges back home as a lack of socioeconomic development. Module 2 discusses in detail the importance of QI for improving market access and competitiveness, trade facilitation and integration into global value chains, innovation and technology diffusion, and productivity. It also examines the QI's role in consumer protection, health and safety, and environmental protection.

  In addition, a country's QI demands begin the process toward both QI capacity building and the identification of effective reforms. Module 2 includes a discussion on how to identify the demand for and needs of important industrial sectors and export markets. It also helps to identify gaps between supply and demand for QI services and discusses specific activities to be pursued, including techniques for providing appropriate information, such as value chain studies and market surveys. Outlining the requirements for generic QI ecosystem capacity building is an important part of the holistic approach to demand assessment.

1

Executive Summary

INTRODUCTION

For the World Bank Group to achieve its twin goals of ending extreme poverty and boosting shared prosperity, the benefits of trade must be extended to all countries. But many countries lack the necessary infrastructure to meet the quality standards for entering global markets, because participation in world trade increasingly requires that suppliers comply with standards, technical regulations, and sanitary and phytosanitary measures. To overcome these technical barriers to trade in the most efficient and cost-effective way and to reap the benefits of trade, a functioning quality infrastructure (QI) ecosystem is crucial.

Using their vast experience in upgrading and reforming QI ecosystems, the World Bank and the National Metrology Institute of Germany (PTB) have partnered to develop the first comprehensive QI diagnostic and reform toolkit, which is designed to help development partners and country governments analyze their QI ecosystems and develop a coherent offering to support QI reforms and capacity development. This toolkit is also a valuable knowledge base for other interested parties to learn more about QI and reform their QI systems or parts thereof. Such reforms could focus on one, or any combination of, the following objectives:

- Improving the legal and institutional framework for efficient and effective QI
- Enhancing trade opportunities by removing unnecessary nontariff barriers and technical barriers to trade through harmonization of technical regulations and mutual recognition of conformity assessments
- Integrating into global value chains
- Enhancing overall quality of products and services
- Encouraging innovative products to be entered into high-value-added markets
- Increasing productivity and efficient use of scarce resources
- Providing for greater consumer protection

1.1 OVERVIEW

In a modern world with rapidly growing international trade, countries compete less based on the availability of natural resources, geographical advantages, and lower labor costs and more on factors related to firms' ability to penetrate and compete in new markets. One of these factors is the ability to demonstrate the quality and safety of goods and services as well as compliance with international standards in target markets. Consumers are the ultimate judges of the quality of goods and services, so products need to comply with specifications that buyers set, and they need to be proven not harmful to human health and the environment. To demonstrate such compliance, a sound QI ecosystem is essential.

1.1.1 What QI ecosystems do

The QI ecosystem can be understood as comprising the organizations (public and private), policies, and relevant legal and regulatory frameworks and practices needed to support and enhance the quality, safety, and environmental soundness of goods, services, and processes.[1] The QI ecosystem 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, and it relies on metrology, standardization, accreditation, and conformity assessment (which comprises testing, inspection, and system or product certification). For a further general introduction to QI and its definition, see module 3: Standards.

Exporters wishing to participate in global trade face many challenges in complying with standards and technical regulations, including sanitary and phytosanitary measures. In the World Trade Organization's (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), compliance with standards is seen as voluntary, whereas compliance with technical regulations is mandatory, has legal standing, and is therefore considered more onerous. For most of the world, 60–80 percent of global trade is subject to technical regulations (ITC 2016). For Africa, the effect is lower (40–60 percent) because much of Africa's trade is in mining materials that are not subject to technical regulations. Figure 1.1 shows the extent of technical regulations' influence on the trade of goods in various regions.

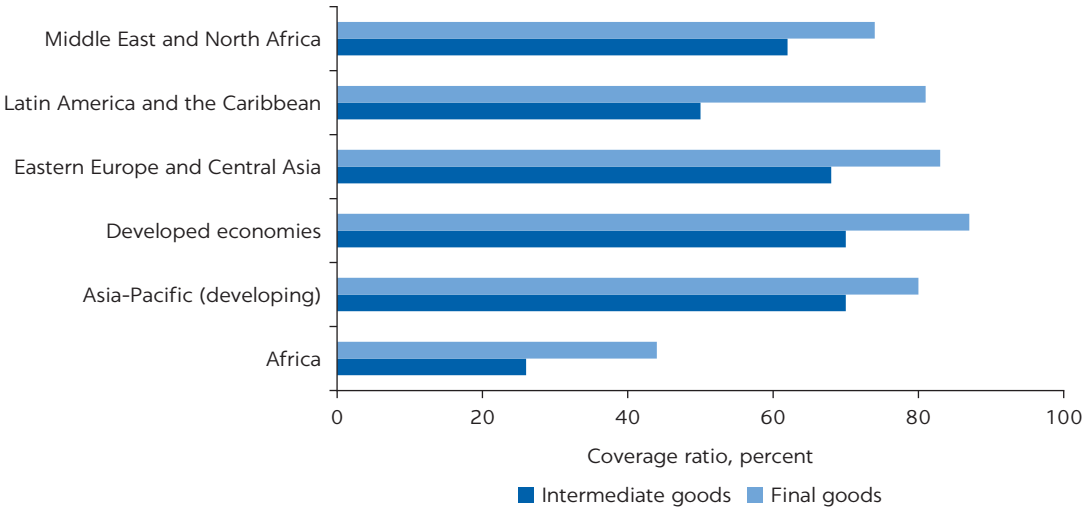
Nontariff trade barriers, consisting of technical and nontechnical barriers (figure 1.2), are equally problematic. The most efficient, cost-effective compliance with standards and technical regulations will help manufacturers, suppliers, and exporters gain access to local and foreign markets.

A modern QI ecosystem serves the needs of governments, businesses, and consumers in several ways:

- *For governments*, a QI ecosystem serves as a mechanism to support relevant trade and industrial policies and ensures enforcement of mandatory technical regulations. A recent study in the United Kingdom found that more than £6 billion in additional U.K. exports per year could be attributed to standards (Cebr 2015).
- *For businesses,* a modern, efficient QI ecosystem helps limit the cost of production, increasing productivity and enabling firms to be more competitive in domestic and foreign markets. Use of standards helps firms adopt new

FIGURE 1.1

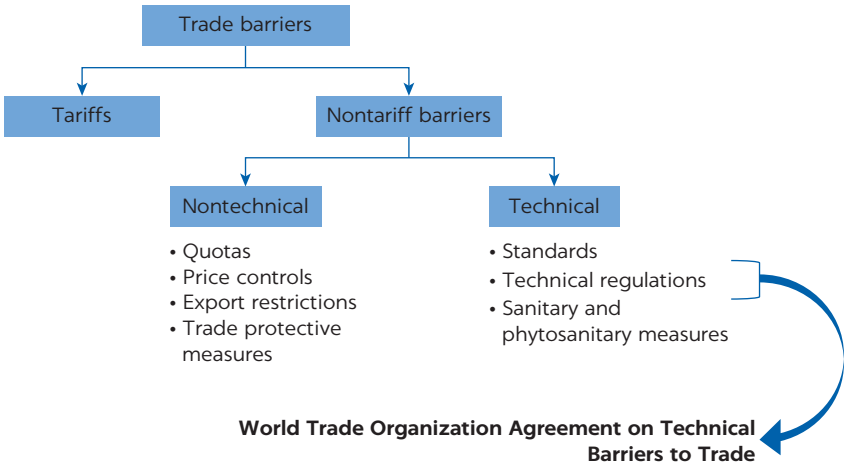
Share of goods trade subject to technical regulations, by region, 2014



Source: ITC 2016.
Note: The "coverage ratio" is the share of trade subject to at least one technical regulation. The 2014 dataset used covered 53 economies, as reported by Franssen and Solleder (2016). The sample of "developed economies" included 25 European Union countries (treated as one country, owing to identical trade regulations); Hong Kong SAR, China; Israel; and Japan. The sample of "Asia-Pacific (developing)" economies included Afghanistan, China, India, Nepal, Pakistan, the Philippines, and Sri Lanka.

FIGURE 1.2

Categories of barriers to trade



technologies and innovation in their production processes. A survey of British companies found that more than 60 percent of product and process innovators used standards as a source of information for innovation (Guasch et al. 2007), and 37.4 percent of productivity growth can be attributed to the use of standards (BSI 2016).

- *For consumers,* a QI ecosystem ensures public health and safety as well as environmental and consumer protection. Technical regulations play an important role in this regard, together with effective enforcement mechanisms such as market surveillance. These mechanisms ensure that fraudulent and counterfeit products are not traded in the marketplace.

1.1.2 Objective of the toolkit

The objective of the toolkit is to help development partners and governments analyze countries' QI ecosystems. Based on the results, the toolkit provides recommendations to bridge gaps in the QI ecosystem, support reforms, and build the capacity of institutions. The toolkit consists of 12 modules to provide a valuable knowledge resource as a holistic reference—supported by practical case studies and examples—for QI diagnostics, reform interventions and approaches, and monitoring and evaluation.

1.2 QUICK START GUIDE

The toolkit has 12 modules, each of which is further described in the concluding section of this executive summary:

- *Module 1:* Executive Summary
- *Module 2:* Importance of QI Reform and Demand Assessment
- *Module 3:* Standards
- *Module 4:* Metrology
- *Module 5:* Accreditation
- *Module 6:* Conformity Assessment
- *Module 7:* Technical Regulation
- *Module 8:* The Quality Infrastructure as a Flexible PPP System
- *Module 9:* Diagnostic Tools
- *Module 10:* How to Reform: Interventions and Approaches
- *Module 11:* Challenges of QI Reform
- *Module 12:* Monitoring and Evaluation: Performance and Impact of the QI Reforms

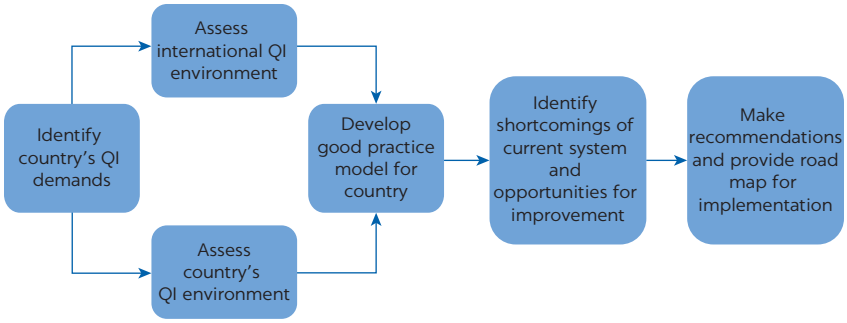
1.2.1 Importance of the QI

QI services are necessary to

- Enhance market access, facilitate product diversification, and increase investment opportunities;
- Enhance productivity by
  - Reducing costs of trade through reduced duplication in testing and inspection, streamlined operations, and fewer restrictive regulations;
  - Benefiting from economies of scale through improved and standardized working methods and interoperability between manufacturers along the value chain; and
  - Enhancing innovation and technology diffusion; and
- Promote public policy objectives through effective enforcement of technical regulations regarding public health and safety and consumer, environmental, and social protection.

To learn more about the importance of QI, see module 2: Importance of QI Reform and Demand Assessment. To learn more about the QI ecosystem and one of its fundamental elements—standards—see module 3: Standards.

FIGURE 1.3
The QI toolkit workflow: Reforming the quality infrastructure



1.2.2 QI toolkit workflow

This QI toolkit has been developed with a logical workflow (figure 1.3). It starts by comparing demand for QI services with supply, which leads to the identification of gaps between what is needed and what is being offered in the QI ecosystem and is addressed through the development of a road map for QI reforms.

Because the QI ecosystem is complex, the current supply of QI services is analyzed in a two-stage process to make the decision-making process more efficient (figure 1.4): (1) After initiation, the project starts with a *rapid diagnostic* of demand for and supply of QI services, resulting in a concept note, which helps determine whether a development project is worthwhile. (2) If it is deemed to be so, a much more *comprehensive evaluation* of the QI ecosystem demand-and-supply situation in the client country is conducted. The project can then develop a reform design to address some or all of the identified gaps, depending on development project objectives, client capacity, and available resources. Guidance on implementation and monitoring modalities are also covered.

1.2.3 The rapid diagnostic

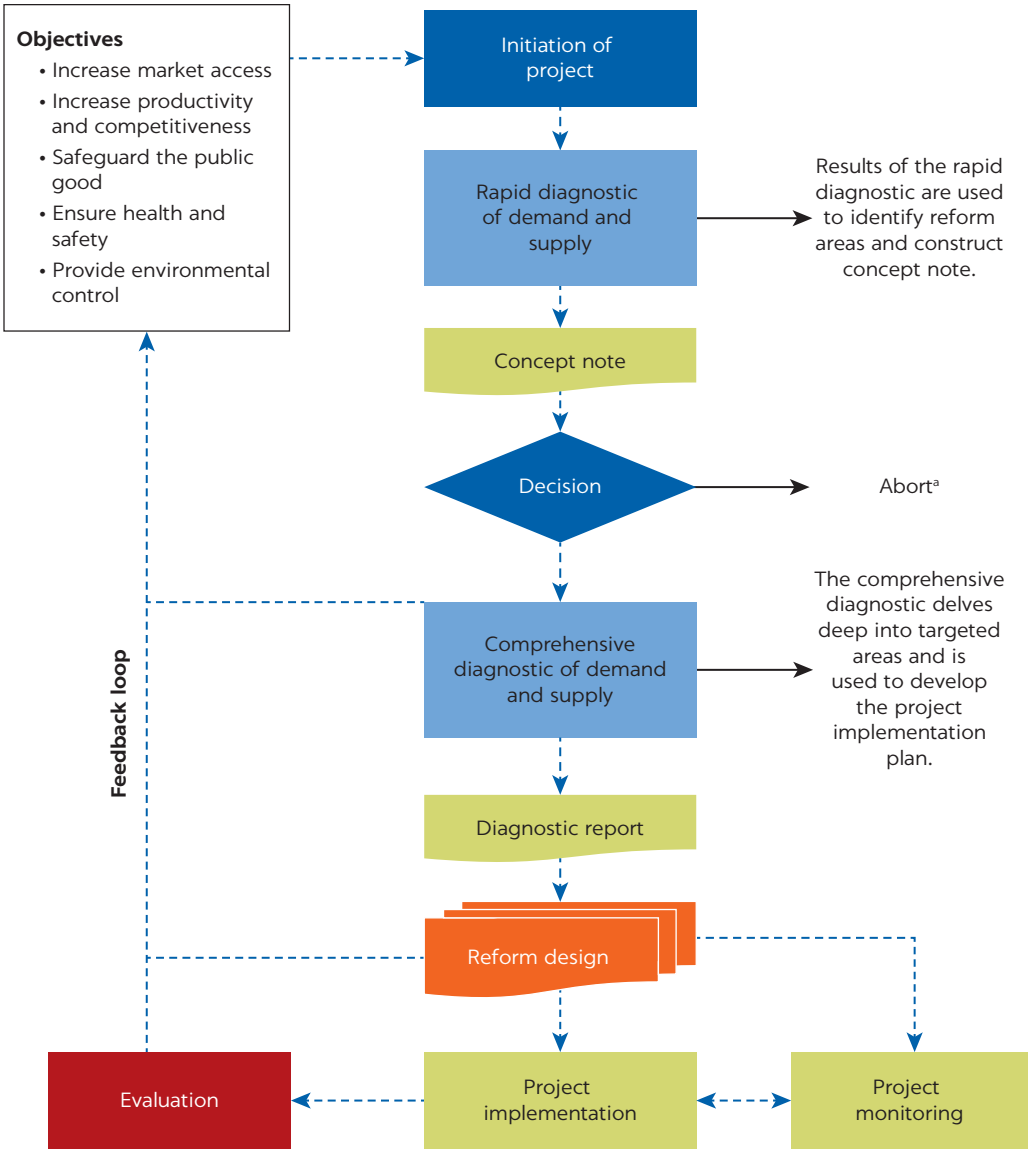
An initial decision to assess a country's QI ecosystem having been made, a *rapid diagnostic* is done of the QI ecosystem to develop a *concept note* (figure 1.5).

1.2.4 The comprehensive diagnostic

Based on the concept note, a decision can be made as to whether to run a QI development project. Design of the development project and its implementation program should begin with a *comprehensive diagnostic*, the outcome of which will be a *diagnostic report* (figure 1.6).

To learn more about how to use the Comprehensive Diagnostic Tool to its full advantage, see module 9: Diagnostic Tools. For discussion of the detailed demand assessment, see module 2: Importance of QI Reform and Demand Assessment.

FIGURE 1.4
Stages of QI toolkit processes



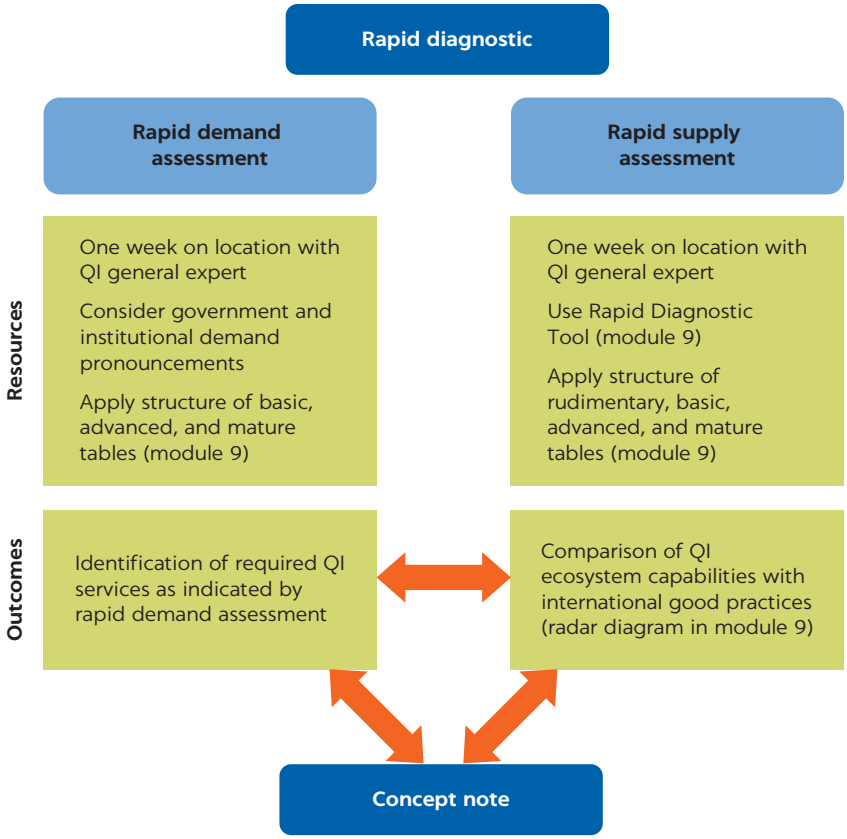
Note: QI = quality infrastructure.
a. The decision to abort a project is made on a case-by-case basis, although projects should be implemented only with full support from the client country, and a reasonable expectation that project objectives will be achieved.

1.2.5 Project cycle

Figure 1.7 illustrates the support to governments in developing modern, efficient QI systems that help producers improve the quality of their products and services to compete domestically and globally. In this project cycle, after identifying key gaps in the QI ecosystem through a market assessment—which analyzes the existing supply and potential demand for quality assurance services (comprising testing, inspection, and certification)—recommendations based on good international practices to meet such demand are suggested. The World Bank and the PTB also provide implementation support for these reforms, tailoring them to specific country conditions.

FIGURE 1.5

Stage 1: Rapid diagnostic and concept note process for a QI development project



Note: QI = quality infrastructure.

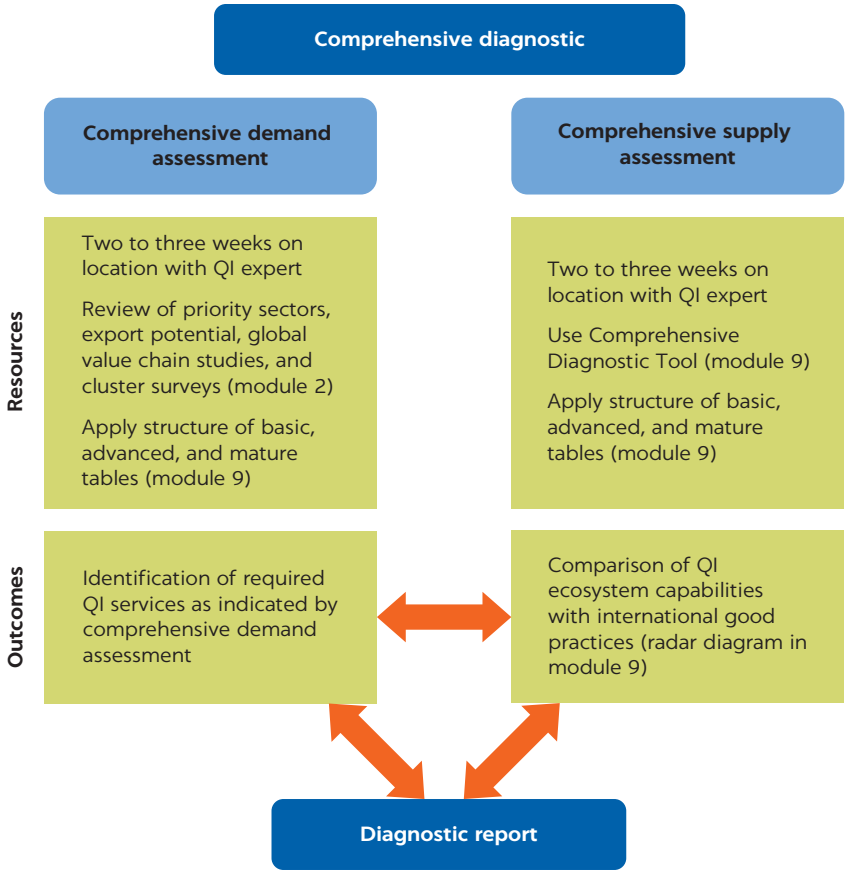
1.2.6 Lessons learned about project design and implementation

A development project, along with its implementation program, should close the gap between demand for and supply of services by QI institutions. Some key principles to be considered in project design include the following:

- *Refrain from setting overoptimistic short-term targets,* instead embedding short-term assistance in longer-term objectives, including those within the beneficiary government's long-term policies and planning.
- *Agree with partners on a stepwise approach* that differentiates reform targets based on the current development stage of a country's QI ecosystem, differentiated in the QI toolkit as follows:
  - *Rudimentary:* Set mainly basic QI targets.
  - *Basic:* Consolidate the basic services, and set mainly advanced QI targets.
  - *Advanced:* Consolidate the basic and advanced services, and set mainly mature QI targets.
  - *Mature:* Consolidate the basic, advanced, and mature services, and broaden the QI intervention scope.
- *Find the right technical assistance balance* between (a) commitment of technical assistance delivery, (b) absorption capacity of the recipient country and

FIGURE 1.6

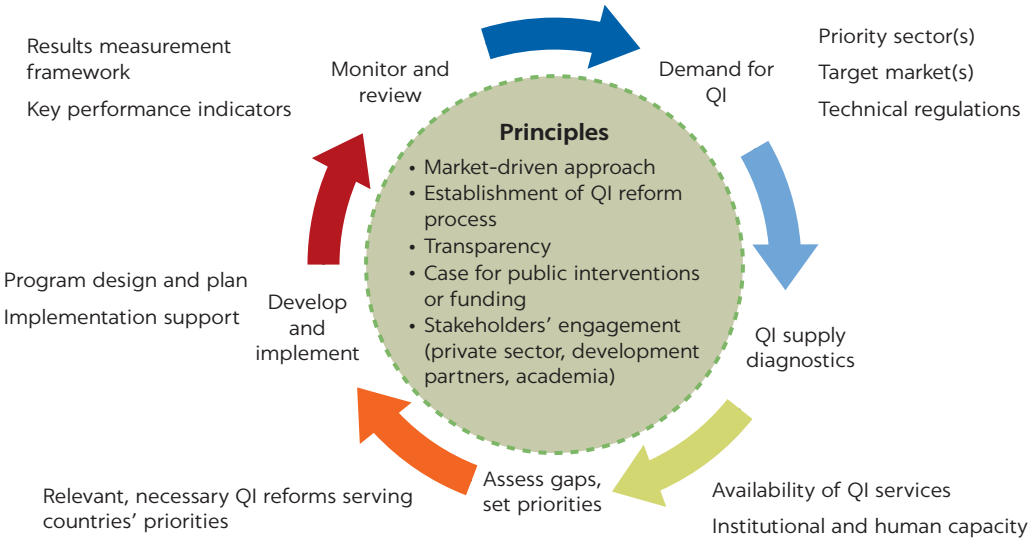
Stage 2: Comprehensive diagnostic and diagnostic report process for a QI development project



Note: QI = quality infrastructure.

FIGURE 1.7

The QI development project cycle



Note: QI = quality infrastructure.

institutions, and (c) provision of highly technical services by the development partner.
- *Take into account the demonstrable demand* for quality-related QI service delivery. If need be, project design should develop demand and supply in parallel.
- *Anchor the project in the right partner institution* (one directly responsible for the field covered) to ensure "ownership." Use project steering committees and continuous information flows to reinforce this ownership.
- *Strengthen business service providers* (intermediaries), which is often more effective and sustainable than providing direct services through the project.
- *Keep a wide range of firm sizes in mind.* Chances of short-term success in supporting larger enterprises should not be the only goal. The small and medium enterprises (SME) sector is more difficult to reach but, in the long run, may be more important for the country.
- *Pursue complementary objectives as needed.* Institutional strengthening may have to be paired with development and promulgation of the appropriate legislative framework, even though the latter is much more demanding in terms of guiding draft or revised legislation through the political process.
- *Choose equipment suppliers selectively* for laboratories or other institutions. Development partners should focus as much as possible on a limited number of suppliers to avoid problems with equipment maintenance.
- *Shift from direct provision of training to local responsibility* to enhance the sustainability of training functions in key institutions.

For detailed information on developing an effective, efficient implementation program, see module 10: How to Reform: Interventions and Approaches and module 11: Challenges of QI Reform. Carefully consider both in the design of an implementation program.

1.2.7 Monitoring and evaluation of QI development projects

Implementation programs need to be monitored continuously to ensure that the designed outputs are achieved within the desired time frame and within budget. Mid-term and end-of-project program evaluations provide feedback on long-term effects and lessons learned to enhance future project designs. Both need to be provided for in project design and agreed upon with the client country and institutions.

Each project is different and thus will require a different set of performance indicators that will inform the Theory of Change and the logical framework (or "logframe") of the change process.[2] Although module 12 provides examples, indicators should be developed on a case-by-case basis. The most important thing to consider when developing indicators is that they be relevant and measurable. Indicators that cannot be measured are not useful, because they would have to rely on subjective interpretations. Once performance indicators are determined, they should be formally agreed upon with the development partner and the recipient country or organization.

For detailed information on implementation program monitoring and project evaluation, see module 12: Monitoring and Evaluation: Performance and Impact of the QI Reforms.

1.3 QI TOOLKIT MODULE DESCRIPTIONS

In addition to this executive summary, the remaining 11 of the 12 modules each has a distinct focus, as described below.

***Module 2*: Importance of QI Reform and Demand Assessment.** Module 2 covers the role of the QI ecosystem in improving market access and competitiveness; trade facilitation and integration into global value chains; innovation and technology diffusion; and productivity. It also examines the QI ecosystem's role in customer protection, health and safety, and environmental protection.

A proper demand assessment is critical to both capacity building in the QI and the identification of effective reforms. The module broadly discusses identification of the demand for and needs of important industrial sectors and export markets. It also explores the identification of gaps between supply and demand for QI services and provides information on specific activities to be pursued. It lists techniques for providing appropriate information, such as value chain studies and market surveys. Outlining the requirements for generic QI ecosystem capacity building is an important part of the holistic approach to demand assessment.

***Module 3*: Standards.** The QI ecosystem is a complex array of the interdependent organizations needed to provide QI services. There are not many definitive publications describing the QI ecosystem holistically that can be referenced to construct a detailed assessment, so modules 3–8 elaborate on each element of the QI ecosystem in detail. Module 3 focuses on the first of the three fundamental elements of the QI: standards.

***Module 4*: Metrology.** Metrology, the science of measurement, is arguably the oldest of the three fundamentals of the QI. It has developed into one of the most sophisticated sciences—and one in which cooperation across the world is absolutely essential to maintain modern technology. Module 4 explores in detail the three categories of metrology: scientific metrology, legal metrology, and industrial metrology.

***Module 5*: Accreditation.** The third fundamental element of the QI is the most recent to be developed: accreditation. Module 5 examines its importance and applicability, especially in countries dependent on global trade, because of its facilitating role in international recognition systems for the services of the QI.

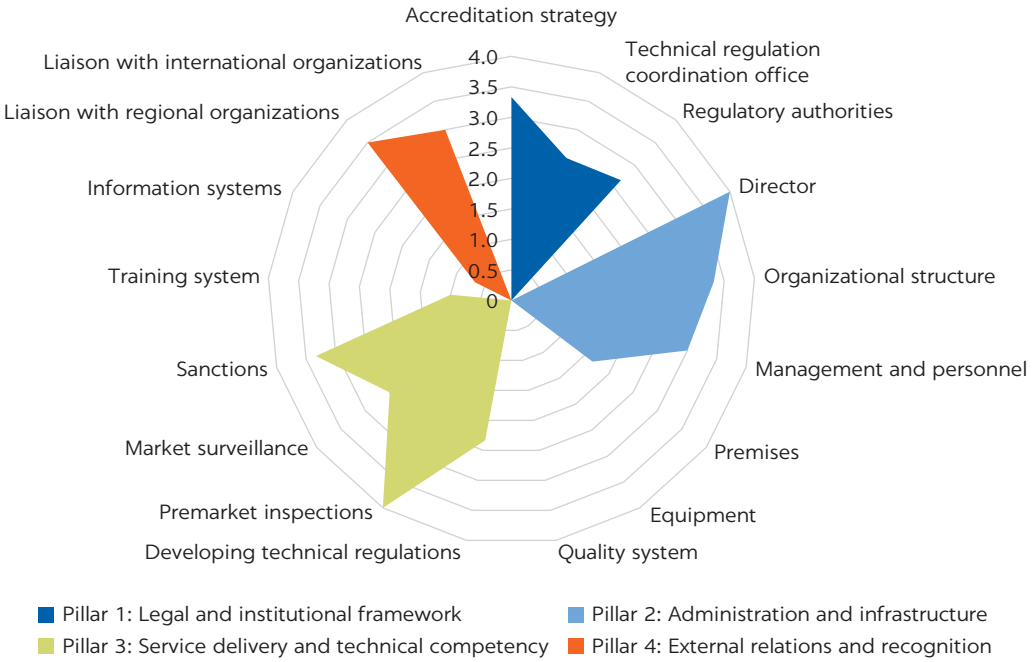
***Module 6*: Conformity Assessment.** Conformity assessment services generally comprise inspection, testing, and product and system certification. Module 6 describes the scope and application of each within the QI.

***Module 7*: Technical Regulation.** Technical regulations are a mandatory part of the QI—being legally binding prescriptions—whereas standards compliance is voluntary. Module 7 explains these distinctions and discusses particularly the provisions in the WTO TBT Agreement regarding the development of technical regulations.

***Module 8*: The Quality Infrastructure as a Flexible PPP System.** The QI ecosystem is presented as a flexible system with a focus on its public-private partnership dimensions.

FIGURE 1.8

Sample radar diagram and snapshot of a country QI ecosystem



Note: QI = quality infrastructure.

***Module 9*: Diagnostic Tools.** The Rapid Diagnostic Tool and the Comprehensive Diagnostic Tool are based on the concept of building blocks arranged in four pillars to describe a specific QI service. The results of a diagnostic can be depicted as a radar diagram (figure 1.8). Application of the Rapid Diagnostic Tool provides users with high-level information on the capacity of a country's QI ecosystem, which together with a rapid demand assessment provides guidance on whether a QI development project would be beneficial to develop and implement.

The Rapid Diagnostic Tool consists of questions whose answers result in a set of scores ranging from 0 to 4, which are then collated to provide an overall score also ranging from 0 to 4. These scores can then be used to construct a QI service radar diagram to indicate the state of QI services at a glance (figure 1.8), as discussed in module 9. The scores are categorized in four levels of implementation:

- *0–1.0:* Little or nothing is in place, and the country must develop the relevant elements of a QI ecosystem from scratch.
- *1.1–2.0:* A rudimentary system needing much fundamental development is in place.
- *2.1–3.0:* A reasonable system is in place but needs further development.
- *3.1–4.0:* A good system is in place with no need for fundamental development, but maintenance is important.

The Rapid Diagnostic Tool can be applied as a spreadsheet that calculates the scores and draws the radar diagrams automatically. An expert should be able to gather information for the Rapid Diagnostic Tool within a week or two on-site, provided that he or she has the full support of knowledgeable local persons. The expert would also be able to use these results to categorize the QI ecosystem as rudimentary, basic, advanced, or mature, which requires a qualitative evaluation of all the results based primarily on his or her experience and knowledge.

Use of the Rapid Diagnostic Tool is not confined to evaluation of the QI ecosystem before any intervention is contemplated; it can also be used as a monitoring and evaluation tool to show the continued development or otherwise of the QI. In this way, policy makers and practitioners can be apprised fairly easily of progress, or the lack thereof, which can lead to appropriate action at the political level or by the recipient organization.

The Comprehensive Diagnostic Tool contains a detailed approach to evaluation of various elements of the QI. It is based on four pillars that address the QI environment, its institution and services, and its recognition (a holistic approach), as follows:

- *Pillar 1:* Legal and institutional framework
- *Pillar 2:* Administration and infrastructure
- *Pillar 3:* Service delivery and technical competence
- *Pillar 4:* External relations and recognition

Each of the four pillars is divided into a number of building blocks that must be in place for the elements of the QI ecosystem to function optimally and to comply with international good practices. Some of the building blocks of the QI ecosystem elements would be similar to each other, but there are also some significant differences, and the building-block number designating each QI ecosystem element will differ depending on individual requirements. The same information can be used to develop a radar diagram.

Module 9 fully describes how to assess each of the QI services. After an in-depth evaluation, which typically takes an expert three weeks on location, a score can be assigned to each of the building blocks and can be presented graphically as four different colors—each denoting, for example, the level of implementation or compliance. This would give a "dashboard" type of picture that policy makers and higher-level officials who may not have a detailed understanding of the QI ecosystem elements can readily understand.

***Module 10*: How to Reform: Interventions and Approaches.** This module covers three major areas:

- *The policy and legislative domain.* The starting point for effective reform of the QI ecosystem is development of a holistic government policy in the form of a national quality policy, the characteristics of which are described. Thereafter, the reform of the QI ecosystem, related legislation, and the institutional framework are discussed in detail, including information on strategies and relevant training of technical staff.
- *The QI ecosystem.* Establishing standardization for competitiveness is discussed in detail in subsections on new standards, compliance with public and private standards, global value chains, and areas policy makers could consider. Also detailed are ways to strengthen the metrology and accreditation systems and to establish and strengthen conformity assessment services. Finally, this section covers alignment of the technical regulation regime with international good practices as well as resolution of conflicts of interest within the QI ecosystem.
- *The external environment.* This section examines the positive influence that global value chains and foreign direct investment can have on the QI ecosystem. It also discusses the QI ecosystem's potential influence on innovation, which is a recognized driver of industrial development and competitiveness.

***Module 11*: Challenges of QI Reform.** Project preparation and management are crucial to project success. This module discusses in detail the good practices for QI ecosystem reforms, which pose unique challenges that need to be considered. It also provides guidance on strategic approaches to supporting development of the QI ecosystem, with a focus on institutions.

***Module 12:* Monitoring and Evaluation: Performance and Impact of the QI Reforms.** Projects need to be monitored regularly to determine progress on project objectives. Progress is usually measured against logical frameworks established before the start of the project, an example of which is discussed. Project evaluation—with one-time exercises being different from monitoring—are also important to determine project outcomes in a broader context and to determine whether development partners have been effective, so as to gain knowledge for future projects. Various evaluation modalities are discussed in detail.

NOTES

1. The "organizations" of the QI ecosystem provide such things as national standards, calibration, test reports, certification reports, and accreditation certificates. "QI services" is used as a collective term to denote these outputs of QI organizations.
2. Theory of Change is a specific methodology for planning, participation, and evaluation. It defines long-term goals and then maps backward to identify necessary preconditions. The logical framework, or "logframe," is a way of presenting the "logic model" as a sequence of modalities illustrating the change process. For a detailed discussion of the Theory of Change and logframes, see module 12: Monitoring and Evaluation: Performance and Impact of the QI Reforms.

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2

The Importance of QI Reform and Demand Assessment

INTRODUCTION

Measurement standards have been around for millennia, starting in the ancient civilizations of Egypt and Mesopotamia. Weights and measures departments have been around for centuries in the industrialized world. In low- and middle-income countries, weights and measures departments were often established around the turn of the 20th century.

Standards bodies were established in the early 1900s in industrializing countries—for example, the British Standards Institution (BSI) in 1901, the American National Standards Institute (ANSI) in 1916, the German Institute for Standardization (DIN) in 1917, and the Japanese Industrial Standards Committee (JISC) in 1921. Low- and middle-income countries followed, establishing national standards bodies in the aftermath of World War II as industrialization spread and as standards, testing, and certification became required. Accreditation is a much later phenomenon, starting in Australia and New Zealand after World War II, and spreading from there around the world.

In many countries, these elements of the quality infrastructure (QI) developed organically, frequently without coordination, resulting in overlaps and gaps in service delivery. In addition, QI organizations have become complacent because of perceived or real monopolies.[1] These arrangements are no longer tenable. Many countries feel the need to evaluate their QI holistically; to reengineer it to become effective and efficient; to support local industry productivity, innovation, and competitiveness; and to support the implementation of efficient and effective health, safety, and environmental controls for the country and its inhabitants.

2.1 WHY COUNTRIES NEED TO DEVELOP COMPETENT AND EFFECTIVE QUALITY INFRASTRUCTURES

Without a competent and effective QI system, it may be difficult to enhance productivity; implement proper technical regulation (important for consumer protection and for the safety and health of the population, fauna and flora, and the environment); and innovate successfully, resulting in the country being less

competitive in global markets. This then translates into challenges back home as a lack of socioeconomic development.

2.1.1 Role of QI in good governance

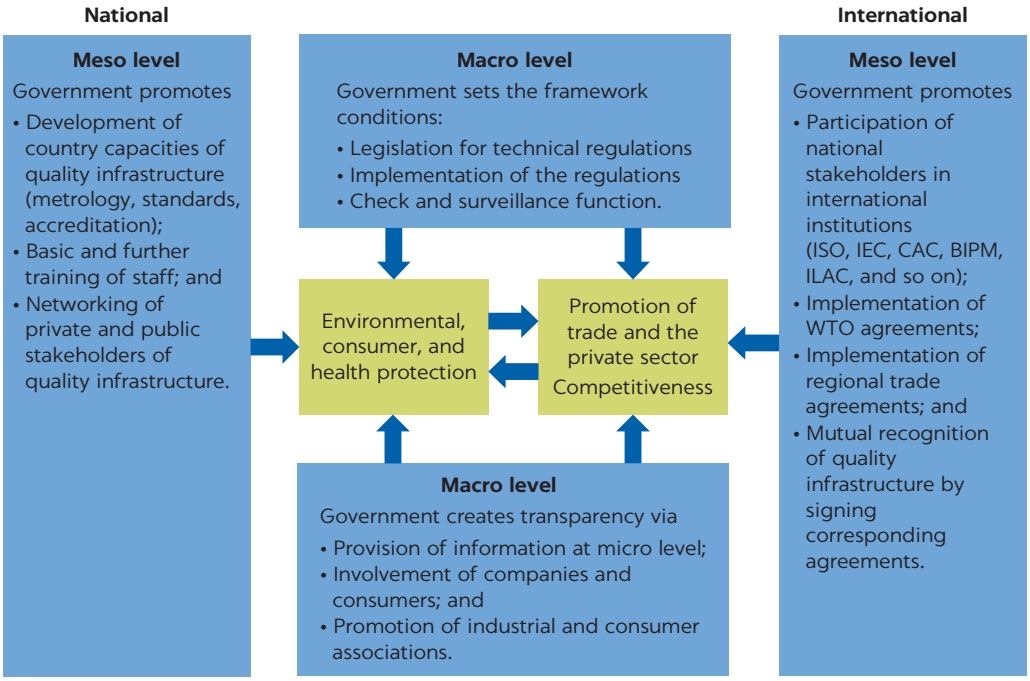
Good governance shapes the framework conditions of a country for its economy and its citizens. These include legislative tasks, linked with a corresponding administrative structure. It means acting in favor of a socioeconomic system that can be enjoyed by all. Hence, good governance is a vital factor for the reduction of poverty and for the promotion of economic development.

Good governance criteria include (a) respect for human rights; (b) public participation in political decision making; (c) the rule of law, signified by an independent judiciary, transparency, and predictability of state actions; (d) a market-friendly socioeconomic order; and (e) development-oriented state action, guided by government policies for ecologically, economically, and socially sustainable development, against corruption, and for an efficient public service.

An effective QI that complies with international agreements; supports the socioeconomic development of the country; supports the implementation of technical regulations for consumer protection and the safety and health of the population, fauna, and flora; and provides affordable services to the small and medium enterprises (SME) sector that makes up a large part of the economy, is a vital part of such a good governance system—and one that the state must foster (figure 2.1).

FIGURE 2.1

Quality infrastructure and government responsibilities: The levels of action



Source: PTB 2007. ©National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt [PTB]). Reproduced with permission from PTB; further permission required for reuse.
Note: BIPM = International Bureau of Weights and Measures; CAC = Codex Alimentarius Commission; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; QI = quality infrastructure; WTO = World Trade Organization.

2.1.2 Role of QI in improving competitiveness and market access

The nature of participation in the global economy has changed dramatically over the past three decades. Selling to a global market has become increasingly complex. Research and development (R&D), design, production, marketing, and sales now involve a chain of interrelated contractual relationships.

In most parts of this chain, standards and their implementation are used to reduce transactional costs and ensure interchangeability among the modular parts, thereby giving control to the lead firm over the quality of goods produced throughout this chain (Racine 2011). Standards and compliance with them (through conformity assessment, the proficiency of which is assured by metrology and accreditation) have emerged as one of the main drivers for suppliers to gain a competitive edge and in this manner gain market share.

Accessing global markets

Standards have become the lingua franca of world trade. International and regional standards provide a common technical language for trading partners throughout the world. For businesses active globally, these standards are major criteria for assessing the suitability of potential business partners and suppliers. They also ensure the compatibility and quality of products and services. The results of studies on the economic benefits of standardization have shown that 84 percent of manufacturing companies in Germany, for example, use European and international standards to gain access to global markets.[2] Compliance with these standards obviously is possible only with a well-developed QI system, including metrology traceable to the International System of Units (SI) and accreditation that is internationally recognized.

One reason for standards' general importance to trade is that they help lower nontariff trade barriers, thus promoting global trade. In the World Trade Organization's Technical Barriers to Trade Agreement, this is codified in that (a) member states are obliged to adopt international standards as national standards with as little change as possible, and (b) technical regulations should be based on international standards. In many of the regional trade agreements, similar notions are demanded of member states, which have to adopt regional standards as soon as they are published while withdrawing any national standards of similar scope.

Controlling global value chains

The lead firms in global value chains (GVCs) make the key decisions over how production is organized, *who* participates, and *how* (that is, the conditions of participation, such as number and delivery times of outputs, price, quality, and other requirements). The lead company enforces these conditions through standards and their implementation. It demands this not only from its first-tier suppliers, but also from the second- and lower-tier suppliers, to ensure compliance throughout the value chain (Humphrey and Schmitz 2000).

Hence, GVC participation is tied to increasing compliance with a variety of technical requirements, contained in both voluntary standards and technical regulations, covering both product and processes. Demonstrable compliance (for example, inspection, testing, and certification supported by accreditation and metrology) with product and process standards signals to lead firms and their buyers the capability of suppliers down the value chain. Without such demonstration of compliance, the opportunities of getting involved in such

GVCs are limited. An effective and efficient QI, appropriately recognized internationally, is a precondition for delivering such demonstrable compliance.

Reducing costs: Standards

Standards and their implementation, demonstrated through trustworthy QI services, can help a company reduce costs in all areas of business—from purchasing, production, and sales to R&D, quality assurance, environmental protection, and occupational health and safety—in the following ways:

- R&D can use the fundamental knowledge contained in standards as a basis for further developments.
- Standards can help rationalize production and boost efficiency.
- Standardizing interfaces enhances compatibility, leading to lower transaction costs.
- Compatible products and systems are in greater demand and are more successful on the market.
- Standards improve quality, which is essential for good customer relations.
- Standards ensure safety, which not only enhances customer trust, but also reduces liability.

By actively taking part in the development of standardization, companies can help shape these technical rules to better reflect their own interests. At the same time, safety interests such as environmental and consumer protection and occupational health are given due consideration. Plus getting involved in the standards development process brings companies in direct contact with specialists in other areas—and with potential competitors. Such companies therefore gain new knowledge ahead of time, and working together with those shaping R&D helps them bring new technologies to market earlier than those that do not.

Reducing costs: Metrology

Sound measurements can have a major impact in a business and can lead to cost savings, as these examples illustrate:

- Energy is a major input cost for many manufacturers. Measuring the volume of heating gas to a higher degree of accuracy can save the company vast sums of money, which otherwise would have to be paid for inaccurate higher readings.
- Accurate measurements regarding time and temperature during heat treatment of specialized materials ensure the heat treatment is optimally conducted, reducing the amount of nonconforming materials after heat treatment.
- Accurate measurements of parts that are provided to the next manufacturer for inclusion in the final product will ensure a seamless integration of the various parts, whereas inaccurate measurements may result in parts that do not fit.
- More accurate measurements of the dosage of fertilizer per surface area can save the farming community millions of dollars per year compared with the cost of spreading too much, and it will result in less stress on the environment as well.

Companies that implement sound measurement practices therefore have the advantage over others that do not, an advantage that reduces production of nonconforming parts or products and hence lowers overall production costs.

Meeting consumer expectations and rights

Standards and their implementation touch every person. From enabling the use of a bank card abroad to ensuring that children's toys do not have sharp edges that could hurt them, from enabling cellular phones to connect to networks all over the world to buying new tires to fit the vehicle, the list is endless. These standards are implemented by companies all over the world to ensure that products and services work as expected.

The right to an informed choice—and to redress, when expectations are not met—is fundamental to effective customer relations, and is a basic right, as outlined in the United Nations Guidelines for Consumer Protection (UNCTAD 2016). Products and services that demonstrably meet standards help to improve customer satisfaction, and in a world where the customer's voice is increasingly prominent, this has become an essential business requirement, for several reasons:

- *Product safety*. Standards and their implementation play a major role in ensuring product safety, covering aspects such as product safety requirements, product recall procedures in the case of product failures, codes of conduct for handling complaints and disputes, food safety and security, child-related safety, requirements for the elderly and infirm, and consumer product guidance for suppliers.
- *Product quality assurance*. Product certification marks have been around for a long time, but their influence in the market has not diminished: customers are still looking for trusted product certification marks in the more expensive products, products for which they cannot easily discern the intrinsic quality.
- *Service quality assurance*. The same applies for services. The International Organization for Standardization (ISO) has even developed and published a guide for developers of standards for services: "ISO/IEC Guide 76, Development of Service Standards—Recommendations for Addressing Consumer Issues" (ISO/IEC 2008).
- *Societal guidance and support*. Public and private standards help societies in areas such as dealing with natural disasters and living in a sustainable way, or provide guidance on social responsibility.

The state also gets involved in the relationship between the QI and consumers to exercise some of its fundamental responsibilities, namely, the protection of country's population, fauna and flora, and environment. Many of the above-noted standards in which consumers have an interest find their way into the technical regulations and sanitary and phytosanitary measures implemented by the state. Compliance with these is not a choice for the supplier but becomes a legal obligation benefiting the consumer.

In addition to transmitting information on the quality and technical specifications of products, compliance with relevant standards is increasingly required to meet social and environmental criteria for both the product and production processes. Consumerism, particularly in high-income countries, is increasingly tied to social and environmental norms; standards on health, safety, ethics, fair trade, labor practices, and environmental sustainability have become important. Leading firms have responded to these pressures and demand the same from their first- and lower-tier suppliers in the value chain. In this respect, relevant standards are used in a self-regulatory mode by the lead firms in GVCs throughout their value chains to convey their responsible practices to customers and critics.

With the views and perceptions of consumers becoming ever more important from a business perspective, even in low- and middle-income countries, the role

of standards and their implementation demonstrated through QI services can only increase. This means that low- and middle-income countries must be even more vigilant in ensuring that their QI is effective, efficient, and recognized internationally to ably support their socioeconomic development.

2.1.3 Role of QI in innovation and technology diffusion

Innovation can be seen from more than one perspective. On the one hand, something that is new to a company or country—like a more modern design of a product or a new cost-saving production process—can be seen as innovative (see module 10, section 10.10). On the other hand, however, innovation is equated with "destructive" technologies: new products that initiate the demise of existing products. Typical examples include the rapid demise of the long-playing record when the compact disc arrived or the equally rapid demise of the film camera when digital technology hit the market.

Catalyst and support for innovation

Whatever the case, the ability to implement new ideas and research findings as innovative products, methods, and services is decisive for competitive ability. Standardization can serve as a catalyst for innovations and helps bring solutions to the market.

To begin with, standards define interfaces, compatibility requirements, and uniform methods of measurement. For example, testing standards and terminology standards are important for new fields of technology and for developing innovative products and services, as are quality standards and safety standards, because they provide the evidence that the innovation requires to be marketed. Just as important are other QI services such as trustworthy (for example, accredited) testing and certification services. And without accurate measurements (metrology), it will be impossible to determine the true attributes of innovative products.

Innovative companies use standardization in its broadest sense (including the implementation of standards) as a strategic instrument for increasing the marketability of their products. Standardizing the right aspects of an innovative product, and demonstrating the same, can play a key role in preparing the product for the market. Thus, deciding on how to use standards for innovative solutions is a fundamental aspect of any company strategy. Standards and their implementation bring transparency and trust to the innovation process (ISO 2015). Not only is it companies that embrace innovation, but the state can also play an important role by providing the framework conditions, as can technical institutions and the educational sector by fostering innovation (see module 10, subsection 10.10.3).

Mutual recognition arrangements

An important vision of the global QI environment is the long-accepted concept, "Inspected, tested, and certified once, accepted everywhere." This notion gained some traction in the early days of accreditation. When the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) were established, it was the outcome many believed would be possible. Once a conformity assessment service provider was accredited by an accreditation body recognized by these organizations, its services should have been recognized all over the world. This has not come about for many reasons, among others that governments still wanted to have the last say in

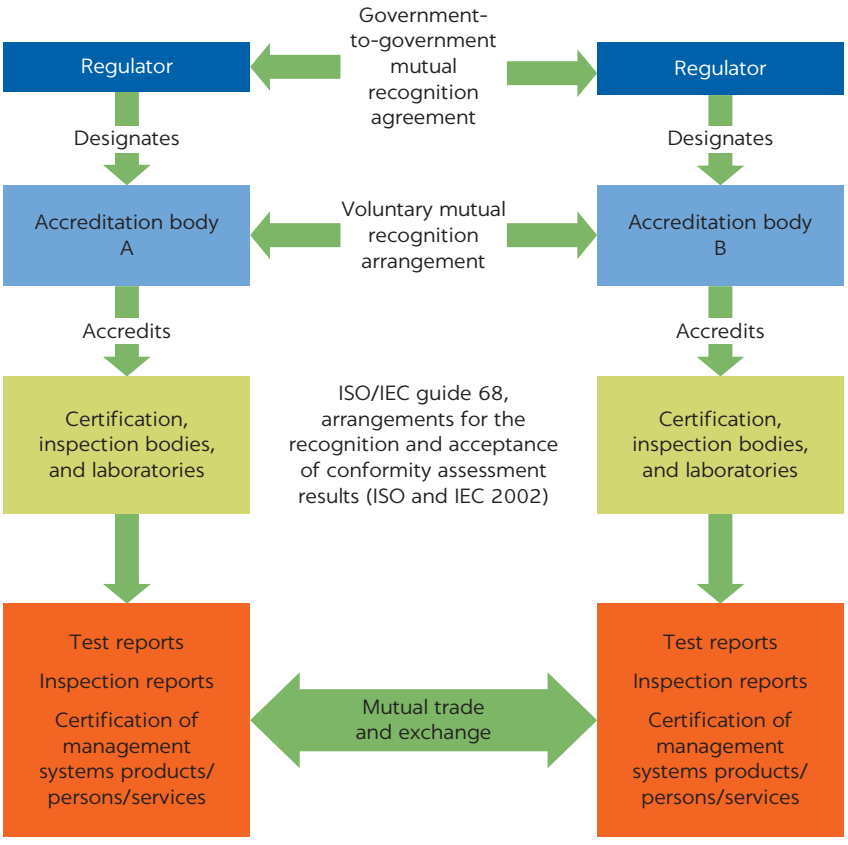
who was going to provide such services in the regulatory domain because of the consequences of any errors, for which the governments were ultimately accountable.

Hence the "accepted everywhere" notion has not been achieved yet and may never be achieved. But the international QI organizations and many governments are endeavoring to bring about coordination. This is done though bilateral or multilateral recognition arrangements and agreements. Governments would agree among each other to accept conformity assessment results from their respective countries if the service provider is accredited by bodies recognized by the ILAC or IAF and thereafter designated by the relevant governments (figure 2.2).

Another possibility, although of a lower level, would be a bilateral or multilateral arrangement among the accreditation bodies or certification bodies themselves. In this case, one body recognizes certificates issued by the other as equal to its own. The international certification schemes operated by the International Electrotechnical Commission (IEC) or International Organization of Legal Metrology (OIML) for electrical and measurement equipment, respectively, are typical schemes of this nature. Participants in these schemes recognize test certificates issued by the others as equal to those issued by themselves and grant certification in their own countries based on the test reports of the other countries, even certification required for regulatory purposes.

FIGURE 2.2

Sample model of accreditation use to recognize conformity assessment results



The final possibility in this respect would be recognition arrangements that are in place in common markets. These recognition arrangements are based on the rules included in treaties, protocols, and agreements relating to trade within the common market. The whole system of "notified bodies" in the European Union (EU), for example, operates on such principles, which include accreditation. A product tested and certified by an appropriate "notified body" in one EU member state for compliance with a specific directive (such as an EU Technical Regulation) can then be legally marketed in all EU member states without having to be retested in another member state.

2.1.4 Quantitative research on the correlation between QI and economic performance

Various studies have considered the relationship between the economic performance of a country and its QI and have shown a positive correlation between performance and QI efficacy. Two examples are discussed here.

Correlation between QI and key economic indicators

QI/Population index. Harmes-Liedtke and Di Matteo (2011) provided a comparison between a QI/Population (QI/POP) index—calculated from publicly available data on accreditation, metrology, standardization, and certification for 55 countries—and various economic indicators such as the World Economic Forum's (WEF) Global Competitiveness Index; World Bank data on gross domestic product (GDP) per capita; Transparency International's Corruption Perception Index; and a few others. Although the authors state clearly that the indexes developed by them are not to be considered as fundamental or definitive, the story they tell is significant.

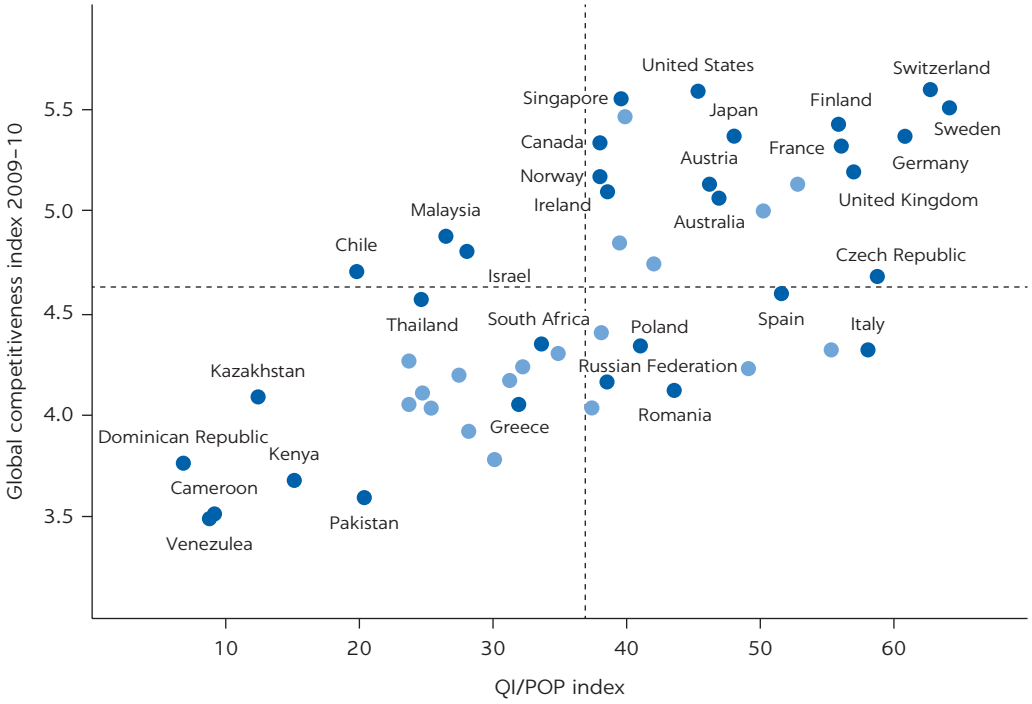
Global Competitiveness Index. The elements considered for the WEF's Global Competitiveness Index include the following: infrastructure, macroeconomic stability, health and primary education, higher education and training, goods market efficiency, labor market efficiency, financial market sophistication, technological readiness, market size, business sophistication, and innovation. Because none of these is used in calculating the QI/POP index, any relationship could be considered causal.

Considering figure 2.3, a trend can be discerned that the more competitive countries have the better-developed QI, whereas the less competitive countries have a less developed one. The relationship tends to be linear, with a moderate-to-strong correlation coefficient of almost 0.7. There are, however, countries with large differences in the competitiveness index that have a similar level of QI/POP or vice versa (for example, Romania and the United States, Chile and the Czech Republic, and Canada and Sweden), indicating some uncertainty as to an absolute relationship between competitiveness and the QI, both as measured for the specific country.

GDP per capita. The GDP per capita is a common indicator used in economic research and is considered to represent a standard of living. The relationship between the GDP per capita and the QI/POP index shows a moderate-to-strong correlation, with a Spearman coefficient of 0.705 (figure 2.4). The tendency for countries to show similar rankings for their performance and their QI remains, as in the earlier example of the Global Competitiveness Index versus the QI/POP index. But there are also large dispersions. For example, China

FIGURE 2.3

Relationship between Global Competitiveness Index 2009–10 and QI/POP index, selected countries



Source: Harmes-Liedtke and Di Matteo 2011.
Note: QI = quality infrastructure. The World Economic Forum's Global Competitiveness Index presents a framework and a corresponding set of indicators in 3 principal categories (subindexes) and 12 policy domains (pillars); the 2009–10 index covered 133 economies. The QI/Population (QI/POP) index is calculated from publicly available data on accreditation, metrology, standardization, and certification for 55 countries. Horizontal and vertical lines designate the median Global Competitiveness and QI/POP values, respectively.

and the Dominican Republic have a similar GDP per capita but a totally different QI/POP index. It is obvious that, in this case, the population sizes, being vastly different, have a marked influence on the results. In a similar vein, China and Norway also have vastly different population sizes, but Norway has the higher GDP per capita by far.

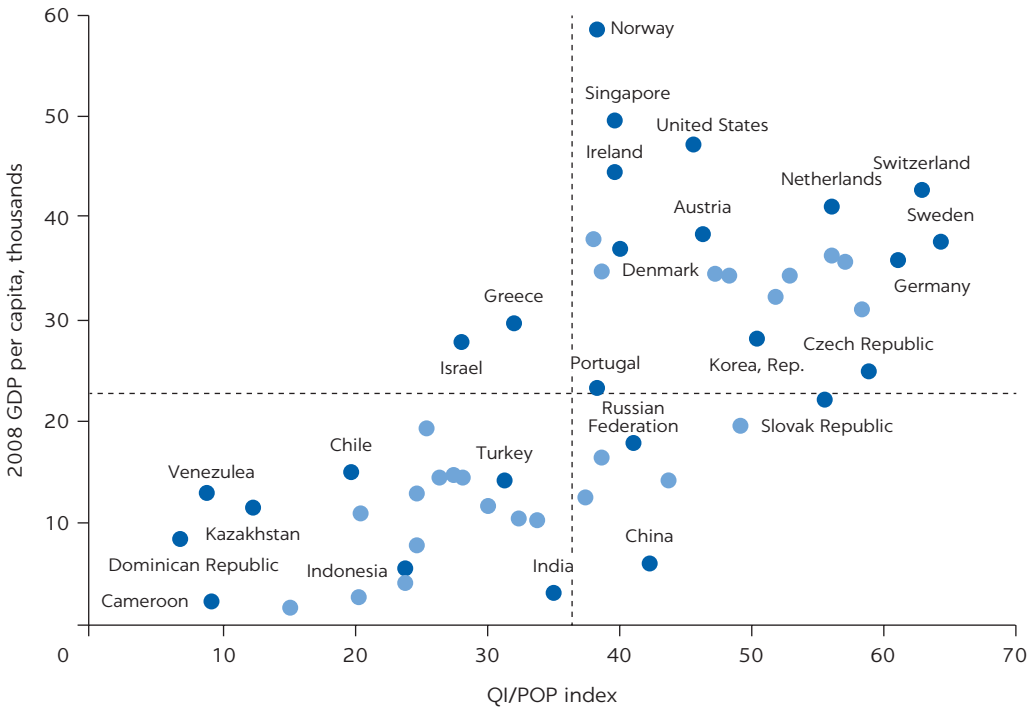
The Harmes-Liedtke and Di Matteo (2011) study concludes that even though one could argue about the absolute values of the indicators used, the examples seem to indicate the need for low- and middle-income countries to establish an effective and efficient modern QI if they wish to increase their GDP per capita and become more competitive in the global economy.

Correlation between QI and compliance with trade standards

The United Nations Industrial Development Organization (UNIDO) commissioned the Institute for Development Studies (Brighton, U.K.) to conduct a study named "Meeting Standards, Winning Markets" in 2010. This was repeated and enhanced in 2015 (UNIDO 2015). This latest study used a three-pronged approach to determine the capabilities of a selection of low- and middle-income countries to comply with "trade standards," which UNIDO defines as any technical requirements a supplier has to comply with to gain access to a specific market. These include public standards, private standards, and technical regulations. The three "lenses" used in the study were the following:

FIGURE 2.4

Relationship between 2008 GDP per capita and QI/POP index, selected countries



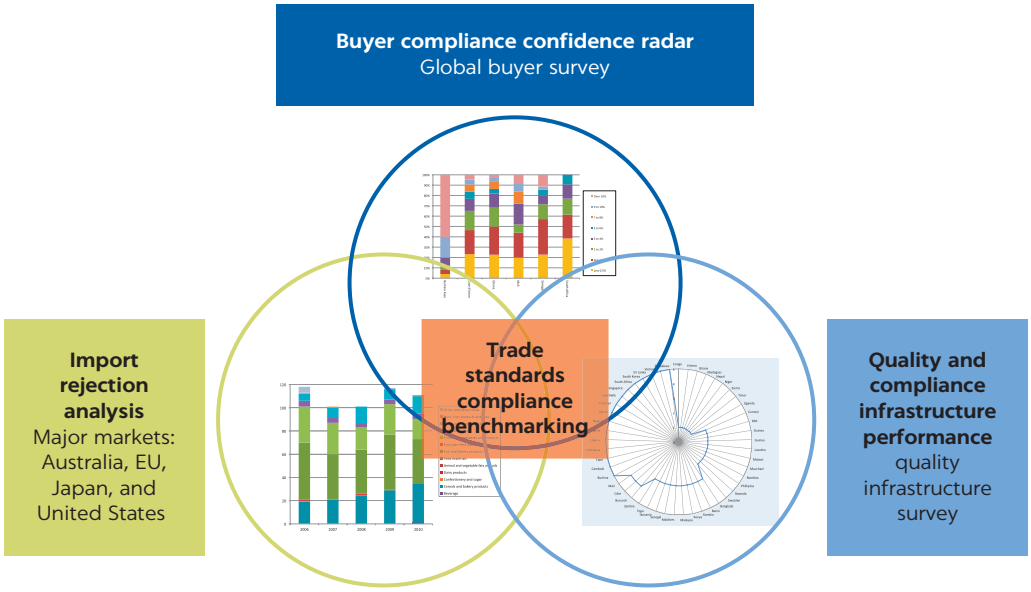
Source: Harmes-Liedtke and Di Matteo 2011.
Note: QI = quality infrastructure. The QI/Population (QI/POP) index is calculated from publicly available data on accreditation, metrology, standardization, and certification for 55 countries. Horizontal and vertical lines designate the median Global Competitiveness and QI/POP values, respectively.

- *Import rejection analysis.* Rejection data of imports of agrifood products into Australia, the EU, Japan, and the United States were used to indicate the scale and root causes of compliance challenges that low- and middle-income countries face when exporting to these major markets. The economic impact of these rejections was estimated.
- *Buyer compliance confidence radar.* Data from a corporate buyers' compliance confidence survey among companies in the export markets provided indicative information on the compliance performance of low- and middle-income countries for particular products. Their perceptions of the compliance capacity of certain countries and the producers in those countries matter for their decisions about where to source from. The study was able to conduct pilot studies in only a few selected countries.
- *Quality and compliance infrastructure performance.* Data from a QI survey provided the perspective of the exporting countries' (mainly public but also private) QI institutions. The QI of 49 African and Asian countries were reviewed, and the status of QI capacity across 10 compliance functions for the countries relative to each other was determined rather than a fixed benchmark.

Together, these three sets of data provide a picture of the importance of the QI in the low- and middle-income countries surveyed for their export performance (figure 2.5).

FIGURE 2.5

Three lenses on the importance of QI in trade standards compliance and challenges



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Note: EU = European Union.

The rejection data from the four major import markets surveyed showed that all had higher import rejection rates from the same exporting countries. These findings largely correlated with low capacities of QI services as measured in these exporting countries. Among the most important factors for the buyers were those related to supply chain performance, particularly issues related to the safety, quality, traceability, and consistency of supply. The strength of the food safety compliance infrastructure was ranked highly among the factors that determined not only the buyers' choice of country, but also how suppliers succeeded in retaining their position within the buyers' supply chains.

Therefore, the conclusion of the UNIDO (2015) study is that poor standards will lead to fewer buyers choosing to source from a particular country and an increased likelihood that the buying relationship will be terminated in a given period. This performance is determined by both enterprise-level competences and the broader public and private compliance infrastructure. This study, even though it focuses on the agrifood business, considers an effective and efficient QI to be a necessity in general for low- and middle-income countries wishing to access global markets and, once accessed, to retain and enhance their market shares in this sector.

2.2 DEMAND ASSESSMENT

Gaining a clear understanding of demand and supply for QI services in the country or region is important because it provides the data to base decisions on—for example, whether QI development programs are needed and what their scope should be. On the demand side, it is important to identify priority needs of both public and private sector clients. In practice, it is advisable to also look at

information that has already been collected, either by other development partners; government agencies responsible for "managing" service providers (such as standards, metrology, and accreditation); or nongovernmental organizations (NGOs) (such as laboratory or metrology associations).

It must be noted that just as QI is not an end in itself, the QI demand assessment should always be aligned with the broader development partner intervention in a country. Hence, it either follows after interventions to strengthen the economy have been identified, or the QI demands are identified simultaneously with higher-level evaluations. The latter is the more efficient methodology. It is also possible that the intervention is solely focused on the QI capacity development. But such a decision will in any case have been made within the context of a broader evaluation of the country's situation.

There are many facets in establishing the demand for QI services. They are interrelated, and it is important to gain a holistic picture at the beginning of any project and make some preliminary decisions before embarking on a more detailed demand assessment, which could be resource-intensive. In general, a demand assessment should consider an appropriate combination of the following types of demand in both the regulated and nonregulated areas:

- *Industrial development for the local and export markets*, which mostly relate to conformity assessment (that is, what is required to satisfy the clients and regulatory authorities on both sides)
- *Potential for future exports,* similar to the preceding point
- *Increases in productivity, efficient use of resources, and promotion of innovation* in national industry and manufacturers
- *Safety and health* of people and the environment in the country regarding QI services, including alignment of technical regulation and food safety regimes with those of major trading partners, thereby enhancing industries' competitiveness in exporting their products to markets of interest
- *Trade equity* in the country (for example, legal metrology protecting both the consumer and the supplier through accurate measurements in trade).

Assessing the demand for QI services would not be complete if the fundamentals of the QI are not considered. This means that over and above the demand emanating from the users for QI services, an assessment of the status quo of the QI fundamentals—namely, standards, metrology, and accreditation (that is, what do we have on the ground in terms of capacity and compliance with good practices?)—has to be conducted to determine whether there is a need to enhance these as well.

2.2.1 Identifying priority sectors important for the country's growth

Many low- and middle-income countries have promulgated industrial development strategies, export policies, rural development policies, and the like. These will inevitably indicate sectors where capacity development is required for the country to grow. In such countries, these sectors frequently include major infrastructure, such as transportation systems, supply of water and electricity, and the like. Such infrastructure development is always in need of QI services over and above all the other issues that need to be addressed. Mapping these will quickly indicate the specific demands regarding QI services.

Making choices regarding the QI services that need to be established or developed is not a simple exercise. Many factors have to be considered, not least the stated demands of the government of the low- or middle-income country. It is also quite obvious that a single project cannot address all the demands identified; some strategic choices will have to be made in allocating the limited resources of the development partner for the maximum impact. In this respect, alignment with the QI capacity building programs of other development partners is important because it will prevent duplication of effort and will benefit the recipient country more.

It is also clear that the development of priority sectors does not depend on the establishment of an effective QI alone; it is but one of many elements that have to be in place for the sector to succeed. In this respect, different development partners have different approaches to determine the level of their involvement in a country. These could relate to the development of a specific industrial sector, development of products for export, implementation of a proper technical regulation regime, and many more. Once these have been identified, the concomitant QI service demands can be ascertained and the appropriate development projects planned. It should be understood that establishing only the QI without considering the greater development environment may lead to redundant QI services being established that may sooner or later flounder.

Industrial development of target sectors

Industries in most low- and middle-income countries are in need of enhancing the quality of their products and services as well as increasing their productivity to be competitive in the marketplace in relation to competing with imported products in the local market or to gain a foothold in export markets. The SME sector is usually worthy of special attention in this regard. The country may have already decided to focus on specific sectors such as the leather trade, food, textiles, and any others where the country may have an identified competitive advantage in world markets.

On the other hand, development partners may wish to identify opportunities for intervention to achieve development of the private sector and to categorize the constraints to achieving that growth, including the QI services required themselves. The World Bank, for example, has developed a Country Private Sector Diagnostic (CPSD) tool that is a useful mechanism to identify sectors for development (World Bank 2017).

Development of current and potential future exports

Low- and middle-income countries may be exporting products to markets that do not place high demands on safety, health, and quality. The negative of this situation is that the price that can be realized is usually on the low side. Enhancing the quality of the products, and especially being able to demonstrate such compliance, may open the door to more discerning markets where higher prices can be realized. Internationally recognized QI services will play a major role in this regard. The identification of priority export markets and the concomitant industrial sectors to be developed can be conducted in many ways, two of which are discussed briefly.

Country Private Sector Diagnostic (CPSD). Domestic suppliers in low- and middle-income countries often find it difficult to access foreign markets on their own. Integrating a country's domestic suppliers into GVCs increases the possibility for local companies to export to a buyer abroad or to supply a multinational

company in the country. The World Bank Group's CPSD methodology, for example, focuses on strategies to help low- and middle-income economies maximize their gains from participation in GVCs (Taglioni and Winkler 2016).

To develop an effective and sustainable strategy of GVC participation, governments must identify key binding constraints and design the necessary policy and regulatory interventions as well as the infrastructure and capacity building that will allow them to achieve distinct objectives and address specific challenges. All in all, GVCs offer a role to play for economies at different levels of development at any point. Economies that have in place a supporting environment and well-functioning institutions (for example, the QI) can, in addition, move along the value chain, strengthen participation, and achieve higher added value in a sustainable way.

Export Potential Assessment. The International Trade Centre has developed an online Export Potential Assessment tool (Decreux and Spies 2016) that is supported by a massive amount of trade flow information in its database with which countries can assess their Export Potential Indicator (EPI) or their Product Diversification Indicator (PDI), the difference being as follows:

- *The EPI serves countries that aim to support established export sectors* in increasing their exports to new or existing target markets. It identifies products in which the exporting country has already proven to be internationally competitive and that have good prospects of export success in specific target markets.
- *The PDI serves countries that aim to diversify and develop new export sectors* that face promising demand conditions in new or existing target markets. It identifies products that the exporting country does not yet export competitively but that seem feasible based on the country's current export basket and the export baskets of similar countries.

Implementation of a technical regulation regime

The technical regulation regime of a country has a marked effect on trade regarding not only imported products, but also exported products. If the technical regulation regime is aligned with that of main trading partners, for example, local companies will find it easier to comply with the technical regulation regimes in the export markets; that is, products destined for the local markets may be able to be exported to foreign markets without any change to the product.

Large differences in the technical regulation regimes may result in local products not being allowed in foreign markets without changes to those products. This is expensive and renders the local industry less competitive. The technical regulation regime is dealt with in detail in module 7.

Application of legal metrology

Consumer protection regarding trade equity (that quantities paid for are actually received) is a major issue for many low- and middle-income countries. The establishment of a QI frequently starts with trade metrology measures as the state endeavors to protect consumers in this regard.

Trade metrology and the wider application of legal metrology requires appropriate fundamental QI services. Establishing proper trade metrology services where these are lacking often means focusing on "low-hanging fruit" that can make a major difference to consumer protection in a low- or middle-income country. Legal metrology and its subset of trade metrology are dealt with in detail in module 4: Metrology, section 4.3.

2.2.2 Necessity for generic capacity building

An issue that needs to be carefully considered is the level of the generic capacity building that would be required before a much more demand-driven approach is followed. In this respect, it is useful to consider the maturity level of the various QI services such as standards, metrology, accreditation, and conformity assessment. The three fundamentals—standards, metrology, and accreditation—need to start with generic capacity. For conformity assessment, a more focused capacity-building trajectory may be appropriate, depending on the need. This will be different from country to country and by specific service, but some general statements can be made (table 2.1).

Once the QI services have developed past the basic QI maturity level, then capacity building should be focusing more on the demands of the country; it is not useful to establish high-level QI services if there is no demonstrable demand for such services. The same applies if regional services are available and appropriate. Such services will only sap resources and slowly deteriorate to the point where they are no longer operational. The identification of the real demands of the country is therefore important; capacity development should not be based on the "nice to have" syndrome of the QI entities.

Considering the product or service value chains (see section 2.2.5) in sectors identified in official industrial development or export policies is a good start. If these are not available or are out of date, evaluations such as those discussed in section 2.2.1 on priority sectors for the economy and export markets would be indicated.

2.2.3 The food safety regime

For many low- and middle-income countries, food production and processing is a major industry. Food production and processing is controlled through mandatory food standards in most countries because of the immediate influence of food on health and safety. The food safety regime entails sanitary and phytosanitary measures, technical regulations, and voluntary certification. In many low- and middle-income countries, it is fragmented, uncoordinated, ineffective, and inefficient because of developments over the years as various ministries and their agencies have gotten involved.

The overlaps, gaps, and turf wars between various agencies are experienced starkly by the industry in that they rapidly escalate transaction costs, but these are seldom considered by the ministries involved, which have myopic vision in this regard. Reengineering the whole system is a worthwhile endeavor, because it not only provides the country with a more effective and efficient food safety regime while enhancing the competitiveness of the food industry, but also can become a major factor in supporting exports. The QI has a major role to play in such a reengineering. A schematic representation of a model food safety system for a low- to middle-income country is shown in figure 2.6.

From the schematic diagram of figure 2.6, the various elements of the food safety system and the role that QI services play in it can be deduced. The national standards body (NSB) provides the national standards on which the central food authority bases its food regulations. Various laboratories and inspectorates at the local level ensure that requirements are met in the marketplace. The national central laboratory is the final arbiter in cases of dispute. All of these are accredited, and their measuring equipment is traceably calibrated to the national standards held by the national metrology institute (NMI).

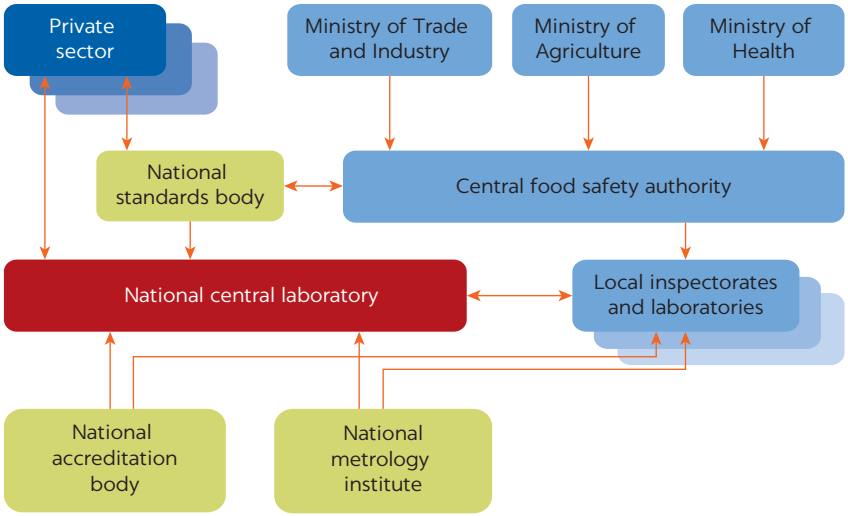
TABLE 2.1 Maturity levels of QI services

QI SERVICE TYPE	RUDIMENTARY QI (LITTLE QI IN PLACE)	BASIC QI (LOW- TO MIDDLE-INCOME COUNTRY OR LDC APPROACH)	ADVANCED QI (ECONOMYWIDE APPROACH, SECTORAL SPECIALIZATION)	MATURE QI (INNOVATIVE, CUTTING-EDGE TECHNOLOGY AND SERVICE DELIVERY)
Legal metrology	Weights and measures may be legally established, but the effect in the market is negligible.	Weights and measures for goods traded over the counter (such as mass and volume of consumer goods) with recognized services	As under basic QI but extended to prepackaged goods, water and electricity meters, selected law enforcement scopes	Measures covering the whole spectrum of trade, law enforcement, health, and safety
Scientific metrology or national measurement standards	The working standards of the legal metrology department are the de facto national measurement standards.	Small number of basic metrology laboratories (including the metrological level), with recognized services	Laboratories (including the CMCs) defined through economywide surveys and sectoral international benchmarks	High-level laboratories for innovative sectors
Standards	A government department is the de facto national standards body without any infrastructure to develop and publish national standards. It may have a rudimentary information service.	Basic infrastructure to adopt and publish international standards; rudimentary information service Correspondent member of ISO and involved in IEC Affiliate Country Programme	More-advanced infrastructure to develop and publish national standards; information service well developed Member of ISO, associate member of IEC; country a member of CAC	Mature processes to develop and publish any standard required by industry and the authorities; advanced information center Member of ISO and IEC; country a member of CAC and ITU
Accreditation	Accreditation not considered a necessity, hence no services obtained from outside the country, either	Accreditation provided by accreditation bodies from outside the country through a bilateral or regional arrangement	Accreditation body established and only recently internationally recognized; accreditation services still limited to main sectors	Accreditation body fully recognized by ILAC and IAF providing the full range of accreditation services
Inspection bodies	A few public sector inspection bodies	A few public sector inspection bodies, with recognized services	Mostly regulatory inspection but with private sector inspection services starting to take on regulatory work and work for major purchasers	Supply of inspection services fully determined by free-market principles
Testing laboratories	Maybe one or two public sector laboratories, understaffed and not accredited	A few public sector testing laboratories, with recognized services	Many public sector testing laboratories in various ministries and agencies; private sector laboratories starting to be established	Multiple private sector testing laboratories catering to the market; public sector testing laboratory importance diminished appreciably
Certification	No certification body in operation	NSB provides product and system certification, with recognized services	NSB provides product and system certification, in competition with a small number of private sector certification bodies	Supply of certification services fully determined by free-market principles, with multinational certification bodies much in evidence

Note: CAC = Codex Alimentarius Commission; CMCs = calibration and measurement capabilities; IAF = International Accreditation Forum; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; ITU = International Telecommunication Union; LDC = least developed country; NSB = national standards body; QI = quality infrastructure.

Once the system has been agreed to and the various agencies are established, the QI has to be aligned to provide the defined services. Developing an implementation plan based on an approved policy framework—for example, a national quality policy, a food safety policy, or a similar policy—to make the system work as a whole will be a huge and complex undertaking, and it will take a few years to complete. But in many low- and middle-income countries, it will make a big

FIGURE 2.6
Model food safety system for a low- to middle-income country



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difference in the level of food safety and will appreciably lower the transactional costs for the food industry, which is more often than not suffering from overlaps in regulations imposed by more than one regulatory authority.

2.2.4 Rapid demand assessment

Once the sectors that would need QI support have been identified (see section 2.2.1), the demand for QI services should be determined at a cursory level rather than a more detailed level, as would be the case in a comprehensive demand assessment. It would still be good practice to do this in terms of the elements of the QI as described in module 9 (the Rapid Diagnostic Tool and Comprehensive Diagnostic Tool) to facilitate the development of a concept note (see module 1: Executive Summary, section 1.2, the "Quick Start Guide").

Standards

Questions that need to be asked and answered regarding the need of standards include the following:

- Are the product requirements based on international or regional standards, or are they based on the national standards of the target markets?
- Are the product standards industry or private standards rather than public standards?
- Can the standards be used as is, or do they have to be adopted as national standards first? And if so, *can* they be adopted?
- Are the standards obtainable and reasonably priced, or are they expensive? If available, are they understood, and can they be implemented?

Although some of the questions are self-evident, one should keep the users in mind. It is especially the SME sector that is often challenged by the cost of international standards, in which case it would be useful to adopt these as national

standards and make them more readily available at lesser cost. Hence, does the NSB have the wherewithal to develop and publish these standards fairly rapidly? Private standards are often available free of charge because the organizations publishing them derive their income from the concomitant certification business. (For more about these private standards, see module 3: Standards, section 3.3.)

Metrology

Metrology is important in production control and in the testing of the products. The related measuring equipment needs to be calibrated. The question that should be asked and answered is whether the calibration capacities for these specific instruments and their accuracy classes are available in the country. Furthermore, can the NMI traceably calibrate the working standards of calibration laboratories to international measurement standards, or do these working standards have to be sent outside the country to be calibrated? This would entail delays and higher costs.

It may be appropriate for the NMI to establish the necessary capacity if it is not yet available or if it is necessary to increase its measurement accuracy capabilities, depending on a positive outcome of a cost-benefit study. But this will take resources and time because the national measurement standards have to be established and then calibrated by a higher-level NMI, and the NMI has to participate in interlaboratory comparisons to establish the relevant calibration and measurement capabilities (CMCs). In some cases, new laboratories may have to be designed and built, which takes even longer and requires additional resources. Metrologists have to be found and trained. Metrology, frequently under the radar of the responsible planners, must be carefully considered because it is costly and time consuming, yet it is an absolutely vital basis for production and many of the other QI services.

Accreditation

Conformity assessment and calibration services need to be technically competent and performed with impartiality—and demonstrably so, to engender trust in suppliers, purchasers, and regulatory authorities. This trust is achieved through accreditation by the relevant ISO or IEC international standards. The conformity assessment and calibration services identified through the demand analysis therefore need to be accredited. The questions that need to be asked and answered to determine gaps, if any, include the following:

- Has a national accreditation body (NAB) been established in the country, or is this still to be done?
- Is a regional accreditation body in place whose services could be used?
- Is the NAB or regional accreditation body a signatory of the ILAC and IAF multilateral recognition arrangements, is it still in the process of achieving this recognition, or has it not even started the process yet?
- Does the services scope of the NAB or the regional accreditation body include the conformity assessment services that need to be accredited?
- Has this NAB been recognized or officially appointed by the state where it is established?

Establishing an accreditation body and getting international recognition is a long process; anecdotal evidence indicates a period of five to seven years. If the country has not yet established an NAB, accreditation services may have to be

obtained from an NAB of another country or from a regional accreditation body if one is available. If the NAB is in the process of obtaining international recognition, does it have a "twinning agreement" with an NAB that is recognized? In that case, accreditation certificates may be issued jointly. Extending the scope of accreditation services of the NAB could also take some time, as assessors have to be trained, documentation has to be developed, and the approval of ILAC or the IAF needs to be sought.

Conformity assessment services

Conformity assessment services could entail a mix of inspection, testing, and certification, depending on the product or service requirements. Whereas the NSB, NMI, and NAB often have monopolies in the country for their core service delivery, conformity assessment services could be provided by any number of public or private sector operators. The challenge for most countries is that the extent of the conformity assessment services available, especially testing services, is unknown.

Before contemplating dealing with any perceived gaps, it is important to obtain quantitative information on the totality of laboratory services in the country—the capabilities, capacities, and technical competencies. A review to determine the overall picture would be indicated, and this should not take too long in a low- to middle-income country. Then meaningful decisions can be made as to the gaps and how they could be closed.

The spectrum of certification bodies (product as well as system) is much smaller and usually fairly well known. But the scope of services of the certification bodies and their technical competencies may need to be more closely looked at. It is the accreditation of local offices of multinational certification bodies that is frequently lacking, as these offices "ride" on the accreditation of their head office.

A major decision regarding the development of new capacity is whether the conformity assessment body should be a public or private sector body. This will depend as much on country customs and practices as on the advantages and disadvantages of public versus private sector business practices and funding sustainability. To gain accreditation for a newly established conformity assessment service provider also takes time; to do it in less than nine months is challenging.

2.2.5 Comprehensive demand assessment

There are many techniques to determine the QI demands of a country. Whereas market surveys are useful, they frequently result in a massive list of QI services that need to be established, which technical support programs just cannot support. Therefore, once the demand for generic QI services has been identified and the NSB, NMI, and NAB have been established and are operating in the basic QI mode (see section 2.2.2), it makes sense to look at QI services in a more detailed manner to move the QI services from the basic to the advanced and ultimately to the mature level. Table 2.1 lists general attributes of the advanced and mature levels, but much more detailed information would be required to identify the relevant higher-level attributes for a specific country situation.

The identification of priority sectors and possible export possibilities (see section 2.2.1) provides the entry point for a more focused needs analysis. Value chain analysis has proved to be a useful instrument to do so. Another useful

approach is to look at the infrastructure clusters that a major new industry could require to be established and become operational.

Value chain analysis

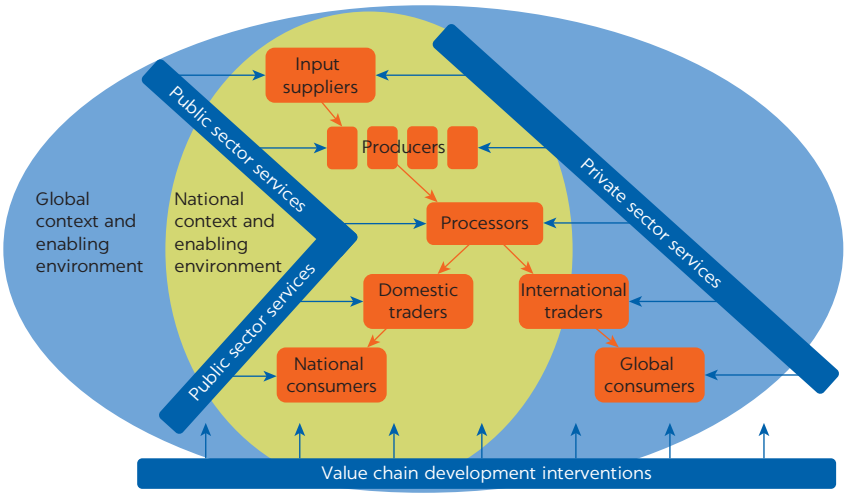
The range of activities that brings a product or a service from its conception to its end use in a particular industry is referred to as the value chain, a term originally coined by economist Michael Porter (Porter 1985). Value chains can be seen as mechanisms that allow producers, processors, and traders—separated by time and space—to gradually add value to products and services as they pass from one link in the chain to the next until reaching the final consumer (domestic or global).

In the globalized market, it is rather unusual for a single company to perform all the activities—from product design and production of components to final assembly and delivery to the ultimate user. Original equipment manufacturers source components from myriad subsuppliers, frequently across many countries. Agents handle the marketing and sales, and specialized freight haulers ensure the product is moved from the factory to the consumer. The manufacturers and suppliers draw from a range of technical, business, and financial service providers as well as public sector services. They depend on the national and global legislative context and sociopolitical environment. In a value chain, the various business activities in the different segments become connected and to some degree coordinated. The value chain analysis covers the whole system in which the organization operates (figure 2.7).

In each of the stages of the value chain, the required QI services can be mapped, and technical assistance can be designed to provide such services effectively and efficiently; otherwise, the suppliers of products and services will not measure up to the minimum requirements in the world markets—that is, they will remain in a suboptimal business environment. Worse, if a country's QI does not meet international requirements, its producers may be hard pressed to join international supply chains. For example, entire ranges of products such as food of animal origin cannot be exported, at least not to high-income markets.

FIGURE 2.7

Generic value chain



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By the same token, if the QI has to be reformed economywide, governments may be guided in the reform process by applying a value chain approach to competitive industries, thereby ensuring more focused action on the QI reform. A useful methodology to map the QI services required in a value chain is the CALIDENA instrument used by the National Metrology Institute of Germany (PTB, for Physikalisch-Technische Bundesanstalt) (Harmes-Liedtke and Schiel 2016).

CALIDENA is a process guided by a participatory methodology developed and implemented by the PTB since 2009. The CALIDENA objectives are twofold: (a) to help identify the quality gap in a value chain as well as to develop an action plan to close the gap, and (b) to help the QI to understand better the needs of value chains and to develop and improve the provision of QI services. CALIDENA can be used for the demand assessment for the preparation of a project or as an integral part of a project.

The CALIDENA process is organized in three phases (Harmes-Liedtke and Schiel 2016):

- *Phase 1: Preparation.* The relevant value chain is selected, the expectations are clarified, and the hosts of the process are defined.
- *Phase 2: Kick-off workshop.* At the main CALIDENA 2.5-day workshop, the relevant actors of the value chain and the QI institutions jointly analyze the quality gaps and challenges of the value chain and develop the action plan.
- *Phase 3: Follow-up.* A follow-up committee monitors the implementation of the action plan.

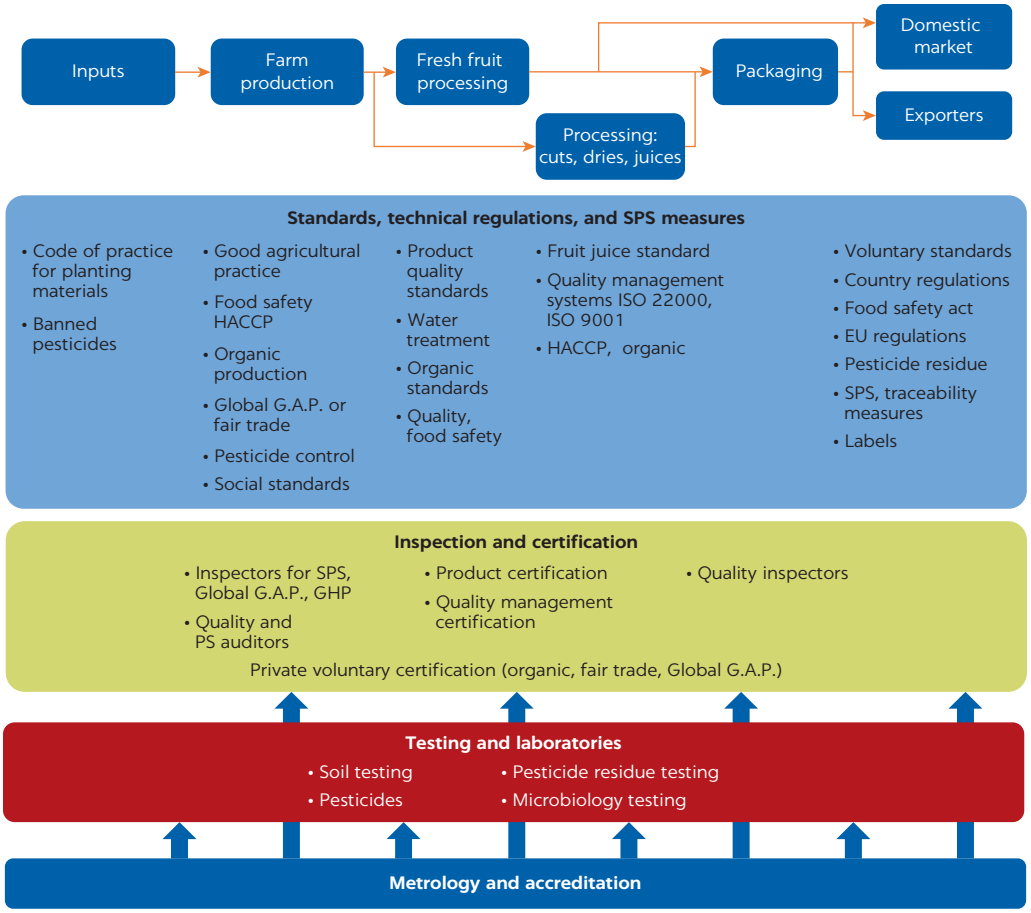
A typical example of a value chain analysis and mapping the required QI services is shown in figure 2.8 for mango farming, illustrating an analysis of how producers and marketers in a low- to middle-income country gain access to the EU market. The result of the value chain mapping indicates all the relevant standards and technical regulations as well as the inspection, testing, and certification requirements that have to be in place before mangoes can be exported to the more lucrative markets of the EU in this case. These have to be supported by appropriate metrology and accreditation services.

The example shows that the technical assistance program to establish the QI services for a simple product like mangoes is complex and will take time but will support the industry and the country in no small measure. This is a much better approach than a more general one that establishes a number of laboratories and gets them accredited, but the laboratories are unrelated to the market needs of the country.

Clusters in support of a new industry

When a new industry is being established, a large number of industry clusters may require capacity development to provide products and services during the construction phase and later during the operational phase of such an industry. A typical example of such an undertaking is the development of the liquified natural gas (LNG) industry in Tanzania after economically relevant gas fields were discovered off its coast. Whereas the LNG production plants would be constructed by the relevant international consortia, a vast array of products and services could be provided by local businesses and industry, provided they meet the standards and quality required by these international consortia (World Bank, EU, and DFID 2014).

FIGURE 2.8
Mango value chain



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Note: EU = European Union; Global G.A.P. = Global [standard of] Good Agricultural Practice; GHP = good handling practices; HACCP = hazard analysis and critical control points; ISO = International Organization for Standardization; PS = product safety; SPS = sanitary and phytosanitary.

In such cases, a comprehensive analysis of industrial clusters that could potentially get involved in the construction and operation of the new industrial plant is indicated. Once all the clusters have been identified, a short list of the more promising clusters can be selected in terms of their "desirability" in similar fashion as in the CPSD (see section 2.2.1). Thereafter, a value chain analysis can be performed to determine the QI service needs of the clusters.

Projection for future QI needs

Establishing QI services and gaining international recognition is a time-consuming endeavor in most cases. A newly established NAB will need about seven years to gain signatory status in the ILAC or IAF multilateral recognition arrangements. Establishing high-level scientific metrology services frequently requires new laboratories; metrologists have to be trained and gain experience in higher-level NMIs; and equipment has to be sourced, built, and put into operation. Thereafter, the NMI needs to participate in interlaboratory comparisons to determine the CMCs of the NMI. This may be a journey of 10 years or more. The NSB may have been established decades previously and have a working

standards development process, but comparing it with modern good standardization practices (GSP) may indicate some serious shortcomings. To reengineer a process that has been entrenched through custom and practice over many years is not an easy task and takes time.

It is therefore clear that establishing a modern QI system is time-intensive. This process is also indicated in part 2: The Quality Infrastructure (figure P2.1), where the interdependence of the QI services is detailed. Hence, it is extremely important that the country has a clear idea as to where it wishes to journey regarding its QI. A long-term strategy, usually laid down in the national quality policy, is important, as is the concomitant implementation plan. Without these, the country will not be able to develop an effective and efficient QI appropriate for its demands.

Countries with a weak QI face the challenge of establishing their QI and QI services from a low base. Countries in transition (for example, countries of the former Soviet Union) face a different challenge. They may have a well-established QI, but it may not comply with market-related international good practices. Hence QI development in such countries also includes the difficult journey of "unlearning" much of what the QI used to be. These could be systems that have been in place for decades—for example, all standards are mandatory, the implementation of which is supported by a large inspection force that now has to be abandoned. Over and above the massive organizational reengineering challenges, ensuring that a vacuum is not created by default in the marketplace regarding the regulatory domain needs to be considered. Otherwise, the safety and health of the population and the fauna and flora may be compromised during the reengineering process. Transitional arrangements are therefore important elements of project planning in such countries.

NOTES

1. The "organizations" of the QI ecosystem provide such things as national standards, calibration, test reports, certification reports, and accreditation certificates. The term "QI services" is used as a collective term to denote these outputs of QI organizations.
2. Data and findings from "Global Trade: Standards Are the 'Lingua Franca' of World Trade," website of the German Institute for Standardization (DIN), https://www.din.de/en/about-standards/benefits-for-the-private-sector/global-trade.

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2 The Quality Infrastructure

The definition of the quality infrastructure (QI) used in this publication is the following:

> 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 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, accreditation, and conformity assessment.

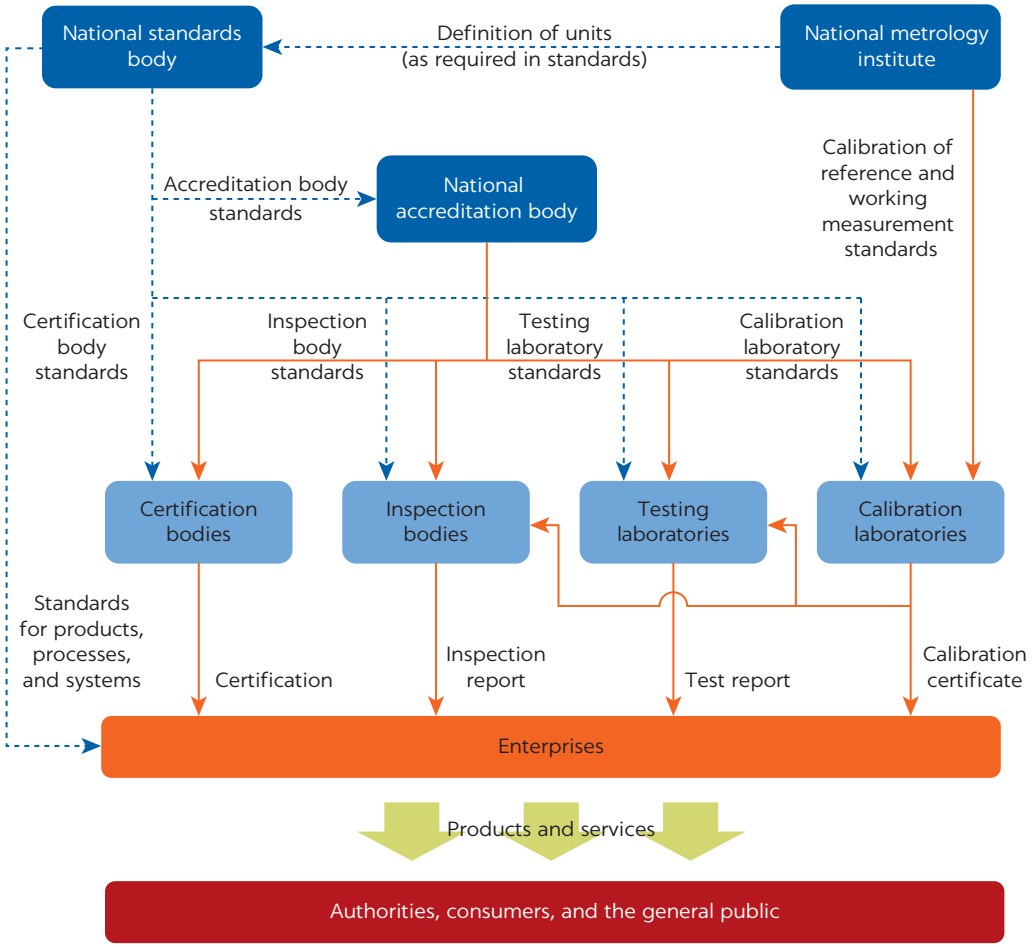
From this definition, the QI can be considered to consist of three core elements, without which its other parts cannot operate optimally. These are standards, metrology, and accreditation. The services based on these three core elements include calibration (part of the metrology system) and inspection, testing, and certification (collectively referred to as conformity assessment). The relationships among the QI elements at the national level are illustrated in figure below.

All of these could be voluntary in nature—that is, compliance is a choice of the supplier or the purchaser; noncompliance is not a legal offense. However, governments do require mandatory compliance in specific instances, known as technical regulations, in which case noncompliance then becomes a legal offense. The development and implementation of technical regulations utilize all the core elements and services of the QI, and QI implementation is further enhanced by market surveillance.

The QI may also be considered at the regional and international levels, where a vast number of intergovernmental and nongovernmental institutions have been established over the years. Over and above the regional and international institutions dealing with the core elements of the QI, there are numerous multinational companies providing a wide range of conformity assessment services in many countries.

FIGURE P2.1

The national quality infrastructure



Source: Adapted from Guasch et al. 2007.
Note: Dashed lines designate "standards and definitions"; solid lines designate "conformity assessment processes."

Conformity assessment is defined as the demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled (ISO and IEC 2004b). Generally speaking, as noted earlier, the elements of conformity assessment include inspection, testing, and certification. Calibration is considered part of metrology and not as conformity assessment.

Module 3 covers one of the core QI elements—standards—specified in the definition above. The other core elements—metrology and accreditation—are covered in modules 4 and 5, respectively. Module 6 then discusses conformity assessment, which collectively refers to a number of services based on these core functions. Module 7 covers technical regulations, and module 8, how the QI infrastructure functions as a flexible public-private partnership system.

3

Standards

3.1 DEFINITIONS AND TYPES OF STANDARDS

3.1.1 Definitions

Standardization is defined as the *activity* of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context (ISO and IEC 2004a). The activity consists in particular of the processes needed to formulate, issue, and implement standards to improve the suitability of products, processes, and services for their intended purposes: prevention of barriers to trade and facilitation of technological cooperation.

A *standard* is defined by the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) as a *document*, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results aimed at the achievement of the optimum degree of order in a given context (ISO and IEC 2004a). Standards should be based on the consolidated results of science, technology, and experience and aimed at the promotion of optimum community benefits.

On the other hand, the definition of a standard in the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) makes it clear that the implementation of a standard is voluntary, not mandatory (WTO 1994).[1] Mandatory implementation is the sole realm of technical regulation. The mandatory or compulsory standards of some countries are therefore technical regulations. Another difference between these two definitions of a standard is that the WTO TBT Agreement definition relates to products only, because the TBT Agreement is limited to products and their processes. The ISO and IEC definition is much wider in its application and would include systems and services as well within its general terminology of "activities or their results" (ISO and IEC 2004a).

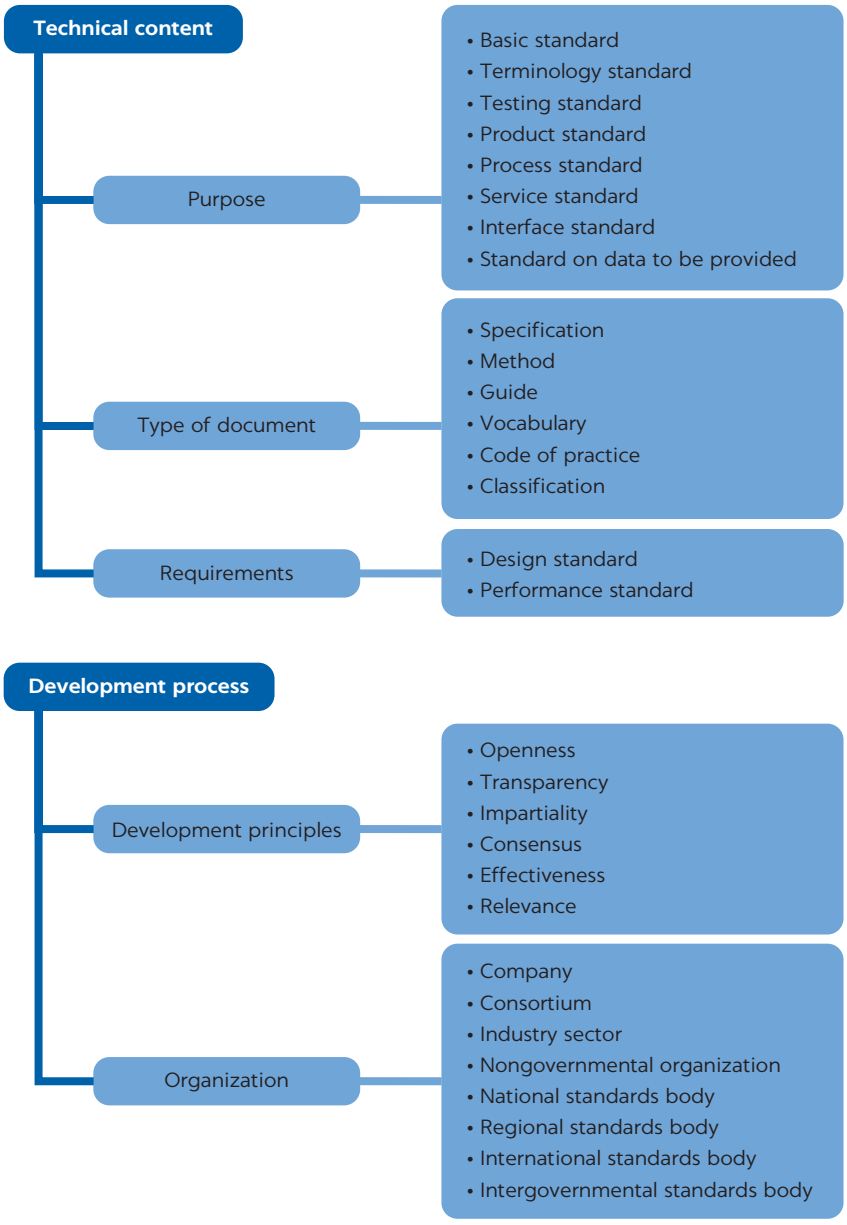
The term "normative document" is sometimes used in the context of standardization; it is seen as a generic term for standards, specifications, codes of practice, and so on. In this publication, the term "standards" is used throughout with the understanding that it also includes specifications, codes of practice, and other normative documents.

3.1.2 Public and private standards

Standards can be classified in terms of their content, the mechanism used for their development, and the organization developing the standard. The classification is shown graphically in figure 3.1, showing the wide range of standards that are possible.

Within this classification, two broad categories of standards are generally recognized, namely, public and private standards. Public standards are developed under the auspices of international, regional, and national standards bodies in accordance with principles aligned with WTO TBT Agreement requirements. Private standards are developed by consortiums, certification bodies, nongovernmental organizations (NGOs), and others for their own purposes and often without transparency, openness, or consensus considerations.

FIGURE 3.1
Classification of standards



Private standards are important in many markets, but generally cannot be used in technical regulation, because they do not necessarily adhere to the same principles as a formal standardizing organization (the WTO TBT Agreement principles of transparency, openness, and impartiality and consensus), nor are the disciplines of the WTO TBT Agreement's annex 3 (the "Code of Good Practice for the Preparation, Adoption and Application of Standards") necessarily used.[2]

3.2 INTERNATIONAL, REGIONAL, AND NATIONAL PUBLIC STANDARDS

3.2.1 International standards

International standards are important in the global economy. The WTO TBT Agreement confers a high level of relevance on international standards; for example, national standards should be the adoptions of international standards, and national technical regulations should be based on international standards (see module 7: Technical Regulation, section 7.4). They are developed and published with full cognizance of the principles detailed by the WTO TBT Agreement Committee: transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, consideration of the development dimension, stakeholder engagement, due process, and national adoption or implementation of international and regional standards (see section 3.4, "Good Standardization Practice").

International standards are published by many intergovernmental or nongovernmental international organizations. Most of them are sector-specific, but a small number are considered broad-based. Although not specifically mentioned in the WTO TBT Agreement, three organizations—the ISO, IEC, and International Telecommunication Union (ITU)—are considered the pinnacle international standards bodies or the most relevant for the WTO TBT Agreement. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) names three organizations—the International Plant Protection Convention (IPPC), World Organisation for Animal Health (OIE), and Codex Alimentarius Commission (CAC)—as being the most relevant for that agreement.[3] Brief descriptions of these six international standards organizations are as follows:

- *International Electrotechnical Commission (IEC):* Nongovernmental, established 1906, head office Geneva, membership representative of national organizations with similar scope, provides international standards for electrical and electronic goods
- *International Organization for Standardization (ISO):* nongovernmental, established 1946, head office Geneva, membership representative of national organizations with similar scope, publishes international standards for scopes not handled by others
- *International Telecommunication Union (ITU):* intergovernmental (part of the United Nations [UN] family), established 1897, head office Geneva, publishes international standards for telecommunication
- *Codex Alimentarius Commission (CAC):* intergovernmental (part of the UN family), established 1963, head office Rome, publishes international standards for food products
- *International Plant Protection Convention (IPPC):* multilateral treaty (part of the UN family), established 1951, head office Rome, publishes international standards for plant protection

- *World Organisation for Animal Health (OIE):* intergovernmental (*not* part of the UN family), established 1924 (as the Office International des Epizooties), head office Paris, publishes international standards for animal health.

Over and above these six, another organization publishing standards that are important from a trade perspective is the International Organization for Legal Metrology (OIML), an intergovernmental treaty organization established in 1955 with its head office in Paris. The OIML publishes international recommendations and standards for legal metrology.

In the ITU, CAC, IPPC, and OIE, all members have the same status. In the case of the ISO and IEC, various levels of membership are possible, with full membership being the highest level. Others, such as associate or corresponding membership, come with lesser privileges. Full membership is generally required to participate fully in technical committees.

There are differences among the organizations in the way in which the technical work on the formulation of international standards is undertaken by their technical committees. The ISO, IEC, and CAC operate a decentralized system whereby member countries are given full responsibility for specific technical committees, whereas the IPPC, ITU, and OIE work with expert-level meetings managed by the secretariats. All of them, however, meet WTO requirements for international standards.

Adopting international standards as national standards is the recommended route indicated in the WTO TBT Agreement. It also makes sense, in that the risk of national standards becoming unnecessary barriers to trade is thereby minimized. To adopt ISO and IEC standards as national standards, membership in the ISO and IEC is necessary because of the copyright status of their international standards.[4] In the case of regional standards bodies wishing to adopt ISO and IEC standards, special arrangements have to be made with the ISO and IEC. None of this is an issue for the standards published by the intergovernmental-type international standards bodies.

3.2.2 Regional standards

The European Norm (EN) standards recognized by the European Union (EU) are probably the best-known regional standards. These are developed and published also to support the implementation of EU technical regulations known as Directives. They are developed and published by three regional standards organizations (RSOs), namely, the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI). Agreements to harmonize the EN standards with international standards are in place, such as the Vienna Agreement (ISO and CEN) and the Frankfurt Agreement (IEC and CENELEC). EN standards may be well known, but they are not the only regional standards published.

A number of organizations have been established to deal with standardization issues at the regional level, but they can be quite different in their responsibilities and activities. Some of the RSOs have been established as a consequence of political decisions, especially those that are charged with coordinating and harmonizing standardization in a regional common market. There are differences among these as well. A few RSOs actually develop and publish regional standards (for example, CEN, CENELEC, and ETSI), whereas others only act as coordination mechanisms, ensuring that national standards among the common market members are harmonized (such as the Southern African Development

MAP 3.1

Coverage of regional standards bodies, 2016

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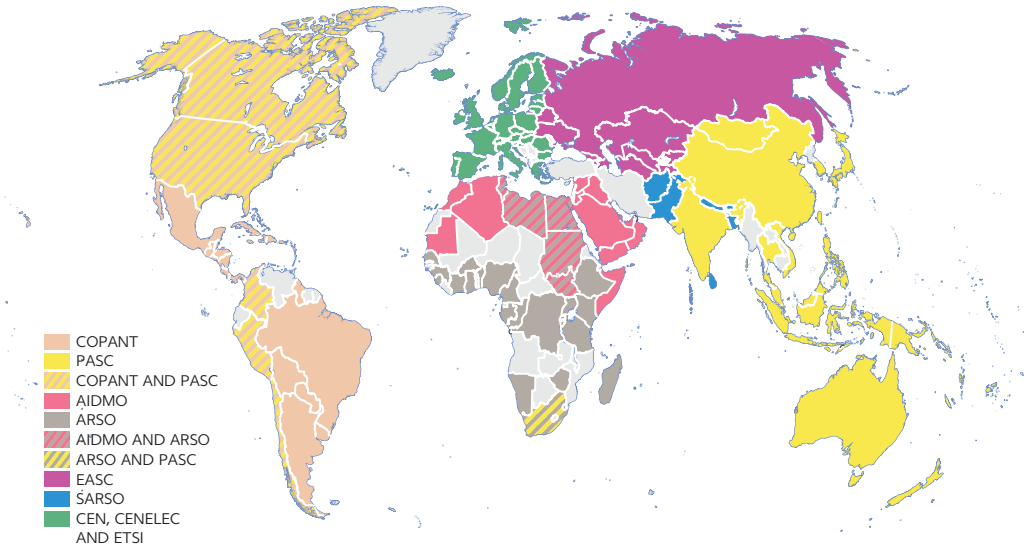


Note: AIDMO = Arab Industrial Development and Mining Organization; ARSO = African Organization for Standardization; CEN = European Committee for Standardization; CENELEC = European Committee for Electrotechnical Standardization; COPANT = Pan American Standards Commission; EASC = Euro-Asian Interstate Council for Standardization, Metrology and Certification; ETSI = European Telecommunications Standards Institute; PASC = Pacific Area Standards Congress; SARSO = South Asian Regional Standards Organization.

Community [SADC] Cooperation in Standards [SADCSTAN]). Some RSOs operate in geographical regions (as does ARSO, on the African continent), and others operate across regions (such as the Pacific Area Standards Congress [PASC]).

The RSOs generally accepted by the ISO and IEC as representative, and with which they foster cooperation, include the following (map 3.1):

- *AIDMO:* Arab Industrial Development and Mining Organization
- *ARSO:* African Organization for Standardization
- *CEN:* European Committee for Standardization
- *CENELEC:* European Committee for Electrotechnical Standardization
- *COPANT:* Pan American Standards Commission
- *EASC:* Euro-Asian Interstate Council for Standardization, Metrology and Certification
- *ETSI:* European Telecommunications Standards Institute
- *PASC:* Pacific Area Standards Congress
- *SARSO:* South Asian Regional Standards Organization

Over and above the RSOs accepted by the ISO and IEC as being representative of a region, a number of subregional standards organizations have also been established to serve the interests of smaller regional common markets, such as the East African Community (EAC), the Economic Community of West African States (ECOWAS), the Southern African Development Community (SADC), the Common Market for Eastern and Southern Africa (COMESA), and others in Africa. Subregional standards organizations include the following:

- *CROSQ:* Caribbean Community (CARICOM) Regional Organization for Standards and Quality

- *EAC Standards Committee*
- *GSO:* Gulf Cooperation Council Standardization Organization
- SADCSTAN: SADC Cooperation in Standards

It is interesting to note that some countries have dual membership, such as in COPANT and PASC or in ARSO and PASC. Whether dual membership can be sustained once regional standards are developed for adoption in member countries is unclear. Other organizations, such as the Regional Institute for Standards, Conformity Assessment, Accreditation and Metrology (RISCAM) of the Economic Cooperation Organization (ECO)—an assembly of Islamic countries in the Middle East and on the South Asian subcontinent—are still in the making at the time of this writing.

A country's national standards body (NSB) is usually required to participate in the RSO when the RSO develops standards for the common market of said region; the NSB has no choice in the matter. Other RSOs offer a choice, and membership will depend on the political and trade alliances the country finds itself in with other members of the RSO. Where RSOs publish standards as a remit of a common market agreement or protocol, the NSBs of the regional common market usually must adopt regional standards once they have been approved and withdraw their national standards of similar scope.

3.2.3 National standards

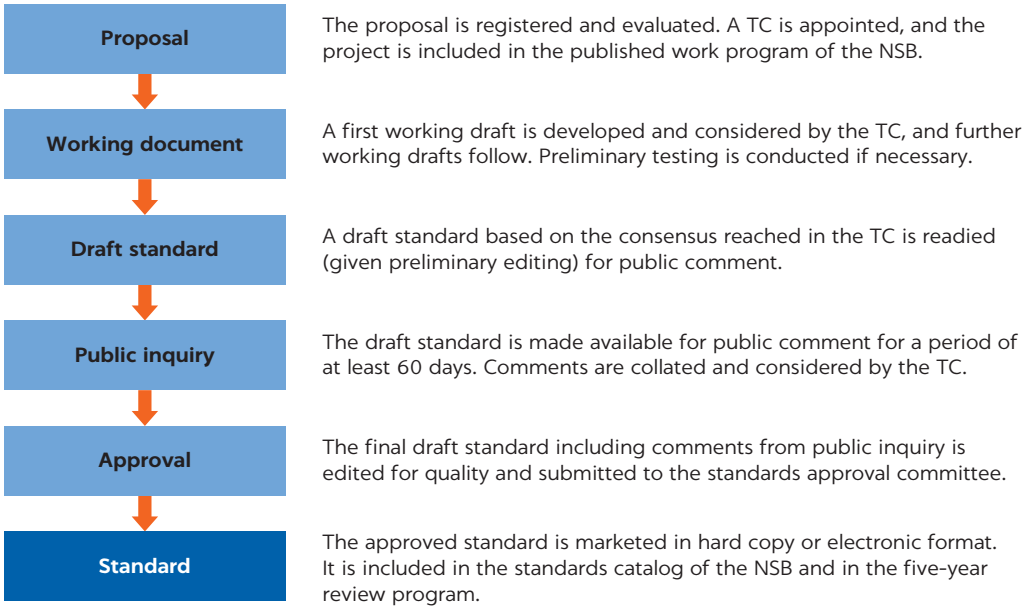
National standards are published by recognized NSBs. The legal status of a national standard is an important parameter to ensure that the standard can be easily referenced in legislation, such as in a technical regulation. In smaller economies, a single organization will act as the NSB, whereas in high-income economies, a more decentralized system for the development of standards may be in operation, with a number of standards development organizations (SDOs) recognized by the NSB in place. Whatever the system, the central government has to ensure that the organizations developing national standards comply with the WTO TBT Agreement requirements if the country is a WTO member.

The pertinent requirements for the development of national standards are contained in annex 3 to the WTO TBT Agreement, the "Code of Good Practice for the Preparation, Adoption and Application of Standards" (WTO 1994). Standards bodies have to formally indicate their acceptance of and compliance with annex 3 of the WTO TBT Agreement. Notifications under annex 3 are circulated by the WTO Secretariat in the document series designated by G/TBT/CS/N/[number]. The complete list of NSBs having accepted the conditions of annex 3 can also be found at the online WTO ISO Standards Gateway.[5] Whereas NSBs accept the conditions of annex 3 as a self-declaration of compliance, it is not a given that an NSB's processes always comply with the requirements. An independent assessment of the standards development processes for compliance with annex 3 frequently highlights challenging areas for many NSBs.

The process of developing national standards should also comply with the principles of good standardization practice (GSP), as discussed in section 3.4. The complete value chain for standards development therefore needs to be properly managed by the NSB. For each of the steps in the value chain (figure 3.2), formal processes should be in place. These should be publicly known and understood.

A developing trend is for the NSB to publish these processes in a "standard for a standard" and make it freely available to any interested party. The training of technical committee chairpersons and secretariats is then based on this standard.

FIGURE 3.2
Standards development value chain



Note: NSB = national standards body; TC = technical committee.

Internal work instructions—aligned with the "standard for a standard" and based on the principles of ISO 9001, for example—are also indicated to further engender trust in the integrity of the standards development system.[6]

Standards used to be marketed in hard copy. The trend, however, is definitely moving toward electronic systems such as online information and sales. Hence, NSBs that fail to embrace modern information technology (IT) systems for standards information and sales lose out. However, online information and sales must be structured in such a way that the copyright of standards is not violated. Read-only mechanisms for standards before they are purchased are being developed by a number of the more advanced NSBs to help clients. Hard-copy sales are still important in economies where the average small or medium enterprise (SMEs) has difficulty in accessing the Internet. In this case, print-on-demand systems are much more efficient than the printing of a large volume of standards that inevitably have to be scrapped a few years later because of revision.

The NSB should operate a standards information service. This service should provide information on the national standards and relevant international and regional standards on request. The request could be telephone- or email-based or made in person by walk-in customers. The standards information service is frequently also designated as the WTO TBT Agreement national inquiry point by the government if the country is a member of the WTO.

3.3 PRIVATE STANDARDS

A vast array of normative documents are lumped together under the generic label "private standards." Generally, a normative document developed and published by an organization outside of the "recognized" SDOs at the national, regional, or international level is considered to be a private standard. There is not only a vast range (and growing number) of private standards, but also significant

differences in the bodies or organizations that develop these standards related to such aspects as governance, development approach, stakeholder engagement, transparency, consensus, and so on.

The reasons for the rise of private standards are manifold, but typical issues are the following:

- The "time to market" for international standards would be at least two to three years, and that is too long for the sponsors of a standard in fast-moving technologies, who then develop a private standard among themselves in a much shorter time.
- Consortiums may develop a private product standard to gain a market advantage over rivals.
- Global brand producers and retailers increasingly require their suppliers to comply with certain social, environmental, and safety norms as they respond to pressures from their customers. These norms are then formalized in private standards, guidelines, or principles that their suppliers have to comply with contractually.
- NGO movements wishing to promote specific social and environmental changes end up developing private standards and establishing certification schemes to foster their goals.
- Multinational certification bodies identify a specific market niche, develop a private standard, and implement a multinational certification scheme as a sound business proposition.

Whatever the reasons for developing a private standard, such standards have become an important factor in accessing the developed markets of Europe and the United States, and they are also spreading into the markets of East Asia. A final—but still embryonic—trend relates to the harmonization and benchmarking of private standards as a response to the overwhelming growth in their number and variety as well as pressures from suppliers on purchasers to harmonize requirements. Yet, notwithstanding this multiplicity of private standards, new ones continue to emerge on a regular basis (UNIDO, Norad, and CBI 2010).

3.3.1 Private standards in the ICT sector

In addition to a hierarchy of public international, regional, and national standards, it has long been recognized that another layer exists in the form of industry or company standards used within or between companies or in contractual arrangements with suppliers. In response to such industry interest in setting its own standards, a phenomenon emerged in the late 1980s and early 1990s of consortiums and forums, principally in the field of information and communication technology (ICT), to develop industry specifications.

In many instances, the first consortiums and forums were closed groups formed by ICT companies to develop specifications that the participants could then implement principally to compete with rival approaches in the marketplace. Such groups were not necessarily seeking to engage with all interested parties, nor were the specifications they produced systematically made available for public inquiry. Typical examples include the Video Home System (VHS) (by Victor Company) and Betamax (by Sony) formats for magnetic tape video systems in the late 1970s; the Advanced Video Coding High Definition (AVCHD) format for digital video systems (by Panasonic and Sony); and many more.

Over time, however, many of these groups have become more open, have achieved recognition in the ICT industry, and have seen certain specifications that they developed become widely recognized as de facto international market standards—for example, the compact disc (CD) and Global System for Mobile communications (GSM) standard for cell phones. The standardization bodies could not ignore these developments and sought to engage with the ICT industry. One result was that the ISO and IEC Joint Technical Committee on Information Technology introduced a special procedure whereby specifications developed by consortiums and forums could be processed through the public standardization system to be transformed into international standards from the ISO and IEC (ISO 2010).

3.3.2 Private standards in the retail and agrifood industries

In many respects, the emergence of private standards in the agrifood and retail sectors has parallels with earlier experiences in the ICT sector, even if the motivations are not the same. A typical example is the Global G.A.P. (previously EUREPGAP) standards—an independent certification system for Good Agricultural Practice (GAP)—used by retailers in the EU to manage their suppliers over and above the requirements imposed by the EU food safety directives. These initiatives tend to be managed by groups of leading companies.

Although such standards may benefit from a high level of expert industry input, they do not necessarily adhere to the same principles as those of a public international standardizing organization (that is, the WTO TBT Agreement's principles of transparency, openness, impartiality and consensus, and so on), nor are disciplines of the WTO TBT Agreement annex 3 (Code of Good Practice) necessarily used (ISO 2010).

Concerns have been expressed—especially by low- and middle-income countries, at the WTO Committee on Technical Barriers to Trade (TBT) and the Committee on Sanitary and Phytosanitary (SPS) Measures—that these private standards at times exceed requirements that are established in international standards developed by the CAC, for example, and that the private standards and their implementation therefore constitute an unnecessary barrier to trade. Although the two WTO committees were generally sympathetic to low- and middle-income country complaints, nothing much transpired because none of the private standards was seen as a technical regulation.

But the retail food industry also felt the need to bring some order to this chaotic and potentially cost-inefficient situation. For example, the Global Food Safety Initiative (GFSI) was formed in 2000 at the request of food retailers' chief executive officers (CEOs) to promote continuous improvement in food safety systems and to ensure confidence and consistency in the delivery of safe food to consumers, while at the same time benchmarking and harmonizing the requirements of a plethora of private standards that had evolved until then.

3.3.3 Private standards for social and environmental goals

Perhaps the most diverse landscape of private standards relates to social and environmental objectives, often with associated claims, certification, and labeling programs. These private standards address such subjects as carbon footprint; eco-labeling; sustainable management of natural resources (forests, fisheries, biofuels, and so on); fair trade practices; organizational accountability; and social responsibility.

These private standards are produced by an array of private standards developers, from retailer consortiums for their private-label schemes to NGOs' movements promoting specific social and environmental changes through their standards and certification activities. The standards development practices of these organizations vary widely. Certain efforts have been made in recent years to improve the consistency of principles and criteria supporting such development activities as well as any associated conformity assessment programs such as certification or labeling (ISO 2010).

In recent times, the public standardization system has helped to consolidate a number of subjects previously addressed only by private standards by providing some important international standards on key social and environmental subjects, as in these examples (ISO 2010):

- *Environmental standards.* In the environmental area, the ISO now provides international standards addressing such subjects as environmental management (for example, ISO 14001); environmental labeling (ISO 14020); lifecycle assessment (ISO 14040); greenhouse gas measurement, verification, and validation (ISO 14064); and drinking water and wastewater services (ISO 24510).
- *Social responsibility standards.* The ISO established a comprehensive stakeholder engagement effort to develop the new ISO 26000 standard on social responsibility. This high-profile project, involving more than 400 global experts from 91 countries and 42 international governmental and nongovernmental organizations, demonstrated how the international standards development process can address complex societal and sustainability issues.

3.3.4 The future of private standards

Private standards are here to stay, but many eventually do migrate into public standards under certain circumstances:

- Private standards frequently predate standards developed by public consensus-driven processes, but they are converted into public standards once their market relevance is demonstrated or when the marketing advantage of the consortiums publishing them has diminished.
- Private standards generally cannot be used in technical regulation, because they often do not meet the WTO TBT Agreement requirements regarding the principles of standards development. Hence, if they address market failures that governments wish to manage, they have to be moved into the public standardization system before they can be used as the basis for technical regulations.
- Finally, when the market realizes that the plethora of private standards covering the same products and their concomitant certification processes actually add unnecessary costs, the public standards developers are often persuaded to act as the honest broker to develop a harmonized standard for all to use.

In spite of these tendencies, the use of private standards may still increase in the future. The reasons are manifold, but a few are worth mentioning. The process for developing the private standard is faster than for public

standards when it is managed by a specific industry sector or scheme owner that relies on the scheme, is tailored to specific needs, and includes innovation on an exclusive basis. It is the latter that is often overlooked. Public standards are publicly available for all to see and implement without exclusion; hence, patented product or system elements cannot be included in principle. In schemes based on private standards, on the other hand, scheme owners are able to include such elements, thereby enhancing the value of the scheme for themselves. The scheme owners may wish to protect their patent rights—rights they may have to relinquish if the patented technology is included in a public standard.

3.4 GOOD STANDARDIZATION PRACTICE

3.4.1 What is "good standardization practice"?

Good "operating" practice is a strategic management term. More specific uses of the term include good agricultural practice, good manufacturing practice, good laboratory practice, good clinical practice, and now also good standardization practice. Generally speaking, a good "operating" practice is a method or technique that has been generally accepted as superior to any alternatives because it produces results that are superior to those achieved by other means or because it has become a standard way of doing things.

Standards are developed and published at the national, regional, and international levels by many bodies, which in general prepare their documents by consensus processes. Driven by the growth of international trade and technological cooperation, standards bodies have developed procedures and modes of cooperation that are commonly considered to constitute good practices for standards development at all levels. Some of these have been codified in international agreements such as the WTO TBT Agreement; others in standards such as "ISO/IEC Guide 59: Code of Good Practice for Standardization" (ISO and IEC 1994); and many are found in the intrinsic knowledge bases of standards bodies all over the world—all of which are collectively known as good standardization practice (GSP).

3.4.2 Principles of good standardization practice

The origin for determining the principles of GSP is the "Decision of the Committee [on Technical Barriers to Trade] on the Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the [WTO TBT] Agreement" (WTO 2000). This decision enumerates six principles that international standards must comply with before they would be recognized by the WTO as such:

- Transparency
- Openness
- Impartiality and consensus
- Effectiveness and relevance
- Coherence
- Development dimension

The ISO has augmented these six principles by adding another three:

- Stakeholder engagement
- Due process
- National adoption or implementation of international or regional standards

These nine principles, although initially developed for international standardization, are now routinely also used in defining GSP at the regional and national levels. The derived principles for the NSB are discussed in the subsections below. Details regarding international standards can be gained from the relevant WTO TBT Agreement and ISO publications (ISO 2010; ISO and IEC 2005, 2018; WTO 2000).

GSP principle 1: Transparency

Transparency is about (a) shedding light on rules, plans, processes, and actions; (b) knowing why, how, what, and how much; (c) officials, managers, and technical committee members acting visibly and understandably as well as reporting on their activities; (d) people outside the system being able to hold those inside accountable; and (e) increasing trust in the people and institutions on which standardization depends.

All essential information regarding the development and publication of national standards must therefore be publicly available in a way that is easily accessible. The Internet has made this much easier than it was a decade or two ago, when information had to be provided in hard copy. The issue, however, is that the website of the NSB must be kept up-to-date continuously. Information that should be readily available to any interested party includes the following (ISO 2010; ISO and IEC 2005, 2018; WTO 2000):

- *The updated work program* must be available at least once every six months in accordance with the WTO TBT Agreement's annex 3 obligations. It would actually be even better if it is updated monthly to take into consideration changes in the work program that have been necessitated by more recent market or regulatory needs.
- *Technical committee establishment information* should be available. Once a new technical committee is to be established, the NSB would normally send invitations to participate to all those interested parties it knows. The NSB should also make the establishment of the new technical committee known on its website for those interested parties that it may not have on its books.
- *Draft standards* have to be circulated for public comment for at least 60 days in accordance with the WTO TBT Agreement's annex 3. The WTO Committee on Technical Barriers to Trade agreed a few years back that in view of the increased use of the Internet, the time could be curtailed to 45 days. Good practice is to post a notice for comment that includes the title and scope of the draft standard and the rationale for its development. The full text should not be posted. The full text should be made available to interested parties on request. A small fee may be charged, but then all should pay it.
- *Approved standards* need to be published promptly after their approval. It is not useful to have standards waiting for weeks and months for publication, whatever the excuse for such delays would be.

It is recognized that the publication and communication of notices, notifications, draft standards, comments, adopted standards, or work programs electronically (via the Internet, where feasible) can provide a useful means of

ensuring the timely provision of information. At the same time, it is also recognized that the requisite technical means may not be available in some cases, particularly with regard to low- and middle-income countries. Accordingly, it is important that procedures are in place to enable hard copies of such documents to be made available upon request.

GSP principle 2: Openness

Openness is about giving interested parties meaningful opportunities to participate in policy development and in all stages of the standards development process. Because the NSB's governance structures are fairly small, the voice of the masses regarding the need for standards is frequently not heard. Many NSBs have therefore established a standards advisory forum or similar mechanism that meets once or twice a year where all interested parties can voice their needs.

The NSB may get requests from a variety of sources on new standards to be developed. It is important that, no matter the source, the NSB consider all the requests at the same level, without discarding a request out of hand because it emanates from an unknown source or a small operator. All requests should be evaluated in accordance with formal criteria, after which a decision is made to proceed or not. If the decision is not to proceed, the NSB should provide the requester with the rationale as to why not.

Membership of technical committees should be open to all interested parties who wish to participate. The NSB has the obligation to try to balance representation such that one specific party does not totally dominate the proceedings. On the other hand, denying membership to any interested party just because the NSB would consider the committee to be too large is also not a good way of handling the situation. Even if the technical committee starts out with a high number of participants, anecdotal evidence would suggest that it will soon settle all by itself into a manageable size.

Comments on draft standards from all sources, even the most unlikely ones, should also be considered when collating them for discussion by the technical committee.

Finally, the NSB should have an appeals procedure in place for interested parties who are unhappy with the decisions of the technical committee or the standards approvals committee. High-level appeals should be heard by the council or board of the NSB.

GSP principle 3: Impartiality and consensus

Impartiality is about evenhandedness or fair-mindedness. Furthermore, decisions should be based on objective criteria rather than on the basis of bias, prejudice, or conferring the benefit to one person over another for improper reasons. The standards development process must therefore not give privilege to or favor the interests of a particular supplier or product, and standards must be developed through a process of consensus that seeks to take into account the views of all parties concerned and to reconcile conflicting arguments (ISO and IEC 2004a).

Achieving a consensus is at the heart of good standards development practices. This is not always easy, as there are sometimes strong opposing views among the interested parties and technical committee members. These are usually not so much based on technicalities, but on the economic impact a national standard might have on the one or the other stakeholder. These could be between industrial competitors, between consumers and suppliers, between regulatory authorities and suppliers, or many others with conflicting interests.

It is a challenge for the skills of the NSB staff and the technical committee chairperson to find common ground that all can support. The NSB and the chairperson of the technical committee should be seen as totally impartial in such debates and confrontations; otherwise, the credibility of the whole process and the standard to come out of it will be compromised. Effective training programs for technical committee chairpersons and secretariats are essential in this respect.

GSP principle 4: Effectiveness and relevance

National standards must facilitate trade, prevent unnecessary trade barriers, not distort the market, respond to regulatory and market needs, and take technological development into account. To address all of these requirements, standards should meet the following criteria:

- Standards should be based on performance criteria wherever possible rather than on a definitive description of characteristics, even if this seems to be a worthy attribute to be included. Technology develops, and such development may be stifled if the standard is prescriptive regarding characteristics, whereas new technologies can be tested against performance requirements.[7]
- The latest technology should be considered in the development of the standard, even though standards are mostly based on proven technology.
- It is important that the standard meet demonstrable market and regulatory needs. If not, it will not be used, and the resources spent on developing the standard would have been wasted. Hence, such demonstrable needs should feature strongly in the decision making of whether to develop the standard.
- GSP suggests that published standards be reviewed at least once every five years. In some technologies that develop quickly, even this may be too long. Some standards may not change; for example, a standard for a brick may have not changed in decades, but it is still useful to review the standard to consider modern advances for its performance. If nothing has changed, the standard is reaffirmed. If things have changed, the standard could be amended, revised, or sometimes even withdrawn if it is no longer in use.
- A meaningful liaison with international and regional standards organizations and using their standards as the basis of national standards, even adopting them without change, can go a long way toward keeping the national standards effective and relevant.

GSP principle 5: Coherence

Coherence is the quality of being logical and consistent to form a unified whole. For national standards, this means that conflicting national standards must be avoided. It is a principle that is not always followed. Coherence becomes more difficult to achieve if the NSB manages many technical committees, with the scopes of some very close to those of others. For example, one technical committee is looking at a standard for a washing machine, whereas another technical committee is looking at the electrical safety of household appliances. If the NSB is not careful, both may end up including safety requirements in their respective standards that may differ.

Second, if the NSB has "recognized" a number of SDOs, it can happen quickly that an SDO and the NSB are both managing technical committees whose scopes of activity overlap ever so slightly or even totally. This can lead to a situation where two differing national standards for exactly the same commodity are being developed—for example, a national standard for bottled water developed

by the Ministry of Health, on the one hand, and a standard for potable water developed by the NSB technical committee, on the other hand.

It is the responsibility of the NSB to ensure that the body of national standards is coherent and that overlaps are avoided at all cost.

GSP principle 6: Consideration of the development dimension

Constraints on less-developed interested parties, especially SMEs, should be taken into consideration. In almost all countries, SMEs and consumer organizations battle to participate effectively in the standards development processes because they lack adequate resources, such as funds and knowledge, for such participation.

The NSB should find innovative ways to facilitate and support the participation of such less-developed interested parties in standards development, such as through financial support, special capacity-building programs, and other means, depending on the customs and practices of the country. It may be useful to exchange experiences of such programs, similar to the exchange of national approaches in workshops arranged by the WTO Committee on Technical Barriers to Trade.

GSP principle 7: Stakeholder engagement

Stakeholders are the lifeline of NSBs, and they should be given meaningful opportunities to participate in policy and standards development. Nearly all of the principles of GSP are underpinned by stakeholder engagement. You need to engage people to get them to become part of the process, and this often requires many promotional or outreach activities making them aware of the benefit and application of standards. They need to be convinced: "What's in it for me?"

The NSB needs to be seen as a friend of industry able to support its development, as the protector of consumer interests, and as a valuable partner of the regulatory authorities—the honest broker. All of this can be achieved only if the NSB consciously, continuously, and honestly engages with all stakeholders. This does not happen overnight; it is a position that is earned over time.

There are many ways to engage with stakeholders; some are universal, and others are country-specific. On the overall work program for developing standards, a standards advisory forum or standards liaison forum are good constructs to engage with a wider stakeholder group. Regarding national standards, focused stakeholder engagement starts with specific invitations to participate in technical committees, continues with specific invitations to comment on draft standards, and can be highlighted with sector-specific workshops to present new standards to stakeholders.

Some specific approaches to stakeholder engagement that should be considered by the NSB regarding standards development include the following:

- The engagement of stakeholders in the standardization process is an essential part of the process, and the earlier that stakeholders can be engaged in new work items and new fields of activity, the more effective the consultation on the proposals for new work will be. This will enable all stakeholders to learn about new proposals for standards and provide valuable feedback to the NSB.
- It is important that technical committee structures be constituted with experts and delegates who are adequately qualified and equipped for the task, broadly representative of all those stakeholder groups with a legitimate interest in the project, and conscious of its potential impact. It is important that the

NSB and the committee leadership identify potential gaps and thereafter approach relevant organizations to nominate experts to the technical committee.

- It should not be assumed that the same diversity aspects will apply to any or all technical committees. For technical committees addressing subjects requiring broader public-interest engagement (for example, in terms of national economic status, geographic diversity, gender, and so on), the appropriate participation diversity will lead to more credible standards development. These elements of diversity should be identified as early as possible at the outset of a new project or in the technical committee.
- It is recommended that NSBs use national networks for consultation and discussion during the standards development activities and support these where possible at the national level to strengthen the input at the technical committee level, especially when engaged in international standards development. In certain subject areas requiring enhanced stakeholder engagement, for example, an informal network of NSB and stakeholder forums could be used to have a dialogue with broader stakeholder groupings on key areas of importance and in advance of technical committee meetings.

GSP principle 8: Due process

Due process in standards development means that all the steps along the whole standards development value chain are provided for in a known and formal way. This provides for clarity and consistency in the process and goes a long way toward building trust in it. Many NSBs have developed and published a national standard in which these steps are described, referred to as a "standard for a standard." In many cases, this national standard is made available free of charge, thereby enhancing the transparency of the process even further.

The "standard for a standard" would describe broadly how a project to develop a standard is approved; how the technical committee is established; the basic steps of standards development; and the process for editing, circulation for public comment, final editing, approval, and publishing. Also included would be the appeals process at various levels. The "standard for a standard" would mostly deal with principles and broad process steps.

The detailed work instructions for NSB personnel should be contained in the quality management documentation of the NSB. Using the principles and requirements contained in ISO 9001 ("Quality Management Systems—Requirements") is a useful idea.

GSP principle 9: National adoption or implementation of international and regional standards

National standards should form a coherent system with international and regional standards; otherwise, they could be experienced as unnecessary trade barriers. The WTO TBT Agreement therefore suggests that national standards should be based on international standards as much as possible to facilitate such cohesiveness.

This means, however, that the NSB should do everything in its power to persuade its technical committees to adopt international standards with as little change as possible. Sometimes local industry does not like this idea and tries to create hidden trade barriers for imported products by having a national standard, especially if it is to be used as the basis of technical regulation, differing

from the international standard without technical reasons. This recommendation does not preclude changes that are based on solid technical evidence, such as a larger voltage variation in electricity supply (for example, ±10 percent instead of 5 percent in the international standard); major climatic differences (hotter climates versus cooler climates identified in the international standard); and so on.

The NSB must work hard to counter this ill-advised tendency. If the country participates actively in international and regional standards development and the national mirror committee is fully involved in the process, such tendencies are less likely to occur.

3.4.3 Compliance with GSP

Ever since the implementation of the WTO TBT Agreement, with its obligations on development of standards, and subsequent pronouncements of its Committee on TBT on principles that international standardization should comply with, the focus on GSP has intensified at the international level, now spilling over to the national level. The use of standards has become more pervasive in world trade, resulting in market pressures on standards bodies to perform better and be "quick to market" with appropriate standards.

Hence, some standards bodies are seriously looking for ways and means to become more effective and efficient. Other standards bodies that have been operating standards development and publication systems for many years may have grown complacent in their customs and practices, which may not be compliant with GSP any longer. Then there are standards bodies that have just recently been established, are still in the process of developing appropriate processes for standards development and publication, and are seeking guidance in this respect.

In all of these situations, standards bodies would do well to consider modern GSP and to evaluate their practices against it. By doing so, they can establish, renew, and maintain their standards development and publication practices and have them conform with modern GSP, resulting in more effective and efficient practices. The need for knowledge about GSP can therefore be considered universal; that is, all standards bodies, from the smallest to the most advanced, will benefit from training staff in GSP.

3.5 OTHER NORMATIVE DOCUMENTS

The NSB's primary responsibility is to have national standards developed and to publish them. Many standardizing bodies (such as NSBs and SDOs) have found that this is not enough to satisfy the demand for informative or normative-type documents emanating from industry and society. Hence, quite a few standardizing bodies are also providing types of documents that cannot be classified as national standards because they fall short of the openness, transparency, and consensus principles underlying standards development. Typical of these types of documents are the following:

- *Normative-type documents* developed by an appointed working group but that have not been subjected to the rigorous consensus and public comment routines. They do, however, provide good practice recommendations on

the chosen subject matter. The ISO/PAS and IEC/PAS (Publicly Available Specification) or the ISO/TS and IEC/TS (Technical Specification) series are typical examples of such documents.

- *Implementation guides* developed and published by the standardizing body to help organizations implement a specific national standard—for example, guidance for the SME sector on the implementation of ISO 9001 ("Quality Management Systems—Requirements") or ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use").
- *Collections of national standards with guidance notes on a specific sector*—for example, all the national standards published for automotive safety or building and construction.

There can be many more examples of such informative and normative-type documents depending on the needs of the industry and society in a specific country, and it is the more progressive NSB that will be able to identify these needs and do something about them. The NSB should, however, make certain that these documents are not perceived as national standards; their numbering and titles should make it clear they are not.

3.6 STANDARDS INFORMATION: FREE OR TO BE PAID FOR?

Standards are useful only if they are implemented by industries, authorities, and society. This means, however, that their existence and content have to be made available to interested parties in the most effective and efficient way. In this respect, the Internet has had a massive influence in recent times on the ease with which standards can be searched for and obtained.

The ISO and IEC international standards are protected by copyright, and the ISO and IEC shield this copyright as a matter of principle. These organizations argue that standards fall within "intellectual property" as defined by the World Intellectual Property Organization (WIPO). Furthermore, making them available free of charge will deny the ISO and IEC as well as the NSBs adopting them as national standards useful income to fund further standards development. Most other international standards bodies do not have such measures in place, and their international standards can be obtained free of charge, even though many also urge users not to misuse this freedom of information.

It has also been argued by many low- and middle-income countries that because governments fund the development of national standards, these national standards should be available freely as a public good. This argument is given even more weight when standards are referenced in technical regulation, because in many countries, legislative text has to be "freely available" to any interested party as a fundamental right. But the understanding of what "feely available" means differs from country to country.

Both sides of the argument have merit, but generally speaking, national standards have to be paid for. A number of measures have been implemented by the ISO, IEC, and NSBs to protect the copyright yet make it easier for interested parties to view standards before purchasing them and to limit purchasing costs. Some of these measures include the following:

- *Reduced cost of adopted ISO or IEC standards.* The cost of a national standard as an adoption from an ISO or IEC standard may be a fraction of the

cost of an original ISO or IEC standard. Both the ISO and IEC accept such practices but urge a limit on the reduction. In the ISO's case, its copyright policy (POCOSA) that members have to adhere to provides guidelines in this respect.[8]

- *Digital rights management (DRM)*. There are currently a number of different DRM techniques in use to protect standards from copyright abuse, and more are being evaluated. Embedding digital watermarks is one of the techniques chosen by the ISO and IEC. Other techniques preventing files from being altered, shared, or copied have also been implemented by ISO or IEC members in the context of specific offerings like pay-per-view or subscription services.
- *Incentives and other options to exploit the content of standards to abide by copyright*. Making the legitimate versions of standards more desirable and useful than copies is a method being employed by a number of distributors of international and national standards. The ISO and IEC and their respective members are offering many different options to companies and standards users to legally use the content of standards—for example, making additional electronic copies; printing multiple copies from one electronic file; extracting parts of a standard for inclusion in the company's internal documentation, user's guide, or manuals, and so on.

Standards are now generally accepted as intellectual property, and their copyright protects the ownership and identity of the standards body. But at the same time, standards bodies are committed to making sure standards are implemented as widely as possible and that users can make appropriate use of the standards they need. Therefore, the price of standards is set at a level appropriate for their intended users, and this may differ from country to country. For example, ISO 9001:2015 ("Quality Management Systems—Requirements") or its national adoption costs Sw F 135 from the ISO (± US$134); £114 from the British Standards Institution (± US$148); R 485.64 from the South African Bureau of Standards (± US$36); and K Sh 2,980.80 from the Kenya Bureau of Standards (± US$28) at the time of this writing.

The "free" availability of standards referenced in legislation such as technical regulation is more challenging. In the EU, the issue has been solved by maintaining the voluntary character of EN standards supporting the implementation of new directives; that is, the EN standards retain copyright and are sold by the EU standardization bodies, and they are freely available but not available free of charge. In some jurisdictions, where national standards are given a specific legal standing in a standards act or a similar law, the copyright of national standards has been safeguarded by a specific article even in the case of them being referenced in technical regulations. The NSB can then provide the standard to any interested party, albeit with a cover charge, thereby fulfilling its obligation to protect the copyright especially of ISO and IEC standards adopted as national standards.

Most jurisdictions, however, fudge the issue and do not state a specific outcome one way or the other. Theoretically, if the copyright of national standards is not safeguarded, the NSB may not adopt ISO and IEC standards as national standards. The argument also becomes a moot point when referencing ISO or IEC standards directly, as is the case in many countries. Such a reference does not invalidate the copyright of ISO and IEC standards, nor does it make them available free of charge either.

3.7 THE ECONOMIC IMPACT OF STANDARDS

Considering the growth of global trade and the necessity of standards in defining product characteristics and quality in individual trade contracts, and as the basis of technical regulation, one can consider the impact of standards to be huge qualitatively (see module 2: Importance of QI Reform and Demand Assessment, section 2.1). *Quantifying* the impact, however, is not so easy. A number of studies have been undertaken over the years to quantify the economic impact of standards both at the national level and on the individual supplier. A few selected examples are given in the next subsections.

3.7.1 World Trade Report 2005

The "World Trade Report 2005," written by WTO economists, points to the growing importance of international standards and identifies the ISO, IEC, and ITU as the most important of the 50 or so international standardizing bodies known to the WTO (WTO 2005). It explains the increase in standardization activity by, among other factors, consumer demand for safer and higher-quality products, technological innovations, the expansion of global commerce, and the increased concern of many governments and NGOs about social issues and the environment, stating that standards have played an important role in fulfilling these needs. The report deals with three key areas:

- The economics of standards in relation to international trade
- The institutional setting in which standard setting and conformity assessment occur
- The role of WTO agreements in reconciling the legitimate policy uses of standards with an open, nondiscriminatory trading system

3.7.2 German Institute for Standardization: Economic benefits of standardization

The German Institute for Standardization (DIN) was one of the first NSBs that initiated studies regarding the economic benefits of standardization. DIN commissioned a study by the Technical University Dresden and the Fraunhofer Institute in 2000 (DIN 2000). The study—covering suppliers in Austria, Germany, and Switzerland—showed that company standards have the greatest effect on businesses in improving their processes. However, in business relationships with suppliers and customers, industrywide standards lower transaction costs and uphold market position. About 84 percent of businesses surveyed used European and international standards as part of their export strategies. Other significant findings of the study were the following:

- Standards make a greater contribution to economic growth than patents or licenses.
- Export-oriented sectors of industry make use of standards as a strategy in opening up new markets.
- Standards facilitate technological change.

The DIN study was followed by a number of similar studies in other countries that showed the quantitative impact of standards on the GDP of these countries (table 3.1).

TABLE 3.1 **National studies of the effects of standards on economic growth**

COUNTRY	PUBLISHER (DATE)	TIME FRAME	GDP GROWTH RATE (%)	CONTRIBUTION OF STANDARDIZATION (%)
Australia	SA (2006)	1962–2003	3.6	0.8
Canada	SCC (2007)	1981–2004	2.7	0.2
France	AFNOR (2009)	1950–2007	3.4	0.8
Germany	DIN (2000)	1960–1996	3.3	0.9
United Kingdom	DTI (2005)	1948–2002	2.5	0.3

Source: Blind, Jungmittag, and Mangelsdorf 2010.
Note: AFNOR = French Association for Standardization (Association Française de Normalisation); DIN = German Institute for Standardization (Deutsches Institut für Normung e.V.); DTI = Department of Trade and Industry; SA = Standards Australia; SCC = Standards Council of Canada.

The DIN study was updated 10 years later, in which data for every five-year period between 1960 and 2006 were considered (Blind, Jungmittag, and Mangelsdorf 2010). The contribution of standards in 2002–06 was considered slightly lower (0.72 percent) than the 0.9 percent obtained in the first study as the average for 1960–96. The conclusion was that standards have a stabilizing effect on GDP growth corresponding to 0.7–0.8 percent.

It furthermore points out that the positive economic benefits extend well beyond the benefits calculated in the study. These include standards for workplace safety that reduce the number of occupational accidents and lower absenteeism; environmental standards that improve quality of life; security standards that help lower the cost of safety and security systems; and so on. In this manner, standards relieve the burden on the state, thus legitimizing the support of standardization through public funds.

3.7.3 British Standards Institution: The economic contribution of standards to the U.K. economy

The British Standards Institution (BSI) commissioned a further study in 2015, 10 years after the DTI (2005) study on the economic contribution of standards to the U.K. economy. The study was conducted by the Centre for Economics and Business Research (Cebr) and was comprehensive, covering 1921 to 2013 (Cebr 2015). The report analyzed the macroeconomic and microeconomic impact of the BSI's consensus-based voluntary standards across the U.K. economy. It concluded that they are a vital part of the strength of U.K. industry and play a crucial and often invisible role in supporting economic growth. Among other findings, the research concluded that standards boost U.K. productivity and improve performance, kick-start innovation, and support U.K. domestic and international trade quite significantly in some sectors. The research also found that investing in standards pays dividends for organizations that use them and that standards always generate more benefits for companies than they cost to implement.

The research highlighted benefits across seven key sectors in the U.K. economy. The most productive sectors use standards the most: Aerospace and defense, for example, increased productivity by 20.1 percent between 2005 and 2014, while the U.K. average was 4.9 percent. The food and drink manufacturing sector saw an increase in turnover by £10.2 billion per year through its use of standards. Standards increased total turnover in all seven sectors studied by £33.3 billion per year.

Of those companies surveyed, 84 percent said that using standards enhances their reputation; 73 percent said that standards allow greater control of environmental problems; 89 percent said that standards help to optimize compliance with regulations such as health and safety legislation; 50 percent said that standards encourage innovation through the diffusion of knowledge; and 70 percent said that standards contribute to improving their supply chains by improving the quality of supplier products and services.

3.7.4 Economic benefits of standards: ISO methodology 2.0

The ISO developed a methodology to determine the economic benefit of the use of standards at the company level (ISO 2013). Between 2010 and 2012, the ISO conducted case studies on the economic benefits of standardization in more than 20 countries.

The fundamental point in the ISO methodology is to consider the company perspective: its environment, objectives, business processes, and activities. To describe and analyze the activities of a company in a structured and consistent way, the value chain model is applied. The impact of standards is determined by quantifying the variation caused by the use of standards of the relevant performance indicators over the period of time considered by the assessment. Finally, the impact is converted into monetary terms by translating changes in the operational indicators into contributions to the company's gross profit.

Three key benefits of standardization were identified:

- Standards used to streamline the internal processes of companies contributed 0.15–5.00 percent to earnings before interest and tax (EBIT) or gross profit.
- Standards can be used as a basis for the international expansion of companies by providing a common management framework.
- Standards were used to create or enter new markets, reaching a contribution to the companies' gross profit of up to 33 percent of annual revenue, helping a company to achieve a leading position in its market for at least a certain period of time.

Typical results for the car industry using this approach provided a figure of 1.19–2.05 percent for the contribution of standardization to EBIT (table 3.2). Projecting the impact on the industry's total revenue indicates that the impact of standardization in this industrial sector in 2008 would have been US$38 billion to US$55 billion.

The ISO Methodology, available as a toolkit from the ISO, can be used by NSBs, SDOs, companies, and academic institutions.

TABLE 3.2 EBIT contribution of standards in the global automotive industry, by value chain segment, 2008

	RANGE OF AVERAGE EFFECT (%)			
SOURCE	R&D	PROCUREMENT	PRODUCTION	COMBINED EFFECT (%)
OEMs	0.017–0.024	1.81–2.58	0.56–0.80	1.19–1.70
Suppliers	0.67–0.96	1.37–1.96	0.64–0.91	1.43–2.05

Source: ISO 2013.
Note: EBIT = earnings before interest and tax; OEMs = original equipment manufacturers; R&D = research and development.

NOTES

1. For a discussion of the WTO TBT Agreement, see module 7: Technical Regulation, section 7.1.
2. See, for example, WTO TBT Agreement Dispute Settlement (DS) 381 of Mexico versus the United States on the issue of dolphin-safe tuna products sold in the United States. The WTO Appellate Body concluded in 2012 that the standard used by the United States (a private standard) did not meet the principles of an "international standard" as contemplated in the TBT Agreement. Hence, Mexico won its appeal against the United States' "dolphin-safe" measure. For more information, see WTO Appellate Body Report WT/DS381/AB/R: https://www.wto.org/english/tratop_e/dispu_e/381abr_e.pdf.
3. The WTO TBT Agreement and SPS Agreement both deal with standards and their regulatory implementation—the former in a general way, the latter specifically dealing with sanitary and phytosanitary measures. They are mutually exclusive by definition; for further details, see module 7: Technical Regulation.
4. ISO and IEC standards are protected by copyright. Membership in the ISO and IEC transfers this copyright to the national member (for example, the country's national standards body [NSB]) and allows for the adoption of the ISO and IEC standards as national standards. In such cases, the ISO and IEC require the protection of the copyright to be extended also to the national standard, and the standards cannot be provided to interested parties free of charge; they have to be sold. An ISO member, for example, signs the Policies and Procedures for Copyright, Copyright Exploitation Rights and Sales of ISO Publications (ISO POCOSA) Agreement to this effect with the ISO.
5. See the WTO ISO Standards Gateway: https://tbtcode.iso.org/sites/wto-tbt/home.html.
6. ISO 9001 is the international standard specifying requirements for a quality management system. For more information, see https://www.iso.org/iso-9001-quality-management.html.
7. For example, dezincification is a major issue for brass water taps. Certain types of water will leach the zinc from the brass metal, resulting in a tap that leaks profusely all over the body within months. It is better to include a test for dezincification rather than specify the minimum percentage of copper in the brass that would prevent dezincification.
8. POCOSA is the abbreviation for the ISO's Policies and Procedures for Copyright, Copyright Exploitation Rights and Sales of ISO Publications.

ISO STANDARDS REFERENCED IN MODULE 3

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4

Metrology

INTRODUCTION

Metrology is the science of measurement, and it is arguably the oldest of the three fundamentals of the quality infrastructure (QI); the other two, standardization and accreditation, are much younger. The first record of a permanent measurement standard was in 2900 BC, when the royal Egyptian cubit was carved from black granite. The cubit was decreed to be the length of the pharaoh's forearm plus the width of his hand, and replica standards were given to builders. The success of a standardized length for the building of the pyramids is indicated by the lengths of their bases differing by no more than 0.05 percent.

Today, metrology permeates every area of human endeavor, and it is virtually impossible to describe anything without referring to weights and measures. Products are bought by size, weight, and volume; production processes are regulated by measurements; health care relies on measurements; science is totally dependent on metrology—the list can go on and on. Metrology has developed into one of the most sophisticated sciences, a science in which cooperation across the world is absolutely essential to maintain modern technology.

4.1 HISTORY

Since time immemorial, agreed-on units of measurement for quantities such as length, weight, and volume were in use for fair trade and for building and construction. Some impressive examples include the cubit from the third millennium BC, which was found in the remains of an ancient Mesopotamian temple, and the renowned royal cubit of the Egyptians, which was used as the basic length measure for building the Egyptian pyramids dating to about 350 BC. Distance was indicated in the Roman Empire by the *mille passuum* (a thousand paces), consisting of eight *stadiums*, and was calculated on the basis of 5 Roman feet (each ± 296 millimeters) to the *pace* (± 1.48 meters). The *libra* was a weight measure in the Roman Empire (about 327.5 grams) divided into 12 *unciae* for smaller quantities.

It was not only trade that required a uniform set of weights and measures. The fear of invasions, the desire of rulers to extend their power, and wars also contributed. Qin Shi Huang, who built the Great Wall of China to keep the Tatars out, announced a set of weights and measures for all the tribes in his empire in about 220 BC to consolidate his rule. After the collapse of these empires and the Dark Ages that followed, much measurement knowledge and standardization were lost. Although local systems of measurement were common, comparability was difficult because many local systems were incompatible. England established the Assize of Measures to create standards for length measurements in 1196, and the 1215 Magna Carta included a section for the measurement of wine and beer. Charlemagne, William the Conqueror, and the French politician Talleyrand all tried to introduce a uniform system of measurement, but none survived.

Modern metrology has its roots in the French Revolution. With a political motivation to harmonize units throughout France, a length standard based on a natural source was proposed, and in 1791 the meter was defined. This led to the creation of the decimal-based metric system in 1795, establishing standards for other types of measurements. Several countries adopted the metric system thereafter. In 1875, a diplomatic conference on the meter took place in Paris, and an international treaty, the Metre Convention, was signed that established the metric system. The metric system was modernized in 1960 with the creation of the International System of Units (SI) as a resolution at the 11th General Conference on Weights and Measures (CGPM).

4.2 DEFINITION AND SCOPE

4.2.1 Definition

Metrology is "the science of measurement and its application" (BIPM 2012), embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology. Metrology consists of three main tasks:

- The definition of internationally accepted units of measurement
- The realization of the units of measurement by scientific methods in measurement standards
- Traceability, linking measurements made in practice to measurement standards

4.2.2 Metrology categories

Metrology is generally separated into three categories with different levels of complexity, accuracy, and outcome:

- *Scientific metrology* at the highest level is concerned with the establishment of units of measurement, the development of new measurement methods, the realization of measurement standards, and the transfer of traceability from these standards to users in a society.[1] At a lower level, it is mostly concerned with the establishment and maintenance of national measurement standards.
- *Legal metrology* concerns activities that result from regulatory requirements regarding measurement units, instruments, and methods. Such regulatory

requirements may arise from the need for protection of consumers and to safeguard fair trade, protection of health and the environment, public safety, and enabling taxation.

- *Industrial metrology,* also known as applied or technical metrology, is concerned with the application of measurements to manufacturing and other processes and their use in society, ensuring the suitability of measurement instruments, their calibration, and quality control. Industrial metrology is important for a country's economic and industrial development, and the condition of a country's industrial metrology program can indicate its economic status.

4.3 SCIENTIFIC METROLOGY

4.3.1 Fields of scientific metrology

Under the Metre Convention, which addresses scientific metrology, there are seven base units: *mole* (dealing with amount of substance—that is, chemical and increasingly biological metrology); *ampere* (electricity and magnetism); *meter* (length); *kilogram* (mass); *candela* (photometry and radiometry); *kelvin* (thermometry); and *second* (time and frequency).

Among the consultative committees (CCs) of the International Committee for Weights and Measures (CIPM), these seven base units are complemented by two further CCs: one for acoustics, vibration, and ultrasound; and a second one for ionizing radiation and radioactivity. There is one cross-cutting CC among all nine base units: the Consultative Committee for Units (CCU).

4.3.2 Measurement standards

A measurement standard, or etalon, for physical metrology or a higher-order method in metrology in chemistry is a material measure, measuring instrument, reference material, or measuring system intended to define, realize, conserve, or reproduce a unit or one or more values of a quantity to serve as a reference.

For example, the meter is defined as the length of the path traveled by light in vacuum during a time interval of 1/299,792,458th of a second. The meter may be realized at the primary level with the help of the wavelength from an iodine-stabilized helium-neon laser. On a secondary level, material measures like gauge blocks may be used, and traceability can be ensured by using optical interferometry to determine the length of the gauge blocks with reference to the above-mentioned laser light wavelength.

The different levels of measurement standards are shown in figure 4.1. For each measurement quantity within the metrology fields and subfields (table 4.1), a variety of measurement standards can be used to establish traceability.

4.3.3 Metrology in chemistry

Metrology has developed from physical measurements and emphasizes results traceable to defined reference standards—normally the International System of Units (SI)—with known uncertainties. With the increase in world trade and the imposition of technical regulations regarding safety and health issues and protection of the environment, metrology in chemistry has grown in importance in

TABLE 4.1 Subject fields of metrology

SUBJECT FIELD	SUBFIELDS
Mass and related quantities	Mass measurement
	Force and pressure
	Volume and density
	Viscosity
Electricity and magnetism	Direct current electricity
	Alternating current electricity
	High-frequency electricity
	High current and high voltage
Length	Wavelength and interferometry
	Dimensional metrology
	Angular metrology
	Forms
	Surface quality
Time and frequency	Time measurement
	Frequency
Thermometry	Temperature measurement by contact
	Noncontact temperature measurement
	Humidity
	Absorbed dose—medical products
	Radiation protection
	Radioactivity
Photometry and radiometry	Optical radiometry
	Photometry
	Colorimetry
	Optical fibers
Flow	Gas flow (volume)
	Flow of liquids (volume, mass, and energy)
	Anemometry
Acoustics, ultrasound, and vibration	Acoustical measurement in gases
	Accelerometery
	Acoustical measurements in liquids
	Ultrasound
Chemistry	Environmental chemistry
	Clinical chemistry
	Materials chemistry
	Food chemistry
	Biochemistry
	Microbiology
	pH measurement and electrical conductivity

Source: EURAMET 2008.
Note: The subject fields shown in this table do not correspond directly with the subject fields of the various International Bureau of Weights and Measures (BIPM) consultative committees, which are more science-oriented, but this list may be more appropriate for determining the needs of low- and middle-income countries.

recent times. Typically, chemical measurements are more complex than physical measurements because of more complex measurement conditions and matrix effects (table 4.2).

Metrology in chemistry can be seen as consisting of (a) the development of reference methods, mainly matrix independent; (b) the production of certified

TABLE 4.2 Metrology in physics and chemistry: Similarities and differences

CHARACTERISTIC	PHYSICS	CHEMISTRY
Measurement	Comparing a quantity (for example, temperature)	Comparing a quantity (for example, DDT in milk)
Units	m, s, kg	mol/kg, mg/kg
Influenced by	Relies mostly on direct measurements	Various factors influence the measurement results
Main impact	Equipment calibration	Chemical treatment (for example, extraction, digestion); reference materials used; and equipment calibration
Depends on	Largely sample independent	Strongly sample dependent
Example	Length of a table	Concentration of lead in seawater, soils, blood, and so on

Source: EURAMET 2008.
Note: DDT = dichlorodiphenyltrichloroethane; kg = kilogram; m = meter; mg/kg = milligrams per kilogram; mol/kg = mole per kilogram; s = second (see further definitions in table 4.3).

reference materials; and (c) the provision of proficiency schemes—all at a higher level to serve as national measurement standards in chemistry in support of agriculture, chemicals, energy, climate change and clean air, food safety, health and environment, pharmaceuticals, metals, law enforcement, and the manufacturing and mining industries.

4.3.4 Certified reference materials

A certified reference material (CRM) is a reference material for which one or more of its property values are certified by a procedure that establishes traceability to a realization of the unit in which the property values are expressed. Each certified value includes an uncertainty statement.[2] CRMs are generally prepared in batches and have expiration dates. The property values are determined within stated uncertainty limits by measurements on samples representative of the whole batch.

4.4 LEGAL METROLOGY

Legal metrology is the second category of metrology. It originated from the need to ensure fair trade, specifically in the area of weights and measures, and is still known as trade metrology in some countries. Legal metrology is primarily concerned with measuring instruments, and its main objective is to assure citizens of correct measurement results when used for official measurements and commercial transactions. These would include trade and law enforcement. A legal metrology system generally comprises four interrelated elements:

- Type approval or conformity assessment of measuring equipment
- Calibration and verification of measuring equipment in use
- Market surveillance of measuring equipment falling within the scope of regulation
- Prepackaging controls of prepackaged goods

All of these have to be appropriately defined and given legitimacy in legal metrology legislation and regulations. Legal metrology is therefore part and

parcel of a technical regulation regime and has to comply with the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) requirements (see module 7: Technical Regulation) if the country is a WTO member.

In addition to trade-related issues, there are fields under regulation that require metrology, many of them to protect the health and safety of individuals, fauna and flora, and the environment. In the European Union, for example, more than 80 different regulations and directives involve metrology, such as the Water Framework Directive, the In Vitro Diagnostic Regulation, the European Atomic Energy Community (Euratom) Basic Safety Standards Directive, and others.

4.5 INDUSTRIAL METROLOGY

Industrial metrology, also known as applied or technical metrology, is concerned with the application of measurements to manufacturing and other processes and their use in society, ensuring the suitability of measurement instruments, their calibration, and quality control. Although the emphasis in this area of metrology is on the measurements themselves, traceability of the measuring device through calibration is absolutely necessary to ensure confidence in the measurement. Systematic measurement with known degrees of uncertainty is one of the foundations of quality control, and in modern industries the costs bound up in taking measurements can constitute 10–15 percent of production costs (EURAMET 2008). Industrial metrology is therefore important for a country's economic and industrial development, and the state of a country's industrial metrology program can indicate its economic development status.

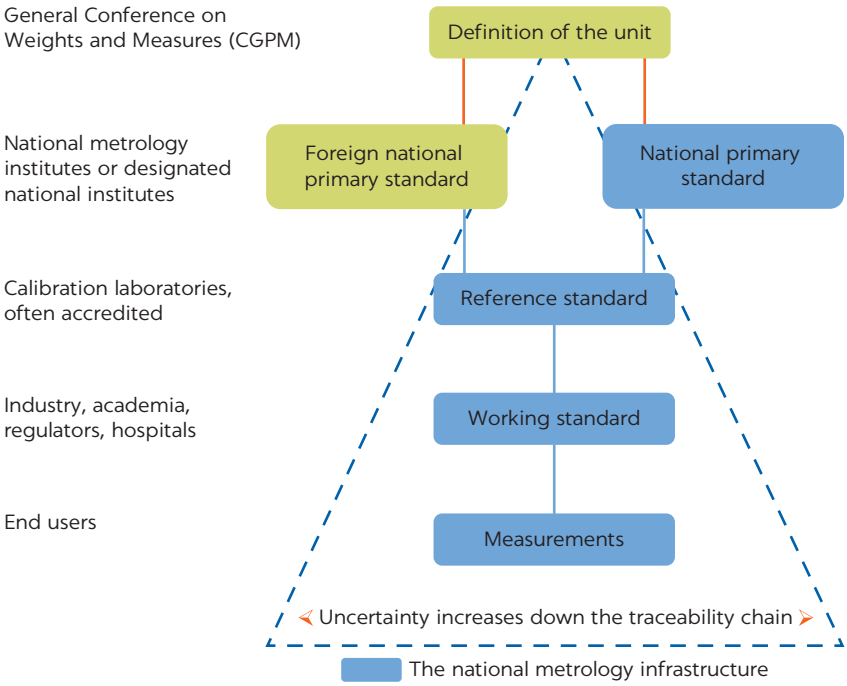
The normal development in industrial economies and in many emerging economies has been a bottom-up approach. A country's national metrology institute (NMI) starts with low-level but traceable, recognized calibrations for industry, and in parallel it promotes independent (largely private) calibration laboratories by transferring knowledge and procedures and assuring traceability. As the NMI and independent calibration laboratories develop competences, the NMI withdraws its calibration service over time from the market to concentrate its resources on scientific metrology, focusing on the development of new metrological services for the benefit of users and the economy. The calibration of industrial measuring equipment then increasingly becomes the purview of the independent calibration laboratories or of major industries or organizations that establish the same in-house.

4.6 THE TRACEABILITY CHAIN AND MEASUREMENT UNCERTAINTIES

4.6.1 Traceability

A traceability chain is an unbroken chain of calibrations, all having stated measurement uncertainties (figure 4.1). This ensures that a measurement result or a standard is referenced to a standard at a higher level, ending at a primary standard that is a physical realization of the international definition of the unit. In chemistry and biology, traceability is often obtained by using CRMs and

FIGURE 4.1
The traceability chain in metrology



Source: EURAMET 2008. ©European Association of National Metrology Institutes (EURAMET). Reproduced with permission from EURAMET; further permission required for reuse.

reference procedures ending at a higher-order method or reference material representing the best possible realization of the chemical measurand.

An end user may obtain traceability to the highest international level either directly from an NMI or via a secondary accredited calibration laboratory (as further discussed in section 4.12). Different primary standards are compared on an international level.

4.6.2 Calibration

Measuring instruments or systems are not always accurate, nor do they maintain their accuracy over time, because of influences of the environment to which they are exposed, wear and tear, and overload or improper use. Hence, they have to be calibrated from time to time to determine their current accuracy and ensure that their results are traceable to known measuring standards. That is, calibration determines the performance characteristics of an instrument, system, or reference material.

Calibration is usually achieved by means of a direct comparison against measurement standards, CRMs, or a higher-order reference method, all of which have a smaller measurement uncertainty than the unit to be calibrated. There are four main reasons for having an instrument calibrated:

- To establish and demonstrate traceability
- To ensure that readings from the instrument are consistent with other measurements (comparability of measurements)
- To determine the accuracy of the instrument readings
- To establish the reliability of the instrument—that is, that it can be trusted

4.6.3 Measurement uncertainty

All measurements are subject to fluctuations or systematic errors, in that the result of a measurement differs from the true value of the unit measured. Measurement uncertainty is a quantitative measure of the quality of a measurement result, enabling the measurement results to be compared with other results, references, standards, or regulative requests.

4.7 THE NECESSITY AND IMPACT OF METROLOGY

4.7.1 Economic necessity and benefits

There are four main areas in which metrology has important economic effects, even in the short term (Swann 2009).

Metrology can increase the productivity of organizations. Increased productivity was first seen in the 18th and 19th centuries with the development of interchangeable parts; this became an important aspect of the so-called American system of manufacturing. The use of precise measurement revolutionized interchangeable manufacture because it enabled an effective and efficient division of labor. Later, measurement became one of the integral parts of process control and continues to be integral to advanced manufacturing. The more precise the measurement and the faster the feedback from measurement to control, the greater the effects on efficiency, quality, and productivity. In modern industries, metrology is considered to represent about 10–15 percent of production costs (EURAMET 2008).

Metrology supports innovation. The Wright brothers used measurement as part of their research into the aerodynamics of aircraft wings and, building on that, as part of their development effort to build the first viable airplane. More modern examples include the publicly funded metrology activities that helped to support innovation by Rolls-Royce and Boeing.

Measurement is also important to the innovator because it offers an objective way to demonstrate to customers that an innovative product is indeed superior to the competition. In the absence of any such measurements, the skeptical customer may be unconvinced, but if the superior product's characteristics can be measured in an objective (and independently verifiable) way, this supports the marketing effort of the innovative producer. In this way, measurement can play an important role in avoiding market failure for innovative new products.

Another related example is the use of measurement to demonstrate the purity and quality of premium products. The intimate relationship between measurement and innovation is illustrated by the case of a company that needed to develop its own measurement instruments to demonstrate the superiority of its products, and this was the first step in the diversification of the company from optical manufacture into instrumentation for advanced metrology (Swann 2009).

Metrology helps to reduce the transaction costs between suppliers and customers in a market economy. One of the most common sources of market failure is asymmetric information between buyers and sellers, where the buyer cannot distinguish good products from bad and therefore does not buy. Often this arises because measurement is difficult or expensive. As measurement improves and becomes cheaper, buyers can measure any product characteristics

they wish, which eliminates asymmetric information and reduces transaction costs. In fact, many producers now use measurements of product characteristics to advertise their products.

Metrology also ensures fair trade. Both the supplier and the purchaser are protected by measuring equipment that is accurate—the purchaser by getting what is paid for, and the supplier by avoiding oversupplying or undersupplying the stated quantity of the product purchased, which in the United States amounts to about US$5 trillion in sales per year (Swann 2009).

Metrology helps societal groups. Many consumers are interested in careful measurement of product characteristics to ensure quality, safety, purity, dosage accuracy, and so on. These could include food composition data, the alcohol content of drinks, the sun protection factor of sunblock, the speed of a car and the temperature of its cooling system, the performance characteristics of a hi-fi stereo system, or the accurate and early detection of carbon monoxide in the home.

In the health service, clinicians depend on the precise measurement of doses, which is essential for efficacy and safety in medicines and for the diagnosis of medical conditions. They also make extensive use of measurement instruments to check patient health (for example, for blood pressure, blood tests, and so on). Such measurements are important not only in managing the health care of individual patients, but also in the context of epidemics.

Those concerned with the environment depend on measurement for accurate information about meteorological conditions (such as wind, rainfall, sunshine, and temperature); pollution and emissions (such as carbon dioxide emissions); geoseismic measures; measures of the ozone layer; measures of the condition of the polar caps; and so on. In addition, measurement has at least three important roles in education and training: as part of the curriculum, as an essential input to the research process, and in assessing student aptitude and performance.

4.8 SYSTEMS OF MEASUREMENT

The SI has been adopted by 59 states that are signatories to the Metre Convention and additionally by 42 associate states and economies. Together they represent more than 98 percent of worldwide gross domestic product (GDP).

In some countries, special units such as those known as imperial units (for example, in the United Kingdom and the United States) are allowed by their governments. These are used either in addition or as an alternative to the SI. It should be noted, however, that in these alternative systems the conversion factors to the SI are fixed and agreed upon. So, scientifically, they can be considered as alternative ways of expressing measurement that are still consistent with the SI.

4.8.1 The International System of Units (SI)

The SI, consisting of seven base units and units derived from them, is a fully coherent system.[3] It developed out of the metric system, which had been in place since 1875. The SI system was established as a decision of the 11th General Conference on Weights and Measures (CGPM) in 1960 (as discussed earlier in section 4.3), during which six units were introduced as base units: the kilogram, meter, second, ampere, kelvin, and candela. During the 14th CGPM (1972), the mole was added as the seventh base unit.

The CGPM approved a redefinition of the SI base units during the 26th CGPM in November 2018, to come into force as of World Metrology Day, on May 20, 2019. These redefinitions are based on the idea to define all seven base units by fixing the numerical value of a natural constant, as was already done for the definition of the second and the meter. The four base units kilogram, ampere, kelvin, and mole are redefined in terms of fixed numerical values of the Planck constant (h), the elementary charge (e), the Boltzmann constant (k), and the Avogadro constant (N_A), respectively. In addition, the luminous efficacy is used to define the candela. The seven SI base units are listed in table 4.3 with their 2018 definitions (BIPM 2018).

A few examples of derived units based on SI base units are shown in table 4.4. Some coherent derived units have been given special names. A few examples of these are shown in table 4.5.

The SI also includes rules for prefixes, prefix symbols, and the writing of SI unit names and symbols. Table 4.6 provides an overview of the prefixes. Rules for writing the SI can be found in a number of publications, notably those of the International Bureau of Weights and Measures (BIPM 2008).

Quite a number of non-SI units are used. These include units such as time (for example, minute or hour); plane angle (degree, minute, and second); volume (such as liter); mass (such as metric ton); and pressure in fluids (such as bar). Then there are also units outside the SI that are accepted within specific subject areas: length (such as nautical mile); speed (such as knot); mass (such as carat); linear density (such as tex); pressure

TABLE 4.3 SI base units and their definitions (valid as of May 20, 2019)

QUANTITY	BASE UNIT	SYMBOL	DEFINITION
Length	meter	m	The meter, symbol m, is the SI unit of length. It is defined by taking the fixed numerical value of the speed of light in vacuum c to be 299 792 458 when expressed in the unit m/s, where the second is defined in terms of $\Delta\nu_{Cs}$.
Mass	kilogram	kg	The kilogram, symbol kg, is the SI unit of mass; its magnitude is set by fixing the numerical value of the Planck constant to be exactly $6.626\ 070\ 15 \times 10^{-34}$ when it is expressed in the SI unit for action J s = kg m^2 s^{-1}.
Time	second	s	The second, symbol s, is the SI unit of time. It is defined by taking the fixed numerical value of the caesium frequency $\Delta\nu_{Cs}$, the unperturbed ground-state hyperfine transition frequency of the caesium 133 atom, to be 9.192 631 770 when expressed in the unit Hz, which is equal to s^{-1}.
Electric current	ampere	A	The ampere, symbol A, is the SI unit of electric current. It is defined by taking the fixed numerical value of the elementary charge to be $1.602\ 176\ 634 \times 10^{-19}$ when expressed in the unit C, which is equal to As, where the second is defined in terms of $\Delta\nu_{Cs}$.
Thermodynamic temperature	kelvin	K	The kelvin, symbol K, is the SI unit of thermodynamic temperature. It is defined by taking the fixed numerical value of the Boltzmann constant k to be $1.380\ 649 \times 10^{-23}$ when expressed in the unit JK^{-1}, which is equal to kg $m^2s^{-2}K^{-1}$, where the kilogram, meter, and second are defined in terms of h, c, and $\Delta\nu_{Cs}$.
Amount of substance	mole	mol	The mole, symbol mol, is the SI unit of amount of substance. One mole contains exactly $6.022\ 140\ 76 \times 10^{23}$ elementary entities. This number is the fixed numerical value of the Avogadro constant, N_A, when expressed in the unit mol^{-1} and is called the Avogadro number.
Luminous intensity	candela	cd	The candela, symbol cd, is the SI unit of luminous intensity in a given direction. It is defined by taking the fixed numerical value of the luminous efficacy of monochromatic radiation of frequency 540×10^{12} Hz, K_{cd}, to be 683 when expressed in the unit lm W^{-1}, which is equal to cd sr W^{-1}, or cd sr $kg^{-1}m^{-2}s^3$, where the kilogram, meter, and second are defined in terms of h, c, and $\Delta\nu_{Cs}$.

Source: BIPM 2018.
Note: SI = International System of Units.

TABLE 4.4 Examples of SI-derived units expressed in SI base units

DERIVED QUANTITY (SYMBOL)	DERIVED UNIT	SYMBOL
Area (A)	square meter	m^2
Volume (V)	cubic meter	m^3
Speed, velocity (v)	meter per second	m/s
Acceleration (a)	meter per second squared	m/s^2
Density, mass density (ρ)	kilogram per cubic meter	kg/m^3
Surface density (ρ_A)	kilogram per square meter	kg/m^2
Specific volume (v)	cubic meter per kilogram	m^3/kg
Current density (j)	ampere per square meter	A/m^2
Magnetic field strength (H)	ampere per meter	A/m
Amount concentration, concentration (c)	mole per cubic meter	mol/m^3
Mass concentration (ρ, ϒ)	kilogram per cubic meter	kg/m^3
Luminance (L_V)	candela per square meter	cd/m^2

Source: BIPM 2008.
Note: SI = International System of Units.

TABLE 4.5 Examples of coherent derived SI units with special names

DERIVED QUANTITY	NAME	SYMBOL	EXPRESSED IN TERMS OF OTHER SI UNITS
Plane angle	radian	rad	1
Solid angle	steradian	sr	1
Frequency	hertz	Hz	s^{-1}
Force	newton	N	$m.kg/s^2$
Pressure, stress	pascal	Pa	N/m^2
Energy, work, amount of heat	joule	J	N.m
Power, radiant flux	watt	W	J/s
Electric charge, amount of electricity	coulomb	C	s.A
Electric potential difference	volt	V	W/A
Capacitance	farad	F	C/V
Electric resistance	ohm	Ω	V/A
Luminous flux	lumen	lm	cd.sr
Illuminance	lux	lx	lm/m^2
Activity referred to radionuclide	becquerel	Bq	s^{-1}

Source: BIPM 2008.
Note: SI = International System of Units; A = ampere; cd = candela; kg = kilogram; m = meter; s = second (see further definition in table 4.3); V = volt.

TABLE 4.6 SI prefixes

FACTOR	PREFIX NAME	SYMBOL	FACTOR	PREFIX NAME	SYMBOL
10^1	deca	da	10^{-1}	deci	d
10^2	hecto	h	10^{-2}	centi	c
10^3	kilo	k	10^{-3}	milli	m
10^6	mega	M	10^{-6}	micro	μ
10^9	giga	G	10^{-9}	nano	n
10^{12}	tera	T	10^{-12}	pico	p
10^{15}	peta	P	10^{-15}	femto	f
10^{18}	exa	E	10^{-18}	atto	a
10^{21}	zetta	Z	10^{-21}	zepto	z
10^{24}	yotta	Y	10^{-24}	vocto	v

Source: BIPM 2008.
Note: SI = International System of Units.

in the human body (such as millimeters of mercury), and so on. Full details of these and many more can be obtained from *The International System of Units (SI)* (BIPM 2006) and other relevant publications.

4.8.2 Imperial and U.S. customary systems

The system of imperial units, or the imperial system, is the system of units first defined in the British Weights and Measures Act of 1824, which was later refined and reduced. The system came into official use across the British Empire. By the late 20th century, most nations of the former empire had officially adopted the SI as their main system of measurement. The imperial system developed from what were first known as English units, as did the related system of U.S. customary units. Neither is a coherent system.

These systems include length measurements such as the inch, foot, yard, and mile; volume measurements such as the fluid ounce, pint, and gallon; area as measured in square inches or acres; and so on. Although the United Kingdom and the United States have officially adopted the SI, there are still many day-to-day instances of the use of the imperial quantities. These include road signs, milk and beer sold by volume, clothing sizes, and quite a few others.

As part of the European Union, the United Kingdom had to implement the SI in trade, especially in prepackaging. Some traders, however, resisted "metrication" and still insist on using only imperial units. Industry, except the railways other than the Channel Tunnel, has largely converted to the SI, arguing that customers in the rest of the world use it.

The United States legalized the use of the SI in 1975. Implementation, however, was never considered as a legally enforceable changeover as in other countries—for example, in South Africa in the 1970s, where the use of imperial units was banned after 1978. Hence, industry in the United States is a mixed bag. Some firms, like General Motors, changed totally to the SI, whereas others such as Boeing are still using the U.S. customary system. Consumer goods are often prepackaged with both measurements depicted on the packaging. Over time, the United States will probably gravitate more and more to the SI in everyday use as well.

4.9 INTERNATIONAL AND REGIONAL METROLOGY ORGANIZATIONS

At the international level, two organizations dominate: the BIPM and the International Organization of Legal Metrology (OIML). At the regional level, the situation can become quite murky, with regional metrology organizations (RMOs) representing major regions and recognized as such by the BIPM and subregional metrology organizations established as an outcome of political decisions to harmonize metrology activities within an emerging common market. Some of the latter are recognized as RMOs; others are not.

4.9.1 The Metre Convention and the BIPM

In 1875, a diplomatic conference on the meter took place in Paris, where 17 governments signed a diplomatic treaty, the Metre Convention. The signatories decided to create and finance a permanent scientific institute, the "Bureau international des poids et mesures" (BIPM). The Metre Convention

was slightly modified in 1921. Presently, it has 59 member states and 42 states and economies that are associates of the CGPM, with the right to attend the CGPM as observers. The organizational structure established by the Metre Convention is shown in figure 4.2.

Representatives of the governments of the member states meet every fourth year for the CGPM. The last meeting at the time of this writing was the 26th meeting, held in November 2018. The CGPM discusses and examines the work performed by NMIs and the BIPM and makes recommendations on new fundamental metrological determinations and all major issues of concern to the BIPM. The CGPM elects up to 18 representatives to the International Committee for Weights and Measures (CIPM), which meets annually.

The CIPM supervises the BIPM on behalf of the CGPM and cooperates with other international metrology organizations. The CIPM undertakes preparatory work for technical decisions to be made by the CGPM. The CIPM is supported by 10 consultative committees. The president of each of the consultative committees is usually a member of the CIPM. The other members of the consultative committees are representatives of the NMIs and other experts.

FIGURE 4.2
The Metre Convention organization

Source: BIPM 2006. ©International Bureau of Weights and Measures (BIPM). Reproduced with permission from BIPM; further permission required for reuse.
Note: CEN = European Committee for Standardization; IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; SI = International System of Units.
* There are currently 10 CCs which advise the CIPM and the Headquarters, for example, on technical matters, and the administration of CIPM MRA.
**The JCRB refers to the Joint Committee of the Regional Metrology Organizations and the BIPM.

Joint committees of the BIPM and other international organizations have been created for particular tasks:

- International Network for Quality Infrastructure (InetQI)
- Joint Committee for Guides in Metrology (JCGM)
- Joint Committee of the Regional Metrology Organisations and the BIPM (JCRB)
- Joint Committee on Traceability in Laboratory Medicine (JCTLM).

4.9.2 Regional metrology organizations

The collaboration of NMIs at regional levels is coordinated by RMOs (map 4.1). The activities of the RMOs include the following:

- Coordination of comparisons of national measurement standards and other activities of the CIPM Multilateral Recognition Agreement (CIPM MRA)
- Cooperation in metrology research and development
- Facilitation of traceability to primary realizations of the SI
- Cooperation in developing metrological infrastructure of the member countries
- Joint training and consultation
- Sharing of technical capabilities and facilities.

Within the CIPM MRA, the RMOs play a crucial role, as it is their responsibility to carry out major elements of the review process of member states of the BIPM and associate states and economies of the CGPM in respect to

MAP 4.1

Regional metrology organizations

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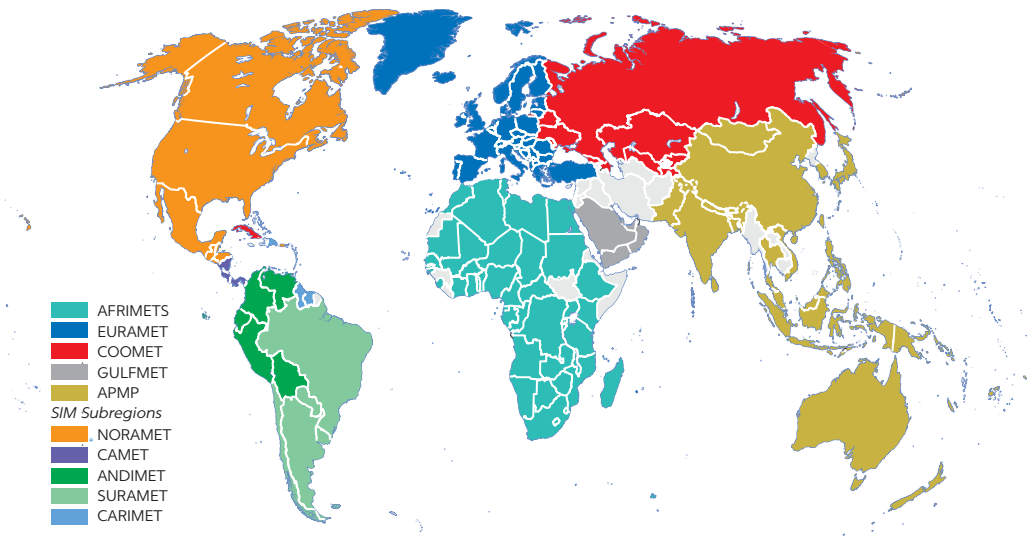


Source: World Bank, from organization membership data.
Note: AFRIMETS = Intra-Africa Metrology System; ANDIMET = Andean Region Metrology; APMP = Asia Pacific Metrology Programme; CAMET = Central American Metrology; CARIMET = Caribbean Metrology; COOMET = Euro-Asian Cooperation of National Metrological Institutions; EURAMET = European Association of Metrology Institutes; GULFMET = Gulf Association for Metrology; NORAMET = North American Metrology Cooperation; SURAMET = South American Metrology; SIM = Inter-American Metrology System.

the CIPM MRA (as discussed in section 4.9.1) and to report their results to the Joint Committee of Regional Bodies (JCRB). At the time of this writing, six RMOs were recognized by the BIPM (map 4.1):

- Intra-Africa Metrology System (AFRIMETS)
- Asia Pacific Metrology Programme (APMP)
- Euro-Asian Cooperation of National Metrological Institutions (COOMET)
- European Association of Metrology Institutes (EURAMET)
- Gulf Association for Metrology (GULFMET)
- Inter-American Metrology System (SIM), which is organized in five subregions: NORAMET, CARIMET, CAMET, ANDIMET, and SURAMET

4.9.3 Other regional metrology coordination committees and bodies

In addition to these recognized RMOs, regional metrology coordination committees or bodies have been established as the outcome of trade agreements leading to regional common markets. Typical examples are found in the common markets that are emerging in Africa: the Southern African Development Community (SADC), East African Community (EAC), and Economic Community of West African States (ECOWAS). All of these African subgroupings, however, are part of AFRIMETS. These should not be confused with the RMOs recognized by the BIPM.

In many cases, NMIs and legal metrology organizations are members, having to represent their countries in these regional structures. They have no choice in the matter. Some of these regional metrology structures have full-time staff and premises; others are liaison-type committees with only a secretariat. Some of these operate as regional metrology institutions and establish and maintain regional measurement standards as a service to smaller member countries that are not able to do so. Some are forums where a regional approach to metrology is discussed and agreed to; some only coordinate metrology development activities across the region. There is no one model that is superior to others (Kellermann and Keller 2014).

4.10 INTERNATIONAL RECOGNITION SYSTEMS

4.10.1 The CIPM Mutual Recognition Arrangement

The CIPM Mutual Recognition Arrangement (CIPM MRA) is the framework through which NMIs demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they issue. The outcomes of the arrangement are the internationally recognized (peer-reviewed and approved) calibration and measurement capabilities (CMCs) of the participating institutes. Approved CMCs and supporting technical data are publicly available from the CIPM MRA's Key Comparison Database (KCDB). The CIPM MRA has been signed by the representatives of 103 institutes—from 58 member states, 41 associates of the CGPM, and 4 international organizations (the International Atomic Energy Agency [IAEA], the World Meteorological Organization [WMO], the European Space Agency [ESA], and the Joint Research Centre [JRC])—and it covers a further 157 institutes designated by the signatory bodies.

The RMOs play an important role in the CIPM MRA. The RMOs are responsible for carrying out comparisons and other activities within their regions to support mutual confidence in the validity of the calibration and measurement certificates of their member NMIs. Through the Joint Committee of the RMOs and the BIPM (JCRB), they carry out an interregional review of declared capabilities before approved CMCs are published in the KCDB, and they make policy suggestions to the CIPM on the operation of the CIPM MRA.[4]

The two preconditions for participating as an NMI in the CIPM MRA are as follows: (a) the country must be a member state of the BIPM or an associate member and economy of the CGPM, and (b) an RMO must be in place through which to submit its CMCs for consideration. Hence, for countries unable to meet these preconditions, accreditation is the only feasible way to gain some recognition until they both become a signatory or associate member and establish an RMO that is recognized by the BIPM.

4.10.2 Accreditation

Under the CIPM MRA, a working quality management (QM) system according to ISO/IEC 17025 has to be demonstrated (ISO and IEC 2017). This can be done through either self-declaration or accreditation. Calibration laboratories on the secondary level are accredited, because the choice of self-declaration is open only for NMIs or designated institutes.

4.11 THE INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY (OIML)

The International Organization of Legal Metrology (OIML) is an intergovernmental treaty organization established in 1955 on the basis of a convention, which was modified in 1968. The office of the OIML is in Paris.

4.11.1 Purpose

The purpose of the OIML is to promote the global harmonization of legal metrology procedures. In 2017, the OIML had 62 member states (states that have ratified the convention) and 64 corresponding members that joined the OIML as observers. The OIML gives effect to its purpose in the following ways:[5]

- Develops model regulations, standards, and related documents for use by legal metrology authorities and industry
- Provides mutual recognition systems, which reduce trade barriers and costs in a global market
- Represents the interests of the legal metrology community within international organizations and forums concerned with metrology, standardization, testing, certification, and accreditation
- Promotes and facilitates the exchange of knowledge and competencies within the legal metrology community worldwide
- Cooperates with other metrology bodies to raise awareness of the contribution that a sound legal metrology infrastructure can make to a modern economy

4.11.2 OIML International Recommendations

The OIML International Recommendations deal with elements such as (a) scope, application, and terminology; (b) metrological requirements; (c) technical requirements; (d) methods and equipment for testing and verifying conformity to requirements; and (e) test report format.

Project Groups (PGs) within the OIML's Technical Committees (TCs) and Subcommittees (SCs) develop the organization's technical publications. The International Committee of Legal Metrology (CIML), the functional decision-making body of the organization, allocates the secretariats of TCs and SCs, and the convenorships of PGs, to member states. TCs, SCs, and PGs are composed of the following:

- *Participating Members (P-Members):* Member states willing to participate actively in the work of TCs, SCs, or PGs. P-members have voting rights.
- *Observer Members (O-Members):* Member states that wish to follow the work of TCs, SCs, or PGs without voting rights. Corresponding members may also be O-Members.
- *Liaison Organizations:* Organizations interested in following the work of the TCs, SCs, or PGs.

After acceptance by a PG, draft publications are submitted to the CIML for approval, where all member states have voting rights.

4.11.3 The OIML Certification System

The OIML Certificate System, introduced in 1991, gives manufacturers the possibility of obtaining an OIML Certificate and a Test Report to indicate that a given instrument type complies with the requirements of the relevant OIML International Recommendations. These certificates can be used by national legal metrology agencies globally to issue national-type approval certificates, thereby avoiding multiple testing and the associated additional costs thereof.

In 2003, the OIML introduced the OIML Mutual Acceptance Arrangement (OIML MAA) as a tool to increase the level of mutual confidence provided by the OIML Certificate System. The OIML MAA was implemented in January 2005, and its purpose is to establish a worldwide multilateral arrangement that offers a wider scope than bilateral or regional arrangements.

In 2018, the single OIML Certification System (OIML-CS) was introduced to replace the former OIML certificate systems. The biggest change was the requirement for so-called Issuing Authorities to demonstrate their competence by peer evaluation or accreditation. Today the OIML-CS remains a voluntary system for issuing, registering, and using OIML Certificates of Conformity and associated OIML Type Evaluation Reports for types of measuring instruments based on the requirements of OIML Recommendations.

Certificates are issued by OIML member states that have established one or more Issuing Authorities responsible for processing applications from manufacturers wishing to have their instrument types certified. Acceptance of these certificates becomes mandatory if a country decides to become an official "utilizer" of the OIML-CS. The Issuing Authorities may send a copy of the certificates to the OIML Bureau in Paris for registration, which requires a registration fee. The list of registered certificates is published on the OIML website.[6]

4.12 METROLOGY ORGANIZATIONS AT THE NATIONAL LEVEL

Some countries operate a centralized metrology system with one NMI or one national legal metrology institute. Other countries operate a decentralized system with a lead NMI and additional designated institutes that hold national measurement standards in areas not covered by the NMI. The second tier of the national metrology system consists of calibration laboratories.

4.12.1 National metrology institutes

A national metrology institute (NMI) is an institute charged by national decision to hold (and in many cases, also develop) national measurement standards for one or more quantities.

Organization and service delivery

An NMI represents the country internationally and regionally in relation to the NMIs of other countries, the RMOs, and the BIPM. Depending on the economy and society needs, a number of NMIs undertake primary realizations of the metrological base units and derived units at the highest achievable international level, while many NMIs (typically in low- and middle-income countries) realize some units using secondary standards that are traceable to other NMIs (see also figure 4.1).

In addition to these activities, NMIs typically are responsible for the following:

- Establishment and maintenance of national measurement standards (primary or secondary) and measurement methods
- Participation in comparisons at the highest regional and international levels (see figure 4.3)
- Research in metrology and the development of new and improved measurement systems
- Dissemination of the SI units to laboratories, industry, academia, regulators, and others through calibration of their reference or working standards
- Provision of technical support to the secondary level of calibration laboratories, the industry, scientific research institutes, testing centers, and regulators in all metrology fields
- Coordination with the national accreditation body (NAB) regarding the accreditation of calibration laboratories and participation in auditing activities of the NAB
- Maintenance of a general overview of the national calibration and traceability hierarchy (that is, the country's national measurement system, as illustrated in figure 4.1)

Interlaboratory comparisons

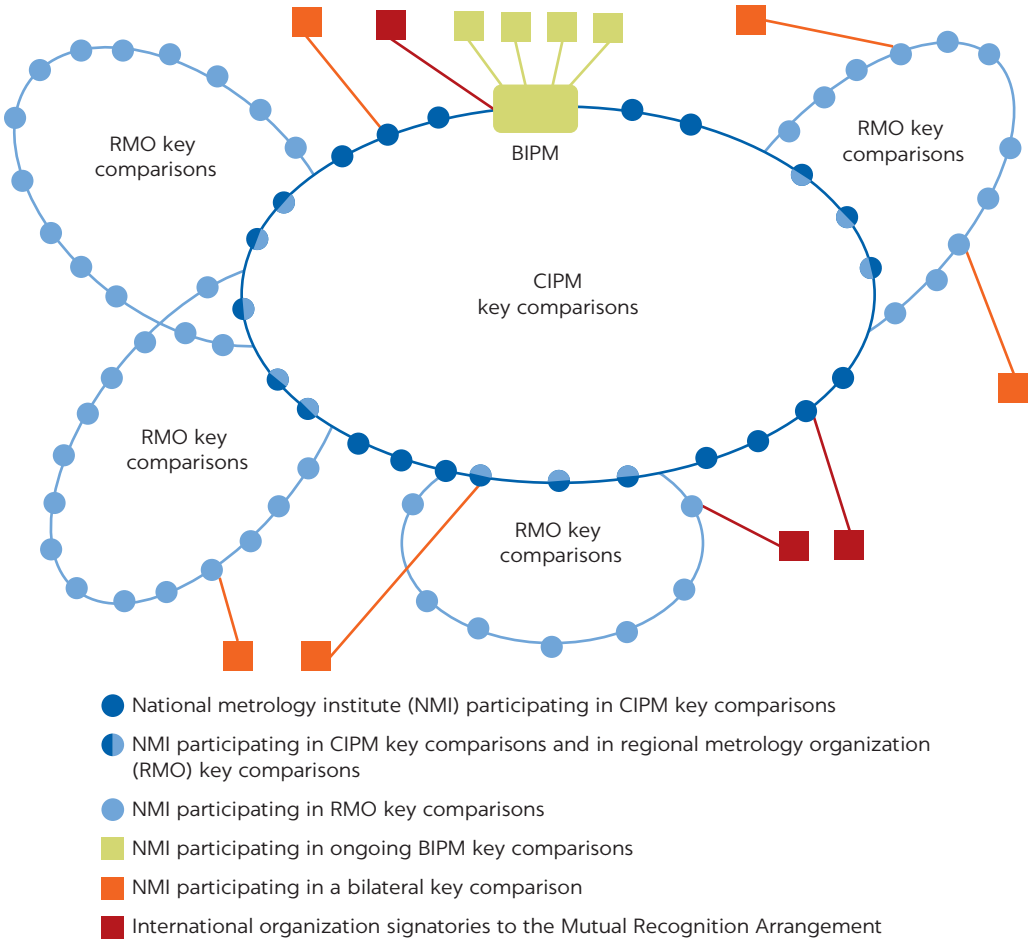
Participation in interlaboratory comparisons provides independent verification of an NMI's measurement capability, shows a commitment to maintenance and improvement of performance, and is a prerequisite for CMC declaration and accreditation. When beginning as an NMI, the interlaboratory comparisons can still be a low-key affair, overseen by a mature NMI acting and involving a smaller number of NMIs. As the NMI develops and matures, interlaboratory comparisons become more complex technologically and there are more of them.

The technical basis of the CIPM MRA is the set of results obtained over time through scientific key comparisons organized by the consultative committees of the CIPM, BIPM, and RMOs; published by the BIPM; and maintained in the BIPM's Key Comparison Database (KCDB). The key comparisons are of two types:

- *CIPM key comparisons,* of international scope, are carried out by those participants having the highest level of skills in the measurement involved and are restricted to laboratories of BIPM member states. The CIPM key comparisons deliver the "reference value" for the chosen key quantity.
- *RMO key comparisons,* of regional scope, are organized at the scale of a region (though they may include additional participants from other regions) and are open to laboratories of BIPM member states as well as BIPM associates. These key comparisons deliver complementary information without changing the reference value.

The key comparisons underpin the development of the CMCs, which are stated in terms of a measured unit and its uncertainty, and may include advice about the instrumentation used. A graphical representation of the BIPM key comparison scheme is shown in figure 4.3.

FIGURE 4.3
International key comparison scheme



Source: BIPM 2006. ©International Bureau of Weights and Measures (BIPM). Reproduced with permission from BIPM; further permission required for reuse.
Note: BIPM = International Bureau of Weights and Measures; CIPM = International Committee for Weights and Measures.

4.12.2 Designated institutes

The NMI or its national government, as appropriate, may appoint other institutes or laboratories in the country to hold specific national standards, and these laboratories are often referred to as "designated institutes," particularly if they participate in the CIPM MRA activities.[7]

Designated laboratories should be nominated in accordance with the metrological strategy for the different subject fields and in accordance with the metrological policy of the country. As the importance of metrology increases in nontraditional areas such as chemistry, medicine, and food, fewer countries have an NMI that covers all subject fields, and hence the number of designated institutes is currently growing.

4.12.3 Central metrology authorities

Legal metrology is the technical regulation part of metrology. The central metrology authority in a country is usually a government organization (for example, a government department, public agency, or similar entity) because of its main responsibility, namely, ensuring that the legal metrology legislation and regulations are being followed. In high-income economies, some of the activities of the legal metrology organization (for example, calibration and verification of measuring equipment falling within the scope of legal metrology legislation) could be devolved to private sector organizations.

Legislation for measuring instruments

People using measurement instruments and results that fall within the scope of legal metrology are not required to be metrological experts, and the government takes responsibility for the credibility of such measurements. Hence, instruments falling within the scope of legal metrology legislation should guarantee correct measurement results (a) under working conditions, (b) throughout the whole period of use, and (c) within given permissible errors.

Requirements are laid down in national legislation for measuring instruments and for measurement and testing methods falling within the scope of legal metrology, including prepackaged products. It is good practice to provide for enabling legal metrology legislation as first-level legislation, which is supported by secondary-level legal metrology regulations for individual measuring equipment or prepackaging. Legal metrology legislation is normally promulgated through a parliamentary process, which then gives the relevant minister the mandate to promulgate regulations for individual instruments or prepackaging. This facilitates keeping legal metrology legislation and regulations up-to-date as technology develops. To facilitate trade within a common market, legal metrology legislation is frequently determined at the regional level for adoption and implementation at the national level.

Typical measuring equipment falling within the scope of legal metrology include the following:

- *Trade*: Scales, fuel dispensers, alcoholic spirit measures, gas flow meters, water meters, electricity meters, taxi meters, and so on
- *Safety and health:* Sound level meters, thermometers, blood pressure meters, and so on
- *Traffic law enforcement:* Speed measuring equipment, weigh bridges, tire tread gauges, breathalyzers, and so on

- *Environmental protection:* Sound level meters, gas monitoring equipment, chemical measuring equipment, and so on

Measuring equipment that should be controlled through legal metrology legislation needs to be identified for each country, and a strategy for implementing the appropriate regulations over time should be in place. Alignment of such regulations with international recommendations as published by the OIML is good regulatory practice.

Type approval or conformity assessment of measuring equipment

Preventive measures are taken before marketing of the instruments; that is, measuring instruments have to be type-approved or conformity assessed. In addition, in some countries, virtually all instruments have to be verified before use.

Manufacturers are granted type approval or conformity assessment certificates by a competent body authorized by the government once that type of instrument demonstrably meets all associated legal requirements. With serially manufactured measuring instruments, verification ensures that each instrument conforms to type and fulfills all requirements laid down in the approval procedure.[8] Alternatively, in several countries, big series of measuring instruments can be conformity assessed by proving the conformity to type based on quality assurance of the production process of the given measuring instrument. This means that the production process has to be arranged in such a way that the testing of parts during the production process leads to conforming instruments. The corresponding quality assurance system for the production process has to support and document this approach.

The certificates are normally based on the definitive description of the instrument, test reports of the instrument type, the instrument's operational instructions, and its recommended calibration intervals. In higher-income economies, the testing may be conducted in an authorized or accredited national laboratory, but low- and middle-income economies often have to rely on test reports from elsewhere, a useful source being other OIML members. Therefore, the OIML-CS, which covers different kinds of measuring instruments, represents an important tool to facilitate easier international trade of measuring instruments and helps low- and middle-income economies if they become utilizers of the OIML-CS.

Market surveillance

The government is obliged to prevent measuring instruments that are subject to legal metrology controls from being placed on the market or put into use unless they comply with legal requirements. Market surveillance is an inspection type measure used in this regard. For trade, market surveillance checks whether the only instruments being used are those that conform to the relevant legislation. For instruments in use, periodic calibration and reverifications need to be carried out to ensure that the measuring instruments continue to comply with legal requirements. Market surveillance checks whether this is the case.

Many basic consumer goods may be marketed only in specified quantities (for example, 125 gram, 250 gram, 500 gram, and 1 kilogram packaging for butter) to help purchasers make appropriate purchasing decisions. Furthermore, all prepackaged goods have to comply with the quantity (such as weight, volume, or length) as stated on the packaging within legally defined

tolerance limits. During market surveillance, random checks are conducted to determine whether these measures are fulfilled by the suppliers of prepackaged goods in the marketplace.

4.12.4 Calibration laboratories

Measuring equipment requires recurrent calibration for a variety of reasons, whether the equipment is operated by industry, suppliers, test laboratories, regulatory authorities, or legal metrology agencies. Calibration to the secondary market (the end users of measuring equipment) can be provided by the NMI and by the legal metrology agency in the early stages of industrial development. But soon the volume of calibration work will require the establishment of secondary calibration laboratories to provide calibration services in this market. These could be independent public or private sector laboratories, or they could also be in-house entities in industry.

As independent calibration laboratories are established, the NMI's responsibilities change. The NMI should no longer be the main provider of calibration services in the secondary market but should rather support the work of the calibration laboratories. In fact, if the NMI does not disengage from its role as calibration provider in the secondary market, it will stifle the development of independent calibration laboratories. Ultimately, the calibration laboratories should provide most of the calibration services in the secondary market by far. The NMI's role to calibrate their measurement or working standards remains.

Calibration laboratories need to be able to demonstrate their technical capability. Hence, they should be accredited to ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories" [ISO and IEC 2017]), and their reference and working standards should be traceably calibrated to the national measuring standards. These could be either the country's own national standards or those of another country. Some calibration laboratories could also get involved in legal metrology—for example, providing calibration and verification services to users of measuring equipment that fall within the scope of legal metrology regulations. For this they would need to be designated by the legal metrology agency on fulfilling relevant requirements.

NOTES

1. The term "fundamental metrology" is also used, and although it is formally undefined, it is considered the top level of scientific metrology, which strives for the highest degree of accuracy.
2. The term standard reference material (SRM) is also used in some parts of the world and is synonymous with a CRM.
3. When coherent units are used, equations between the numerical values of quantities take exactly the same form as the equations between the quantities themselves. Thus, if only units from a coherent set are used, conversion factors between units are never required (BIPM 2006).
4. The detailed documentation of the rules and procedures of the CIPM MRA are available from the BIPM website (http://www.bipm.org/en/cipm-mra/), as is the list of all the signatories and the complete KCDB.
5. See "What Is the OIML?" on the OIML website: https://www.oiml.org/en/about/about-oiml.

6. See the "Registered OIML Certificates" search tool: https://www.oiml.org/en/oiml-cs/certificat_view.
7. This designation should not be confused with the act of a government in "designating" an entity to provide QI services in the regulatory domain. In the case of metrology, the NMI signs the CIPM MRA and designates "other" metrology organizations (called Designated Institutions) to establish and maintain national measurement standards that it does not itself establish and maintain after signing the CIPM MRA. In the case of regulatory work, the government performs any designations because the government is ultimately accountable for the implementation of technical regulations.
8. Calibration determines the differences between the measured value, as indicated by a measuring instrument, and a measurement standard. Verification determines whether this difference falls within stated legal limits.

STANDARDS REFERENCED IN MODULE 4

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5

Accreditation

INTRODUCTION

Of the three core elements of the quality infrastructure (QI), accreditation is a much more recent phenomenon than standards and metrology, having developed mostly after World War II. But accreditation has become as important as standards and metrology, especially in countries that are dependent on global trade, because of its facilitating role in international recognition systems for the services of the QI.

5.1 DEFINITION AND SCOPE

Accreditation in the QI context is the formal attestation or statement by an independent third party (the accreditation body) that a conformity assessment body or calibration laboratory is competent to carry out a specific conformity assessment task or calibration services. This statement is based on the positive outcome of a review determining whether the conformity assessment body or calibration laboratory fulfills the relevant criteria for its accreditation (ISO and IEC 2004).

From the point of view of conformity assessment, accreditation is applicable in the case of laboratories, inspection bodies, certification bodies, validation and verification bodies, and bodies that certify personnel. Accreditation has been practiced in laboratories since the 1940s. Users of laboratory services are therefore often familiar with accreditation and have a good understanding of its value. Accreditation of certification bodies is a more recent activity. This has come about in response to the extraordinary demand for certification and hence the need to demonstrate the technical competency of the certification bodies. Similarly, accreditation of inspection bodies is a recent and growing activity.

Generally speaking, the international standards of the International Organization for Standardization and International Electrotechnical Commission (ISO/IEC) 17000 series ("Conformity Assessment") have come to dominate the accreditation environment, but national standards or norms not harmonized with the ISO/IEC 17000 series are still used in some countries.

For international recognition, however, the application of the ISO/IEC 17000 series is very much an imperative.

Other international systems related to the QI that require accreditation include the following:

- *Good Manufacturing Practices (GMP)*, as defined by the World Health Organization (WHO), which are used by pharmaceutical regulators and the pharmaceutical industry worldwide
- *Principles of Good Laboratory Practice (GLP)*, as defined by the Organisation for Economic Co-operation and Development (OECD), which are applicable to nonclinical studies conducted for the assessment of the safety or efficacy of chemicals (including pharmaceuticals) to humans, animals, and the environment and have been introduced in many countries

Private sector certification systems based on private standards (see module 3: Standards, section 3.3) frequently use their own accreditation criteria to recognize conformity assessment bodies wishing to participate in the particular certification scheme. The same applies to the automotive industry: the vehicle manufacturers operate their own accreditation mechanisms to manage their suppliers.

Accreditation as a concept is also used in many disciplines other than conformity assessment—for example, the accreditation of universities, financial institutions, medical facilities, vocational training institutions, and so on. Although the concept of accreditation is similar to that practiced in the QI, these disciplines are not considered in this module; the standards and norms they use are different from the ISO/IEC 17000 series, for example. The scopes of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) and Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) can also be considered for refining the scope of accreditation within the context of the QI.

5.2 INTERNATIONAL STANDARDS

The international standards published by the ISO and IEC dealing with accreditation are listed in table 5.1. As these are continuously updated, details on the latest issues should be obtained from the ISO. Accreditation of each type of conformity assessment body (CAB) is further discussed below.

5.2.1 Accreditation of QI services

Calibration laboratories. Accreditation has traditionally covered calibration laboratories (as discussed in module 4: Metrology) as well as, more recently, other supporting services for laboratories such as proficiency testing providers, reference material providers, and metrology research laboratories.

Testing laboratories. Accreditation initially focused on laboratories undertaking conventional testing of products and materials in biology, chemistry, engineering, and physics. The scope of accreditation is very specific and is expressed in terms of a combination of disciplines, products, tests, and standards. For example, a laboratory may be accredited for chemical testing of steel for carbon and various alloying elements by the methods described in a particular standard,

TABLE 5.1 Standards for the accreditation of common conformity assessment bodies (CABs) and calibration laboratories

TYPE OF CONFORMITY ASSESSMENT BODY (CAB)	INTERNATIONAL STANDARD FOR ACCREDITATION OF THE CAB	REQUIREMENTS AND STANDARDS FOR CAB CLIENTS
Calibration laboratories	ISO/IEC 17025:2017	Various measurement- and instrument-specific requirements
Testing laboratories (general)	ISO/IEC 17025:2017	Various measurement- and product-specific requirements
Proficiency testing providers	ISO/IEC 17043:2010	Providers of proficiency testing schemes
Producers of certified reference materials (CRMs)	ISO 17034:2016	The production and assignment of property values of CRMs
Medical laboratories	ISO 15189:2012	Various diagnostic tests
Inspection bodies	ISO/IEC 17020:2012	Various product and regulatory requirements
Certification bodies		
a) Quality management system	ISO/IEC 17021-1:2015	ISO 9001:2015
b) Environmental management system	ISO/IEC 17021-1:2015	ISO 14001:2015
c) Food safety management system	ISO/IEC 17021-1:2015	ISO 22000:2005 HACCP[a]
d) Product certification	ISO/IEC 17065:2012	Various product-specific requirements
e) Service and process certification	ISO/IEC 17065:2012	Various service- and process-specific requirements
f) Certification of persons	ISO/IEC 17024:2012	Various skill-specific requirements
g) Validation and verification	ISO/IEC 17029 (under development)	Various validation and verification requirements

Note: IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; Listed ISO and ISO/IEC standards are further described among the references at the end of module 5.

a. Hazard analysis and critical control points (HACCP) is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe. An international guideline is published by the Codex Alimentarius Commission (CAC/RCP 1-1969) that has been adopted as a national standard by many countries.

but the same laboratory may not be accredited for other methods. In recent years, the same principles have been applied to laboratory medicine (where the principal objective is diagnosis and monitoring rather than conformity assessment), diagnostic imaging (medical radiology and others), forensic science, and software testing.

Certification bodies. Accreditation for certification bodies in the early 1980s was originally concerned with product certification bodies whose scopes could be readily defined in terms of products and standards and in relation to performance or safety. Accreditation for certification bodies for management system standards was developed in the 1990s with the advent of ISO 9001 ("Quality Management Systems—Requirements"), and it became extraordinary successful. The definition of the scopes became much broader than the very precise definitions for laboratory work and product certification because they relate to general industry activities. Certification schemes for other system standards—such as ISO 14001 ("Environmental Management Systems"), ISO 22000 ("Food Safety Management Systems"), and hazard analysis and critical control points (HACCP)—followed.

Inspection bodies. Inspection bodies are the most recent type of conformity assessment service being subjected to accreditation. The significance of this accreditation is on the increase as government inspectorates in many countries are reduced and their activities are taken over by the private sector. In these situations, accreditation provides assurances of continuing competence and

is used by governments as an element in the recognition or designation of inspection bodies.

Certification of persons. Although not a conformity assessment service, certification of persons is considered part of the ISO/IEC 17000 series ("Conformity Assessment"), and international recognition is arranged through the International Accreditation Forum (IAF) recognition arrangements. This certification relates to the recognition of individuals possessing particular knowledge, experience, or skills and demonstrating the ability to apply those skills. These criteria are distinct from having acquired academic qualifications, although such qualifications may be a prerequisite for the certification process.

The process of personnel certification must be independent of the training programs leading to certification. The breadth and scope of certification programs today are tremendous; programs exist for safety professionals, nondestructive testing experts, supply and purchasing management professionals, the construction industry, quality system auditors, and many others.

Validation and verification bodies. Validation and verification is a confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Validation and verification as conformity assessment are understood to be a confirmation of the reliability of information contained in claims. Other terms in use for the object of assessment by validation and verification are statement, declaration, assertion, prediction, or report.

Both activities are distinguished according to the perspective of each assessment regarding the timeline of the assessed claim. *Validation* is applied to claims regarding an intended use or projected effect (confirmation of plausibility). *Verification* is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

5.2.2 Accreditation as the measure of competence and impartiality

The final objective of accreditation is to provide an independent view on whether the entity accredited is technically competent and impartial. Hence, over and above the management system documentation and controls that must be implemented, the technical competence of the individuals working in this entity is of paramount importance.

Likewise, the accommodation and environmental control requirements can be quite substantial, especially in the field of metrology. The controls are usually more stringent as the measurement, calibration, and testing accuracies increase. All of these will be assessed during the accreditation process.

5.3 UTILIZATION AND OUTCOMES OF ACCREDITATION

Accreditation has grown from its humble beginnings as just a measure of a laboratory's competence within a specific economy to a system with wide acceptance and use worldwide. The increase in trade of the past two or three decades demanded more certainty across borders regarding the integrity of conformity assessment results. Accreditation emerged as the vehicle to provide this

certainty, countering expensive and time-consuming reassessments every time a product enters a new market.

5.3.1 Users of accreditation

Governments. Accreditation is used by governments as a robust and credible framework to establish and enhance government-to-government trade agreements. These could be bilateral or multilateral negotiated agreements, or accreditation could be required as the precondition for the acceptance of conformity assessment outputs across member states of a common market. The long-term aim is the fully accepted use and recognition, by both the public and private sectors, of accredited conformity assessment services among the members of the agreements. In this way, the free-trade goal "inspected, tested, and certified once, accepted everywhere" is slowly being realized.

Regulatory authorities. Accreditation represents an internationally recognized "stamp of approval" of conformity assessment services used to demonstrate compliance of products with technical regulations and sanitary and phytosanitary measures. Credible accreditation schemes that are developed with due recognition of international standards are at the core of such acceptance. Such accreditation schemes can therefore help regulatory authorities meet their own legislative responsibilities in a globally accepted manner.

Businesses. Accreditation provides businesses that are producing goods and services with greater confidence in obtaining competent services from inspection bodies, laboratories, and certification bodies. Businesses can therefore select such suppliers from further afield, knowing they will receive services that conform to recognized standards of competency. Having products assessed and certified as conforming to a particular standard allows manufacturers and service providers to distinguish themselves from less reputable suppliers, thereby creating a competitive advantage. Accreditation also ensures that standards, specifications, and conformity assessment methods are the same, allowing one accredited certificate to be recognized worldwide. This lowers the cost of conformity assessment and reduces the risk of goods or services being rejected by international trading partners.

Consumers. Goods and services that have been tested and certified create consumer confidence if the conformity assessment is impartial and technically competent. Accreditation supports the notion that such testing and certification, from whichever country of origin, can provide trustworthy answers regarding quality and safety.

5.3.2 Outcomes of accreditation

Economy. Accreditation contributes to the overall development of the economy in that it helps open export markets to national industries, it underpins industrial development by strengthening competition, and it creates transparency in the markets by the clear description of competency scopes of accredited organizations. Accreditation also supports the implementation of anticorruption measures in that it requires of accredited organizations the traceability of results, annual audits, on-site assessments, peer evaluations, and management of records all along the process value chain.

Health and safety. Accreditation provides authorities and society with the assurance that services related to health and safety—such as medical laboratories, inspection bodies for occupational health and safety, inspection bodies for pressurized equipment, inspection bodies for lifts and escalators, and so on—are competent, thereby enhancing the safety and health of society as a whole. For medical laboratories, the ISO has published a specific international standard (ISO 15189, "Medical Laboratories—Requirements for Quality and Competence"), whereas other health- and safety-related services are handled by a combination of inspection and laboratory standards as relevant.

Environment. Environmental concerns are continuously growing, and many services are required by authorities, communities, and individuals regarding the efficacy of environmental protection measures. These could be inspection, laboratory, and certification services or a combination thereof. Accreditation assures authorities and communities that such services are competent, thereby underwriting the truthfulness of environmental protection measures.

5.4 IMPACT OF ACCREDITATION

5.4.1 U.K. Department for Business, Innovation, and Skills: The economics of accreditation

Attempting to estimate, in monetary or equivalent terms, the impact of accreditation presents considerable challenges because accreditation is an additional layer of assurance in a complex QI that could operate without it. A study conducted in the United Kingdom reached a number of indicative conclusions (Frenz and Lambert 2013). The research drew upon a wide spectrum of evidence, including published literature and case studies, interviews with experts in businesses and associations, empirical and statistical data, and a survey of United Kingdom Accreditation Service (UKAS) customers.

The report shows that accreditation provides assurance of technical and managerial competence and reliability across diverse parts of the economy, in both the market and public service sectors. The direct total cost to users was relatively low, but the leverage was high—that is, by supporting the QI, which in turn enabled higher-quality, more innovative, and safer economic activity.

There are multiple routes to economic benefit, and each shows a significant return on investment, although not all could be directly quantified. Commercial benefits to businesses, and to economic performance, arise through the promotion of innovation and productivity. It has been possible to arrive at an indicative quantification of these benefits, using information from the UKAS surveys:

- *In the market for the services covered by UKAS*, the immediate value to users—measured in willingness to pay and in-service quality—could be indicatively estimated at around £295 million per year.
- *Downstream effects on growth and productivity*—through support for both innovation-enhancing knowledge flows and technical and managerial efficiency—have been shown to be significant in estimated models of economic performance. These could be indicatively quantified as a further value of approximately £320 million per year.

Therefore, the measurable benefits of accreditation were estimated to be £600 million per year. Additionally, the following channels of impact could

be identified, although it was beyond the resources of the study to undertake the research and evidence gathering that would enable quantification. It would, however, be a plausible assumption that the totality of these benefits could be substantial, even though an educated guess at the order of magnitude was not possible:

- *Public health and safety* are advanced by accredited services in areas as diverse as diagnostic imaging, pathology laboratories, forensic testing, and the management of the risks from asbestos in buildings.
- *International trade* is enabled through the assurance of quality and reliability, while international mutual recognition of accredited testing and certification reduces potential barriers to trade.
- *Efficiency in industry* is promoted by accreditation support for the integrity of the national calibration and traceability hierarchy—the national measurement system (as discussed in module 4: Metrology)—which, among other things, leads to the avoidance of costs such as from waste and reworking arising from nonconforming measurement.

5.4.2 Technopolis Group and German Institute for Standardization: Development prospects for conformity assessment and accreditation in Germany

A research study on conformity assessment and accreditation in Germany was funded in 2012–13 by what was then the Federal Ministry for Economic Affairs and Technology (BMWi). The aim of the project was twofold: (a) to determine the economic importance of conformity assessment and accreditation, and (b) to identify the guidelines for future political involvement of the BMWi in this area (Technopolis Group and DIN 2013). The former determination was based on an analysis and forecast of the market for conformity assessment. Then, based on the conclusions regarding demand for the conformity assessment, demand for accreditation in selected areas was formulated. Two additional issues were also addressed:

- Which economic and technology areas should be part of the regulatory domain (for example, technical regulations, sanitary and phytosanitary measures, pharmaceutical regulations, and so on)?
- In which fields of the regulatory domain would a proof of competence through accreditation make sense?

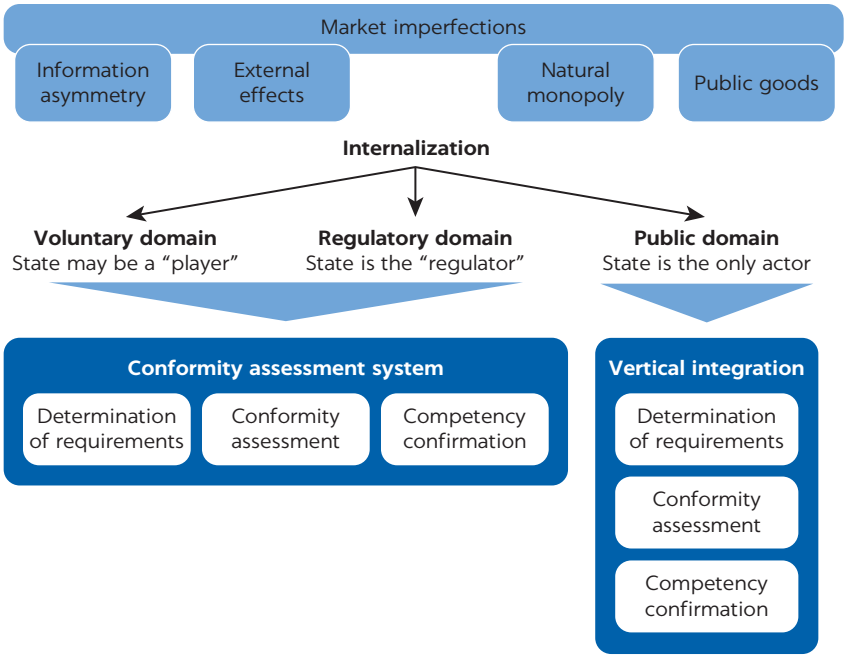
The Technopolis Group developed an economic model to determine or at least estimate the economic importance of conformity assessment and accreditation (figure 5.1). The elements of the conformity assessment system included the following:

- *Determination of the requirements* (for example, standards)
- *Conformity assessment*—that is, a demonstration that a product, process, system, person, or conformity assessment body meets specified requirements
- *Confirmation of the competence* of the conformity assessment service providers, which can be performed by public authorities or an independent accreditation body

In 2010, nearly 5,400 conformity assessment service providers were active in Germany, with a turnover of €8.8 billion. The study estimated that approximately €6 billion of this turnover was generated in Germany. About 3,300 of the service providers held one or more accreditation certificates of the German

FIGURE 5.1

The role of conformity assessment to address market failures



Source: Technopolis Group and DIN 2013. ©Federal Ministry for Economic Affairs and Technology (BMWi). Reproduced with permission from BMWi; further permission required for reuse.

Accreditation Body (DAkkS). But the economic importance of conformity assessment and accreditation is significantly higher because of their indirect effects:

- There is a "leverage effect" of the two instruments, because sales volume depends on them in the product and services markets. These are large multiples, estimated as a factor of 35–60 in conformity assessment, which translates to about 100 for accreditation.
- Public policy considerations show that many markets would not function at all or far less than optimally if conformity assessment and accreditation could not be used to address market imperfections.

As for the second objective of the study—to set guidelines for the future political activities of the BMWi in this area—two possibilities presented themselves in the regulatory domain: (a) shifting some of the voluntary domain sectors into the regulated domain, and (b) moving some of the public domain sectors (that is, the state conducting conformity assessment) into the regulated domain (that is, the state relinquishing conformity assessment but retaining regulatory authority responsibilities).

The latter could be construed as a type of deregulation. The German government should therefore evaluate its relevant public domain activities to decide whether the private sector's conformity assessment service providers could not take over the state's activities without compromising the health and safety of society in the process—that is, if and when the state's role changes to that of the regulator. On the other hand, moving voluntary domain activities into the regulatory domain should be contemplated only in specific cases where market imperfections or failures have resulted in demonstrable medium- and long-term health and safety risks that will not be addressed by the voluntary domain actors.

5.5 INTERNATIONAL AND REGIONAL RECOGNITION

Accreditation is considered one of the main facilitators for the recognition of conformity assessment results in foreign markets—expressed as "inspected, tested, and certified once, accepted everywhere." Hence international recognition, including regional recognition, is an important parameter for any national or regional accreditation body to pursue.

5.5.1 International recognition: The IAF and ILAC

The two major international organizations managing conformity-assessment recognition arrangements are the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF).[1] ILAC provides for multilateral recognition arrangements regarding accreditation of testing and calibration laboratories, medical laboratories, and inspection bodies. The IAF provides for them regarding accreditation of management system certification bodies, product certification bodies, and personnel certification bodies. ILAC and the IAF work closely together to ensure that no overlaps exist between their portfolios.

Accreditation bodies can become "associate members" (ILAC) or "accreditation bodies" (IAF) as a precursor to becoming signatories to the recognition agreements or arrangements. Signatory status is achieved only once a peer evaluation resulting in a positive outcome is conducted, based on the requirements of ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies") and the related interpretation documents of ILAC and the IAF. The peer evaluations of accreditation bodies by recognized regional cooperation bodies or groups are accepted in full by both ILAC and the IAF (as further discussed in section 5.5.2 below, "Regional Recognition").

Signatories commit to (a) maintain compliance with ISO/IEC 17011 and the relevant IAF and ILAC interpretation documents, and (b) recognize the competence and impartiality of accredited conformity assessment bodies by all other signatories to the recognition arrangements. This facilitates the acceptance of the output of accredited organizations (for example, test reports, calibration certificates, and product- and management-system certificates), not only in the territories of all the signatories, but also worldwide. Such acceptance by other actors is not guaranteed; it still depends on the customs and practices of the markets and regulatory authorities.

Therefore, international recognition through the ILAC and IAF systems can be productively used by market actors and regulatory authorities to accept the certificates and results of conformity assessment bodies and laboratories that are accredited by accreditation bodies (even those in other countries) that are signatories to the relevant recognition arrangements. This, however, requires the market actors or regulatory authorities to engage positively with this international system; it is not a given that this must happen. The situation is strengthened if the governments involved formalize such recognition in a bilateral or multilateral recognition agreement. In regional common markets, such recognition is often provided for in the regional markets' legal instruments.

5.5.2 Regional recognition: Regional accreditation cooperation bodies and groups

At the regional level, a number of organizational types related to accreditation have developed over the past few decades that should not be confused. These consist of the bodies and groups involved in the recognition of accreditation bodies as well as the committees and forums established in common markets to harmonize accreditation issues (similar to the regional metrology organizations, as covered in module 4: Metrology, section 4.9). For regular regional accreditation bodies providing accreditation services, see section 5.6.

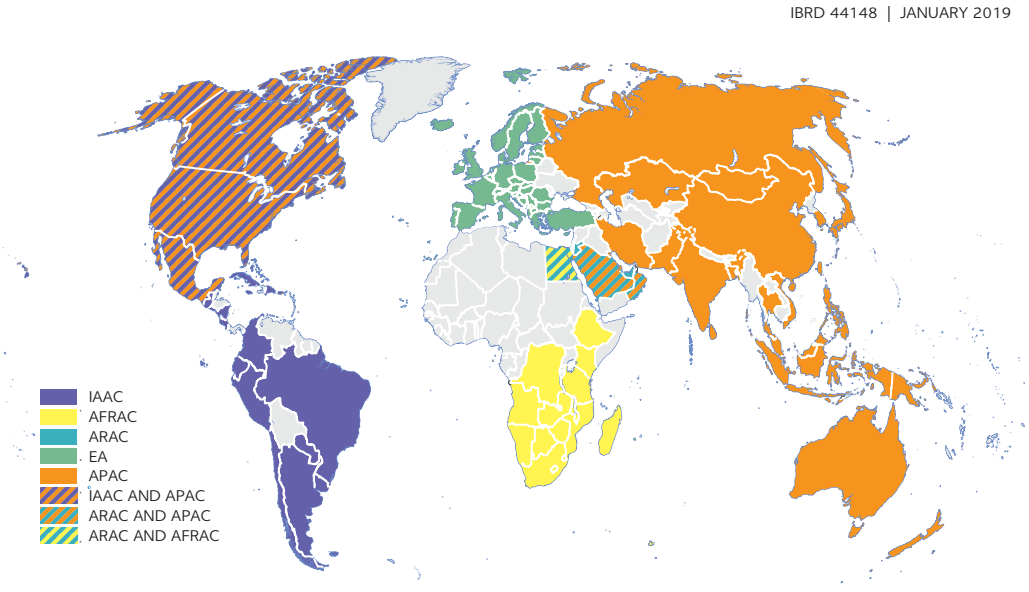
Owing to the increase of accreditation bodies worldwide, many peer evaluations for international recognition are now arranged through recognized regional cooperation bodies and groups rather than directly by ILAC and the IAF themselves.[2] Liaison between national accreditation bodies and these bodies and groups is therefore an important necessity. The situation regarding recognition of these bodies and groups by ILAC and IAF is very fluid, and the latest information regarding the status of such bodies needs to be obtained from the ILAC and IAF websites.[3]

At the time of this writing, six such bodies or groups were recognized, as it is these groups that perform most of the peer evaluation activities, no longer ILAC and the IAF (map 5.1):

- European Cooperation for Accreditation (EA), recognized by both ILAC and the IAF
- Asia Pacific Laboratory Accreditation Cooperation (APLAC), recognized by ILAC

MAP 5.1

Regional accreditation cooperation bodies and groups recognized by the IAF and ILAC, 2018



Source: World Bank, from ILAC and IAF membership data.
Note: The breakdown indicates countries whose accreditation bodies are signatories to multilateral recognition arrangements or agreements. Countries of nonsignatory members, e.g., associate members, are not included. Breakdown is as of January 2019. AFRAC = African Accreditation Cooperation; APLAC = Asia Pacific Laboratory Accreditation Cooperation; ARAC = Arab Accreditation Cooperation; EA = European Cooperation for Accreditation; IAAC = InterAmerican Accreditation Cooperation; IAF = International Accreditation Forum; ILAC = International Laboratory Accreditation Cooperation; PAC = Pacific Accreditation Cooperation.

- Pacific Accreditation Cooperation (PAC), recognized by the IAF
- InterAmerican Accreditation Cooperation (IAAC), recognized by both ILAC and the IAF
- African Accreditation Cooperation (AFRAC), recognized by both ILAC and the IAF
- Arab Accreditation Cooperation (ARAC), recognized by both ILAC and the IAF

In addition to the ILAC- and IAF-recognized regional cooperation bodies and groups, regional accreditation cooperations, committees, and forums have been established as the outcome of trade agreements leading to regional common markets. These common markets do not always coincide with the accreditation bodies and groups recognized by the IAF and ILAC. In many cases, NABs and RABs are members by default, having to represent their countries in these regional constructs. Some of these have full-time staff and premises; others are liaison-type committees with only a secretariat. Some are forums where a regional approach to accreditation is discussed and agreed to; others only coordinate accreditation development activities across the region. Many of them coordinate their activities with the recognized IAF and ILAC regional cooperation bodies and groups.

5.5.3 Other recognition mechanisms

A number of sector-specific accreditation and recognition schemes are managed by organizations other than ILAC and the IAF, including these typical examples:

- *Automotive sector:* United Nations Economic Commission for Europe (UNECE) 1958 and 1998 Agreements, managed by the World Forum for Harmonization of Vehicle Regulations (also known as UNECE Working Party 29)
- *Electrotechnical sector:* The IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) Certification Body (CB); Equipment for Use in Explosive Atmospheres (IECEx); and Quality Assessment System for Electronic Components (IECQ) schemes, managed by the IEC
- *Legal metrology equipment:* Mutual Acceptance Arrangements (MAAs), managed by the International Organization for Legal Metrology (OIML)
- *Pharmaceutical sector:* Good Manufacturing Practices (GMP), managed by WHO
- *Environmental health and safety research facilities:* Principles of Good Laboratory Practice (GLP), managed by the OECD
- *Private sector standards:* Certification schemes based on private standards such as GLOBAL G.A.P., Fairtrade, the Forest Stewardship Council (FSC), the Marine Stewardship Council (MSC), and others (see module 3: Standards, section 3.3 on "Private Standards")
- *Food sector:* Establishment of Halal certification schemes in some Muslim countries, the certification bodies of which are accredited

All of these entities have their own scheme-specific requirements, and details can be found on their respective websites. National accreditation bodies can get involved in some of these (for example, GMP and GLP), but others are managed by the relevant private sector multinational certification organizations.

5.6 REGIONAL AND NATIONAL ACCREDITATION BODIES

Accreditation services are provided either by national accreditation bodies or regional accreditation bodies.

5.6.1 Regional accreditation bodies

Regional accreditation bodies (RABs)—organizations that provide accreditation services to smaller countries in a region established by a trade agreement—have been established in some regions and are slowly gaining recognition through ILAC and the IAF, such as Southern African Development Community Accreditation Services (SADCAS). These are usually registered as not-for-profit private sector entities in one of the countries of the region. They are not membership organizations, but their governance may include representatives of the region. They may even be provided with funds from the member states of the region in the initial stages until they become self-sufficient.

A country without a national accreditation body can enter into a formal agreement with an RAB to act as the de facto, or in some cases even the de jure, national accreditation body. The RABs face some serious challenges in managing the logistics to service the extensive areas and multiplicity of the membership of such a regional common market—challenges that are exacerbated if language differences exist among member states. Sometimes, political issues and general distrust between members states get in the way. A further complication to be managed concerns the relations between the RAB and national accreditation bodies that may have been established in some of the member states.

5.6.2 National Accreditation Focal Points

In regions with an RAB, member states may establish national accreditation focal points (NAFPs) to act as liaisons between the RAB and entities wishing to be accredited. Furthermore, these NAFPs may play a role in the training and registering of local assessors to be used by the RAB to bring down accreditation costs for conformity assessment bodies in the smaller economies. In addition, they are often tasked with promoting the role of accreditation through awareness seminars, training of potential accredited organizations, and so on.

The focal point may be established in a relevant ministry (good option) or in the national standards body (not such a good option due to possible conflicts of interest). The role of NAFPs as liaison mechanisms is diminishing, however, because of modern communication links that result in entities wishing to be accredited communicating directly with the RABs.

5.6.3 National accreditation bodies

National accreditation bodies (NABs) provide accreditation services mostly within their countries, although some operate outside their national borders as well. There is no international agreement in place that would limit the number of accreditation bodies operating in a country, but it makes sense to do so (even though some governments may prefer to have more than one, each operating in a specific sector) for two reasons: First, every accreditation body has to obtain international recognition on its own. This is a costly process for the country unless the accreditation market is so big that it does not really matter.

Second, the question as to which one represents the country in international or regional forums could lead to some disquiet among the NABs and the government.

The EU required all member states to ensure that a single NAB be established for the implementation of technical regulations as of 2010. Germany, for example, had to merge nearly 20 accreditation bodies into a single NAB as a result.

To eliminate market uncertainty and competitive behavior among NABs that could compromise the accreditation process, many NABs sign agreements to keep out of the others' markets. In the Southern African Development Community (SADC), for example, the SADC Accreditation Service (SADCAS, the regional accreditation body) and SANAS (the South African National Accreditation Service) signed an agreement whereby SANAS would transfer all its accreditations that were outside South Africa but within SADC to SADCAS once SADCAS had achieved the appropriate international recognitions through the IAF and ILAC.

The same applies in the EU, where the NAB of one member state is not supposed to operate in the territory of another member state if both are internationally recognized. European accreditation bodies do, however, operate in countries outside the EU, but often transfer the accredited organizations to an NAB once it has achieved international recognition for the relevant scopes. In the United States, however, a limited measure of competition is tolerated.

Accreditation has become an important tool for the government in determining the technical capabilities of conformity assessment service providers. In general, governments are withdrawing more and more from direct inspection, testing, and certification activities in the regulatory field, transferring them to private sector operators. On the other hand, NABs could be public or private sector bodies. The legal issue that has to be managed is whether private sector bodies can operate with the required legal immunity in the technical regulation or sanitary and phytosanitary domain. This will depend on the legal system of the country; such immunity can be conferred on private sector bodies in some countries but not in others.

NABs and RABs can become signatories (that is, gain international recognition) for specific types of accreditation functions. The NAB or RAB does not gain a blanket international recognition through the IAF or ILAC. These are generally aligned with the international standards shown in table 5.1.

Becoming a signatory to the IAF or ILAC is a long journey; it takes quite a few years, even though the peer evaluation through regional bodies recognized by ILAC and the IAF is largely standardized. The NAB or RAB has to demonstrate compliance with the requirements of ISO/IEC 17011, and it must demonstrate that it can conduct assessments successfully. The peer evaluation is conducted on three levels:

- *Documentation review*. Records, documents, reports, certificates, decisions, minutes, rules, procedures, quality manuals, curricula vitae (CVs) of auditors, and the like of the NAB or RAB are evaluated by the peer evaluation team for compliance with ISO/IEC 17011, ILAC, or IAF requirements.
- *Participation, observation, and tracing back*. The peer evaluation team observes the NAB or RAB assessment team during an actual assessment to evaluate their performance and to determine whether they follow the NAB or RAB procedures.

- *Interviews and outcome analysis*. The peer evaluation team interviews accreditation staff, assessors, experts, committees, board, auditors, and evaluators and checks the quality and training systems to determine whether the overall operation of the NAB or RAB has, as an outcome, accreditations that are trustworthy.

The time that it takes to get recognized is a challenge, because the companies seeking accreditation are looking for internationally recognized accreditation certificates. One way out of this dilemma is for the NAB or RAB seeking recognition to sign a "twinning agreement" with another NAB that is already recognized. The assessments are conducted by teams representing both, and the accreditation certificate may be issued jointly. They are considered adequate evidence of successful accreditations by the IAF and ILAC. Once the NAB or RAB is internationally recognized, it becomes the sole accreditation organization for the entities accredited, and the twinning partner relinquishes its certificates.

A related issue is whether the NAB should be an independent organization or whether it can be combined with others in the QI. The main challenge is to ensure that the accreditation body operates totally autonomously from any financial pressures and other services that could compromise its impartiality. Therefore, most countries opt for a totally independent NAB. In a few countries, a combination of the NAB with the national standards body is operational (for example, the Standards Council of Canada, Standards Malaysia, and the like). The important parameter that precludes a conflict of interest is that no conformity assessment and calibration services may be provided by the entity.

The accreditation body could lose its recognition status. This is possible should the accreditation body consistently no longer meet the requirements of ISO/IEC 17011 and the related ILAC and IAF documents. All accreditation bodies are evaluated from once a year to once every four years where such evidence could be generated. Another reason for losing its signatory status would transpire if the accreditation body fails to pay its ILAC and IAF membership fees. Both ILAC and the IAF try to get the delinquent accreditation body on board again rather than summarily and publicly rescind its signatory status. Eventually, however, when the accreditation body does not respond in a positive way, it will disappear from the official list of ILAC and IAF signatories.

NOTES

1. The term "multilateral recognition arrangement" is used throughout this section as a generic term for various forms of recognition agreements or arrangements without denoting a specific form thereof. ILAC uses the term "mutual recognition arrangement" (MRA) for its scheme, whereas the IAF uses the term "multilateral recognition arrangement" (MLA). The word "agreement" is sometimes reserved for intergovernmental agreements, but this practice is not universal.
2. Because these organizations cannot be named regional accreditation bodies (RABs), in that this would bring about confusion with RABs providing actual accreditation services, ILAC and the IAF have given the organizations different names. ILAC lists them as Regional Cooperation Bodies or Recognized Regional Cooperation Bodies, whereas the IAF calls them Recognised Regional Accreditation Groups.
3. For up-to-date information, see the ILAC "Recognised Regional Cooperation Bodies" web page (https://ilac.org/ilac-mra-and-signatories/recognised-regional-cooperation-bodies/) and the IAF "Regional Accreditation Groups" web page (https://www.iaf.nu/articles/Regional_Accreditation_Groups/130).

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6

Conformity Assessment

6.1 CONFORMITY ASSESSMENT SPECTRUM AND DEFINITIONS

Conformity assessment is the collective term for a number of services based on the core functions of the quality infrastructure (QI): standards, metrology, and accreditation. It is defined as the demonstration that specified requirements of a product, process, system, person, or body are fulfilled in ISO/IEC 17000 ("Conformity Assessment") of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). The specified requirements may typically be stated in regulations, standards, and technical specifications.

Generally speaking, the elements of conformity assessment include inspection, testing, and certification used in all fields of investigation, innovation, process improvement, productivity, product development, product compliance, and many more. In some quarters, calibration is also considered conformity assessment, but it is not. Calibration belongs firmly within the metrology environment (as covered in module 4: Metrology).

6.2 INSPECTION

Inspection is the examination of a product design, product, process, or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Inspection of a process may include inspection of persons, facilities, technology, and methodology (ISO/IEC 17000).

Inspection therefore includes the concepts of information gathering (which could include testing and measuring), observation (including the conditions), and forming a judgment on the suitability for use or compliance with requirements. Judgment is an essential element of the process, and therefore inspection could be prone to some variability of outcome. For this reason, it is crucial that inspectors are thoroughly trained for the sectors in which they are expected to work.

TABLE 6.1 Users of inspection in trade-related activities

CATEGORY OF ACTIVITY INSPECTED	MANUFACTURER	CUSTOMER	REGULATOR	TRADER
Process control	X			
Compliance in relation to safety and other regulatory issues	X	X	X	X
Design verification		X	X	
Installation of a major plant		X	X	
Commission of a major plant		X	X	
Maintenance		X	X	
Quantity	X			X
Quality	X	X		X

Source: ITC 2011.

The definition also indicates that inspection is not limited to products or their manufacturing processes. Inspection is also applied in diverse activities such as design verification, installation and commissioning of equipment, in-service monitoring, regulatory affairs, financial auditing, and failure investigations. Table 6.1 provides an overview of the interests of organizations that use inspection in trade-related matters as an example of the wide application of inspection.

Such a variety of applications demands a careful consideration of the use of the term "inspection." For example, in quite a few economies, inspection is mostly used in the context of regulatory work, whereas in others it also covers commercial supervision by third-party bodies and in-house production control by the manufacturer.

6.2.1 Scope of inspection

Inspection is not limited to manufacturing processes or products. It is also widely used in such diverse activities as design verification, regulatory affairs, financial auditing, and failure investigation in both the regulated and nonregulated domains. In some economies, inspection is understood and mostly used in the context of regulatory control, while in reality it also covers commercial supervision by third-party bodies and in-house production control by manufacturers, as in the following cases:

- *In regulatory control,* inspection includes both premarket and in-market surveillance of products subject to technical regulations, for example. Inspection of the regulatory kind could also include the regular examination of products and installations for safety purposes, such as motor vehicles, cranes and lifting gear, lifts and escalators, boilers and pressure vessels, and electrical installations.
- *In the manufacturing sector,* inspection is an essential element of manufacturing control, and it includes testing and gauging or measurement. It includes the inspection of raw materials and components before production starts, physical examination of in-process product to assess its fitness to proceed in the manufacturing process, and the final inspection of the product before it is dispatched. Inspection departments are sometimes also responsible for calibrating process control instrumentation.

- *In complex manufacturing* (manufacture of complex products, assemblies, or installations) or if a product may have dire safety or economic consequences for the customer if it does not meet specified requirements, it is not uncommon for customers to either conduct their own inspections in parallel to the inspections of the manufacturer throughout the production cycle or to engage a specialized third-party inspection body to represent their interests. In such cases (for example, in shipbuilding, aircraft manufacturing, production installations, and the like), the customer will pay great attention to the inspection systems employed by the manufacturer and the management of those systems. Some of these inspection systems may also be defined in technical regulations (for example, regarding boilers and pressure vessels).
- *In export markets,* the government of an economy building its image as a high-quality manufacturer may deem it appropriate to institute inspection programs to ensure the quality of exported products. This was a key strategy for Japan for its optical sector, for example, implementing such export inspection after World War II and maintaining it for a few decades until the Japanese optical sector developed to the point where it conquered world markets.
- *In import markets,* a number of countries impose import inspection for the safety and health of the population, fauna and flora, and the environment. This could be in the form of inspection of imported goods at the border, but often multinational inspection organizations are contracted by the government to conduct such inspections at the source (preshipment inspection).

The scope of inspection is therefore extremely large and varied and is implemented by manufacturers, purchasers, and regulatory authorities alike. The latter may include regulatory authorities for products and legal metrology.

6.2.2 Types of inspection bodies

Inspection bodies can be in either the public or private sector. Whereas public sector inspection bodies are mostly engaged in regulatory-type work, private sector inspection bodies cover a vast spectrum of inspection activities in both the regulatory and nonregulatory domains. Three types of inspection bodies are generally recognized and defined in the relevant international standard (ISO/IEC 17020) on the basis of their formal separation from possible sources of influence (figure 6.1):

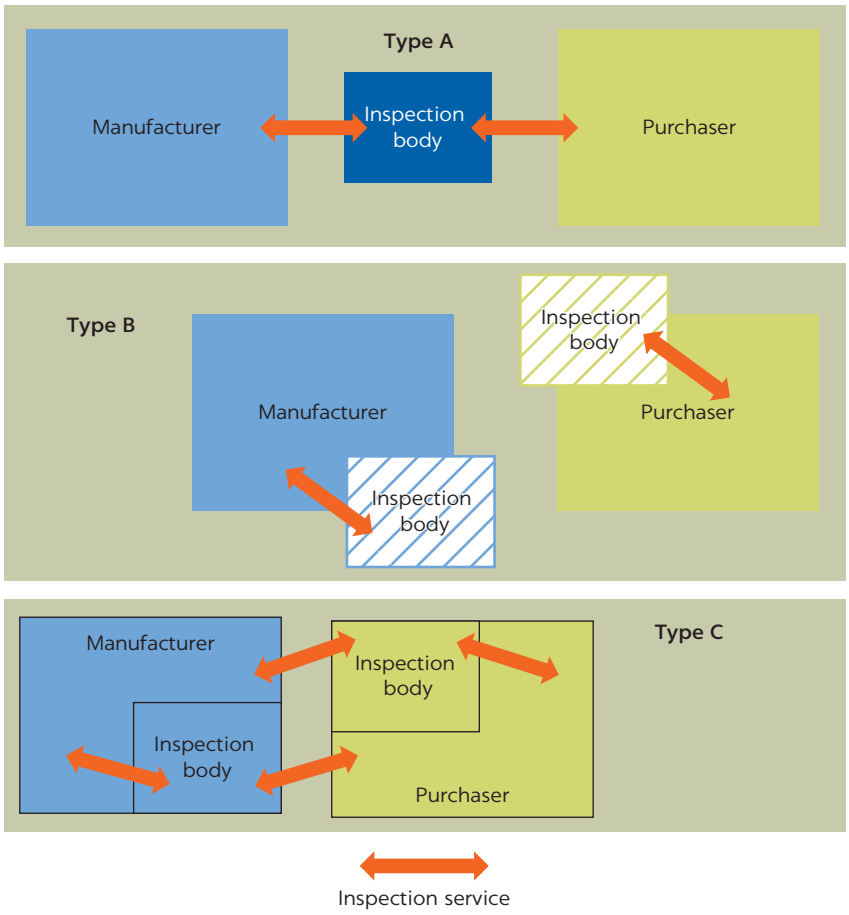
- *Type A:* Third-party inspection bodies not directly linked to the organization involved with the design, manufacture, use, or maintenance of items subject to inspection
- *Type B:* First- or second-party inspection bodies that are part of a supplier or user, forming an identifiable and separate part of the parent organization and providing only in-house inspections to the parent
- *Type C:* First- or second-party inspection bodies forming an identifiable, but not necessarily separate, part of the parent and providing inspection services to the parent organization or others

ISO/IEC 17020 also lists specific requirements regarding the impartiality of each part:

- *Type A inspection bodies* must be independent from both the supplier (first party) and the purchaser (second party) and not even remotely part of their legal identities. Furthermore, they must not directly be involved in the design,

FIGURE 6.1

Types of inspection bodies defined by ISO/IEC 17020



Note: ISO/IEC 17020 is the standard, "Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection." Types A, B, and C are defined on the basis of the extent of formal separation from possible sources of influence. *Type A* refers to third-party inspection bodies; *Type B* to first- or second-party bodies that are an identifiably separate part of the parent organization and supply only in-house inspections; and *Type C* to first- or second-party bodies that are an identifiable, but not necessarily separate, part of the parent and supply inspections to both the parent and others.

manufacture, supply, installation, purchase, ownership, use, or maintenance of the items to be inspected, nor should they be organizationally linked to any of the parties involved in the design, manufacture, supply, installation, purchase, ownership, use, or maintenance of the items to be inspected.

- *Type B inspection bodies* shall supply inspection services only to the organization of which the inspection body forms a part. This could be either the supplier or the purchaser. But a clear separation of the responsibilities of the inspection personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the inspection body within the parent organization. The inspection body and its personnel shall not be engaged in the design, manufacture, supply, installation, use, or maintenance of the items inspected.

- *Type C inspection bodies* form an identifiable, but not necessarily separate, part of the supplier (first party) or the purchaser (second party). They may provide inspection services to either the supplier or the purchaser and shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities between inspection and other activities. In other words, the design, manufacture, supply, installation, servicing, or maintenance of an item and the inspection of the same item carried out by a Type C inspection body shall not be undertaken by the same person. The inspections of Type C inspection bodies are not considered third-party inspections like the other two.

6.2.3 Relationship of inspection with other conformity assessment services

The international standard ISO/IEC 17020 has been developed considering inspection as a stand-alone activity. From its various uses as described above, it is quite clear that some form of inspection is frequently combined with, or part of, other conformity assessment services, such as product certification (see section 6.4) and testing (see section 6.3). When inspection is part of another conformity assessment activity, it may be necessary to adjust the requirements in ISO/IEC 17020 depending on inspection's role in the activity. Relationships between inspection and other conformity assessment activities that need to be considered, when relevant, include the following:

- When an inspection is used to reach a conformity assessment decision about the specific product being inspected, inspection may use testing, a service that should comply with ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories") to inform this decision. Product certification also relies on testing in accordance with ISO/IEC 17025 and even on inspection to inform the product certification decision. But product certification differs from inspection, in that it provides for the certification of an ongoing series of products where they are subject to a range of conformity assessment activities, whereas inspection determines compliance of only the inspected product.
- With product certification, the supplier is always the customer of the certification body, whereas with inspection the customer could be the supplier, the purchaser, or somebody else (such as a regulatory authority). The goal of product certification is to give confidence to the market regarding the supplier's capability of meeting the product requirements continuously. Hence, the certification body's decision will always rely heavily on its confidence regarding the supplier's control of the manufacturing process—confidence that is demonstrated by the supplier's quality control or quality management systems. The aim of inspection is only to give the party on behalf of which the inspection body is acting information on the compliance of the actual product being inspected.
- In product certification, when a certification body finds a nonconforming product during surveillance visits to the supplier or the market, it will require the supplier to implement corrective action to ensure that all future products comply. The certificate is not immediately withdrawn. If a product is found to be noncompliant during an inspection, the product is rejected; a certificate of compliance is not issued. Depending on the circumstances, the supplier

may have to replace the product, repair it, or lose the sale. Obviously, if the inspection takes place in-house during the manufacturing process, corrective action has to implemented to rectify the problem also for future products, which may include changes to the manufacturing process or controls.

- The scope of ISO/IEC 17020 does not cover quality management system certification. It may, however, be necessary for inspection bodies to examine certain aspects of the quality management system or other documented systems to justify the inspection results—for example, in the examination of processes.
- The scope of ISO/IEC 17020 also does not cover personnel certification activities. It may, however, be necessary for inspection bodies to consider aspects of the qualification of personnel (as inspectors or in the course of their inspections) to justify the inspection results.

6.3 TESTING

Testing is the determination of the characteristics of a product or commodity and, in the QI context, the evaluation thereof against the requirements of a standard (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). The output of a test laboratory is a test report or a test certificate. The scope of testing is immense, and it ranges from mechanical, electrical, metallurgical and civil engineering, and biological and chemical sciences to food technology, fiber technology, and many other areas.

Testing can be of a destructive or a nondestructive nature. It can be mundane, extremely complex, or anything in between. It can involve routine, state-of-the-art, or cutting-edge technology. Although testing is usually seen as taking place in a laboratory, it can also take place in the field or on-site following delivery and installation.

In short, the scope of testing is extremely wide. There are, however, some parameters that determine the integrity of testing services irrespective of the level of complexity or technological development (UNIDO 2011).

6.3.1 Uses of testing

The results of testing are used for many purposes. It is also important to realize that the boundaries between testing and inspection are sometimes quite blurred because there is some overlap; the same activity may be labeled as being in either field depending on country practices (as discussed earlier, in section 6.2). Some of the uses of testing include the following:

- Testing may provide adequate information to permit a conclusion on whether a product or commodity complies with requirements specified by regulatory authorities, purchasers, or other users.
- Testing of a prototype product is part and parcel of product certification, as is the continuous testing of samples of the subsequent production (see section 6.4).
- Testing of each individual product may be a prerequisite for the certification of low-volume, high-risk products such as medical devices or products for use in explosive environments.

- Testing is very much part of production control throughout the production value chain to ensure that completed products meet specifications and standards.
- A substantial amount of testing is concerned with data collection for scientific purposes, medical prognosis, and law enforcement rather than product compliance (for example, environmental measurements, testing of blood samples, and so on).

As manufactured goods become more technically sophisticated and market demand grows more stringent, testing will become an increasingly important part of trade protocols and trade agreements. The move to freer movement of goods, on the other hand, will call for a greater recognition of testing carried out in the country of origin, but this can happen only if end users have confidence in the competence of laboratories conducting tests in the first place. The ultimate objective is to have the product inspected, tested, or certified once and recognized everywhere.

6.3.2 Demand assessment

In a well-developed market economy, testing services are provided by a multitude of testing laboratories in both the public and private sector domains. These are exposed to market forces, just like any other service, to satisfy the needs of the country or markets. In low- and middle-income economies, however, this may not yet be the case. In such economies, the state is often required to establish and maintain the bulk of the test laboratories before a self-perpetuating market for testing has developed. Depending on a cost-benefit analysis, it may even be more cost-effective to send test samples to an existing laboratory outside the country rather than establishing one in the country.

A proper assessment as to the real needs of the authorities and industry is indicated. This should also include an overall assessment of the country's laboratory capacity, whether latent or active. Where they exist, regional laboratories should also be factored into the considerations. The information from such an assessment is an extremely useful point of departure for planning the further development of testing capacity in the country, the role of government in this respect, and the division of labor. The last is extremely important to counter the tendency of ministries, together with the donor community, to each establish their own public laboratories without regard to the unnecessary and costly duplication of resources.

This duplication has some further negative consequences, in that the financial sustainability of the individual laboratory is compromised, the small pool of trained laboratory personnel is stretched, and the amount of work in the country is barely enough to even keep one laboratory operating at an optimum capacity—with dire consequences for the quality of testing services among all of them.

6.3.3 Premises and environmental controls

Many testing laboratories are subject to some very specific accommodation requirements—for example, separating functions to ensure that no cross-contamination of samples can occur, separating laboratory space and offices to

ensure that personnel spend only testing time in the laboratories, and so on. In addition, most product testing follows the same rule: same temperature, same humidity, same altitude, same test speed, same test force, same test sequence, same number of test cycles, and so on.

Testing of textiles and polymers to ISO standards, for example, requires an environment of 20 ± 2 degrees Celsius and 65 ± 2 percent relative humidity. For paper and many rubber products, the requirement is 23 ± 1 degree Celsius and 50 ± 2 percent relative humidity. On the other hand, most mechanical and electrical engineering testing can be conducted at 15–30 degrees Celsius with a relative humidity not exceeding 70 percent. Continuity of electricity supply (24 hours per day, 7 days per week) is of major importance when tight environmental controls are to be maintained. These requirements need to be carefully articulated and provided for when building new premises or refurbishing old ones.

Another issue that is often overlooked when laboratories are designed in the Northern Hemisphere is the window orientation: the sun comes from the south; hence the main windows are oriented to the north so that the sun does not shine directly into laboratories. In the Southern Hemisphere, this situation is reversed: the sun comes from the north; hence the main windows should be oriented to the south. Architects appointed from donor countries—generally from the Northern Hemisphere—have to be sensitized regarding this issue. Otherwise laboratories are built with windows that are incorrectly oriented, resulting in impossible environmental control and a tendency for "hot spots" to develop.

6.3.4 Test equipment and consumables

Procurement of any test equipment has to be preceded by a clear choice of the particular test methodology to be applied. This is to ensure that the test equipment meets the test methodology requirements in all aspects, not just the preferences of the testing staff. It must be able to deliver test results under similar conditions that are consistent with results from other laboratories. The same applies to consumables that affect testing operations, such as the quality of gases, availability of chemicals, and so on.

A second major issue for low- and middle-income economies is the availability of maintenance and technical support for a particular make of test equipment. In this respect, it often is more useful to purchase a slightly more expensive piece of test equipment, but one for which maintenance is available, than to take the less expensive option for which no technical backup is obtainable in the country or in neighboring states.

6.3.5 Electricity supply

Electricity supply in many low- and middle-income economies does not meet the generally accepted stability criteria existing in high-income economies, for example, ±5 percent variance on voltage. In low- and middle-income countries, this variance can be as large as ±15 percent, interspersed with frequent electricity supply failures. Additional voltage stabilizers and uninterruptible power supply (UPS) equipment may need to be provided; otherwise, equipment may not perform to expectations or may even be damaged by voltage fluctuations.

6.3.6 Calibration and certified reference materials

Calibration of test equipment needs to be properly addressed. This presupposes a functioning metrology infrastructure within the country or access to one in a neighboring country. In addition, some test equipment has to be calibrated by using certified reference materials (CRMs) (discussed in module 4: Metrology, section 4.3.4) that are frequently available only from limited sources and are always costly. The long-term availability of such CRMs has to be assured, which often has more to do with the availability of scarce foreign exchange to pay for the CRMs than anything else. Obtaining customs clearance for toxic reference materials poses additional challenges.

6.4 PRODUCT CERTIFICATION

Product certification is the mechanism whereby a certification organization attests that products—either a batch or the continuous production thereof—have been inspected and tested by it and that the products collectively comply with specified requirements, usually contained in a standard (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). The attestation by the certification body is in the form of a certificate supported by a product certification mark that the manufacturer is entitled to affix on the product after being licensed to do so. The certification body therefore visibly endorses the quality of the product.

6.4.1 Product certification bodies and marks

Product certification services are offered by many certification bodies—in both the public and private sectors, at both national and international levels, and providing services in both the regulated and nonregulated domains. In low- and middle-income countries, the national standards body (NSB) is frequently the only organization offering a product certification service with any market relevance. The NSB's product certification mark is generally known as the national product certification mark. In high-income economies, product certification is provided by private sector certification bodies more so than NSBs, eventually leading to the total withdrawal of the state in many instances.

Because product certification requires immense marketing resources for a specific product certification mark to become well known and trusted by consumers in more than one country, multinational product certification bodies have developed in recent decades. National product certification marks, on the other hand, often find it difficult to gain market acceptance outside their countries of origin.

Product certification marks cover many types of products or product characteristics. Typical examples include the following, among many others:

- The British Standards Institution (BSI) Kitemark for general products, United Kingdom
- The South African Bureau of Standards (SABS) mark for general products, South Africa

- The Geprüfte Sicherheit (GS, for "tested safety") mark for product safety, Germany
- The Association for Electrical, Electronic & Information Technologies (VDE) mark for electrical and electronic equipment, Germany
- The Underwriters Laboratories (UL) mark for product safety, United States
- The American Society of Mechanical Engineers (ASME) mark for pressure vessels, United States
- The Canadian Standards Association (CSA) mark for general products, Canada
- The Keuring van Elektrotechnische Materialen te Arnhem (KEMA, for "Inspection of Electrotechnical Materials in Arnhem") mark for electrical equipment, Netherlands
- AGMARK for agricultural products, India

It must be noted that the ubiquitous Conformité Européenne (CE) marking is not a product certification mark but a regulatory device of the European Union (EU).[1]

6.4.2 Product certification schemes and processes

The process for product certification will always include an assessment of the product, whether sampled at the factory, from the batch, or from the marketplace. It may include an audit of the manufacturing process initially or on a continuous basis, or it may just be based on surveillance testing in the marketplace. Compliance with international standards for quality management systems such as ISO 9001 ("Quality Management Systems—Requirements") or hazard analysis and critical control points (HACCP) may be required, or manufacturing controls may be defined specifically for the product by the certification body.[2] Once compliance has been demonstrated, the manufacturer may be licensed to affix the product certification mark on the relevant product, on the packaging, or both, thereby denoting compliance with the standard and the endorsement of the certification body.

The various product certification schemes are defined in ISO/IEC 17067 (table 6.2), and the process is shown graphically in figure 6.2.

Which type of product certification scheme would be the most appropriate in a given situation will depend on circumstances, the mode of operation of the certification body, the sophistication of the industry sector, and other factors; there are no definitive rules. Type 1 (batch inspection) and type 6 (services) are clear. Types 4 and 5 are similar, in that both the product and the production process are considered. In type 4, the production is subject to process control, whereas type 5 requires a complete management system that includes process control. Type 4 is sometimes used for small and medium enterprises (SMEs) that do not have the resources for a quality management system, whereas type 5 is used for the more sophisticated industries.

Some certificates for schemes other than 1a or 1b would be valid for a limited period (typically one to three years), after which the certification body conducts a more in-depth review, rather than surveillance audits, and reissues the certificate. Other schemes have no time limit; as long as the certified organization pays the annual certification fees and surveillance audits do not identify major nonconformities that are not dealt with promptly, the certificate stays valid.

TABLE 6.2 Product certification schemes (ISO/IEC 17067)

SCHEME TYPE	DESCRIPTION
1a. Type certification	One or more samples are subjected to determination activities. A certificate of conformity is issued for the product type. Subsequent production is not covered.
1b. Batch certification	A representative sample is selected from a batch of products and subjected to determination activities. If the outcome is positive, the whole batch is certified.
2. Open market surveillance	Periodic samples of the product are taken from the marketplace and subjected to determination activities, after which the products are certified. The scheme identifies continuous conformity throughout the distribution channel, but the resources required are substantial. Effective corrective measures in the case of nonconformities may be limited.
3. Product testing in the factory	Periodic samples of the product are taken from the point of production and subjected to determination activities, after which the products are certified. The surveillance process may include a periodic assessment of the production process. The impact of the distribution channel is not known, but nonconforming products may be identified before distribution.
4. Product testing in the factory and from the market	Periodic samples are taken from the point of production, from the market, or both and are subjected to determination activities, after which the products are certified. The surveillance includes periodic assessment of the production process. The impact of the distribution channel on product quality is provided for, as is a premarket mechanism to identify nonconformities. Duplication of effort may take place for products that are not affected by the distribution process.
5. Product testing combined with quality assurance	A quality management system must be in place. After initial type testing, periodic samples are taken from the point of production, from the market, or both and are subjected to determination activities. The surveillance includes periodic assessment of the production process and the quality management system. The extent to which the four elements are used in surveillance depends on the definition of the scheme and on circumstances.
6. Services and processes	Determination activities consider intangibles (such as service quality, time delays, management responsiveness, and so on) and tangibles in service quality support (such as cleanliness of vehicles, process controls, and so on). The surveillance includes periodic assessments of both the management system and the quality of the service or process.

Note: ISO/IEC 17067 is the standard, "Conformity Assessment—Fundamentals of Product Certification and Guidelines for Product Certification Schemes" (ISO and IEC 2013).

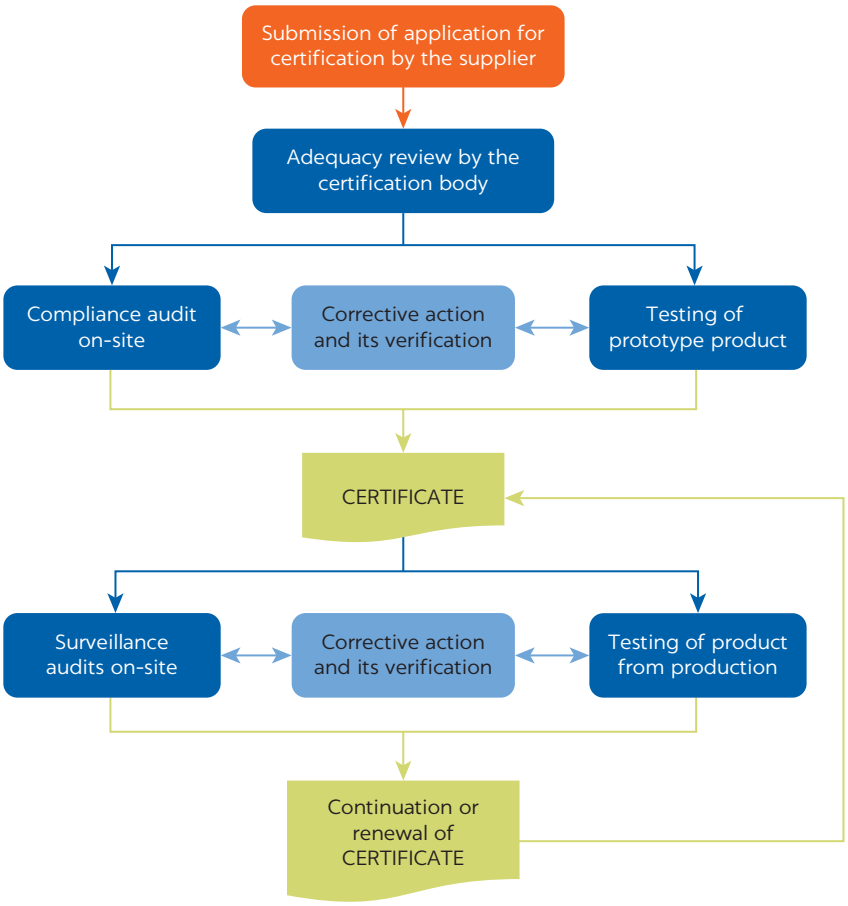
Obviously, the manufacturer has to pay for the certification process. Payments will have to cover the product testing (initial and control tests after licensing), the initial and surveillance audits of the manufacturing process, review of the clearance of nonconformities found during audits and testing, and an annual license fee. The license fee may be a flat fee, but it is more generally related to production volumes—that is, the number of units produced with the product certification mark. Typical product certification costs are in the region of 0.5–2.5 percent of production costs.

6.4.3 Value of product certification

Product certification, especially national product certification marks, have for many years been used as a requirement for products falling within the scope of technical regulation before they could be legally put on the market. This approach was fine when products were manufactured only in the country, but it has fallen out of favor in the global economy with massive products and services moving across borders. It is now seen as a restrictive trade practice, arguably noncompliant with the principles of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement).

Hence, many countries are under pressure to change the system of mandatory product certification for regulatory purposes into a more modern technical

FIGURE 6.2
Schematic of the product certification process



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regulation approach (see module 7: Technical Regulation, section 7.5). But this has become a real challenge for the NSBs in those countries because the bulk of their income emanates from such mandatory product certification practices, and changing the system will result in some serious pressure on their business models.

Product certification has remained topical at both the national and multinational levels, in spite of its associated costs, for the following reasons:

- The manufacturer wishes to build its reputation, expand its market share, gain access to new markets, improve competitiveness, or promote new products by leveraging the trusted position of the specific product certification mark in the target market.
- The purchaser (for example, the individual, wholesaler, manufacturer, public procurement organization, importer, supplier, or employer) wishes to have an independent guarantee of the quality of the product purchased and of its compliance with known standards.
- In some countries, product certification marks, even though not mandatory, are considered evidence of compliance with technical regulation requirements insofar as the technical regulation and the standard against which the

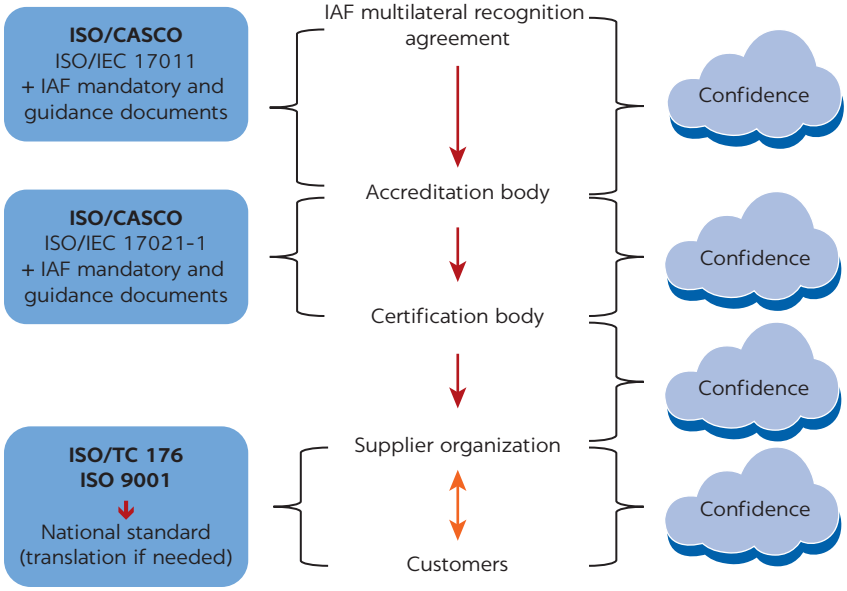
product is certified are equivalent. The CSA mark (for electronic products in Canada), the ASME mark (for pressure vessels in the United States), the BSI mark (for liquefied petroleum gas [LPG] cylinders in India), and the Tanzania Bureau of Standards (TBS) mark (for compulsory standards in Tanzania) are typical examples (UNIDO 2011).

6.5 MANAGEMENT SYSTEM CERTIFICATION

Management system certification is all about building confidence in the supplier, and it is the mechanism whereby a certification organization attests that a management system of a manufacturer, producer, supplier, or service provider has been assessed by it and that the management system complies with specified requirements, usually contained in a standard (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles").[3] The attestation by the certification body is in the form of a certificate, frequently supported by material that the certified company can use in marketing. The certification body therefore also visibly endorses the management system of the supplier. The certification organization, in turn, is accredited, thereby completing the "chain of confidence" (figure 6.3).

Whereas product certification is important for the supplier-consumer relationship (as its outcome defines the product quality), management system certification is more of a business-to-business issue, with the product standard being

FIGURE 6.3
"Chain of confidence" of system certification for ISO 9001



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Note: IAF = International Accreditation Forum; ISO/CASCO = International Organization for Standardization Committee on Conformity Assessment; ISO/TC 176 = ISO Technical Committee 176 (*Quality Management and Quality Assurance*); ISO 9001 = "Quality Management Systems—Requirements"; ISO/IEC 17011 = "Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"; ISO/IEC 17021-1 = "Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems."

defined in contracts or other purchasing arrangements. The management system certification denotes the capability of the supplier to continuously provide products or services complying with contractual obligations; it does not assess or make any claims about the product quality per se. Hence, the management system certification emblem should not be affixed to the product, because it does not denote product compliance.

6.5.1 Management system standards

The best-known management system certification schemes are based on ISO 9001 ("Quality Management Systems—Requirements"), for which more than 1 million certificates have been issued worldwide since its introduction in the late 1980s. Other international standards, and a growing number of private standards, are also used for management system certification (table 6.3). Some are important in specific sectors of the economy; others are of a more general nature.

TABLE 6.3 Selected management system certification schemes

LEVEL	SECTOR	STANDARD
International standard	Generic	ISO 9001:2015
	Environmental	ISO 14001:2015
	Food safety	HACCP
		ISO 22000:2005
	Information security	ISO/IEC 27001:2013
	IT service management	ISO/IEC 20000-1:2011
	Medical	ISO 13485:2016
	Supply chain security	ISO 28000:2007
	Petroleum and gas	ISO/TS 29001:2010
	Energy	ISO 50001:2011
Private standard	Aerospace	AS 9100
	Automotive	IATF 16949:2016[a]
	Food safety and horticulture	British Retail Consortium (BRC)
		GLOBAL G.A.P.
		FSSC 22000
	Social accountability	SA 8000
		Fairtrade
	Telecommunication	TL 9000
	Occupational health and safety	OHSAS 18000
	Ecolabeling	EU Ecolabel
		Forest Stewardship Council (FSC)
		Marine Stewardship Council (MSC)
		Green Dot

Note: The international standards are listed in the reference section of this module, whereas details regarding the private standards should be obtained from the websites of the relevant certification bodies. AS = Aerospace Standard; EU = European Union; FSSC = Food Safety System Certification; GLOBAL G.A.P. = Global Good Agricultural Practice; HACCP = hazard analysis and critical control points; IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; IT = information technology; OHSAS = Occupational Health and Safety Assessment Series; SA = social accountability; TL = telecommunication.

a. IATF 16949 is the revision of the previous ISO/TS 16949. It is no longer published by the ISO, but by the International Automotive Task Force (IATF). The IATF has created five Oversight Offices (in France, Germany, Italy, the United Kingdom, and the United States) that are responsible for managing the certification scheme.

Most of the standards are clear, in that a single management system certification scheme is operated worldwide, albeit with a multiplicity of certification bodies. Exceptions occur primarily in the food and horticulture sector, where there are a number of standards being used. HACCP was the original standard, and one that has become a regulatory requirement in some markets, such as the EU, Canada, South Africa, and the United States. The principles of HACCP have been codified in a Codex Alimentarius Commission (CAC) international recommendation that has been adopted as a national standard for regulatory purposes in many countries ("CAC/RCP 1:1969—General Principles of Food Hygiene"). The principles are also included in the international standard ISO 22000 ("Food Safety Management Systems—Requirements for Any Organization in the Food Chain").

Retail organizations in Europe and the United Kingdom developed their extended versions of food safety standards, such as the Global Good Agricultural Practice (GLOBAL G.A.P.) and British Retail Council (BRC) private standards, respectively. These came about as retail organizations wished to have more specific requirements than the EU directives to certify the integrity of their suppliers. These two were not the only ones, and the proliferation has taken its toll on compliance and transaction costs. Hence the chief executive officers (CEOs) of a number of the main retail organizations in Europe have pleaded for a more standardized approach in food safety system certification, and the Global Food Safety Initiative (GFSI) came into being. The GFSI does not certify but rather benchmarks various food safety certification schemes to determine which ones the GFSI and the European retail organizations will recognize, thereby cutting down on multiple certification of their suppliers collectively.

Some of the private standards eventually initiate development of international standards. A good example is SA8000 ("Social Accountability 8000: International Standard"), which was developed in 1997 by Social Accountability International and used quite extensively for certification purposes. The ISO developed a pendant to SA 8000 and published ISO 26000 ("Guidance on Social Responsibility") in 2010 after an intense worldwide campaign to get it started. ISO 26000, however, is not a management system–type standard and should not be used for certification purposes; it is only a guidance document. Hence, SA 8000 remains as one of the management system certification standards in this regard.

A similar development awaits the OHSAS 18000 series ("Occupational Health and Safety Management"), which was developed in 1999 by a consortium of NSBs, with the British Standards Institution (BSI) holding the secretariat as a private standard after ISO members could not agree on developing an international standard for occupational health and safety. The success of the OHSAS 18000 series as a management system standard used for certification as well as the growing concern regarding safety in the workplace worldwide has brought about a change in thinking among ISO members, and the ISO 45001 standard ("Occupational Health and Safety Management Systems—Requirements with Guidance for Use") was approved in 2018. ISO 45001 is replacing the OHSAS 18000 series, and companies already certified under OHSAS 18001 have been given three years to comply with the new ISO 45001.

6.5.2 The certification process

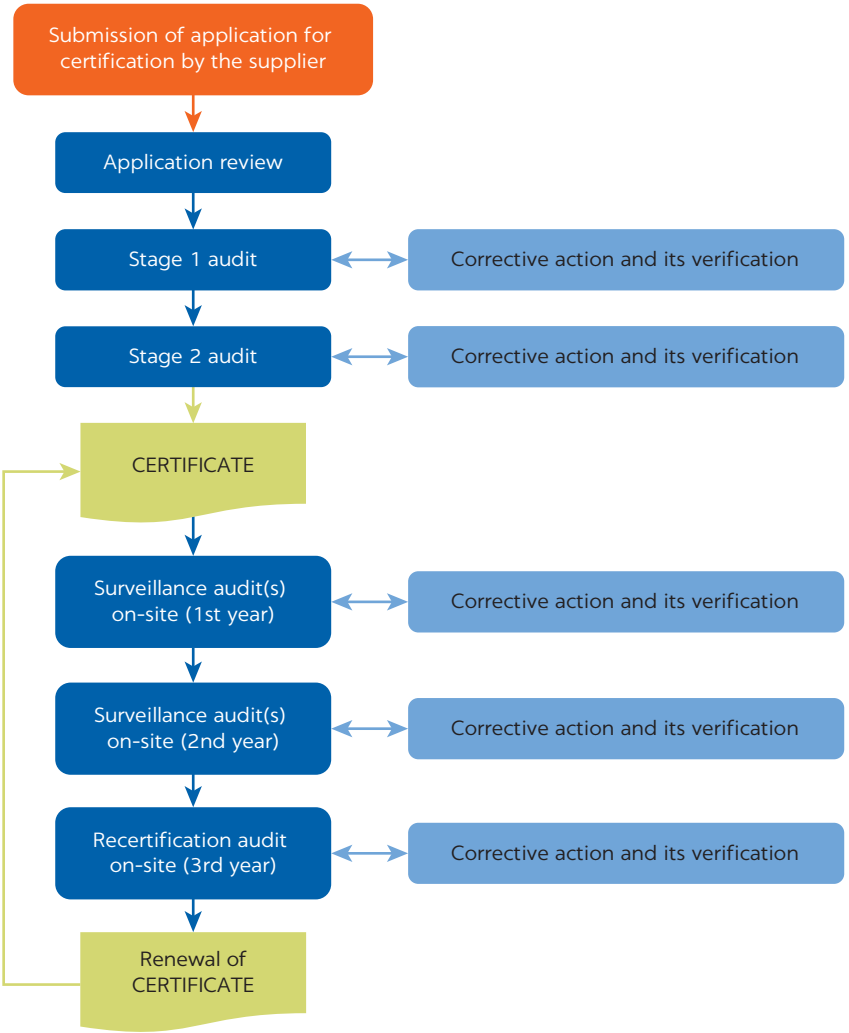
The approach and processes that certification bodies follow to certify a company have been harmonized to a great extent and generally follow the structure as

defined in ISO/IEC 17021-1 (Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems"). Small variations may occur when other standards are used to accredit the certification body, but the fundamentals will remain the same. The process consists of the following steps (figure 6.4):

- *Application:* Application forms must be completed and specified information on the company and its operations provided for the certification body to determine the scope of certification and appoint a team leader for the audit.
- *Stage 1 audit:* The certification body evaluates the quality management system documentation of the applicant to determine whether to proceed to the Stage 2 audit.
- *Stage 2 audit:* The team leader assembles a team of auditors and experts concomitant with the scope of certification and the complexity and size of the operation. The team evaluates the implementation and effectiveness of the quality management system on-site and prepares a final report after nonconformities have been cleared.

FIGURE 6.4

Schematic of the system certification process



Source: Adapted from ITC 2011. ©International Trade Centre. Reproduced with permission, further permission required for reuse.

- *Certification:* Authorized persons, or a committee totally independent of the audit team, review the audit report and decide whether to grant certification. Certification documentation is issued to the applicant if the decision is positive.
- *Surveillance audits:* After certification, the certification body conducts surveillance audits at defined intervals, usually once or twice a year, for two years to determine the continued compliance of the certified company with stated requirements. The surveillance audits are not as comprehensive as the stage 2 audit.
- *Recertification audit:* In the third year after certification, the certification body conducts a recertification audit similar to the stage 2 audit to renew the certificate for another three years, and the cycle repeats itself.

Details of certified companies, together with their scope of certification, are made public on the certification body's website. Failure to deal with identified nonconformities can ultimately lead to the withdrawal of the certificate, or the company can decide not to continue with certification, in which case the certificate is withdrawn as well.

6.5.3 Value of management system certification

Management system certification is resource-intensive to implement and to maintain over and above the certification costs. It is especially the SME sector that frequently battles to obtain certification in the first place and then to maintain it. Hence, the value of management system certification has to be a clear business proposition for the company seeking it. A number of factors need to be considered in this regard:

- *Market entry.* Management system certification is seen as a minimum requirement to enter specific markets. It is often ISO 9001 certification that opens doors for trade. Certification to ISO 9001 ("Quality Management Systems—Requirements") does not guarantee business, but without it a company may have a more difficult time convincing potential customers that it can deliver high-quality products consistently, especially in markets where it is not well known.
- *Regulatory compliance.* Management system certification has found its way into the regulatory domain, with compliance with ISO 9001, HACCP, and other standards frequently demanded by the regulatory authorities to help ensure the integrity of products influencing the health and safety of people, the environment, and the fauna and flora of the country.
- *Competitive advantage.* Some of the private sector management system certifications are a necessity for companies wishing to be competitive in sophisticated markets. Typical examples are
    - *The EU food and horticulture sectors,* where the BRC, GLOBAL G.A.P., or Food Safety System Certification (FSSC) 22000 certification is an imperative if the company wishes to trade with the major retail organizations;
    - *The automotive sector,* where certification to IATF 16949 is a prerequisite to supply components to the major automotive companies; and
    - *Certification to socioeconomic standards,* such as Forest Stewardship Council (FSC), Fairtrade, and other standards in countries with a high level of consumer activism.
- *Improvement incentives.* The implementation of a formal quality management system helps the organization to streamline its production, reduce the

incidence of nonconforming products, make product quality more consistent, and lower inspection costs. The certificate, as a formal demonstration of the implementation of such a system, is an additional bonus.

6.6 IMPACTS OF CONFORMITY ASSESSMENT

The impact of conformity assessment on trade is immense, and this will increase as technology becomes more sophisticated and consumers more discerning. Furthermore, the manufacturing global value chains stretching over many countries demand the seamless integration of components and subassemblies into the final products. This requires a continuous demonstration of compliance with standards and specifications.

6.6.1 Conformity assurance challenges for export businesses

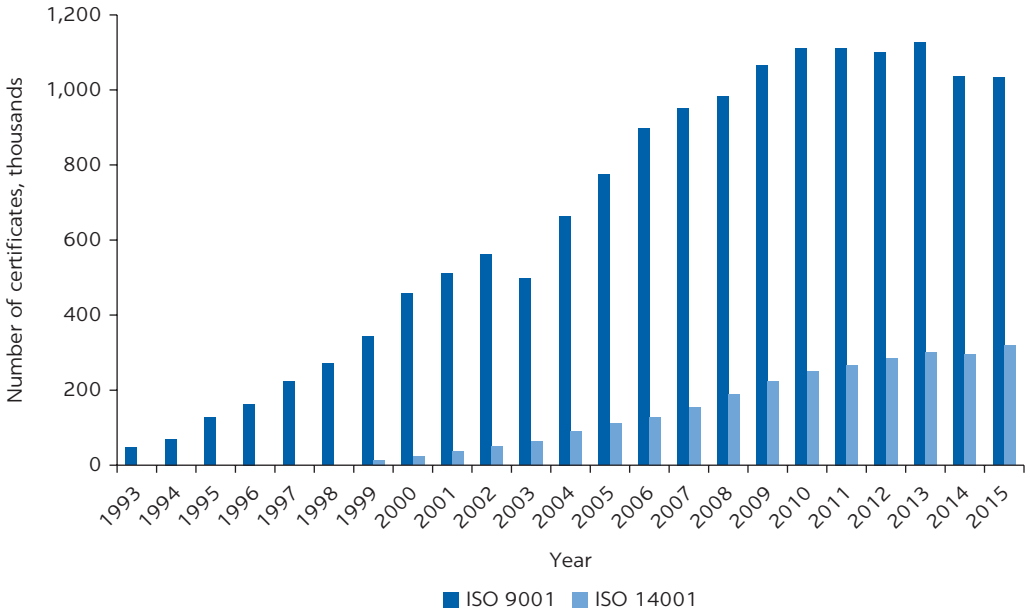
A recent survey by the International Trade Centre (ITC) conducted in 23 countries with a sample of over 11,500 companies revealed the major impact that conformity assessment requirements in sophisticated markets have on smaller companies in low- and middle-income economies that wish to export (ITC 2015). Some of the major findings point to the highly uneven impact that nontariff measures (NTMs) (including import quotas, licensing, rules of origin, content requirements, labeling, testing, and certification) have on companies and countries. Some of the conformity assessment-related challenges include the following:

- *Small companies are most affected.* Up to half of the firms, depending on their size, are affected by NTMs. Those most affected are small companies (over 50 percent), which have less capacity to overcome fixed or variable export costs.
- *Private sector concerns with NTMs are not limited to the strictness of regulations, but often relate to local procedures that present obstacles to trade.* Contrary to the common perception that nontariff barriers are faced in the destination market, the survey revealed that 25 percent of the challenges relate to measures applied by the home country of the exporting businesses, such as export quality inspections.
- *High-income countries are difficult markets for agriculture, and regional markets are difficult for manufacturing.* For agricultural products, high-income countries are perceived as comparatively more NTM-restrictive than other markets. The opposite is the case for manufactured products. This may be due to the integration of exporters from low- and middle-income countries in the industrial global value chains.
- *Conformity assessment in the agricultural sector is one of the key challenges.* Companies in the agrifood sector are particularly affected by sanitary and phytosanitary (SPS) regulations; 48 percent reported trade obstacles in the form of certification or quality control.

6.6.2 Management system certification

Since its first publication in 1987, ISO 9001—the international standard for quality management systems—has had a major impact on businesses. The international standard for environmental management, ISO 14001, has shown a similar pattern, even though its growth has not been as marked as that of ISO 9001 certification.

FIGURE 6.5
ISO 9001 and ISO 14001 certifications, 1993–2015



Source: International Organization for Standardization (ISO) annual surveys (https://www.iso.org/the-iso-survey.html).
Note: ISO 9001 = "Quality Management Systems—Requirements"; ISO 14001 = "Environmental Management Systems—Requirements with Guidance for Use."

The growth of ISO 9001 certifications has been monitored by the ISO over the years (figure 6.5). The "dips" in the growth pattern generally coincide with the publication of revised ISO 9001 standards, after which many companies do not update their quality management systems to the new requirements and hence lose their certification or voluntarily relinquish it. An additional reason may also be that ISO 9001 is considered too generic by businesses using management system certification as a qualification criterion for their suppliers, and they are therefore turning to sector-specific management standards containing sector-specific requirements, many of which are private standards marketed aggressively by their certification bodies. The developments regarding the latest revision of ISO 9001, which includes even more stringent risk assessment requirements, will be interesting to watch.

ISO 14001 certification has made steady gains over the past decade (figure 6.5), but its growth is nowhere near that of ISO 9001 before 2010. ISO 14001 has also been revised recently, and whether certification will continue its steady pace with added requirements—such as the increased prominence of environmental management within the organization's strategic planning and the focus on continuous improvement of its environmental performance—will be decided by the markets.

6.6.3 Certification to private standards as a differentiator of competitors

Standards are essential to trade and play a key role in facilitating economic activities between anonymous agents. In reducing uncertainty, standards are instruments to manage risk, to provide credibility, and to build trust. Standards also

make exchanges more efficient by simplifying transactions, guaranteeing a minimum quality, and allowing for a certain level of predictability. But the role of standards in trade has changed to also being an instrument for product differentiation and market segmentation—that is, differentiation between competitors.

The Organisation for Economic Co-operation and Development (OECD) notes that the relations between the public and private sectors in the establishment and development of food quality standards—of the public, consensus-driven types versus the private sector organization-specific types (see module 3: Standards, section 3.3)—are becoming increasingly complex as the numbers of both types of standards proliferate and become generally more stringent and varied in their applications in both national and international food markets (ITC 2011).

According to the GFSI, certification to private standards—mostly on food safety and quality—accounted for about 22 percent of total retail food sales in 2010. Food safety and quality standards are less prevalent in traditional commodities (for example, grains, sugar, coffee, cocoa, and tea), where traceability standards and labeling initiatives play a more important role. In forestry, the certified forest area amounts to 18 percent of total forest covered by a management plan and 9 percent of global forest coverage (ITC 2015).

Particularly in the food sector, firms use private standards to differentiate themselves from competitors, to build brand recognition and consumer loyalty, and to define and occupy market niches. This leads to companies establishing standards beyond public requirements for food safety. Examples of such private schemes include Tesco Nature's Choice, Filière Agriculture Raisonnée by Auchan, or Carrefour's Filière de Qualité. This development has challenging implications for producers and exporters. Many private standards exceed the requirements of public standards, and hence are more difficult to comply with. One result is that private food standards tend to impose the same requirements on suppliers all over the world, where they face very different preconditions in meeting them (ITC 2015).

6.7 RECOGNITION CRITERIA AND CHALLENGES, INTERNATIONAL AND LOCAL

In general, the acceptance of product certification based on national product certification schemes is still limited to the country of residence of the certification body, even though a number of multinational product certification schemes have begun to change this situation. There are also some product certification schemes that have spread across borders within common markets because of the freedom of movement of products. The situation regarding management system certification is more favorable; for example, ISO 9001 and ISO 14001 certificates from accredited certification bodies are more readily accepted in foreign markets. On the other hand, the situation is quite diffuse for products falling within the scope of technical regulations, where requirements include the certification of management systems to support the quality of the products.

6.7.1 Accreditation at home

In the past, inspection, testing, and certification, especially in the regulatory domain, was the sole purview of government bodies. Their competency may have been contentious, but it was not open for discussion because their authority

was protected by law. This has changed quite dramatically in high-income economies, and these changes are spilling over into low- and middle-income economies as they endeavor to increase their exports to high-income countries. The competency of conformity assessment service providers now has to be demonstrated (such as through accreditation), whether they are public entities or not.

These changes have come about as the state and its organs are extracting themselves from service delivery and are concentrating more on policy and policy implementation. The private sector inevitably has been the "winner" regarding the provision of such conformity assessment services in the regulatory domain. But the private sector conformity assessment bodies must now demonstrate their technical competency, because they do not have the privilege of being considered the ultimate authority by law.

The same tendencies can be observed in the nonregulatory domain, where purchasers of conformity assessment services wish to have assurance that the services for which they contract are indeed technically competent. Hence, in many countries, accreditation has become the common yardstick to determine the technical competency of conformity assessment service providers in both the public and private sectors (as discussed in module 5: Accreditation, section 5.3).

6.7.2 Accreditation across borders

Accreditation bodies have been working hard toward the universal acceptance of inspection and test reports and certification from accredited organizations. This has resulted in networks of mutual recognition overseen by the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). These two organizations have established and managed mutual recognition arrangements among their members, whereby each member, having become a signatory to the multilateral recognition arrangement, undertakes to recognize the inspection and test reports and certificates issued by another party in the system as being equal to the one issued by itself, even in the regulatory domain.

This is generally the case in Europe, Australia, New Zealand, and South Africa. In contrast, in China, India, and the United States, the acceptance of test results and certificates is not yet fully implemented, and designated laboratories and certification bodies are still very much the norm in the regulatory domain. On the other hand, for products outside the regulatory domain, acceptance of test results and certificates from internationally accredited service providers is increasing in most countries (ITC 2015).

In the most widely accepted recognition systems, conformity assessment bodies are accredited to the relevant international standard by the national or regional accreditation body—ISO/IEC 17020 (for inspection bodies), ISO/IEC 17021-1 (for management system certification bodies), ISO/IEC 17025 (for testing laboratories), and ISO/IEC 17065 (for product certification bodies)—as also discussed in module 5: Accreditation, section 5.2, on international standards in accreditation. If the national or regional accreditation body is a signatory to the relevant ILAC or IAF multilateral recognition arrangements, then the output of the accredited conformity assessment service provider stands a good chance of being accepted in other countries.

Private sector certification schemes, on the other hand, frequently operate their own "accreditation" systems for certification bodies, although they are based on the same principles as the international standards listed above.

These include the SA 8000, IATF 16949, and GLOBAL G.A.P., and BRC certification schemes, for example. For some private sector certification schemes, no certification bodies other than the proprietary certification bodies are entitled to certify companies—for example, Fairtrade, Worldwide Responsible Accredited Production (WRAP), and the Forest Stewardship Council (FSC).

This proliferation of accreditation schemes and mutual recognition arrangements is not likely to end anytime soon because of the immense financial returns that are still considered to be advantageously locked up in the various systems. A truly universal recognition system is therefore unlikely even in the medium to long term.

6.7.3 Mutual recognition agreements

During negotiations between countries or trading blocs, recognition arrangements or agreements on the mutual acceptance of certification schemes, especially for regulatory purposes, are sometimes signed or ensconced in the regional common market legislative instruments. One such example is the mutual recognition of national product certification marks among the members of the East African Community (EAC). But even so, this recognition is tempered by the required demonstration of competency through accreditation or peer reviews.

Another, more international system is the recognition arrangement—referred to as "WP.29"—managed by the United Nations Economic Commission for Europe (UNECE) World Forum for Harmonization of Vehicle Regulations. Contracting parties to its 1958 Agreement subscribe to the reciprocal acceptance of approvals of vehicle systems, parts, and equipment issued by other contracting parties.

6.7.4 Recognition among certification organizations

It is possible to establish recognition arrangements between certification organizations on a contractual basis but on a higher level than subcontracting. This comes about when a certification body in a high-income country, for example, accepts inspection certificates, test reports, and even product certification from a certification body in another country, even a low- or middle-income country, as adequate evidence of product compliance to issue its own product certification for its domestic market. The basis for such recognition varies, but is always based on the demonstration of competence between the two partners. This could entail accreditation by an accreditation body or mutual reviews by the partners.

The advantage of such recognition arrangements is that the more senior partner in the agreement obtains a "presence" in the junior partner's country without having to establish its own offices. The surveillance on the certified company is then much more effective, and the cost of surveillance activities is lower, also benefiting the supplier. For smaller certification bodies in low- and middle-income countries, this could be a lucrative model financially when recognized by one of the major certification bodies in a high-income country.

6.8 PUBLIC VERSUS PRIVATE SECTOR SERVICE PROVIDERS

During the developmental phases of a national QI, the state largely has to provide for the establishment of conformity assessment service providers.

The private sector will invest in such services only if a market exists for such services, which is not the case at the beginning. Investments in testing laboratories can run into the millions of dollars before a viable market is established. Once a market has developed, it is quite obvious that the private sector, sensing that there are profits to be made in providing conformity assessment services, would like to establish profitable conformity assessment service providers. This frequently leads to tensions between the public and private sectors.

6.8.1 Public sector service providers

Public sector service providers have the advantage that they seldom have to repay the investments for their establishment; nor do they have investors who wish to see large profits as a payback for their investment. On the other hand, they are often then required by the state to provide conformity assessment services far below market prices to support the SME sector as a political necessity. This approach puts a strain on their finances and is a negative regarding their future financial sustainability. It also distorts the market and creates barriers for private sector service providers to be established. The SME sector needs support, but demanding below-cost services from the public sector service providers is not an appropriate strategy. Direct financial and technical support for the SMEs, properly structured, is a better approach.

On the other hand, public sector service providers can provide lower-cost services to the SME sector, even if they are just covering costs, because they do not operate with a profit motive. In addition, operating without a profit motive allows public sector operators to provide services to rural or sparsely populated areas with little prejudice. As long as there is no private sector competition, everything works fine. However, once private sector service providers are established, they usually can adapt much more quickly to market realities and changes, and in this way, take market share from the public sector operators.

The real challenge surfaces when conformity assessment services for the regulatory domain are liberalized, and public sector operators lose their legal or perceived monopoly to provide such services. The public service operators are incensed and will fight to the bitter end not to lose this monopoly. The government will have to take a clear and unambiguous stand in this matter; otherwise, the country will be the loser in the end.

As for acceptance in the local marketplace, the public sector operators sometimes have the advantage because they are the "government." This is not a universal truth, and the opposite also happens, especially if service delivery is not good. Where public sector operators have a real challenge is gaining acceptance in foreign markets or for the testing and certifying of products to be exported to lucrative markets such as the EU, the United States, and others. In this case, the dominant market position of the multinational conformity assessment service providers in the foreign markets (such as the various TÜV companies, SGS S.A., Bureau Veritas S.A., and others) is a very hard nut to crack.

This situation is exacerbated by policies such as that in the EU, whereby only conformity assessment service providers resident in Europe are designated as "notified bodies" for the testing and certification of products falling within the scope of technical regulations. These policies exclude public sector conformity assessment bodies from low- and middle-income countries and raise the cost of compliance for exporters in such countries, unless the country reach a mutual recognition agreement with the EU. There are few of those, however.

6.8.2 Private sector service providers

Private sector conformity assessment service providers start to be established once a viable market for their services has developed. The policy of the government also has to favor the establishment of private sector operators by liberalizing the conformity assessment service regimes for the implementation of technical regulations rather than limiting such services to a public sector entity. In high-income economies and increasingly also in many low- and middle-income economies, this is the case; the state and its agencies are slowly disengaging from service delivery, concentrating on policy and the implementation of the law.

Generally speaking, private sector operators are also more flexible in adapting to changing market situations, and market forces to some extent ensure that service quality remains high. If the laboratory or certification body does not provide good service, and if there is a choice, customers will go elsewhere. The difficulty in smaller economies is that there is usually not a great choice because of the high levels of investment required to establish speciality laboratories. The technical competency of private sector service providers, just like public sector service providers, should be demonstrated through accreditation.

A significant challenge regarding certification schemes based on private standards is that they frequently operate as a closed shop with respect to certification bodies—that is, only certification bodies that are part of the organization publishing the standard are mandated to provide certification services. In low- and middle-income countries, this may mean that a certification body from abroad must be used, with the much higher costs that this entails. In some cases, it may be possible to establish a certification body at the national level for private standard certification schemes, or a national certification body may be contracted to conduct the audits with the parent body still issuing the certificate, but this would depend on their business model. In all of these cases, the parent body usually conducts a form of accreditation.

A related challenge for low- and middle-income countries regarding service delivery by private sector operators is that the SME sector is often neglected. SMEs frequently do not have the finances to pay for private sector conformity assessment services, and they are often based in rural or sparsely populated areas. Both factors militate against the provision of services that are based on a profit motive. In such cases, the government and its agencies may have to continue to provide conformity assessment services at affordable prices for the SME sector. Such a division of labor can work, but there needs to be a good understanding between the government, its agencies, and the private sector for it to be successful.

6.9 INTERNATIONAL CERTIFICATION SCHEMES

Over the years, several large conformity assessment bodies have established themselves by providing inspection, testing, and certification services in many countries. They are the *multinational* organizations in the conformity assessment service domain, even though they are sometimes touted as *international* organizations, which they are not. There are, however, a few international organizations that manage international conformity assessment schemes. Three of them are discussed below.

6.9.1 International Electrotechnical Commission (IEC)

The IEC, unlike its counterparts the ISO and the International Telecommunication Union (ITU), operates international certification schemes for four various types of electrical and electronic products:

- *IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE):* The IECEE schemes address the safety, quality, efficiency, and overall performance of components, devices, and equipment for homes, offices, workshops, and health facilities, among others. In all, the IECEE covers 23 categories of electrical and electronic equipment and testing services.
- *IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx):* The IECEx schemes address the safety and performance of equipment destined for use in hazardous locations or explosive atmospheres—that is, areas where flammable liquids, vapors, gases, or combustible dusts are likely to occur in quantities sufficient to cause a fire or explosion.
- *IEC Quality Assessment System for Electronic Components (IECQ):* The IECQ scheme is an approval and certification system covering the supply of electronic components and associated materials and assemblies (including modules) and processes. It includes both a product and a facility certification scheme.
- *IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications (IECRE):* The IECRE scheme is an approval and certification scheme relating to equipment for use in renewable energy applications, including the safety thereof.

The schemes are based on the principle of mutual recognition (reciprocal acceptance) by scheme members of test results and factory audits carried out for the purpose of obtaining certification or approval at the national level. Products or factories are inspected, tested, and audited as relevant against IEC standards and under the auspices of a member of the relevant IEC scheme, referred to as a national certification body (NCB). The NCB designates the laboratory to be used. The list of recognized NCBs is posted on the relevant scheme's website.

A manufacturer is then entitled to take the test and audit results to an NCB in another country, and the NCB in that country will issue the certification in that country as required by the marketplace or the regulatory authorities. In the case of the IECEx scheme, the manufacturer is licensed to affix the IECEx conformity mark on the product, which is recognized by the other member countries of the scheme as evidence that the product complies with the relevant IEC standard. Equipment used in explosive atmospheres is subject to technical regulations in most countries, and these regulations are often based on IEC standards.

6.9.2 International Organization for Legal Metrology (OIML)

The International Organization for Legal Metrology (OIML) operates two international conformity assessment schemes: the OIML Basic Certificate System and the OIML Mutual Acceptance Arrangement (MAA). The aims of the OIML conformity assessment schemes are to

- Foster mutual confidence among participating OIML member states and corresponding members in the results of type evaluations that indicate conformity of measuring instruments;

- Promote the global harmonization, uniform interpretation, and implementation of legal metrological requirements for measuring instruments; and
- Promote efficiency in time and cost of national type evaluations and approvals, or recognition of measuring instruments under legal metrology control in support of facilitating global trade of individual instruments.

The OIML Basic Certificate System for measuring instruments enables manufacturers to obtain an OIML Basic Certificate and an OIML Basic Evaluation Report indicating that a given measuring instrument type complies with the requirements of the relevant OIML international recommendation. Certificates are issued by OIML member states that have established one or several Issuing Authorities responsible for processing applications from manufacturers wishing to have their measuring instrument types certified. The OIML Issuing Authorities must demonstrate compliance with ISO/IEC 17065 ("Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services") using the results of testing laboratories that comply with ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories").

These certificates may be accepted by national legal metrology authorities on a voluntary basis, thereby simplifying the type approval process for manufacturers and legal metrology authorities by eliminating expensive duplication of test procedures. The Basic Certificate System offers a viable and trustworthy alternative to countries where relevant test facilities are not available.

In addition to the Basic Certificate System, OIML has also developed a Mutual Acceptance Arrangement (MAA). Within the OIML MAA, confidence in test and examination results is reinforced by a formal and mandatory peer evaluation process. This process verifies the compliance of the OIML Issuing Authorities and the testing laboratories with the respective standards and also the capability of the testing laboratories to perform the tests. To prove this compliance, the Issuing Authorities and the testing laboratories must be accredited for the field covered by the respective OIML Recommendations or undergo peer assessment.

6.9.3 UNECE World Forum for Harmonization of Vehicle Regulations

The UNECE World Forum for Harmonization of Vehicle Regulations—commonly referred to as Working Party 29 (WP.29)—currently has the leading role in the global harmonization of automotive safety regulations. It is responsible for the implementation of two major agreements reached by the participating countries, known for short as the 1958 Agreement and the 1998 Global Agreement.

The UNECE 1958 Agreement provides for the mutual recognition of governmental certifications based on the Economic Commission for Europe (ECE) Regulations (approximately 135 at the time of this writing), while the purpose of the 1998 Global Agreement is to harmonize automotive transportation-related regulations globally. Mutual recognition is not part of the 1998 Global Agreement; its focus is limited to the adoption of agreed-on Global Technical Regulations for vehicles by contracting parties. The ECE Regulations—now called UN Regulations under the 1958 Agreement and the UN Global Technical Regulations under the 1998 Global Agreement—are both developed and discussed within UNECE WP.29.

The mutual recognition of approvals provided under the 1958 Agreement aims to facilitate the international trade in vehicles and their components. If a component type is approved according to a UNECE Regulation by any of the

contracting parties to the 1958 Agreement, all other contracting parties that have signed the Regulation will recognize this approval. This avoids repetitive testing and approval of components in the various countries to which the components are exported. It also helps to reduce the time and resources devoted to design, manufacturing, and approval as well as the entering into service of vehicles and their components.

Around 50 countries are contracting parties to the 1958 Agreement, the most notable exceptions being Canada and the United States, which have a different approach to vehicle component certification than countries operating a formal approval thereof by regulatory authorities. Approved components are typically marked with a capital "E" within a circle also containing the number assigned under the 1958 Agreement to the approving country. Roughly the same number of countries are contracting parties to the 1998 Global Agreement, but the number of UN Global Technical Regulations is still much lower than the UN Regulations under the 1958 Agreement, about 15 at the time of this writing.

6.10 CONFORMITY ASSESSMENT SERVICES AND THE SME SECTOR

One of the major challenges for SMEs seeking to enter the more sophisticated markets and integrate into global value chains is obtaining the relevant inspection and test reports and certification that demonstrate product or component compliance with stated requirements. This is important in the low- and middle-income country context because SMEs often make up the bulk of those countries' industrial base. It is, however, easier said than done. SMEs—over and above all the other challenges, such as financing, management capacity, and product or service design—find it difficult to implement the appropriate manufacturing controls, never mind the more sophisticated quality assurance systems required for ISO 9001 certification, for example. The same applies to obtaining appropriate positive test reports from accredited testing laboratories.

Many governments of low- and middle-income economies, in implementing industrialization or export policies, will try to support the SME sector in this regard. A number of strategies are available:

a. *Providing training and consultancy services* to SMEs in specific sectors that are important to the economy. Such schemes are frequently supported by the donor community in technical development projects.
b. *Forcing public sector conformity assessment bodies to provide inspection, testing, and certification services* for the SME sector at below-market related prices, sometimes even below cost.
c. *Providing financial support to SMEs* to gain the relevant management system or product certification.
d. *Affording preferential treatment* to SMEs in state purchases if they are certified.

Of the three possibilities, (b) is the most inappropriate strategy to follow. In this case, the public sector conformity assessment body will have to be subsidized by somebody, usually the government or sometimes the development partners in an indirect way. This approach compromises the financial sustainability of the conformity assessment body, distorts the market, and acts as a barrier for private sector conformity assessment bodies to be established.

Strategy (c) has a good chance of having a lasting impact if it is designed in an appropriate way. Countries that have achieved notable success in this regard would refund part of the testing or certification fees (usually around 50 percent) after the SME has obtained certification, and then would refund a further percentage (usually around 25 percent) after three years if the SME has successfully maintained its certification. Schemes that refund 100 percent or close to it after successful certification seldom make a lasting impact because the SMEs frequently drop the certification once they have been refunded.

Among the support systems under strategy (a) that have had a fair amount of success are systems whereby SMEs are given a small percentage of government or large company contracts to supply mundane products or consumables, such as toilet paper, school furniture, grass cutting machetes, and so on. The government or large company will at the same time contract the NSB, insofar as it has the capacity to do so, to help the SMEs set up appropriate manufacturing controls and to conduct the final inspection on a batch-by-batch basis for the products in question. After a while, the SME will have developed to the point where such support is no longer necessary.

6.11 THE CERTIFICATION CHOICE FROM THE SUPPLIER'S PERSPECTIVE

With the tremendous number of product and system certifications on offer, an economic operator has a difficult choice. All of these schemes have a cost, hence the choice needs to make good business sense. In general, the choice of a certification scheme will depend on the answers to the following questions (ITC 2011):

- Is a product certification scheme relevant, or should it be a management system certification scheme?
- If the choice is a product certification scheme, is one offered by a multinational certification body the right choice, or would a national one be more appropriate and sufficient to serve the purpose in the short and long terms?
- Is a more general management system certification required, or would a sector-specific scheme be more appropriate?
- If a general management system certification scheme is chosen, would it be focusing on quality, the environment, information security, or a combination of these?
- If a sector-specific certification scheme is necessary, in which sector should it be; for example, automotive parts, medical devices, software development, and so on?
- Is the cost of implementing the necessary controls and systems, plus initiating and maintaining the certification, worthwhile relative to the advantage gained in the marketplace?

Selecting the most appropriate certification scheme and certification body should ensure a valuable long-term partnership. A structured approach to the selection process is therefore essential. Some of the key issues that may help the selection process are described below.

6.11.1 Product certification scheme selection

Some product certification marks have gained a predominant position in the marketplace, and products carrying these marks are recognized as good value for money

or as high-quality products by purchasers. This is especially true in the home markets of major product certification bodies in both high-income and low- and middle-income countries, and less so in their markets abroad. It is therefore important to obtain relevant information in this regard, because the appropriate product certification marks can be invaluable in gaining market share where the market does not yet recognize the brand names of the products. This holds true for both local and imported products and is relevant in the case of government purchases where a product certification mark could be an advantage in the tender process.

If the product to be marketed falls within the scope of a technical regulation, it is useful to determine whether product certification would be considered a demonstration of compliance acceptable to the regulatory authorities. This acceptability could depend on accreditation of the product certification body, on its designation by the regulatory authority, on a unilateral recognition as "deemed to satisfy" evidence, and other considerations. The international schemes offered by the IEC and OIML, for example, may be interesting in this respect as well (see section 6.9 on international certification schemes). As is the case for market acceptance, obtaining reliable information in this respect could be invaluable in lowering the overall cost of compliance with the relevant technical regulation.

Product certification schemes vary tremendously in how they are financed. In some cases, there is an annual fee based on actual production that will carry the product certification mark; this fee covers all surveillance audits and post-award testing activities. In other schemes, these are paid for separately. Some have a base charge independent of production combined with an additional fee based on the production figures. Others include costs for each surveillance audit, interim testing of mark-bearing products, recertification fees, and so on. These costs have to be determined and factored into the production costs to decide whether it makes good business sense to obtain the relevant product certification; that is, whether the potential growth in sales warrant the product certification costs.

6.11.2 Management system certification scheme selection

General management system certification schemes as well as sector-specific schemes abound. The choices are immense. The most pertinent question that should be asked relates to the purpose of the management system scheme envisaged. Table 6.4 provides guidance on some of the better-known schemes, even though it is nowhere near comprehensive. Specific situations may require totally different schemes, especially when considering sector-specific schemes (of which there are far too many to list here).

As is the case for product certification, the costs of management system certification can vary quite a bit, depending on the business model of the certification body. Annual certification fees, audit fees, auditor costs, and recertification fees need to be factored into the decision making, and the most cost-effective and beneficial ones for the company to be certified should be selected.

6.11.3 Certification body competency and focus

It is important to select not only the appropriate certification scheme, but also the most relevant certification body. Questions that need to be asked and

TABLE 6.4 Selection criteria for management system certification schemes

PURPOSE OF IMPLEMENTATION	RELEVANT STANDARD
Generic management system certification	
To obtain customer satisfaction by consistently providing conforming products or services	ISO 9001
To ensure the security of the company's valued information and create confidence among customers in the security of information they provide	ISO/IEC 27001
To demonstrate to stakeholders that the company is environmentally responsible	ISO 14001
To provide a safe workplace for employees by managing occupational health and safety risks in the workplace	OHSAS 8000
To ensure employees' welfare and demonstrate compliance with social accountability policies, procedures, and practices to interested parties	SA 8000
To improve energy performance, including energy efficiency, energy use, and consumption	ISO 50001
Sector-specific management system certification (see also table 6.3)	
To become a reliable supplier of automobile production materials, parts, and services meeting OEM requirements	IATF 16949
To become a reliable supplier of equipment and materials needed by the petrochemical, oil, and gas industry supply chain	ISO/TS 29001
To become a reliable supplier to companies involved in the design, production, installation, and servicing of medical devices	ISO 13485
To become a reliable supplier in the aviation, space, and defense industry supply chain	AS 9100
To demonstrate the ability to supply products or services to telecommunication service providers and their suppliers	TL 9000
To become a reliable provider of IT services, either within the organization or to external organizations obtaining outsourced services	ISO/IEC 20000
To reduce risks to people and cargo within the supply chain	ISO 28001
To become a reliable supplier of food safe for human consumption, whether of animal or vegetable origin; fresh or processed; perishable or with long shelf life; or with or without additives, vitamins, and biocultures	HACCP ISO 22000 FSSC 22000 BRC GLOBAL G.A.P.
To ensure the safe packaging, storage, and distribution of safe food and consumer products	BRC GLOBAL G.A.P.

Source: ITC 2011.
Note: BRC = British Retail Council; GLOBAL G.A.P. = Global Good Agricultural Practice; HACCP = hazard analysis and critical control points; IT = information technology; OEM = original equipment manufacturer. For full information about each of the listed standards, see the references at the end of the module.

answered in the affirmative regarding the competency of the certification body include the following:

- Is the certification body accredited for the public or private standard to which certification is required?
- Is the accreditation body by which the certification body is accredited a signatory to a multilateral recognition arrangement covering the scope you are interested in, such as those operated by the IAF for public standards, or in the case of private standards, the relevant multinational one?
- Does the accreditation of the certification body cover the scope of the scheme the organization wishes to be certified against, both locally or abroad, as relevant?

Another important selection parameter is whether the certification body is recognized in the marketplace. If the certification body includes well-known names in its list of certified companies, that could be a useful indicator. A certification body that has confidence in its operations will not object to putting

potential clients in touch with certified companies for feedback on its performance. If the certification body is operating in a number of countries, that may also be of interest to potential exporters.

The certification needs of a company may be manifold, either now or in the future. Some certification bodies can provide an integrated service—that is, a system that integrates quality management certification with certification relating to environmental management, and/or health and safety, and/or risk management, and/or even product certification. If this is a desirable feature for the company, such an integrated certification service may be more cost-beneficial than obtaining stand-alone certification for each area. SMEs may find it difficult to obtain and maintain certification. Some certification bodies provide specialized schemes for the SME market, and these may be the obvious choice for SMEs.

NOTES

1. The CE marking (a "CE mark" does not exist) is placed on the product and/or packaging by the manufacturer or supplier once all the requirements of the relevant new directive of the EU have been fulfilled, thereby denoting that the manufacturer or supplier takes full responsibility for the compliance of the product with specified requirements. These may involve third-party conformity assessment service providers (that is, notified bodies) depending on the new directive, but the manufacturer or supplier is not licensed by a product certification body or anybody else to affix the CE marking on the product; it is done totally on that manufacturer's or supplier's own responsibility.
2. HACCP is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe. An international guideline is published by the Codex Alimentarius Commission (CAC/RCP 1-1969) that has been adopted as a national standard by many countries.
3. In some countries, management system certification is termed registration, and the certification body a registrar.

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7

Technical Regulation

7.1 THE TECHNICAL REGULATION SPECTRUM AND DEFINITIONS

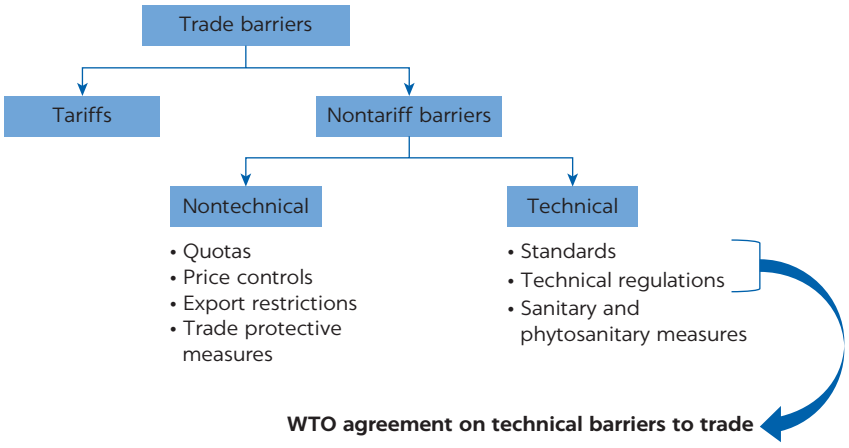
Products in the market could fail and become hazards for the people or the environment. The reasons are manifold: they may not comply with relevant standards, manufacturers might have skimped on manufacturing controls, suppliers may just take a chance to see whether they can get away with substandard products, and so on. Consumers generally cannot distinguish between products that may fail and those that will not. Hence governments have taken the responsibility to establish controls over products in the marketplace that would limit such failures in order to protect their citizens and the environment. These mechanisms have been, and still are, known by different names in many countries, but they are now collectively understood as technical regulations at the international level.

In the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), a technical regulation is defined as a "document which lays down product characteristics or their related processes and production methods, including applicable administrative provisions, with which compliance is mandatory" (WTO 1994, annex 1). Technical regulations are therefore legally binding prescriptions and must be applied by all economic operators in a given market, irrespective of their size or where they come from.

Technical regulations have been around for centuries. They are, in essence, barriers to trade. With the development of global trade, some differences in technical regulations across trading partners were being highlighted as *unnecessary* barriers to trade, and the first efforts to harmonize technical regulations at the international level were incorporated into the General Agreement on Tariffs and Trade (GATT). These were reviewed and refined for the various agreements underpinning the Marrakesh Agreement, which was signed in 1994. The Marrakesh Agreement provided for the establishment of the WTO, which came into being in 1995.

The WTO distinguishes between tariff barriers and nontariff barriers (figure 7.1). Of the various nontariff barriers, standards and technical regulations are dealt with in the TBT Agreement. Sanitary and phytosanitary (SPS) measures—the companion to technical regulations—are dealt with in

FIGURE 7.1
Categories of barriers to trade



Note: WTO = World Trade Organization.

another agreement: the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). The two agreements are mutually exclusive by definition, as discussed further in section 7.10.

The WTO TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are nondiscriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety or of the environment. The TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade. Through its transparency provisions, it also aims to create a predictable trading environment.

Five principles underpin the WTO TBT Agreement:

- The same treatment has to be accorded to imports from all WTO member states.
- Imported and domestic products should be treated the same.
- Standards, conformity assessment procedures, and technical regulations should not be disguised trade barriers.
- Technical regulations should achieve their objectives by means that minimize restrictions on trade.
- Draft standards and technical regulations should be published in a timely manner to enable other WTO member states to comment.

Technical regulations are implemented by governments for many reasons. To limit these to justifiable causes, the WTO TBT Agreement provides guidance on which policy objectives are considered legitimate, namely, that no country should be prevented from taking measures necessary to ensure (a) national security; (b) the protection of human, animal, or plant life or health; (c) the protection of the environment; or (d) the prevention of deceptive practices. These, however, should not be applied in a manner that would constitute either a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade (WTO 1994, Article 2.2).

7.2 DIFFERENCES BETWEEN STANDARDS AND TECHNICAL REGULATIONS

There are similarities between standards and technical regulations, but there are also some major differences. Technical regulations should be implemented only for legitimate reasons, whereas standards go beyond that. Technical regulations are used by the state to regulate and control products that may be deleterious to the health and safety of the population, fauna, flora, and the environment, whereas standards are used by all parties to provide for a common understanding and implementation of requirements for products and services by agreement or contract. Other differences relate to their legal status, the responsibilities for development, and implementation, rather than the technical details of the products dealt with (Inklaar 2009).

7.2.1 The state and its authorities

Technical regulations are part of the body of legislation of a country or a region. The responsibility for the development and promulgation of technical regulations lies with the state and its competent authorities. In developing technical regulations, the transparency provisions of the WTO TBT Agreement must be honored. The enforcement of technical regulations, too, is the sole responsibility of the state and its competent authorities. For this reason, technical regulations include administrative provisions, which are generally absent from standards.

Standards, on the other hand, are developed and published by public or private standards bodies and principally in accordance with internationally recognized principles such as transparency, openness, and consensus (see module 3: Standards, section 3.4, on good standardization practice). The governance structures of the bodies responsible for the approval of standards may include representatives from the state in the case of public standards bodies. Standards are also considered voluntary; that is, implementation is by choice of the user.

The state may decide to delegate certain tasks in connection with the development of technical regulations to "nonauthorities." For example, the state may subcontract the regulatory impact assessment (RIA) to an organization specializing in such assessments. Or market surveillance may be delegated to a private inspection body. It is good practice to base the technical regulation on a standard; hence the state may request the national standards body to develop the national standard that will be referenced in the technical regulation. But the state or its competent authority must remain in control of the regulatory process at all times. It cannot delegate its legislative competency and accountability to "unauthorized" parties that do not have the relevant constitutional legitimacy.

Other than the provisions in the WTO TBT Agreement regarding the development of technical regulations, the way in which the state fulfills its regulatory responsibilities and tasks is not prescribed in any binding regional or international instruments. There are, however, tried and tested international good practices that should be considered (as discussed below in section 7.9).

7.2.2 Users and affected parties

Standards are recommendations. Interested parties or organizations apply them on a voluntary basis. These users decide for themselves which standards

are relevant and whether the benefits warrant the cost of implementation. Standards can be part of a contractual obligation, or they can be implemented on the strength of market perceptions. Noncompliance may certainly limit market opportunities, result in relinquishing a lucrative contract, or impose civil-law consequences for noncompliance, but noncompliance is not an offense by itself, punishable by the state.

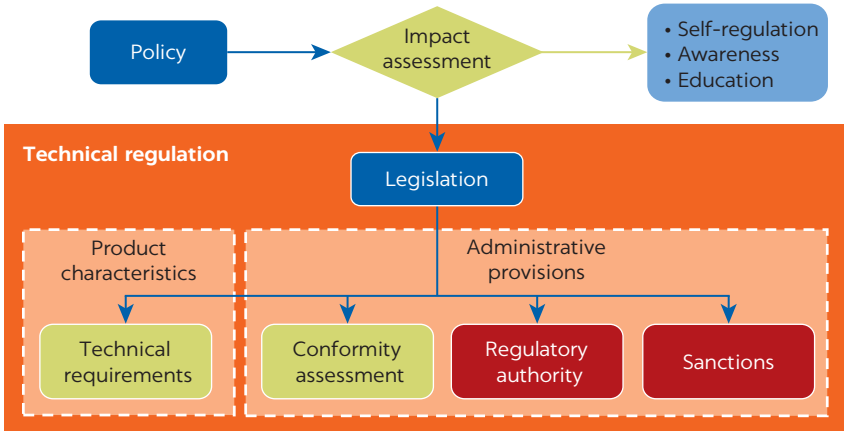
In contrast, technical regulations are legally binding prescriptions. They must be complied with by all parties in the market, whether big or small, local or foreign, and regardless of the costs of implementation. Noncompliance is an offense punishable by law. This may become an existential threat for small and medium enterprises (SMEs) if compliance is technically challenging or expensive. Technical regulations are sometimes also a hindrance to innovation because of their prescriptive nature. This may damage the competitiveness of industry because a technical regulation has to be complied with in its totality.

Standards that are badly written, difficult to understand, or ambiguous are seldom used and ultimately are forgotten. Technical regulations that are difficult to understand or even ambiguous must nevertheless be complied with. This places a responsibility on the state to ensure that technical regulations are clear, stated in simple language, and use performance criteria rather than design or prescriptive characteristics (WTO 1994, Article 2.8).

7.3 ELEMENTS OF A TECHNICAL REGULATION SYSTEM

An international binding standard for the development and implementation of a technical regulation does not exist. Technical regulations are developed in accordance with the customs and practices of countries or in accordance with state prescriptions regarding national legislation. A type of building-block approach for technical regulations (figure 7.2) has emerged over the past two decades that helps tremendously in understanding the various approaches practiced by countries regarding technical regulation content. Anecdotal evidence suggests that if any of the building blocks are not properly provided for in the technical regulation, then the regulation may prove to be ineffective.

FIGURE 7.2
Building blocks of a technical regulation



Source: Adapted from Racine 2011.

Some governments endeavoring to implement regulatory management (see section 7.9) have defined the development steps, structure, and implementation modalities—the building blocks—of technical regulations for their countries. These are generally known as a technical regulation framework and are given legal certainty through an appropriate legislative instrument. This is necessary because the technical regulation framework has to be implemented by all regulatory authorities at the national, provincial, or local levels. Such a framework is the most effective manner for ensuring the compliance of all the regulatory authorities with the country's obligations in relation to the WTO TBT Agreement or similar regional arrangements.

A technical regulation is initiated through an intention (for example, contained in a policy statement) by the government to deal with a specific market failure and to ensure a legitimate objective. Before a technical regulation is contemplated, an RIA should be conducted to determine how big the problem is, what the socioeconomic costs and benefits are, and whether the infrastructure to implement the technical regulation exists in the country.

If the decision is to develop and implement a technical regulation, then it should contain a description of the following:

- *Technical requirements.* These should be based on international standards (or their national adoption), and they can either be included in the text of the technical regulation (no longer seen as good practice) or referenced. Referencing standards in technical regulation is good practice, and a number of possibilities for doing so are available (as discussed in section 7.4).
- *Conformity assessment.* This would be any combination of inspection, testing, and certification, either by the supplier (that is, a supplier's declaration of conformity [SDoC]) or by independent third parties whose competency is demonstrated by accreditation and who are acceptable to the regulatory authority (that is, designated organizations).
- *Regulatory authority.* The regulatory authority is primarily responsible for in-market surveillance (which may include manufacturers' premises and warehouses) to ensure all suppliers' continued compliance of products with the technical regulation. For very high-risk products, premarket approvals may be required as well. The regulatory authority has to initiate sanctions if suppliers do not meet requirements.
- *Sanctions.* The regulatory authority applies administrative sanctions such as directives for the recall and destruction of noncompliant products. If suppliers do not heed administrative sanctions, then courts of law should get involved. Regulatory authorities should not be given the mandate to impose fines; that only invites corrupt practices. Fines are best reserved for courts of law.

7.4 THE ROLE OF STANDARDS AND WAYS TO REFERENCE THEM

The WTO TBT Agreement clearly requires that technical regulations be based on international standards where these exist or where their completion is imminent, except where such standards would be ineffective or inappropriate—for example, because of fundamental climatic or geographical factors or fundamental technological problems. The TBT Agreement does not identify the organizations it considers to be international

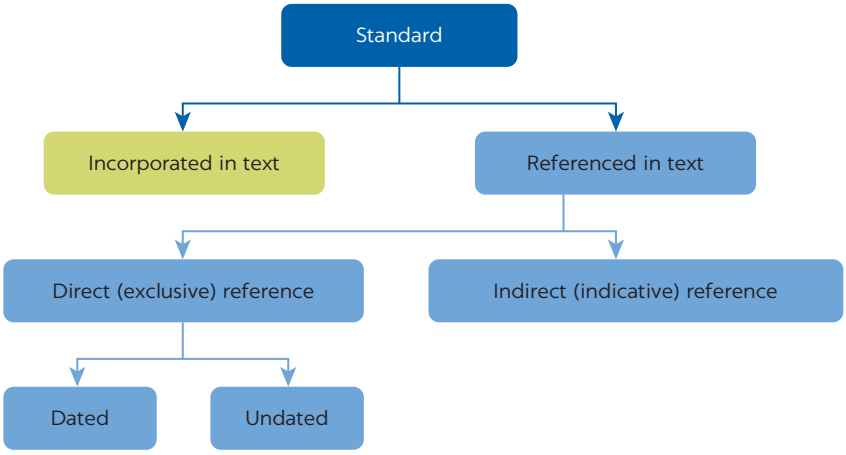
standards developers by name; nor does it provide a list of international standards. The WTO's Committee on Technical Barriers to Trade therefore published a decision in 2000 (WTO 2000) on the principles to be used for deciding whether a standard is an international standard (as discussed in module 3: Standards, section 3.4, on good standardization practice) rather than naming specific international standards bodies, as does the WTO SPS Agreement.[1]

Over and above the requirements of the WTO TBT Agreement, the use of standards for defining the technical requirements of a technical regulation also holds some important advantages:

- The legislator can rely on recognized solutions and does not need to reinvent the wheel.
- The methodology of developing standards—including principles such as consensus, openness, and transparency—more readily facilitates the acceptance of the technical regulation.
- Standards can be more readily updated if and when technology or circumstances change.
- The overall development process is more efficient (for example, avoiding costly duplication of effort), and the costs of developing the technical requirements are largely shifted from the public to the private sector.
- To the extent that many sources of expertise are involved in standards development, and that the final outcome must receive support from interested parties to be accepted, standards may better reflect technical reality in the market than do technical regulations developed in isolation.

A few possibilities present themselves for using international standards as the basis for technical regulations. These include incorporation of the standards text in the technical regulation itself, various ways of direct (exclusive) referencing of standards, and indirect (indicative) referencing of standards (figure 7.3). Obviously, national or regional standards that are adoptions of international standards would also qualify as a means of meeting the WTO TBT Agreement requirements.

FIGURE 7.3
Use of standards in technical regulations



7.4.1 Incorporation of the text

Incorporation of the text of the standard into the text of the technical regulation is the time-honored way of using the standard. Many legislators would prefer this methodology because it is straightforward and legally sound.

However, it comes with some serious disadvantages:

- The technical regulation can quickly be rendered out-of-date, especially in fast-developing technologies. It is a truism that once on the statute books, it is unlikely that legislation (and a technical regulation is part of legislation) is reviewed continuously and consistently. Technologically outdated technical regulations are problematic because they still have to be complied with, and imported products manufactured in accordance with updated international standards are technically frozen out of the market. It is an even bigger challenge for local industries that then can no longer export their products if complying only with national technical regulation.
- Many standards reference other standards, and if this approach is followed to its logical conclusion, all of these will also have to be incorporated into the technical regulation. This becomes a complicated and inefficient way of dealing with technical requirements.
- There are known instances in which the text of the standards has been copied inaccurately in technical regulations, resulting in challenges to implement irrational requirements at best and impossible requirements at worst.

Including the text in the technical regulation does have the advantage that only relevant parts of the standard having a direct bearing on safety and health issues, for example, can be selected. For this reason, some jurisdictions still favor this approach above referencing the complete standard, which may include requirements not considered relevant for regulation.

However, given the disadvantages, incorporating the full text of a standard in the technical regulation has fallen out of favor in many jurisdictions, and preference is given to referencing standards instead.

7.4.2 Referencing standards

Referencing standards is a good regulatory practice to describe the technical requirements of the technical regulation. There are a few possibilities for this approach, all of which are being used in various jurisdictions. Each has its own advantages and challenges. The two main groups are direct and indirect referencing.

Direct (exclusive) referencing

In direct, or exclusive, referencing, the standard is referenced by at least the number and the title. An abstract is sometimes included, but this is not absolutely necessary as long as the number and title identify the standard unambiguously. The demonstration of compliance with the technical regulation is, in this case, always in accordance with the referenced standard.

The exclusive reference may be dated or not. If the reference to the standard includes its date of publication, then only this version can be used for compliance purposes. The regulatory authority remains the "master of the procedure" because any revision of the standard does not automatically lead to the revision of the technical regulation. The regulatory authority has to update the reference

to the revised standard for the technical regulation to be updated. Although some legislators may prefer this situation, it also places responsibility on the regulatory authority to keep track of developments regarding the revisions of the referenced standards. If only certain parts of the standard are required for regulatory purposes, dating the reference would be the only way to do it.

If the exclusive reference is not dated, then the technical regulation is updated automatically if and when the standard is revised; that is, it will always be the current version of the standard that is cited when contemplating compliance. This is an elegant way to keep the technical regulation updated for fast-moving technologies. The challenge of this methodology is that the regulatory authority is no longer the sole "master of the procedure"; some of the regulatory authority's jurisdiction has been relinquished in favor of the standards body. Whether this is a real issue is a risk the regulatory authority has to consider before adopting this methodology.

Indirect (indicative) referencing

In indirect, or indicative, referencing, the relevant standard is not defined in the technical regulation by number and title. The technical regulation provides for essential requirements that have to be complied with in an indicative way. The relevant standards are then published in a separate official journal. Compliance with these standards confers compliance of the product with the technical regulation's essential requirements. The list of standards can obviously be either dated or undated.

The European Union (EU) New Approach directives are probably the best-known exponents of this system, and in their case, the standards—EN harmonized standards—remain "voluntary."[2] A further element of the EU system is that suppliers can in theory also use standards other than the EN harmonized standards, but then the burden of proof that these other standards also fulfill the essential requirements of the New Approach directives is shifted to the supplier. In practice, therefore, it is debatable whether any supplier would go this route, because it is much less of a hassle to use the EN harmonized standards.

Choice of referencing system

The choice as to which system should be used depends on the customs and practice of the country and on the relationship between the regulatory authorities and the national standards body. If a good understanding is in place, then using undated references is a useful mechanism to keep technical regulations up-to-date. The regulatory authority then also does not have the challenge of putting a resource-intensive maintenance system in place. If there is not a good working relationship between the regulatory authorities and the national standards body, dated references may be the better option, but the regulatory authority then has to establish a proper maintenance system to keep the references up-to-date. Whatever the choice, it should be applied consistently across all regulatory authorities and should be part of the formal technical regulation framework (see section 7.9.3).

Anecdotal evidence suggests that for the indicative referencing to work well, a good product liability regime has to be in place, especially if standards other than those on the official list are used by suppliers. The regulatory authority must be given additional muscle to deal with products that do not comply with the listed standards but with standards chosen by the supplier that are still considered noncompliant with the technical regulation by the

regulatory authority. If such a product liability system is not in place, then direct referencing would be the better approach, even though it is more restrictive regarding standards that may be used by the supplier.

7.5 CONFORMITY ASSESSMENT MODALITY GOOD PRACTICES

In all technical regulation regimes, compliance evidence (for example, inspection, testing, or certification) in some shape or form is required by the regulatory authorities to assess whether products falling within the scope of technical regulations actually comply with their technical requirements. The conformity assessment requirements should be defined in the technical regulation. Such evidence can be provided by the supplier (the first party) or by an entity independent from the supplier (the third party). In the case of technical regulations, the purchaser, consumer, or user (the second party) is not directly involved in demonstrating compliance of the product with stated requirements.

7.5.1 Supplier's Declaration of Conformity (SDoC)

A declaration by the supplier that the product complies with the requirements of the technical regulation is called the Supplier's Declaration of Conformity (SDoC). Sometimes the expression "self-certification" is used, but this is totally incorrect because "certification" by definition involves a third party. This is so even if the supplier uses the services of an outside laboratory to test the relevant products but issues the declaration of conformity on its own responsibility. The international standards ISO/IEC 17050-1 and 17050-2 (Parts 1 and 2 of "Conformity Assessment—Supplier's Declaration of Conformity") detail the requirements for an SDoC and have been adopted by the EU and many national standards bodies.

An SDoC is considered the most cost-effective approach for suppliers to demonstrate conformity because it does not require third-party inspection, testing, or certification. Additional savings may be realized in costs associated with sales losses because of the time otherwise needed for third-party approvals. The Organisation for Economic Co-operation and Development (OECD) has shown that the use of SDoCs instead of third-party conformity assessment regimes leads to an increase in trade (Flies, Gonzales, and Schonfeld 2008). It therefore does not come as a surprise that major industry groups such as the information technology and automotive industries are advocating the use of SDoCs wherever they can.

An SDoC is acceptable for demonstrating compliance with a technical regulation if the regulation provides for such a mechanism. In general, this will be the case only if the following conditions are in place: (a) the market demands or allows it; (b) the risks associated with noncompliance are relatively low; (c) the penalties for noncompliance are implemented and are effective deterrents; (d) options for efficient recourse in the event of noncompliance exist; and (e) the industry sector to which it applies is highly dynamic, responsible, and has a history of compliance (Flies, Gonzales, and Schonfeld 2008).

SDoCs are acceptable for technical regulations in quite a few instances in high-income economies. Typical examples include toys, personal protective equipment, and recreational craft in the EU; radio and telecommunication

equipment in Australia, Canada, the EU, Japan, New Zealand, and the United States; and motor vehicles and motor vehicle components in Canada, the Republic of Korea, and the United States. SDoCs are not common in low- and middle-income economies, probably because of the lack of proper product liability legislation that would support regulatory authorities in dealing with noncompliant products and the bitter experience of the dumping of unsafe products in the market by unscrupulous traders.

7.5.2 Third-party conformity assessment service providers

If SDoCs are not applicable, because if the technical regulation does not allow for them, then third-party conformity assessment organizations provide inspection, testing, and certification services to demonstrate compliance of the product with technical regulation requirements. Quite a few modalities are possible, as discussed below.

Regulatory authorities

In the past—and this is still the case in many countries—regulatory authorities have the responsibility to inspect, test, and certify products for compliance with technical regulations. This is specifically the case where premarket approvals are required before a product can be legally sold. The ubiquitous use of the national product certification mark (see module 6: Conformity Assessment, section 6.4 on product certification) in many low- and middle-income countries is a typical example of this mechanism. The same applies to the inspection and testing of imported products by the regulatory authorities at the port of entry.

This system is no longer considered good regulatory practice for all types of products. Some of its issues include the following:

- If the regulatory authority's technical competency is suspect, the supplier has nowhere else to go.
- The regulatory authority may choose to reinspect and retest products just to keep its own laboratories occupied.
- Using the national product certification mark for regulatory purposes is arguably an unnecessary barrier to trade and hence is contrary to WTO TBT Agreement principles.
- The regulatory authority is given a license to extract rent in the form of levies that suppliers have to pay irrespective of whether their products are properly inspected and tested.
- The regulatory authority is perceived to take the responsibility for the integrity of the products, whereas that responsibility should remain with the supplier.

Good regulatory practice would indicate that the regulatory authority has the responsibility to conduct market surveillance and impose sanctions in the case of noncompliance. Conformity of the product should be the responsibility of the supplier and the assessment thereof provided by technically competent third-party organizations. Changing from the mandatory application of the national product certification mark to a more modern technical regulation regime is a major challenge for the national standards bodies in many countries because this would affect their income (which is often 80 percent or more dependent on the national product certification mark), over and above the fact that the state may then have to shoulder the additional costs of market surveillance.

Designated organizations

Designation is defined as the governmental authorization of a conformity assessment body to perform specified conformity assessment activities (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). Good regulatory practice would suggest that conformity assessment should be provided by third-party service providers that are technically competent. Technical competency is now generally demonstrated through accreditation by an internationally recognized accreditation body. But before designating a conformity assessment body, the regulatory authority may wish to add requirements not assessed by accreditation.

These requirements could include the ability to take a conformity assessment body to court; for example, it has to be registered in the country, it should be in good standing with other government authorities, it should be up-to-date with tax returns, and so on. In such cases, the regulatory authority would demand evidence additional to the accreditation certificate before it designates the conformity assessment body to provide conformity assessment services for specific technical regulations. The "notified bodies" in the EU are a typical example of such designation.[3]

Designation without accreditation is still being practiced in some countries, but such a system may or may not provide an assurance that the technical competency of the conformity assessment bodies meets minimum requirements, and it is debatable whether it will be accepted by major trading partners, even within the realm of a common market.

Unilateral acceptance

In smaller economies, the regulatory authorities are frequently confronted by a lack of conformity assessment bodies in the country as well as the absence of bilateral or multilateral recognition agreements between their government and the governments of major trading partners. They would then have to resort to the unilateral acceptance of conformity assessment results—at best from accredited conformity assessment bodies abroad, at worst from conformity results provided by suppliers. Either way, the regulatory authority will have little recourse in the case of fraudulent or improper conformity results. The regulatory authority should therefore carefully weigh the risks of accepting such conformity results before accepting them at face value.

Bilateral or multilateral recognition agreements

Trade agreements between countries, either bilateral or multilateral, often include recognition agreements of conformity assessment regimes of the trading partners. These could even be entrenched in treaties and protocols, provided that recourse in the case of incorrect or fraudulent conformity assessment results or noncompliant products is provided for. The recognition of national product certification marks among the common market members is a typical example, as is the recognition of test results from accredited laboratories among major trading partners. These multilateral recognition agreements are difficult to negotiate and take a long time before they start operating.

Other recognition mechanisms are provided for through international systems (see module 6: Conformity Assessment, section 6.9) such as those operated by

- *The International Electrotechnical Commission (IEC)* for electrical and electronic products, such as the IECEE, IECEx, IECQ, and IECRE schemes;[4]

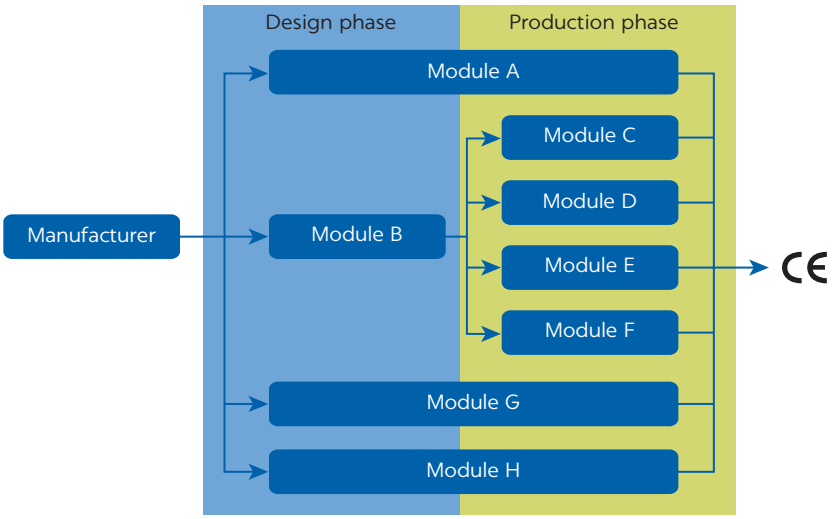
- *The International Organization of Legal Metrology (OIML)* for measuring equipment (Basic Certificate System) and the Mutual Acceptance Arrangement; and
- *The United Nations Economic Commission for Europe (UNECE)* 1958 Agreement for motor vehicle components (see module 6: Conformity Assessment, section 6.9.3).

7.6 REGULATORY AUTHORITY VERSUS SUPPLIER RESPONSIBILITIES

Good regulatory practice indicates that the supplier should at all times remain responsible for the integrity of the product; that is, the supplier must ensure that the product complies with technical regulation requirements. The regulatory authority is responsible for evaluating whether this is the case, but it should never take the responsibility for the integrity of the product, and it should steer clear of actions that could be perceived as such.

Modern technical regulation regimes require the supplier to have all the inspection, testing, and certification conducted to demonstrate the compliance of the product with requirements. These actions should be defined in the technical regulation. A typical example involves the eight modules used in the EU directives (figure 7.4). These modules range from an SDoC for low-risk products (module A) through the involvement of designated test laboratories and certification bodies (the "notified bodies") in increasing levels of involvement (all the other modules), after which the product should receive the

FIGURE 7.4
Simplified chart of EU conformity assessment procedures



Module A: Internal control of production
Module B: EC type examination
Module C: Conformity to type
Module D: Production quality assurance
Module E: Product quality assurance
Module F: Product verification
Module G: Unit verification
Module H: Full quality assurance

Source: EC 2000. ©European Commission. Reproduced with permission from EC, further permission required for reuse.
Note: EU = European Union. The Conformité Européenne (CE) marking is placed on the product and/or packaging by the manufacturer or supplier once all the requirements of the relevant New Approach directive of the EU have been fulfilled.

Conformité Européenne (CE) marking.[5] Another example is the Fastener Quality Act of the United States, which requires that suppliers have their fasteners tested by an accredited laboratory against the requirements of the relevant standard and that the fasteners be marked with a trademark registered with U.S. authorities.

7.7 MARKET SURVEILLANCE, RISK, AND SANCTIONS

Market surveillance is an essential tool for the enforcement of technical regulations. The purpose of market surveillance is to ensure that the products placed on the market comply in all respects with the requirements of the relevant technical regulation to safeguard the health and safety of the country's people, fauna and flora, and the environment. Market surveillance is also important from the perspective of the economic operators because it helps to reduce unfair competition.

7.7.1 Regulatory authorities

To ensure the impartiality of market surveillance operations, market surveillance is the responsibility of the state. The state therefore has to establish regulatory authorities to serve as its market surveillance infrastructure. The number of regulatory authorities and their fields of responsibility are decisions the state has to make. In most countries, each ministry will establish one or more regulatory authorities with specific mandates. Some countries, to better use scarce resources, will establish only four or five larger regulatory authorities for specific sectors (for example, food safety, manufactured products, telecommunication, transportation, building and construction, and so on). Very small countries may even consider the establishment of a single regional regulatory authority for all products falling within the scope of technical regulations. The choice will be determined by political custom and practice, availability of resources, and the extent of the work to be done.

The major issue for the market surveillance infrastructure is that there should not be obvious gaps and overlaps in the spheres of responsibilities of the various regulatory authorities. Gaps might allow products into the marketplace whose failure could be deleterious to the safety and health of the population or the environment. Overlaps, on the other hand, create uncertainty in the marketplace as suppliers are subjected to differing sets of requirements, resulting in unnecessarily high transaction costs for more than one regulatory authority. It is also debatable whether such duplication supports safety and health; the argument may even go in the opposite direction, because suppliers may take risks they otherwise would not have taken to circumvent one or another technical regulation.

Cooperation among the regulatory authorities is therefore important, and many countries have established supranational technical regulation coordination offices for this purpose (Jacobzone, Choi, and Miguet 2007). These offices also effect proper cooperation between the regulatory authorities and the various organizations in the QI that provide standards, metrology, accreditation, and conformity assessment services in support of the implementation of technical regulations. A further responsibility of these offices is to ensure that the country as a whole (that is, all ministries and regulatory authorities) complies with its obligations in relation to the WTO TBT Agreement.

Regulatory authorities should have the necessary resources and powers to conduct their surveillance activities. This is to monitor products placed on the market and, in cases of noncompliance, to take appropriate action to enforce conformity. The regulatory authority should have the appropriate number of suitably qualified and experienced personnel who have the necessary professional integrity. Testing should be conducted by technically competent (accredited) laboratories. The regulatory authority should also be free from undue political influence and carry out its responsibilities in an impartial and nondiscriminatory way.

7.7.2 Market surveillance principles

For market surveillance to be efficient, resources need to be concentrated where risks are likely to be higher or noncompliance more prevalent. On the other hand, regulatory authorities need to carry out market surveillance with due respect for the principle of proportionality. This means that action should be in accordance with the degree of risk, and the impact on the free movement of products should not be more than is necessary. Statistics and risk assessment procedures are a great help in getting this balance right.

Market surveillance normally does not take place during the design and production of the relevant product. In other words, suppliers should be responsible for premarket inspection, testing, or certification, as required by the relevant technical regulation (see section 7.6). Nevertheless, efficient enforcement usually requires collaboration with manufacturers or suppliers early in the process to ensure that nonconforming products are not placed on the market.

Market surveillance consists of scheduled activities and unscheduled investigations based on information from the marketplace or requests by authorities, a court of law, or written complaints by consumers. Typical market surveillance activities—consisting of (a) inspection of an audit sample of products falling within the scope of the relevant technical regulation, and (b) scrutiny of relevant documentation—therefore include the appropriate mix of the following:

- Planned regular visits to commercial, industrial, and storage facilities
- Planned regular visits to workplaces and other premises where products are put into service
- Random and spot checks
- Investigations of reported nonconformities
- Taking of audit samples of products and having them tested against the requirements of the technical regulation
- Requiring and reviewing all the necessary documentation

Voluntary product and management system certification can contribute to the reduction of risks. However, regulatory authorities should remain impartial regarding these certifications and may take them into consideration in a transparent and nondiscriminatory way only. Therefore, products with product certification marks or that are produced by companies with management system certification should not be excluded from market surveillance activities.

An issue that should not be forgotten when establishing market surveillance schemes is the question of controls at borders. In the global trading system, many products will be imported into the market of any given country. Many of these products will fall within the scope of technical regulations. The market

surveillance schemes should therefore also be extended to include products imported into the country, whether by boat, train, road, or air. The border controls will require even more careful planning to ensure that products are not held up unnecessarily at the border while being inspected for compliance with the relevant technical regulations. A system of bond warehousing is often implemented whereby products can be moved from the border to specific warehouses, but the products cannot be marketed until released by the regulatory authority.

7.7.3 Imposition of sanctions

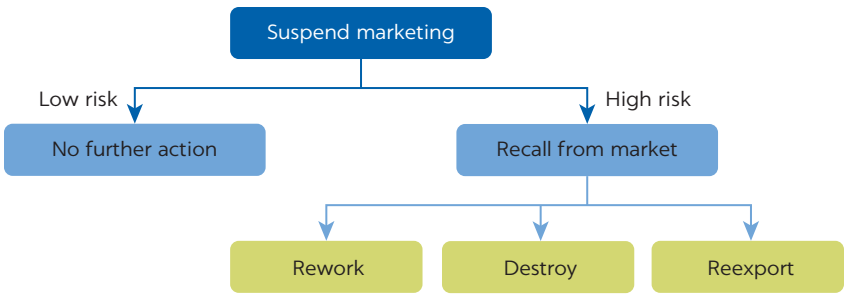
Regulatory authorities must take action to enforce conformity when nonconforming products are discovered in the marketplace. The corrective action will depend on the degree of noncompliance and should also follow the principle of proportionality. The difference between nonsubstantial and substantial noncompliance will frequently have to be based on the sound judgment of the regulatory authority. Small labeling errors, for example, can be considered as nonsubstantial, whereas noncompliance with requirements that may be deleterious to the health or safety of users must be considered as substantial.

Typical actions taken by the regulatory authority can be considered on a number of levels (figure 7.5):

- *Rectification:* In the case of nonsubstantial nonconformities, the regulatory authority prevails on the supplier to rectify all future products.
- *Suspension:* In the case of substantial nonconformities, any further marketing of the product must be suspended immediately.
- *Recall:* In serious cases, the supplier must recall nonconforming product from the marketplace, and consumers must be informed to return identified products to the point of sale.
- *Postrecall decisions:* A decision has to be made whether a recalled product can be rectified to render it compliant and be marketed again or whether the nonconformity is of such a nature that the product must be destroyed.

A decision to destroy a consignment should be mindful of the environmental impacts such an action would entail, and specialist companies may have to be contracted by the supplier to do so as directed by the regulatory authority. In some countries, the regulatory authorities direct the supplier to reexport noncompliant imported products to the country of origin. This decision should

FIGURE 7.5
Typical administrative sanctions against noncompliant products



be taken cautiously because once the product is no longer within the country's jurisdiction, it is anybody's guess as to where it will be exported. It may just end up in a country without a proper technical regulation regime, consequently bringing misery to the purchasers there.

If none of these administrative-type measures has the desired effect, the regulatory authority must take legal action, such as taking the offending party to court to enforce compliance in the marketplace. Until court proceedings are completed, the marketing of such products remains suspended, and consumers should be informed accordingly. Failure to do so may just give some suppliers the sense that the regulatory authority is unwilling to go to court, and rogue suppliers may just be strengthened in their resolve to circumvent requirements to gain greater profits.

7.8 IMPACT OF TECHNICAL REGULATIONS

The potential impact of implementing technical regulations could be profound. Yet there is no definitive conclusion about the impact of technical regulations on trade or on the safety and health of the population, fauna and flora, and the environment, even though many studies have been undertaken. All the studies have highlighted the challenges in getting meaningful answers because of the general lack of data (WTO 2012).

A few general trends have been identified in various studies. These studies mostly deal with nontariff barriers (as a whole, which include TBT and SPS issues). The following sections are summarized from the WTO's *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century* (WTO 2012).

7.8.1 Are nontariff measures on the increase?

Despite common perceptions about a rising trend in nontariff measures (NTMs), evidence is inconclusive.[6] NTMs appear to have risen in the mid-1990s; but between 2000 and 2008, activity remained relatively flat, before picking up again following the 2008–09 global financial crisis. However, WTO notifications suggest an upward trend in technical barriers to trade (TBT) and sanitary and phytosanitary (SPS) measures.

According to historical data from United Nations Conference on Trade and Development (UNCTAD) databases, shares of product lines and trade values covered by NTMs rose between the late 1990s and early 2000s but then stayed flat or declined slightly up to 2008. WTO data on notifications, however, show increasing use of TBT or SPS measures since the mid-1990s. This increase is also reflected in an increase in the number of specific trade concerns raised by WTO members in the TBT and SPS committees.

7.8.2 Most-burdensome NTMs: TBT and SPS measures

Evidence from business surveys conducted by the International Trade Centre (ITC) in 11 low- and middle-income countries suggests that TBT and SPS measures are the most burdensome for exporters (ITC 2015). In 2010, the share of TBT or SPS measures in all NTMs perceived as burdensome by exporting firms

was 48 percent. Similarly, survey-based data show a large share of TBT or SPS provisions in measures affecting EU exporters (just over 50 percent), but the U.S. share is lower (around 20 percent).

The impacts of TBT or SPS measures vary across sectors but are more prevalent in the agriculture sector, where even TBT concerns (29 percent) were the most prevalent NTMs, over and above the expected SPS concerns (ITC 2015). Evidence also suggests that procedural obstacles are the main sources of difficulties for exporting firms from low- and middle-income countries—time constraints and unusually high fees being the most-cited obstacles.

7.8.3 Impact of TBT and SPS measures on trade

The results from the current studies have shown that, in general, TBT or SPS measures have prevalently positive effects for more technologically advanced sectors but negative effects on trade in fresh and processed goods. The negative effects are generally the result of badly designed technical regulations or SPS measures as well as the less-than-effective or totally inconstant implementation thereof.

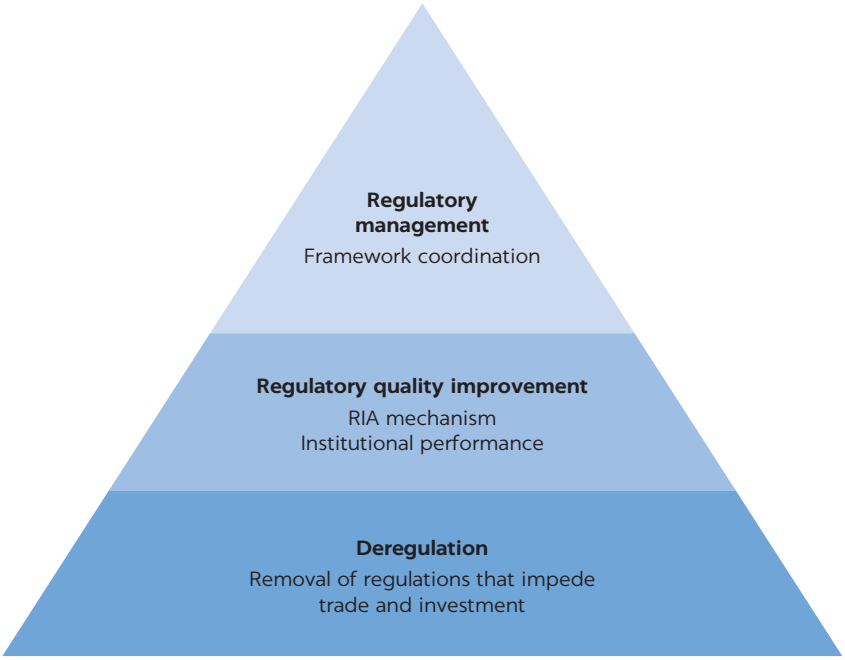
Furthermore, when negative, the effect of TBT or SPS measures on trade is found to be driven by the impact on low- and middle-income countries' exports, especially from small countries. There is some evidence that conformity assessment is particularly burdensome on food and agricultural trade, much more so than for manufactured goods. Larger firms in high-income economies are also less sensitive than smaller companies to TBT or SPS measures.

7.9 GOOD TECHNICAL REGULATORY PRACTICE

In most countries, technical regulations have been developed and implemented by any number of authorities over many years without official guidance as to their modalities. Hence, many countries have a real mix of technical regulations on the statute books, with some of them decades old. Many of these older ones are no longer relevant or are technically outdated, and they are sometimes even unknown to the authorities. Development and implementation modalities vary across regulatory authorities, and compliance with WTO TBT Agreement requirements is patchy or unknown. The technical regulation regime can therefore be considered as fragmented and disordered, and differences among regulatory authorities have the tendency to increase over time.

With the development of global trade and the necessity for countries to gain access to these markets, the need for regulatory reform of how technical regulations are developed and implemented has therefore become pressing. Good regulatory practices have to be established across all regulatory authorities, and all of these should follow similar patterns. A country needs to show a "single face" to the world regarding its technical regulations. This brings about clarity and consistency in the marketplace and is the better way to get rid of unnecessary trade-restrictive practices. Such regulatory reform can be divided into three phases: deregulation, regulatory quality improvement, and regulatory management (figure 7.6).

FIGURE 7.6
Phases of regulatory reform



Source: Racine 2011.
Note: RIA = regulatory impact assessment.

7.9.1 Deregulation

As a first step, all the existing technical regulations on the statute books should be identified. Once this is accomplished, the responsible ministries should establish a proper review of all current regulations and (a) *withdraw* them (if they are no longer relevant or if product integrity can be achieved with fewer regulatory controls); (b) *revise* them (if they are technically outdated); or (c) *confirm* them (if they are still necessary and technically relevant). Such a review program has to have a time limit; otherwise, it will drag on forever.

7.9.2 Regulatory quality improvement

It is possible, using a variety of scientific sources and methods, to arrive at fairly good estimates of the protection improvement likely to result from new or revised technical regulation. These estimates can be combined with information about the estimated costs of implementing such technical regulation to generate a regulatory impact assessment (RIA).

The second element of regulatory quality improvement has to do with the improvement at the technical, organizational, and performance levels of the many institutions that are involved in a modern technical regulation regime. These include technical regulation development, standards and conformity assessment issues, metrology, and accreditation—in fact, the totality of the QI.

7.9.3 Building a regulatory management system

Assessments in various parts of the world have highlighted a number of weaknesses in national technical regulation regimes that are in need of serious overhaul. Some of the common results from these assessments indicate the following:

- In most economies, technical regulations are developed and implemented by many ministries, authorities, or agencies, each of them following their own customs and practices.
- Authorities have developed their own unique ways of developing and implementing technical regulations over time, and these customs and practices may or may not comply with WTO TBT Agreement requirements.
- Invariably, overlaps and duplication developed among the authorities' spheres of responsibility and activity, and hence in the regulatory regimes as well.
- Regulatory authorities, having grown accustomed to a position of absolute power in the past, do not easily shift toward a more consultative approach.
- The use of voluntary standards as the basis for technical regulation is not the norm. In certain countries, the two are confused.

To deal with these weaknesses in a systematic way, an effective national regulatory management system has to be developed, agreed to at the highest political level, and rigorously implemented. Two important elements of such a regulatory management system are a technical regulation framework and a coordination mechanism.

Technical regulation framework

To ensure that the technical regulation regime of a country meets the requirements of the WTO TBT Agreement, it is good regulatory practice that the principles, approaches, and modalities for the development and implementation of technical regulations be harmonized across all ministries and regulatory agencies at the national and subnational levels. Such a coordinated approach is important for consistency in the marketplace and is useful in ensuring that the technical regulation regime is both effective and efficient.

The community legislative instruments of the EU New and Global Approach directives are probably the best-known exponents of such a technical regulation framework. The point is that such a consistent approach is only possible if the framework is given legal substance by a legislative instrument (such as a law, decree, or the like) that takes precedence over any other legislative instrument mandating that authorities develop and implement technical regulations.

The contents of the technical regulation framework can be deduced from the building blocks of a technical regulation (see section 7.3). They should therefore cover at least the following:

- The necessity of conducting an RIA to determine whether a technical regulation is necessary or whether the market failure can be dealt with in another way
- The way in which standards will be used as the basis for technical regulation

- The modalities for the demonstration of conformity
- The responsibilities of the regulatory authority—for example, premarket approvals, market surveillance, and the imposition of sanctions
- The type of sanctions to impose when nonconformities are discovered in the marketplace

The technical competency of conformity assessment bodies needs to be addressed—highlighting the role of accreditation and metrology. Also important is to stress the responsibilities of suppliers, not only in ensuring that products meet requirements and that the necessary conformity evidence is in place, but also in supporting the market surveillance activities of the regulatory authorities. The technical regulation framework will also establish a supranational technical regulation coordination office, if relevant (see below).

Technical regulation coordination office

Technical regulation is complex, and it has become one of the major issues hindering the movement of goods across borders and within countries. Because technical regulations are developed and implemented by many authorities at the national and even subnational levels, coordination of their responsibilities—among each other and between them and the QI organizations providing standardization, metrology, accreditation, and conformity assessment services—has become an imperative for trade facilitation.

Many countries have established supranational regulatory coordination entities (Jacobzone, Choi, and Miguet 2007). A typical organizational relationship between such a coordination entity and the ministries, regulatory authorities, and QI institutions for technical regulation activities is shown in figure 7.7. This example is by no means the only possibility, but it can serve as a useful departure point for national debate and decision making regarding such a construct. Even smaller countries—such as Costa Rica, the Czech Republic, and the Kyrgyz Republic—have established such coordination offices and mechanisms, and others are in the process of doing so.

It is important that such an office have the relevant legal and perceptual authority to deal with ministries and agencies that are powerful in their own right. Hence, it is usually accountable to the holder of a high political office, such as the prime minister or president (Racine 2011).

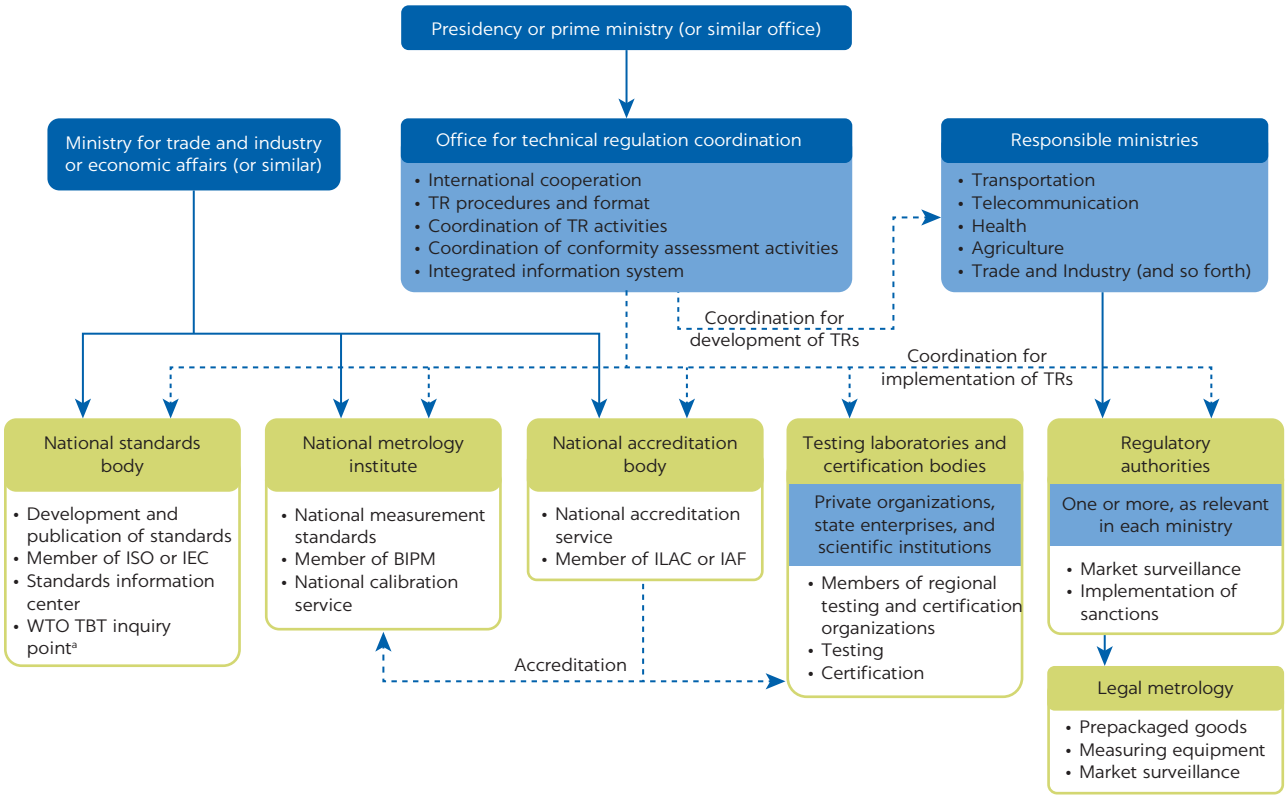
7.10 DIFFERENCES BETWEEN TBT AND SPS MEASURES

The terminology of standards, technical regulations, and SPS measures is frequently a source of confusion. Common usage of these terms does not always correspond to the legal meanings provided in the WTO TBT and SPS Agreements. For example, many countries have food standards that are mandatory, whereas the WTO TBT Agreement considers standards to be "voluntary" in nature. Furthermore, the WTO TBT and SPS Agreements differ slightly in the meaning of the word "standard"; in the WTO TBT Agreement, a standard is purely voluntary, whereas in the WTO SPS Agreement, a food standard could be mandatory.

It is important to understand that the WTO TBT and SPS Agreements are complementary but mutually exclusive. A measure falling within the scope of the WTO SPS Agreement is by definition excluded from the WTO TBT Agreement.

FIGURE 7.7

Typical organizational relationships between QI service providers and technical regulation authorities



Source: Racine 2011.
Note: Dotted lines denote coordination relationships; continuous lines denote oversight relationships. BIPM = International Bureau of Weights and Measures; IAF = International Accreditation Forum; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; QI = quality infrastructure; TR = technical regulation; WTO TBT = World Trade Organization Agreement on Technical Barriers to Trade.
a. An "inquiry point" is an official or office in a WTO member government designated to deal with inquiries from other WTO members and the public on a subject such as technical barriers to trade or sanitary and phytosanitary measures.

An important point is that it is the *measure* that is mutually exclusive, not the *product*. There are numerous examples of products that are subject to both the WTO TBT Agreement and the SPS Agreement, depending on the product characteristic that is being dealt with (table 7.1). Another common fallacy is that food products are subject only to the WTO SPS Agreement. This is not true, either. The WTO TBT Agreement is applicable not only to manufactured products, but also to agricultural products insofar as they are not subject to an SPS measure.

The WTO SPS Agreement defines an "SPS measure" as any measure to

- Protect human life or health from risks arising from additives, contaminants, toxins, or disease-causing organisms in food and beverages, or from diseases carried by animals or plants or their products, or from pests;
- Protect animal life or health from risks arising from additives, contaminants, toxins, or disease-causing organisms in feedstuffs, or from diseases carried by animals or plants, or from pests, diseases, or disease-carrying organisms;
- Protect plant life or health from pests, diseases, or disease-causing organisms; and
- Protect or limit other damage to a country from the entry, establishment, or spread of pests.

TABLE 7.1 Selected comparisons between typical SPS and TBT measures

CATEGORY	COVERAGE OF SPS MEASURES	COVERAGE OF TBT MEASURES
Food and drink	• Additives in food or drink • Contaminants in food or drink • Toxic substances in food or drink • Residues of veterinary drugs or pesticides in food or drink • Processing methods with implications for food safety • Labeling requirements directly related to food safety	• Labeling on composition or quality of food or drink • Quality requirements for fresh food • Weight, volume, shape, and appearance of packaging for food or drink
Plants and animals	• Plant and animal quarantines • Declaration of areas free from pests or diseases • Prevention of the spread of pests or diseases to or within a country	• Packaging and labeling of dangerous chemicals and toxic substances, pesticides, and fertilizers
Manufactured goods	n.a.	• Electrical safety of appliances • Vehicle safety • Safety of toys • Labeling of textiles and garments

Sources: "Understanding the WTO Agreement on Sanitary and Phytosanitary Measures," World Trade Organization (WTO), May 1998, https://www.wto.org/english/tratop_e/sps_e/spsund_e.htm; O'Connor and Company 2002; World Bank.
Note: n.a. = not applicable; SPS = sanitary and phytosanitary; TBT = technical barriers to trade.

Some of the elements of food standards enforced by governments to ensure the safety of foods and the biosecurity controls enforced at international borders to keep out exotic animal and plant pests are typical SPS measures. The differences between SPS and TBT measures are further elaborated in table 7.1 through a few examples dealing with food, safety, and health.

The WTO SPS Agreement requires that WTO members base their SPS measures on the international standards, guidelines, and recommendations developed by three specific organizations: the Codex Alimentarius Commission (CAC), the World Organisation for Animal Health (OIE), and the Secretariat of the International Plant Protection Convention (IPPC). The WTO TBT Agreement also requires that WTO members base their technical regulations on international standards, without specifically mentioning any international standards body by name. Furthermore, WTO members shall ensure that any SPS measure is based on scientific principles and is not maintained without sufficient scientific evidence. The WTO TBT Agreement does not specifically mention such a focus on scientific principles when deciding on whether to implement a technical regulation; it broadly lists only valid reasons.

NOTES

1. The WTO SPS Agreement lists three international standards bodies by name: the Codex Alimentarius Commission (CAC), the International Plant Protection Convention (IPPC), and the World Organisation for Animal Health (OIE).

2. The EU's so-called New Approach to technical harmonization and standards was introduced in 1985. For more information, see "New Approach and Other Directives," European Committee for Standardization (CEN) website: https://www.cen.eu/work/supportLegislation/Directives/Pages/. Harmonized standards are European Norms (EN)—referring to either the German or French equivalent of a European standard—that are elaborated by the European standardization bodies under a mandate from the European Commission.
3. The EU has published a number of directives detailing the requirements for "notified bodies," but the EU member state decides which conformity assessment bodies under its jurisdiction it wishes to "notify" for a specific directive. The "notified body" is answerable to the competent authority in the EU member state.
4. The IEC schemes for electrical and electronic products are as follows: IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE); IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx); IEC Quality Assessment System for Electronic Components (IECQ); and IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications (IECRE).
5. The CE marking is placed on the product and/or packaging by the manufacturer or supplier once all the requirements of the relevant new directive of the EU have been fulfilled, thereby denoting that the manufacturer or supplier takes full responsibility for the compliance of the product with specified requirements.
6. A nontariff measure (NTM) is a regulatory requirement other than tariffs imposed by a country on traded products. If the NTM has a marked and unnecessary negative effect on trade, then it becomes a nontariff barrier (NTB). Not all NTMs become NTBs, but many have the potential to do so.

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8

The Quality Infrastructure as a Flexible PPP System

INTRODUCTION

The modern quality infrastructure (QI) has evolved over decades as a flexible public-private partnership (PPP) system, with a clear understanding of the relevant responsibilities, strengths, and weaknesses of both the public and private sectors.

8.1 GOVERNMENT RESPONSIBILITIES

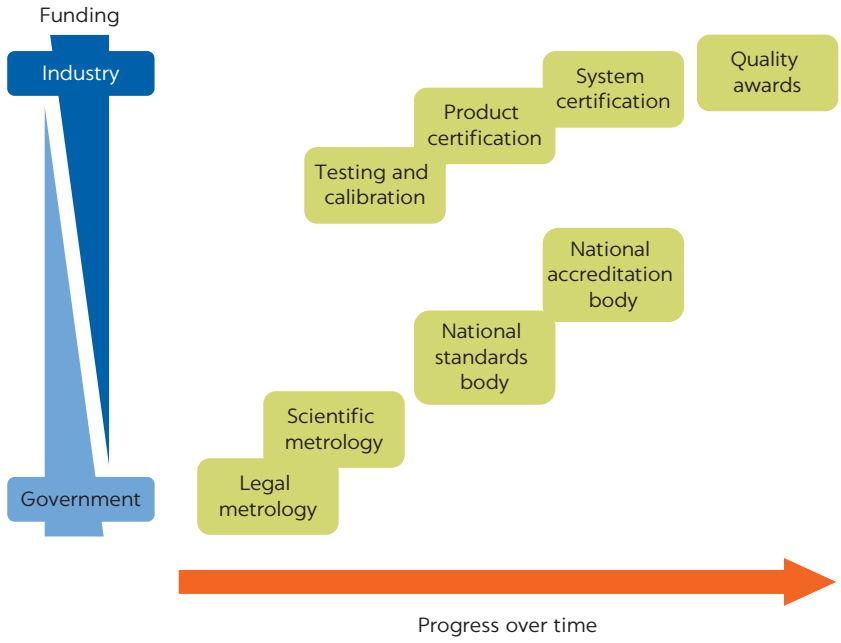
A country's QI, at its most fundamental level, is a system for the common good. Without organizations providing standards, metrology, and accreditation, none of the conformity assessment services can flourish. Without appropriate conformity assessment services, it will be difficult for any country's industry to integrate into the manufacturing value chains spanning the global economy or to access interesting markets.

The path, therefore, for any government is to (a) establish the QI fundamentals; (b) initiate the development of conformity assessment services; and (c) at an appropriate stage, withdraw from the latter to let private sector conformity assessment bodies take over service delivery. The challenges that any government faces involve political understanding, resources, timing, and boundaries—where to start and where to withdraw. The evolution of the QI in the Organisation for Economic Co-operation and Development (OECD) countries does provide a road map that low- and middle-income countries could emulate with success (figure 8.1).

8.2 METROLOGY

Metrology was established already centuries ago as governments in antiquity realized that accurate measurements are necessary for building and construction as well as for equitable trade transactions (as further discussed in module 4). The necessity for the state to gather appropriate taxes probably also played a part. The state established measurement standards and controlled the

FIGURE 8.1
Typical evolution and funding of the quality infrastructure



Source: Racine 2011.

measuring equipment used in trade. These developed into the weights and measures departments of the late 19th century. The same applied to the massive building and construction projects that the state undertook. As science and technology developed, the need for more accurate measurements arose, and the state established scientific metrology institutes during the Industrial Revolution in the technologically advanced nations.

These developments of many years ago hold true even today. Many low- and middle-income countries do have government weights and measures departments that are responsible for the control of measuring equipment used in trade. Many of these countries have also realized that a level of scientific measurement capability is required, and this responsibility has been given to the weights and measures departments. As the country develops technologically, the scientific metrology capability has to be extended, and as socioeconomic development takes place, so also does the need for legal metrology, rather than just weights and measures.

Both elements of the metrology infrastructure—scientific metrology and legal metrology—remain a government responsibility in almost all countries. A review of the membership of the International Organization for Legal Metrology (OIML) and the General Conference on Weights and Measures (CGPM) of the Metre Convention indicates that few, if any, private sector entities operate as national legal metrology authorities or national metrology institutes (NMIs). Scientific and legal metrology is a paramount example of a system for the common good of the country. Therefore, the responsibility for the establishment, funding, and continuous operations of a metrology system remains largely with the state.

It is true that scientific and legal metrology institutions can and do provide services for which they get paid by their customers, but this revenue is nowhere near adequate to cover operational and especially development costs. It is also

arguably the incorrect approach to push the scientific and legal metrology institutions to become financially self-sufficient, because the common-good services will suffer as money-making services are pursued for purely financial reasons. Long-term financial planning (for at least 5–10 years) and the unstinting support of the government in this regard are important for the establishment and maintenance of an effective metrology system in any country.

Calibration, however, is different. Even though the legal metrology and scientific metrology entities initially have to provide calibration services, in modern QI systems, calibration services are largely provided by private sector calibration laboratories. The NMI provides the technological link between international measurement standards and these calibration laboratories through the calibration of the laboratories' working standards, and the national accreditation body ensures their technical competence through accreditation. The major challenge for a country seeking to establish a vibrant and market-related calibration infrastructure is for the two governmental metrology entities to relinquish any actual or perceived monopoly on calibration services. This is a government policy issue as well as an operational challenge on the part of governmental metrology entities, with government funding for scientific and legal metrology at the core of it.

8.3 STANDARDS

The next step in the evolution of the QI is the establishment of a national standards body (NSB) (as also shown in figure 8.1). NSBs are responsible for the development of national standards and provide the link to the international standardization world. Looking at the membership of the International Organization for Standardization (ISO), for example, it is abundantly clear that most NSBs are either government bodies or organizations mandated by public law. Private sector NSBs are in the minority, and those that do exist are registered as organizations without a profit motive. This underscores the notion that NSBs are also part of the common good for the country's QI system.

In industrialized nations, NSBs established by the private sector have evolved (for example, in Germany and the United States); but even there, a formal agreement exists between the state and these NSBs for the provision of national standards and liaison with the international standardization environment, coupled with state funding. Some of these NSBs may obtain the bulk of their funding through the sales of standards and standards-related information, but they have the backing of a well-developed and standards-knowledgeable industry. This is certainly not the case in low- and middle-income countries and is also the exception in many high-income countries.

Hence, either the state has to provide the bulk of the funding for national standardization activities (development of national standards, liaison with the international standardization environment, operation of a standards information center, provision of a World Trade Organization [WTO] Technical Barriers to Trade [TBT] Inquiry Point, and so on), or the NSB needs to obtain funds from other sources such as the provision of conformity assessment services. The concept of "core funding" evolved in this respect, with the state providing finances for the common-good activities of such NSBs, whereas their conformity assessment services are not cross-subsidized by the state and have to operate as financially self-sufficient services (ISO 2010).

In recent decades, several private sector standardization bodies—removed from the general needs environment—have been established. These consortiums and nongovernmental organization (NGO)–type standards bodies develop standards mostly for use in private sector certification schemes, either as a business venture or as a result of socioeconomic pressures from consumers who are worried about environmental and social issues. Although these standards have become important in trade, they are not the responsibility of the state. Hence, the state generally does not support their development.

The relationship between private standards and national standards is an evolving one, and more collaboration may develop as both sides realize, on the one hand, that standards need to be harmonized internationally to foster trade but, on the other hand, that the needs of industry and society also have to be addressed much more rapidly than international or even national standards currently are capable of doing (von Hagen and Alvarez 2012).

8.4 ACCREDITATION

The most recent step in the development of the fundamental QI services is accreditation. It developed really only in the aftermath of World War II, in the wake of increased trade among trading partners. It is now the preferred methodology to demonstrate the technical competency of conformity assessment bodies, both within common markets and beyond those markets' boundaries. This is so because, in most industrialized countries, conformity assessment activities increasingly migrated from the public to the private domain during this time, and some type of independent verification of their technical competence became necessary (Racine 2011).

Accreditation services are generally provided in a noncompetitive manner worldwide, even though they did not start that way. When a national accreditation body (NAB) has been established and has been internationally recognized, it typically retains a monopoly over its activities. This is so because accreditation plays such an important role in determining the technical competency of conformity assessment bodies, initially in the regulatory domain (from which governments are slowly extracting themselves, even though they still like to keep oversight over service delivery). Accreditation has in the meantime developed to the stage where it is also a factor for industries wishing to export and needing conformity assessment services that are internationally recognized.

In some countries, a number of accreditation bodies that developed sectorally over the years have been merged into one national body, such as in Germany and Italy, albeit at the instigation of the European Commission. Private sector accreditation bodies still do exist, and some have been designated as their countries' NABs and given a measure of regulatory authority, such as in Germany and the Netherlands. Some other private sector accreditation bodies operate only within a given conformity assessment scheme, such as the SA 8000 (social accountability), the Marine Stewardship Council (sustainable seafood), and the IATF 16949 (automotive components), among others.

The accreditation environment is also still evolving, but the notion of it being noncompetitive will probably be strengthened rather than weakened. That is, NABs will refrain more and more from providing services other than in their own countries, and regional accreditation bodies will remain within their regions.

In addition, international recognition will remain as a peer review process; that is, at some point the oversight function has to be contained and not be subjected to ever-increasing layers of national, regional, or international bureaucracy. The establishment of an NAB is a long-term process, with quite a few years needed to gain international recognition through the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF) multilateral recognition arrangements. This means government financing for the short to medium terms is essential even after such recognition has been achieved. With the accreditation body frequently limited in the fees it may charge (because of its regulatory-related activity), state support is usually required also in the medium to long term for regional and international liaison and recognition activities.

8.5 PRIVATE SECTOR INVOLVEMENT IN THE QI

As can be deduced from figure 8.1, in high-income countries, conformity assessment services (testing and inspection, product certification, and so on) are largely established and funded by the private sector. This does not come about all by itself; it is the combined result of (a) a liberalization policy rigorously implemented by government, and (b) the growth of the market for such services to a size that will attract private sector investments.

8.5.1 Liberalization of conformity assessment services

In the initial stages of the establishment of the QI in a country, the government has to take the lead not only in establishing the fundamentals (standards, metrology, and accreditation services) but also in establishing conformity assessment services (inspection, testing, and certification), because there is not yet a market for such services that would entice the private sector to do so. The growth of the market for conformity assessment services comes only with time, as industries develop to the point where they require it or as technical regulation regimes are implemented that demand proof of compliance from suppliers of products.

Such conformity assessment services are provided by various government-type institutions, such as the NSB, the NMI, the legal metrology authority, scientific research organizations, various regulatory authorities, and the like. Increasingly, however, the possibilities for the private sector to invest in conformity assessment bodies will manifest themselves. The government then needs to make and forcefully implement the policy decision that it will also use conformity assessment services from independent private sector conformity assessment bodies, and not only from state-owned ones—in other words, that it will liberalize the conformity assessment market.

This takes a fair amount of political resolve, because state-owned bodies will invariably be subjected to increased competition, when in previous times they enjoyed a real or perceived monopoly. This may have an impact on state finances, as state-owned institutions can no longer rely on their privileged position to extract fees and levies from suppliers without worrying too much about quality of service and hence become more reliant on financial support from the state. Alternatively, state-owned institutions may have to downsize—a move with political consequences in many countries where the state is a major provider of secure employment opportunities.

Once such a liberalization of conformity assessment service delivery has taken root, the country will benefit from one or more of the following as the private sector plays an increasing role in providing such services:

- Private sector conformity assessment bodies generally operate much more efficiently than public sector bodies, thereby cutting down on the time taken to deliver the service.
- Private sector bodies usually are able to react much faster to changing markets than public sector bodies subject to multilevel government decision-making processes, thereby aligning their service delivery in real time instead of months or years after the fact.
- Suppliers may be able to access the services of more than one conformity assessment body, thereby invoking market forces to optimize service delivery versus price decisions.
- The state is no longer required to invest heavily in laboratory infrastructure, thereby relieving some pressure on state finances.
- Remuneration levels for scarce human resources become market-related, and trained and experienced technical staff are more likely to remain in conformity assessment rather than migrating from the civil service to unrelated but better-paying jobs.

Failure to liberalize conformity assessment services (that is, retaining them solely within the public service) will result in fewer choices for the clients of such services. In addition, market forces will not be brought to bear on the level and quality of service delivery, and it is debatable whether the public service's technical competency can be maintained in the long run. The government may choose to retain some high-level testing services as a reference laboratory in specific regulatory areas. In many low- and middle-income countries, the government is also the only organization that funds precompetitive research. Such laboratories can obviously also provide the more mundane testing services when so requested by industry or regulatory authorities.

In such a liberalized conformity assessment market, the need for an independent demonstration of the technical capabilities of the conformity assessment bodies becomes more important from both public and private sector perspectives. Accreditation by an independent accreditation body is the vehicle that has evolved in the past few decades for this purpose, slowly replacing other government department-specific type systems.

8.5.2 Conformity assessment services and the NSB

The national standards body often leverages its knowledge about standards by providing conformity assessment services. If this is not a decision by the NSB itself, it is often predestined by its founding legislation, if it is a government-type organization. Any government obviously also wishes to optimize scarce human and other resources in the delivery of conformity assessment services. A question that invariably surfaces every now and again is whether this is a useful solution or whether this constitutes a conflict of interest.

In some countries, conformity assessment services are heavily subsidized by the state to support industrial development, especially in the small and medium enterprise (SME) sector. When industry has developed to the point where it could and should pay market-related prices for such services, government conformity assessment bodies should start charging such prices in order to not

continue distorting the market; that is, government subsidies should fall away. In many high-income countries, such as OECD members, the governments have even withdrawn from the conformity assessment market, leaving service delivery totally to the private sector.

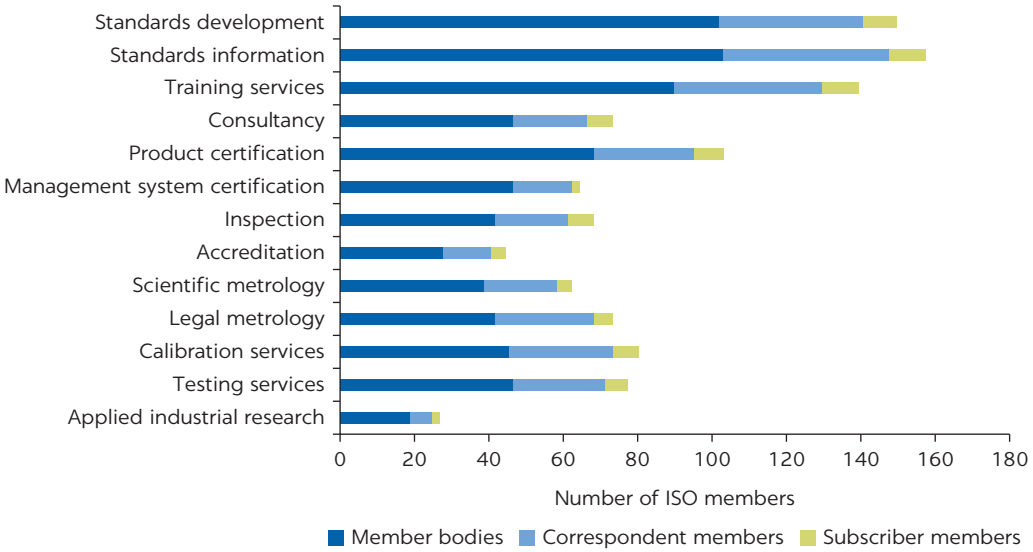
Two points of view regarding the provision of conformity assessment services by NSBs have emerged. On the one hand, critics argue that testing and certification should be separated from the NSB to ensure that the NSB stays focused on its core (but not very lucrative) function, namely, the development and publication of national standards. If the NSB also provides conformity assessment services, this focus tends to shift to the development of standards needed by the NSB rather than by industry or the authorities. The situation is even worse if national standards are designated as mandatory or compulsory standards by the relevant ministry but the implementation thereof is vested in the NSB.

On the other hand, the rationale for the NSB to offer conformity assessment services is that (a) the industry is not yet at a stage of development where such services can be offered through the market, or (b) the surplus income from such services can help subsidize standards development. In low- and middle-income countries, this approach can provide a more effective "one-stop shop" approach and give more visibility to the NSB. This approach also limits the number of directors, other executives, and buildings that otherwise would have to be funded by the state.

Considering the membership of the ISO, the latter is the situation for many of the NSBs making up its membership, even though there are NSBs that only develop and publish standards, mostly in highly industrialized countries or where operating as government departments. A breakdown of services that ISO members offered in 2009 is shown graphically in figure 8.2. (More recent information is not available, but it probably has not changed much.)

FIGURE 8.2

Services offered by ISO members, by membership type, 2009



Source: ISO 2009.
Note: ISO = International Organization for Standardization.

Even in some OECD and European Union countries, NSBs are sometimes involved in providing conformity assessment services. However, they are never involved in activities linked directly to the implementation of technical regulations or mandatory or compulsory standards, such as premarket approval of products, market surveillance, or the imposition of sanctions. These activities are considered to be a conflict of interest in more than one way, and industry tends to see the NSB as a regulator rather than as an organization established to support business and product development. Therefore, in countries where this is still the case, governments should seriously consider separating these technical regulation tasks from the NSB. The NSB may still provide conformity assessment services, but it should do so in competition with others, and it should be accredited for such services, just like all the others.

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3 Implementation

A full understanding of all components of a country's quality infrastructure (QI)—its core elements, its supporting policies and legal frameworks, and ultimately its importance to both the effective operation of domestic markets and access to foreign markets—equips policy makers to begin a process of country-specific QI assessments and reforms. The third part of this toolkit shows the way, comprising four modules:

- *Module 9: Diagnostic Tools.* The Rapid Diagnostic Tool provides high-level information on the capacity of a country's QI ecosystem. This information, along with a rapid demand assessment, helps policy makers identify both key gaps in their quality infrastructure through a market assessment and whether a QI development project would be beneficial to develop and implement. If so, then the Comprehensive Diagnostic Tool enables knowledgeable

experts to conduct a more detailed, resource-intensive assessment to ensure reforms are tailored to specific country conditions. Module 9 describes both tools, which are available for direct download from the websites of the World Bank (http://www.worldbank.org/qi) and the National Metrology Institute of Germany (PTB) (https://www.ptb.de/qitoolkit).

- *Module 10*: *How to Reform: Interventions and Approaches.* This module covers effective QI reforms in three major areas: (a) *policy and legislation,* including development of a national quality policy and a supportive institutional framework; (b) *the QI ecosystem,* including standardization for competitiveness, strengthening of core QI elements and conformity assessment services, and alignment of a country's technical regulation regime with international good practices; and (c) *the external environment,* including the influences of global value chains and foreign direct investment, as well as a strong QI ecosystem's impact on innovation, industrial development, and competitiveness.
- *Module 11*: *Challenges of QI Reform.* National QI ecosystem capacity building and reforms pose several project preparation and management challenges, especially because they entail long-term undertakings that require donor commitment beyond a single project. This module discusses good practices for such reforms and provides guidance on strategic approaches to QI ecosystem development, with a focus on institutions.
- *Module 12: Monitoring and Evaluation: Performance and Impact of the QI Reforms.* Projects must be monitored and evaluated regularly to ensure that they stay on track and achieve the envisaged outcomes. This final toolkit module explains the difference between monitoring and evaluation and discusses in detail the various monitoring and evaluation modalities. It also provides methodologies for using Theory of Change and logic models to plan, monitor, and evaluate QI ecosystem reform projects.

9

Diagnostic Tools

INTRODUCTION

This module describes two companion tools for assessing a country's quality infrastructure (QI): the Rapid Diagnostic Tool (section 9.1) and the Comprehensive Diagnostic Tool (section 9.2). The evaluation questions and complete methodology are not included in this publication because of their volume. Practitioners or other users of the toolkit can find them in the online annex to this publication: http://www.worldbank.org/qi and https://www.ptb.de/qitoolkit.

The Rapid Diagnostic Tool allows for a much quicker but less detailed assessment of the QI of a country. It can be used for a quick assessment that would help enable better decision making regarding the need for a more detailed assessment, which would be much more resource-intensive.

The Comprehensive Diagnostic Tool enables a comprehensive assessment of a country's QI. Using this tool will require the involvement of knowledgeable experts, the full support of the country to be assessed, and quite a long time frame. The outcome of such an evaluation will be a detailed report on the status and efficacy of the QI of a country.

9.1 RAPID DIAGNOSTIC TOOL

9.1.1 Aims of the Rapid Diagnostic Tool

The Rapid Diagnostic Tool is designed to provide its users with rapid feedback on the state of a country's QI regarding its (a) legal and institutional framework, (b) administration and infrastructure, (c) service delivery and technical competency, and (d) external relations and recognition. The Rapid Diagnostic Tool is based on the Comprehensive Diagnostic Tool and evaluates the same four pillars of the QI (as further described below), but it is nowhere near as comprehensive.

The Rapid Diagnostic Tool consists of a series of questions resulting in quantitative answers. The answer to each question is given a value, a series of which

are compounded. The values can then be shown as a radar diagram that may help in deciding whether it is worthwhile to conduct a comprehensive assessment of the QI of a specific country. The Rapid Diagnostic Tool is designed to provide a high-level snapshot of the state of a country's QI and to indicate a need for further development.

9.1.2 Structure of questions in the Rapid Diagnostic Tool

The questions deal with a number of major elements for each QI service. For each of the elements, a series of questions needs to be answered. A few of these will be for information only, but most of them will be scored depending on how well they meet the stated benchmark. The scoring is based on a 0- to 4-point system, and the evaluation of the aggregated scores can be broadly considered as follows:

- *Score 0–1.0:* Little or nothing is in place, and the country has to develop the relevant element from scratch.
- *Score 1.1–2.0:* A rudimentary system, needing much fundamental development, is in place.
- *Score 2.1–3.0:* A reasonable system is in place but needs further development.
- *Score 3.1–4.0:* A good system is in place with no need for fundamental development, but maintenance is important.

Aggregate scores should be calculated to at least one decimal place to allow for a meaningful depiction in the radar diagram. But the quantitative analysis is a coarse one, and the aggregate scores should not be taken as absolutes. They provide a quick reference as to the current state and future development of the QI. This tool does not replace a proper assessment of processes such as would be undertaken to determine compliance with, for example, ISO 9001 ("Quality Management Systems—Requirements"); ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories"); or other in-depth management system assessment techniques. It is designed to be used in the QI toolkit workflow as described in module 1: Executive Summary, section 1.2.2.

9.1.3 Using the results of the Rapid Diagnostic Tool

The output of the Rapid Diagnostic Tool is a set of numbers. These can be used quite readily to develop the graphical depiction of the state of the QI or of its relevant elements in the "building block" approach or with radar diagrams, as detailed below, as well as in module 1: Executive Summary, section 1.3. These depictions can then be used to decide whether a comprehensive diagnostic should be conducted. They can also be used by a country's institutions to benchmark their QI performance against international good practice.

When considering the outcome of such a rapid diagnostic, care should also be exercised when comparing it with the level of QI development, as discussed in detail in module 2: The Importance of QI Reform and Demand Assessment, section 2.2.2. The outcome of the rapid diagnostic will be a good indication of whether a "basic" QI is in place and will even provide some information regarding an "advanced" QI. To gain a full understanding of the "advanced" or "mature" QI stages in a specific country, a comprehensive diagnostic will have to be conducted, as described in section 9.2 below.

9.1.4 Rapid Diagnostic Tool evaluation questions

As noted earlier, the Rapid Diagnostic Tool's evaluation questions are not included in this publication because of their volume. Practitioners or other users of the toolkit can find them in the online annex to this publication on the World Bank website: http://www.worldbank.org/qi, and on the PTB website: https://www.ptb.de/qitoolkit.

9.2 COMPREHENSIVE DIAGNOSTIC TOOL

9.2.1 Introduction

The Comprehensive Diagnostic Tool provides information on the evaluation of the QI in a number of important elements:

- National policies and legal environment
- The fundamentals
  - Standards
  - Metrology
  - Accreditation
- Conformity assessment
  - Inspection
  - Testing
  - Product certification
  - Management system certification
- Technical regulation framework
  - Technical regulation
  - Legal metrology

The Comprehensive Diagnostic Tool questionnaire is provided as an online tool for practitioners. The questionnaire and details of its use can be found in the online annex to this publication on the World Bank website: http://www.worldbank.org/qi, and on the PTB website: https://www.ptb.de/qitoolkit.

9.2.2 Approach of the Comprehensive Diagnostic Tool

The Comprehensive Diagnostic Tool follows a specific logic, starting from the policy and legal environment, before it deals with each of the QI elements. The outcome of the evaluation provides qualitative results that an expert can turn into quantitative results. Over and above in-depth reports, the results can therefore also be made visible in "dashboard"-type images for a more rapid understanding of situations when discussing them with counterparts.

Coordinating the QI: The policy and legal environment

The various elements of the QI are interrelated, and coordination of their responsibilities and services is an important parameter. Hence, while dealing with the various elements of the QI individually, their overall coordination should not be neglected.

Such coordination is usually provided for in government policy, such as a country's quality policy, that clarifies the interdependence between the

fundamentals, QI services, technical regulations, and the market. It should also be related to broader trade and export development policies. Furthermore, the coordination between (a) the fundamentals and QI services, and (b) technical regulation (as the mandatory manifestation of the QI) is provided for in what is generally known as the technical regulation framework. Therefore, evaluation of the quality policy and the technical regulation framework are included in the Comprehensive Diagnostic Tool.

The "pillar and building block" approach

In constructing a diagnostic tool for each of the identified elements of the QI, it is useful to consider the "effectiveness" of each of the QI elements in relation to four pillars:

- *Pillar 1: Legal and institutional framework*, in which the broader environment within which the entity is legally established and operating is considered
- *Pillar 2: Administration and infrastructure*, in which the organizational structure and the necessary infrastructure of the entity to fulfill its responsibilities are considered
- *Pillar 3: Service delivery and technical competency*, in which the output and services of the entity are considered, with special emphasis on their demonstrable quality
- *Pillar 4: External relations and recognition*, in which the important liaisons of the entity with relevant regional and international organizations are considered in view of the need to be acknowledged for its output and services

Each of these pillars consists of building blocks that have to be in place for the QI element to function optimally and to comply with international good practices and requirements. Some of the building blocks for each of the QI elements would be similar, but there will also be quite a few differences. Such an approach can be illustrated as being a "building" (figure 9.1).

Weighted or not weighted

In allocating a quantitative measure to the various building blocks, the question of whether all of them are of equal weight needs to be clarified. Arguably, some of the building blocks must be in place; otherwise, the QI element has no chance of being considered established or recognized. These could be considered "fundamental." At a second level are the "major" building blocks: those necessary for the service delivery to be effective and efficient. At the third level are the "minor" building blocks: those in which the custom and practice of the country play a role rather than international practices. The quantitative evaluation will have to take cognizance of such differences.

A supplementary way of looking at the absolute necessity or otherwise of a specific element or service of the QI would be to consider it as part of the basic QI (relevant for a low- or middle-income country approach); an advanced QI (relevant for an economywide approach); or ultimately, as a mature or innovative QI (relevant for a high-income economy or world-class approach). If there is virtually no QI established, a rudimentary state exists, which is a major challenge for the country irrespective of its development status (see also module 2: The Importance of QI Reform and Demand Assessment, section 2.2.2). The country's development status is not equally relevant for all the QI elements; it is more relevant for those that are of a more technical nature, such as metrology.

FIGURE 9.1
Building blocks of a QI (conceptual)

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Note: QI = quality infrastructure; WTO TBT Agreement = World Trade Organization Agreement on Technical Barriers to Trade.

It certainly influences the decision about which level of technical support a country needs. This evaluation is included in all of the elements of the QI because of the differences—it is difficult to provide a structure valid for all.

Assessment and infrastructure

A comprehensive assessment of the QI of a country is a complex undertaking. It is virtually impossible to reduce the outcome of such an assessment to a single figure or a simple pronouncement. There are just too many possibilities and nuances that have to be considered, too many externalities that have an influence.

Therefore, the Comprehensive Diagnostic Tool endeavors to provide for a qualitative and quantitative approach for each of the QI elements, which can be made visible in a "building" showing the state of implementation through different-colored "bricks" (figure 9.2), a radar-type diagram (figure 9.3) for the individual elements, or a dashboard illustration for the QI collectively (figure 9.4), supported by an extensive narrative.

For each of the building blocks, the comprehensive diagnostic

- Provides details about the best practices with which the building block should be compared, under the heading "*What is meant*";

FIGURE 9.2

Implementation of a QI entity, by building block status (conceptual)

Source: Adapted from PTB 2007. ©National Metrology Institute of Germany (PTB). Reproduced with permission from PTB; further permission required for reuse.
Note: QI = quality infrastructure; WTO TBT Agreement = World Trade Organization Agreement on Technical Barriers to Trade. Figure shows a "dashboard"-type illustration that tells the viewer at a glance what the implementation status is without having to read through lengthy reports. Once all building blocks are green, then implementation is complete.

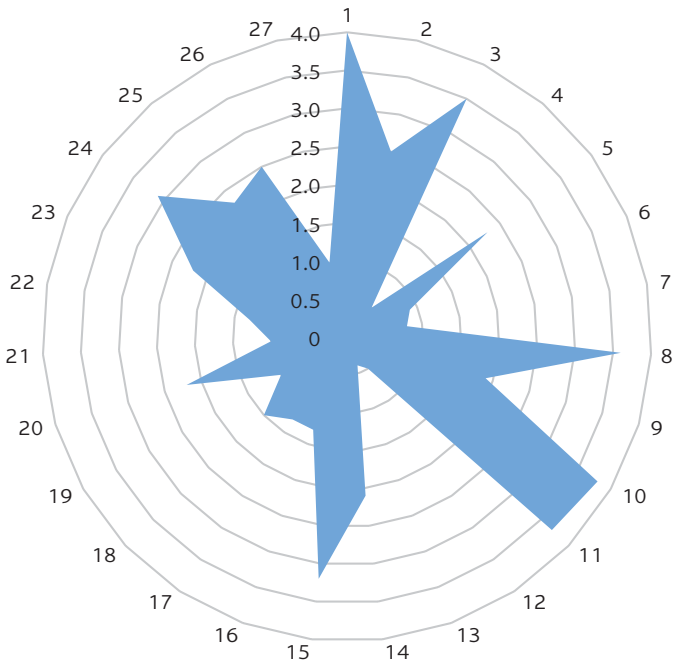
- Shows how the building block can be demonstrated (that is, describing the elements that indicate that the practice exists), under the heading "*How can it be demonstrated*"; and
- Shows where the assessor could find information to support the existence of such practices, under the heading "*Existing information/reporting/monitoring*."

For each building block, an indication as to whether it is "fundamental," "major," or "minor" is also provided. This will help the assessor to determine the extent and significance of the gap between the current situation and international good practices, which in turn will be an indication of the "effectiveness" or otherwise of the QI elements in the country, leading ultimately to a judgment call on how much support the country would need to develop its QI to the point where it meets the needs of its stakeholders.

The evaluation is therefore a complex array of levels of (a) *implementation* (implemented, mostly implemented, partially implemented, or not implemented); and (b) *classification* (fundamental, major, or minor). A judgment call will have to made to determine how far a project wishes to take the capacity-building exercise. A reasonable approach would be that the "fundamentals" must be dealt with, and the "major" issues likewise. The "minor" issues are, to some extent, "nice-to-haves" or "nonmandatory," and would be included, resources permitting.

FIGURE 9.3

Radar diagram of QI entity's implementation status (conceptual)



Note: QI = quality infrastructure. Each number around the outside corresponds to a building block, whereas the values 0–4 are either a direct result of the rapid diagnostic or the representation of the percentile-based results of the comprehensive diagnostic (4 being 100 percent and 2 being 50 percent).

To depict the "building" (figure 9.2) or construct a radar diagram (figure 9.3), the implementation status of each of the building blocks has to be given a numerical value (that is, the percentage implemented). In this Comprehensive Diagnostic Tool, the expert assessing the QI will have to provide a quantitative and qualitative result based on his or her experience and the narrative in the various sections of this diagnostic tool, and it has to be an evaluation based on a matrix-type approach. The question-and-answer methodology in the Rapid Diagnostic Tool (discussed earlier in section 9.1) can provide some guidance in this respect.

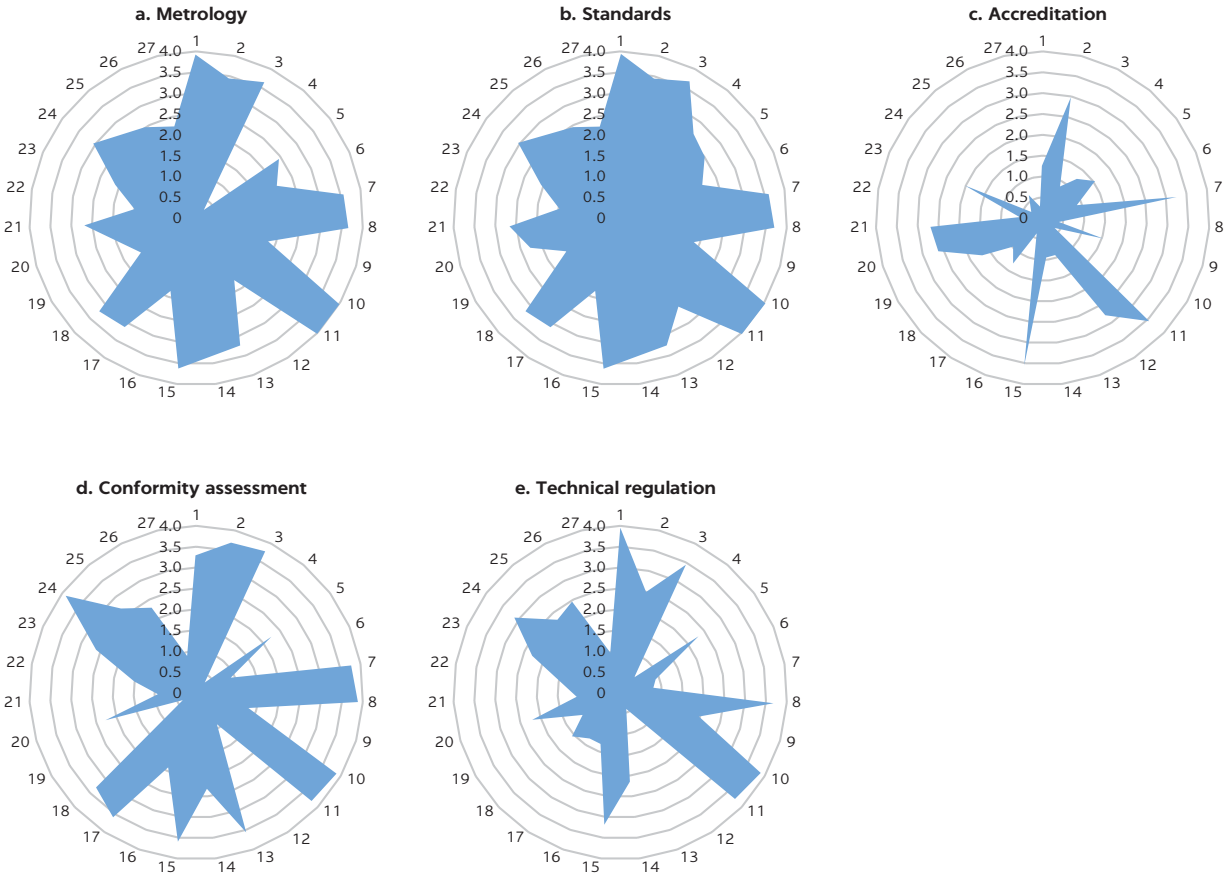
Once the percentages are determined, it is fairly easy to construct a radar diagram (figure 9.3). To depict the "building" will take an additional step. The percentages can be grouped into four categories, such as the following:

- Above 75.1 percent: Implemented
- Between 50.1 percent and 75 percent: Mostly implemented
- Between 25.1 percent and 50 percent: Partially implemented
- Between 0 and 25 percent: Not implemented

The four groups (or more, if the four are considered too coarse a grading) can then be given different colors in the "building" (as in figure 9.2). It helps if the colors are chosen to coincide with a color scheme psychologically understood by potential readers.

FIGURE 9.4

Dashboard illustration of QI implementation status, by QI element (conceptual)



Note: QI = quality infrastructure. In each radar diagram, the numbers around the outside correspond to building block numbers, whereas the values 0–4 are either a direct result of the rapid diagnostic or the representation of the percentile-based results of the comprehensive diagnostic (4 being 100 percent and 2 being 50 percent).

STANDARDS REFERENCED IN MODULE 9

ISO (International Organization for Standardization). 2015. "ISO 9001: Quality Management Systems—Requirements." 5th ed. Ref. no. ISO 9001:2015(E), ISO, Geneva.

ISO and IEC (International Organization for Standardization and International Electrotechnical Commission). 2017. "ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories." 3rd ed. Ref. no. ISO/IEC 17025:2017(E), ISO, Geneva.

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PTB (National Metrology Institute of Germany [Physikalisch-Technische Bundesanstalt]). 2007. "The Roadmap to an Accreditation System: 30 Milestones for Developing Countries." Booklet, PTB, Braunschweig, Germany. https://www.ptb.de/cms/fileadmin/internet/fachabteilungen/abteilung_9/9.3_internationale_zusammenarbeit/publikationen/007_Accreditation/PTB_Q5_Accreditation_EN.pdf.

10

How to Reform: Interventions and Approaches

INTRODUCTION

Once the needs for quality infrastructure (QI) services have been clearly identified (as covered in module 2) and the elements of the QI have been mapped using the diagnostic tools (module 9), then the challenge is how to go about developing appropriate projects to close the gap between demand and supply regarding QI services. For the successful development of the QI, a policy environment that recognizes its importance, and through which its effective development can be guided, is of paramount importance. Hence, this module starts with the policy environment that must precede more specific interventions and approaches for each of the main QI service groups.[1] The reengineering of the technical regulation regime is as important in this respect as developing capacity in the QI. Completing this module are discussions about financing such developments, enabling innovation, and resolving conflicts of interest.

10.1 QUALITY POLICY AND STRATEGY

Many countries established national standards bodies (NSBs) in the wake of industrial development after World War II. These were mostly established by governments and then left to their own devices in accordance with the motto, "Standardization is technical, you are technical, get on with it."

These NSBs were given the responsibility to develop and publish national standards, with testing and certification services frequently added. Many times, they were also mandated to implement compulsory standards (a form of technical regulation)—in a way, a "one-stop shop" approach. Thereafter, other ministries and their agencies developed and implemented technical regulations as they saw fit as they sought to protect the citizenry and environment from harmful market failures or for political purposes such as protecting local industry from imports—the latter obviously being unacceptable in terms of the requirements of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement).[2]

Evaluations of the QI and technical regulation regime in many low- and middle-income countries in the past decade have confirmed this picture. With countries wishing to gain the maximum advantage from the developing global trade, this ad hoc and fragmented QI and technical regulation situation has to be streamlined, starting with the government creating a clear policy environment in this regard.

In general, a national policy can be seen as a set of interrelated government decisions concerning the selection of goals and the means of achieving them within a specified situation where those decisions, in principle, are within the power of the government to achieve. The private sector is an important partner in the implementation of the national quality policy (NQP), but without a policy environment conducive to the development of an effective and efficient QI, the private sector will be hard pressed to play its proper role.

From a practical perspective, the policy environment translates into the way in which the government converts its political vision into programs and actions to deliver desired outcomes or changes in the real world. Hence, developing an NQP starts with examining the underlying rationale for and future effectiveness of the QI and technical regulation regime. Thereafter, it is about deciding what needs to be done and how to do it as well as reviewing, on an ongoing basis, how well the desired outcomes are being delivered.

10.1.1 The policy environment

The NQP does not exist on its own. There are usually quite a number of policies already in place that contain references to standards, quality, and technical regulations. These policies typically deal with industrial development, enhancement of the export trade, environmental controls, food safety or security, science and technology development, and similar issues.

These references to standards, quality, and technical regulation do not relate to a holistic view of a national QI, nor do they provide guidance on a common approach to technical regulation; they focus on the specifics of that policy. The NQP should *link and coordinate* the policy measures relating to standards, quality, and technical regulation contained in all of these important policies.

10.1.2 Typical NQP content

The typical content of an NQP is listed in table 10.1. The following subsections then discuss some of the individual elements in more detail.

10.1.3 Review of current situation

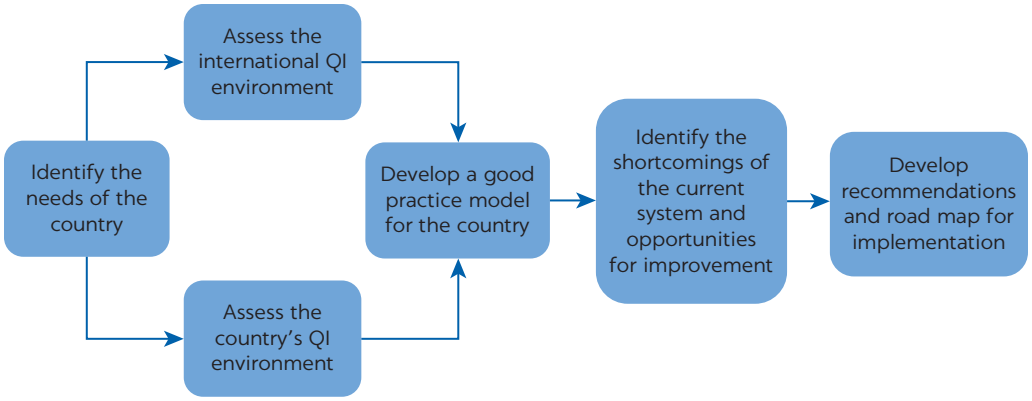
The current situation should be carefully mapped and considered in the light of international good practices and the demonstrable needs of the country. Often, an analysis of the strengths and weaknesses (internal) and threats and opportunities (external) of the current QI are also included. From this information, a gap analysis can be performed, which then leads to the policy objectives and policy measures (figure 10.1).

TABLE 10.1 Typical content of a national quality policy

NQP SECTION	SUBSECTIONS AND COMMENTS
Foreword	The relevant minister (for example, Trade and Industry) expresses political support for the implementation of the policy.
1. Introduction	• International and regional context • Trade as a driver for development and poverty reduction • Definition of the national quality infrastructure and technical regulation framework • Policy environment
2. Review of the current situation	• National quality infrastructure (QI) • Technical regulation framework (TRF) • Compliance with WTO TBT Agreement and related regional obligations • Gap analysis
3. Vision	• Where the country wishes to be in time (5 or 10 years)
4. Objectives of the NQP	• QI that meets country needs and is accepted internationally • A technical regulation regime common across all authorities compliant with international and regional obligations
5. The future NQI	• Organization and responsibilities of the NSB, NMI, and NAB • Provision of calibration, inspection, testing and certification services • Role of government in relation to the private sector
6. The TRF	• The necessity of regulatory impact assessments (RIAs) • Use of standards as the basis for technical regulation • Conformity assessment for regulatory purposes • Regulatory authorities, their responsibilities, and activities • Coordination of the technical regulation system
7. Education and training, awareness, and communication	• The role of tertiary education institutions • Registration of quality-system professionals
8. Information network	• National TBT Inquiry Point[a] • Cooperation with the trade promotion organization
9. Role of other stakeholders	• Private sector • Nongovernmental organizations • International development partners • Academia
10. International and regional liaison	• Liaison with international and regional organizations • Commitment for active participation in international and regional technical committees
11. Financing the NQI and TRF	• Government responsibility for standards, metrology, and accreditation • Conformity assessment: "user pays" principle • Technical regulation
12. Legal framework	• Review of current legislative instruments • Development of new legislative instruments
13. Implementation	• Lead ministry • The private sector as one of the key drivers of the NQP • Interministerial and private sector coordination committee • Implementation plan or strategy (five years)

Source: Adapted from Kellermann 2011.
Note: NAB = national accreditation body; NMI = national metrology institute; NQP = national quality policy; NSB = national standards body; QI = quality infrastructure; WTO TBT Agreement = World Trade Organization Agreement on Technical Barriers to Trade.
a. The TBT Inquiry Point is an official or office in a member government designated to deal with inquiries from other WTO members and the public on technical barriers to trade.

FIGURE 10.1
Process for designing the future QI



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Note: QI = quality infrastructure.

10.1.4 Notes on recommended NQP content

Vision. Vision is considered as the future state of affairs that should be realized in a given time. Many low- and middle-income countries have established a fairly comprehensive vision regarding the development of the country, called "Vision 2030" or something similar, and supported by a variety of development policies. The NQP vision likewise should support such a national vision for the country.

Policy objectives. The policy objectives describe what is to be achieved for the benefit of the country, for society, or for the environment once the policy has been fully implemented. The objectives show the way toward the policy vision or goal. They may include new infrastructure, new systems, new processes or procedures, new knowledge, increased skills, better employment opportunities, or changed attitudes. It is good practice to limit the objectives to four or five main ones to avoid diluting the focus of policy implementation.

The future QI. The future QI must be clearly articulated—especially the fundamentals of standards, metrology, and accreditation—because these are basically government responsibilities in most low- and middle-income countries. If the country has had a QI for many years, it is fairly certain that it may have to be reengineered either partially or in totality. This may entail adjustments to current structure or even the establishment of new organizations. If the fundamentals comply fully with international good practices, then they should be reaffirmed. It is important to create confidence that the country will be well served in terms of these three fundamental QI services.

As for the provision of calibration and conformity assessment services, space should be provided for the development of market-related services, whether provided by public or private sector organizations. The main responsibilities of all the future QI organizations have to be clearly spelled out. In a more modern economy, the government will progressively withdraw from this sector, allowing the private sector to play an increasingly important role.

Technical regulation framework. The NQP should clearly articulate the government's desire to reengineer an ad hoc and fragmented regulatory regime.

It may already list some high-level measures that a technical regulation framework will comply with, including use of standards as the basis for technical regulations, provision of conformity assessment services by accredited and designated organizations, responsibilities of the regulatory authorities, performance of regulatory impact assessments (RIAs), and so on. The main policy measure would be the development of a definitive technical regulation framework that will eventually become law.

An important issue that needs policy guidance is the coordination of the technical regulation activities of the various regulatory authorities as well as their interface with the QI services. Many countries are considering the establishment of a coordination office or similar facility to ensure such coordination.

Education and training. QI services rely heavily on properly trained and experienced people. The policy should spell out how their competencies will be developed and what the roles of tertiary education institutions are in this regard. Some quality-system technologists, such as quality-system auditors and nondestructive testing technicians, have to be registered either internationally or within a national system. The policy measures regarding these should be elucidated.

Roles of other stakeholders. The roles and responsibilities of stakeholders other than the government should be clearly spelled out. These stakeholders would include the private sector and nongovernmental organizations (NGOs). The international development partners should also be featured strongly in the policy if the country is the recipient of such technical development cooperation. The main issue here is that such projects should support the implementation of the NQP instead of being geared to the "wants" of specific recipients.

International and regional liaison. International organizations exist for all three of the fundamental QI services—standards, metrology, and accreditation. In the case of the latter two, international recognition is gained through these international organizations. Most of the process to gain international recognition is operated through the relevant regional organizations. The policy should clearly spell out how the country envisages active participation in such organizations for the benefit of the country, not only in general assemblies, but especially in technical committee structures.

Financing the QI. This is an important element of the NQP, where the government commits to the funding of the fundamentals (standards, metrology, and accreditation) as "good for country" services. It should also be made clear that conformity assessment services should be market-related and paid for by the clients, including the government.

Legal framework. The QI fundamentals—that is, the organizations providing standards, metrology, and accreditation services—are mostly established by legislation, except where they are not-for-profit private companies. Such legislation is necessary to give legal certainty to the status of national standards, measurement standards, and the use of accreditation in conformity assessment for regulatory systems. The legislation may exist but may need review and revision, or it may have to be developed. All of these possibilities need to be clearly articulated in the policy.

Implementation. Responsibilities for the implementation of the NQP must be detailed, because nobody will undertake those responsibilities otherwise. This is

specifically necessary because the NQP is cross-cutting in relation to ministry sectors, and one ministry will have to be given the lead responsibility.

10.1.5 NQP development

Many countries have specific processes in place to develop government policy and to have them approved by the cabinet or parliament as relevant, and these must be followed when developing the NQP; otherwise, its approval may be compromised. However, it has been shown in many countries that a fully participative process before even starting to write the text is the most profitable approach. It is especially the private sector that needs to be intimately involved in its development, because it will have to implement many of the policy measures and finance even more of them.

The following steps for NQP development have been usefully employed in various technical assistance programs:

- *Assessment of the current QI system and technical regulation regime* of the country and their compliance or otherwise with international good practices
- *Seminars for the public and private sectors* to convey information regarding international good practices and the possible weaknesses of the national system
- *Separate workshops for the public and private sectors,* in which the needs of both the public sector (ministries and their regulatory authorities involved in technical regulation development and implementation, including those involved in sanitary and phytosanitary [SPS] measures) and the private sector (organized industry and business associations, major companies, NGOs, and so on) can be determined in a nonconfrontational way
- *Workshops combining both the public and private sectors* that may be contemplated
- *Development of a first working draft of the NQP* based on the information gleaned in the workshops and the assessment against international good practices
- *Circulation of the working draft* to the main interested parties (such as ministries, organized business, and industry associations) for comment
- *Collation and analysis of the comments* as well as one-on-one discussions with organizations raising substantive comments, to gain a better understanding of their positions
- *Updating of the working draft* to include relevant comments
- *Workshops with various stakeholders to validate the content* of the NQP working draft
- *Finalization of the draft NQP* before submitting it to the political level for approval—that is, the lead ministry, cabinet, and parliament (if required)

Once the working draft of the NQP is taking shape, it is useful to start the development of an implementation plan in cooperation with the various ministries, agencies, and QI institutions that will have to implement its measures. These discussions may also influence the content of the NQP in a positive way. This parallel development will eventually save a fair amount of time because in many countries a high-level implementation plan with a budget has to accompany the draft NQP in its journey through ministries and cabinet for approval.

10.2 REFORMING THE QI LEGAL AND INSTITUTIONAL FRAMEWORK

A review and revision of the QI legal framework is mostly a political process. The reengineering of QI institutions, on the other hand, is more complicated at the human level. Issues such as workplace, level of appointment, loss of influence, and many more play an increasing role as the level of reengineering rises. In some countries, this may entail discussions and negotiations with trade unions. Careful planning, with attention to the minutest details, as well as open and honest discussion with staff representatives is extremely important to prevent silent sabotage tactics or stalling of the process in courts of law.

10.2.1 Reforming the legal framework

In many countries, the fundamental QI organizations—standards, metrology, and accreditation—are government-type organizations established by legislation. In many cases, this legislation is quite a few years old owing to the reluctance of the institutions to start a review and revision process, because these processes take many years to be concluded. The result is that such legislation is out-of-date, does not contain measures important in a modern economy, and in some cases is no longer workable. This means that it requires urgent attention and renewal.

The review and revision of current legislation, as well as the development of new legislation, should follow the development and approval of the NQP because this would indicate the contents of the revised or new legislation. Each country has its own processes to develop draft legislation that should be followed. Whatever the final steps are to get the draft legislation approved by the ministry, then by the cabinet, and ultimately by parliament, a consultative process with stakeholders to determine content is an important start.

Where such QI organizations are private sector organizations, albeit registered as nonprofit organizations, legislation may still have a role to play. For example, whenever a private organization is given a role in regulatory affairs, this has to be governed by appropriate legislation. The government may confer regulatory mandates if the legal system of the country allows for it, or a contractual arrangement may exist between the government and such a private sector organization. Another example is that the national standards require legal standing, even though they may be developed by a private sector organization. These types of legislation and their outcomes must also be reevaluated from time to time to ensure that they remain up-to-date and that they serve the country in an appropriate manner.

10.2.2 Reengineering the institutional framework

Things get a bit more complicated if the institutional framework has to be reengineered. A typical example would be if the NSB loses its mandate to develop and implement technical regulations or mandatory or compulsory standards. In this case, the responsibilities and activities of the NSB must be transferred to a regulatory authority—either an existing one or a new authority that must be established. This will require a new set of legislation to start the process. The actual transfer will need to be carefully planned to ensure that the transitional period does not lead to an "anything goes" situation in the marketplace.

Experience would suggest that, in this example, the regulatory activities to be transferred should be reorganized in the NSB in a separate division or department, together with all the relevant personnel, long before the actual transfer takes place. In this interim period, the personnel will be able to stabilize, and new processes can be developed and implemented where necessary. When the transfer date comes about, personnel, equipment, and processes can be transferred as a complete package without much interruption to the new organization. Other examples could follow a similar trajectory.

10.2.3 Establishing a new organization

Establishing a new organization—whether a test laboratory, an accreditation body, or a regulatory authority—will have its own challenges, such as the following:

- A council or board has to be established, and it has to develop its own working procedures.
- A director or similar head has to be found and appointed, and then the required technical and administrative personnel have to be recruited and appointed.
- In most cases, intense training programs will have to be implemented to ensure that the new personnel are in a position to provide the required services.
- Quality management systems have to be developed and implemented in accordance with international standards from the relevant ISO/IEC 17000 ("Conformity Assessment") series or even ISO 9001 ("Quality Management Systems—Requirements") in the absence of the former. Ultimately, international recognition will have to be sought through accreditation or peer reviews.
- Appropriate premises have to be found and equipment purchased, installed, and commissioned. This is a task for the experts, especially in the case of laboratories, and less so in the case of organizations with mostly administrative functions.

In almost all of these cases, it does help if the country can gain the support of a similar organization in another country that is known to follow international good practices or is at a more advanced level of development. This support can be in the form of a consultancy, or "twinning arrangement," whereby the experienced organization seconds some of its personnel to help the new organization establish viable and effective systems or provides attachments for the new organization's people—that is, enabling them to work in the experienced organization for some time—to learn at the hand of existing, proven processes.

10.2.4 Reengineering the technical regulation regime

Establishing a new technical regulation regime is probably the most challenging institutional reform in the QI environment. Many countries operate a decentralized technical regulation regime, whereby each ministry is responsible for the development and establishment of technical regulations in its own sphere of responsibilities. These ministries and technical regulations may have developed their own ways over the years, and the differences may be quite large, over and

above the question of whether they make sense or are in compliance with WTO TBT Agreement requirements.

The implementation of a new technical regulation regime has to start with the promulgation of appropriate legislation in this regard. This must give legal standing to the technical regulation framework (see module 7: Technical Regulation, section 7.9.3, and section 10.7 below), the concepts of which should have been developed in a consultative manner among all the relevant ministries and their agencies as well as organized business and industry to give it the best chance of success. Thereafter, a detailed implementation plan, approved by the cabinet or a similar body, needs to be in place to ensure total support from all the affected authorities. The appropriate budget will also be required to be available. All of these steps demand clear and resolute leadership at the highest political and public administration levels.

To change the entrenched processes will take intense training on the new technical regulation processes (which includes the difficult "unlearning" of the old ways), establishment of new internal and publicly available procedures, and in some cases even new organizational structures. The support of an experienced development partner well versed in modern technical regulation regimes is a bonus. It is useful if a time limit is set for the changeover, after which the old technical regulations cease to exist. Otherwise, the process can drag on indefinitely as some authorities procrastinate, to the detriment of the country.

Such a reengineering of the whole technical regulation regime will require the appointment of a lead ministry, supported by a coordination committee representative of all the affected ministries and their agencies, to take overall responsibility for implementing the changes. The lead ministry and coordination committee should be accountable to the cabinet and report at least every six months on progress or otherwise, so that high-level decisions can be made to unblock institutional lethargy or address reluctance for change. As an alternative, a technical regulation coordination office with sweeping powers over ministries and their agencies in relation to technical regulation development, implementation, and maintenance can be established by legislation to spearhead such a process.

10.3 CREATING AN AWARENESS, INFORMATION, AND TRAINING CAMPAIGN

The QI could be seen as having a multiplicity of stakeholder groups, among which awareness needs to be created, information provided, and training programs offered. Creating understanding and a general awareness among producers and manufacturers about the benefits associated with supplying products that comply with standards and technical regulations is not an easy task. Moreover, the authorities will use the services of the QI only in developing and implementing regulations if the QI is fully trusted. For their part, consumers are continuously looking for a body that will ensure the quality of products and services in the marketplace, but it should not cost so much that businesses are unable to effectively use the services.

The QI certainly strives to satisfy these demands by delivering appropriate services, but more is needed. It also has to sensitize its stakeholders to the necessity and uniqueness of its services in a world that suffers from information overload. A proper communication strategy is required to reach the

relevant target audience with the appropriate message and to cleverly use the channels of communication. Such a strategy can emanate from the government or from the individual QI organizations, depending on the QI structure and government practices. Experience has shown that training in some of the QI service disciplines is a useful strategy to enhance awareness among specific stakeholders.

10.3.1 Developing a communication strategy

A communication strategy, once developed, should be reviewed at least annually to ensure it remains up-to-date. Some of the issues that need to be clearly thought through include the following:

- *Objective.* The communication strategy should have a key objective. There are many permutations possible regarding the communication channels, content, and stakeholders. The process of planning for this multichannel, multicontent, multistakeholder environment can become extremely complicated. A key objective to serve as the rallying point is therefore important.
- *Budget*. Communication requires a budget. Having a fixed budget is not a bad idea, as it focuses minds on achieving the maximum impact with the budget available.
- *Audience.* Targeting the appropriate audience is important, whether in the public sector, private sector, or society at large. The results from stakeholder mapping could be a useful source of information.[3]
- *Message.* The message needs to be articulated in a way that will grab the attention of the target audience. In a time-starved world, people will pay attention only to an idea or truth they cannot resist. This idea will help in deciding on the appropriate channel of communication.
- *Channels.* The channels of communication must be carefully chosen. Some of the possibilities include *media* (local, national, international, print, broadcast, web, social); *lobbying* (local and national government, funding bodies, special interest groups); *marketing* (brand, website, advertising, brochures, fliers, video); and *events* (conferences, launch events, public speeches, tours of building sites).
- *Synergy.* It is important that the chosen channels work together. Each channel will have a specific role in achieving the overall objective, but each one should be leveraged or supported by the other—that is, the whole should be greater than the sum of the parts.
- *Evaluation.* It is important to get feedback on the communication strategy's efficacy or otherwise. A multichannel approach is much more difficult to evaluate than a single channel for which the communication industry has developed metrics.

10.3.2 Creating awareness

In the QI environment, there are world days for standards, metrology, and accreditation. The international organizations provide communication materials for these events that are based on a specific theme each year. A successful awareness-raising event can be a national conference based on the theme, inviting foreign dignitaries from the IAF, ILAC, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC),

the International Bureau of Weights and Measures (BIPM), or the International Organization of Legal Metrology (OIML), together with speakers from major national stakeholders. A keynote address by the relevant minister ensures that the local news media will be there in force.

If newspapers are still a major part of the communication world in the country, a weekly QI supplement that explains the need for effective and efficient use of QI services can reach the general population. Advertising on television is expensive, and if it is contemplated, the message must be carefully designed to ensure that it has impact and guides viewers to wish to seek more information. The publication of a new standard that may affect society widely may be launched at an event to which a wide variety of stakeholders are invited. The same applies to new metrology, accreditation, and conformity assessment services. New and appropriate legal metrology issues affect the consumer directly and are often the basis of good stories to use in creating awareness.

10.3.3 Disseminating information

Printed material should be developed that can be distributed in one-on-one discussions, meetings, conferences, visits, and so on. Practical guidelines for the implementation of standards and quality assurance systems in the small and medium enterprise (SME) sector help in the understanding of adopted international standards that require a specific level of knowledge not always in place in this sector.

The electronic media have become the most effective way to communicate. The importance of an effective and up-to-date website for the QI institution cannot be overemphasized. All the relevant information regarding the QI organization and its services should be available. A useful strategy is to link the websites for the bodies representing the three QI fundamentals—standards, metrology, and accreditation—in such a way that the viewer can migrate from one to another without having to do a search. The same applies to linking these with the website for the country's trade promotion organization.

10.3.4 Providing training

Technically skilled personnel are required in inspection bodies and laboratories, conducting quality management audits and accreditation assessments. In addition, manufacturers and suppliers need to be trained to implement quality management systems effectively and regulatory authorities to conduct risk-based market surveillance.

It is frequently QI organizations that have to provide such training. The appropriate training and technical support material has to be developed. The trainers have to be carefully selected; not everyone who is a skilled and knowledgeable technical person is a good trainer. It is useful to establish more technical training as a joint venture between the QI organization and a tertiary education institution such as a technical college. One provides the training expertise, the other the technical expertise. Registration schemes based on training and on-site evaluations for quality system auditors and assessors have to be established in line with international practices.

Anecdotal evidence would suggest that an effective training program for private industry frequently results in further conformity assessment business for the QI service provider. The multinational QI service providers are a good

example of this approach. The one issue that needs to be carefully considered is that such training must not become consultancy, which is a conflict of interest with the provision of conformity assessment services and which would result in the denial of accreditation.

10.4 DEVELOPING STANDARDIZATION FOR COMPETITIVENESS

This topic has two elements: One is the development of standards and their implementation to enhance the competitiveness of the local industry. The other—and the more likely scenario for low- and middle-income countries—is the enhancement of local industry's capacity to comply with the standards, including the technical regulations, of the more developed markets to render them more competitive in the home market as well as for exports.

Standards can support local industry competitiveness, in both respects, as follows:

- International standards describe the product requirements for international markets. National standardization can support their implementation by translating the international standards into the local language, reducing the standards' coverage and complexity to the product processing level of the country, incorporating local specificities (such as those requested by technical regulations), and developing guidelines and other products that support the implementation of the standards. The same applies to management system standards such as ISO 9001 ("Quality Management Systems—Requirements"); ISO 22000 ("Food Safety Management Systems—Requirements for Any Organization in the Food Chain"); hazard analysis and critical control points (HACCP); and others.
- National standards could describe the quality requirements for community products in local markets or for native products in local and international markets.
- National standards or guidelines could describe processes and methods to be followed to support the compliance of products with international standards.
- National standards or guidelines could describe processes and methods to increase productivity.
- National standards could support innovation (see section 10.10).
- International and national standards should be used as a basis for technical regulation, hence reducing inconsistencies and duplication between the voluntary system and the state-regulated system.

10.4.1 New standards and competitiveness

When establishing a standardization system, a low- or middle-income country's first priority is usually to publish the standards that are going to be used as the basis for technical regulations. That is also the driver for the development of regional standards, because technical regulations are the most frequent nontariff trade barriers to deal with. These national and regional standards are, more often than not, adoptions of international standards in compliance with the WTO TBT Agreement requirements, albeit with small variations to deal with local peculiarities.

Once this need has been satisfied to a large degree, the question then surfaces: What next? Can a low- or middle-income country develop an indigenous national standard for local products that is then recognized at the international level to give the local industry a competitive advantage, even for a short time? The standardization system realities would suggest that this scenario would be unlikely. The "making" of public standards recognized at the international level is controlled by the standards-making countries, and less so by low- and middle-income countries.

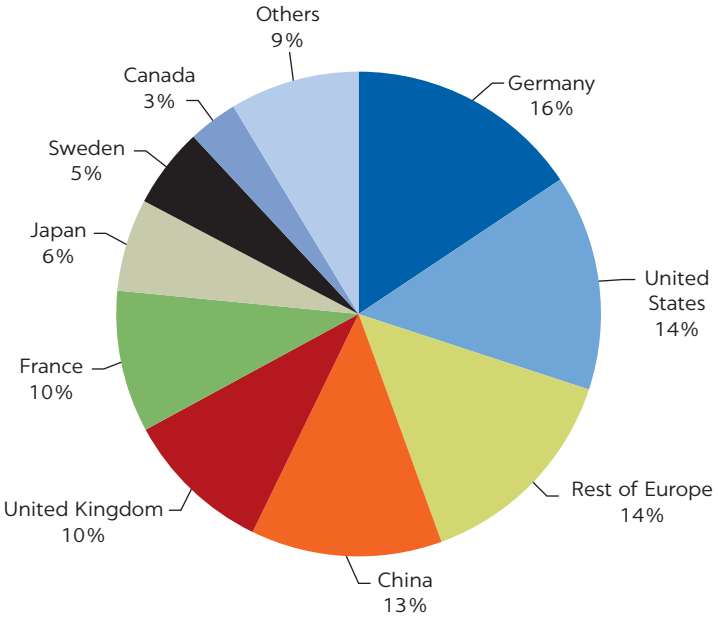
There are obvious exceptions, where indigenous standards that have been developed for purely local products have gained relevance in regional markets—for example, cassava, quinoa, Caribbean hot sauce, and other products in some African and South American countries. However, although more than 75 percent of ISO members are from low- and middle- income countries, the countries that hold the secretariats of the 246 active ISO technical committees (subcommittees are excluded from this data set) are dominated by the major industrialized countries.[4] Particularly, China, France, Germany, Japan, the United Kingdom, and the United States collectively control nearly 70 percent of the ISO technical committees (figure 10.2).

The second question under this "What next?" scenario is whether the NSB should adopt and publish the international or regional standards that will support innovative industries and foster higher productivity (see also section 10.9). These could be the standards published for quality management systems or emerging technologies, or they could be standards dealing with social issues such as environmental management, workplace safety—the list can go on and depends on the country realities and demands.

The answer depends to some extent on the language issue. International standards, such as those from the ISO and IEC, are usually available only in

FIGURE 10.2

Countries' control of ISO technical committees, by share of secretariats held, 2017



Source: World Bank, from ISO 2017 data.
Note: ISO = International Organization for Standardization.

English and French. The same applies to the private standards used in trade. ISO and IEC standards used to be available in Russian as well, but since the demise of the Soviet Union, they no longer are. Local entrepreneurs such as SMEs are not always well versed in these languages. Therefore, it is useful, if such standards are adopted as the national standard, to make them available in the local language. If English or French is well understood, the ISO and IEC standards may even be adopted as national standards in their original language but offered at a lower price to make them more accessible for the SME sector.

10.4.2 Compliance with standards to enhance industry competitiveness

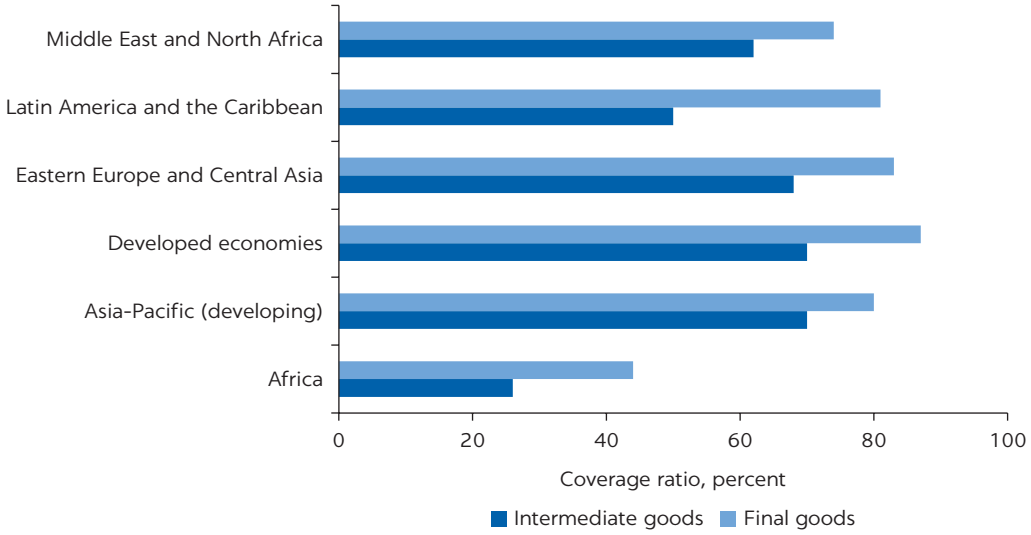
Standards and their mandatory counterpart, technical regulations, are pervasive, affecting economic operators throughout the production chain within the company as well as in national and global value chains. Any company wishing to place products or services on the market or trying to export will encounter them. Figure 10.3 shows just how pervasive technical regulations are in trade in intermediate and final goods in various parts of the world.

Capacities for compliance

If a manufacturer wishes to export, the important question is what the quality requirements are. It matters little to the manufacturer whether the requirements are contained in a technical regulation set by government; based on a national, regional, or international standard; or contained in a private standard with the concomitant certification providing access to the target market. The challenge is to meet the requirements.

FIGURE 10.3

Share of goods trade subject to technical regulation, by region, 2014



Source: ITC 2016.

Note: The "coverage ratio" is the share of trade subject to at least one technical regulation. The 2014 dataset used covered 53 economies, as reported by Franssen and Solleder (2016). The sample of "developed economies" included 25 European Union economies (treated as one economy, owing to identical trade regulations); Hong Kong SAR, China; Israel; and Japan. The sample of "Asia-Pacific (developing)" economies included Afghanistan, China, India, Nepal, Pakistan, the Philippines, and Sri Lanka.

Smaller and less productive firms find it harder to cover fixed costs to comply with standards and regulations. The same requirement represents a bigger obstacle to a low- and middle-income country's small firms, which are likely to have lower capacity to comply. The International Trade Centre (ITC) has found that when the frequency of regulatory or procedural trade obstacles increases by 10 percent, the value of exports decreases by 1.6 percent for large firms and by 3.2 percent for small firms (ITC 2016).

Impact of private standards

Private standards mainly aim at environmental conservation, ensuring food safety, protecting social and human rights, or promoting good agricultural and manufacturing practices (see also module 3: Standards, section 3.3).

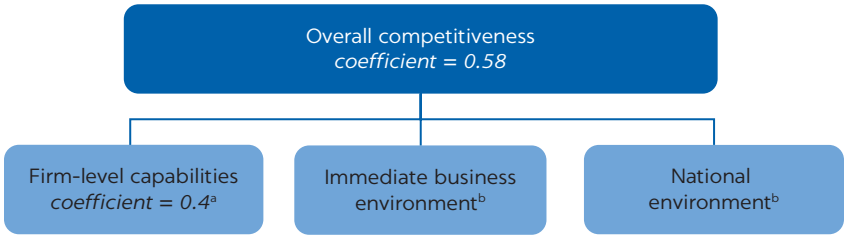
New research, based on 180 private sector standards worldwide, indicates that strong positive connections exist between the number of voluntary standards operating in a country and its gross domestic product (GDP), institutional quality, and logistics performance (ITC 2016). A country's SME competitiveness is also a strong predictor of standards' availability.

Among the factors influencing competitiveness (such as firm-level capabilities, immediate business environment, and national environment), firm-level capability is the variable most strongly associated with the number of standards operating in a country (ITC 2016). A 1.0 unit increase in the ITC firm-level capabilities score (on a range of 0–100) is associated with a 0.4 unit increase in the number of available standards (figure 10.4). The other two factors are not influenced meaningfully by the number of standards operating in the country.

Considering this high level of interdependence, the question is what comes first: the private standards operating in the country or the higher level of competitiveness of the SME sector? Certification bodies operate as commercial entities and choose the locations for their business operations based on where they can make a profit. This will happen only if the economy has a sufficient number of potential clients; that is, the competitiveness has to be established first. In general, one or two progressive companies in a low- or middle-income country may obtain certification from abroad, after which a market may develop, enticing the certification organization to set up shop in that country.

FIGURE 10.4

Influence of standards availability on factors in country competitiveness



Source: ITC 2016. ©International Trade Centre. Reproduced with permission from ITC, further permission required for reuse.
Note: Coefficients are based on a linear model explaining standards availability, controlling for GDP and income level (the only coefficients significant at the 10-percent level).
a. A 1.0 unit increase in the firm-level capabilities score (on a range of 0–100) is associated with a 0.4 unit increase in the number of available standards in a country.
b. Neither the immediate business environment nor the national environment is influenced significantly by the number of available standards in a country.

Advantages of global value chains

The ITC research indicates that compliance costs are lower for the more competitive economic operators, especially when they can become involved in global value chains (ITC 2016). When standards are set by companies, producers and other stakeholders (such as buyers in the supply chain) are more likely to share implementation and certification costs. This evidence suggests that when lead firms set standards, they are more likely to help defray some of the compliance costs that otherwise would be borne entirely by suppliers.

Accessing global value chains, however, is easier said than done (see module 2: The Importance of QI Reform and Demand Assessment, section 2.2.5). Lead firms have an incentive to look for the most suitable suppliers before entering into commercial relationships with them. Therefore, SMEs must be competitive to integrate successfully into such chains.

In view of this situation, during the initial QI reform period, SMEs will likely need some support through training, awareness raising, or financial levers such as tax breaks if they are to comply with the more stringent standards. Otherwise, there is a risk of pushing entire SME clusters out of the market. For more information on how to help SMEs meet higher standards, see section 10.9 of this module ("Enabling a Higher Quality of Domestic Products to Meet Standards").

Standards for enhancing the competitiveness of economic operators

To make standards work for trade and to reap the maximum benefits from trade opportunities, policy makers may focus on five areas:

- *Make information on standards and technical regulations accessible to firms.* Information on standards and technical regulations operating in target markets is not always easy to obtain. It is especially the SME sector, with limited capacity in this regard, that is most helpless. An effective standards information center and WTO TBT Inquiry Point are a good start.
- *Encourage and enable firms to adopt standards and comply with technical regulations.* Support in the form of technical consultancy and financial assistance (bonus system or subsidized fees) are avenues to explore.
- *Invest in quality assurance services.* The QI services must be available and affordable. They need to be internationally recognized.
- *Improve governance at home to facilitate border crossing.* This is a major challenge because the technical regulation regimes of many countries are fragmented, and costly overlaps are common. A common technical regulation framework, compliant with international good regulatory practices and acceptable to main trading partners, is an absolute necessity to enhance the competitiveness of local economic operators, especially in the SME sector (see section 10.2.4 above).
- *Leverage international mechanisms that facilitate trade.* These are bilateral and multilateral recognition agreements to get trading partners to accept national QI service outputs (see module 7: Technical Regulation, section 7.5.2, regarding technical regulations; and module 5: Accreditation, section 5.5.1, regarding accreditation systems).

Trade promotion organizations (TPOs) are likely to play a key role in such an action plan, notably because they are active in the technical infrastructure relevant for standards and regulations in many countries (ISO and ITC 2010).

10.5 STRENGTHENING METROLOGY AND ACCREDITATION

Metrology is highly technical, whereas accreditation is a more administrative type of operation. Both require highly skilled personnel and the implementation of formal quality management systems.

10.5.1 Metrology

It is an expensive and technologically demanding exercise to establish a national metrology system. At the top of the system, as a rule, is a national metrology institute (NMI) that is legally empowered to establish and maintain the national measurement standards, and thus (a) ensures their traceability to international measurement units, and (b) guarantees the dissemination of the measurement units to private and state institutions. Even if the NMI decentralizes its tasks, it remains accountable for the metrology system of the country; and in this case, the monitoring of the designated institutes now responsible for the various national measurement standards will place special demands on the umbrella organization.

The process of establishing a viable and internationally recognized metrology system consists of a number of essential elements, including the following:

- *Informed knowledge of the country's economy-related metrology needs* as well as regulatory-related demands in terms of measuring equipment subject fields and accuracy classes
- *Demonstrated relationship of the national measurement standards to the international measurement units* through accreditation mechanisms and ultimately through the determination of the country's calibration and metrology capabilities (CMCs)
- *Ensuring of the traceability chain* from the national measurement standards to state metrology systems (for example, legal metrology) and the private sector through appropriate calibration systems
- *Integration into international and regional metrology organizational structures,* their expert committees, and interlaboratory comparison schemes as a mechanism for knowledge transfer and establishing the country's position as trustworthy regarding metrology

The development trajectory of a national metrology system can be usefully characterized as a basic stage, which develops into an advanced stage, ultimately culminating in a mature stage, as follows:

- *In the basic stage,* capacity is available in terms of a small range of equipment for measurements such as mass, length, volume, temperature, and pressure used in everyday activities in basic manufacturing, in processing plants, and in legal metrology.
- *In the advanced stage,* the range of equipment is extended as defined through economywide surveys and sectoral benchmarking at the international level, resulting in more sophistication, higher accuracy classes, and a broader scope of measurements.
- *In the mature stage,* high-level laboratory capacity is available to support the innovative sector of the country while maintaining the basic- and advanced-stage gains.

The metrology system of many low- and middle-income economies would probably hover somewhere between the basic and advanced stages.

Establishing even the basic metrology system is a long-term endeavor. Major challenges include the availability of appropriate laboratory space complete with the necessary environmental controls, the appointment and training of skilled metrologists, the sourcing and commissioning of measurement equipment, the establishment of a quality management system, and interlaboratory comparisons of the measuring equipment or alternatively the calibration thereof at an advanced NMI. A cooperation or twinning agreement between the fledgling NMI and an advanced NMI in another country is a profitable approach. Advanced and mature NMIs are generally ready to share their knowledge; for example, metrologists can be trained or attached to gain practical experience, and measuring equipment can be calibrated.

In the advanced stage, cooperation agreements between NMIs are equally valid. The focus, however, shifts to collaborative research projects and the development of more effective or more accurate measurement equipment and processes. As a mature NMI, the organization becomes the twinning partner of newly established NMIs. Most development projects will focus on establishing NMIs and supporting their quest to establish the first basic national measurement standards and initiate the calibration system. A few long-term projects may even take the NMI into the advanced stage.

A major challenge for development projects is the propensity of leading experts to replicate the high levels of accuracy they are accustomed to in their own institutes, not realizing that it is not needed by the low- or middle-income country and that the capacity to maintain such high levels of accuracy is frequently beyond the capabilities of the recipient country. This leads only to frustration and eventually the collapse of the established technical infrastructure.

By the same token, it is of vital importance that the technical capacity to maintain the newly acquired national measurement standards is established at the same time as getting the NMI off the ground. Failure to do so will eventually lead to the sad situation that the national measurement standards are no longer operational or properly calibrated—in other words, no longer useful.

10.5.2 Accreditation

A newly established accreditation body, whether at the national or regional level, faces a number of challenges:

- *Managing the start-up financing* (subsidies) in the first few years before its business has expanded to the point where the income from accreditation services covers costs
- *Finding lead assessors, system assessors, and technical assessors* with the relevant technical backgrounds who have been properly trained in accreditation processes and who have been evaluated in this respect and registered
- *Developing and fully implementing the quality management documentation* of the accreditation body, compliant with ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies")
- *Designing and populating the website with all the relevant information* so that organizations seeking accreditation can prepare themselves properly and stakeholders seeking information on accredited organizations and their scopes can be informed fully

- *Gaining customers before it is internationally recognized* as a signatory of the ILAC and IAF multilateral recognition arrangements (potential customers are looking for an internationally recognized accreditation certificate)
- *Managing the process of becoming a signatory* to the ILAC and IAF multilateral recognition arrangements through peer reviews

This is a steep learning curve, and although it is possible for an accreditation body to deal with these challenges on its own, this will take quite a few years. Support from development partners that are well versed in accreditation matters is recommended because this can speed up the process appreciably and helps avoid costly and time-consuming mistakes. The development partner will be able to train assessors and monitor their performance, provide consultancy on developing and implementing the quality management system, assess the performance level and state of implementation of the elements required for international recognition, and conduct risk assessments to highlight deficiencies that may require political intervention.

Entering into a "twinning arrangement" with a more experienced accreditation body that has already been internationally recognized is a possibility that should be explored (see also module 5: Accreditation, section 5.6.3). The twinning partner not only provides information on proven systems, but also supports operations in a meaningful way. Assessments will be conducted by a team from both organizations, and a joint accreditation certificate may be issued. This gives the accredited organization a recognized certificate and helps the newly established accreditation body gain practical experience and a track record before it is peer-reviewed for international recognition.

Regarding financing, the setup and start-up phases would have to be financed by the government or a similar authority. In most cases, these financing arrangements would have to cover at least the years until international recognition is attained. To determine the fee structure, benchmarking against an accreditation body in a country of similar economic power provides good information. With this information, together with an understanding of the number of potential clients and the capacities of the accreditation body, the expected income can be deduced and a break-even point ascertained.

Of crucial significance is the understanding that initial assessments will generate a much higher income than the income from annual monitoring once organizations have been accredited. This results in much lower turnover after a few years, once the bulk of potential clients have been accredited. Developing new accreditation services (that is, for sectors not included in the start-up phase) can alleviate this to some extent.[5]

Becoming a signatory of the ILAC and IAF multilateral recognition arrangements is the final step for achieving international recognition. Anecdotal evidence suggests that this process can take five to seven years. The application process is well defined and includes a peer evaluation by teams established by ILAC and the IAF or a recognized regional cooperation body. The peer evaluation will include the witnessing of an actual assessment without the "twinning partner." The development partner will be able to conduct a pre-peer assessment evaluation, thereby highlighting last-minute issues that need correction.

10.6 SPECIAL CONSIDERATIONS FOR QI DEVELOPMENT PROJECTS

Whereas standards bodies and metrology institutes may require a certain basic infrastructure and operational systems before any specifics can be accommodated, this is generally not the case for conformity assessment service providers such as inspection bodies, test laboratories, and certification bodies. The scope of their services needs to be clearly defined before any capacity building or even their establishment is planned. The scope will be determined by the demonstrable needs of the country to support the private sector or the regulatory authorities (see module 2: The Importance of QI Reform and Demand Assessment). Some of the issues that need to be considered for developing capacity in this area are discussed below.

10.6.1 Whether to establish national or regional QI institutions

The establishment of full-fledged national QI institutions requires considerable investment and ties up resources on a long-term basis. For smaller low- and middle-income countries with limited financial means and a relatively modest demand for QI services, this may be neither feasible nor useful. Instead, the common use of a regional QI service provider may be the better approach. For an initial estimation of the extent to which QI capacities could be established at a regional level, it is useful to consider a clustering of QI services in terms of "cost" and "demand" criteria (Miesner 2009).

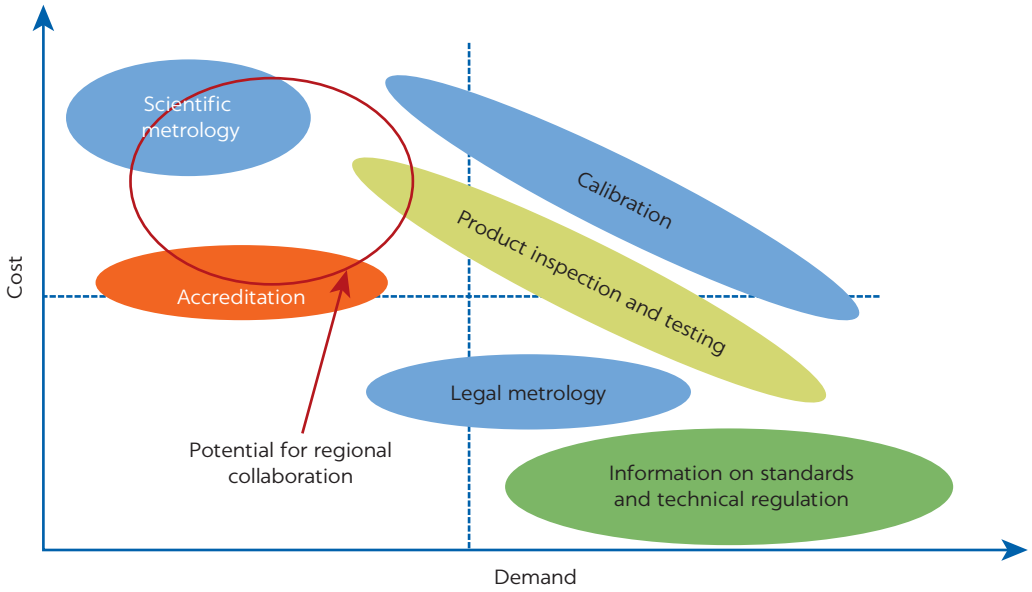
Figure 10.5 provides a conceptual picture of a region's QI services landscape, with the cost of the services on the vertical axis and the demand for such services on the horizontal axis. Smaller countries in the region may decide that the higher cost of establishing services such as scientific metrology is beyond their resource capabilities, in which case a regional structure would make sense. On the other hand, even a costly service such as calibration, because of the frequent uptake of such services, may warrant the cost of establishing such a service at the national level.

Hence, figure 10.5 indicates that even the smallest country should establish legal metrology and information services. For the implementation of legal metrology measures, a local presence is required. Legal metrology is a sovereign task of the state. This is also an area where the positive impact of even rudimentary (that is, cost-effective) measures will rapidly be felt by consumers. As for information systems, we are living in the information age. A well-designed standards information system will connect the country with international systems, thereby providing local industry and authorities with vital information on international standards and technical regulation information.

The areas of product testing and calibration contain a wide range of possible services that prevent a clear allocation, but inspection and testing for technical regulations (a high-demand area) may have to be provided for at the national level. High-end calibration and accreditation, on the other hand, are low-demand or low-frequency, high-cost services that are prime candidates for a regional approach. Before coming to a conclusion for a specific region, real data should be factored into the evaluation.

System certification is an area that shows a wide spread of cost versus demand or frequency. Establishing certification services such as Global G.A.P. (Good Agricultural Practice) or Forest Stewardship Council (FSC) are expensive, and the demand may not be that high at the national level; hence, a regional approach

FIGURE 10.5
Clustering of QI services by cost and demand



Source: Adapted from Miesner 2009. ©National Metrology Institute of Germany (PTB). Reproduced with permission from PTB; further permission required for reuse.
Note: QI = quality infrastructure.

may be indicated. On the other hand, ISO 9000 ("Quality Management System" series) type certification would be of great benefit to the SME sector. Establishing a local certification service would better serve this important sector, owing to lower costs, language issues, and better knowledge regarding local conditions.

Cost and demand are not the only aspects to be considered in deciding whether to establish regional or national QI institutions. Other aspects that could play a role include the proximity of service delivery to where it is needed, strategic interests, financial sustainability, availability of technical expertise, transportation logistics and rapid customs clearance for test sample movements, and national sensitivities. The last should not be dismissed out of hand; it may be that they are important to the recipient countries. A proper business case should be developed that carefully considers all of these before any national or regional organization is established.

10.6.2 Whether to support one organization or multiple ones

During the planning stage of development projects, it needs to be decided whether the capacity building will target only one organization or whether a whole group should become beneficiaries. This can be analogized to a balanced or unbalanced strategy. In the case of a central laboratory required for the testing of food products for the European Union (EU) market, for example, only one such laboratory is required in a low- or middle-income country, and the development project can be focused on that specific laboratory. If broad-based support for the domestic economy is required, it may be advisable to support the whole network of QI.

For example, if calibration laboratories should be the beneficiaries, it may be far more profitable for the country if a few calibration laboratories are supported, thereby avoiding a monopolistic marketplace. On the other hand, if a case could be made for developing the capacity in one laboratory

(for example, microbiological testing), external requirements may indicate that more than one laboratory is needed, such as one for testing fish for export and another for testing red meat for export because the European Commission has designated them so.

10.6.3 Whether to support multinational providers

A tough decision is whether to support capacity building in a multinational conformity assessment service provider, such as Global G.A.P., Fairtrade, or FSC. On the one hand, their presence in a low- or middle-income country may be a significant element in fostering exports; on the other hand, they have their own finances to do so.

A related issue that needs to be carefully considered in this case is whether supporting such a multinational provider will lead to a situation in a low- or middle-income country that binds trade to a system governed by a private standard, which may be detrimental to SMEs that would have difficulty in accessing services because of price pressures. The services of these multinationals do not always come cheap; they are in business to generate profits for their shareholders, after all.

10.6.4 Additional basic considerations

Avoid overcapacity. The major challenge for development partners is the "silo" mentality of ministries in a low- or middle-income country, a number of which wish to have their own capacity, when it would make much more sense if only one laboratory were established (that is, properly equipped, with technical staff trained and helped to gain accreditation) because of the limited amount of testing that is required. A lot of modern test equipment is designed to be operational most of the time to retain its accuracy, rather than switching it on once a week or twice a month for the little testing that comes its way. The inevitable result of setting up two laboratories, when one would be more than enough, is that both will run far below capacity, the financial sustainability of both will be compromised, and scarce human resources will be spread thinly—over and above the fact that the electronic equipment will become less accurate more rapidly.

Laboratory space and environmental controls. Test laboratories and inspection bodies need specific equipment with known measurement characteristics that functions optimally in a specific laboratory space. The equipment has to comply with specific environmental requirements (for example, temperature, humidity, freedom from dust, and lack of vibration). And the appropriate safety and health requirements (for example, for X-ray machines, handling of explosive gases, handling heavy test samples and materials, and so on) need to be considered. To specify such requirements, experts in the specific field should be consulted.

No laboratory space, no equipment. Without the necessary laboratory space with related environmental controls being available up front, it is bad practice to deliver equipment. The equipment cannot be commissioned, and many cases exists in low- and middle-income countries where such equipment has not been unboxed for years. When it is eventually commissioned, it is no longer up-to-date, or components have perished and cannot be replaced because parts are hard to come by, with the end result that the expensive equipment is basically useless—and scarce funding has been totally wasted.

Electricity supply. Electricity supply is a challenge frequently overlooked by development partners. In high-income countries, electricity supply voltage is fairly stable, at 230 volts ± 5 percent or 110 volts ± 5 percent. In low- and middle-income countries, this is seldom the case where variations of more than 10 percent are common and spikes of more than 100 percent are experienced, over and above the fact that electricity can become very intermittent—that is, the overload on the system leads to blackouts, sometimes for hours on end. Sensitive electronic testing and measuring equipment is not always able to operate accurately in these conditions, and projects must ensure that uninterruptable power supply (UPS) equipment is installed where required.

A related issue concerns the plugs that electronic equipment is frequently delivered with. For safety reasons, the plugs are an integral part of the equipment and cannot just be unscrewed and replaced with others if the standards for plugs and sockets in the low- or middle-income country differ from those of the supplier country. Removing the integral plug mostly results in the warranty becoming void, or worse, the wiring is stripped bare and pushed into sockets without a plug, thereby creating an unsafe condition.

Maintenance. A major issue to consider, and one often overlooked when providing sophisticated electronic equipment to low- and middle-income countries, is the availability of maintenance services. This challenge becomes even more pronounced when different donors provide equipment with similar functions but from different manufacturers. A better option would be if both donors were to provide the same manufacturer's equipment, thereby enhancing the possibility of a proper maintenance service being established in the country. In metrology, it may be good practice to also develop this capacity in the NMI as part of the project.

10.6.5 Proficiency testing

For complex testing regimes, proficiency testing (that is, interlaboratory comparisons) is frequently the only way in which the technical capability of a specific laboratory can be demonstrated. These comparisons can be part of the project design, and regional interlaboratory comparisons help alleviate the challenge of too few laboratories existing in the country to conduct them in a meaningful way.

Developing the ways and means to transport test samples across borders without having them tampered with by customs officials also is a major challenge. Sometimes the only way to do so is for technicians to take them across personally, together with very official government letters explaining the purpose of such samples. This holds true for samples for both calibration and testing laboratories.

10.7 STREAMLINING AND HARMONIZING TECHNICAL REGULATIONS WITH INTERNATIONAL STANDARDS AND TARGET MARKETS

Whereas compliance with standards is a voluntary decision, compliance with technical regulations is mandated by law, should the manufacturer or supplier wish to enter a specific market.

The harmonization of standards across economies is generally at an advanced stage because of the adoption of international standards by national

standards bodies all over the world. In low- and middle-income countries, it is not uncommon to find that more than 80 percent of the national standards are adoptions of ISO, IEC, or Codex Alimentarius Commission (CAC) standards, albeit sometimes with small changes to deal with local realities (for example, voltage variations of 10 percent rather than 5 percent in high-income countries).

Technical regulations are a totally different picture. Surveys in many low- and middle-income countries have shown that the country's technical regulation regime is fragmented and of an ad hoc nature, sometimes not even fully compliant with WTO TBT Agreement requirements if the country is a WTO member. The various ministries and their agencies develop and implement technical regulations in a manner they see fit, frequently without even considering their compliance with WTO TBT Agreement requirements. The technical requirements contained in these technical regulations are often not based on international standards either; they are local developments with major differences from the international standards.

The net result of such situations, which have developed organically over many years, is that trade is hampered by the multiplicity of regulatory approaches, overlaps between regulatory authorities regarding specific products, different technical requirements imposed by the different authorities, less-than-transparent compliance systems, regulatory fees payable to more than one regulatory authority for the same product, and many other impediments. The increase in transaction costs to the industry can be quite substantial, running higher than 20 percent in some cases, thereby compromising the competitiveness of the local industry relative to its international competitors.

To alleviate this problematic situation, some low- and middle-income countries have embarked on reviews of their technical regulation regimes, sometimes compelled into doing so as a result of bilateral trade negotiations with major trading blocs or countries. These major trading partners obviously wish to reengineer the technical regulation regime of the low- or middle-income country in a way that would be beneficial for their own exporters and importers. Such a country then has an unenviable decision to make: whether it will align its technical regulation regime with that of the one trading partner while maybe compromising trade relations with some of its other trading partners.

Unfortunately, these decisions are often fudged at the political level by not considering all the facts and risks—for example, wishing to sign such trade agreements as quickly as possible without fully understanding the long-term ramifications of their decisions or while being pressured by promises of massive technical development support. A typical example would be the alignment of the technical regulation regime for products falling within the narrow scope of the trade agreement while keeping the rest of the country's technical regulation systems intact. The result of such a decision would be the further fragmentation of the technical regulation regime to the detriment of the overall trade environment, thereby compromising the competitiveness of the country's own industry even more.

Another challenge arises when the sophisticated technical regulation regimes foisted in such a manner upon a low- or middle-income country presuppose a sophisticated QI and/or legal system that is totally beyond the country's capacity. As a result, the country readily accepts imports from the trading partner, but its export industry still finds it extremely difficult to penetrate the other trading partner's markets.

An appropriate approach would be to review the whole technical regulation regime, and if it needs to be modernized, to do so across the board (see module 7: Technical Regulation). It would be much more profitable all around to develop and implement a modern and transparent technical regulation regime, based on international good regulatory practices, that is consistently followed by all of its regulatory authorities and would satisfy most of its trading partners. If the low- or middle-income country is a member of a regional trade agreement, its obligations in relation to the regional obligations have to be factored into the decisions as well.

This is, of course, a much more involved reengineering exercise that would take years to complete. Hence many governments are reluctant to embark on such a massive undertaking fraught with potential political upheavals and backlashes from regulatory authorities that see no reason for change, often fearing for the safety of their jobs.

10.8 THE ROLE OF STANDARDS COMPLIANCE IN GLOBAL VALUE CHAINS AND FOREIGN DIRECT INVESTMENT

Global value chains (GVCs) and foreign direct investment (FDI) are important elements for industrial development. Local companies wishing to participate in GVCs or benefit from FDI will need to use QI services. GVCs and FDI can be instrumental in developing the relevant QI services where these do not yet exist, but there are differences between what GVCs and FDI can accomplish—differences that have to be taken into account when establishing QI development projects.

10.8.1 Global value chains

A value chain is considered to be made up of the full range of activities that are required to bring a product—from its conception, design, sourcing of raw materials and intermediate inputs, and manufacturing to marketing and distribution—to the final consumer (see module 2: The Importance of QI Reform and Demand Assessment, section 2.1.2). Some value chains operate across country boundaries (that is, at the global level) and are therefore known as global value chains.

GVCs make a significant contribution to international development (UNCTAD 2013). GVC-related value-added trade contributes an estimated 30 percent to the GDP of low- and middle-income countries—significantly more than the 18 percent in high-income countries. Furthermore, the level of participation in GVCs is associated with stronger growth of GDP per capita. GVCs can be an important mechanism for low- and middle-income countries to enhance productive capacity by increasing the rate of technology adoption as well as workforce skill development, thus building the foundations for industrial development.

There are, however, challenges for low- and middle-income countries associated with a GVC approach:

- GVCs' contribution to growth may be limited if the work done in-country is relatively low-value-adding (contributing only a small part of the total value added for the product or service).

- There is no automatic process that guarantees diffusion of technology, skill building, and upgrading. Low- and middle-income countries thus face the risk of operating in permanently low-value-added activities.
- GVCs have potential negative impacts on the environment and social conditions, including poor workplace conditions and suboptimal occupational safety and health systems.
- The value chain's "owners" can relocate their production (often to lower-cost countries) with relative ease, which create additional risks such as job insecurity.

Countries therefore need to carefully assess the costs and benefits of proactive policies to promote GVCs or GVC-led development strategies. Promoting GVC participation implies targeting specific GVC segments, and GVC participation can form only one part of a country's overall development strategy (see module 2: The Importance of QI Reform and Demand Assessment, section 2.1.2).

Once the decision has been made to embrace a specific GVC, then the infrastructure to participate needs to be put in place. Over and above the management, financial, and transportation-related challenges, compliance with the relevant standards and technical regulations becomes extremely important because the in-country part of the production needs to fit absolutely seamlessly into the global chain of production. Some of the QI-related elements that may be required include the following:

- *An in-depth study to identify the standards required for in-country production.* Such a study is vital to identify international standards and the national standards of other countries, all of which will be augmented by company-specific standards and specifications. Various technical regulations may also play an important part in the value chain and need to be identified.
- *Technical capacity to meet the identified standards and technical regulations.* Local industry may need to develop this capacity through training of the workforce and establishing testing facilities that need to be accredited. The provision of metrology capabilities in relation to national measurement standards and accredited calibration laboratories will feature prominently.
- *Certification of in-country manufacturers.* Manufacturers may need to be certified to ISO 9001 ("Quality Management Systems—Requirements"), for example, or to environmental management standards such as ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use"). In the food processing industry, certification to HACCP or a similar facility is required in most cases. A national certification body, suitably accredited by an internationally recognized accreditation body, has to be established if it does not yet exist, or such services have to be "purchased" from abroad.

An effective public-private partnership between the government of the low- or middle-income country and the GVC "owner" is a useful vehicle to implement the required QI services and to address the challenges described here. The GVC "owner" usually has the technical know-how to develop the particular QI services required in the country, even if it can access them abroad. Whether it *will* develop them in the country may differ from one GVC "owner" to another.

It would be useful if the government could provide political support and resources for the QI services' establishment and capacity development and get

the cooperation of the GVC "owner" in this respect to establish them as part of the local QI. Even development projects could consider this as a strategy. In this way, the transfer of technology, skill building, and upgrading becomes more sustainable. If the GVC "owner" then decides to move the in-country part of the GVC to another country, the low- or middle-income country may be able to lure other GVCs because of the availability of a recognized QI infrastructure specifically geared for such production.

10.8.2 Foreign direct investment

Foreign direct investment is an investment in the form of a controlling ownership in a business in one country by an entity based in another country. FDI is distinguished from portfolio foreign investment (the purchase of one country's securities by nationals of another country) by the element of control. Strategically, FDI comes in three types:

- *Horizontal:* The company carries out the same activities abroad as at home (for example, an automotive company assembling cars in both Japan and South Africa).
- *Vertical:* Different stages of activities are added abroad. "Forward vertical FDI" is where the FDI takes the firm nearer to the market (for example, a Japanese vehicle manufacturer acquiring a car distributorship in the United States). "Backward vertical FDI" is where international integration moves back toward raw materials (for example, a Chinese vehicle manufacturer acquiring a tire manufacturer or rubber plantation in Malaysia).
- *Conglomerate:* An unrelated business is added abroad. This is the most unusual form of FDI because it involves attempting to overcome two barriers simultaneously—entering a foreign country and a new industry. This leads to the analytical solution that internationalization and diversification are often alternative strategies, not complements.

10.8.3 GVC and FDI outcomes

There are many similarities between GVC and FDI outcomes at the operational level. The main difference is that, in the case of FDI, the foreign company has a controlling interest in the local company, whereas in a GVC this is not the case. A local company acquired through FDI can become a part of the GVC of the parent company; in fact, this is usually the driver behind such investments.

Once a foreign company has invested in a local company, it will not consider moving the in-country production part to another country as easily as would be the case if it just subcontracts. Hence, the sustainability of such foreign-owned companies may be higher than if they are local companies that have been subcontracted into a GVC. FDI may therefore facilitate more sustainability in the long term.

The challenges regarding QI services in companies established through FDI are, to a large extent, the same as those noted earlier for the GVC situations.

10.9 IMPROVING THE QUALITY OF DOMESTIC PRODUCTS TO MEET STANDARDS

A real desire of many low- and middle-income countries' governments is to enable manufacturers and suppliers to produce higher-quality domestic

products meeting international or just national standards. This is difficult to achieve without the wholehearted desire of the local industry to do so. Local industry, especially the SME sector, is able to sell its products to the local market on price rather than quality. Investing in the design, manufacturing controls, final inspection, and third-party testing and certification is not always at the forefront of its thinking. There are a number of approaches that have been used successfully in some countries, as detailed in the following paragraphs.

If the state purchases a vast number of products and services in all countries, a scheme whereby the government rewards SMEs for implementing and maintaining quality measures is a useful one to consider. A typical example would be that the state gives suppliers that provide products that demonstrably meet national standards (for example, carrying the product certification mark of the NSB) preferential treatment in the tender process. This means that their product can be a bit more expensive than the cheapest by a small percentage (for example, 2 percent), and they would still get the contract. The state gets products that are quality-guaranteed, and the SME gets reimbursed for its certification costs.

A second possibility is for the state to directly support the SME sector financially for implementing a quality management system such as ISO 9001 and then to defray some of the certification costs. A useful scheme to consider is one whereby the state pays back 50 percent of the certification costs once the company has been certified. If the company maintains its certification for another two years, then the state pays back another 25 percent. Providing such finances *before* certification does not work, nor does paying back the full costs when certified. There has to be an incentive for the company to maintain its certification.

A third possibility is a joint approach by a major private sector company such as a mining group and the NSB. The mining group pledges 10–15 percent of its purchases from SMEs. These have to comply with private purchasing specifications that are issued by the NSB or even by the mining company. The NSB then has a contract to inspect the production controls of the SME against requirements agreed to between the mining company and the NSB, in the process helping the SME to implement controls where they are lacking. The final products are batch-inspected and tested to ensure compliance.

In many countries, public procurement constitutes a major share of the market. Therefore, going beyond the SME sector, the role of government in public procurement can be leveraged to stimulate the quality of products at all levels and eventually inculcate a quality culture. Possibilities include (a) requiring compliance with standards in all state tenders; and (b) tax incentives for new technologies (such as solar heating or energy efficiency in housing) only if compliance with standards is proven.

In this way, the state can try and "pull" a sector toward compliance. For a scheme to succeed, it must have a financial or social benefit for the company to become interested and to maintain quality criteria once they have been implemented.

10.10 ENABLING INNOVATION

An innovation is defined generally by the *Oslo Manual* of the Organisation for Economic Cooperation and Development (OECD) and Eurostat as "a new or

improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)" (OECD and Eurostat 2018). More radical thinking considers innovations as mutations that revolutionize the economic structure from within by destroying old ones and creating new ones.

In our technological age, with ever faster technology developments, innovation is widely recognized as one of the essential drivers of successful businesses and a key contributor to the productivity and socioeconomic development of nations. Hence, in many countries, there is a strong focus on public funding of research and development (R&D) and on intellectual property rights as instruments of innovation policy and business strategy. The question is, what is the role of the QI in all of this?

It is now generally accepted that the QI can support innovation in a number of ways (ISO 2015):

- Existing standards can codify and spread the state of the art in various technologies, disseminating knowledge both within and outside the relevant industry community.
- Standards can facilitate the introduction of innovative products by providing interoperability between new and existing products, services, and processes, hence providing a technological platform on which other innovation can take place.
- Innovations can more easily gain market acceptance if they comply with existing standards for safety, quality, and performance.
- Standards can have an important catalytic role in demand-side measures to encourage innovation such as outcome-based regulations or public procurement of innovation.
- Standards can help to bridge the gap between research and marketable products or services. A standard can codify the results of publicly funded research, thus making them available as a basis for further innovation.

10.10.1 The QI and innovation systems

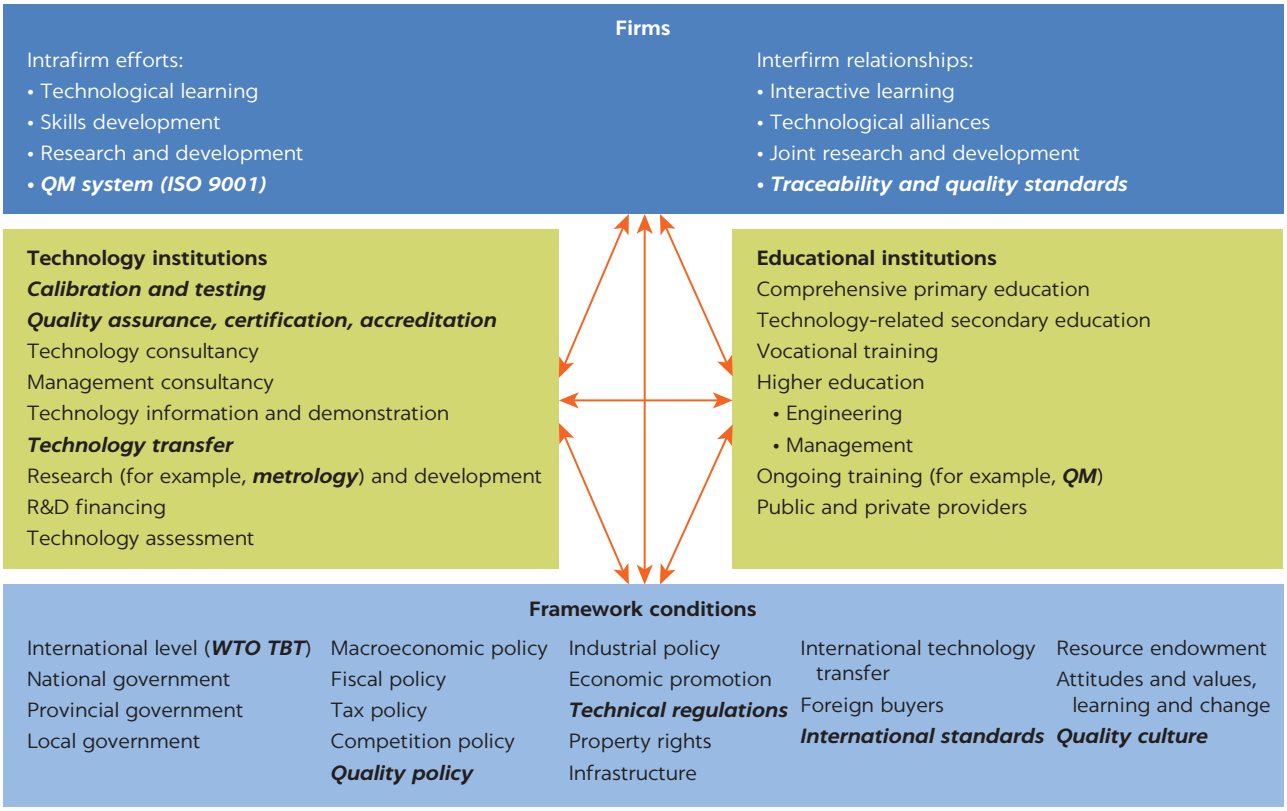
It has been argued that innovation can be fostered in a systematic way where firm-level innovation is central to the whole endeavor. However, certain framework conditions are also necessary, as well as support from technology institutions and the education sector. Together, these factors constitute the four-pillar model of innovation (Harmes-Liedtke 2010).

If innovation can be fostered in this way, it may be useful to consider the elements of such an innovation system when developing QI development programs. These are then also elements that need to be addressed in the demand assessment of the country. The four-pillar model is depicted graphically in figure 10.6.

Pillar 1: the firm. This is where a large part of innovation takes place, and firms should be the target of any efforts to stimulate innovation. The measure of effectiveness of an innovation system is the extent to which firms use innovation to create a competitive advantage. Within the firm, the implementation of a quality management system, such as ISO 9001, is the backbone of a continuous improvement and learning process. Interaction with other firms, in particular suppliers and customers, is also a key driver of technological learning and innovation.

FIGURE 10.6

The four-pillar innovation model and the QI's relevance within it



Source: Harmes-Liedtke 2010. ©National Metrology Institute of Germany (PTB). Reproduced with permission from PTB; further permission required for reuse.
Note: QI-related elements are bold and italicized. ISO = International Organization for Standardization; ISO 9001 = "Quality Management Systems—Requirements"; QM = quality management; R&D = research and development; "WTO TBT" = World Trade Organization Agreement on Technical Barriers to Trade.

Benchmarking, or the application of standards in value chains, is an example related to quality issues in the interfirm relationship.

Pillar 2: framework conditions. Macroeconomic, regulatory, political, and other framework conditions define the set of incentives firms can appropriate. For example, technical regulations for consumer protection or to meet the quality requirements of global buyers may push the firms to adapt and innovate. The legal framework and the development level of the QI show the level of the quality culture in a given country and may induce firms to either innovate or be an impediment to innovation.

Pillar 3: technology institutions. In a low- or middle-income country, the diversity of such institutions may be quite limited. There could be some public research institutions (such as agriculture extension), but their agendas and outcomes are rarely related to the needs and absorption abilities of local firms. More relevant for such countries are service providers of the QI like calibration and testing laboratories or certification bodies. Nevertheless, because the demand for such services is still small, it requires a lot of support from the government and the development partners to make these services accessible, especially to the local SMEs, in low- and middle-income countries.

Pillar 4: educational and training institutions. Other entities, such as vocational training institutes and sometimes business associations, have their own training providers. Quality management and other quality-related topics often are part of the training curricula. There is certainly some overlap with the third pillar; some research institutions will do some training, and some training institutions (especially universities) may be involved in R&D. However, it is crucial to understand that even in the case of universities, their core mission is training. Another type of overlap may occur as specialized training providers offer quality-related consultancy and support in the implementation of quality management systems.

Highlighting the quality issues within the model shows the relevance of the QI in all four pillars. On the other hand, the existence of QI elements within the whole system does not mean that these elements are already connected with each other and with the rather distant elements of the innovation system. The task of the innovation system promotion is therefore to "build" bridges within and between each pillar to overcome fragmentations.

It is important to point out that the relevance of different elements of an innovation system depends on the country's stage of development. In a country where "catch-up innovation" is the predominant pattern, a highly specialized, leading-edge R&D institution will battle to find clients for its services. Fundamental technology services, such as those provided by the QI, may be more appropriate. The demand assessment preceding any QI development project should take these realities in account.

10.10.2 The QI and "incremental" innovation

Innovation can be considered simply as being a new idea, device, or method. This can be accomplished by newer and higher-quality products or by more efficient processes—a notion that would resonate more with the realities of a low- or middle-income country than would the idea that innovation presupposes a radically new technology, as further described below.

Programs of organizational innovation should be linked to organizational goals and objectives, to the business plan, and to competitive market positioning. Typical goals of innovation in manufacturing and services organizations could include the following:

- Improved quality
- Extended product range
- Reduced labor costs
- Improved production processes
- Reduced material costs
- Reduced environmental footprint of the organization
- Replacement of products
- Reduced energy consumption
- Compliance with regulatory requirements

These goals vary among the improvements to products, processes, and services and dispel a popular myth that innovation deals mainly with new product development. Most of the goals could apply to any organization. Whether innovation goals are successfully achieved depends greatly on the environment

prevailing in the firm. Conversely, common causes for failures in programs of innovation include poor goal definition, poor alignment of actions to goals, poor participation by staff, poor monitoring of results, and poor communication and access to information.

Looking at these goals of innovation and mapping them against the QI services, it quickly becomes apparent that almost all of the goals would benefit from the proper use of standards, metrology, accreditation, and conformity assessment.

10.10.3 The QI and "radical" innovation

For years after World War II, many thought that standardization and radical innovation were opposites and that standardization inhibited innovation. This has been proven to be a totally false concept. Even radical innovation needs standardization more than ever before. One example: The cell phone was an innovation—a radical, disruptive technology—when it was first brought to market. Soon a number of major electronics and telephone companies provided cell phones to the market, but each had its own connectivity system; global communication was difficult and frequently not possible. It was only with the advent of the Global System for Mobile communications (GSM) standard, enforced by the European Commission to ensure seamless communication in Europe, that global communication became a reality. In the meantime, the GSM standard has become the de facto international standard that has made the cell phone the success that it is (ISO 2015).

Three fields—health care, digital photography, and the commercialization of new technologies—exemplify the effective use of standards in innovative technologies (ISO 2015).

Modern health care. Advances in wireless health care are providing improved sources of understanding of diseases and their treatment and are revolutionizing the provision of health services in both high-income and low- and middle-income countries. But the medical technology sector is highly fragmented, highly competitive, and highly regulated.

The challenge is to ensure connectivity among all the wireless devices to gain full interoperability for the benefit of the whole system. Standards are the only way to do so, and they can even support differentiation of products as long as they connect. Standards must be applied when systems are "exposed"—that is, not part of a bigger system—not necessarily when they are not.

Digital photography. Digital photography was a disruptive innovation that replaced film-based photography in a very short time. In its initial phases, every company offering digital cameras had its own file formats for the digital images, with the result that general connectivity between camera, printer, and other software was challenging. It was only when the ISO and IEC established the Joint Photographic Experts Group (JPEG) in 1986 to develop an International standard for digital photography files that this issue was addressed.

The first JPEG standard was issued in 1992 and quickly became the preferred method for the whole industry. Today, all digital cameras, irrespective of manufacturer (which may still employ unique company file formats), can also provide JPEG files, as do all cell phones with built-in cameras. All printers and other peripherals recognize such files, as does all word processing and Internet software. Digital images have become a lingua franca of the information technology (IT) age, and billions of images are uploaded daily to various social media sites.

Commercialization of newly developed technologies. Standards create a common framework for innovation: they define common vocabularies; establish the essential parameters of a product or service; and provide for safety considerations, testing processes, and how to move to prototyping and full commercial production. As the "set of rules," standards make a difference in that (a) it becomes less likely to duplicate what has already been produced, allowing the organization to concentrate on innovative activities that will really add value; (b) innovative products will more easily integrate with the rest of the system; and (c) investors may have more confidence that the innovation will be successful.

10.10.4 The specific role of QI institutions in innovation

The above sections describe why QI services are important in innovation. It is important however, that the QI institution consider the way in which it engages with the private sector to foster innovation. This could include joint research projects, testing, or consultancy toward the improvement of products or processes, for example.

Building capacity in QI institutions is in itself an innovative process, but the understanding of the QI institution's role in an innovation system (as described earlier, in 10.10.2) should likewise be fostered. It is easy for the QI institution to be focused on providing QI services for the more effective implementation of technical regulations, because this is a major issue in many low- and middle-income countries. The role it can play in innovation by cooperating with the private sector in a proactive way—thereby establishing services that go beyond the conformity assessment related to technical regulation implementation—should not be neglected. Development projects can play a useful role in establishing such synergies in relation to innovation, because it may be unlikely to come naturally to the QI institution.

The importance of innovation and its reliance on standards has been given further substance in the establishment of a new ISO technical committee: ISO/TC 279, Innovation Management. ISO/TC 279's scope is defined as "standardization of terminology, tools and methods, and interactions between relevant parties to enable innovation."[6] At the time of this writing, the technical committee was in the process of developing seven international standards:

- "Fundamentals and Vocabulary"
- "Innovation Management System—Guidance"
- "Assessment—Guidance"
- "Tools and Methods for Innovation Partnership—Guidance"
- "Strategic Intelligence Management"
- "Intellectual Property Management"
- "Idea Management"

Adopting these international standards may be a useful approach in countries where innovation systems are seriously considered as a mechanism for development.

10.11 SOLVING CONFLICTS OF INTEREST

Two related areas of conflict need to be considered. It is inevitable in the reengineering of the QI, and especially the technical regulation regime, that conflicts surface between some of the operators as one has to relinquish "powers" that

have been part of its business model for years. Such powers may guarantee an income more through legislated fees than from an operator's own performance—that is, income independent of its technical performance or effectiveness. The second conflict of interest that needs to be addressed is that some QI services cannot or should not be provided by the same organization.

10.11.1 Conflicts regarding QI services

At the international level and in high-income economies, the three fundamentals of the QI—standards, metrology, and accreditation—are institutionally separated. In fact, at the international level, standards are developed and published by many international organizations. The three pinnacle organizations regarding the WTO TBT Agreement are the IEC, the ISO, and the International Telecommunication Union (ITU). The three bodies referenced in the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) are the CAC, the World Organisation for Animal Health (OIE), and the International Plant Protection Convention (IPPC). In metrology, we have the BIPM and OIML, and in accreditation ILAC and the IAF.

In smaller low- and middle-income economies, a complete separation is not always feasible owing to resource constraints, and the question becomes which services can be combined without creating a conflict of interest. The major issue is where the provision of conformity assessment services fits in. The basic rule is that conformity assessment services and accreditation must be kept strictly separated. In many low- and middle-income countries, NSBs also provide conformity assessment services and even calibration services.

In some examples of combined services, conflicts may be avoided:

- Although not common, there is no conflict of interest if standardization and accreditation are combined, provided that the organization does not offer conformity assessment services and the impartiality of the national accreditation body (NAB) can be demonstrated. Typical examples are the Standards Council of Canada (SCC), Standards Malaysia (SM), and the Cyprus Organisation for Standardisation (CYS).
- There is no conflict of interest if the NSB is also the designated NMI. This is the case in many low- and middle-income countries.
- There is no conflict of interest if the NSB develops and publishes standards and provides conformity assessment services on the basis thereof. In this case, the NSB may not also be the NAB; that would be a clear conflict of interest. This is the case in the bulk of NSBs in low- and middle-income countries. In the EU, this construct is frowned upon, albeit for reasons related to the EU technical regulation regime modalities rather than for being a basic conflict of interest.
- Metrology and accreditation make for an uneasy combination because calibration services should be accredited, and most NMIs in low- and middle-income countries provide calibration services over and above their responsibilities for maintaining the national measurement standards.

There are business issues that also could determine whether the NSB should be providing conformity assessment services. But these have to do with service quality, adaptability to deal with changing market circumstances, competition in the marketplace, and the like. These decisions would be dependent on the level of maturity of the conformity assessment market, not on inherent conflicts of interest.

10.11.2 Conflicts regarding technical regulations

In many countries, NSBs were mandated to implement mandatory or compulsory standards (that is, technical regulations). At the time, this was quite acceptable. The NSB developed the standard; the minister declared it mandatory; and the NSB inspected, tested, and certified products before they could be marketed. This approach had quite a few advantages; for example, scarce resources could be optimally used, and the NSB, as the center of technical excellence, could be used to best effect to safeguard the health and safety of the population and protect the consumers. When international trade was at a low level, all of this was fine.

But this approach has become far less acceptable as international trade flows have increased. It is seen as an unnecessary trade restriction or technical barrier to trade (TBT) by trade partners because of the premarket certification conducted by one organization—that is, tests and certification of products conducted in the country of origin often had to be repeated. Furthermore, this work of the NSB is funded by the payment of levies by the suppliers—levies specified by legislation. The income from this source has become the bulk of the income for the NSB, a situation that was supported by the government, because it relieved the financial pressure on state funding.

The outcome, however, was that the NSB collected the levies but was not always as diligent in conducting the inspection, testing, and certification. Second, the system lent itself to corrupt practices, with suppliers paying the fees to get rid of the inspectors without having to deal with the actual inspection, testing, and certification. In other words, the NSB was given a license to extract rent.

This system is now considered a conflict of interest by quite a few of the major trading nations. Hence, during negotiations on trade agreements, pressures are mounting on low- and middle-income countries practicing such a system to implement a more modern and trade-friendly technical regulation regime. This is a major undertaking with massive organizational and especially financial ramifications. The regulatory activities of the NSB have to be separated and placed in a regulatory authority, if one exists, or a new one has to be established. The conformity assessment measures have to be liberalized such that suppliers get a choice of technically competent service providers. In the process, the NSB loses its guaranteed funding and has to radically change its business model to that of a service provider competing with the other designated service providers.

The NSBs are understandably reluctant to go this route, and it takes resolute political will on the part of the government to implement such changes. The government also has serious decisions to make regarding the funding of the regulatory authority, which in all probability will no longer be collecting levies from suppliers.

Anecdotal evidence from countries where such radical changes have been implemented indicate that, if handled correctly, the NSB can flourish as a conformity assessment service provider provided the regulatory authority does not conduct the conformity assessments and the NSB delivers good service. The reengineering modalities were discussed earlier in sections 10.2.2 and 10.2.4.

10.11.3 Conflicts between mandatory standards and food safety systems

NSBs predate food safety authorities by many years in quite a few low- and middle-income countries. It was therefore quite natural for these countries to

implement food safety through the mechanism of mandatory or compulsory standards (as discussed earlier, in section 10.11.2). As these countries developed, the necessity for a food safety authority became more pressing, and many established food safety authorities.

Unfortunately, the interface between the previous mandatory standards system and the food safety system was not always clearly articulated or a transition period was not agreed to. The situation became even more complex because the NSB and the food safety authority reported to different line ministries—for example, the Ministry for Trade and Industry and the Ministry of Health. Furthermore, the legislation of the two systems was not aligned to ensure a clear description of the interfaces, resulting in two pieces of overlapping legislation mandating two different regulatory authorities to control the same products. This situation was exacerbated by establishing similar premarketing controls for the food safety system—for example, certification of the product before it could be marketed. The result was that suppliers had to comply with two sets of regulations, frequently with differing technical requirements; had to pay two sets of levies for two sets of product certification; and saw their transactional costs increase dramatically—increases of 20 percent being not uncommon.

Some governments have requested that the two regulatory authorities sort out the overlaps, but that usually fails. The reasons are manifold: the NSB stands to lose too much income from mandatory standards for food products; the food safety authority does not wish to use the laboratories of the standards body because it is establishing its own; the legislation of both has to be revised, and everybody is reluctant to do so, because it takes too much time and energy; and so on.

The only way to resolve this impasse is for the government to take the lead by first developing the policy that provides clear guidance on the overall system it wishes to implement, and then developing and promulgating the necessary legislation, after which a massive reengineering program has to be embarked on by all the relevant ministries and their agencies.

Development projects can make a major difference in this regard, but such projects must appreciate that a holistic approach is required. Too often they are aligned with the wishes of the recipient ministry, without considering other ministries that are also involved. Such projects unintentionally worsen the situation, hardening the attitudes of both the NSB and the food safety authority to the detriment of the low- or middle-income country's safety and health systems as well as diminishing the competitiveness of the local suppliers.

Modern thinking and CAC standards on food safety systems (for example, CAC/GL 82-2013, "Principles and Guidelines for National Food Control Systems") consider the whole value chain to be controlled—the "field to fork" approach. Product certification methodologies based on the systems as defined in ISO/IEC17067("ConformityAssessment—FundamentalsofProductCertification and Guidelines for Product Certification Schemes") are not seen as adequate any longer because they deal mostly with the final product and its method of production in the factory. What happens on the field and during transportation of the product after it has left the processing plant, for example, is not considered. The elements of a modern food safety system and its interface with laboratories, inspection bodies, and the NSB are described in module 2: The Importance of QI Reform and Demand Assessment, section 2.2.3.

The best approach to deal with this conflict is to get the three ministries involved in a modern food safety system—the ministries responsible for

agriculture, health, and trade and industry—to cooperate and develop a new approach for the country. This approach should take cognizance of the WTO TBT and SPS Agreements, good standardization practice (module 3: Standards, section 3.4), and the CAC "Guidelines for National Food Control Systems" (CAC/GL 82-2013), and it should be based on a "field to fork" approach. It should clearly define the responsibilities of the various agencies involved, liberalize conformity assessment, and base market surveillance on good international practices, including risk assessments. This approach should be finalized as a government policy that is approved for implementation at least by the cabinet to ensure the unstinting support of all the relevant ministries.

An implementation plan has to be developed that will have far-reaching consequences—a plan starting with the development or revision and promulgation of the necessary legislation, organizational restructuring, training of a skilled labor force, and many more actions. This is a massive undertaking, demanding clear leadership and the unstinting political support of the whole of government because difficult and painful decisions will have to be made regarding the deconstruction of entrenched systems, relocation of personnel, establishment of new structures, accentuating the role of accreditation, and developing the appropriate funding models for the system as a whole.

The impact of such a reengineering exercise would be extremely positive for the country's socioeconomic development, providing it with a viable food safety system while at the same time enhancing the competitiveness of the producers and food processing industry.

NOTES

1. The "organizations" of the QI ecosystem provide such things as national standards, calibration, test reports, certification reports, and accreditation certificates. The term "QI services" is used as a collective term to denote these outputs of QI organizations.
2. The WTO TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are nondiscriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety and protection of the environment. The TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade. Through its transparency provisions, it also aims to create a predictable trading environment (see module 7: Technical Regulation, section 7.1).
3. Stakeholder mapping is a technique whereby the organization lists and considers all its stakeholders in various categories, such as clients, influencers, authorities, consumer organizations, the media, and so on.
4. See "Who Develops Standards," ISO website: https://www.iso.org/who-develops-standards.html.
5. The recognition of an accreditation body is related to the specific accreditation services it provides. These could include the accreditation of inspection bodies, testing and calibration laboratories, product and management system certification bodies, bodies providing certification of persons, and many more. Details can be obtained from the ILAC and IAF websites: respectively, https://ilac.org/ and https://www.iaf.nu/.
6. For more information, see "ISO/TC 279 Innovation Management" on the ISO website: https://www.iso.org/committee/4587737.html.

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11

Challenges of QI Reform

INTRODUCTION

Building new capacity in the quality infrastructure (QI) or reforming customs and practices that have been around for decades is a challenging business in the best of times. The project evaluations of development partners that are available in the public domain are a useful source of positive and negative outcomes and the reasons thereof. Many of these are the sources of the discussions in this module (Kellermann and Keller 2014).

11.1 PROJECT PREPARATION AND MANAGEMENT

11.1.1 Start with long-term planning to build the QI

Key message: *Embed technical assistance for building the QI into longer-term planning, going beyond a single-phase project. This allows governments to mobilize their contributions to ensure that they are sequenced with international input. It is furthermore important to seek commitment and support for long-term strategies among key stakeholders, including the industry and nongovernmental organizations (NGOs).*

Strengthening national QIs is a long-term undertaking that requires donor commitment beyond a single project. The international recognition process for accreditation bodies, for example, takes—if everything is implemented as planned—about five to seven years, as does the establishment of metrology capacity of reasonable accuracy. The time to establish a national standards body (NSB) and operate it effectively will not be much different.

Yet, the short-term perspectives of development partners that are driven by donors' budget cycles of two to four years often negatively affect project results. Typical challenges associated with such short time frames include the following:

- Overambitious targets may be set because of the need to "deliver" tangible results quickly.

- Short-term planning causes "stop and go" donor support, with gaps between different projects, during which parts of initial achievements are lost.
- Patchiness of technical assistance without a clear overall plan leads to poor donor coordination, duplications among projects, and resource redundancy.

The need for a longer-term engagement is especially evident where national QIs are at the initial stage of development and the support required clearly exceeds the scope and length of one single intervention. Experience shows that achieving the technical and financial sustainability of newly established institutions in particular requires sustained support over a longer period. Clear planning of donor support beyond the limited duration of one project gives partner countries the visibility needed to mobilize their own resources or to call on complementary donor assistance. In addition, longer-term plans of donors that are widely shared with the government and the development community also contribute to enhancing aid harmonization.

Good practice is to embed projects into a longer-term plan for stepwise assistance over several project phases, including the following elements:

- Align planning with the beneficiary government's own strategies.
- Outline the longer-term objectives and explain how the project intends to achieve them over time.
- Set clear and realistic intermediate objectives for each project phase.
- Make funding of subsequent phases conditional on achieving intermediate objectives.
- Use the input from periodic evaluations to adjust the overall strategy and to tailor subsequent project phases to evolving changes in context and needs.

Moreover, it is not only donor support that may follow short cycles. Recipient priorities and strategies also shift with election cycles or changes in global policies. Donors should therefore seek commitment and support widely for long-term strategies among key stakeholders, including the government, industry, and NGOs.

11.1.2 Analyze demand and supply for quality services to set the right priorities

Key message: *In project preparation, gain a clear understanding of demand and supply for QI services in the country or region to be covered by the project to set the right priorities.*

Many if not most projects include components that aim at "upgrading" institutions that provide quality-related services (for example, inspection, testing, and certification) to serve the needs of the private sector. This upgrading is often expected to enable local companies to conform to quality standards and technical regulations—an important element of their competitiveness both at home and in export markets. To prevent redundancies and duplications, donor support needs to be geared toward strengthening those quality-related services that are in demand but not available or accessible for users.

The rivalry between ministries or their agencies, rent seeking, and national pride that gets in the way of common sense or good business practice are frequently the underlying challenges in this regard, leading to some of the typical undesirable side effects of QI development projects:

- The purchase of expensive testing or calibration equipment that is already available in the country may lead to the underuse of both (see module 10: How to Reform: Interventions and Approaches, sections 10.5.1 and 10.6.3). This happens quite easily if the partner institutions in the country are not the same for the different development partners—for example, if two microbiology laboratories are established under two different ministries, whereas one central laboratory could be more than adequate.
- An undesirable outcome of funding redundant capacities might be market distortion and crowding out of other, often private, service providers by establishing a public sector laboratory that becomes the de facto testing facility for technical regulations or sanitary and phytosanitary measures (SPS).
- Limited domestic demand might not justify significant investments in expensive equipment for some highly specialized services. On the supply side, not all services necessarily need to be available domestically. This is especially the case where such services exist at competitive prices in neighboring countries and are accessible or where regional capacity has been established (see module 10: How to Reform: Interventions and Approaches, section 10.6.1).

Therefore, pivotal for project preparation is an in-depth assessment of demand for and supply of QI services in the country or region—not, as is often done, a simple assessment of the capacities of potential beneficiary institutions. The modalities for conducting an in-depth needs assessment are discussed in detail in module 2. Because of its complexity, the demand assessment will require dedicated resources (funding and experts) and should be conducted as a preparatory stage. If this is not possible, such an assessment should at least be conducted, albeit at a lower level, during a project inception phase.

As an additional caveat, beneficiary institutions that operate as profit centers are often interested in developing services that are potentially most profitable. Although such a focus may contribute to their financial sustainability, it may at the same time leave gaps in other areas that are critical for export capacity, for example, but are not profitable enough for private players to provide. Stimulating but not distorting markets and taking into account the "public good" dimension of certain services should be one of the guiding principles of any needs assessment.

11.1.3 Use regional projects appropriately

Key message: *Use regional approaches to project design that are appropriate to the project environment. In strengthening the quality systems in regional projects, pay attention that enhancing the QIs at the national level does not disproportionally benefit the more advanced economies.*

Current wisdom tends to favor "regional approaches" as a means to support the establishment of QI services in a cost-effective manner for a group of smaller economies in which a purely national approach would be cost prohibitive.

To capitalize on economies of scale and scope, a development partner may choose to deliver assistance to several countries of a region within the same project. This could be particularly beneficial in the case of regional common markets. *Economies of scale* may include sharing of scarce resources (for example, a specific expert getting involved in several countries) or sharing

project overhead cost (for example, one preparation mission, one shared project office for several countries). An *economy of scope* could involve the potential for exchanging experiences and transferring know-how among recipient countries; in other words, less-developed recipient countries should be able to profit from a more advanced country's knowledge.

Whereas the economies of scale and scope are worthy project targets, the difficulties in coordinating such large projects should not be underestimated. Challenges that need to be considered include the following:

- Regional projects are more complicated to design and plan than a national project because they have to cater to the multiplicity of needs of more than one country.
- If the countries' interests are not aligned, that can lead to "competition" for resource allocation.
- Logistics can be more challenging. For example, travel becomes more complicated, language differences among recipient countries may require continuous translation or interpretation services, and transferring samples (such as for interlaboratory comparisons) without having them tampered with by customs officials can be quite daunting.
- Design of regional projects that are of high relevance to all countries covered is particularly difficult in cases of "asymmetry" of economies or their development stages and where there are no common key industries. The need to make "one fit for all" might lead to schematic designs that are unsatisfactory for everyone.

The presence of a more advanced "lead country" (for example, Vietnam in the Mekong Region or South Africa in Southern Africa) through which know-how is transferred can facilitate regional cooperation, both formal and informal. On the other hand, political sensitivities (such as the risk that the lead country is perceived as too dominant) need to be taken into consideration. Not only may a leading country be perceived as dominant; it may even be tempted to take advantage of the situation. An enhanced QI established at regional level for the benefit of all may have a disproportionately beneficial effect on the dominant, more advanced economy and widen the gap among participating countries rather than narrowing it.

Approaches that have proved to be successful in regional projects include the following:

- Economies of scale and learning have been achieved by coordinating input, such as by combining expert missions to a number of countries.
- By coordinating related elements of different national projects in the region, some benefits of economies of scale and scope can be realized while avoiding the pitfalls of a "schematic approach."
- Strengthening the existing formal and informal regional cooperation structures between QI institutions in the region and using the expertise available in more advanced countries in projects in less advanced countries has paid dividends in both transnational and regional projects because such links tend to remain in place after project closure.

Where a regional QI institution is the recipient of development support within such a regional project, care should be taken not to overlook the need for a national presence of QI institutions. (See module 10: How to Reform: Interventions and Approaches, section 10.2.2 for a detailed discussion of institutional reengineering.)

11.1.4 Work through the right counterpart

Key message: *Counterpart institutions for QI projects should be directly responsible for the fields covered.*

The selection of the right counterpart institution for the project is a crucial success factor. The counterpart institution may be in the public or private sector. Experience has shown that cooperation with an organization directly responsible for the fields addressed by the project is the most effective. Elements that need to be considered during project design and planning include the following:

- The choice of the counterpart institution should not be influenced by factors such as historical bias or political expediency (for example, "Our partner has always been the Ministry of Trade and Industry").
- If the QI development project covers a variety of technical fields that fall within the competences of several organizations, it may be necessary to work with several counterparts (a multistakeholder approach). It is important that the ownership of the project is "anchored" within the right one.
- Care should be taken not to get embroiled in institutional rivalries where an institution not formally mandated for a certain function tries to "capture" most of the project benefits to the exclusion of other key players, or where there is a sense among institutions of "whose turn is it next" to channel project resources.

Creating win-win situations when establishing new institutions, especially when transferring responsibilities from one organization to the next, is important to consider. It is especially the transfer of responsibilities (for example, separating regulatory functions related to mandatory standards from the NSB, establishing independent entities for scientific and legal metrology, separating various accreditation functions from ministries to establish a national accreditation body serving all, and so on) that needs high-level political support and careful planning. This is because the institution "losing" the responsibility may fight relentlessly to maintain the status quo, as the change could have a major influence on its annual income or constitute a loss of power, real or perceived.

11.1.5 Execution modalities, project governance, and management

Key message: *Define, agree upon, and implement enabling governance and management structures for projects. Sound project planning, monitoring, and evaluation are key success factors for development assistance projects in the field of QI because they often address issues of high technical complexity through working with multiple partners. Active and diverse project steering committees add significant value. Beyond the project level, a formalized mechanism of donor coordination at the country and regional levels is essential.*

Experience and postproject evaluations show that the success or failure of development projects in the field of QI is directly related to the project governance and operational management. This includes the application of proper planning, monitoring and evaluation, and logical frameworks. Although this may be true for any project, the complexity of building QI renders this more general principle even more important. Clear terms of reference and the separation of

the strategic and day-to-day management are important elements of good project governance. The same applies to decision-making powers that match accountabilities and responsibilities.

Execution modalities

In line with their commitments under the Paris Declaration on Aid Effectiveness (OECD 2005), many development partners are gradually shifting toward some degree of national execution for their projects. National execution means that donor funds are channeled through the national systems of beneficiary countries and that recipient governments have the final "executive" responsibility for project implementation.

To ensure efficiency and reduce transaction costs, the following challenges need to be managed:

- The key challenge is to strike a balance between commitments to national execution of aid delivery and aid effectiveness (that is, "managing for results"), considering the specific absorption capacities of each country and its institutions. Delivery modalities should be tailored to the institutional capabilities of the counterparts while at the same time ensuring that a healthy degree of ownership is transferred.
- Where development agencies have the choice to decide on modalities of delivery, forms of "joint execution" or "mixed execution," combined with mutual accountability, seem to work best. Subcontracting the elements of projects to local counterparts seems to be a reasonable way to gradually move toward more partner-led implementation, as are forms of joint decision making.
- National procurement systems are often cumbersome and not yet ready to cope with the sourcing of sophisticated technical equipment. Similarly, gaining access to the right, highly qualified expertise is not an easy task for low- and middle-income countries. Hence, sourcing sophisticated equipment and highly qualified expertise may still best be done by the international counterpart.

Project governance

QI capacity development usually involves many different stakeholders. To gain their active support, representatives of the main interested parties should be involved in project governance. Approaches that could be considered include the following:

- A project steering committee representing the broad stakeholder groups may add significant value. But, within the steering committee, the functions of "stakeholder involvement" and decision making at the strategic level should not be mixed—that is, changes to project agreements can be made only by its signatories. The tension between involving many stakeholders in project steering while not blurring decision-making power might be lessened by dividing the steering committee into voting members and observers.
- The decision-making process (consensus or executive) should be transparent and clear to all committee members.
- In addition to the status regarding the implementation of activities, the steering committee should be kept informed of all important financial data. Sharing financial data with counterparts is also a good way of capacity building, because it allows counterpart institutions to gain experience in planning their own projects in the future.

- Including representatives from related donor-funded projects as observers is a good way to improve informal donor coordination.

Operational management

At the operational level, a choice has to be made between day-to-day management on the "field level" or managing the project at the development agency headquarters. Both have positives and negatives that need to be considered for a specific project. Normally, these decisions depend on the financial volume of the project and the practices of the development agency. Therefore, the liberty to choose is limited.

Where decision-making power is delegated to the field office or counterparts, implementation risks need to be minimized by strengthening the financial and operational monitoring systems that should operate continuously during the project implementation phases. The task of monitoring complex projects may be commissioned externally, at least for strategically important projects with high implementation risks. Whatever the modalities chosen for project governance and management structures, these should be agreed to by all project partners before implementation.

Use of experts

A decision will have to made regarding the use of experts, who could be either (a) embedded in the local project office for most of the project duration, or (b) available only for short, intermittent stays. Both approaches have strengths and weaknesses (table 11.1).

The decision of whether to embed experts in the local office or use short-term experts could also depend on the state of the QI and the gaps that need to be addressed. The establishment of a QI institution and moving it from rudimentary to basic level (as discussed in module 2: The Importance of QI Reform and Demand Assessment, section 2.2.2) may necessitate an embedded expert, whereas for enhancing an advanced or mature QI institution, short-term experts would suffice.

TABLE 11.1 Strengths and weaknesses of embedded versus intermittent experts

EXPERT TYPE	STRENGTHS	WEAKNESSES
Embedded	• Always available in a consultative capacity when the recipient needs support. • May become better known and hence would be able to guide, manage, or drive development on a day-to-day basis. • Can keep their "finger on the pulse" regarding political and other developments and sensitize the project management group accordingly—useful in countries that are undergoing political upheaval or major shifts in policy when new governments come into power.	• May be "misused" to conduct activities that the recipient organization's staff should be conducting, especially if milestones have to be met. • If an embedded expert is not accepted by the recipient institution for whatever reason, then the project will suffer due to silent sabotage or outright refusal of cooperation. • Overhead costs of the project have to consider the not-insignificant costs of establishing the expert in the field.
Intermittent	• Having to use recipient institution staff may have the advantage that what has been implemented will be sustainable after the end of the project. • Not "misused" for daily work but can concentrate on giving advice. In a project implementation based on milestones, experts will not be used until the "homework" has been done. This increases the pressure to act and leaves the responsibility with the recipient institution.	• Available for short periods of time and may or may not be available when the recipient is urgently seeking answers to a specific challenge. • Intermittent experts have to rely on the work ethic of the recipient institution staff to get things done.

11.2 CHALLENGES OF QI INSTITUTIONS IN LOW- AND MIDDLE-INCOME COUNTRIES

Many low- and middle-income countries established NSBs decades ago, either as government departments or as statutory bodies. Owing to limited resources, they were established as organizations providing all services—they developed standards, looked after scientific metrology, and provided conformity assessment and calibration services. Sometimes they were even tasked with the evaluation of other laboratories in the country. Frequently, they were also given a mandate to implement mandatory standards. As low- and middle-income countries endeavor to gain the maximum advantage from the massive increase in global trade, this QI model is coming under increasing pressure because of some inherent conflicts of interest.

In addition, many of these institutions' business models cannot cope with the technological advances in QI service delivery, or they have become less effective and efficient through complacency. The financial challenge is that if the institution is involved in the implementation of mandatory standards, it is paid a levy by suppliers and this income is to some extent independent of whether it provides decent service, leading to allegations that it has been given the wherewithal to extract rent. Such behavior increases the transaction costs unnecessarily for suppliers.

11.2.1 Institutional arrangements

Key message: *Ensure that institutional arrangements do not lead to conflicts of interest.*

At the international level, independent organizations look after the interests of each of the fundamental QI functions: standards, metrology, and accreditation. Such independence is mirrored in most high-income economies. In low- and middle-income economies, it is frequently too resource-intensive in terms of finances, buildings, and skilled staff to establish independent organizations for each of these functions. Hence, some of the functions are combined. This is not an issue as long as specific conflicts of interest are considered (accreditation and conformity assessment in the same organization, for example, being a clear conflict of interest) and if governance, management, and business model risks and concerns are appropriately addressed.

11.2.2 Standards development and publication

Key message: *Standards development and publication should be benchmarked against modern good standardization practices: streamlining the technical committee structures and activities at the national level through effective project management, actively participating in regional and international technical committees where it matters for the country, and making standards available to market as rapidly as possible.*

The process of developing consensus-based standards at the international level by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and others is largely regulated by the World Trade Organization (WTO) Agreement on Technical Barriers to Trade

(TBT Agreement) and ISO/IEC Directives (ISO 2017). The body of international standards is comprehensive and easily accessible. A similar situation exists at national level in the more developed economies. It is, however, difficult to obtain a complete picture in many low- and middle-income countries, where the processes may vary widely.

Typical challenges regarding the development of standards that are experienced in some NSBs of low- and middle-income countries include the following:

- The annual or six-monthly standards work program is established by the NSB without meaningful input from stakeholders; it is based on what the NSB believes the needs to be. In addition, it is extremely rigid, and any emerging need is "parked" until the next financial year or two, after which the private sector finds another avenue to fulfill its needs.
- In some cases, technical committees are limited in size by NSB rules, and representation is mainly from the public sector rather than the private sector that would be the main affected party. This is exacerbated if members are paid sitting fees that strain the budget of the NSB, over and above the fact that it attracts members who have little input into the process; they attend only to gain the sitting fee.
- Adopting international or regional standards is very much a preferred methodology, but language problems surface quite frequently. The ISO, IEC, and other international standards are readily available in English or French, but these may not be well understood in a low- or middle-income country. Therefore, standards have to be translated, an aspect that requires resources over and above the difficulty of translating technical English or French into a language that may not have the technical vocabulary in the first place.
- Active participation in the technical committees at the international level is limited if not totally absent, even though NSBs have registered as participating or observer members in many of them. This comes about mainly because of financial constraints and sometimes a perception in the low- or middle-income country that it lacks the expertise to participate at the international level. On the other hand, such NSBs often have an exemplary record (typically more than 95 percent) of voting on draft international standards. However, they do not provide any comments during the public commentary period nor when voting, raising the suspicion that it is a mechanistic-type voting of ticking the right boxes without considering what they are voting for.

Typical challenges for low- and middle-income countries regarding the publication of standards include the following:

- The changeover from a purely hard-copy system to an information technology (IT)–based system is not complete or has not been planned well. Older national standards—and these could still be the bulk of standards published—are available only in hard copy, and there is no plan in place to get them digitized as soon as possible.
- National standards cannot be obtained through Internet-based systems; for example, the IT infrastructure is not capable of providing such services, or payment through credit card or electronic funds transfer (EFT) is not possible or limited to in-country transactions.

- Standards, once approved, are printed in hard copy with a print run of a few hundred or thousand. Standards that are not in great demand sell slowly, and after a few years when the standard is updated or revised, most of these copies have to be trashed, wasting precious resources.
- Print-on-demand systems that would alleviate the situation described above are waiting for capital expenditure approval, which is not forthcoming because it is not seen as a priority. Once the print-on-demand system is installed, the older standards cannot be provided in this way because they have not been digitized yet.
- Documentation control of the final, approved text of national standards is weak or totally absent. Files reside on the computers of the technical committee secretariats, and there is no central depository with controlled access to ensure that the text is not tampered with after approval.
- The five-year cycle of review of published standards is not fully implemented. Even when implemented in part, there is no indication in the standard itself whether it has been reviewed and reissued without change or revised.

In addition, as technology develops at an ever-increasing pace, the approaches to standardization are also evolving quite rapidly at the international level, shifting the goal posts in ways that challenge the NSBs in low- and middle-income economies. Predicting the trajectory of these changes is a challenge even for international standards bodies and standards bodies in high-income countries. Hence, NSBs in low- and middle-income countries and their development partners will need to keep a close watch on developments and adjust projects accordingly.

11.2.3 Metrology in one institution

Key message: *Metrology is technology-intensive. The facilities, skilled staff, and technical support must be available and maintained at a high level for the metrology institution to succeed.*

Metrology services in low- and middle-income countries usually start with the state controlling weights and measures in trade through a legal metrology department or agency, which is then often given the responsibility to establish and maintain national measurement standards. When national standards are procured, they may even come with calibration certificates traceable to international standards.

The challenges to maintain these national standards, and to enhance them as industry develops, are numerous:

- There is a big difference between operating a legal metrology service and maintaining national measurement standards. The former is a regulatory function, whereas the latter is a more scientific endeavor. The psychological makeup of the metrologists involved in these two functions would be different. In countries where the legal metrology department is responsible for national measurement standards, anecdotal evidence indicates that they are of a much lower priority and maintenance often suffers, because the bulk of the staff would be legal metrologists focused more on the implementation of the measurement controls in trade than on spending time with the "less interesting" laboratory equipment.
- Maintaining the calibration status of national measurement standards is a major challenge. Issues that need to be resolved on a continuous basis include

obtaining adequate foreign exchange to pay for the calibration thereof abroad as well as the logistics to get measuring equipment to the foreign national metrology institute (NMI) and back without physical interference that would negate the calibration status. Such measuring equipment also requires high-level mechanical and electronic maintenance, both of which are difficult to source in many low- and middle-income countries.

- Maintaining the laboratory conditions, especially environmental controls, required for the continued functioning and accuracy of the national measurement standards is challenging. These frequently include the less-than-reliable power supply, which in some countries could be interrupted weekly for hours on end. This means that an uninterruptible power supply (UPS) has to be provided, which could strain project budgets.

Over and above these challenges, every now and then, low- and middle-income economies need to upgrade their national measurement standards to allow for new technological developments within the country. These could require a much higher level of technical sophistication than what the current infrastructure can provide. Developing such higher technical capabilities is a major challenge for a low- or middle-income country, one that it seldom can manage on its own within a reasonable time frame. A challenge of similar nature but with quite different consequences is the propensity of some experts to recommend very sophisticated measuring equipment that the country does not need, and worse, cannot operate and maintain.

11.2.4 Accreditation

Key message: *An internationally recognized accreditation service is no longer a "nice to have" but a necessary precondition for gaining acceptance for conformity assessment results of local companies in the international markets. Establishing such an accreditation service is a long journey of quite a few years—requiring finances, dedication, and the assurance that it will be independent from undue political interference or financial pressures that would affect its trustworthiness.*

Few low- and middle-income countries have national accreditation bodies (NABs) that have been fully operational and internationally recognized for a number of years. If one exists, it will be of very recent date. Many such countries do, however, have some mechanism akin to accreditation in some ministries or even in the NSB that is responsible for the evaluation of laboratories, for example.

Establishing a fully functional NAB is a daunting task. Some of the challenges that a low- or middle-income country may face include the following:

- In smaller countries, the amount of accreditation work in the private sector and technical regulation may not warrant the establishment of an NAB. From a financial sustainability perspective, it has been shown that 200–250 accredited organizations are the break-even point for NABs.
- In many low- and middle-income countries, the number given above is unattainable unless the medical and pathology laboratories, for example, are forced to acquire accreditation as a precondition for providing such services. In this case, the full cooperation of the Ministry of Health must be sought, and the discussions of whether it will allow an organization outside its control (the NAB) to conduct the assessment of these laboratories can become quite intense.

- If an NAB is not an option, a regional accreditation body (RAB) might be (as further discussed in module 5: Accreditation, section 5.5). In this case, the modalities and mandate of the RAB's involvement in matters related to regulatory work will have to be carefully defined.

From the establishment of an NAB until it can gain international recognition takes between five and seven years, or even longer. Before the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), or recognized regional cooperation bodies will send peer review teams to assess the accreditation body, the newly established accreditation body needs to (a) train its assessors and lead assessors; (b) develop and implement its management system and documentation compliant with ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"); and (c) gain experience in conducting assessments and actually accredit a few organizations. Frequently, being able to demonstrate their independence to gain international recognition is another challenge for accreditation bodies that are part of organizational structures vulnerable to political and financial interference.

Until the NAB gains international recognition, companies will be reluctant to make use of its services because the accreditation certificate will be of limited value internationally. To overcome this "chicken and egg" situation, newly established accreditation bodies can enter into "twinning agreements" with an accreditation body that is already internationally recognized. This arrangement will help the newly established accreditation body gain the necessary experience for the peer review as clients may be issued a joint accreditation certificate (see module 10: How to Reform: Interventions and Approaches, section 10.5.2, for a more detailed discussion). But finding the appropriate twinning partner can be a major challenge; not many accreditation bodies are keen on such arrangements because they affect their operational efficacy.

11.2.5 Conformity assessment

Key message: *Conformity assessment is a reality in commercial transactions. Hence, conformity assessment services should be technically competent and market-related regarding cost and service delivery. The appropriate balance between public and private sector service providers is of paramount importance to deliver affordable conformity assessment services to both larger enterprises and the SME sector without distorting the market.*

Conformity assessment is not a trade barrier as such but an everyday reality in commercial transactions. Yet conformity assessment arrangements can have important implications for competitiveness and market access. A number of international and regional systems have developed with the objective of establishing networks of conformity assessment bodies (mostly within the private sector) whose competence can be relied upon by all members and users. In low- and middle-income countries, however, the provision of conformity assessment services is often inadequate, costly, government-driven, and centralized.

Over and above all the challenges related to providing a technically competent service, public sector providers of conformity assessment services are frequently hamstrung by the civil service bureaucracy they have to operate within. The obvious solution would be to liberalize the conformity assessment environment—that is, implement policies whereby these services are

progressively shifted toward the private sector. This, however, means that public service providers no longer enjoy their real or perceived monopolistic situation, and their business model may not be able to deal with the new market realities. In addition, governments may be reluctant to let organizations over which they have no direct control provide such services in the regulatory domains.

Such a change in the policy environment will require well-structured arguments based on the business case showing the cost savings from liberalizing conformity assessment services, to convince the government to initiate and push through the changes, and to withstand the inevitable backlash from public sector organizations that see only their income threatened. Access to the highest political levels is a prerequisite for such discussions to be fruitful. The possibilities of generating synergies between public sector institutions and private sector service providers should not be underestimated.

On the other hand, public sector organizations may be receptive to moving services to the private sector if they can be convinced of the advantages of doing so—of moving away from stifling bureaucratic systems.

The third stakeholder group to be convinced would be the regulatory authorities responsible for technical regulation, food safety, and SPS measures. They need to understand that market-related conformity assessment services are actually more effective and efficient in the long term and that technical competency needs to be ensured through accreditation.

11.2.6 Cross-cutting challenges

Key message: *Establishing a vibrant QI requires the understanding and commitment of high-level public sector officials, a holistic approach to QI-related legislation, representative governance structures, and the retention of skilled personnel in the QI insititutions.*

Low- and middle-income countries are often challenged to implement good practices in QI development. It is one thing for development partners to establish QI institutions, appropriately train people, and provide expensive equipment, but it is quite another for the recipient country to do these same things.

Challenges of a cross-cutting nature that should be taken into consideration in any development work include the following:

- The reengineering of the QI generally entails a drastic review of legislative instruments. In low- and middle-income countries, this is a time-consuming and tiresome endeavor. But without the review of out-of-date or insufficient legislation, or the development of new legislation and promulgation thereof, the QI cannot be transformed into an effective and efficient support service for the benefit of the whole country. Generally, any legislation older than about 5 years *should* be reviewed, and anything older than 10 years *must* be reviewed.
- Metrology, standards, and accreditation are activities for the common good that are seldom self-financing in a low- or middle-income country context. Hence government commitment to adequate and long-term funding through the national budget is an absolute necessity.
- The QI organization's service delivery is heavily dependent on trained and skilled personnel. Hence, development partners spend large sums on training. These skilled people often are then frustrated by civil service remuneration packages that do not take cognizance of their competencies. They leave the

public QI institutions, which are then without the necessary skills and may even lose accreditation or recognition. Means should be found to compensate such personnel adequately, even within a civil service context.

- Governance, in the form of councils or boards, is important because there are fiduciary and strategic responsibilities regarding the QI institutions. Custom and practice in low- and middle-income economies is to load these bodies with representatives from the public sector (that is, ministries), and the private sector is underrepresented. This alienates the QI institution from the very sector it needs to serve. The challenge is to get eminent industrialists to serve on councils or boards: they bring business acumen, act as marketing agents in the private sector, and have a far better idea of the strategies the QI institution needs to pursue to render a proper service.
- The knowledge regarding the role and importance of the QI in the well-being of the low- or middle-income country is often inadequate in the public sector, even though the notion of a regime to protect the consumer from market failures is in place. The challenge is to establish a knowledge base regarding what constitutes good QI practices across all the various ministries and their agencies—and not only the ones responsible for the implementation of the WTO TBT and SPS Agreements.

11.3 STRATEGIC APPROACHES TO SUPPORT QI DEVELOPMENT

The concept "strategy" has many meanings. For this discussion, a "strategic approach" is seen as the framework that guides the choices that determine the nature and direction of the development partner's support for QI development in a given low- or middle-income country.

Such a "strategic approach" must enable development partners to make a difference that matters to a critical mass of appropriate stakeholders. This means, however, that the "strategic approach" would be different depending on the country being considered and depending on the resources the development partner is able to muster for the specific project. Obviously, the demand assessment of the country (see module 2: The Importance of QI Reform and Demand Assessment) defines the technological requirements regarding the QI, and it should have a major influence on the project design, but there are a few other strategic issues that need to be considered as well (Racine 2011).

11.3.1 Institutions and sound governance for a modern, effective QI

Key message: *Good governance is absolutely essential for the effective and efficient operation of QI institutions—governance in which political interference is minimized and board or council members have the necessary business acumen and are fully representative of the public and private sectors.*

An effective QI is dependent on the principles of good standardization practice (as detailed in module 3: Standards, section 3.4), including transparency, consensus, impartiality, and technical credibility. These principles depend on institutional rather than technological factors. If they are ignored, no amount of investment in technology or staff training can create a modern, effective QI. Fulfillment of these principles depends largely on the overall structure of the QI and the governance of individual institutions.

Most high-income countries have made good progress in establishing high-quality governance and legislation for their QI organizations in recent years. Regional trade arrangements like that of the European Union were often the drivers initiating such developments. In low- and middle-income countries, the picture is different. Some of these countries have adopted or are in the process of adopting a more modern approach to QI governance, whereas others are still stuck in governance systems of the Soviet era or systems that were established decades ago, when an "all-in-one" type thinking was prevalent.

Step 1: Restructure the QI to remove political interference and conflicts of interest

Low- and middle-income countries with a largely monolithic QI or a QI integrated with political institutions will need to restructure their QI. Removing political interference and conflicts of interest requires providing more autonomy to QI institutions, a goal best achieved by establishing independent institutions. Several possibilities need to be factored into such decisions:

- Good practice is for the accreditation body to be independent from other QI institutions, although in some countries it is combined with the NSB, provided that conformity assessment services are not available from such a construct.
- Scientific metrology, accreditation, and standards bodies should not be involved in the implementation of technical regulations, mandatory standards, or other regulatory activities. Their involvement in the development of the same should be limited to services contracted for by the regulatory authority on a needs basis.
- QI organizations should be free from political interference and have the autonomy to respond to market demands and to represent their country in the relevant regional and international organizations.
- The provision of conformity assessment services by the NSB, or calibration services by the NMI or legal metrology department or agency, should be carefully considered. If these bodies can operate in respect of market forces, and there is generally good governance of public entities, they may be fine. If not, it may be better for them to be separated.

Step 2: Follow good governance principles

As a second step, principles of good governance should be applied. The composition and terms of reference of the boards or councils of the fundamental QI institutions responsible for standards, metrology, and accreditation should reflect the need for stakeholder involvement. Too often, especially if they are public sector organizations, their boards or councils are mostly made up of lower-level bureaucrats as representatives of ministries, together with a few private sector representatives from business and industry associations. In addition, such boards or councils are acting more like an executive management than as a governance structure directing and controlling the institution regarding the interests of its many stakeholders, objectives and strategy, and overall finances.

Issues that would need to be addressed include the following:

- The membership of the board or council should reflect the main stakeholders of the institution. These would normally be the public and private sectors. The private sector will to a large extent determine the demand and therefore

the financial sustainability of the institution, either through monies appropriated through taxes (government funding) or through payments for services. Hence, they should constitute the majority of the board or council, even if they are appointed by the relevant minister in the case of a public entity. The boards of private sector QI organizations would obviously be appointed by the shareholders. The number of board or council members should not be too small nor too big: 10–16 has proven to be a useful number. The members should be appointed for their expertise and knowledge regarding standards, marketing, and finances.

- The board or council should have the authority to determine the strategy of the institution. Checks and balances can easily be included to ensure that this strategy is aligned with relevant government policies such as export, industrial development, food safety and security, and the like. The board or council should also have a meaningful say in the appointment of the head of the institution if it does not appoint the person outright. The head of the institution should not be susceptible to changes in government administration. Given the learning curve involved in managing a QI institution effectively, frequent changes to the head of the institution reduce technical capacity and institutional memory.
- The board or the council should be given the fiduciary responsibility for the QI institution. If it is a public sector institution, these would have to comply with the framework of approved government policy. If it is private sector institution, these would be subject to the requirements set by the shareholders' meeting. The fiduciary responsibility should include the approval of the annual business plans and annual budgets. The management of the institution should be able to operate within this approved budget without having to obtain approval for normal expenditures from the board or council, or even from the ministry in the case of public sector organizations. Finally, the board or council should have the responsibility to appoint financial auditors and demand compliance to generally accepted accounting practices by the management.

11.3.2 Involving public and private sector stakeholders for a demand-driven QI

Key message: *Stakeholders, especially those that will be affected by QI services, must be involved in QI-related decision making.*

Upgrading the QI requires addressing the technological gaps and worker skills identified through proper demand assessments (see module 2: The Importance of QI Reform and Demand Assessment). But that alone will not create an effective QI capable of achieving lasting international recognition. Nor is there a technocratic solution for developing a QI over time that can respond to economic and social needs. Getting a broad range of stakeholders involved in the decision making about the QI and providing them with a measure of political autonomy is a first step in achieving a demand-driven QI that will have a better chance of remaining relevant to its client base.

International practice often requires a QI institution to establish a forum where stakeholders and interested parties can provide input and recommendations for the government or the board or council to consider regarding the institution's services and operations. Forum members may include representatives or individuals from industry, importers, academia, authorities, purchasers, and consumer organizations. Such a forum should not have any governance

authority over the QI institution but should provide the governance structures with appropriate advice on policy and practice.

11.3.3 Coordinating the QI organizations

Key message: *The QI is complex, and its institutions require a holistic approach and coordination to ensure that there are no gaps and overlaps in responsibilities. This requires a clear policy environment within which they can operate as well as an overarching coordination office overseeing the relationships between the QI and the technical regulation environment.*

Coordinating the QI is another element that needs to be addressed, especially in low- and middle-income countries where market demand is still underdeveloped and consumer pressure is too weak to articulate the needs of the economy. Coordination is important during the early stages of QI development to ensure that a holistic goal is pursued. It is also important once the QI has developed; otherwise, gaps and overlaps develop between the actual and perceived responsibilities of institutions, especially in the regulatory domain, resulting in unnecessary transaction costs for suppliers.

Laws determine which areas are regulated by whom through technical regulations, food standards, or SPS measures. In turn, regulatory authorities prepare technical regulations, food standards, and SPS measures using standards developed and published by the standards body. For implementation, these require inspection, testing, and certification as well as accurate measurements. Trained inspectors, auditors, and assessors are required in all of them. The calibration and testing laboratories need to be accredited to demonstrate their technical competency, as do the certification and inspection bodies. In addition, all of these require international acceptance if they are to remain relevant in export markets. Such a system can become very complicated very quickly, and this web of relationships makes it difficult to operate effectively and efficiently without proper coordination.

Develop a national quality policy

The QI structure, governance, and coordination should be given substance in the development and implementation of a national quality policy (see module 10: How to Reform: Interventions and Approaches, section 10.1, for a detailed discussion of quality policy development). The quality policy should be developed with the meaningful involvement of all the stakeholders from the public and private sector as well as academia and NGOs.

An effective quality policy will clearly define the overall QI organizational structures, their governance, coordination, required reforms, and timelines for implementation. This is a useful place to start a high-level discussion and reach a consensus on the way forward on QI strategy and modalities between the government, public sector, private sector, and consumers.

Establish a technical regulation coordination office

A technical regulation coordination office can make a big difference in coordinating the QI's interface with the technical regulation regime. Many of the Organisation for Economic Co-operation and Development (OECD) countries have established a high-level office with regulatory powers to coordinate the various activities and systems related to technical regulation development and implementation, including the role the QI plays in this respect. This office can

make sure that no gaps and overlaps exist among the regulatory authorities in terms of their mandates and the products they are responsible for. It ensures the country's compliance with international or regional obligations such as the WTO TBT Agreement when given the mandate to vet any newly developed technical regulation for compliance with such obligations. Where a country has embarked on a major technical regulation regime reengineering exercise, this office can act as the coordinator.

In the case of low- and middle-income countries, such a coordinating office can have an even bigger impact in streamlining and modernizing the technical regulation regime. Many such countries battle with a legacy of ad hoc and uncoordinated technical regulation systems across their many ministries and agencies—regimes that may not comply with WTO TBT Agreement requirements, may not even be effective, and may result in high transaction costs for suppliers and industry. Many low- and middle-income countries also battle with the legacy of overregulation through mandatory standards, which need to be reduced.

Such a coordinating office, backed by the highest political level of the low- or middle-income country, has the time and inclination to oversee a project of such major proportions—whereas ministries and their agencies may be inclined to retain the status quo, for whatever reasons—because it would have more staying power than a development project with its limited time horizon.

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12

Monitoring and Evaluation: Performance and Impact of the QI Reforms

INTRODUCTION

Projects have to be monitored and evaluated from time to time to ensure that they are still on track and that the envisaged outcome is achieved. In this module, the difference between monitoring and evaluation is explained, and the modalities of monitoring and evaluation are enumerated with guidance on how they can be developed through the theory of change.

12.1 MONITORING AND EVALUATION

Evaluation should be distinguished from monitoring, which is the continuous follow-up on activities and results in relation to preset targets and objectives. The distinction is primarily one of analytical depth, as both can be focusing on similar project elements. Whereas monitoring may be nothing more than a simple recording of activities and results against plans and budgets, evaluation probes deeper (UNDP 2002).

12.1.1 Definitions

Monitoring can be defined as "a continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing development intervention with indications of the extent of progress and achievement of objectives and progress in the use of allocated funds" (OECD-DAC 2002).

Evaluation can be defined as "the process of determining the worth or significance of a development activity, policy or program, to determine the relevance of objectives, the efficacy of design and implementation, the efficiency or resource use, and the sustainability of results. An evaluation should enable the incorporation of lessons learned into the decision-making process of both partner and donor" (OECD-DAC 2002).

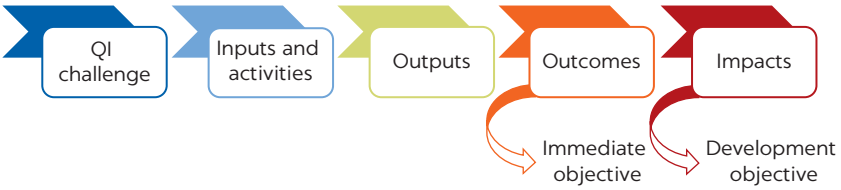
Although monitoring signals failures to reach targets and other problems to be tackled along the way, it cannot usually explain *why* a particular problem has

TABLE 12.1 Modalities of monitoring and evaluation

MONITORING	EVALUATION
Continuous or periodic	Episodic, ad hoc
Program objectives (outcome) taken as given	Program objectives (outcome) assessed in relation to higher-level goals or to the development problem to be solved, such as determined through the QI diagnostic
Predefined indicators of progress assumed to be appropriate	Validity and relevance of predefined indicators open to question
Tracks progress against small number of predefined indicators	Deals with wide range of issues
Focuses on intended results	Identifies both unintended and intended results
Quantitative methods	Qualitative and quantitative methods
Data routinely collected	Multiple sources of data used, including the QI diagnostic
Does not answer causal questions	Provides answers to causal questions
Usually an internal management function	Often done by external evaluators and often initiated by external agents

Note: QI = quality infrastructure.

FIGURE 12.1
The QI project cycle



Source: Adapted from World Bank 2015.
Note: QI = quality infrastructure.

arisen or *why* a particular outcome has occurred or failed to occur. To deal with such questions of cause and effect, an evaluation is normally required. An evaluation may also help gain a better understanding of how a development intervention relates to its social and cultural environment, or it can be used to examine the relevance of a particular intervention to broader development concerns. The differences between the modalities of monitoring and evaluation are shown more clearly in table 12.1.

12.1.2 Project cycle

In general, a project cycle is considered to contain inputs and activities, outputs, outcomes, and impacts (figure 12.1). For example, in establishing a national accreditation body,

- *Inputs and activities* could be consultancy and preassessment of the recipient organization;
- *Outputs* could include the implementation of a management system compliant with ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies");
- *Outcomes,* such as an immediate achievement, could include the international recognition of the national accreditation body by the International Laboratory Accreditation Cooperation (ILAC) or the International Accreditation Forum (IAF); and

- *Impacts* could include the acceptability of conformity assessment results in foreign markets, thereby facilitating exports.

All parts of the project cycle can be the subject of both monitoring and evaluation, even though outcomes and impacts fall more in the realm of evaluation. The *monitoring of inputs and outputs* keeps track of financial resources and other inputs such as goods and services (for example, consultancy) planned for the project. The *monitoring of outcomes* seeks to register the intended effect of the delivered goods and services on the project's target groups or systems. Although *impacts* can also be part of the monitoring exercise, this is where an evaluation becomes more informative.

The project cycle (some development partners may use slightly different cycles, but the principles remain) is generally also the basis of the project logical framework, as discussed further in section 12.3 on logframes.

12.2 THEORY OF CHANGE AND LOGIC MODELS

"Theory of Change" and "logic models" are two types of methodologies used in planning, monitoring, and evaluating projects. The latter finds its way into the matrix known as a "logframe" that many development partners use to plan a project and monitor its progress or the lack thereof. The two methodologies are related, but there are also differences.

12.2.1 Similarities and differences

Theory of Change

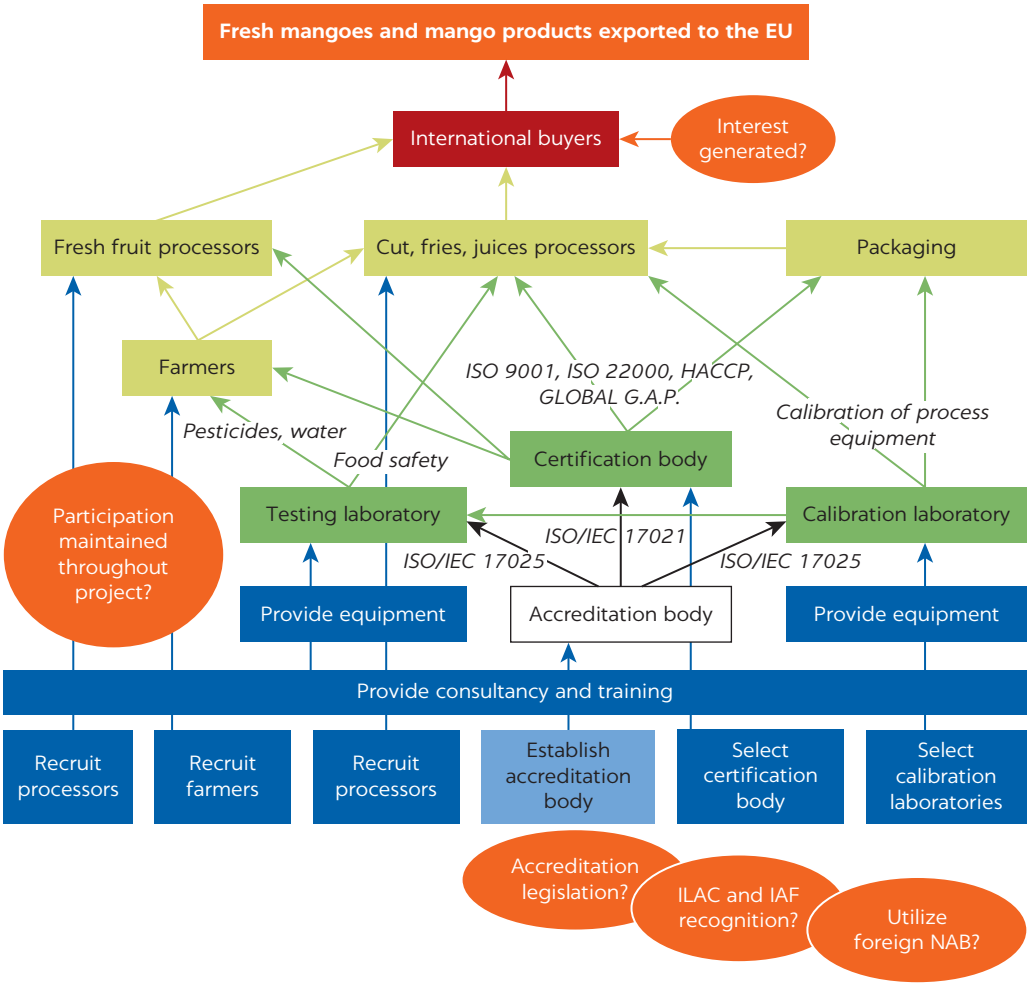
Theory of Change is a specific methodology for planning, participation, and evaluation. It defines long-term goals and then maps backward to identify necessary preconditions. Theory of Change explains the process of change by outlining causal links in an initiative—that is, its shorter-term, intermediate, and longer-term outcomes. The identified changes are mapped as the "outcomes pathway," showing each outcome in a logical relationship with all the others, as well as in a chronological flow. The links between outcomes are explained by "rationales" or statements of why one outcome is thought to be a prerequisite for another, and cyclical processes or feedback loops are clearly shown.

Theory of Change diagrams are "messy," showing the interconnections between a variety of project elements; hence, there is no common format for a Theory of Change diagram. A simple example is shown in figure 12.2, which illustrates the case for mango exports to the European Union (EU) from a low- or middle-income country.

Logic model

The logic model is a sequence of project modalities to illustrate the change process. It is a "bottom-up" approach starting with the inputs and activities, then listing the outputs and outcomes, and finishing with the envisaged impact (as summarized in the figure 12.1 project cycle). These are normally presented in a logical framework, or "logframe," format within the project documentation. Only components directly connected to the project element are depicted. It is linear, which means that all inputs and activities lead to outputs, which lead to outcomes and ultimately to the goal; there are no cyclical processes or feedback loops.

FIGURE 12.2
Sample theory of change diagram for mango exports



Note: EU = European Union; GLOBAL G.A.P. = Global Good Agricultural Practice; HACCP = hazard analysis and critical control points; IAF = International Accreditation Forum; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; NAB = national accreditation body; ISO 9001 = "Quality Management Systems—Requirements"; ISO 22000 = "Food Safety Management Systems—Requirements for Any Organization in the Food Chain"; ISO/IEC 17025 = "General Requirements for the Competence of Testing and Calibration Laboratories"; ISO/IEC 17021 = "General Requirements for the Competence of Testing and Calibration Laboratories."

The logframe can be considered as a specific pathway of the Theory of Change diagram. In general, there is little room for the emergence of unexpected outcomes within the logframe. You can glance at the logframe and see whether outcomes are out of sync with inputs and activities, but it does not show *why* the activities are expected to produce the outcomes. Therefore, nowadays, the logframe is visualized by a so-called impact logic model.

12.2.2 Developing a Theory of Change diagram

The Theory of Change process uses backward mapping, requiring planners to think in backward steps from a long-term goal to intermediate and then early project changes that would be required to achieve the desired goal, which in itself is the major change. The process therefore starts with setting a long-term goal or impact.

Thereafter, all the necessary and sufficient conditions required to bring about the long-term goal must be defined. Each one of these is in turn considered, and their preconditions are identified. The process of identifying preconditions continues, drilling down the pathway by posing fundamental questions such as "What has to be in place for this outcome to be achieved?" and "Are these preconditions sufficient for the outcome to be achieved?"

The Theory of Change diagram depicted in figure 12.2 was developed in this manner from the value chain analysis (shown in module 2: The Importance of QI Reform and Demand Assessment, figure 2.8) for a project that had as its goal the export of mangoes from a low- or middle-income country to the EU, where previously there were none.

During the process of creating the pathway of change, planners are required to articulate as many of their assumptions about the change process as they can so that they can be examined and even tested to determine whether any key assumptions are hard to support (or even false). There are typically three important types of assumptions to consider:

- Assertions about the connections between long-term, intermediate, and early outcomes on the map
- Substantiation for the claim that all of the important preconditions for success have been identified
- Justifications supporting the links between program activities and the outcomes they are expected to produce

A fourth type of assumption—regarding the contextual or environmental factors that will support or hinder progress toward the realization of outcomes in the pathway of change—is often an additional important factor in illustrating the complete theory of change.

12.3 LOGFRAMES

A logframe is a type of logic model that uses a table or matrix to summarize the key elements of a project, namely the envisaged impact, the outcomes, planned outputs, and project inputs and activities. It also outlines the indicators that will be used to measure progress or achievement of results, the sources of data (means of verification), and the assumptions necessary for project success. The latter are important in managing the risks associated with the project.

Logframes are a project management tool. They help project managers and teams to plan and manage projects and to measure whether the project is achieving what it is meant to achieve. Different development partners have different logframe templates and may use slightly different terminology, but all logframes typically outline

- What will be done and what the results should be;
- Indicators that will be used to gauge whether what has been done is what was planned;
- Where to find the data or information to determine whether the indicators have been achieved; and
- Assumptions that must hold true for the project to accomplish what it is meant to accomplish.

TABLE 12.2 Typical logframe (conceptual)

PROJECT ELEMENT	RESULT CHAIN	INDICATORS	BASELINE	TARGET	SOURCES AND MEANS OF VERIFICATION	ASSUMPTIONS AND RISKS
Overall objective or impact	The broader, long-term change that will stem from the project as well as interventions by other projects	Evaluate the long-term change to which the project contributes	The current situation regarding the envisaged long-term change	The policy or strategy goal of the client country	Evaluation of the situation regarding the strategic goal	n.a.
Outcome(s)[a]	The direct effects of the project that will be obtained at the medium term and that tend to focus on the changes in behavior and capacity resulting from the project (multiple outcomes may relate to the impact)	Measure the change in factors determining the outcome(s)	The starting point of the indicators	The intended value of the indicators	Sources of information and methods used to collect and report (including who, when, and how frequently)	Factors outside project management's control that may affect the outcome-impact link and external conditions necessary for the overall objective to be achieved
Outputs[b]	The direct or tangible results (infrastructure, goods, and services) delivered by the project (multiple outputs will relate to each outcome)	Measure the degree of delivery of the outputs	The starting point of the indicators	The intended value of the indicators	Sources of information and methods used to collect and report (including who, when, and how frequently)	Factors outside project management's control that may affect the output-outcome link
Inputs and activities[c]	Key activities to produce each of the outputs	*Means:* What are the means required to implement these activities, such as staff, equipment, training, studies, supplies, operational facilities, and so on? *Costs:* What are the action costs? How are they classified (breakdown in the budget for the action)?				Factors outside project management's control that may affect the input or activity-output link

Note: n.a. = not applicable.
a. Number the outcomes as 1, 2, 3, and so on.
b. Number the related outputs as 1.1, 1.2, 2.1, 2.2, 2.3, 3.1, and so on.
c. Number the related inputs and activities as 1.1.1, 1.1.2, 1.1.3, 1.2.1, 1.2.2, and so on.

The logframe can be derived from the Theory of Change diagram. It can also be based on past projects for which the logframe has proven to be workable. A conceptual logframe is shown in table 12.2, and the various elements thereof are discussed in the section following. An example of a simple logframe (table 12.3) completes the discussion.

12.3.1 Project's overall objective or impact

The overall objective or impact is the long-term condition or state that the project is expected to achieve, usually at the national level. It may not be solely the result of the quality infrastructure (QI) project; more often than not, it is a condition or state that requires a number of interventions in a variety of areas in the country. Typical examples for QI projects would include the following:

- Development of an industrial sector to the point where it can export products to difficult markets, whereas before the interventions it could not do so
- Enhancement of the productivity of firms in a specific sector to the level of international benchmarks
- Safeguarding of the public by establishing or strengthening consumer protection systems

TABLE 12.3 Logframe for establishing testing laboratories for mango exports to the EU

PROJECT ELEMENT	RESULT CHAIN	INDICATORS	BASELINE	TARGET	SOURCES AND MEANS OF VERIFICATION	ASSUMPTIONS AND RISKS
Overall objective or impact	Country P is able to export mangoes and mango products to the EU	Tonnage and value of mango exports to the EU	Zero	€150,000 worth of mangoes exported to the EU in final year of the project	Export data	n.a.
Outcome(s)	1. Mango processors use testing services to show mangoes meet EU requirements	Number of tests performed by the test laboratory for the mango processors	Zero	Every potential shipment of mango products tested	Production records of the mango processors	Mango processors agree on marketing contracts with EU retail organizations. Transportation and warehousing complies with EU traceability requirements.
Outputs	1.1. Test laboratory accredited to ISO/IEC 17025 1.2. Processor certified for HACCP[a] 1.3. Warehouses certified to Global G.A.P.[a]	Test laboratory accredited	Test laboratory not accredited	Test laboratory accredited within two years after commencement of project	Accreditation records of the accreditation body	Accreditation body remains signatory of the ILAC MRA.
Inputs and activities	1.1.1. Training for test laboratory personnel 1.1.2. Development of quality manual in accordance with ISO/IEC 17025 1.1.3. Conducting proficiency testing of test methods 1.1.4. Providing high-level test equipment as required by EU					Laboratory staff, once trained, remain with the laboratory. Laboratory finances accreditation costs.

Note: n.a. = not applicable; EU = European Union; Global G.A.P. = Global Good Agricultural Practice; HACCP = hazard analysis and critical control points; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; MRA = mutual recognition arrangement; ISO/IEC 17025 = "General Requirements for the Competence of Testing and Calibration Laboratories."
a. Outputs that will each have their own set of inputs and activities, numbered 1.2.X and 1.3.Y (not shown in the example).

- Enhancement of human health and safety in the country
- Enhancement of environmental protection and the health of the fauna and flora of the country

It is quite obvious that such impacts are not easy to measure, nor are they always readily discernible during or at the end of the project. It may also be difficult to ascertain the specific contribution of the QI project when a positive impact is determined in the evaluation. Impacts are therefore mostly appraised by an evaluation rather than project monitoring activities (see section 12.4 on evaluation).

12.3.2 Project outcomes

Project outcomes are the planned or achieved results of an intervention's activities and outputs—changes that contribute to the project's overall objective or impact. Project outcomes are achieved in the short and medium terms. Whereas the project's *impact* is mainly gauged at the national level, the *outcomes* are seen more at the institutional level. Usually, a small number of project outcomes are necessary to achieve the project's impact.

The indicators should be quantitative or qualitative factors or variables that provide a simple and reliable means to measure achievement or to reflect the changes connected to an intervention (that is, a variable that represents a valid measure of change).

12.3.3 Project outputs

The project outputs are the products, capital goods, and services that result from a project's inputs and activities. They are closely related to the project outcomes, and for each outcome there may be a number of outputs. Typical indicators are measures indicating whether what has been produced regarding the output is of good enough quality to achieve the outcomes.

12.3.4 Project inputs and activities

The project activities are tasks or interventions required to achieve the outputs. They include the inputs and resources required to carry out activities, such as finances, staff, time, facilities, and equipment.

12.3.5 Simple logframe example

Taking the Theory of Change diagram of the mango exports (figure 12.2) as an example, a simple logframe for the establishment of testing laboratories to test the mangoes and mango products for compliance with EU regulatory requirements can be developed. The resulting logframe (table 12.3) shows just one stream of the logframe; the actual logframe will be much longer, considering the complexity of the project.

12.4 EVALUATION

12.4.1 Main purposes of evaluation

Regarding development projects, the two main purposes of an evaluation can be seen as a measure of "accountability" and to what extent the project facilitates "learning" (Molund and Schill 2007).

In general terms, an evaluation for *accountability* seeks to find out whether the organizations that are responsible for the intervention have done as good a job as possible under the circumstances. This means trying to find out whether and to what extent the intervention has achieved the results that it was intended to achieve or that it could reasonably have been expected to achieve. This also includes an assessment of the processes of planning and implementation.

When the purpose of evaluation is *learning*, the study is expected to produce substantive ideas on how to improve the reviewed activity or similar activities. The real importance of the learning part of an evaluation lies in the translation of new knowledge into better practices for the future.

12.4.2 Objectivity and impartiality

An evaluation is not just any assessment of the merits of an activity but one that aims to be as objective and impartial as possible. The requirement for objectivity and impartiality is always strong when the evaluations are for accountability, and it can be equally strong when the evaluations are for

learning and the creation of new knowledge. Objectivity and impartiality can be safeguarded in the following ways:

- *Organizational independence.* A direct line of reporting between the evaluation unit and the management of the organization should exist. The evaluation unit should be outside the operational staff and line management functions. The evaluation unit should be free from "political" pressures and able to operate without fear of repercussions.
- *Behavioral independence.* The evaluation unit should be able and willing to produce strong and uncompromising reports.
- *Avoidance of conflicts of interest.* Stakeholders should be consulted in evaluations to guard against evaluator bias. Procedures must be in place that ensure that evaluators do not evaluate activities where they or their close associates have had, or in the future may expect to have, a substantive interest.
- *Protection from external influence.* The evaluation unit should be able to decide on the design, scope, timing, and conduct of the evaluation without undue interference. It should be given adequate funds to conclude the evaluation, and the judgment of the evaluators as contained in the report should not be overruled by external authorities.

The distinction between external and internal evaluation is closely associated with notions of independence, impartiality, and bias. While the external evaluator tends to have an advantage over the internal evaluator regarding objectivity and bias—and is usually regarded as the more credible of the two—the internal evaluator is sometimes better placed to understand the workings of the organizations and activities to be assessed. For this reason, evaluations are often conducted by a combination of external and internal evaluators.

Some development partners contract with totally independent evaluators, but they have to be budgeted for. Others have central evaluation units reporting directly to their top management, which also takes care of these requirements. Some development partners distinguish between evaluations commissioned internally (by the organization itself) or externally (by higher-level bodies).

12.4.3 Evaluation quality standards

An evaluation should comply with the following quality standards (Molund and Schill 2007):

- *Propriety* is an ethical norm meant to ensure that evaluations are conducted with due regard for the rights and welfare of affected people. Evaluators should ensure that stakeholders are properly informed regarding the evaluation and its purpose before involving them actively. The evaluation should be balanced and fair, and all stakeholders should be given a chance to voice their opinions.
- *Feasibility* is a norm intended to ensure that evaluations are realistic and efficient. To satisfy these requirements, an evaluation must be based on practical procedures, not unduly disrupting of normal activities, and planned and conducted in such a way that the cooperation of key stakeholders can be obtained. An evaluation should also be cost-efficient: if the cost of an evaluation cannot be justified by the usefulness of the results to intended users, it should not be undertaken.
- *Accuracy* is meant to ensure that the information produced by an evaluation is factually correct, free of distorting bias, and appropriate to the evaluation

issues at hand. By setting high standards for accuracy, the very function of an evaluation—as a means of making sure that plans and expectations are based on reality and not the result of prejudice or wishful thinking—is secured.

- *Utility* is a norm meant to ensure that an evaluation serves the information needs of its intended users. An evaluation that users consider irrelevant is hardly a success, regardless of its other merits. To be useful, an evaluation must be responsive to the interests, perspectives, and values of the stakeholders. It is important that an evaluation be timely in relation to stakeholders' practical agendas, and that stakeholders regard it as credible.

To ensure that evaluation quality standards are complied with, an evaluation needs to be carefully planned by the evaluation team, taking the norms described above into consideration. Therefore, it is nowadays a good practice to compile the requirements and procedures described above in an inception report and to make it available in advance to all parties involved.

12.4.4 Evaluation criteria

The scope of the evaluation should be clearly defined. Considering the earlier definition of an evaluation (see 12.1), a number of criteria should be included in its scope, depending on the defined project outcomes, recipient country situation, and the future strategies of the development partner. The five evaluation criteria of the Organisation for Economic Co-operation and Development's Development Assistance Committee (OECD-DAC) are frequently used (table 12.4).

The Theory of Change model (see 12.2) is an additional tool for the evaluation team and the development partner to scope the evaluation exercise rather than just using the logframe (which would be the basis of the ongoing monitoring of a project). By using the Theory of Change model, the strict linearity of the logframe regarding inputs, outputs, and outcomes is broadened to also include the project's causal issues and impacts for the project evaluation (figure 12.1).

12.4.5 Evaluation report

The terms of reference for the evaluation exercise should contain the requirements for the report thereof. The evaluation team is bound by these terms of

TABLE 12.4 OECD-DAC evaluation criteria

CRITERION	QUESTIONS TO BE ANSWERED
Relevance	Are we doing the right thing? How important is the relevance or significance of the intervention to local and national requirements and priorities?
Effectiveness	Are the objectives of the development interventions being achieved? How big is the effectiveness or impact of the project relative to the objectives planned?
Efficiency	Are the objectives being achieved economically by the development intervention? How big is the efficiency or utilization ratio of the resources used (ratio of resources applied to results)?
Impact	Does the development intervention contribute to reaching higher-level development objectives (preferably, the overall objective)? What is the impact or effect of the intervention in proportion to the overall situation of the target group or those affected?
Sustainability	Are the positive effects or impacts sustainable? How are the sustainability or permanence of the intervention and its effects to be assessed?

Source: OECD-DAC 2001.
Note: OECD-DAC = Development Assistance Committee of the Organisation for Economic Co-operation and Development.

reference to ensure that they are adequately addressed in the report. There should be some flexibility allowed for the team to add issues that it feels are important, even though they are not part of the terms of reference. The draft report should be circulated to selected stakeholders for comments, and these should be carefully considered for inclusion.

In the past two decades, as the scope and ambitions of evaluation have expanded, the range of target audiences for evaluation feedback has also increased. The characteristics and demands of these audiences vary, as does their relative importance in accountability and learning terms (OECD-DAC 2001). The reporting format should be aligned with the expectations of the target audience, which could vary from (a) *development partner structures,* including senior management, governance bodies, financing organizations, and ministries; (b) *counterpart structures,* including their senior management and ministries; and (c) *interested parties,* such as other development partners, other ministries, parliament, the media, and so on.

12.4.6 Following up

The evaluation process does not end with the submission and acceptance of the evaluation report. Rather, the findings, conclusions, recommendations, and lessons learned need to be internalized and acted upon. Therefore, the final step in managing and conducting any evaluation is to follow up on the evaluation report and implementation of change. This step is closely linked to the knowledge and learning processes, as discussed earlier in 12.4.1.

12.5 PERFORMANCE AND IMPACT INDICATORS

Performance and impact indicators are important in project monitoring and evaluation. The performance indicators for *outputs* of an intervention are usually fairly easy to determine; for example, training shall be provided to 30 trainee auditors, or consultancy on ISO 9001 ("Quality Management Systems—Requirements") shall be provided to 10 selected small and medium enterprises (SMEs). The impact indicators for the *outcomes* are a bit more difficult; for example, 80 percent of the trainees should pass the examination and go on to become respected quality auditors in a certification body, or all 10 SMEs should gain ISO 9001 certification and retain the certification over a period of years. The former is under the control of the project manager; the latter is dependent on the willingness and effort of the trainees or the recipient SMEs.

12.5.1 Relevance of indicators

Measurability and causality

First, the major attributes of performance indicators are that they have to be relevant and can be measured.[1] Indicators that cannot be measured are not very useful, as they would have to rely on subjective interpretations. Setting performance indicators must be carefully considered, as in the examples below.

Be careful of setting indicators as just numbers. Whereas it may be appropriate to define the project's outcome as five laboratories having achieved accreditation, because the project provided six laboratories with consultancy in this regard, other indicators may be more problematic. For example, it is not useful

to require the number of new standards developed and published to exceed a specific number—say, 1,000—within three years after the national standards body's (NSB) standards development system has been streamlined, even though this is easy to verify. The NSB may meet the target, but whether all of these standards are actually needed by the stakeholders is a totally different matter.

A quantitative indicator has to be linked to the needs of the country—for example, the need for accredited laboratories to provide test services as determined by the demand assessment. A "wrong" performance indicator expressed as an arbitrary number, such as an arbitrary number of standards, can actually result in a misguided business approach being established within the QI organization.

Be aware of other influences. An indicator may be dependent on a number of factors, of which only a few are addressed by the project. For example, if the export performance of an industrial sector increases, the question is whether this can be attributed to the conformity assessment services that have been accredited, the manufacturers that have been certified, the enhanced marketing of the trade promotion organization, changed attitudes toward exports by the manufacturers, enhanced logistics infrastructure, and so on. In such cases, it is difficult to attribute the increase in export performance solely to a single or even a select few interventions of a project, never mind all the unknown factors unrelated to the project that may also have had an influence.

Be wary of anecdotal evidence. It is not all that useful to just indicate that an outcome should increase (for example, an increase in exports for a specific product) without providing numbers. A magnificent increase as perceived by one person may be just a so-so increase as perceived by another person.

Documentation of sources

Second, it is good practice to indicate the most likely sources of information in the logframe. This ensures that monitoring is conducted efficiently and that the recipient country or organization ensures that the appropriate records are being generated and kept. (See table 12.3 for examples.)

Agreement of the parties

Third, performance indicators should be formally agreed to between the development partner and the recipient country or organization. Performance indicators are not only used to monitor the performance of the day-to-day activities of the development agency, but in a worst-case scenario, can also lead to the suspension (temporarily or permanently) of the project if the recipient does not perform as agreed to when the project was signed. Obviously, such a drastic step should be carefully considered by the parties concerned, and relevant information should be shared in an open and transparent manner.

12.5.2 Baseline measurement

A baseline is a description of conditions or the situation in an organization or sector prior to a development intervention. A baseline provides benchmarks against which change and progress can be measured and evaluated. Without baseline information, assessments of outcome and impact are nearly impossible. Baseline information can sometimes be assembled retrospectively, but as a rule,

a reconstructed baseline is inferior to baseline information generated before the intervention commences (Molund and Schill 2007).

The outcomes of the Rapid Diagnostic Tool and the Comprehensive Diagnostic Tool (see module 9: Diagnostic Tools) should provide all the data to construct the baseline against which the development intervention should be monitored and evaluated. The baseline information in the logframe, especially information relating to the performance indicators, should be consistent with the outcome of the diagnostics.

NOTE

1. A useful mnemonic acronym to consider are SMART indicators: **S**pecific, **M**easurable, **A**ttainable, **R**elevant, and **T**ime-bound.

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